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Global Health: Science and Practice

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Cover caption: A female school student practicing the wrist grab release in front of her self-defense class, Nairobi, Kenya. © 2018 Peter Omondi/Ujamaa Africa

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Neil Gupta, Ana Mocumbi, Said H. Arwal, Yogesh Jain, Abraham M. Haileamlak, Solomon T. Memirie, Nancy C. Larco, Gene F. Kwan, Mary Amuyunzu-Nyamongo, Gladwell Gathecha, Fred Amegashie, Vincent Rakotoarison, Jones Masiye, Emily Wroe, Bhagawan Koirala, Biraj Karmacharya, Jeanine Condo, Jean Pierre Nyemazi, Santigie Sesay, Sarah Maogenzi, Mary Mayige, Gerald Mutungi, Isaac Ssinabulya, Ann R. Akiteng, Justice Mudavanhu, Sharon Kapambwe, David Watkins, Ole Norheim, Julie Makani, Gene Bukhman; NCDI Poverty National Commissions Authorship Group; NCDI Poverty Network Secretariat

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Valerie L. Flax, Emily Ouma, Lambert Izerimana, Mary-Ann Schreiner, Alice O. Brower, Eugene Niyonzima, Carine Nyilimana, Adeline Ufitinema, Agnes Uwineza

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Amelia J. Brandt, Bonnie Katalenich, David W. Seal

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Zelege Yimechew Nigusie, Nebreed Fesseha Zemichael, Gizachew Tadele Tiruneh, Yibeltal Tebekaw Bayou, Getnet Alem Teklu, Esubalew Sebsibe Kibret, Kristin Eifler, Sarah E. Hodsdon, Dessalew Emaway Altaye, Leona Rosenblum, Yeshiwork Aklilu Getu, Zinar Nebi, Ephrem Tekle Lemango, Eyob Kebede, Wuleta Aklilu Betemariam

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Anna Kalbarczyk, Svea Closser, Aditi Rao, Oluwaseun Akinyemi, Humarya Binte Anwar, Eric Mafuta, Piyusha Majumdar, Olakunle O. Alonge

Glob Health Sci Pract. 2021;9(3):682-689  
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Lynn G. Jiang, Peter W. Greenwald, Michael J. Alfonzo, Jane Torres-Lavoro, Manish Garg, Ally Munir Akrabi, Erasto Sylvanus, Shahzmah Suleman, Radhika Sundararajana

Glob Health Sci Pract. 2021;9(3):690-697  
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**REVIEWS****Implementation of GeneXpert for TB Testing in Low- and Middle-Income Countries: A Systematic Review**

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Scott Brown, Justine E. Leavy, Jonine Jancey

Glob Health Sci Pract. 2021;9(3):698-710

<https://doi.org/10.9745/GHSP-D-21-00121>

# What Potential Authors Should Know About Publishing in *Global Health: Science and Practice*

Stephen Hodgins,<sup>a</sup> Sonia Abraham<sup>b</sup>

In 2013, the U.S. Agency for International Development (USAID) and the Johns Hopkins Center for Communication Programs launched *Global Health: Science and Practice* (GHSP), responding to what we saw as an important gap in access to robust program-related evidence in global health. It was our conviction that a new kind of journal<sup>1</sup> could both bridge that gap and better serve those engaged directly in program work. Our vision was to contribute to stronger, more effective programs and policies, helping to achieve greater population health impact.<sup>2</sup> It has also been our ambition to exercise influence on global health-related publishing more broadly, shifting norms on inquiry into and documentation of program implementation issues, ultimately to better inform global health policy and practice.

## ■ THE SCIENCE OF PRACTICE

The “practice” in GHSP’s name has remained a central focus. As with other peer-reviewed journals, we certainly have been striving to contribute to evidence-based practice. What is not so typical of journals in this field, but that has been a central preoccupation for us is *practice-based evidence*—lessons that can be drawn from actual programs, especially those implemented at scale.

For programs to be more effective and achieve greater impact, the various actors of the system that create and use practice-based evidence need to be better connected.<sup>3</sup> Program developers and managers, policy makers, advocates, and researchers need to be in continuous dialog, learning from each other, engaged in work informed by what other actors bring to the table.

“Science” is also centrally important to us, in several ways. Robust evidence on the effectiveness of interventions is certainly of interest to us, so methodologic rigor is an important criterion in our review process. In that respect, GHSP is similar to many other journals. But at least equally important for us is the real-world *utility* of study findings.

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Furthermore, we believe *there’s a science to practice*; good, critical, reflective practice requires that we bring rigor and objectivity to our program inquiry. We need to take program performance measurement seriously, be open to disconfirming evidence, and be ready to move in new directions if evidence points us there. We believe that those engaged in program work are continuously drawing useful lessons from their work and that rigorously assessing and documenting and then sharing these lessons can benefit others. We’re interested in drawing lessons from exemplary programs, but we’re equally interested in those that have struggled. We’re concerned with what works (and doesn’t work), under what conditions, to achieve impact at scale on a sustained basis.

There is rich learning to be had from things that don’t work as well as we planned. We understand that the success of a program is almost invariably attributable not only to the intervention itself but to a complex and dynamic interaction between the intervention and the specific context in which it is delivered. At GHSP, we expect authors to provide sufficient detail on the setting or context to allow readers to understand the interplay between intervention and context so they can make better-informed judgments of transferability to their own work settings. An important part of what we do at GHSP is to provide a platform for sharing such insights.

## ■ HOW DO WE UNDERSTAND RIGOR AT GHSP?

Certainly, experimental designs provide stronger evidence for causal inference, but we don’t believe in an evidence hierarchy that automatically places randomized controlled trials and meta-analytic systematic reviews at the pinnacle. There are other kinds of evidence and other ways of understanding rigor or robustness that may be equally relevant when we’re trying to understand what works in the real world.

We are not saying that rigor, as conventionally understood, is not important. What we may think of as research principles certainly apply to program-based evidence. Authors need to be thinking about measurement validity, representativeness, counterfactuals and comparators, confounding, appropriate analytic methods, and sound causal reasoning. Even in opinion pieces,

such as viewpoints and commentaries, authors need to offer well-supported arguments.

## ■ PROMOTING LOCAL VOICES AND PERSPECTIVES

Although work is often done in low- and middle-income countries by researchers based in high-income countries, it's problematic for us when we receive articles on which the authors are overwhelmingly from high-income countries. This is not only a matter of fairness and equity but also of validity. Articles reflecting only an external perspective neglect valuable insights into the realities and nuances of the local system that authors and actors in LMICs can provide.<sup>4</sup> We want to ensure that in-country authors are engaged and meaningfully contributing to documenting and making sense of practice-based evidence.

Similarly, though we welcome papers from donor-funded, in-country projects, we are especially interested in articles that reflect the input and perspective of those working in ministries of health and other in-country institutions.

Over the past year, we have intentionally refocused efforts to ensure that the articles we publish adequately reflect in-country voice and perspective. Last year, we updated our editorial policies to reflect our efforts to ensure that articles reporting findings from specific countries have meaningful participation from in-country authors.

## ■ DIVERSITY, EQUITY, AND INCLUSION

Similarly, last year,<sup>5</sup> we recognized a need for a greater breadth of perspective within our associate editorial team and editorial board and greater diversity in gender, race, ethnicity, and geography. Appointing Abdulmumin Saad as deputy editor-in-chief and recruiting Rajani Ved as an associate editor were among the first steps in bringing broader programmatic expertise and experience as well as diverse perspectives and insights to our editorial team.

We are continuing to identify new editorial board members who can bring valuable research and program experience to help inform GHSP's vision in the future.

## ■ ELIMINATING BARRIERS TO PUBLISHING

In the field of open-access peer-reviewed journals, GHSP has the luxury of publishing articles with no submission fees to authors because of our special funding arrangements with USAID. This allows us to eliminate financial barriers disproportionately affecting early-career professionals and individuals in low- and middle-income countries, as they seek to share learning.<sup>6</sup> To ensure access for authors who are under-represented in peer-reviewed journals, we aim to continue to publish GHSP without fees.

We recognize that we still have much to do in realizing our mission to contribute to more effective health programs and greater population health impact. We invite readers, authors, and reviewers to work with us toward this end and invite your suggestions on how we can do a better job.

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# Multisectoral Policies and Programming: High-Income Countries Can and Should Be Learning From the Philippines and Other Low- and Middle-Income Countries

Madeleine Short Fabic<sup>a</sup>

➔ See related article by *Siy Van et al.*

The global health field often makes a false distinction between research of relevance to low- and middle-income countries (LMICs) and research of relevance to high-income countries (HICs). This practice feeds into and mirrors development practices wherein technical assistance unidirectionally flows from HICs to LMICs; where HICs have experience and teachings to share with LMICs but generally do not recognize the reverse is also true; and where partnership is limited by power hierarchies that elevate the expertise and knowledge of HICs above that of LMICs.<sup>1</sup>

Reading the Siy Van et al. article,<sup>2</sup> “Trends in national-level governance and implementation of the Philippines’ Responsible Parenthood and Reproductive Health Law from 2014 to 2020,” reminded me of the opportunities we miss if the global health field implicitly insists that its research and programmatic learnings are of primary relevance to LMICs. Indeed, I would argue that the challenges the authors present related to multisectoral coordination, collaboration, integration, and accountability parallel issues of public health importance in my home country, the United States. Through this lens, I offer a brief synthesis of the challenges described by Siy Van et al.,<sup>2</sup> as well as some thoughts on how learnings from the Philippines’ experience could be applied to the United States. In the U.S. context, I focus on 2 multisectoral approaches to pandemic prevention, detection, and response that have increased in prominence in the wake of the coronavirus disease (COVID-19) pandemic—global health security and One Health.<sup>3,4</sup>

## ■ PROBLEM A: SILOED IMPLEMENTATION HAMPERED SUCCESS IN ATTAINING OBJECTIVES AND GOALS

### Findings

Governmental collaboration floundered despite the 2012’s Responsible Parenthood and Reproductive Health Act

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(RPRH)<sup>5</sup> law’s guiding principles, which call for “a multifaceted process” that necessitates

*the harmonization and integration of policies, plans, programs and projects that seek to uplift the quality of life of the people.*

Governmental agencies more readily fulfilled mandates that did not require coordination either within or between agencies. Conversely, agencies delayed or altogether missed mandates that relied on multiple institutional structures for reasons generally attributed to bureaucratic delays and inefficiencies. The RPRH was specific about the role of the Department of Health but lacked specificity about the role of other governmental agencies. Additionally, the RPRH law outlined a host of issues to be addressed but did not identify how a multisectoral approach would better address the issues than a set of siloed approaches.

### Recommendations

Competing sectoral interests can be partially mitigated through legislation. As the U.S. Congress contemplates legislation on the heels of the current pandemic, multisectoral governance, including “One Health” and global health security, seems to be gaining traction.\* The Philippines’ experience provides valuable lessons for new legislation: to successfully address multisectoral problems, legislation should clearly articulate a problem statement that identifies why a multisectoral response is required and preferable to a siloed response; additionally, legislation must clearly articulate the roles and responsibilities of each identified organizational entity. Threading this legislative needle of being directive without being overly prescriptive will be an ongoing challenge. Executive branch agencies can help alleviate this challenge by making clear via strategy documents and

\*A quick search on July 19, 2021, of Congress.gov reveals that since the start of the current 2021–2022 U.S. Congress, 10 pieces of legislation have been introduced in the House or Senate that include the term “One Health,” and 21 pieces of legislation have been introduced in the House or Senate that include the term “global health security.”

in Congressional briefings how each agency understands the multisectoral problem, what unique capabilities each agency brings to bear, and how each agency perceives the opportunities afforded by holistic policy making.

## ■ PROBLEM B: DOMINANCE OF 1 TECHNICAL AREA OVER ALL OTHERS OVERLY LIMITED THE SCOPE OF WORK

### Findings

Despite the multidimensional nature of reproductive health and the fact that the RPRH law defined reproductive health care as having 12 elements, RPRH implementers limited the scope of their efforts, focusing predominantly on family planning. As Siy Van et al.<sup>2</sup> report, family planning received “disproportionately more efforts and resources from RPRH implementers than did any other element.” This may have occurred in part because the National Implementation Team, created in 2014 to manage and coordinate interagency RPRH activities, chose key result areas that included only 5 of the 12 elements. Additionally, family planning programs had a strong foundation, having already been explicitly required by law, with widespread implementation throughout the country. Family planning program implementation challenges were already well known. Meanwhile, family planning was under continued attack by various entities in the Philippines, prompting its proponents to amplify focus and attention. Ultimately, interagency conversations focused narrowly on family planning commodities and service provision to the detriment of focus on other elements of reproductive health.

### Recommendations

The adage, “what you measure is what you get,” is worth reciting. If multisectoral programs are intended to have multiple, multisectoral impacts, then legislative and executive branches of government must identify and incorporate multisectoral indicators into monitoring and evaluation plans, ideally in collaboration with civil society and other nongovernmental stakeholders. In the context of One Health, this means that animal, human, and environmental health should all have equal footing and focus, including measurement focus. It also means that no one sector can dominate the narrative or dominate the policy and programming approach. In the Philippines, for example, the Department of Health was tasked with leading the overall reproductive health effort, and the approach became dominated

by the Department’s biomedical understanding of the problem. As the U.S. Government and new administration consider how best to organize to tackle complex problems like pandemic prevention or climate change, organizational structures that elevate multiple sets of expertise and problem perspectives are more likely to yield effective multisectoral responses. For example, were the United States to support a pandemic prevention convening body, rotating organizational leadership chairs from varied executive branch agencies with stewardship and support from the White House and/or Congress can serve to elevate multiple perspectives in advancement of an overarching strategy. Additionally, moving away from narratives like “global health security,” where a human health context dominates the discourse and programming, and toward narratives like “One Health,” where an interconnected human-animal-environment health context dominates, can further support effective multisectoral collaboration and programming approaches.

## ■ PROBLEM C: FOCUS ON PROGRAMMATIC CONCERNS LIMITED DEVELOPMENT AND IMPLEMENTATION OF AN OVERARCHING MULTISECTORAL STRATEGY AND RESPONSE, WHICH INHIBITED SUCCESS

### Findings

Interagency meetings narrowly focused on programmatic issues that concerned only 1 or 2 agencies, never allowing time or space for collaborations to coalesce. Such narrow emphasis likely stemmed from a lack of clear multisectoral expectations and identified outputs. Moreover, accountability tools were missing. Without an objective arbiter, interagency disagreements were rarely raised or addressed. And without a shared monitoring and evaluation plan that included measures of multisectoral success, indicators of progress remained within their original organizational silos.

### Recommendations

Multisectoral work requires effective stewardship and leadership, which Siy Van et al. suggest needs 3 things: (1) clear outcomes and goals known by all engaged parties; (2) necessary resources—including financial, human, policy infrastructure, and related tools to enforce agreed upon mandates/deliverables; and (3) designated participants with clearly identified roles and responsibilities.

While leadership within U.S. agencies and large bureaucracies is generally vertical and top-down, horizontal stewardship and leadership can also play a role in forging relationships and partnerships, building trust, and identifying shared goals. Learning from the Philippines' experience, were the United States to move toward multisectoral One Health work, it would benefit by having top-down leadership from the Executive branch, for example, a Presidential Czar, coupled with horizontal leadership from various engaged agencies. The legislative branch would need to ensure that the efforts were appropriately financially resourced, and each respective agency would need to ensure that requisite staff were identified and actively engaged. At the outset, a multisectoral group would need to develop shared, codified outcomes and goals, and a monitoring and evaluation plan that effectively represents multisectoral work, which is not simply a repackaging of existing workstreams but is instead a new way of collaboratively operating.

In conclusion, and as I hope I have well illustrated herein, the United States and other HICs

can and should be learning from the experiences of the Philippines and other LMICs.

**Disclaimer:** This manuscript was produced and prepared independently by the author. The contents of this manuscript are the author's sole responsibility and do not necessarily reflect the views of the United States Agency for International Development or the United States Government.

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# It's Time to Move Beyond Traditional Health Care Worker Training Approaches

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➔ See related article by Traicoff et al. and Tchoualeu et al.

Increasingly, donors and ministry of health officials are recognizing that historical approaches to training and supervision have not resulted in desired changes in provider performance, quality of care, and improved health outcomes. The traditional, classroom-based trainer of trainer (TOT) and cascade approach evolved in an era when access to knowledge was limited to a small set of individuals, or master trainers, and the process of bringing individuals into an off-site, hotel-based location catered to the logistical convenience of international or regional trainers. Evidence has accumulated that such approaches yield disappointing results. A 2016 review of national surveys in sub-Saharan Africa found that these traditional interventions were associated with only modest improvements—<sup>1</sup>

*equivalent to 2 additional provider actions out of the 18–40 actions expected per visit.*

At the same time, evidence has shown that there are approaches that deliver training more effectively and efficiently than the classic group-based training, which removes health care workers from the workplace, and that instead develop their skills in the workplace itself.<sup>2</sup> Consequently, emphasis has increased on workplace-based training combined with mentorship and follow-up. Such approaches have been facilitated through expanded access to digital technology and real-time data to support just-in-time mobile learning.

This issue of *Global Health: Science and Practice* has 2 articles from Traicoff et al.<sup>3</sup> and Tchoualeu et al.<sup>4</sup> on an intervention for improving knowledge and practices of immunization programming in 3 regions of Ghana. The authors of these articles would like to reflect on increasing the effectiveness and rigorous evaluation of cascade training models. These articles describe the methods and results of a multi-pronged effort that relied on cascade training. Traicoff et

al.<sup>3</sup> point out the inherent risks of TOT, including but not limited to a lack of resources or planning for the cascade. They describe their efforts to mitigate the risks via design, delivery, and post-training support. One divergence of the approach from the traditional cascade model was that the trainers were trained on the training role itself and on adult learning methods. All too often, in traditional cascade training models, trainers are assumed to have the requisite abilities and attitudes needed to carry out training and are simply trained on the learning content. Also, trainers in the program were given clear expectations from management, action planning, mentoring, and several job aids to assist them as they cascaded the training. Still, a majority of their interventions were in classroom rather than workplace settings (“65 workshops, 43 field visits, and 4 review meetings, reaching 1,378 HCWs within 7 months”<sup>3</sup>).

The results from these mid-scale interventions seemed to have been incrementally better than those that could be expected from the traditional approach. Tchoualeu et al. wrote<sup>4</sup>:

*Modest but not statistically significant improvements were found in knowledge on [Expanded Programme on Immunization] policy, immunization data management, and communication skills with caregivers. Health care workers reported that they had improved several attitudes and practices after the [Second Year of Life] training. The most improved practice reported by [health care workers] and observed in all 3 regions was the creation of a defaulter list.*

While these interventions were not shown to be statistically significant, qualitative data were informative to determine the impact of the trainings on changes in provider behaviors.

**Still, we should ask ourselves “isn't it time that we, as a global community, move even more boldly beyond traditional training and supportive supervision models?”** If so, what would that look like? A 2013 literature review on effective in-service training techniques, setting, frequency, and media found that interactive, case-based learning, hands-on practice or simulation, delivered in the workplace can improve learning outcomes; and that computer or mobile-delivered instruction, if appropriately designed for user engagement, can be equally as effective as live instruction.<sup>5</sup> In 2009, Rowe et al. published a landmark literature review on interventions to improve

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health care provider performance in low- and middle-income countries. This review concluded that “training alone results in low effect size.”<sup>6</sup> These findings support the extensive research that has been done in the field of human performance technology, which confirms the relatively low impact of training compared to the environmental factors affecting a worker.<sup>7</sup> Rowe recently published an update, using an expansion of the database that he and his collaborators had established that now includes data from 199 studies from 51 countries. This update concluded that educational outreach visits to facilities\* (i.e., mentoring visits) were somewhat more effective than in-service training and that in-service training effectiveness was greater if it included clinical practice, occurred within the workplace, and was combined with supervision.<sup>8</sup> Not only can experiential, on-site approaches be more effective in improving learner and clinical outcomes, they also reduce health worker absenteeism and disruption of services.

Significant challenges remain in terms of operationalizing these newer approaches to improving health provider capacity, especially at scale and under routine conditions. During this transition period, the practical tools and evaluation described in these articles can be useful to training programs. To move forward, sustainable mechanisms need to be built into systems to give providers protected time to learn new or additional skills. Managers can use Gottfredson and Mosher's risk analysis model to identify those skills that carry the greatest risk of harm if done improperly and prioritize them for supervision and workplace support.<sup>2</sup> There are also questions about how best to ground these efforts to support and improve health care provider performance in more comprehensive quality improvement initiatives. There are ample opportunities to leverage technology to support effective learning and more cost-effective and targeted supervision. The coronavirus disease (COVID-19) pandemic has increased access and acceptability of distance-based delivery methods and has provided opportunities for innovative training, peer learning, and support-

ive supervision. Whether providing the means for just-in-time learning moments, virtual mentorship visits, facilitation of targeted in-person supervision based on performance, or real-time monitoring of data on key indicators via dashboards, the opportunities to thoughtfully integrate appropriate and sustainable digital solutions have never been greater. Finally, there is a need to commit to evaluating the learning experience and tracking outcomes, including emphasizing qualitative data analysis and measuring informal learning.<sup>9</sup> A fresh approach to training design, workplace support, and independent evaluation can support accountability and help public health programs develop a competent, confident, and continually improving workforce.

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\*Rowe et al. define education outreach visits to facilities as an “on-the-job training strategy with face-to-face visits to individual health care providers at their workplace by persons who health care providers regard as an expert or opinion leader to promote best practices. Also known as academic detailing.”

COMMENTARY

# The Conundrum of Low COVID-19 Mortality Burden in sub-Saharan Africa: Myth or Reality?

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## Key Messages

- Evidence suggests the demographic age structure of sub-Saharan Africa is the leading factor of the low morbidity and mortality of COVID-19 compared to other regions of the world.
- Widespread social mitigation strategies, such as lockdowns, have resulted in severe economic and societal consequences in terms of food security, adolescent pregnancy, gender-based violence, and disruptions in treating other diseases.
- It is imperative to weigh the risks and benefits of social mitigation strategies for future waves.

## BACKGROUND

COVID-19 has impacted the world immensely since its discovery in the city of Wuhan, China, in December 2019.<sup>1,2</sup> As of June 27, 2021, approximately 181.9 million COVID-19 cases have been confirmed with more than 3.9 million deaths.<sup>3</sup> COVID-19 has dramatically impacted the Americas, Europe, and Asia. As of June 27, 2021, in the Americas, 73.1 million confirmed COVID-19 cases with 1.9 million deaths have been reported, 47.8 million confirmed cases with more than 1 million deaths in Europe, and 55.4 million confirmed cases with 784,965 deaths in Asia.<sup>4</sup>

The impact of COVID-19 in Africa has been substantially lower compared to countries in the Americas, Europe, and Asia. The World Health Organization (WHO) African Region reported more than 3.9 million confirmed cases and 94,217 deaths, as of June 27, 2021.<sup>5</sup> Moreover, the mortality rate of COVID-19 per million in Africa is considerably lower than in all other WHO regions other than the Western Pacific (Table 1).<sup>5-11</sup> Public health preparedness is a significant aspect in the success of reducing COVID-19 transmission. Lessons learned from countries across Eastern Asia imply the need for community-oriented strategies and rapid response from public health officials to successfully contain the COVID-19 pandemic.<sup>12</sup> Strategies such as early case identification, widespread laboratory testing and screening, outbreak mitigation (up to and including lockdowns), contact tracing, health education, physical distancing, and quarantine measures have been demonstrated as essential interventions in curbing the pandemic.

This article critically examines the hypotheses that have been attributed to the apparently lower than expected morbidity and mortality of COVID-19 in SSA to help guide public health decision making regarding essential interventions for containing COVID-19.

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**Lessons learned from Eastern Asia imply the need for community-oriented strategies and rapid response from public health officials to successfully contain the COVID-19 pandemic.**

**POTENTIAL MITIGATING FACTORS INFLUENCING THE MORBIDITY AND MORTALITY OF COVID-19 IN SUB-SAHARAN AFRICA**

It is posited that the low impact of COVID-19 in SSA is due to 1 or several of 6 main hypotheses (Figure 1).

**Hypothesis 1: Demographics of sub-Saharan Africa**

Global mortality trends of COVID-19 show marked differences by demographic characteristics including age (increased risk of severe illness in older individuals), sex (higher among males), socioeconomic status, and race (higher among Blacks). In the United States, the Centers for Disease Control and Prevention (CDC) report that 80% of COVID-19-related deaths occur in individuals aged 65 years and older.<sup>13,14</sup> Data from the United Kingdom has demonstrated that the strongest risk for death is advanced age, which dramatically outweighs the risks associated with any other demographic factor or medical condition.<sup>15</sup> Demographic structures for Europe, the Americas, and Asia demonstrate median age ranges from 32 years to 42.5 years,<sup>4,16-19</sup> with 8.9% to 19.1% of the population older than 65 years.<sup>20-23</sup>

In contrast, the median age of the SSA population is considerably lower, with a median age of 18 and only 3.0% of the African population older than 65 years.<sup>24,25</sup> Figure 2 compares the population pyramids of Uganda and Canada, which are similar in overall population size. The median age of Canada (41.1 years) is remarkably higher than that of Uganda (16.7 years).<sup>26,27</sup> In Uganda, less than 0.2% of the population is in the highest-risk

group of developing more severe illness (aged 80 years and older).<sup>28</sup> Conversely, the proportion of individuals aged 80 years and older in Canada is higher (4.4%).<sup>29</sup> Further, Figure 3 illustrates the distribution of COVID-related deaths in Canada as of June 25, 2021.<sup>30</sup> A large proportion of deaths are attributed to older age; approximately 98.0% of COVID-related deaths occur in individuals aged 50 years and older, with approximately 64.7% in individuals aged 80 years and older.<sup>30</sup> With the rollout of COVID-19 vaccinations and prioritization of those aged 70 years and older in North America and other areas, the mean age of those being admitted to hospital has decreased.<sup>31,32</sup> However, it is still highly likely that those aged 70 years and older remain the highest risk among the unvaccinated population.

Comparison of the age demographics of Uganda with other lower-middle-income countries in regions such as Latin America and the Caribbean and South Asia demonstrates the uniqueness of the demographic structure in SSA. The median age in Brazil is 33.5 years, Peru 31.5 years, and Mexico 29.2 years, which are all markedly higher than in SSA. Low-income countries in Latin America and the Caribbean, such as Nicaragua, El Salvador, and Haiti also have greater median ages (24.0–27.6 years) and a larger proportion of the population age 65 and older (5.2%–8.7%) than in SSA.<sup>33-38</sup> Similar demographics are observed for countries in South Asia, such as India and Pakistan; median age ranges from 22.8–28.4 years with 4.4%–6.6% of the population aged older than 65 years.<sup>39-42</sup>

Older age is associated with more degenerative and metabolic disorders that have also been shown to heighten the risk of death from COVID-19. Therefore, it is posited that the demographic

**TABLE.** Confirmed COVID-19 Cases and Mortality Rates per WHO Region<sup>a</sup>

WHO Region <sup>b</sup>	COVID-19 Cases	COVID-Related Deaths	Population <sup>c</sup>	Mortality Rate per Million
Africa <sup>5</sup>	3,942,448	94,217	1,019,922,000	92.4
Americas <sup>6</sup>	71,959,063	1,891,291	992,155,000	1,906.2
South-east Asia <sup>7</sup>	34,657,785	485,398	1,947,632,000	249.2
Europe <sup>8</sup>	55,821,905	1,181,992	916,315,000	1,289.9
Eastern Mediterranean <sup>9</sup>	10,916,353	215,799	664,336,000	324.8
Western Pacific <sup>10</sup>	3,521,244	54,069	1,889,901,000	28.6

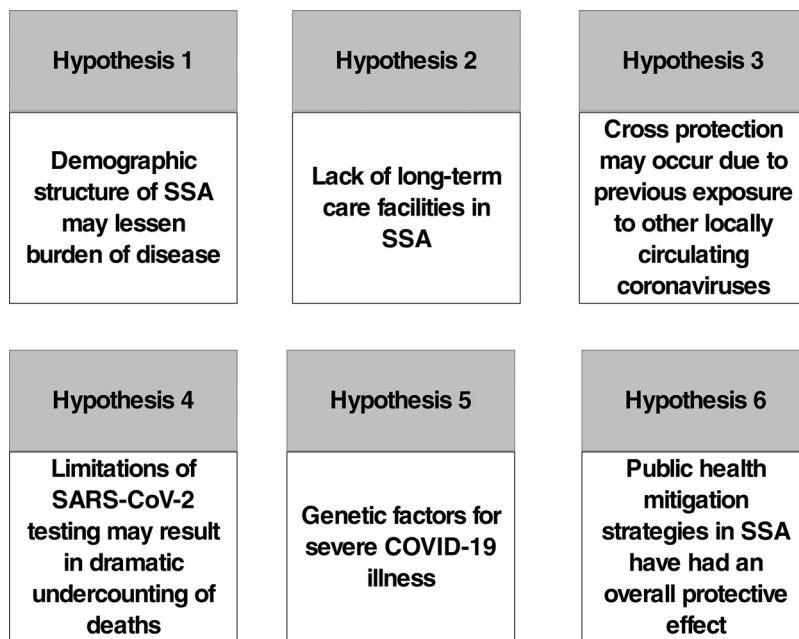
Abbreviations: COVID, coronavirus disease; WHO, World Health Organization.

<sup>a</sup>Information up to date as of June 27, 2021.

<sup>b</sup>Refer to the Supplement for a comprehensive list of WHO Member States.

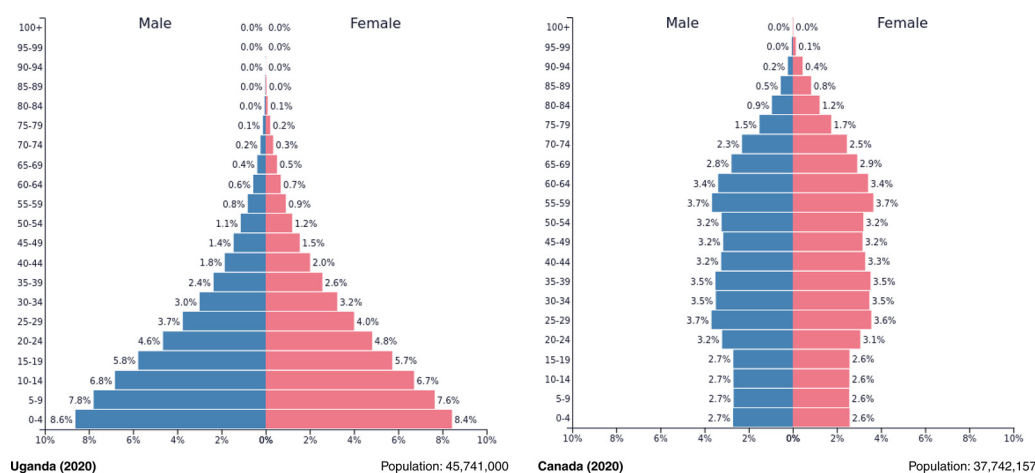
<sup>c</sup>Population data taken from the 2016 WHO Global Health Observatory data repository.<sup>11</sup>

**FIGURE 1.** Proposed Hypotheses Explaining the Limited Impact of COVID-19 in SSA



Abbreviations: COVID-19, coronavirus disease; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; SSA, sub-Saharan Africa.

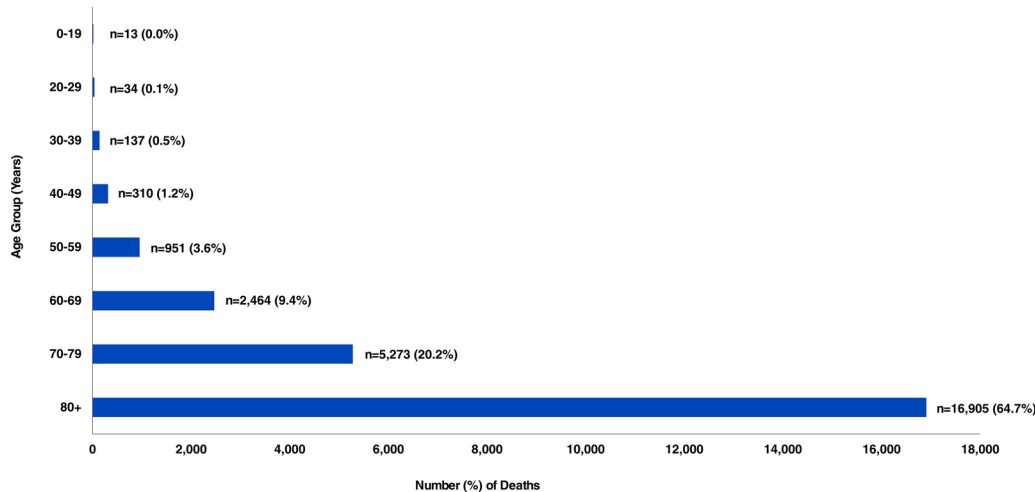
**FIGURE 2.** Population Pyramids of Uganda and Canada<sup>28,29</sup>



structure of SSA plays a critical role in the low morbidity and mortality of COVID-19. It is possible that the burden of severe disease and death may be low despite suspected and undetected widespread transmission. In fact, it is possible that widespread transmission has already occurred

without precipitating the high death rates seen elsewhere due to the relatively small proportion of elderly and lack of large long-term care facilities for the elderly, which have been the epicenters of mortality in Canada and elsewhere.<sup>43</sup> It is notable that some areas of SSA, such as South Africa, have

**FIGURE 3.** Age Distribution of COVID-19 Cases Deceased in Canada as of June 25, 2021<sup>30</sup>



**It is possible that widespread transmission has already occurred without precipitating the high death rates seen elsewhere due to the relatively small proportion of elderly and lack of large long-term care facilities.**

a much higher median age (27.6 years), which could be a reason for the higher COVID-19 death rates seen there.<sup>44</sup>

### Hypothesis 2: Lack of Long-Term Care Facilities

In addition to the demographic pyramid demonstrating very low numbers of elderly, the elderly in SSA do not tend to live in long-term care facilities. The CDC defines long-term care facilities as those whereby elderly who are unable to live independently receive medical and personal care.<sup>45</sup> Unfortunately, long-term care facilities pose a significant risk for infectious and communicable diseases; approximately 1.0–3.0 million infections occur in these facilities per year.<sup>45,46</sup> During the first wave of the epidemic in Canada, 81.0% of all deaths occurred in long-term care facilities.<sup>47</sup> Transmission to the elderly can be particularly efficient in these settings and lead to a markedly higher infection fatality rate.<sup>48</sup>

Across SSA, long-term care facilities are almost nonexistent, with the notable exception of South Africa, leaving the provision of care to families.<sup>49,50</sup> Large young families with high levels of unemployment and low labor costs enable care to be provided by individual relatives rather than a team of professionals, which limits the number of caregivers that may transmit infection. In the first wave, approximately 33% of South African long-term care facilities experienced outbreaks.<sup>51</sup> Furthermore, data from South Africa have demonstrated that COVID-19-related deaths are highly correlated with increased age; approximately 2.2% of all COVID-19-related

deaths occurred among persons younger than 30 years, despite their consisting of 54.2% of the population.<sup>52,53</sup> This is a further potential explanation for South Africa being an outlier with a higher death rate than in other African countries.<sup>54</sup>

### Hypothesis 3: Prior Exposure to Coronavirus Infection

In addition to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, 6 other human coronaviruses have been identified. Seasonal human coronaviruses, such as NL6, 229E, OC43, and HKU1, are common and result in cold- or flu-like symptoms.<sup>55</sup> Zoonotic coronaviruses, such as Middle East Respiratory Syndrome (MERS)-CoV and SARS-CoV, are responsible for more severe diseases.<sup>55</sup> Previous exposure to locally circulating coronaviruses and the development of antibodies is posited to mediate cross-protection to COVID-19 and induce partial immunity.<sup>56</sup>

Several studies have been conducted to investigate this unique relationship. Studies assessing antibody prevalence to SARS-CoV-2 in pre-pandemic serum samples observed a significant increase in the prevalence of cross-reactivity among sera in SSA compared to other continents.<sup>57</sup> In addition, previous studies have demonstrated high false positivity when testing pre-pandemic sera from SSA using European assays.<sup>58,59</sup> The discrepancy of seropositivity may be attributed to widespread exposure to various endemic coronaviruses before the emergence of

the SARS-CoV-2 pandemic. A limitation of these studies was the use of serological assays to determine previous exposure, particularly because there can be discrepancies in results when comparing T-cell versus antibody evidence of exposure and immunity.<sup>60</sup> In contrast, a study by Sagar et al.<sup>61</sup> used results from previously performed comprehensive respiratory panel polymerase chain reaction assays to examine the impact of previous exposure to endemic coronaviruses in COVID-19 patients. Their results demonstrated a significant decrease in odds of mortality and odds of being admitted to an intensive care unit in patients who had evidence for previous exposure to endemic coronaviruses compared to those who did not.<sup>56,61</sup> These findings indicate that exposure to other coronaviruses may reduce the severity and burden of COVID-19. Furthermore, a recent study by Uyoga et al.<sup>62</sup> observed increased rates of antibody prevalence to SARS-CoV-2 among Kenyan blood donors between April 30–June 16, 2020, that are higher than case counts would predict.

#### Hypothesis 4: Limited Access to Adequate Testing

There are concerns regarding the recording of COVID-19 cases in SSA. It is hypothesized that there has been a dramatic undercounting of deaths due to lack of SARS-CoV-2 testing as was suggested in the mass media to have happened in Kano, Nigeria.<sup>63,64</sup> Current data may not reflect the true extent of the disease. The true numbers of infected and deaths could be higher given that, at least in South Africa where the median age is much higher than SSA as a whole,<sup>44</sup> the excess mortality observed is far higher than the officially reported totals for deaths from COVID-19. Lack of local access to testing and contact tracing, and insufficient data collection have interfered with the ascertainment of the incidence and prevalence of COVID-19 in SSA. The WHO reports varying levels of testing across Africa, however, testing is still relatively low compared to other areas of the world.<sup>65</sup> As of June 25, 2021, testing rates ranged from as low as 7.7 tests per 1,000 population in Madagascar to as high as 215.3 and 389.9 tests per 1,000 in South Africa and Gabon, respectively.<sup>66</sup> However, these numbers are far lower than rates in the United States (1,401.8 tests per 1,000 population) and the United Kingdom (2,973.0 tests per 1,000 population).<sup>66</sup> Although low testing rates likely resulted in a much lower case rate, the lack of hospital overcrowding and widespread deaths likely

resulted from lower morbidity and mortality in this region. This would suggest a lower predisposition to severe illness. The initial priority for the Africa Task Force for Novel Coronavirus was to expand COVID-19 testing capability. This expansion proceeded rapidly; at the outset of the pandemic, only 2 labs in Africa were capable of SARS-CoV-2 detection, but by mid-March 2020, 43 countries had this laboratory capability.<sup>67</sup> Preliminary observations from the poorly maintained civil and vital registration systems seem to indicate that it is unlikely that there has been excess all-cause mortality in the region.<sup>68</sup> Studies are underway in Kenya assessing excess mortality through verbal autopsies and population-based serosurveys for past infections to assess past exposure.<sup>69</sup>

The concerns of recording the impact of COVID-19 across SSA offers the opportunity of novel means of data collection to expand current knowledge on COVID-19 morbidity and mortality. Morbidity may be further explored through the use and purchase of oxygen as a proxy of the current situation in hospitals. Further, data collection on death may be extended to churches and faith groups, obituaries, and morticians. These and other means should be further explored to help better understand the impact of COVID-19 on SSA as a whole.

#### Hypothesis 5: Genetic Risk Factors

Studies from developed countries have demonstrated a higher risk of death in racialized communities, including those of African or South Asian descent.<sup>15</sup> This predisposition is likely related to socioeconomic factors including poverty, crowding, and working in essential services. Therefore, overall environmental exposures are likely far more important than genetic exposures in disease susceptibility.

#### Hypothesis 6: Effective Government Public Health Response to COVID-19 Threat

Another hypothesis is that African governments and public health organizations moved remarkably swiftly in response to the threat of COVID-19. Early in January 2020, African governments began to plan for the arrival of COVID-19 as high flight volumes between China and Africa predicted early spread to multiple locations including South Africa, Nigeria, and Kenya.<sup>70</sup> As early as January 2, 2020, Côte d'Ivoire implemented enhanced screening measures for passengers arriving from China.<sup>71</sup> Other African countries swiftly followed suit. In February 2020, the first meeting of the newly established Africa Task Force for Novel Coronavirus convened. The first confirmed

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case of COVID-19 on the African continent was reported in Egypt on February 14, 2020, and linked to travel from China. By March, almost all African nations had suspended flights from China. After March 2020, most cases imported to Africa originated from Europe, as the epicenter of the disease had shifted there.<sup>72</sup> By May 2020, more than 40 African nations had closed their borders to all but cargo.<sup>71</sup>

National public health institutions are responsible for disease surveillance, diagnostics, and rapid response to outbreaks, making them essential for curbing the emergence and re-emergence of infectious diseases in the African context, especially COVID-19.<sup>73</sup> As of 2019, Botswana, Ethiopia, Ghana, Liberia, Morocco, Mozambique, Namibia, Nigeria, Rwanda, Sierra Leone, South Africa, Uganda, and Zambia all had highly functional national public health institutions with experience in battling infectious diseases.<sup>73,74</sup> These organizations focus on infectious disease threats, which is in contrast to those organizations in high-income countries that have focused on non-communicable diseases. Uganda is a leading example of curbing the impact of COVID-19 in the African context. Rapid response and implementation of risk communication, testing, social and physical distancing measures, and contact tracing were critical for the success seen in Uganda.<sup>75</sup>

Additionally, new programs to promote regional sharing of COVID-related information were initiated across SSA. For example, the East African Community created the Regional Electronic Cargo and Drivers Tracking System. This system electronically shares the COVID test results of truck drivers between member countries. In addition, the program uses the drivers' cell phones to track their routes and record stops. This tracking allows for quick contact tracing in the event of a COVID-19 outbreak.<sup>76</sup> Furthermore, several African countries have scored particularly well in critical policy areas in terms of public health directives, financial responses, and fact-based public communications to help control COVID-19.<sup>77</sup> In particular, Kenya, Ghana, and Ethiopia scored more than 95 on a 100-point scale.<sup>77</sup> This may have helped to mitigate the scope of the pandemic although further validation of the scores would be helpful.

### Other Hypotheses

#### **Adherence to Preventative Strategies**

Some studies suggest that adherence to recommendations for handwashing, social distancing, and public masking has been widespread in SSA,<sup>78,79</sup>

however, the generalizability of these observations to multiple SSA countries and contexts, as well as comparative data between African and non-African countries require further study.

#### **Drugs Against Parasitic Infections**

Infections with parasites have been suggested to be associated with less severe COVID-19 in an as yet non-peer-reviewed Ethiopian study although this finding requires replication in other locales.<sup>80</sup> SSA countries within the tropical and equatorial regions appear to have the lowest proportion of confirmed COVID-19 cases and the highest burden of malaria infection.<sup>81</sup> Several factors have been posited to contribute to the low incidence of COVID-19 in these malaria-endemic countries, including cross-protection from consistent use of antimalarial medication.<sup>81</sup> However, the failure of hydroxychloroquine to prevent COVID-19 in randomized studies makes this hypothesis less likely.<sup>82</sup> In addition, ivermectin, an antiparasitic drug used to treat several neglected tropical diseases, such as onchocerciasis, strongyloidiasis, and lymphatic filaria,<sup>83,84</sup> has been widely used across SSA since the 1990s.<sup>85</sup> A study conducted by Caly et al.<sup>86</sup> found ivermectin to be an inhibitor of the SARS-CoV-2 virus *in vitro*. Despite the hypothesized association between antiparasitic medications and COVID-19, at present, there is still only limited evidence to support it.<sup>87,88</sup>

#### **Prevalence of Noncommunicable Diseases**

Noncommunicable diseases, such as hypertension, diabetes, and obesity, have been observed to increase the severity of COVID-19 illness.<sup>89</sup> In comparison to North America, the rates of non-communicable diseases, such as diabetes and obesity, are remarkably lower in SSA. Data from 2017 demonstrate that the prevalence of diabetes in the United States and Canada was observed to be 10.8% and 7.4%, respectively.<sup>90</sup> Conversely, the prevalence of diabetes among SSA was observed to range from 1.0%–7.8%, with exception of Sudan and South Sudan, whereby the prevalence of diabetes was 15.7% and 10.4%, respectively.<sup>90</sup> Further, approximately 70.2% and 67.5% of adults in the United States and Canada, respectively, have been observed to be either overweight or obese (BMI greater than 25).<sup>91</sup> Conversely, among countries in SSA, these rates range from 18.1%–38.4%, with exception of South Africa whereby 51.9% of adults are either overweight or obese.<sup>91</sup> The prevalence of hypertension, however, is considerably higher in SSA compared to

North America.<sup>92</sup> Further studies should be conducted to understand the roles of noncommunicable diseases and COVID-19 severity in the African context.

### Mobility

It also has been hypothesized that lower mobility and spending a greater amount of time outdoors may have reduced the risk of COVID-19, especially in impoverished rural areas.<sup>93</sup> Reduced travel between African countries due to limited visa-free relationships may have also limited spread across the continent.<sup>94</sup> Further study would be necessary to confirm these hypotheses.

## ■ SOUTH AFRICA AS AN OUTLIER

South Africa appears to have had a particularly high incidence of COVID-19 hospitalizations and deaths. This has been attributed to several phenomena. As noted above, South Africa has a higher median age as well as an established long-term care facility sector. The very high HIV and TB burden in South Africa may be another factor as both of these were found to be associated with an increased COVID-19 mortality rate in a South African cohort.<sup>54</sup> Maintaining antiretroviral therapy is particularly important in light of the data demonstrating poor COVID-19 outcomes in patients with low CD4 counts.<sup>95</sup> In addition, the effects of noncommunicable diseases may contribute to the higher burden of COVID-19 seen in South Africa. The prevalence of hypertension in South Africa has been reported to range from 26.9%–30.4% and is increasing.<sup>96,97</sup> Furthermore, the prevalence of diabetes in South Africa has been reported to be 12.8%<sup>98</sup> and was found to be the second leading cause of death in South Africa in 2015.<sup>99</sup> Moreover, obesity rates among men and women in South Africa have been reported to be 31.0% and 68.0%, respectively. Further research needs to be conducted on various noncommunicable factors that may contribute to the increased COVID-19 burden seen in South Africa.

Better diagnostics and health care documentation, including death registries, may also allow for higher reporting rates. The emergence of the SARS-CoV-2 variant, 501.V2, has demonstrated the potential for greater transmissibility and risk of reinfection as well as a concern of relative vaccine resistance, leading to severe future waves of infection in South Africa.<sup>100,101</sup>

## ■ IMPLICATIONS FOR POLICIES AND PROGRAMS

Based on the current COVID-19 situation in SSA, to help policy makers and programs improve health practice, the following policy prescriptions have emerged:

- Reduce emphasis on lockdowns, which may disproportionately affect young people and the poor and may lead to other severe health consequences as noted in the article.
- Emphasize the importance of good governance regarding health directives and open communication.
- Provide financial support to vulnerable sectors as per experience in Kenya and Ghana.<sup>77</sup> In light of the limited resources of many African countries, this may require the assistance of external agencies.
- Prioritize an international effort to develop vaccines tailored to the SARS-CoV-2, 501.V2.
- The impact of oxygen shortages in a developing country suffering a COVID-19 outbreak has been severely apparent in India.<sup>102,103</sup> Therefore, governments must ensure the availability of medical infrastructure should an unexpected rapid system-wide severe outbreak occur.
- Prioritize efforts to establish molecular epidemiology to be aware of the emergence of new variants. In particular, the emergence of new variants of concern, which may be more virulent in younger populations, would require a reconsideration of Africa's susceptibility to a severe epidemic.
- Conduct studies to determine the risk factors for severe disease in the African context. These may include detailed cohort studies of patients who do get severely ill in SSA countries with appropriate controls (such as patients who test negative for SARS-CoV-2).

## ■ CONCLUSIONS

In reviewing the totality of the evidence, we believe that it is suggested that in SSA the overall death rate is lower than in most other regions primarily due to the demographic structure with a low median age and a small percentage of vulnerable elderly, although as noted, other factors likely also play a role. Some localized areas with a greater number of older individuals, such as South Africa, may be exceptions to this trend. The presence of a long-term care facility sector as well as extremely high rates of HIV and TB coinfection,

**Diabetes and obesity have been observed to increase the severity of COVID-19 illness, but the rates of diabetes and obesity are remarkably lower in SSA compared to North America.**



and effects of noncommunicable diseases may also have led to South Africa having a higher disease burden. Limited resources for disease diagnosis, effective public health campaigns, and other factors discussed are also important considerations. Further studies to clarify these various hypotheses for the low mortality presently reported in Africa are required. While data accrue, the risks and benefits of widespread social mitigation strategies such as lockdowns, need careful consideration. The continent is reeling from the effects of the pandemic; the economic and societal tolls in terms of hunger, teen pregnancy, gender-based violence, and disruptions in the treatment of malaria, TB, and HIV are enormous. Furthermore, the 501.V2 variant of SARS-CoV-2 heightens the risks of further waves and raises the risk to the rest of the continent, including the danger of hospitals reaching capacity in other SSA countries.<sup>104</sup> However, as discussed, widespread adoption of stringent lockdown strategies used previously should be undertaken only with great caution. Consideration must be given to local, unique conditions such as the age structure of the population, competing health risks, and food security.<sup>104</sup>

With the recent experience of a severe second wave in India, it is imperative to establish adequate molecular epidemiology to monitor emerging variants that have the potential to cause severe infection in the younger population. As full vaccine rollout in Africa with widespread coverage will likely not occur for some time, these issues remain of critical importance. This review of the literature will aid countries in adopting unique strategies for limiting the spread of COVID-19 without the need for stringent lockdowns. Further research on the potential mechanisms needs to be carried out to understand other possible reasons for the observed discrepancy in mortality seen in SSA.

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# A Quality Improvement Intervention to Inform Scale-Up of Integrated HIV-TB Services: Lessons Learned From KwaZulu-Natal, South Africa

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## Key Findings

- The quality improvement (QI) intervention was able to guide clinic staff in developing simple but effective change interventions, using resources already available, to improve HIV-TB integrated service delivery.
- The QI intervention implemented dramatically improved isoniazid preventive therapy initiation rates among eligible HIV patients and resulted in moderate improvements in HIV testing and screening, TB screening, and viral load monitoring.

## Key Implications

- Program managers should ensure that all categories of health care workers from all levels of the health care system are included in QI workshops or learning sessions to harness the knowledge and experiences of all role players working within the system.
- QI implementers should consider adopting a combination approach to improvement interventions, such as QI training combined with mentorship, collaborative learning, and data QI activities.
- To strengthen and ensure the success of QI interventions, senior-level program managers should consider allocating resources (human, financial, and infrastructure) dedicated to data QI for a sustainable and effective QI program.

## ABSTRACT

**Introduction:** In South Africa, mortality rates among HIV-TB coinfecting patients are among the highest in the world. The key to reducing mortality is integrating HIV-TB services, however, a generalizable implementation method and package of tested change ideas to guide the scale-up of integrated HIV-TB services are unavailable. We describe the implementation of a quality improvement (QI) intervention, health systems' weaknesses, change ideas, and lessons learned in improving integrated HIV-TB services.

**Methods:** Between December 1, 2016, and December 31, 2018, 8 nurse supervisors overseeing 20 primary health care (PHC) clinics formed a learning collaborative to improve a set of HIV-TB process indicators. HIV-TB process indicators comprised: HIV testing services (HTS), TB screening among PHC clinic attendees, isoniazid preventive therapy (IPT) for eligible HIV patients, antiretroviral therapy (ART) for HIV-TB coinfecting patients, and viral load (VL) testing at month 12. Routine HIV-TB process data were collected and analyzed.

**Results:** Key change interventions, generated by health care workers, included: patient-flow redesign, daily data quality checks; prior identification of patients eligible for IPT and VL testing. Between baseline and post-QI intervention, IPT initiation rates increased from 15.9% to 76.4% ( $P=.019$ ), HTS increased from 84.8% to 94.5% ( $P=.110$ ), TB screening increased from 76.2% to 85.2% ( $P=.040$ ), and VL testing increased from 61.4% to 74.0% ( $P=.045$ ). ART initiation decreased from 95.8% to 94.1% ( $P=.481$ ).

**Discussion:** Although integrating HIV-TB services is standard guidance, existing process gaps to achieve integration can be closed using QI methods. QI interventions can rapidly improve the performance of processes, particularly if baseline performance is low. Improving data quality enhances the success of QI initiatives.

## INTRODUCTION

In South Africa, TB remains a public health challenge largely driven by a high background prevalence of HIV, estimated at 12% in the general population.<sup>1</sup> In 2019, an estimated 58,000 people died from TB, of whom 36,000 (62%) were coinfecting with HIV.<sup>2</sup> For South Africa to achieve its goal of reducing TB deaths by 95% by 2035, steps to accelerate the reduction in TB mortality are needed, specifically in HIV-TB coinfecting patients.<sup>3</sup>

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Integrating HIV and TB services (hereafter written HIV-TB services) is a key strategy in reducing TB-related deaths among people living with HIV.<sup>4</sup> HIV-TB services refers to screening, diagnosis, and treatment services provided for both diseases at the same clinic, by the same clinic team, on the same visit day.<sup>5,6</sup> We have previously published the key evidence-based, clinical HIV-TB integration activities that have been shown to reduce TB-related mortality among people with HIV, TB, and both HIV and TB.<sup>7</sup> Specific integration services include HIV testing services (HTS) for all TB patients, TB screening for all clinic attendees, isoniazid preventive therapy (IPT) initiation for eligible HIV patients, antiretroviral therapy (ART) and cotrimoxazole for all HIV-TB coinfecting patients, and retention and treatment adherence monitoring.<sup>7</sup> All HIV-TB integration activities mentioned are incorporated into the South Africa National Department of Health (DOH) HIV treatment guideline document.<sup>8</sup> However, suboptimal implementation of HIV-TB services in public health facilities has been observed where opportunities to screen patients for TB, test for HIV, and subsequent linkage to treatment have been missed.<sup>3,9,10</sup> While patient-related factors such as stigma and fear of HIV testing may be contributing to gaps in the HIV-TB care cascade, there is mounting concern that weaknesses in health care systems at the frontline are not adequately addressed.<sup>11</sup>

Operationalizing and delivering high-quality HIV-TB services is complex and challenging in resource-constrained settings.<sup>5,12</sup> The need for simple, low-cost, and sustainable solutions to enhance service delivery was the impetus for introducing quality improvement (QI) methods in public health settings.<sup>13,14</sup> The defining principle of QI is the focus on improving underlying health systems and addressing gaps with feasible solutions.<sup>15</sup> In South Africa, QI was successfully implemented to reduce mortality in mothers, neonates, and infants.<sup>16,17</sup> However, little is known of the effectiveness of QI in reducing mortality in patients accessing public health facilities for HIV, TB, and HIV-TB services.<sup>7</sup>

The Centre for the AIDS Programme of Research in South Africa (CAPRISA), implemented a cluster-randomized trial, the scaling up TB and HIV treatment integration (SUTHI) trial, designed to test the effectiveness of a QI intervention in enhancing HIV-TB service integration to reduce mortality in HIV-TB patients.<sup>7</sup> CAPRISA, in partnership with the Institute for Healthcare Improvement (IHI), designed and implemented a

QI intervention to enhance HIV-TB service delivery by identifying and addressing the health system's weaknesses at the primary health care (PHC) clinic level.<sup>7</sup>

In this article, we describe the QI intervention, our theory of change, report the impact of the intervention on HIV-TB services, identify changes that were associated with improved processes outcomes, and elucidate challenges associated with implementing QI to improve HIV-TB services in PHC clinics.

## METHODS

### The SUTHI Trial

The design and rationale for the SUTHI trial are published elsewhere.<sup>7</sup> Briefly, SUTHI was a cluster-randomized trial in which 16 PHC nurse supervisors (clusters) and the 40 PHC clinics under their oversight were randomly assigned to receive either a structured program of QI training and mentorship to expand the skill and capacity of health care workers in improving HIV-TB services (QI intervention group) or to the standard of care supervision and support (SOC) group as carried out by the South Africa DOH. Eight nurse supervisors and their 20 clinics were assigned to the QI intervention group and 8 nurse supervisors and their 20 clinics were assigned to the SOC group. All clinics were followed up for 18 months.

### Setting

The SUTHI trial was located in the King Cetshwayo District and Ugu District in KwaZulu-Natal Province, South Africa. The King Cetshwayo District and Ugu Districts have reported incident TB rates of 859 per 100,000 and 810 per 100,000, respectively; antenatal HIV prevalence rates of 33.4% and 41.7%, respectively; and mortality rates attributable to TB and HIV of 36% and 35%, respectively.<sup>18</sup> Given the high rates of TB and HIV, both districts were ideal locations for the SUTHI trial. In South Africa, PHC clinics are the first point of entry into the health care system for a large majority of the population and services are free.<sup>7</sup> The South African DOH HIV treatment guidelines recommends provision of integrated HIV-TB health care as standard practice.<sup>8</sup>

### Standard Support and Supervision

The QI intervention in the SUTHI trial was implemented in parallel to other improvement activities undertaken by the district management team (DMT). Improvement initiatives undertaken by the DMTs were considered as a SOC and were

**A QI intervention was implemented to enhance HIV-TB service delivery by identifying and addressing the health system's weaknesses at the primary health care clinic level.**

available to the QI group clinics and the SOC group clinics. Both study districts were supported by a highly motivated DMT who conducted routine, in-person, quarterly PHC clinic visits, and weekly data-driven progress update meetings with representatives from all facilities, including SUTHI study clinics. DMT involvement was maintained throughout the study period. Support from local, nongovernmental organizations (NGOs) for the improvement of the HIV and TB programs in both districts were present both before and during the study.

### CHANGE THEORY

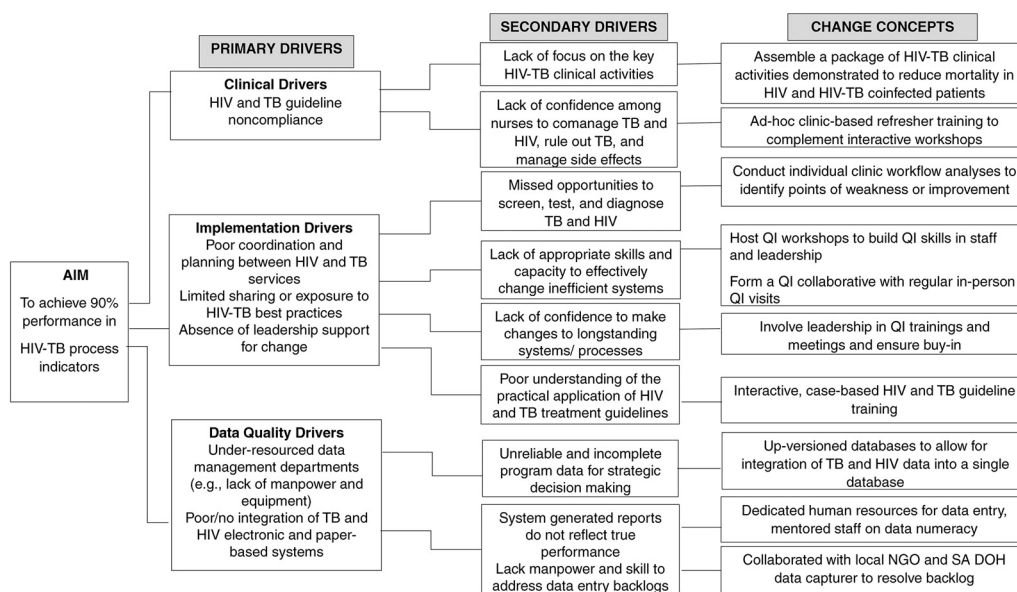
A change package to guide implementation of HIV-TB services was not available. Instead, we implemented an intervention that would allow change ideas to emerge from the input and experiences of the clinic staff and nurse supervisors in the QI intervention group. Our change theory was premised on a collective understanding from published articles and feedback from implementers on the primary and secondary drivers of poor performance in HIV-TB service integration (Figure 1). Primary elements of our change theory were:

(1) HIV-TB clinical content comprising a package of essential evidence-based interventions supported by an implementation algorithm suitable for a clinic setting, (2) implementation content comprising health care worker training and clinical skills capacity building for improved identification and treatment of HIV-TB patients as well as training in QI methodology; and (3) data quality improvement to enhance reliability and completeness of routine HIV-TB data.

### Clinical Content

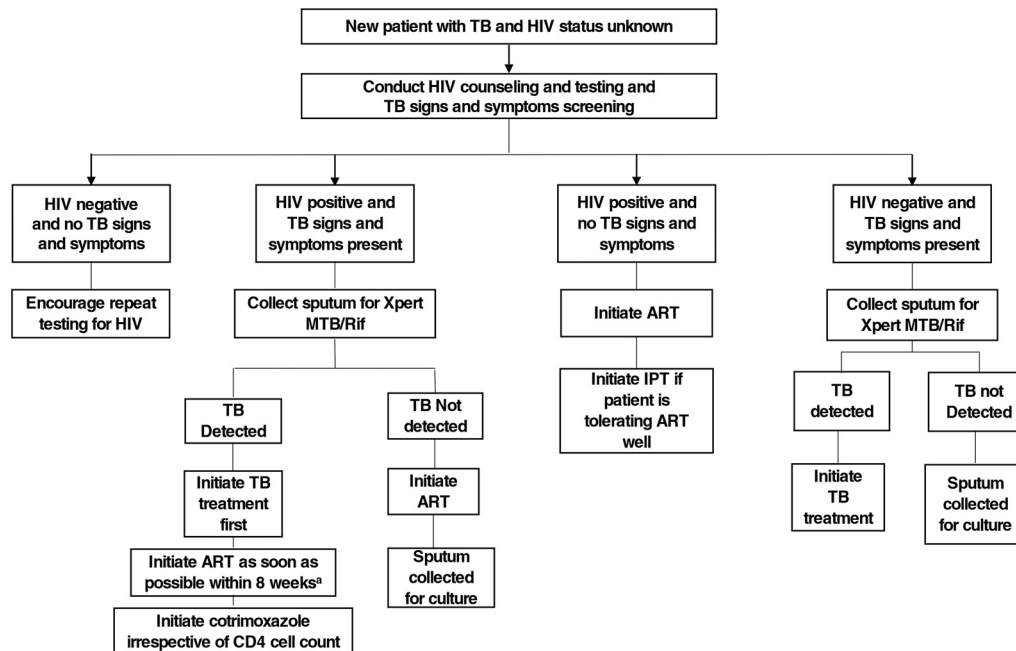
The development of the package of HIV-TB services was preceded by a review of published literature, South African HIV and TB treatment guidelines and policies, and input from experts in the field of HIV-TB co-management to identify the most effective evidence-based clinical activities associated with a reduction in mortality in HIV-TB coinfected patients. We assembled key HIV-TB clinical services into an HIV-TB care algorithm (Figure 2) that served as a training tool for QI group clinics. Health care workers in the QI collaborative were trained to appropriately identify, triage, and treat HIV-TB patients and prevent TB in HIV patients.

**FIGURE 1.** Change Theory Based on Primary and Secondary Drivers of Poor Performance in Integrated HIV-TB Services and Change Concepts Used in a Quality Improvement Intervention for HIV/TB Service Integration in KwaZulu-Natal, South Africa



Abbreviations: NGO, nongovernmental organization; QI, quality improvement; SA DOH, South African Department of Health.

**FIGURE 2.** Key HIV-TB Services Care Algorithm Training Tool Used in a Quality Improvement Intervention for HIV/TB Service Integration in KwaZulu-Natal, South Africa



Abbreviations: ART, antiretroviral therapy; IPT, isoniazid preventive therapy; Xpert/MTB/Rif, a rapid, molecular, cartridge-based test used for TB diagnostics that provides an immediate rifampicin resistance result.

<sup>a</sup> For HIV-TB coinfecting patients: If CD4 < 50 cells/μl, initiate ART within 2 weeks of starting TB treatment AND if CD4 > 50 cells/μl, initiate ART within 2–8 weeks of starting TB treatment.

### Implementation Content

Historically, HIV and TB services operated separately; however, the directives, policies, and guidelines from South Africa National DOH to collocate and integrate both services at a single facility, without adequate implementation guidance, failed to integrate HIV-TB health care delivery.<sup>5</sup> Efficient integration of services requires joint planning and coordination between different departments within a clinic together with the provision of relevant training.<sup>19</sup> We undertook to ensure that staff had the clinical skills to find and treat HIV-TB coinfection and quality improvement skills to strengthen and optimize HIV-TB patient flow and workflow processes.

### Improving Clinical Skills in Screening, Diagnosis, and Management of HIV-TB Coinfection

At the start of the study, a 1-day training workshop in each district was conducted for the QI collaborative with a study-appointed clinician trainer and members of the DMT serving as facilitators.

The training session emphasized that integrated HIV-TB services meant delivering both HIV and TB care and treatment at the same facility, by the same clinic team on the same day, also known as “the single facility approach.”<sup>5</sup> Training content included a review of the Xpert MTB/RIF algorithm for the screening and diagnosis of TB; timing and criteria for ART initiation in TB patients; HIV-TB comanagement in adults, pregnant women, and pediatrics; and utilization of data reports from routine electronic databases to track health systems performance. An interactive, case-based mode of teaching was adopted where treatment and patient scenarios resembled typical real-world situations to which the audience could relate.

### Use of QI Methods to Improve Integrated HIV-TB Services

In this study, we used the Model for Improvement as the methodological framework to identify systems’ weaknesses and optimize workflow to enhance the performance of HIV-TB services to



acceptable standards stipulated in the UNAIDS 90-90-90 strategy document (Supplement Figure 1).<sup>20</sup>

Each clinic in the QI collaborative reviewed their clinic patient flow to understand the system and identify weaknesses, bottlenecks, or potential improvements that would strengthen HIV-TB care delivery. The clinic QI team consisted of 1 representative from each staff category to ensure all perspectives were represented. Whenever possible, PHC clinic supervisors and clinic operations managers participated in biweekly QI meetings.

The plan-do-study-act (PDSA) cycle was the guiding framework used to test and accumulate knowledge on proposed change ideas. During the plan phase, appropriate clinic team members, who would test the change idea, were identified and roles and responsibilities explained. Change ideas were recorded and as a QI team member tested changes (do phase), other team members collected process data and made observations of any unintended or negative impacts on the system. During the study phase, annotated run charts were used to track the performance of HIV-TB service outcomes and reviewed every 2 weeks by QI clinic teams. In the act phase, the QI team decided on adapting, adopting, or abandoning change ideas. On average, 4 PDSA cycles per HIV-TB indicator were completed before a change idea was perfected and adopted.

**By partnering with IHI, the SUTHI trial gained an experienced leader in QI implementation methods.**

#### **Participation in a Learning Network**

All nurse supervisors and clinics in the QI intervention group formed a learning collaborative that was based on an approach designed by the IHI called a Breakthrough Series Collaborative.<sup>21</sup> The Breakthrough Series Collaborative operates on the principle that, when brought together, organizations working toward a common goal can accelerate learning by sharing knowledge, data, challenges, and experiences.<sup>21</sup> In this study, the learning collaborative was brought together for 3 learning sessions timed at 6-month intervals from the month of study enrollment (details of the learning session content are available in Supplement Figure 2). Key elements of the learning sessions were: (1) didactic teaching emphasizing the global and local seriousness of the HIV-TB co-epidemic and the evidence for integrating HIV-TB services, (2) an analysis of local PHC clinic data and identification of gaps in meeting HIV-TB service delivery targets, and (3) interactive group sessions among clinic teams to discuss challenges and potential solutions. Two study-appointed QI nurse mentors conducted bi-monthly face-to-face visits in the first 12 months

and thereafter reduced to monthly face-to-face visits in the last 6 months of the study. Face-to-face visits included meeting with the clinic QI teams, observing the clinic teams in their daily routine, and ensuring implementation of QI plans.

#### **Improving Data Quality**

A roving team of study-appointed data capturers conducted regular quality assurance checks on patient registers, chart notes, and electronic HIV and TB databases maintained at the clinic. Paper-based systems were checked for completeness, legibility, and accuracy. Every 6 months patient chart note data were compared to the electronic system data for a randomly selected sample of HIV, TB, and HIV-TB patients. Feedback on discrepancies, incorrect, or missing data was given to clinic teams. The roving team assisted with clearing major backlogs in data entry.

#### **Key Inputs for QI Intervention Implementation**

The implementation of the QI intervention required the establishment of a partnership between CAPRISA and IHI, appropriately skilled staff to drive the QI activities, and technically skilled data staff to improve data quality.

Local QI expertise, with formal QI training and practical experience, was a scarce resource at the start of the trial. By partnering with IHI, the SUTHI trial gained an experienced leader in QI implementation methods. At the design phase of the study, IHI played a key role in training study staff in QI methods using a train the trainer model. Two study-appointed professional nurses (1 per study district) trained by IHI, drove the QI process at the clinic level and were under the oversight of a QI advisor from IHI who provided mainly virtual support. Each nurse supported 10 QI clinics. Between study enrollment to month 12 made fortnightly, the nurse made in-person mentorship visits to QI clinics. These visits were reduced to monthly mentorship visits between month 13 and month 18.

A data manager based at the CAPRISA headquarters oversaw the roving data quality improvement team that consisted of 2 data coordinators (1 per district), and 6 data capturers (3 per district). The intervention was implemented in the context of a cluster-randomized trial and to ensure that we had comparable data in the QI clinics and SOC clinics, the data team conducted improvement activities in both study groups during the

study. The data team made fortnightly visits to QI improvement clinics and similarly to SOC clinics.

In addition, due to the nature of the trial design, learning sessions were held in conference venues and not on South Africa DOH premises. All costs of the venues, accommodation for trainers, and transport of health care workers were borne by the study.

### Study Outcomes and Data Collection

HIV-TB process indicators were collected every month from paper-based registers (ART, TB, and HIV registers), electronic databases, and patient chart notes. These data were recorded onto paper-based data collection tools and faxed to the central office. Training registers were completed at each QI workshop, recording the number and designation of health care workers that attended. The QI nurse mentor and clinic QI team maintained detailed records on a PDSA template (provided by IHI) of the dates that QI work began per indicator and the change ideas, adaptations, and challenges encountered. The completed PDSA templates were submitted for analysis. Table 1 defines the HIV-TB process indicators that clinic teams selected for improvement and data elements used to calculate

performance. For ease of reference, a shortened name (abbreviation) was assigned to each indicator in Table 1 and will hereafter be used in all subsequent sections.

### Statistical Analysis

We analyzed data at the nurse supervisor level (the cluster). Monthly performance for each HIV-TB process outcome was calculated by summation of numerators of all clinics that comprised a cluster and divided by the sum of the denominators of all respective clinics in the cluster. The mean of all cluster means reflected the monthly performance, which was then plotted as *xmr*-charts (Figure 3). A run of 8 or more data points on 1 side of the center line was defined as a shift and a run of 8 or more data points in an upward or downward direction was defined as a trend.<sup>22</sup> Geometric means were calculated as a single estimate of baseline performance (last 6 months before study enrollment) and for the post-QI intervention phase (months 13–18) (Table 2). The absolute difference between the post-QI intervention geometric mean and the baseline geometric mean was calculated to reflect the size and direction of the improvement. Paired *t*-test was used to determine if differences between

**TABLE 1.** Definitions of HIV-TB Process Indicators Used in the Quality Improvement Intervention to Integrate HIV-TB Services in KwaZulu-Natal, South Africa

HIV-TB Process Indicator	Abbreviation	Definition
HTS for PHC clinic attendees	HTS	Percentage of patients that accessed HIV tests, expressed as a percentage of the clinics' HIV testing target <sup>a</sup> Numerator: Number of patients tested for HIV Denominator: Clinic assigned target for HTS
TB screening among PHC clinic attendees	TB screening	Percentage of clinic attendees screened for TB signs or symptoms <sup>b</sup> Numerator: Number of clinic attendees screened for TB signs and symptoms (adults and children) Denominator: Clinic headcount (Number of people accessing any health services at a facility during a specified period)
Initiating IPT among eligible new ART patients	IPT initiation	Percentage of new ART patients initiated onto IPT Numerator: Number of new ART patients initiated on IPT Denominator: Number of new ART patients with no signs or symptoms of TB
ART initiation among TB/HIV coinfecting patients	ART initiation	Percentage of TB/HIV coinfecting patients initiated on ART Numerator: Number of TB/HIV coinfecting patients initiated on ART Denominator: Number of confirmed TB patients tested positive for HIV
VL testing at month 12 after ART initiation <sup>c</sup>	VL testing	Percentage of eligible ART patients who had a VL test at month 12 after ART initiation Numerator: Number of ART patients who received a VL test at month 12 after ART initiation Denominator: Number of ART patients eligible for a VL test at month 12 after ART initiation

Abbreviations: ART, antiretroviral therapy; HTS, HIV testing services; IPT, isoniazid preventive therapy; PHC, primary health care; VL, viral load.

<sup>a</sup> All clinics receive a monthly target for HIV Testing Services from their respective District Offices.

<sup>b</sup> TB signs and symptom screening refers to the verbal screening checklist which documents the common signs and symptoms of TB (current cough of any duration, fever for >2 weeks, drenching night sweats, Unexplained weight loss of >1.5kg in a month).

<sup>c</sup> According to the South African National Department of Health National Consolidated guidelines, a viral load test is required at month 6 and month 12 after ART initiation and annually thereafter. This study focused on the month 12 viral load only.

**TABLE 2.** Summary of Changes in HIV-TB Process Indicators Used in the Quality Improvement Intervention to Integrate HIV-TB Services in KwaZulu-Natal, South Africa

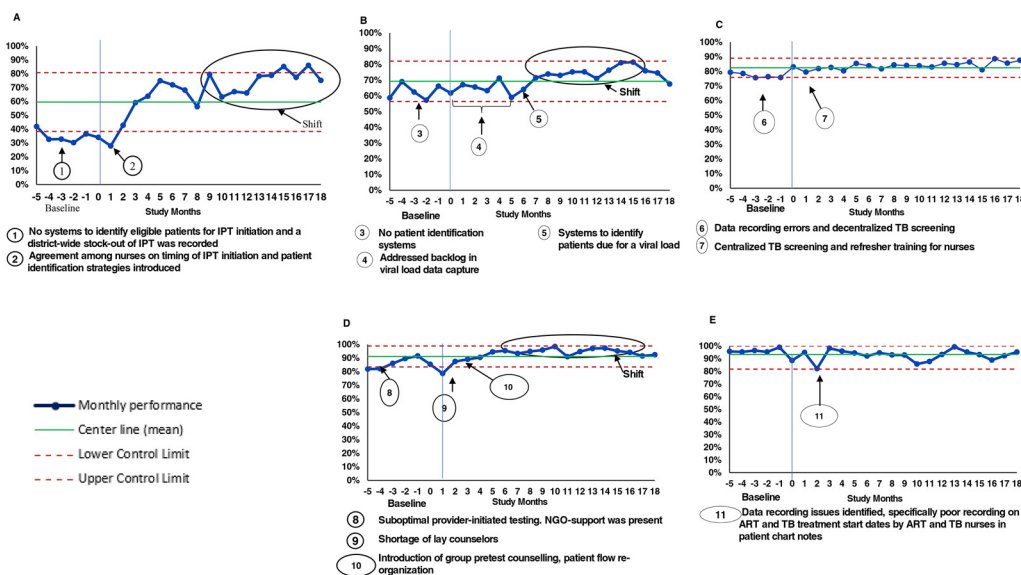
HIV-TB Process Outcomes	Proportions (95% CI)		Absolute Difference	P Value	Clinics <sup>a</sup> (N=20)	PDSA Cycles Mean, (Range)
	Baseline	Post-QI Intervention				
HTS	84.8 (75.5,95.3)	94.5 (89.3,99.9)	9.7	.110	12	3 (1–7)
TB screening	76.2 (65.4, 88.9)	85.2 (78.7,92.2)	9.0	.040 <sup>b</sup>	17	4 (1–9)
IPT initiation in new ART patients	15.9 (4.8,52.5)	76.4 (66.3,88.1)	60.5	.019 <sup>b</sup>	20	4 (1–11)
ART initiation in HIV-TB patients	95.8 (93.3,98.3)	94.1 (89.7,98.6)	-1.7	.481	3	1 (1–3)
Viral load monitoring	61.4 (56.4,66.8)	74.0 (65.5,83.6)	12.6	.045 <sup>b</sup>	20	4 (1–7)

Abbreviations: ART, antiretroviral therapy; CI, confidence interval; HTS, HIV testing services; IPT, isoniazid preventive therapy; PDSA, plan-do-study-act; QI, quality improvement.

<sup>a</sup> Number of clinics engaged in quality improvement.

<sup>b</sup> P value significant at <.05 using paired t-tests.

**FIGURE 3.** xmr Charts of Monthly Performance in HIV-TB Process Indicators in a Quality Improvement Intervention for HIV/TB Service Integration in KwaZulu-Natal, South Africa (a) Percentage of Eligible New ART Patients Initiated on IPT; (b) Percentage of ART Patients With a Viral Load Test Conducted; (c) Percentage of PHC Clinic Attendees Screened for TB; (d) Percentage of HIV Target Achieved; (e) Percentage of HIV-TB Coinfected Patients Initiated on ART



Abbreviations: ART, antiretroviral therapy; IPT, isoniazid preventive therapy; PHC, primary health care.

baseline and post QI intervention phases were statistically significant for each indicator. Completed PDSA templates were examined by 2 study staff members and common systems weaknesses and associated change-ideas were identified and summarized.

### Ethics

The SUTHI trial was approved by the Biomedical Research Ethics Committee of the University of KwaZulu-Natal (BREF Ref 108/14). Informed consent for the study was waived.

The KwaZulu-Natal Health Research and Knowledge Management committee granted permission to access PHC clinics in the study districts of KwaZulu-Natal (HRKM309/14).

## RESULTS

The QI intervention was conducted from December 1, 2016, to January 1, 2019. Table 3 provides a summary of health care workers who attended the 3 learning sessions. At no learning session were all 8 PHC clinic supervisors present.

Clinic QI teams identified HIV-TB processes for improvement based on findings of patient- and work-flow analyses and suboptimal performance at baseline (Table 4). Systems weaknesses and opportunities for improvement were identified in all clinics for IPT initiation and VL testing at month 12 after ART initiation. However, HTS, TB screening, and ART initiation became the foci of QI initiatives in, 17 and 3 clinics, respectively. Clinics that did not actively engage in improving an indicator continued to monitor performance only. All clinics were included in analyses of the performance of the collaborative.

IPT initiation at baseline was 15.9% (95% confidence interval (CI)=4.8,52.5) (Table 2). The main causes of poor IPT initiation were identified as uncertainty among nurses on timing of IPT initiation in new ART patients and weak systems to

identify returning ART patients who were eligible for IPT (Table 4). The improvement in IPT initiation observed after the start of the QI intervention was due to a district-level IPT stock-out in the baseline period. (Figure 3A). By study month 6, a 64.8% IPT initiation rate was achieved. In the last 6 months of the study, the QI collaborative achieved a mean of 76.4% (95% CI=66.3,88.1), a 5-fold higher mean than at the baseline phase,  $P=.019$  (Table 2). On average clinics carried out 4 PDSA cycles to improve IPT initiation, and while major improvement was observed, the target of 90% was never attained in the study. Improvement in IPT performance is observed from month 1; however, a shift above the mean was observed from month 9 to 18 (Figure 3A).

At baseline, the mean rate of VL testing was 61.4% (95% CI=56.4,66.8), 28.6% below the 90% desired target. Major backlogs in VL data entry that generated inaccurate VL completion reports were the main cause of poor performance identified by the QI teams. In the first 6 months post-study enrollment, no QI activities were recorded in any QI clinics to improve VL, instead, efforts to reduce the data entry backlog for the last 12 months were undertaken and QI activities were started closer to study month 6 (Figure 3B). A shift above the mean was observed from month 6 to 16. During the last 6 months of the study, the

**TABLE 3.** District and Clinic Staff Trained in Quality Improvement Methods for a Quality Improvement Intervention for HIV/TB Service Integration in KwaZulu-Natal, South Africa

Staff Category	Pool of Health Care Workers Available N=259	Actual Number Trained in QI		
		Learning Session 1 N = 63 n (%)	Learning Session 2 N=61 n (%)	Learning Session 3 N = 45 n (%)
<b>District Management Team</b>				
TB program manager	3	2 (3)	1 (2)	2 (4)
HIV/AIDS/Sexually transmitted infection and TB manager	2	2 (3)	2 (3)	2 (4)
Training coordinator	2	2 (3)	2 (3)	0
Nurse supervisors	8	5 (8)	4 (6)	3 (7)
<b>Subtotal</b>	<b>15</b>			
<b>Clinic Staff Categories</b>				
Operations managers	19	11 (17)	9 (15)	9 (20)
Professional nurses	85	6 (10)	11(18)	8 (18)
Enrolled nurses/ enrolled nurse assistants	61	8 (11)	6 (10)	1(2)
Data capturers	36	17 (27)	18 (30)	19 (42)
Lay counselors	43	10 (16)	8 (13)	1 (2)
<b>Subtotal</b>	<b>244</b>			

**TABLE 4.** Health Systems Weaknesses Identified and Associated Change Ideas for a Quality Improvement Intervention for HIV/TB Service Integration in KwaZulu-Natal, South Africa

HIV-TB Process	Health Systems' Weaknesses Identified	Change Concepts
<b>HTS</b>	Relying only on patient requests or referrals for HIV testing.	<p><b>Introduced strategies to enhance provider-initiated testing:</b></p> <ul style="list-style-type: none"> <li>Offered group pretest counseling in all patients' waiting areas</li> <li>Implemented a daily roster system of staff to conduct pre-test counseling</li> <li>Nurse in charge or designee to check accountability log daily</li> </ul>
	<p>Missed opportunities to offer HTS to all patients</p> <ul style="list-style-type: none"> <li>Acute patients were overlooked for HTS services (e.g., wound care patients)</li> </ul>	<p><b>Redesigned clinic patient flow</b></p> <ul style="list-style-type: none"> <li>Ensure that acute patients are directed to lay counselors after vitals assessments<sup>a</sup> are conducted</li> <li>If above not possible, then staff caring for acute patients were (i) trained in HIV testing and counseling and (ii) provided with the appropriate HTS stationery</li> </ul>
	<p>HTS data inaccuracies caused by:</p> <ul style="list-style-type: none"> <li>Not completing HTS registers in real-time</li> <li>Misplacing HTS registers</li> </ul>	<p><b>Daily data quality control checks</b></p> <ul style="list-style-type: none"> <li>Daily quality control of HTS registers and frequent audits of patient files and electronic data to ensure HIV status is known for all patients</li> </ul>
	<p>Overdependence on lay counselors</p> <ul style="list-style-type: none"> <li>HTS viewed as the work of lay counselors</li> <li>Lack of counseling skills among nurses to relieve/stand-in for lay counselors</li> </ul>	<p><b>Increasing the accountability and responsibility for the HTS program</b></p> <ul style="list-style-type: none"> <li>On-site HTS refresher training was held which addressed: pre- and post-test counseling messages, conducting HIV rapid tests, and data recording</li> <li>Awareness of clinic target set by the district health office was disseminated</li> </ul>
<b>TB screening among PHC clinic attendees</b>	Missed opportunities to offer TB screening to all clinic attendees	<p><b>Centralized TB screening</b></p> <ul style="list-style-type: none"> <li>Made TB screening mandatory at an identified strategic point visited by all patients, such as, vitals assessment<sup>a</sup> station</li> <li>Visual prompts and reminders to conduct TB screening included large and colorful TB posters, printed and easily accessible signs, and symptoms checklists</li> <li>Made TB screening mandatory for acute patients</li> </ul>
	Inaccurate TB screening data	<p><b>Data quality control checks</b></p> <ul style="list-style-type: none"> <li>Daily data quality control checks conducted by nurse in charge or designee to check:                             <ul style="list-style-type: none"> <li>Completeness and accuracy of daily TB screening register</li> <li>Number of symptomatic patients and number of sputum samples sent for Xpert/ MTB Rif<sup>b</sup> testing</li> </ul> </li> <li>Quality control of clinic headcount<sup>c</sup> data:                             <ul style="list-style-type: none"> <li>Exclude patient representatives or family members</li> <li>Subtract TB confirmed patients from the clinic headcount</li> <li>Mass TB screening campaigns conducted in communities must be distinguishable from screening conducted in the clinic</li> </ul> </li> </ul>
<b>IPT initiation among new ART patients</b>	<p>Ambiguity in IPT initiation guidelines</p> <ul style="list-style-type: none"> <li>Nurses lack clarity on timing of IPT initiation</li> <li>Individual nurses use own discretion to start IPT</li> </ul>	<p><b>Clarify IPT initiation timing and arrive at mutually agreed upon timing for initiation</b></p> <ul style="list-style-type: none"> <li>Each clinic team arrived at a common time to start IPT (e.g., 7, 14, or 30 days after starting ART)</li> <li>Agreed upon timing was documented and standardized for entire clinic</li> </ul>

Continued

**TABLE 4** Continued

HIV-TB Process	Health Systems' Weaknesses Identified	Change Concepts
	Confusion about roles and responsibilities of clinic staff	<b>Enhancing accountability and responsibility for IPT program</b> <ul style="list-style-type: none"> <li>Roles and responsibilities were assigned to all staff categories and documented</li> </ul>
	No system for identifying patients eligible for IPT	<b>Strategies to identify patients returning at the agreed upon time for IPT</b> <ul style="list-style-type: none"> <li>The "box system" -eligible patients' files placed in a decorated box for easy identification, OR</li> <li>Tagged files of eligible patients with stickers or red ink OR</li> <li>The "diary system" reminder note in clinic diary to initiate IPT at next visit and note attached to patient file</li> </ul>
	Poor recording of IPT initiation date in clinic chart notes	<b>Refresher training on clinic stationery to document IPT</b> <ul style="list-style-type: none"> <li>Nurses directed to document start date in designated fields and data capturers shown where to find the start date</li> </ul>
	Nurses lack confidence to rule out TB	<b>Host a training for nurses, lay counselors, and data capturers highlighting the importance and potential benefit of IPT for HIV-infected patients</b> <ul style="list-style-type: none"> <li>Link this training with the TB screening training (above) to boost confidence to rule out TB</li> </ul>
<b>ART initiation among HIV-TB coinfecting patients</b>	<b>Patient chart notes for TB and ART kept separately</b> <ul style="list-style-type: none"> <li>TB and ART files not integrated</li> <li>No unique identifier for TB and ART file</li> </ul>	<b>Combining ART and TB files</b> <ul style="list-style-type: none"> <li>For HIV-TB coinfecting patients, ART and TB chart notes were physically combined</li> <li>The district health office agreed upon a common unique identifier to be used</li> <li>The TB module on the electronic ART database was activated to accommodate TB and ART data</li> </ul>
	Poor coordination between NIMART and TB nurses regarding ART and TB treatment initiation	<b>Refresher training for nurses</b> <ul style="list-style-type: none"> <li>Clarified patient flow for ART initiation visits in TB/HIV coinfecting patients</li> <li>Improved chart notes for ART and TB treatment start dates</li> </ul>
<b>VL monitoring at month 12 after ART initiation</b>	No system to identify patients eligible for month 12 VL tests	<b>Generate report from electronic system of patients due for VL</b> <ul style="list-style-type: none"> <li>Address the data capturing backlog of VL results and ART initiation</li> <li>Draw on the assistance of local nongovernmental organizations and support partners for assistance with data capture</li> <li>Generate VL reports from the data system to determine which patients have not had or are due for VL test (filter out deceased and transferred-out patients)</li> <li>Tag/mark the files of patients due for VL for easy identification</li> <li>Trace patients who were missed for a VL test</li> </ul>

Abbreviations: ART, antiretroviral therapy; HTS, HIV testing services; IPT, isoniazid preventive therapy; NIMART, Nurse Initiated Management of Antiretroviral Therapy; PHC, primary health care; VL, viral load.

<sup>a</sup>Vitals assessments refers to general measures of well-being which typically include weight, body temperature, blood pressure measurements.

<sup>b</sup>Xpert/MTB RIF a rapid, molecular, cartridge-based test used for TB diagnostics that provides an immediate rifampicin resistance result.

<sup>c</sup>Clinic headcount refers to the total number of patients who accessed the clinic for any type of clinical service.

mean VL monitoring rate was 12.6% higher than the baseline rate ( $P=.045$ ), which was less than 50% of what was needed to meet the target (Table 2).

Data inaccuracies were noted at baseline for TB screening (Figure 3C). Data quality checks and refresher training were change ideas tested for improvement (Table 4). Mean TB screening rates

improved by 9% between the baseline period and post-QI intervention (Table 2), and the 90% target was not achieved by the collaborative.

Mean ART initiation rates were greater than 90% at baseline and continued post-intervention period (Table 2). The monthly performance in ART initiation was addressed only in 3 clinics, and the decrease of 1.7% was not significantly different from baseline performance ( $P=.481$ ). HTS was the only indicator that was improved and exceeded the 90% target (Figure 3D, Table 2).

## DISCUSSION

This article describes the QI intervention implemented in the SUTHI cluster-randomized trial to improve HIV-TB health care performance. In South Africa, integrated HIV-TB services are mandatory, and this study shows that improvement in HIV-TB process outcomes is needed and possible. Using the Model for Improvement, we showed that IPT initiation improved substantially; whereas HIV testing, TB screening, and VL monitoring were moderately improved, and ART initiation among HIV-TB coinfecting patients was an already well-performing indicator that required monitoring and only a few clinics had to strengthen coordination between the TB nurses and ART-initiating nurses. An important output of the QI intervention was a set of change ideas that are potentially transferrable to other settings and could contribute to the improvement of integrated HIV-TB services.

Several factors can be attributed to the success of IPT initiation rates in this study. First, clarifying nonspecific initiation guidelines improved decisiveness among nurses in the timing of IPT initiation. Second, as IPT is an indicator monitored at the district and provincial levels, clinic staff were motivated to improve IPT performance. Third, low performance at baseline (15.9%), increased the likelihood and potential for improvement. Fourth, improving IPT initiation and data completeness in patient files and on IPT dispensing and stock charts, subsequently improved the IPT supply chain. The supply of IPT depends on demand for IPT. Improved IPT dispensing data provided a better reflection of the clinics' demand for IPT, and the ordering of stock was adjusted accordingly. Interestingly, approximately 6 months of QI to improve IPT and HTS was undertaken before the shift was observed. This may indicate that clinics require approximately 6 months to completely embed new processes into the clinic.

Three systematic reviews evaluating the effectiveness of QI collaboratives concurred that the

size of improvement observed is often a function of baseline performance and low-performing indicators are more likely to have larger improvement.<sup>23,24</sup> A QI approach to improving IPT initiation was successful in other resource-constrained settings. In a Namibian case study of QI capacity development, IPT initiation resulted in a 12% increase (from 16% to 28%) at a national level.<sup>25</sup> In a Nigerian case study, situated at a single state-run hospital, IPT initiation improved by 39% (11% to 50%).<sup>26</sup> Interestingly, the Namibian study was at a national level and the Nigerian study was conducted at 1 facility.<sup>25,26</sup> Similar to the SUTHI study, the Nigerian study was more active in addressing issues of organization, process, management, and systems. The authors surmise that root cause analysis and first-hand involvement of clinic staff in developing systems played a role in achieving improvement.<sup>26</sup>

A systematic review of strategies to improve health care performance showed that large improvements (defined as 20–30 percentage point improvement) are generally achieved in strategies that used a combination of training, collaborative learning, supervision, and improvement of infrastructure (such as data quality improvement), as was done in the SUTHI trial.<sup>27</sup> Yet, provider-initiated HIV testing and TB screening achieved modest improvement (defined as 5–10 percentage points). VL monitoring moderately improved from baseline (defined as between 10–20 percentage points) and ART initiation slightly decreased. These results are evidence that other factors drive the success of an improvement strategy. The role of contextual factors in influencing improvement outcomes is emerging as an important consideration when assessing QI initiatives.<sup>28,29</sup> Work culture, access to knowledge resources, QI leadership, supportiveness of work environments, and staff motivation and willingness to question the status quo, are but a few examples of contextual factors that may influence the success of QI initiatives.<sup>28,30,31</sup>

## Lessons Learned

In the SUTHI trial, we identified important factors that may explain the suboptimal improvement for some indicators. The effect of baseline performance was to the advantage of IPT improvement; however, HIV testing services and ART initiation in HIV-TB coinfecting patients were high at baseline, and there was little room for improvement thereafter. Future QI interventions should consider baseline performance when setting expectations for improvement, however, we do not recommend that

**An important output of the QI intervention was a set of change ideas that are potentially transferrable to other settings and could contribute to the improvement of integrated HIV-TB services.**

**The role of contextual factors in influencing improvement outcomes is emerging as an important consideration when assessing QI initiatives.**

baseline performance be considered the sole criteria for selecting indicators for improvement. This study showed that there are indicators that are close to reaching targets but appear to be plateauing, for example, VL testing (Figure 3B) and TB screening (Figure 3C). QI improved both indicators and still has a role to play in addressing the barriers that prevent these indicators from reaching the desired target of 90%.

Capacitating clinic staff with data analytic skills is an important factor in ensuring the success of QI interventions because it improves technical skills, confidence, and self-efficacy of clinic teams.<sup>32</sup> In addition, monitoring improvement using routine data is fundamental to the QI intervention. Learning sessions covered the basics of how routine data can be analyzed (e.g., calculation of percentages, means, and medians), plotted onto run charts, and interpreted using run-chart rules. QI mentors reinforced this knowledge at QI mentorship visits. Poor data quality threatens clinic teams' efforts to monitor improvement and is a barrier to successful QI implementation.<sup>33</sup> Despite our attempts to address the completeness and accuracy of routine data, poor data quality undermined our QI intervention. For example, TB screening data were adversely impacted by inflated clinic headcount numbers (the denominator), incorrect completion of TB screening registers, and misplaced TB registers. The success of VL monitoring improvement depended on accurate and complete data entered into the patient electronic database; however, nearly 6 months of addressing data entry backlogs reduced the time available to improve the indicator coupled with challenges of tracing of patients to return to the clinic. Tracking patients is a resource-intensive effort due to poor telephonic services, lack of vehicles, and incomplete patient contact information (namely, telephone/mobile data, lack of street addresses).

A Ugandan-based QI project that aimed to improve TB case notification also relied on routine data to monitor improvement and went beyond checking clinic registers for completeness and accuracy.<sup>34</sup> A data tool was used to triangulate patient data from multiple sources, that is, laboratory data, patients' chart notes, and TB laboratory data.<sup>34</sup> Unfortunately, no data metrics were available to quantify the extent to which data was improved. A South African QI project to prevent mother-to-child transmission of HIV in labor wards used a specially designed checklist that included prompts for nurses to complete and document important tasks.<sup>17</sup> Following this

intervention, there was a marked improvement in data quality with erroneous data, namely, percentages greater than 100% being eliminated. These studies demonstrate that innovative measures are needed to improve the quality of routine data and adding additional human resources to improve the completeness and accuracy of data may not be sufficient.

We intended for PHC clinic supervisors to lead the QI intervention, but their involvement was limited by their workloads and conflicting meetings. Clinic staff selected to attend the learning sessions did not always pass on their learnings from the workshops to their colleagues and the study-appointed nurse mentors reported resistance from non-workshop attendees to the workflow changes. A mixed-methods study identified personal- and work-environment-related factors that influence a health care worker's ability to transfer knowledge from QI trainings to peers.<sup>35</sup> Health care workers that are successful in transferring training knowledge have a positive attitude to implementing changes, interpersonal skills to address resistance from peers, and the ability to question the status quo.<sup>35</sup> A work environment in which teams are receptive to new ideas, supportive of change, and leadership support is present, facilitates the transfer of training knowledge.<sup>35</sup> In the SUTHI trial, selection of clinic staff to attend learning sessions was at the discretion of the PHC clinic nurse supervisor and nurse in charge of the clinic. While individuals from all clinic departments were trained, staff categories, such as data capturers and lay counselors may not have been empowered enough to transfer their new knowledge to more senior colleagues. Future QI interventions must consider screening potential QI trainees for the appropriate qualities that will allow for the transfer of QI knowledge.

### Challenges in QI Implementation

Implementation of QI at the clinic level was accompanied by several challenges. First, QI was vaguely understood in both districts and clinic teams often believed that they were implementing QI by virtue of the weekly nerve center meetings and discussing problems and challenges at staff meetings. The need for the SUTHI QI intervention was initially unclear to QI clinics. The learning sessions established the importance of using a QI approach that is guided by a framework (Model for Improvement and PDSA), uses tools (e.g., process charts), locally developed strategies (change ideas), and monitoring progress with

**Despite our attempts to address the completeness and accuracy of routine data, poor data quality undermined our QI intervention.**

**Future QI interventions must consider screening potential QI trainees for the appropriate qualities that will allow for the transfer of QI knowledge.**



**Consistent visits and mentorship by the QI nurse mentors were critical in demonstrating how the frameworks and tools translated to practice.**

data. Importantly, the consistent visits and mentorship by the QI nurse mentors were critical in demonstrating how the frameworks and tools translated to practice.

Secondly, QI implementation adds additional work for clinic staff, in that data needed to be collected and recorded to track progress more frequently. While change ideas were implemented, it was a challenge to keep staff motivated to track their performance. For example, in HTS, group pretest counseling was a key change idea; however, the source documents developed to track the number of group pretest counseling sessions in patients' waiting areas were not completed.

Third, leadership at the clinic level was supportive of the QI intervention; however, due to many commitments in and outside of the clinic, there was little involvement of clinic leaders in the QI meetings. This delayed implementation of some change ideas, as junior-level clinic staff do not have major decision-making power to make changes, such as in clinic patient flow.

### Limitations

The study had limitations. First, while the QI intervention was implemented in the context of a randomized controlled trial, we were unable to prevent exposure of QI clinics from other improvement interventions to enhance integrated HIV-TB services, particularly, improvement efforts of the DMTs and technical assistance from local NGOs. Motivated DMTs in both study districts frequently monitored the progress of HIV and TB process indicators, fed back to poorly performing clinics, and conducted quarterly in-person visits to all clinics. The true effect of the QI intervention has likely been masked by the improvement efforts of the DMTs and local NGOs. Although the study was unable to separate the effect of the DMTs' efforts and QI intervention efforts on improvements observed, the baseline period (Figure 3A–3E) offers some insight into the performance before and after the QI intervention was implemented. The QI intervention ideally complemented the performance monitoring and feedback efforts of the DMTs which were seldom able to conduct in-depth root cause analyses of systems weaknesses and develop clinic-specific interventions. Second, the study was not adequately resourced to determine if improvements in the QI clinics were sustained beyond the study period or if the QI tools, strategies, and best practices were scaled up to more clinics in other areas. Staff turnover and changes in key personnel, who were trained in QI methods, may add to the

challenge of sustaining and scaling up QI activities once the study ended. Third, as per the study design, all analyses were at the cluster level and clinics within each cluster were considered as 1 unit. However, the QI intervention was at the clinic level, and different clinics within a cluster adopted different change ideas (such as the different timing of IPT initiations in Table 4), and we could not compare clinics to determine which change ideas translated to larger improvements.

### CONCLUSION

This study showed that a QI approach to improving HIV-TB health care delivery is feasible and uptake of QI among clinic teams is evident across all indicators. With guidance, clinic staff can reveal weaknesses and gaps known only to the people who work within a system. Baseline performance of an indicator should be considered when setting expectations and assessing the size of improvement. Efforts to improve the quality of routine HIV and TB data need to be intensified for future QI efforts to be successful. The importance of basic clinical skills training should not be underestimated; however, innovative approaches to teaching health care workers need to be introduced for information to be retained and facilitate practical application. Lastly, QI complements the efforts of local NGOs and routine monitoring activities of the South Africa DOH.

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**Author contributions:** SG was responsible for the study conduct, had oversight of the study operations, development of the first draft of the manuscript, intellectual input, analysis, and interpretation of the results. KN edited and reviewed the manuscript and had oversight of the study. RM led the field team and edited the manuscript. MFT provided guidance to the field

team on QI implementation and interpretation of results. AJN and NYZ provided input on the analysis and interpretation of results. NP provided intellectual input and contributed to the writing of the manuscript. MT edited the manuscript and provided intellectual input. PMB provided input on the study design and manuscript. ML provided input on the interpretation of the data, intellectual input, and editing of the manuscript.

**Competing interests:** None declared.

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COMMENTARY

# Social and Political Dimensions of Disseminating Research Findings on Emerging Zoonotic Viruses: Our Experience in Sierra Leone

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## Key Messages

- We discuss the complexities and challenges in disseminating research findings on the discovery of a new ebolavirus in bats in Sierra Leone, particularly in light of the previous outbreaks.
- This experience pointed to the tensions that can arise between discoveries of emerging viruses with zoonotic potential and their impact on the people in direct proximity to the ecosystems in which they are found as well as on the governments charged with protecting the health of those people.
- Future research may benefit from considering the following: (1) prioritize dissemination of findings as a distinct step within a project with a detailed plan, (2) understand and support the role of government leaders in the dissemination process, and (3) prioritize the perspectives and potential reactions of communities when framing information and recommendations.

## INTRODUCTION

Sharing research results with communities is a key stage of implementing global health research. This stage is widely accepted not only as essential to conducting ethical, fair research but also as integral to improving the relevance and impact of research for participants and their communities.<sup>1,2</sup> The various activities that compose results sharing may be conducted as part of a research project’s ongoing community engagement strategy or dissemination plan. However, although sharing research results with communities is widely regarded as a best practice in

global health research, little systematic guidance exists for considering the social and political implications of those findings alongside government leaders and as part of community-level dissemination strategy. Although the discipline is growing and an increasing number of scholars are interested in dissemination and implementation science, the focus is on clinical research and provider uptake.<sup>3</sup> Little consideration has been given to how to manage the dissemination of research findings that may be perceived as negative and may require negotiation not only at the community level but also at the subnational and national levels.

This issue is especially true of research projects on emerging zoonotic diseases. Such research centers on discovering or understanding existing pathogens in animals that have the potential to cause diseases in humans. Much of this research involves not only humans but also the animals that humans co-exist with and rely on. Findings may be framed as estimates of the risk of viral contagion from animals to humans (spillover) and potential outbreaks. Such findings can be particularly complex to communicate because of the social, economic, and political implications and perceptions of the risk of outbreaks.

This commentary discusses these complexities and challenges in disseminating findings on viral hemorrhagic fevers in bats in Sierra Leone. The findings were the result of research conducted under the Ebola Host Project (EHP) in Guinea, Sierra Leone, and Liberia. All 3 countries experienced devastating Ebola outbreaks, and the discovery of a new ebolavirus was part of efforts to build systems for prevention, detection, and response to future outbreaks under the Global Health Security Agenda. However, the process of disseminating research findings on discoveries of a new species of ebolavirus presented unique social and political challenges in managing the information and how it would be released to the affected communities, nationally and globally. This commentary describes these experiences and lessons learned and proposes elements that could inform a framework to guide processes of publicizing sensitive research findings on new zoonotic viruses.

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**Dissemination of findings on a new ebolavirus presented social and political challenges in managing the information and its release to affected communities.**

■ **THE EBOLA HOST PROJECT**

In response to the 2014–2016 Ebola virus outbreak, in 2015, the United States Agency for International Development (USAID) supported the EHP as part of an effort to strengthen zoonotic disease surveillance under its Global Health Security Agenda programs in 3 Ebola-affected countries. EHP, which was part of the USAID-supported PREDICT Project, was a research project that aimed to identify the range of possible animal hosts for all filoviruses as well as the human behaviors and conditions associated with the increased likelihood of spillover into humans and other animals.<sup>4</sup> Such information is believed to be a key aspect of reducing the risk of future outbreaks. The project also aimed to increase national capacities for a multisectoral One Health approach for zoonotic disease surveillance, outbreak preparedness, laboratory systems strengthening, and workforce development.

The EHP was implemented similarly in all 3 countries. Strong local engagement was fostered through partnerships with local government and academic research institutions and training teams, often young graduates of science programs from those institutions, to collect data. The project also took a similar approach to community engagement in all 3 countries. This engagement took the form of smaller meetings with local leaders to create awareness and buy-in for the project, identification of community members who would work with the project during data collection, and larger meetings to inform community members about what the project would be doing and how.

After obtaining all the necessary permissions and commitments to collaborate, the project would plan and implement data collection and capture and sample animals. In each community, several types of wildlife (bats, rodents) were humanely captured. Samples collected from each animal included blood, oral and anal swabs, and urine if possible. The animal was then released. Samples were collected in duplicate. In Sierra Leone, over 10,000 animals were safely sampled and tested. One set of samples was stored at a designated laboratory in-country, and the other set was shipped to University of California (UC) Davis for further testing.

The project also included methods aimed at better understanding the human behavioral characteristics that increased the risk of exposure to hemorrhagic viruses. Group discussions, interviews, and observations were conducted with communities adjacent to sampling sites for this purpose.

The achievements of the EHP were captured in news and scientific articles documenting findings of a new strain of the ebolavirus (Bombali virus),<sup>5</sup> Marburg virus<sup>6</sup> in bats in Sierra Leone, and the discovery of Ebola Zaire virus in a bat in Liberia.<sup>7</sup> The scientific significance of these achievements was 2-fold. The first was the discovery of an entirely new species of ebolavirus (*Bombali ebolavirus*) in bats before any known human or animal illness or deaths, and the second was the discovery of a known and deadly human pathogen (Marburg virus/MARV) in bats for the first time in West Africa in Sierra Leone, more than 2,500 km from any known endemic area. However, before these findings became global news, host governments, donors, and researchers needed to consider how and when this information should be shared with the communities where samples were collected and the wider public. In the case of the *Bombali ebolavirus* discovery in Sierra Leone, these considerations led to a significant amount of time between the virus' discovery and the point at which information about the discovery was publicized (Figure 1).

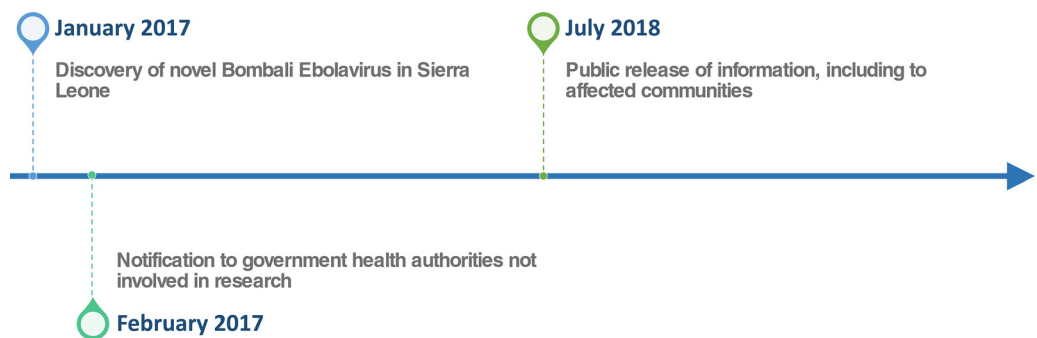
■ **SOCIAL AND POLITICAL CONSIDERATIONS AROUND DISSEMINATING RESEARCH FINDINGS**

The amount of time that passed between the discovery of the Bombali virus and the publicization of information reflects the time needed to navigate social and political questions and reach consensus on a contextually appropriate process for dissemination. The EHP prioritized government leadership in the dissemination of results. In practice, this meant that laboratory detection and confirmation of a viral finding was followed by meetings with national government officials to discuss the findings and their implications. Decisions on whether, when, and how findings would be released were ultimately those of the national government.

However, news of the *Bombali ebolavirus* finding initially raised significant questions around the potential social implications and consequences of the discovery. Specifically, we were concerned about the potential of findings to amplify collective memories of devastation and loss around the relatively recent outbreak and undermine the progress that communities had demonstrated responding to the outbreak and ultimately moving forward. Furthermore, as we began working with the various levels of government to consider a dissemination strategy, the political implications of

**News of the Bombali ebolavirus finding raised significant questions around the potential social implications and consequences of the discovery.**

**FIGURE 1.** Timeline of Findings on New Ebolavirus in Sierra Leone



the finding were illuminated. The various issues can be broadly categorized into the following 3 domains.

**Questions of Social Consequences and Behavioral Responses**

Our first consideration around the *Bombali ebolavirus* finding was how the finding would affect communities. The virus was found in bats that resided in the roofing structures of homes. These homes were also in communities that experienced some of the highest incidences during Sierra Leone’s ebolavirus outbreak. These factors raised the possibility of fear, panic, and re-traumatization.

The provision of information in a clear and empowering manner was identified as one means of mitigating potentially negative emotional and psychological impacts. However, there were few examples of how to go about this and even fewer communication materials that articulated concepts such as the potential for viruses to pass from animals to humans or provided contextually appropriate messages and imagery.

A second issue we grappled with was that of social and contextually appropriate actions to recommend. It was widely recognized that the logical response to learning of this vulnerability would be for people to attempt to remove bats in their houses either by renovating their houses or by catching or killing bats. These response options pointed to underlying political and economic drivers of how and where people lived that are known to increase vulnerability to other zoonotic diseases such as Lassa fever in Sierra Leone.<sup>8</sup> However, neither the government, the community, nor the EHP was equipped to provide structural solutions such as building better quality housing or moving people from the area to reduce exposure to bats.

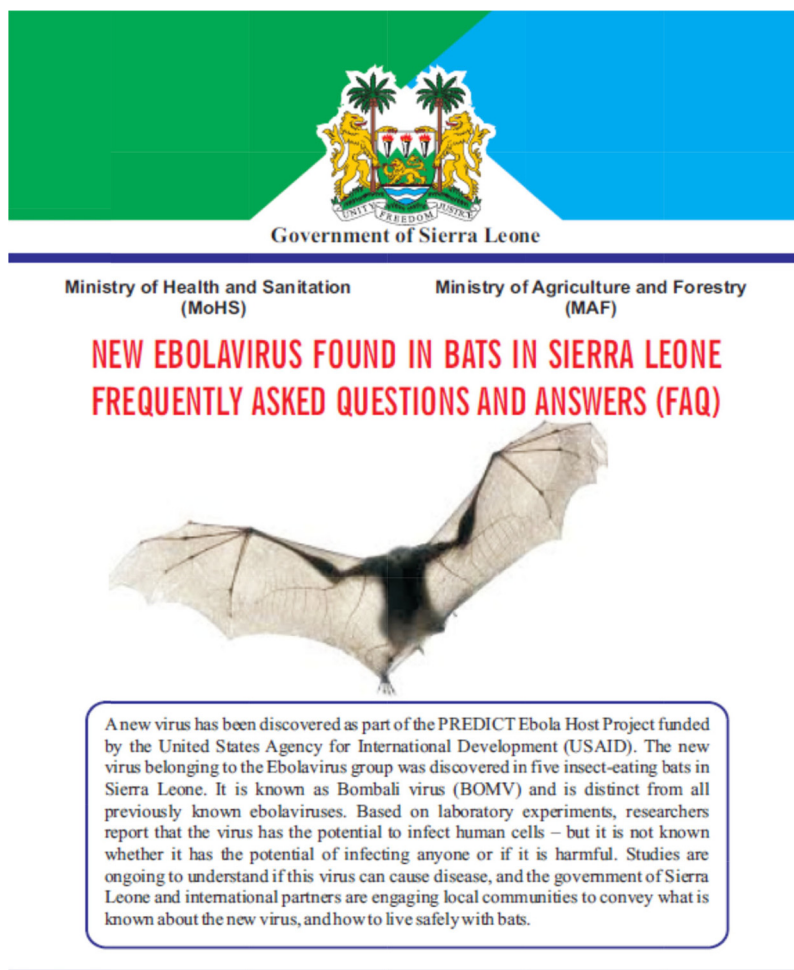
Moreover, other rational responses such as trying to kill bats could put people at greater risk of exposure to this virus while creating unintended ecological consequences. Significant consideration was given to contextually appropriate behavioral responses that could be safely recommended in the absence of options for addressing the structural inequities that continue to expose communities to risk.

**Questions of Intersections With National Politics**

Sierra Leone was declared free of Ebola on November 7, 2016. The *Bombali ebolavirus* finding occurred less than a year after the official end of the outbreak. The politicization of the early stages of the outbreak and initial responses to the outbreak by the country’s 2 main political parties has been documented.<sup>9</sup> They included rumors that an initially slow and inadequate response was motivated by the outbreak’s origins in a part of the country controlled by the opposition party. The government’s ability to make headway in the response, end the outbreak, and steer the country through recovery was an important overarching narrative in the country’s experience. The then President of Sierra Leone instituted a recovery plan targeting all sectors of society. The culmination of this recovery plan also coincided with campaigns for a national election. The narrative of overcoming the outbreak, recovery, and moving on stronger appeared to be complicated by the narrative of a scientific discovery of a new species of ebolavirus. The resolution of these conflicting narratives took a lot of time and consideration.

The findings ultimately were released after the election and under different government leadership. A reconciliatory narrative between government

**FIGURE 2.** Cover of Government of Sierra Leone's Information Pamphlet on New Ebolavirus That Was Distributed to the Public



leadership and scientific discovery guided the process: The country’s disease systems had progressed to enable early detection of this virus in bats, long before it might be harmful to humans.

**Questions arose about global-level scientific research practice, including ethical considerations around sharing results about potential risk without information to qualify that risk.**

**Questions of Global Scientific Norms and Practice**

In addition to country-level social and political implications, questions arose about global-level scientific research practice. One such question raised ethical considerations around sharing results indicating potential risk in the absence of further information to qualify that risk. Even when a pathogen is known to cause human disease, identification in a host reservoir does not mean that it is a public health threat. Therefore, providing such information when the immediate

public health implications are not clear can raise more questions than are resolved.

Other questions touched on scientific practices, such as naming the virus after the town in which it was discovered. The global public health sector moved away from such practice following the H1N1 pandemic, but research scientists continue to take different approaches.<sup>10,11</sup> Although government leaders ultimately determined it was not only socially acceptable but desirable to name the new virus after the town in which it was discovered, there is still a need for further consideration and evaluation of impact.

These social and political issues were multi-level and multidisciplinary. Context-specific questions of practice became intertwined with those of global best practice. There were no easy answers

**FIGURE 3.** Cover of Living Safely With Animals, a Book Used by Local Health Officials in Sierra Leone to Engage the Community in Discussions on Research Findings on New Ebolavirus

**How to Live Safely with Animals for Healthier Communities**



nor a clear way on how to proceed. Each issue required extensive consideration and negotiation by the Government of Sierra Leone, in-country project managers, and the U.S. Mission in Sierra Leone to navigate. This process took a significant amount of time and contributed to the delay in publicizing information.

**■ PROCESS OF DISSEMINATING RESEARCH RESULTS**

Overcoming political issues associated with research findings translated into government leadership of the dissemination process. The approval to release information around the discovery of *Bombali ebolavirus* ultimately came from the office of the President of Sierra Leone. Research findings were presented at a high-level meeting with senior government officials from various ministries and led by the president. This approval catalyzed what were previously nascent plans for a multiphased public dissemination process. The dissemination plan had 3 components: a central meeting of district health personnel and media, a meeting of local leaders and residents in the community where the virus was detected, and global dissemination of findings beyond the country level.

With political will behind the dissemination of results, we devised a communication strategy to address some of the social and behavioral issues

identified. Communication aids such as talking points and draft press releases were developed in collaboration with the Ministry of Health and Sanitation and the Ministry of Agriculture and Forestry for dissemination to the public (Figure 2). However, it was agreed that more specific communication tools akin to those used in health promotion were needed for the meetings with local leaders and residents.

For this reason, we engaged another USAID-funded program, Breakthrough ACTION, which focused on social and behavioral communication around the zoonotic disease. Breakthrough ACTION worked with the EHP to develop early drafts of a picture book on communication with bats. Bringing a social and behavioral communication partner into this process allowed us to apply an evidence-based approach to clarifying key messages, adapting imagery, and piloting and revising the book into something that could be used by local health officials to engage communities in discussions around the findings. A key adaptation resulting from these processes was the need to broaden the focus of the book beyond bats to one that promoted safe behaviors with all animals routinely encountered in the community. The emphasis became “Living Safely with Animals” (Figure 3). This shift in emphasis was agreed on as being necessary to reduce the likelihood of behaviors, such as killing bats, that could increase the risk of exposure to the virus. The book also provided

**Bringing a social and behavioral communication partner into the information dissemination process allowed use of an evidence-based approach to clarify key messages to the public.**



something tangible to be left with health promotion and social mobilization teams to use in the ongoing work.

### ■ INSIGHTS FROM OUR EXPERIENCES WITH DISSEMINATION

Our experience of navigating the social and political challenges around the discovery of *Bombali ebolavirus* in Sierra Leone can inform future research on emerging zoonotic diseases as part of the Global Health Security Agenda. This experience pointed to the tensions that can arise between discoveries of emerging viruses with zoonotic potential and their impact on the people in direct proximity to the ecosystems in which they are found, as well as the governments charged with protecting the health of those people. This experience also demonstrated that the interests of the global scientific community must be balanced, negotiated, and navigated alongside those of national governments and the communities that bear the burden of the consequences of this information. Similarly, national governments must also be open to receiving scientific information with potential health impacts and formulating timely, contextually appropriate responses. This is not only important for navigating the process of publicizing findings in ways that mitigate fear but also empowers people and societies to adopt appropriate behaviors to protect their health. Future research may benefit from consideration of the following steps.

#### **Prioritize Dissemination of Findings as a Distinct Step Within a Project With a Detailed Plan**

The complicated set of social and political factors previously described in combination with the various activities and resources that were required to prepare for dissemination represented a substantial effort. Much of this occurred ad hoc because there was no written plan or protocol to guide this stage of the research project. A dissemination plan with an associated budget can be a helpful tool from the onset of the project both as a basis of coordination among stakeholders and as a basis for ongoing adaptation to social and political contexts. Wherever possible, the research team should consider incorporating the dissemination plan into the research protocol from the beginning of the project with a view toward adapting as needed and working alongside government counterparts as the project progresses.

**A dissemination plan can be a helpful tool from the onset for coordinating stakeholders and for ongoing adaptation to social and political contexts.**

#### **Prioritize Understanding and Supporting the Role of Various Government Leaders in the Dissemination Process**

Prioritizing government leadership means understanding what is meant by “government.” There may be a risk for those without a country-level understanding to use the term “government” monolithically and not recognize the multiple levels of government from community to national level and the embedded hierarchies for decision making. This is especially important when research projects say “government is involved.” The government officials involved in the research may not be the same officials who have the authority to release research findings. This may require continued engagement of higher-level authorities or the departments involved in research. Having a nuanced view of a country’s government structure is also important for thinking more broadly about the range of potential support needed for their leadership in decision making. This means thinking beyond national-level press releases to consider, for example, what a district health manager needs to communicate to local communities.

#### **Prioritizing the Perspectives and Potential Reactions of Communities When Framing Information and Recommendations**

Prioritizing potential social impacts and behavioral responses to research results was key to determining not only what people were told about the finding but what they could do to protect themselves from perceived risks. Prioritizing community perspectives requires careful consideration of a range of responses and the potential for misunderstanding. Ultimately, a comprehensive community engagement strategy is crucial for the dissemination of research results while countering potential misconceptions, misinformation, myths, and fake news. However, completely preventing misinformation may be impossible. For this reason, social listening, rumor monitoring, and plans for response should be part of a community engagement strategy. This strategy includes considering scenarios whereby misunderstandings could result in various forms of backlash. In this instance, the safety of community members who have been involved in the research also needs to be considered.

The **Table** lists activities that can be considered as part of a comprehensive framework for disseminating findings on emerging infectious diseases in contexts with histories of outbreaks.

**TABLE.** Illustrative Activities for Planning Dissemination

Phase of Dissemination	Potential Activities at Community, National, and Global Levels
Pre-dissemination	Create dissemination plans with government stakeholders at various levels – (i.e., community, district, regional and national)
	Consider behaviors and actions that people can reasonably take based on findings
	Prepare locally appropriate information materials in collaboration with Ministries of Health, Agriculture/Veterinary Services, and Health Education/Social Mobilization
	Prepare rumor monitoring and response plans at various levels
	Consider safety and security plans for research staff and community members
	Consider scenarios for sensitive findings
Dissemination and Post-dissemination	Review conduct and dissemination of research with government counterparts
	Implement and monitor rumor management system
	Assure ongoing communication with government counterparts at various levels

## CONCLUSION

Discovering emerging zoonotic pathogens before they pose threats to humans is an essential aspect of detecting and preventing future outbreaks and pandemics. The ongoing COVID-19 pandemic has highlighted the importance of these efforts and the need for ongoing research on emerging pathogens. However, the current COVID-19 pandemic is also showing us that pandemics and research on emerging zoonotic viruses have social and political implications.

Our experience in Sierra Leone highlighted some of these implications, and it suggests that greater consideration should be given to the overall approach and processes involved in the dissemination of research findings. Dissemination should consider the social and political contexts of stakeholders, such as national and local governments, local communities, and global scientific research communities. While these groups may overlap in terms of an overall goal of protecting public health, they have distinct responsibilities and accountabilities.

In Sierra Leone, these distinctions emerged more so in the dissemination phase and presented challenges to publicizing information. The process of dissemination should prioritize local community engagement and multilevel communication strategy. This prioritization may require collaboration with entities with a specialized skill set in social and behavioral communication to develop or adapt communication tools to incorporate new

research findings and implications for health behaviors. Communication preparedness plans with risk mitigation elements, including engagement with various levels of government and community members, should be built into projects, along with corresponding budgets.

The interdisciplinary nature of these considerations requires an operational framework for research dissemination that involves those with social and behavioral expertise working alongside virologists, government leaders, and communities. Such a framework must also capture best practices and inform wider efforts related to community-based research for health security. If effectively implemented, dissemination of research findings on emerging zoonotic viruses can be government owned and led while applying practices that mitigate fear and build community trust for prevention, detection, and response to future outbreaks and pandemics.

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## COMMENTARY

# Protecting Mental Health Data Privacy in India: The Case of Data Linkage With Aadhaar

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## Key Messages

- Under the Aadhaar system, biometric and demographic data stored in a central database can pose a significant threat to the data privacy of individuals with potentially stigmatizing conditions such as mental health disorders.
- The emerging use of artificial intelligence in digital solutions (including health interventions) can further complicate this situation. There is often patient exclusion in the development of artificial intelligence systems in mental health research and clinical practice.
- Based on Global Data Protection Regulation and other data privacy regulations, this article provides guidelines for mental health policy makers, professionals, technologists, and related health system stakeholders to protect the individual's data privacy.

## INTRODUCTION

The Mental Health Care Act 2017 in India represents a landmark legislation advocating for the rights, dignity, and autonomy of persons facing the challenges of mental illness and aims to transform the delivery of mental health care across the country.<sup>1,2</sup> The new law mentions digital data privacy; yet few studies have focused on this to date.<sup>3</sup> This has contributed to its low prioritization in emerging digital mental health programs in India.

The Government of India has made a systematic effort to ensure that all health service clients have a unique health identity (UHID), a digital identity issued by health care providers to track patients and secure relevant health documents, and link the UHID to the unique identification number assigned to every Indian

resident, called the “Aadhaar” number.<sup>4,5</sup> This linkage raises critical questions of how well the system and the community-at-large are prepared for such a large-scale data linkage and its implications for privacy. This has especially important implications for individuals living with mental illness, as safeguarding their data privacy is essential to reduce their risk of being judged or facing stigma, hostility, or adversities in personal or workplace relationships.

In this commentary, we discuss the challenges in protecting mental health data privacy, guidelines to protect the personal data privacy of individuals with mental health disorders in India, and implications for digital mental health services in other low-resource settings.

## BENEFITS AND RISKS OF DIGITAL DATA SHARING

Internet penetration in India has shown consistent growth in adoption in urban and rural areas,<sup>6</sup> which has brought about increasing interest in digital tools for various aspects of health care. This includes mobile-based services for providing health information<sup>7,8</sup> and mobile phone reminders for offering education or counseling in the context of HIV,<sup>9,10</sup> diabetes,<sup>11</sup> TB,<sup>12</sup> and cardiovascular diseases.<sup>13,14</sup> There is also mounting interest in digital resources for mental health care, reflected in recent analyses of short message service (SMS)-based services<sup>15,16</sup> for mental health issues, with SMS and voice reminders used to reduce missed appointments and improve follow-up at an urban community mental health clinic<sup>15</sup>; and use of tele-helplines for crisis resolution and follow-up.<sup>16</sup> Use of artificial intelligence (AI) has also been reported in the case of commercial smartphone applications in India that are freely accessible to users.<sup>17,18</sup> One such example is “Wysa,” an AI-enabled, empathetic, text-based conversational mobile mental well-being app, that has shown improvement in the mood of users with self-reported symptoms of depression.<sup>17</sup>

Importantly, the Government of India has emphasized the need to scale up digital mental health solutions due to the significant gap between those in need of care and those who receive mental health care, referred to as

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**The consequences of poorly regulated data linkage have begun to show.**

the “treatment gap.”<sup>19,20</sup> It is estimated that 90% of the roughly 200 million people in India who live with mental health disorders<sup>21</sup> lack access to necessary services<sup>22</sup>; yet many of these individuals own smartphones (as phone users represent 88.5% of people in India and more than 625 million internet subscribers<sup>23</sup>). The National Mental Health Survey (2016) also recommended an expanded usage of smartphone-based applications, digital tools for decision-support (due to the scarce number of psychiatrists), and electronic databases for follow-up of individuals with mental health disorders.<sup>24,25</sup> This would enable large-scale mental health data sharing between the heterogeneous providers (i.e., specialists, primary care doctors, frontline workers, informal healers), patients, and other stakeholders.<sup>26</sup> Among the existing studies that have evaluated digital mental health services in India,<sup>3,15,16,27</sup> there has been limited focus on data privacy.<sup>27</sup> With the increase in digital data sharing on clinical, demographic, occupational, and social variables, this potentially raises individual privacy concerns.

Furthermore, there is significant social stigma surrounding mental health conditions, which impedes individual care seeking, social participation, and access to treatment.<sup>28</sup> With the widespread challenges in overcoming stigma and negative attitudes toward mental health conditions,<sup>29,30</sup> it is critical to safeguard the privacy and confidentiality of users’ mental health data, especially as they interface with digital health systems. Stigma is negatively correlated with help seeking for allopathic or modern medical treatment in the Indian context, while a positive association has been shown with previous informal help seeking.<sup>28,31</sup> Stigma motivates families to conceal the affected person, often hiding the condition and its perceived causes (driven by shame) such as previous sins or bad acts, which can substantially delay or inhibit timely access to treatment.<sup>28,31</sup> Therefore, protecting the data privacy of individuals with potentially stigmatizing mental health disorders is critical as unintended disclosure could impede their access to care, result in possible denial of additional services, or result in possible discrimination by employers or agencies providing financial aid for treatments.

## ■ THE AADHAAR SYSTEM AND ITS LINKAGES

Under the Government of India’s Ministry of Electronics and Information Technology, the Aadhaar is a 12-digit unique number assigned to

every Indian resident to record demographic (name, address, date of birth, and sex) and biometric data (fingerprints, iris scans, and a photograph). Aadhaar identification helps deliver subsidies, cash benefits, and incentives to intended beneficiaries, but the number has been increasingly linked to bank and income tax accounts, mobile phone numbers, and social welfare programs such as disability and elderly pension schemes.<sup>32,33</sup> This is pertinent in the context of seeking treatment for stigmatizing mental health conditions, where accessing care will be tied to compulsory linking of personal identification information (i.e., Aadhaar).

## Health Consequences of Linking Data

The consequences of poorly regulated data linkage have begun to show. In 2017, the Government issued a notification to mandatorily link the Aadhaar number with the patient identification number for patients with TB to receive cash assistance under the Revised National TB Control Program. This led to an interruption in treatments, particularly in cases of patients from lower socioeconomic segments, due to the documents and procedures required for availing an Aadhaar number.<sup>34</sup> There have been instances of patients with HIV and AIDS dropping out of antiretroviral therapy, fearing a breach of privacy, when it was made compulsory to include Aadhaar numbers in their treatment reports.<sup>35</sup> It should be noted that similar to mental health disorders, TB and AIDS carry a considerable social stigma in India.

A breach of privacy leading to the denial of a health service to an individual also leads to loss of their autonomy (when benefits are denied and there is no alternative mode of identification that is permitted) and loss of dignity (compromise of the individual’s right to physical or mental integrity, as confidential data are leaked without consent). Both of these losses can potentially worsen the situation for individuals with a mental illness and their families.<sup>36</sup> Moreover, being identified as having a mental health problem in India can lead to institutionalized discrimination and loss of civil rights; for example, the loss of a job,<sup>19,37</sup> denial of the right to vote,<sup>38</sup> divorce on grounds of mental illness (under the Hindu Marriage Act),<sup>39</sup> and automatic questioning of an individual’s capacity to make a will.<sup>40</sup>

## Unique Challenges of the Aadhaar Data Linkage

Poor regulation of data linkage has other grave consequences such as systemic leakages, as illustrated by the case of about 200 government websites that

inadvertently displayed the Aadhaar numbers of individuals<sup>41</sup> and technologists now working for for-profit companies, who were previously involved in the formulation of the Aadhaar system, in the absence of strict regulations to prevent conflict of interest.<sup>42</sup> It is not uncommon for health systems to adopt more integrated digital infrastructures, requiring the implementation of new protections for the privacy of users. However, in the case of the Aadhaar system, there are unique challenges and serious threats to privacy,<sup>43</sup> as described in the following points.

1. Other laws in India such as the Registration Act (concerning the mandatory registration of documents of Indian citizens), collect biometric information, as with the Aadhaar system. However, such usage of biometric data comes with stringent legal restrictions specified in the Act,<sup>43</sup> adhering to the principle of “purpose limitation,” (or processing of personal data for specified, explicit, and legitimate purposes only; further processing shall not be incompatible with initial purposes). These restrictions have not been mentioned in the Aadhaar Act of 2016.<sup>33</sup>
2. Under the Aadhaar system, biometric and demographic data are stored in a centralized database and associated with the individual’s unique Aadhaar number. This number is sought to be “seeded” (added as a new data field) with other public and private databases in the country.<sup>43</sup> Normally, we have access to our different data “buckets” (e.g., details on air travel, bank accounts, mobile phones, employment histories, or health records), and only we can construct our full “profile” through these separate data buckets. But if the Aadhaar number is seeded into databases, which to some extent has already begun via linkage of Aadhaar numbers with bank accounts and mobile phone numbers, then these data buckets will become integrated. Therefore, individuals lose control over who can reconstruct their profile. There is a serious concern reported that potentially unauthorized persons in the government would then be able to “profile” an individual by pulling out information from various databases using the Aadhaar number.<sup>43</sup> This has other implications too, such as self-censorship and the likely suppression of dissent or public opinion sharing in democratic systems of governance.<sup>44</sup>
3. Aadhaar proponents claim that this system allows us to “see individual lives in different spheres”<sup>43</sup> to conduct big data analysis, such as econometric and epidemiological analyses, and thus, discover hidden data patterns to establish predictive and/or causal relationships between multiple domains of the economy. However, this very “personal data economy”<sup>43,45</sup> could potentially monetize information about individuals’ private lives, much before the creation of sufficient digital literacy or safeguards.
4. While we have become aware that smartphones, social media platforms, or Internet search engines may violate our privacy, technologies such as encryption or virtual private networks can protect user privacy to an extent. Aadhaar’s centralized system of data integration lacks these safeguards.<sup>43</sup>
5. The safeguards against data breaches in the 2016 Aadhaar Act warrant greater scrutiny and strengthening. For example, if data are “leaked,” only the Unique Identification Authority of India<sup>32,33</sup>—not the affected person—is authorized to file a First Investigation Report, which invests the power to prosecute in the government agency and not the individual whose privacy has been violated.

### Broken Consent Mechanism

The Aadhaar system suffers from a “broken consent mechanism” as best illustrated in the recent case of registration of Indian citizens on the Government’s CoWin vaccine portal for COVID-19 vaccination.<sup>46</sup> While the government has reiterated that Aadhaar is not mandatory for vaccine registration and that any identity proof would be accepted for vaccination, the realities are playing out differently. The Government’s operational guidelines encourage vaccine officers to verify the recipient’s identity with Aadhaar ID, compared to other forms of identification. In other words, Aadhaar is the “preferred mode” for authentication, and although described as “voluntary,” it is being made “mandatory” for all practical purposes, as in the case of other services such as linkage with bank accounts or registration for mobile phones.

### Data Erasure

Finally, the Aadhaar system suffers from an absence of the facility of data erasure offered to the data subject or user,<sup>33</sup> as enshrined in data

**Aadhaar suffers from a “broken consent mechanism” as best illustrated in the recent case of registration of Indian citizens on the Government’s CoWin vaccine portal for COVID-19 vaccination.**

protection and privacy laws in other regions globally such as the General Data Protection Regulation (GDPR) in the European Union (further detailed in the next section). This means an absence of the user’s “right to be forgotten” where the data subject has the right to the erasure of personal data concerning themselves without undue delay on certain grounds as mentioned in Article 17 of the GDPR.<sup>47</sup> Some examples of such grounds for data erasure include the subject withdrawing consent or opposing the processing of their personal data, unlawful processing of data, or the personal data being no longer necessary in relation to the purposes for which they were originally collected or processed.

### ■ FRAMEWORKS FOR PROTECTING PERSONAL DATA PRIVACY

There are key international frameworks and methodologies aimed at protecting personal data privacy. These can inform the development of similar frameworks for the Indian context or incorporate key features into existing Indian policy, legal, and/or ethical frameworks.

#### General Data Protection Regulation

The GDPR, which came into force in May 2018, is a case in point. Although GDPR guidelines apply to organizations in the EU, they have important privacy considerations that are generalizable. GDPR encourages the development of digital systems that are less privacy invasive. The GDPR defines data pertaining to health as<sup>48</sup>:

*Personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status.*

GDPR also describes “genetic data” as the characteristics of a natural person that give unique information about her physiology or health, and “biometric data” as information obtained from a specific technical processing relating to the physical, physiological, or behavioral characteristics of a natural person, which allow or confirm their unique identification.

The processing of these kinds of personal health data is prohibited unless the subject has given “explicit consent” or if the processing of such data is necessary for preventive or occupational medical care (e.g., assessment of an employee’s working capacity, medical diagnosis, provision of health care, or social benefits), for

reasons of public health interest such as protecting against serious cross-border threats to health, or ensuring optimum standards of quality and safety of health care products or services. Table 1 details the principles of the GDPR.<sup>49</sup>

Under the GDPR, organizations must conduct a Data Protection Impact Assessment (DPIA)<sup>50</sup> that includes documentation of the need to conduct such an assessment, a detailed explanation of data processing, the data controller’s (e.g., the project head) consultation with relevant stakeholders, compliance and proportionality measures undertaken in the project, and a description of likely data privacy risks, their potential impact on individuals, and steps taken to mitigate/eliminate these risks. Table 2 includes a summary of the DPIA requirements.

#### Global Initiative on Ethics of Autonomous and Intelligent Systems

The Institute of Electrical and Electronics Engineers (IEEE) Global Initiative on Ethics of Autonomous and Intelligent Systems addresses ethical issues raised by the development and dissemination of new digital systems, which is especially relevant to emerging ways of obtaining digital health data.<sup>51</sup> This initiative offers guiding principles of “ethically aligned design” (Table 3<sup>52</sup>) and has identified more than 120 key ethical issues and provided recommendations to address them. Currently, the IEEE standards association is developing “standardization projects” to guide technologists and organizations to mitigate the chances of ethical violations of personal data privacy.<sup>51</sup>

#### Applying Frameworks to Protect Mental Health-Related Data

There is an immediate need to consider the data protections outlined in the GDPR, DPIA, and IEEE Global Initiative on Ethics of Autonomous and Intelligent Systems given the rising interest in digital mental health technologies in India<sup>53</sup> and resulting personal data sharing at scale. Moreover, the absence of an existing Indian framework on mental health data privacy (except for the clauses in the Mental Health Care Act) has generated limited knowledge on data privacy risks for individuals living with mental health conditions, which faces additional threats posed by the comprehensive Aadhaar linkage spanning individuals’ personal data domains.

**The absence of an existing Indian framework on mental health data privacy has generated limited knowledge on data privacy risks for individuals living with mental health conditions.**

**TABLE 1.** Principles of the GDPR Guidelines From the European Union

Principle	Description
1. Lawfulness, fairness, and transparency	Transparent processing of personal data in relation to the subject.
2. Purpose limitation	Processing of personal data for specified, explicit, and legitimate purposes only; further processing for archiving in the public interest, or for scientific/historical/statistical research (according to Article 89[1] of GDPR) shall not be incompatible with the initial purposes.
3. Data minimization	Personal data should be adequate, relevant, and limited in relation to the purpose of processing.
4. Accuracy	Personal data should be accurate and up-to-date; inaccurate data should be erased or rectified without delay and regarding the purposes for which they are processed.
5. Storage limitation	Personal data are to be kept in a form that permits identification of subjects for no longer than is necessary for the purposes for which their data are processed; personal data may be stored for longer periods for archiving in the public interest, or for scientific/historical/statistical research (according to Article 89[1] as above), subject to the technical and organizational measures required by this regulation.
6. Integrity and confidentiality	Personal data are to be processed to ensure their appropriate security, including protection against unauthorized or unlawful processing, accidental loss, destruction, or damage, using appropriate technical or organizational measures.
7. Accountability	The “controller” (for example, the project head or signing authority of the project) shall be responsible for, and be able to demonstrate compliance to the aforesaid principles.

Abbreviation: GDPR, General Data Protection Regulation.

**TABLE 2.** DPIA Checklist (points for documentation) to be Followed by Organizations Who Are Bound by the GDPR Guidelines

Section	Description
1. The need for a DPIA	The aims of the project; types of data processing involved; and the reasons to identify the need for a DPIA
2. Data processing	<p>Nature: method of collection, usage, storage, and deletion of data; source of data; details on sharing of data with anyone; any likelihood of high-risk data processing</p> <p>Scope: nature of data, any inclusion of special category or criminal offense data, sample size and data collection frequency, duration of data storage, scope of geographical area and individuals affected</p> <p>Context: nature of the relationship between the data controller [for example, the project head] and the individual, degree of control exercised by the individuals on their data, individuals’ expectations on the usage of their data, any data on children or vulnerable groups, prior concerns or security flaws or current public concerns related to the data processing, novelty of data processing, current state of technology around data processing, and whether the controller has signed up for any approved code of conduct</p> <p>Purposes: aim of the project, intended effects on individuals, benefits of data processing for the controller, and broader benefits</p>
3. Controller’s consultation with stakeholders	The controller’s consultation process with relevant stakeholders; the need and timing of seeking individuals’ views on their data; the details of project collaborating partners; any consultations planned with information security or other kinds of experts
4. Compliance and proportionality measures	Lawful basis for data processing; justification of its purpose; alternate ways of achieving project aims; steps to ensure data quality and data minimization; nature of information provided to the individuals and ways to support their rights; ways to ensure that data processors and analysts comply with all stated steps; methods of safeguarding domestic and international data transfers (if any)
5. Privacy risks and their impact	The source(s) of potential data privacy risk and nature of their potential impact on the individual
6. Mitigation	Measures taken to reduce or eliminate the privacy risks

Abbreviations: DPIA, Data Protection Impact Assessment; GDPR, General Data Protection Regulation.



**TABLE 3.** General Principles of Ethically Aligned Design of A/IS Outlined by the IEEE Global Initiative on Ethics of Autonomous and Intelligent Systems

#	Principle	Description
1	Human rights	A/IS should be created and operated to respect, promote, and protect internationally recognized human rights.
2	Well-being	A/IS creators should adopt increased human well-being as a primary development criterion.
3	Data agency	A/IS creators should empower individuals with the ability to access and securely share their data (thus, control their identity).
4	Effectiveness	A/IS creators should provide evidence of the system’s effectiveness and fitness for its intended purpose.
5	Transparency	The basis of a particular A/IS decision should always be discoverable.
6	Accountability	A/IS should be developed for providing an unambiguous rationale for all decisions made.
7	Awareness of misuse	A/IS creators should guard against all potential misuses/risks of A/IS in action.
8	Competence	A/IS creators should specify and operators should adhere to the knowledge and skill required for safe and effective operation.

Abbreviations: AIS, autonomous and intelligent system; IEEE, Institute of Electrical and Electronics Engineers.

### ■ ARTIFICIAL INTELLIGENCE AND PRIVACY IN MENTAL HEALTH

Artificial intelligence has begun to penetrate digital mental health solutions, driven in part by the National Strategy on Artificial Intelligence released by the Government of India.<sup>54</sup> Digital interventions allow opportunities for immense data collection, and AI systems using mathematical algorithms<sup>55</sup> can seek to make sense of these complex and vast datasets.<sup>56</sup> The use of AI has been reported in certain algorithm-based mental health applications<sup>17,18</sup>; however, such an intervention ecosystem has a fundamental contradiction to the importance of consent and data minimization, as articulated in Indian data protection frameworks such as the Sri Krishna report.<sup>57</sup> Linking Aadhaar can make such systems more invasive by obtaining far greater amounts of personal data from individuals. Mental health data points vary due to the context and characteristics of the individual and the disorder, which can complicate the correlations made by AI systems. In addition, meaningful consent is already hard to achieve in the majority of clinical settings in India due to low awareness, literacy, and agency to exercise the right to informed choice; and therefore, consent can get further complicated if clinical data are automatically fed into an AI system. In these situations, it will be difficult for individuals living with mental health conditions to interpret and/or exercise consent, or for their family members, because data are often correlated in ways that are not identifiable, or where the impacts are not immediately known.<sup>56</sup>

AI algorithms have several other complex applications, notably, predictive modeling.<sup>58</sup> Broadly, predictive modeling leverages large quantities of personal data to uncover patterns to predict future health outcomes, which could inform treatment selection and treatment personalization.<sup>59</sup> However, this approach fails to recognize the central role of the patients, especially when their personal data will be used for developing such algorithms.<sup>58</sup> Consequently, the mental health patient is not sufficiently mentioned as a central collaborator, or the final beneficiary to whom both clinicians and data scientists are accountable.<sup>60</sup> These challenges related to the use of AI in mental health research and practice demand far greater scrutiny and effort on the part of regulators and policy makers to safeguard the personal data privacy of individuals with mental health conditions.

### ■ RECOMMENDATIONS TO SAFEGUARD MENTAL HEALTH PRIVACY

The Government of India’s policy think-tank, NITI Aayog, published a discussion paper on the National Strategy on Artificial Intelligence having guidelines concerning privacy issues in India.<sup>54</sup> In the absence of specific guidelines for the mental health context, we refer to NITI Aayog’s guidelines to draft customized recommendations for safeguarding the data privacy of individuals in India with mental health conditions. The following 10 measures can be considered by mental health

policy makers, professionals, technologists, and related health system stakeholders to protect the individual's data privacy, in the context of increasing access to and use of digital interventions for mental health.

1. Organizations working in the mental health space should adhere to the core principles of data protection such as informed consent and "data minimization" (i.e., personal mental health data should be adequate, relevant, and limited to the purpose of data collection). This should be supported by data-protection laws that are flexible to include changing technologies, relevant in mental health where a range of digital interventions are being piloted in low-income or middle-income countries or "technology agnosticism."<sup>53</sup>
2. Provision of the Aadhaar number by an individual having a mental health condition or by his/her family member should be made completely voluntary and not encouraged by the care provider, staff member, or anyone else in the health system interfacing with the individual. The number should be de-linked from the provision of service or any information related to the service. We frame this recommendation based on the Supreme Court of India's 2018 decree that Aadhaar is not mandatory<sup>61</sup> and the preceding Supreme Court 2017 judgment protecting the Right to Privacy, as an intrinsic part of the Right to Life and Personal Liberty as guaranteed under the Indian Constitution. In the 2017 judgment, 3 distinct connotations of individual privacy were defined<sup>62</sup>: (1) "spatial control" or creation of private spaces; (2) "decisional autonomy" or intimate choices such as those governing reproduction, faith, or modes of dress; and (3) "informational control," or use of privacy as a shield to retain control over personal information.
3. Organizations in digital and traditional mental health systems seeking personal data (including passwords, financial data, and biometric information) should maintain reasonable security to protect sensitive personal data and should be held liable for damages when their negligence results in wrongful loss or harm to any person. In India, this aligns with Section 43A of the Information Technology (IT) Act 2000.<sup>63,64</sup> The act was amended in 2011 to frame the "IT Rules"<sup>63</sup>

(Table 4), which should be upheld at all levels of a mental health system. Rule 3 of these "2011 IT Rules" includes the following as "sensitive personal data": information relating to passwords, credit or debit cards, biometric information (DNA, fingerprints, voice patterns, etc.), physical, physiological, and mental health condition, medical records and history, and sexual orientation.

4. Apart from a centrally enacted law, mental health sectoral regulatory frameworks are equally important to establish and concerning that, mental health professionals in India are accountable to the central and state mental health authorities under the Mental Healthcare Act 2017.<sup>65</sup> Therefore, these sectoral authorities can supervise the kind of data obtained by digital interventionists and evaluate the extent of privacy protection.
5. India's health laws should cover mental health and define privacy protection frameworks and continually update those to reflect an understanding of new and evolving risks by referring to established international standards.<sup>48-50,54</sup>
6. AI systems developers working in mental health should conduct a DPIA<sup>50</sup> and refer to the IEEE Global Initiative on Ethics of Autonomous and Intelligent Systems.<sup>51,52,54</sup>
7. When considering the role of AI algorithms for supporting symptom monitoring or informing the diagnosis or care of mental health conditions, attention is necessary to avoiding harm to patients and accounting for risk of bias. Developers and researchers should be made aware of the possibilities of such biases due to the subjective and expressive nature of clinical data in text form as reported by mental health patients, and the inherent risks of associating mental disorders to certain patient groups or ethnicities.<sup>66</sup> AI systems may reproduce biases in existing data,<sup>67</sup> with potentially detrimental consequences to individuals. Also, poor quality data can adversely affect the use of AI systems<sup>68</sup> and is further compounded in resource-constrained settings such as in India where there may be additional gaps, errors, or delays in data collection mechanisms. Accepted ethical principles such as autonomy, beneficence, and justice should be prioritized, particularly in the case of using data collected from patients from

**Provision of the Aadhaar number by an individual having a mental health condition or by his/her family member should be made completely voluntary.**

**TABLE 4.** The Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules 2011: Rules 4, 5, 6, and 8

Salient Rules	Details
Rule 4	Organizations (referred to as the “body corporates”) seeking sensitive personal data should draft a privacy policy and make it easily accessible for individuals providing such data. The privacy policy should be clearly published on the website of the body corporate, and it should contain details on the type of information that is collected, its purpose, and the reasonable security practices that are undertaken to maintain the confidentiality of sensitive information.
Rule 5	(a) The body corporate should obtain consent from the person(s) providing information in writing/by fax/e-mail, before collecting sensitive personal data. (b) Information shall be collected only for lawful purposes, and it should be necessary for the purpose. It should be used only for its purpose, and shall not be retained for a period longer than required, for the purposes for which the information may lawfully be used, or is otherwise required under any other law for the time being in force. (c) The individuals providing sensitive data should be made aware of the fact that the information is being collected, its purposes and recipients, and the names and addresses of the agencies obtaining and retaining the information. (d) Offer the person(s) providing information an opportunity to review the information, and make corrections if required; (e) The body corporate should provide an option (before collecting the information) to the person(s) to not provide the information sought. (f) The body corporate should maintain the security of the information provided; and appoint a grievance officer, (with name and contact details on the website), responsible to address and resolve grievances of information providers over a maximum period of 1 month.
Rule 6	The body corporate must seek prior permission of the individual who provides sensitive data, before disclosing it to a third party, except if the request for such information is made by government agencies/third parties mandated under law or by a legal order.
Rule 8	International Standards (IS/ISO/IEC 27001) can be implemented by a body corporate to maintain data security. An audit of reasonable security practices and procedures should be conducted at least once a year or as and when the body corporate undertakes significant upgradation of its processes and computer resources.

**Efforts are equally needed by AI researchers to bridge the gaps in data and technology literacy for both patients and clinicians.**

vulnerable groups who are susceptible to stigma and discrimination, such as many individuals seeking care for mental health challenges.<sup>69</sup> Further, clinicians and therapists, due to lack of formal training in this space, may be unaware of managing granular data reported by an AI-based system or app, or may not feel completely confident with clinical insights gathered through these systems.<sup>70</sup> To that end, efforts are equally needed by AI researchers to bridge the gaps in data and technology literacy for both patients and clinicians. The challenge herein is that there remain insufficient guidelines for the use of AI in health care settings,<sup>71,72</sup> a challenge that is especially stark in lower-resource countries such as India. Even the NITI Aayog’s recommendations need further strengthening by adding dedicated guidelines on deploying AI research for patients with mental health disorders and other potentially stigmatizing conditions, in connection with point 6.

8. Caution is also needed due to the risk of perpetuating existing racial or ethnic biases or stigma with AI algorithms. A prominent study from the United States<sup>73</sup> showed that an algorithm assigned the same level of risk of chronic diseases (i.e., hypertension, diabetes, renal failure, high cholesterol) to Black patients, who presented more risk factors and comorbidities than white patients. This racial bias reduced the number of Black patients identified as requiring additional medical care by more than 50%. The algorithm used health costs as a proxy indicator for health needs, which resulted in this bias. As less money was spent on Black patients who reported the same level of need, the algorithm falsely inferred that Black patients were healthier than white patients with the same medical problems. In the Indian context, there is a similar risk of exclusion of stigmatized groups. As part of the National Digital Health Mission, the Government of India has commenced the process of assigning a digital health ID to every citizen, which is voluntary “until all health data

are mandatorily digitized.”<sup>74</sup> As the digital health ID would offer the entire health data of an individual across providers and treatments (i.e., digital health profile) and given the risk of its potential linkage to the Aadhaar ID, there may be an unauthorized or unintended disclosure of an individual’s mental illness or other stigmatizing conditions (e.g., HIV, TB) resulting in the denial of access to crucial services or perpetuation of stigma. For example, a transgender individual may experience discrimination by an insurer or financial institution because they would have to reveal their gender and any prescription drugs or treatments taken.<sup>74</sup> The linking of data across health care providers may accidentally worsen pre-existing social, cultural, and/or institutional stigma. Developers of algorithms under the National Digital Health Mission should be educated on these threats to users’ rights to access services. One example of improving algorithms is to avoid the use of convenient and seemingly effective proxy measures (e.g., health costs in the aforesaid U.S. study<sup>73</sup>) for ground truth, which could introduce bias.

9. We encourage investment and collaboration by mental health researchers and their technology partners to study and co-develop new mathematical models that can preserve privacy by limiting the information that one can obtain from released data, regardless of the extent of associated information.<sup>54</sup> An example is “multi-party computation,” a “toolbox” of cryptographic techniques that allows joint computation of data by different partnering organizations working on a digital project, just as if they are sharing a database. Cryptographic techniques protect the data, so the involved parties can view relevant information of

individuals, without their underlying sensitive data. This enables a secure analysis of data from different sources, which is pertinent in digital mental health interventions.<sup>75</sup>

10. Increasing awareness of data privacy among individuals with mental health conditions and their families is of paramount importance. People often tend to give consent to sharing their data, especially when interfacing with technology, which they would not have done had they known the purpose of providing such information. There is an urgent need for the inclusion of privacy rights and advisories in all digital mental health program material that is disseminated among beneficiaries, and at a deeper level, in the medical and technological training curricula to instill the fundamentals of privacy in medical and engineering graduates.<sup>54</sup>

While it is important to recognize that these 10 measures are not exhaustive, these guidelines can inform efforts to strengthen data protection frameworks and laws, including the existing draft of the Digital Information Security in Healthcare Act 2018 (DISHA) in India, which the Government of India plans to implement.<sup>76</sup> DISHA includes provisions that regulate the generation, collection, access, storage, transmission, and usage of digital health data and the related personally identifiable information. Presently, DISHA includes the details of its regulated entities, affirmative rights of the individual providing sensitive data, guidelines on collection and processing of DHD, types of breach of DHD, and adjudication and enforcement in case of such offenses. Table 5 summarizes the Rights of the Data Subject under DISHA.<sup>76</sup>

**Linking of data across health care providers may accidentally worsen pre-existing social, cultural, and/or institutional stigma.**

**TABLE 5.** Rights of the Data Subject Under the Digital Information Security in Healthcare Act 2018 from the Ministry of Health and Family Welfare, Government of India

<b>All Digital Health Data (DHD) is owned by the individual providing such data (the Owner), and her affirmative rights include:</b>
<ol style="list-style-type: none"> <li>1. The right to privacy, confidentiality, and security of this data.</li> <li>2. The right to give or refuse consent for the generation, collection, storage, transmission, access, or disclosure of this data. The owner may not be refused a health service if they exercise the right to refuse consent.</li> <li>3. The right to require the owner's explicit permission for each instance of transmission or use of their DHD.</li> <li>4. The right to access their DHD and the right to rectify inaccurate or incomplete DHD.</li> <li>5. The right to seek compensation for damages caused by a breach of DHD.</li> </ol>

**TABLE 6.** Data Safety/Security Policies and Laws in South Asian Countries Adjoining India

Country	Data Safety Policies/Laws
Bangladesh	<ul style="list-style-type: none"> <li>Concerning the newly enacted Mental Health Act in 2018, it has been critiqued that patient’s confidentiality and associated accountability of medical practitioners for failure to maintain confidentiality are not included in sufficient detail.<sup>77</sup></li> <li>Privacy laws are lacking; instead, there is a dependence on provisions within several other existing laws, or relevant sections in the country’s constitution such as Article 32 (protection of right to life and personal liberty), Article 39 (freedom of thought and conscience and of speech), and Article 43(b) (right to privacy for each citizen, of his correspondence and other means of communication).<sup>78</sup></li> <li>In December 2020, the government passed the Digital Security Rules, which call for organizations to establish “help desks” so that they could comply with the Digital Security Act 2018.<sup>78</sup> As a consequence, employees can register complaints related to personal data misuse via these help desks.</li> <li>The Digital Security Act 2018 is inadequate to regulate a right as fundamental as data privacy, calling for new legislation.</li> <li>Requirements in GDPR may be difficult or costly to implement for many small companies in Bangladesh<sup>78</sup>; therefore, the proposed Personal Data Protection Bill in India serves as a reference,<sup>78,79</sup> as it offers flexibility to smaller organizations.</li> </ul>
Bhutan	<ul style="list-style-type: none"> <li>Limited legislation related to mental health.<sup>80</sup></li> <li>The Information, Communications and Media Act of Bhutan 2018 includes data protection principles, which includes 7 of the 10 “second generation” principles of the 1995 European Union Data Protection Directive.<sup>81</sup></li> </ul>
Nepal	<ul style="list-style-type: none"> <li>Privacy Act 2018 restricts processing of “sensitive data” in control of a public entity.</li> <li>Physical or mental health of a person are included as part of sensitive data, which can be processed “only during the diagnosis, treatment, and management of public health, and the delivery of health services to a person if such data has been made public by the concerned individual themselves.”<sup>82</sup></li> <li>Privacy Act has impacted the legal usage of “personal information” as it stipulates how “personal information” in public entities can be used, along with liabilities for breach.<sup>81</sup></li> </ul>
Pakistan	<ul style="list-style-type: none"> <li>No specific law relating to data protection.<sup>83</sup></li> <li>In April 2020, the country’s Ministry of Information Technology and Telecommunication released a draft Personal Data Protection Bill for consultation before being presented to Parliament for debate.</li> <li>The Bill defines “sensitive personal data” as that which includes biometric data; information on the subject’s physical, psychological, or mental health conditions as well as medical records, among other details.</li> <li>Sensitive personal data can be processed only with the explicit consent of the subject and only for defined purposes, such as: exercising any right or obligation conferred by law on the data controller in connection with the subject’s employment; protection of vital interests of the subject/another person; and where processing is undertaken for medical reasons/ by a health care professional.</li> </ul>
Sri Lanka	<ul style="list-style-type: none"> <li>The Personal Data Protection Bill is comprehensive<sup>81</sup> covering both public and private sectors.</li> <li>The bill requires lawful grounds for processing users’ data and includes obligations of controllers and rights of users based on GDPR provisions. Key rights of GDPR are present, such as users’ “right to be forgotten” and protections against automated processing of data.</li> <li>The independence of the data protection authority, an independent public body authorized to supervise the application of the data protection law, provide expert advice on data protection issues, and handle complaints lodged against GDPR violations or relevant national laws, is not guaranteed.<sup>81</sup></li> <li>While mental health literacy has improved in Sri Lanka, the absence of consensus among stakeholders and legislative delays have hindered recent attempts to develop a new mental health act to replace the existing Mental Diseases Ordinance of 1956.<sup>84</sup></li> </ul>

Abbreviation: GDPR, General Data Protection Regulation.

### ■ IMPLICATIONS FOR OTHER COUNTRIES IN SOUTH ASIA

While the examples presented draw extensively from the case of data linkage with Aadhaar in India, these recommendations are relevant for many additional settings globally. Consideration

of data safety in the context of emerging digital mental health interventions and expanding delivery of necessary care to those living with stigmatizing mental health conditions is relevant for many other lower-income countries, particularly among countries in the South Asian region where

data safety policies are not yet well-established. In Table 6, we have illustrated the various contexts related to data protection in Bangladesh, Bhutan, Nepal, Pakistan, and Sri Lanka.

These countries in the South Asian region account for more than 30% of adolescents globally<sup>85</sup> while also experiencing a disproportionately greater share of the global burden of mental disorders.<sup>86</sup> These challenges are compounded by having few mental health resources,<sup>87,88</sup> highlighting the potential for digital interventions<sup>89–91</sup> to bridge the care gap in the region. It should be noted that digital mental health interventions, particularly those involving online platforms and social media, could potentially lead to exposure of young users to hurtful content and hostile interactions with other users,<sup>92,93</sup> threats to their data privacy,<sup>94,95</sup> stigmatizing experiences that could impact their personal relationships, and unintended effects of online disclosure of personal information.<sup>96</sup> Regulatory, systemic, and governmental efforts will be essential, with the participation of specialist and non-specialist health providers, technologists, and mental health interventionists to prioritize the protection of personal data and privacy of all individuals who receive these emerging interventions.

## CONCLUSIONS

In India, digital mental health practitioners and interventionists can refer to the guidelines outlined in this commentary and exercise substantial privacy protection while obtaining, storing, and using the personal data of individuals seeking care for mental health concerns. Regulatory agencies in this space should also consider the GDPR, DPIA, the IEEE Global Initiative on Ethics of Autonomous and Intelligent Systems, and NITI Aayog to further develop and refine their data protection efforts. Interventionists, who are obligated to adhere to these regulations, would then be enabled to conceive and develop privacy-sensitive intervention models. Data privacy policies are often complex and difficult to navigate, particularly for users with low literacy or those experiencing mental health symptoms; therefore, interventionists should clearly and succinctly communicate the kinds of data they would obtain from users.

Obtaining informed consent should mandatorily follow the privacy policy statement to ensure transparency rather than involve a checkbox indicating “agreement,” thus, giving the user ample opportunity to make an informed decision about their participation (which is often difficult due to the fast-paced nature of installing and using

digital applications). Individuals refusing consent should be allowed to use the intervention, with their data excluded from outcome analysis. Provision of services should be de-linked with the receipt of individual personal data. A brief, clear, and comprehensive statement on the protection of personal data privacy, fully exercising “data minimization” and dissociation from Aadhaar would build greater trust and confidence in the digital intervention. This is particularly important as the digital mental health field continues to advance rapidly, where the implications of Aadhaar will require continued scrutiny to ensure the protection of the privacy, rights, and dignity of those living with mental health disorders.

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VIEWPOINT

# Strategies for Improving Quality and Safety in Global Health: Lessons From Nontechnical Skills for Surgery Implementation in Rwanda

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## Key Messages

- Efforts to increase access to surgical care will achieve improved health outcomes only if those efforts are intertwined with efforts to increase surgical safety and quality.
- The World Health Organization Surgical Safety Checklist and Non-Technical Skills for Surgeons (NOTSS) framework are 2 tools to increase surgery quality and safety.
- The NOTSS for variable resource contexts is a new 1-day educational course developed in Rwanda that integrates contextually appropriate behaviors and values and can be implemented with low costs in any health care context.
- Program managers should provide context-specific NOTSS training for surgeons and operating theater staff.
- Policy makers should implement NOTSS framework into health care policy focusing on modern virtual teaching methods.
- Surgeons and operating theater staff should be familiar with the NOTSS framework and regularly update their knowledge through didactic courses, simulation, and online trainings.

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

## INTRODUCTION

In 2015 the Lancet Commission on Global Surgery published its report “Global Surgery 2030: evidence and solutions for achieving health, welfare, and economic development,”<sup>1</sup> helping to galvanize a global movement to increase access to safe, timely, and affordable surgical and anesthesia care with an emphasis on equity. A goal of the movement is to enable the benefits of these efforts to be reaped most by impoverished and marginalized populations. The authors laid out 5 key messages, including the great number of operations required annually (approximately 143 million), especially among the poorest third of the world’s population, which receives only 6% of the operations. The commission called on nations to track and report on 6 metrics related to surgical care. Two of these metrics—surgeon, anesthetist, and obstetric (SAO) density (the number of specialist surgical, anesthetic, and obstetric providers per 100,000 population) and surgical volume (number of operations performed in operating rooms annually per 100,000 population)—are measurements of surgical delivery. To achieve the proposed targets of 20 SAOs and 5,000 operations/100,000, the surgical workforce and the capacity to perform surgery must be greatly expanded.

Such efforts to grow the surgical workforce are currently being undertaken by regional professional colleges such as the College of Surgeons of East, Central, and Southern Africa,<sup>2</sup> the Pan-African Academy of Christian Surgeons,<sup>3</sup> the West African College of Surgeons,<sup>4</sup> and country-specific health professions training institutions. These efforts, when tied to initiatives to strengthen essential surgical care at district hospitals, hold promise for substantially increasing access to surgical care for destitute sick and injured populations and individuals served at these facilities. The current global COVID-19 pandemic has affected access to surgical care because most health resources have been mobilized toward the prevention and management of patients with COVID-19. A total of

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**Efforts to increase surgical volume will achieve greater measures of health and economic wellness, but only if surgery is of high quality.**

28,404,603 surgical procedures are estimated to have been canceled globally due to COVID-19. In sub-Saharan Africa, 520,458 surgical procedures were estimated to have been canceled due to COVID-19.<sup>5</sup>

Efforts to increase surgical volume will achieve greater measures of health and economic wellness but only if surgery is of high quality. In contrast, expanded access to unsafe, poor-quality surgery will increase complications and surgical deaths, in essence, trading the disease burden of untreated surgical conditions for an epidemic of iatrogenic perioperative complications. This problem may be developing even now. For example, countries throughout Africa have invested in increasing access to cesarean delivery, which is needed to improve maternal and neonatal safety by treating obstructed labor and other complications of delivery. Proper and timely treatment of obstructed labor will decrease maternal and neonatal death rates and also eliminate obstetric fistula. While obstetric fistula due to untreated obstructed labor is decreasing, the incidence of iatrogenic vesicovaginal fistula and surgical site infections due to poorly performed cesarean delivery is on the rise.<sup>6</sup> Hence, it is imperative that efforts to increase safety and quality in surgery be intertwined with efforts to increase access.

The World Health Organization Safe Surgery Checklist was developed to increase the safety of operating teams by encouraging communication and establishing shared mental models for teams performing surgical operations. Similarly, the Non-Technical Skills for Surgeons (NOTSS) framework was developed to improve intraoperative patient safety. NOTSS are defined as social (leadership, communication, and teamwork) and cognitive (situational awareness and decision making) skills that underpin medical knowledge, technical skills, and appropriate use of resources.<sup>7</sup>

The NOTSS framework has 4 categories, and each category has 3 elements (Figure). The framework provides scaffolding for teaching and assessing that has been demonstrated to be useful across multiple contexts that vary richly in language, culture, resources, level of care in the health system, and surgical epidemiology.<sup>8-11</sup> Finally, by emphasizing team training, since surgical care is delivered by multidisciplinary groups of health care specialists, updated versions of NOTSS serve as a model of team care that will increase safety and quality throughout health systems. This article describes how lessons learned from NOTSS implementation in Rwanda can be used to improve quality and safety in global health programs. Based on

our experience in developing and implementing a NOTSS training program in Rwanda, we describe strategies that can be used to improve the quality of surgical care in efforts to improve access to timely and affordable surgery.

## ■ NOTSS AND PATIENT SAFETY

*Nontechnical skills* (NTS) is a behavioral construct that originated in the aviation industry. An analysis of root causes of airplane crashes revealed that these events were not only due to lack of technology and technical skills but also a result of ineffective human factors among crew members. Crew resource management was subsequently developed as a way of reducing airplane disasters.<sup>12</sup> Similar to the airline industry, 80% of errors in anesthesia<sup>13</sup> and more than 50% of intraoperative surgical errors are due to ineffective communication between members of the surgical team.<sup>14</sup> Crew resource management transitioned to the health care industry through various NTS courses that were developed by different disciplines. In this regard, Anesthetists' Non-Technical Skills, Scrub Practitioners' List of Intra-operative Non-Technical Skills, and NOTSS were developed and largely taught in respective disciplines. In this article, we use the NOTSS framework as an example to describe how safety and quality of care can be improved as global access to care is increased.

Improvement of NOTSS can be achieved by appropriate training<sup>15,16</sup> that can be integrated into undergraduate, postgraduate, and continuous health professions education curricula.<sup>16</sup> NOTSS for variable-resource contexts (NOTSS-VRC) is a novel educational curriculum for NTS for surgery that was developed in Rwanda by integrating contextually appropriate values and implemented as a 1-day course for surgical teams (general practitioners/surgeons, perioperative nurses, and anesthetists).

Before implementing the NOTSS course in Rwanda, Scott et al.<sup>9</sup> conducted a systematic review to understand the contextual challenges to patient safety in low- and middle-income countries (LMICs). They identified that overburdened health care systems, lack of provider empowerment, and deficiencies in provider training compromise safe patient care in LMICs. Furthermore, a needs assessment to understand the critical NTS for surgeons needed for high performance in LMICs was conducted. This assessment identified that the categories of high NOTSS performance required in LMICs were identical to those in high-income countries, but the examples of specific behaviors indicative of those skills were different.<sup>11</sup>

**The categories of high NOTSS performance required in LMICs are identical to those in high-income countries, but the specific behaviors indicative of those skills are different.**

**FIGURE.** Nontechnical Skills for Surgeons Rating Tool

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Hospital ..... Trainer name ..... Date .....

Trainee name ..... Operation .....

Category	Category rating*	Element	Element rating*	Feedback on performance and debriefing notes
Situation Awareness		Gathering information		
		Understanding information		
		Projecting and anticipating future state		
Decision Making		Considering options		
		Selecting and communicating option		
		Implementing and reviewing decisions		
Communication and Teamwork		Exchanging information		
		Establishing a shared understanding		
		Co-ordinating team activities		
Leadership		Setting and maintaining standards		
		Supporting others		
		Coping with pressure		

\* 1 Poor; 2 Marginal; 3 Acceptable; 4 Good; N/A Not Applicable

1 Poor Performance endangered or potentially endangered patient safety, serious remediation is required  
 2 Marginal Performance indicated cause for concern, considerable improvement is needed  
 3 Acceptable Performance was of a satisfactory standard but could be improved  
 4 Good Performance was of a consistently high standard, enhancing patient safety; it could be used as a positive example for others  
 N/A Not Applicable

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NON-TECHNICAL SKILLS FOR SURGEONS

Based on these findings, Lin et al.<sup>8</sup> developed a NOTSS-VRC consisting of teaching videos, didactic lectures for a 1-day course, and a handbook for instructors. The curriculum can be implemented without significant financial cost in a resource-constrained country as an educational or quality-improvement strategy.

During course implementation, instructors collected feedback from participants. Based on this information, the course was revised and expanded to include other members of surgical teams (obstetricians, gynecologists, anesthetists, and perioperative nurses).

To accommodate all members of the surgical team; the terminology and examples of skills indicative of effective and ineffective behaviors were revised and they integrate all specialties. In addition, local instructors were trained and supported to teach NOTSS to surgical care providers from Rwandan district hospitals.

Although there are no patient-related data from Rwanda, a report by Scott et al.<sup>11</sup> showed that understanding of NOTSS among residents improved significantly after taking the course, which is a strong argument for its usefulness in LMICs. Evaluation of the NOTSS-VRC course showed

that participants' knowledge of NTS improved after the course. In addition, the training was perceived as "enjoyable, practical and informative" by the course participants.<sup>8</sup> Furthermore, Abahuje et al.<sup>17</sup> found that after completing a NOTSS program, participants were able to translate NTS in a clinical environment, and they perceived that the NOTSS program empowered them to speak up and helped them to improve team dynamics and to provide safe patient care. Similarly, Mossenson et al.<sup>18</sup> evaluated the impact of the Vitals Anesthesia Simulation Training (VAST) course in Rwanda. The VAST course is a 3-day simulation-based program that teaches core clinical skills and NTS required by anesthesia providers in limited-resource settings. This evaluation showed that participants acquired and retained knowledge up to 3 months after completing the VAST course. Participants reported that after taking the course, they were empowered to advocate for better patient care and system improvement.

Gordon et al.<sup>19</sup> carried out a systematic review to analyze the effect of different NOTSS training interventions on patient safety. Over half of the 22 analyzed studies described interventions

delivered to multidisciplinary teams. The teaching methods included simulation and role-playing, observation, didactic teaching, and games. The authors acknowledged that the analyzed studies had significant heterogeneity, which hindered drawing conclusions on the effectiveness of the interventions. However, most studies reported positive outcomes of the teaching interventions, which suggests they have educational utility. The content themes of the studies analyzed were communication, error, systems, team working, leadership, and situational awareness.

**The NOTSS training program may improve safety while global access to surgical care is being expanded.**

We argue that the NOTSS training program may improve safety while global access to surgical care is being expanded. Based on our experience of developing and implementing the NOTSS-VRC program in Rwanda, we recommend teaching NOTSS at the hospital level because that is where health care providers, who were trained in different centers, meet and work. The course can be easily contextualized to address the challenges of the course participants, and the opportunity exists to assess the patient-related impact of the course. Teaching NOTSS should go beyond knowledge transfer in the classroom, simulation center, or online environment to support and provide mentorship to course participants as they implement NTS in the clinical environment. Effective NTS training needs to recognize the barriers and facilitators of skills implementation in clinical practice and help trainees to use facilitators to overcome the challenges. After taking the NTS course in Rwanda, health care providers identified an unpredictable working environment, work overload, hierarchy, and lack of interdisciplinary communication as barriers to behavior change. Most of these barriers can be addressed by the effective implementation of a NOTSS teaching program.<sup>17</sup>

### ■ STRATEGY FOR TEACHING NOTSS

During course preparation, instructors have to understand factors that may affect the ability of translating NOTSS into clinical practice and tailor the course in a way that enables learners to acquire skills necessary to overcome these barriers. For example, they can learn how to communicate with their superiors and improve communication with people from other disciplines, how to prioritize work when they are overloaded, and how to optimize patient care in a variable-resource setting.

Following the course, trainees should develop an action plan or quality improvement projects. Action plans ensure that learners continue to use their new skills and teach them to colleagues,

thereby improving the quality of services at their facilities. Through mentorship, the instructors need to continuously mentor trainees and support them as they implement their quality improvement projects. Mentorship can be delivered through virtual online group discussions as well as onsite visits by the instructors. Follow-up and supportive supervision are key to helping participants apply new skills in real life. The instructors and the participants would have to agree on the frequency of the mentorship meetings, depending on the progress of the participants on their projects and the amount of support they need from the instructors. Using performance standards (harmonized and standardized with training materials) within a post-training follow-up approach or supportive supervision system can also support performance improvement. Following the increased popularity of virtual teaching sessions in the COVID-19 era, refresher courses can be easily organized and thus allow long-term assessment through questionnaires, which will provide evidence on how the skills taught in the course are implemented in the workplace environment and retained by the trainee.

To make an impact on the local surgical training landscape, integration of the NOTSS-VRC course into the university curriculum is desired. Involvement of other partners such as the Ministry of Health, Professional Societies (e.g., surgical, anesthesia, and nurse societies) may allow the implementation of the framework on a national scale and allow for continuous iterative development of the taxonomy to the local needs.<sup>8</sup>

### ■ SCALING UP NTS

Expansion of NOTSS to new geographical areas should be preceded by a contextual and needs assessment to understand the factors that may have an impact on the successful implementation of the course. Findings from this assessment inform the design and delivery of the course. Although Rwanda has many similarities with other LMICs, the steps that we used while developing and implementing a NOTSS training program in Rwanda may not transfer exactly to other LMICs. However, similar processes may be used to identify context-specific factors to facilitate the development and implementation of a NOTSS training program in any country. Future steps include expanding NOTSS to reach the College of Surgeons of East, Central, and Southern Africa, the Pan African Academy for Christian Surgeons, and the West African College of Surgeons surgical training

programs. The COVID-19 pandemic has challenged educators, and technology was leveraged to meet educational needs. From this experience, we anticipate being able to produce online and blended NOTSS courses and reach people from different geographical areas.

## ■ STRATEGIES TO ASSESS THE OUTCOME OF NOTSS EDUCATION PROGRAMS

Similar to other educational programs, NOTSS can be assessed through different levels using the Kirkpatrick model of educational program appraisal.<sup>20</sup> The first level consists of an assessment of course participants' reactions to the course. The second level assesses acquisition of knowledge, skills, and attitudes and involves pre- and posttest evaluations.<sup>20</sup> The third level of this model assesses the behavior change or transfer of learning to the clinical environment. This level can be assessed by direct observation in the clinical environment or by asking participants if they implemented the NTS in a clinical environment. The fourth level assesses the impact of the course on organizational practice and patient outcomes.<sup>20</sup> The majority of the educational program assessments focus on the first 2 levels. Assessment of the higher levels of the Kirkpatrick model is complex because multiple confounding factors may affect the outcomes of interest.<sup>20</sup>

We acknowledge the paucity of data on the impact of NOTSS training programs on behavior change and patient outcomes. Our future NOTSS training programs will be delivered at the institution; we will assess NTS behaviors of participants before and after the course, and collect patient-related metrics before and after implementing the program. This will enable gaining insight into the impact of the NOTSS training program on patient outcomes.

## ■ CONCLUSION

The current paradigm of global surgery emphasizes an equitable increase in access to surgical delivery to counteract the global imbalance that disadvantages the world's impoverished and marginalized populations. Surgeon density and surgical volume are important outcome measurements to assess institutions' efforts to increase surgical care delivery. However, high-quality surgical care is equally important to prevent complications, surgical death, and reputation loss. Safe surgery will ensure that the disease burden of untreated surgical conditions is not exchanged for an epidemic of iatrogenic perioperative complications.

The World Health Organization Safe Surgery Checklist and the NOTSS framework are tools to increase quality and safety in the operating room by improving team performance through encouraging communication and by providing a taxonomy of cognitive and social skills. These tools can be used by global surgery interventions to improve access to safe and affordable surgical care.

NOTSS-VRC developed in Rwanda in 2013 is an educational curriculum implemented as a 1-day course for surgical teams practicing in VRCs that provides a practical guide for NTS. The framework encourages trainees to establish an action plan or a quality improvement project to teach acquired skills to colleagues, thus allowing scale-up of the training program. The outcome of the education program can be assessed using the 4 levels of the Kirkpatrick model. Lessons learned from the implementation in Rwanda include the importance of context-specific adaptation of the framework and inclusion into local institutions to increase long-term success of the program.

The efforts to improve global surgical care have been compromised by the COVID-19 pandemic, which has led to a shift of health care resources towards prevention and management at the cost of surgical care. Similarly, educators have been challenged because didactic or simulation-based training programs were compromised. However, the crisis has paved the way toward online and blended NOTSS courses that are forward-looking teaching modalities to reach people from different geographical areas.

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**During the COVID-19 pandemic, technology was leveraged to meet educational needs, and these lessons may help in offering NOTSS courses to people in different geographical areas.**

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## En français

### Stratégies d'amélioration de la qualité et de la sécurité en santé mondiale: leçons tirées dans le développement et l'exécution d'un programme de formation des compétences non techniques de la chirurgie au Rwanda

**Message clé pour TOC :** Les compétences non techniques pour les chirurgiens (NOTSS) est une taxonomie des compétences cognitives et sociales qui complètent l'expertise et les connaissances médicales dans la salle d'opération. NOTSS peut être utilisé comme une méthode pour améliorer la qualité des soins chirurgicaux dans les efforts mondiaux visant à améliorer l'accès à une chirurgie abordable.

#### Message clé :

- Les efforts visant à accroître l'accès aux soins chirurgicaux ne permettront d'améliorer les résultats de santé que si ces efforts sont étroitement liés aux efforts visant à accroître la sécurité et la qualité de la chirurgie.
- La liste de contrôle de la sécurité chirurgicale de l'Organisation mondiale de la santé et le cadre des compétences non techniques pour les chirurgiens (NOTSS) sont deux outils qui peuvent améliorer la qualité et la sécurité de la chirurgie.
- Le cadre NOTSS pour les contextes de ressources variables est un nouveau cours éducatif d'une seule journée développé au Rwanda qui intègre des comportements et des valeurs contextuellement appropriés et peut être mis en œuvre à faible coût dans n'importe quel contexte de soins de santé.
- Les directeurs de programme doivent fournir une formation sur compétences non techniques spécifique au contexte pour les chirurgiens et le personnel du bloc opératoire.
- Les décideurs devraient mettre en œuvre le programme de compétences non-techniques dans la politique de soins de santé en se concentrant sur les méthodes modernes d'enseignement virtuel.
- Les chirurgiens et le personnel du bloc opératoire doivent se familiariser avec les compétences non-techniques et mettre régulièrement à jour leurs connaissances par le biais de cours didactiques, de simulations et de formations virtuelles.

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ORIGINAL ARTICLE

# Applying Adult Learning Best Practices to Design Immunization Training for Health Care Workers in Ghana

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## Key Findings

- The published literature regarding adult learning and training of trainers provides practical guidance for developing performance-based training of trainers, such as for the Ghana Health Service immunization workforce.
- Training of trainers (TOT), while a common capacity-building strategy, presents several risks that must be carefully mitigated.
- The Ghana 2YL TOT was designed with a systems approach, including audience selection, class activities, evaluation methods, and postworkshop action planning.
- Performance-focused class activities, including practice teaching, increased participants' confidence as technicians and trainers.

## Key Implications

- Program managers should consider the risks involved in TOTs and be prepared to support the cascade with human and financial resources.
- Technical experts can take practical steps to ensure TOTs follow adult learning and TOT best practices.
- TOT designers should include opportunities for practice teaching and feedback to prepare participants for their training role.
- Program managers and designers should develop reporting tools and processes and monitor trainers' field activities.

## ABSTRACT

**Introduction:** A 2016 assessment of frontline health care workers (HCWs) in Ghana identified knowledge, skill, and attitude gaps related to immunization during the second year of life (2YL). The U.S. Centers for Disease Control and Prevention subsequently supported the Ghana Health Service Immunization Program to apply best practices of adult learning and training of trainers (TOT) for a cascade training program for 2YL.

**Methods:** Five districts from each of the 3 regions (Greater Accra, Northern, and Volta) were selected for the TOT based on key measles and rubella vaccination coverage indicators. The design incorporated best practices of adult learning and TOT. The curriculum integrated 3 major topical themes: technical (immunization topics), operational, and training adults. The technical and operational content was based on HCW tasks most directly affecting 2YL objectives. A cross-functional team developed all classroom, field activity, and training evaluation materials.

**Results:** Seventy-four participants attended TOT workshops in 2017. Based on a rubric defined by the course designers, 99% of the participants reported an acceptable level of confidence to apply and teach the course content. After the TOTs, participants conducted 65 workshops, 43 field visits, and 4 review meetings, reaching 1,378 HCWs within 7 months. Fifty-four percent of HCWs who received training from TOT participants reported an acceptable level of confidence in using the skills, and 92% reported they would prioritize applying the skills acquired during the training.

**Discussion:** The success factors for effective adult learning and TOT can be applied to design and implement high-quality TOT even in resource-limited settings. The factors include using a variety of approaches, spending enough class time to prepare TOT participants for their training role, setting specific expectations for cascading the training, and following up through mentorship and reporting. Strong collaboration across the administrative levels of the Ghana Health Service enabled cascade training.

## INTRODUCTION

Since 2006, the Ghana Health Service Expanded Programme on Immunization (GEPI) has sustained coverage levels of at least 85% with the first dose of the measles-containing vaccine (MCV1).<sup>1</sup> In 2012, Ghana introduced the second dose of MCV (MCV2), yet coverage remained well below the intended target, reaching only 63% in 2015.<sup>2</sup> This level is well below the recommended 95% target needed to stop transmission of measles. Additionally, there were gaps in immunization

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**The training of trainers model faces several challenges that dilute its effectiveness.**

**A baseline assessment identified knowledge, skill, and attitude gaps among HCWs in crucial aspects of immunization service delivery for children in their second year of life.**

coverage among districts for other vaccines, with 1 in 5 districts not achieving the goal of >80% coverage with pentavalent vaccine in 2015.<sup>2</sup>

To strengthen country capacity to prevent, detect, and respond to vaccine-preventable disease threats, GEPI, in collaboration with the United States Centers for Disease Control and Prevention (CDC), led an initiative to strengthen the demand and delivery of vaccines, organized under the term “second year of life” (2YL). Three of the 10 administrative regions, Greater Accra, Northern, and Volta, were selected for the interventions because they contained the greatest number of districts with low MCV2 coverage and inequitable access to immunization services.<sup>3</sup>

To understand the underlying causes of performance gaps contributing to low MCV2 coverage, GEPI and CDC surveyed the knowledge, beliefs, and practices of caregivers and health care workers (HCWs) in 2016, and reviewed the availability of resources at the health facility level that support the 18-month routine immunization visit.<sup>3</sup> This baseline assessment identified knowledge, skill, and attitude gaps among HCWs in crucial aspects of immunization service delivery for children in their 2YL, particularly concerning national immunization policies, data recording and reporting, tracking children who did not return for additional vaccinations they were due to receive (known as defaulter tracking), and communicating with caregivers. These findings informed the design, implementation, and evaluation of an array of interventions that CDC supported, such as organizing data improvement teams, conducting social mobilization campaigns, and training staff at the district and health facility level. One training intervention was a 2.5-day pilot workshop for community health nurses and their supervisors in Greater Accra. After positive results from the pilot, GEPI requested CDC assistance in scaling up the training using a training of trainers (TOT) approach.

Also known as cascade training, TOT is an internationally recognized method for training a large cohort of learners who are usually dispersed geographically.<sup>4</sup> TOTs rely on a small group of qualified (“master”) trainers who train a larger group of individuals, who then in turn train others. This process continues until the entire learner population has been reached. TOTs have been shown to be effective in health settings.<sup>5</sup> In low-resource countries, TOTs are generally conducted entirely through traditional face-to-face classroom instruction, as technology constraints limit distance-based modalities. Although a popular method in both the private sector and

public institutions, the TOT model faces several challenges that dilute its effectiveness. For example, studies have indicated several drawbacks to using experts as trainers. Frequently, these individuals are selected based on their technical expertise, a characteristic that does not necessarily translate into an ability to transfer knowledge to novices.<sup>6,7</sup>

Hahn et al.<sup>8</sup> and Orfaly et al.<sup>9</sup> point out additional concerns including fidelity to the content, both in terms of accuracy and in adjusting the emphases of content based on the specific target audience. They also describe a more common challenge centered on follow-through, which is the number of trainers who go on to conduct trainings of their own. Pearce et al.<sup>5</sup> cite turnover of trainers and trainees as threats to long-term impact. In addition, like other workplace learning interventions, factors such as motivation, supervisor support, and triggered action planning can affect whether the trainers apply their new skills.<sup>10</sup> Finally, it is often challenging to design and implement a valid evaluation method. A key question is whether TOT success should be measured based on the number of trainers trained, the trainers’ self-assessment of confidence as a trainer, or the improved proficiency or behaviors by the learners at the lowest level of the training chain. Still, as Hayes<sup>11</sup> points out, it may not be the TOT model itself that is the problem, but the way it is implemented. Hayes<sup>11</sup> has proposed 5 critical success factors for TOT in the educational setting that hold promise as a best practice in the public health environment:

1. The method of conducting the training must be experiential and reflective rather than transmissive (i.e., one-directional, such as lectures).
2. The training content and delivery method must be open to reinterpretation rather than prescribe a rigid adherence to a predefined method (i.e., should be sensitive to the local context, while maintaining fidelity to the intent of the content).
3. Expertise must be diffused through the system as widely as possible.
4. Decentralization of responsibilities within the cascade structure is desirable.
5. A cross-section of stakeholders must be involved in the preparation of training materials.

These practices harmonize and overlap with the body of knowledge related to adult learning, as described by andragogy scholars such as Knowles et

**TABLE 1.** Ghana Training of Trainer Workshop Topics To Improve Competency in Primary Second Year of Life Vaccination Services

Technical Topics	Operational Topics	Adult Learning
Regional EPI performance EPI policies 2YL project Measles immunogenicity Monitoring data for action Monthly reporting Data analysis Defaulter tracking Communicating with caregivers	Problem analysis and prioritization Process analysis and improvement Best practices of supportive supervision	Characteristics of adult learners Five moments of learning need Classroom delivery techniques Managing the classroom Choosing the best learning strategy: classroom, small groups, one-on-one Developing training action plans

Abbreviations: 2YL, second year of life; EPI, Expanded Programme on Immunization; TOT, training of trainers.

al.<sup>12</sup> and Dirksen.<sup>13</sup> Specifically, Knowles et al.<sup>12</sup> proposed 4 principles to apply to adult learning:

1. Adults want to know why they need to learn something.
2. Adults need to learn experientially, based on tasks not theories.
3. Adults approach learning as problem solving or to accomplish a specific goal.
4. Adults learn best when the topic is of immediate value.

This article describes our experience incorporating adult learning best practices and the recommendations of Hayes<sup>11</sup> into the design and delivery of the TOT intervention for Ghana 2YL and proposes their application in public health workforce development.

## METHODS

The 2 objectives of the TOT were to improve the competency of district health management teams (DHMTs) regarding primary 2YL vaccination services and to improve their capacity as trainers. The training interventions were implemented in all 3 2YL regions: Greater Accra, Northern, and Volta.<sup>3</sup> The target audience included staff at the regional and district levels who were already responsible for providing supportive supervision at the immediate lower level. Five districts from each region were purposively selected to include 2 high-performing districts and 3 low-performing districts based on their MCV2 vaccine coverage, drop-out rates between MCV1 and MCV2, and other Expanded Programme on Immunization (EPI) performance indicators. In each selected district, participants included the regional health management team (RHMT) and approximately 4 DHMT members. Participants worked as a group with their district throughout the workshop.

## TOT Curriculum Design

To achieve the workshop objectives, the curriculum was designed to integrate 3 major themes: technical, operational, and training adults. Training materials were developed by a cross-functional team composed of GHS and CDC staff with expertise in national immunization policy, immunization practices, and adult learning. The technical and operational content was based on the knowledge, skill, and attitude gaps identified by the baseline assessment and is summarized in Table 1.

The 5-day workshop included 2.5 days of technical content, such as GEPI 2YL policy and data analysis, and operational content, such as problem analysis and interpersonal skills. The remaining workshop time was dedicated to strengthening participants' ability and confidence to plan and deliver training to HCWs in their districts. After each workshop, the team made changes to the materials, schedule, or tools to improve and localize subsequent workshops.

## Application of TOT Best Practices

The curriculum design was guided by a fundamental principle for adult learning: workplace training should be learner focused and performance based.<sup>14</sup> Thus, all technical and operational content was developed and organized based on specific immunization tasks, using participants' own data as much as possible. Hayes' 5 success factors<sup>11</sup> were integrated into the design and used as a quality check.

## Experiential and Reflective Learning

Adhering to both andragogy principles of Knowles et al.<sup>12</sup> and recommendations of Hayes<sup>11</sup>, the sessions were highly interactive and used the participants' local context and local immunization data. The workshop introduced practical aspects of

**The TOT was intended to improve competency of DHMTs regarding primary 2YL vaccination services and to improve their capacity as trainers.**

**The curriculum design was guided by a fundamental principle for adult learning: workplace training should be learner focused and performance based.**

adult learning to help the trainers plan and deliver the 2YL training themselves. Participants were introduced to the 5 moments of learning need, an adult learning model that helps trainers determine what types of content should be taught in a formal setting and what types of content can be learned informally using job aids or coaching.<sup>15</sup> This model also reinforces the importance of on-the-job coaching as a factor to encourage learning application. A master trainer conducted review sessions at the end of each day, to review not only the technical content but also the teaching methods. For example, the master trainer led discussions to help participants determine the best training delivery method: workshop, coaching during a health facility visit, or small group review meetings. These daily sessions enabled participants to reflect on what they learned and how they would diffuse the information.

### Open to Reinterpretation

The organizers wanted to balance flexibility while promoting content fidelity. Therefore, the training materials for each topic included formal presentations with speaker notes, exercises with answer keys, and a facilitator's guide. In-class discussions and activities helped participants consider how to localize the content. A detailed lesson plan for the TOT component of the workshop, as well as examples of participant materials, is available in a Supplement.

Teachback was a key activity to support these principles. Participants formed teams of 2 and chose a 20-minute lesson from the 2YL curriculum. They were given electronic versions of all training materials to prepare for their teachback lesson. They were encouraged to customize their lesson while adhering to the lesson's learning objective(s). The master trainers completed a feedback worksheet as they observed the lessons. The participants also received written feedback from their peers immediately after they taught their lesson. Finally, participants applied what they had learned and their knowledge of their district to develop a preliminary training plan, mapping out the number, location, and timeframe of site visits and workshops they expected to deliver.

### Diffusion of Expertise and Decentralization of Responsibilities

Addressing 2 of Hayes' 5 factors,<sup>11</sup> the design also included components to support the participants after the training as they implemented their plans in the 3 regions. In addition to obtaining electronic

versions of all materials, they were mentored by national and regional staff. The participants were encouraged to assess knowledge and skill gaps of the HCWs in their jurisdiction. Their assessment results could help the participants deliver the appropriate content and delivery method and monitor results. Application of operational topics could come in the form of teaching others or applying what they learned to the way they do their work, such as using the lesson *Best practices of supportive supervision* to improve one's own supervision practices. GEPI instituted a requirement for DHMTs to submit field activity reports specific to this initiative to the higher levels.

### Cross-Section of Stakeholders

The cross-functional team that developed the content also served as master trainers and modeled adult learning best practices when leading the classroom sessions. In addition, RHMTs facilitated the classroom activities to provide local context and joined the national-level staff as mentors for the post-classroom field activities. Table 2 summarizes the program design as it relates to the key practices of effective adult learning and to Hayes'<sup>11</sup> recommendations.

### Monitoring and Evaluation Methods

Seven methods were used to monitor and evaluate the intervention, either during the workshop, at the end of the workshop, or after the workshop. The evaluation methods were intended to capture if and how the TOT affected the participants, as well as if and how the trainers applied what they learned. Funding was provided to allow master trainers to conduct mentoring visits. In addition, the project budgeted for an impact evaluation that would be conducted after the end of the entire 2YL initiative. Data were collected at 3 key points: at the end of the TOT workshop, via field activity reports submitted by the trainers for the duration of their training activities, and via surveys of the HCWs after they were trained by DHMTs. Table 3 summarizes the intervention's monitoring and evaluation methods and the objective(s) that each addressed. A more detailed description follows.

### During the Workshop

Technical exercises and the teachback were used to evaluate participants' learning. A daily "temperature check" at day's end consisted of plenary discussions to get real-time feedback about how each day went and obtain suggestions for the

**Participants had an immediate opportunity to practice teaching the content and to plan how they would deliver the training to others.**

**TABLE 2.** Summary of Adoption of Adult Learning and Training of Trainers Best Practices

Best Practice	Application for Ghana TOT
Adult learning	
Adults want to know why they need to learn something.	<ul style="list-style-type: none"> <li>• Lessons on foundations of adult learning, to help participants understand the strategies behind the curriculum design</li> <li>• Practical, performance-based content for technical, operational, and adult-learning topics</li> </ul>
Adults need to learn experientially.	<ul style="list-style-type: none"> <li>• Interactive small group work</li> <li>• Activities to apply knowledge</li> <li>• Minimal theoretical lectures</li> </ul>
Adults approach learning as problem solving.	<ul style="list-style-type: none"> <li>• Daily sessions to review content from the trainer’s point of view, such as tips for explaining confusing content</li> <li>• Scenario-based exercises and role plays</li> </ul>
Adults learn best when the topic is of immediate value.	<ul style="list-style-type: none"> <li>• Use of local examples and data</li> <li>• Action planning: developing field training plans</li> <li>• <i>Handling challenging situations</i> handout to support trainers when managing problem participants</li> </ul>
TOT	
Method of training must be experiential and reflective	<ul style="list-style-type: none"> <li>• Interactive sessions, simulating the work environment</li> <li>• Teachback sessions to provide the opportunity to practice teaching in a safe-fail environment and receive constructive feedback from master trainers and peers</li> <li>• Participant individual development plans, to self-reflect and develop a plan to improve their teaching skills</li> <li>• Multiple training events at the health facility level, which reinforced training skills while diffusing the knowledge</li> </ul>
Training content and delivery method must be open to reinterpretation	<ul style="list-style-type: none"> <li>• Participant and instructor training materials provided in easily editable format, while at the same time adhering to national immunization policy standards</li> <li>• Class discussions to identify ways to localize content</li> <li>• Guidelines to help trainers choose best training delivery strategy</li> </ul>
Expertise must be diffused through the system	<ul style="list-style-type: none"> <li>• Peer and mentor feedback during and after the workshop</li> <li>• Participant action plans for delivery to health facility level</li> <li>• National, regional, and district-level supervision and mentoring</li> <li>• Accountability to next level of the system via field reports</li> </ul>
Involve a cross-section of stakeholders	<ul style="list-style-type: none"> <li>• Cross-sectional team for content development and planning</li> <li>• Multiple levels of Ghana Expanded Programme on Immunization for implementation</li> </ul>
Decentralize responsibilities within the cascade structure	<ul style="list-style-type: none"> <li>• Responsibilities diffused as TOT was rolled out; ultimate responsibility was at the district level</li> <li>• Periodic and on-demand support from national and regional Expanded Programme on Immunization experts</li> <li>• Distance-based support by adult learning expert</li> </ul>

Abbreviation: TOT, training of trainers.

subsequent day. The master trainers conducted daily debriefings to incorporate the suggestions.

**End of Workshop**

The purpose of the end of workshop evaluations was to capture lesson usefulness and workshop quality. We used Thalheimer’s<sup>16</sup> method of

performance-focused surveys to evaluate workshop quality because it aims to avoid positive bias and measurements that are statistically invalid. This method has participants respond to a series of statements and interprets the quality of training based on a rubric developed by the design team that ranks the acceptability of each statement. Table 4 provides a sample question using the

**TABLE 3.** Summary of Ghana Second Year of Life Immunization Training of Trainers Monitoring and Evaluation Methods

Intervention Phase	Method	Description	Training Objective
During the workshop	Technical exercises	Exercises using local data to practice new skills and evaluate learning. Facilitators and peers provided feedback.	2YL vaccination services competency
	End of day temperature check	Informal focus group to understand participants’ concerns and adjust for the following day	2YL vaccination services competency
	Teachback feedback	To evaluate learning and give trainers constructive feedback about their training delivery skills	Capacity as a trainer
End of workshop	End of workshop data collection	Activities to collect opinions on training effectiveness and usefulness	2YL vaccination services competency Capacity as a trainer
After workshop, field activities	Activity reporting tool	Electronic survey measuring frequency and process indicators (where, what, who, when) by recording activities that happened at the subdistrict level	Capacity as a trainer
	Field activity reports	Reports submitted from DHMTs following their workforce development intervention at the subdistrict level	Capacity as a trainer
After workshop, evaluation of impact	Health care worker assessment of DHMT trainers (part of the postsurvey)	Survey investigating the value added from the TOT: How did health facility workers perceive the quality of the training they received?	Capacity as a trainer

Abbreviations: 2YL, second year of life; DHMT, district health management team; TOT, training of trainer.

**TABLE 4.** Sample Question From the Training of Trainers Immunization Workshop Evaluation in Ghana

In regard to the technical topics taught, select the SINGLE answer that best describes what the workshop enabled you to do, if anything.	Ranking Standard
It DID NOT enable me to UNDERSTAND NEW CONCEPTS or USE NEW SKILLS.	Unacceptable
It enabled me to UNDERSTAND SOME NEW CONCEPTS but did NOT PREPARE ME TO USE NEW SKILLS on the job.	Unacceptable
It enabled me to BEGIN TRYING NEW SKILLS on the job.	Acceptable
It enabled me to CONFIDENTLY USE NEW SKILLS on the job.	Superior
It enabled me to BE THOROUGHLY CONFIDENT AND PRACTICED IN USING NEW SKILLS on the job.	Superior/Unlikely

Thalheimer method and includes the acceptability rubric that the team defined. Among other reactions, the survey reported participants’ confidence after the workshop from 2 perspectives: their ability to apply what they learned in their workplace and their ability to teach others.

**After the Workshop: Field Reporting**

After each 2YL training activity, DHMTs used *Open Data Kit (ODK)*<sup>17</sup> (<https://getodk.org>) software on tablets to report quantitative and qualitative data such as type of training (e.g., workshops, on-the-job training) and when and where trainings

occurred. Content was uploaded to a secure cloud server using a mobile data collection platform. They also included their 2YL training activities in the field reports that they were already providing regularly. These written reports enabled the trainers to reflect on their experiences while providing accountability to the higher levels.

**After the Workshop: Evaluation of Impact as a Trainer**

*Impact* for a TOT is defined as the ability of the new trainers to effectively deliver knowledge and skills.

Pre- and post-competency assessments were conducted at the health facility level among a systematic random sample of HCWs. As part of the post-assessments, HCWs responded to 7 statements about the quality of the training they received. To define “quality training,” the HCWs were asked questions related to trainers’ subject matter expertise and trustworthiness, the 2 factors that define a “good” trainer.<sup>16</sup> We present the HCW assessment on the quality of the training, while data on change in HCW competencies are presented by Tchoualeu et al.<sup>18</sup>

## ■ RESULTS

### TOT Participant Characteristics

From July to September 2017, 3 TOT workshops were held: Greater Accra (24 participants), Northern Region (28 participants), and Volta Region (22 participants). Participants included 4 or 5 health managers from each DHMT, the RHMT, and 2 DHMT members from the next planned TOT location (e.g., 2 district managers from Volta attended the Accra workshop and thus took an active role in the subsequent Volta workshop).

### During the Workshop

Participants worked as district teams throughout the workshop, with multiple opportunities for small-group work as well as plenary discussions. Pairs of participants selected their teachback topic and were coached by the master trainers as they prepared their lessons. In addition to suggestions documented on the teachback feedback sheets, teachback debriefs enabled participants to discuss the training techniques they observed from their peers and share how they would apply them in their own trainings. Participants reported appreciating obtaining specific suggestions from the master trainers as well as from their peers.

### End of Workshop

Of the 74 workshop participants, 68 (92%) completed the workshop evaluation survey, responding to 4 questions. Table 5 summarizes the survey responses and shows that participants’ confidence ranged from “able to begin” applying what they learned to “fully confident” in applying both the technical and the training content. Of these 68, 67 (99%) reported a level of confidence that was deemed acceptable or better by the rubric. Fifty-six of 68 responses (82%) related to learning engagement fell into the acceptable range. For the

question related to opportunities for practice, participants were invited to agree with multiple statements, 80% of which fell into the acceptable range. Ten responses were unacceptable, and the statement, “I was given too much practice,” defined in the rubric as a red flag, meaning it would require further investigation, received 11 (16%) responses. For the unacceptable and red flag responses, further investigation was done by inspecting the comments sections of the surveys and by interviewing the workshop facilitators. Based on the feedback, the team improved the materials and/or the workshop schedule.

### After the Workshop: Field Activities

Using the reporting tool, field activities were reported between November 2017 and June 2018. All 5 districts in Greater Accra and 3 of 5 districts each in Northern and Volta Regions submitted reports, reporting a total of 112 activities across the 3 regions.<sup>18</sup> Most reported that they had conducted workshops (n=65), followed by health facility visits (n=43). Very few reported that they had conducted review meetings (n=4). The TOT participants reported training a total of 1,378 HCWs (Greater Accra=440, Volta=405, Northern=533). Northern Region submitted the greatest number of activity reports (n=60), followed by Volta Region (n=30) and Greater Accra (n=22). DHMTs also reported the topics they taught. The Figure provides a summary of all training activities by region.

### After the Workshop: Evaluation of Impact as a Trainer

In addition to being assessed for knowledge, skill, and attitude, 575 HCWs were surveyed about the training usefulness and facilitator presentation skills: 90 in Greater Accra (Adenta district), 54 in Northern (Tamale Metro), and 431 in Volta (all 5 districts).<sup>17</sup> Related to increased aptitude, 54% of all respondents reported confidence in using the new skills, with 45% reporting the ability to *begin to try* the new skills. Moreover, 92% of all respondents reported that they would make it a high priority to use their new skills, and 81% reported that the concepts will “help me significantly to improve my work outcomes.” As defined by the analysis rubric agreed upon by the stakeholders, only 1 question received any unacceptable response: 2% of respondents reported that the content would “Will help me *slightly* to improve my work outcomes.” Regarding their experience with the instructors, a question that

**TABLE 5.** Summary of Ghana Expanded Programme on Immunization Training of Trainers Workshop Evaluation (n=68)

	Survey Statement	Rubric Ranking Standard	Percentage of Total Responses, All Regions
Technical content confidence	It did not enable me to understand new concepts or use new skills.	Unacceptable	1
	It enabled me to begin trying new skills on the job.	Acceptable	10
	It enabled me to confidently use new skills on the job.	Superior	35
	It enabled me to be thoroughly confident and practiced in using new skills on the job.	Superior/Unlikely	68
Teaching/mentoring confidence	I am generally comfortable with the concepts taught, but I will need more training/practice to be able to teach or mentor others.	Acceptable	6
	I am able to teach others, but I'll need more hands-on experience to be fully competent as an instructor.	Acceptable	25
	I am able to teach or mentor others at a fully competent level about the concepts taught.	Superior/Unlikely	66
	I am able to teach or mentor others at an expert level about the concepts taught.	Superior/Unlikely	6
Engaged in the learning	I felt completely uninterested.	Unacceptable	4
	I was often uninterested.	Unacceptable	3
	I was often interested, but sometimes not.	Unacceptable	10
	I was almost always interested.	Acceptable	82
Opportunities to practice	I was given almost no practice.	Unacceptable	1
	I was given inadequate amounts of practice.	Unacceptable	12
	I was given too much practice.	Red Flag	16
	I was often asked to practice something right after we learned it.	Acceptable	53
	I did not get enough helpful feedback when we were practicing.	Unacceptable	1
	I generally received sufficient and helpful feedback after we practiced a task.	Acceptable	71

allowed for multiple responses, all responses fell within the rubric’s definition of acceptable. Of the 575 responses, 300 (52%) reported the instructor “demonstrated a high level of real-world experience,” 162 (28%) reported the instructor “showed deep subject matter expertise,” 377 (66%) reported “I was often asked to practice something right after we learned it,” and 237 (41%) reported, “I generally received sufficient and helpful feedback after we practiced a task.” No unacceptable responses (e.g., “I was given inadequate amounts of practice”) were reported.

**DISCUSSION**

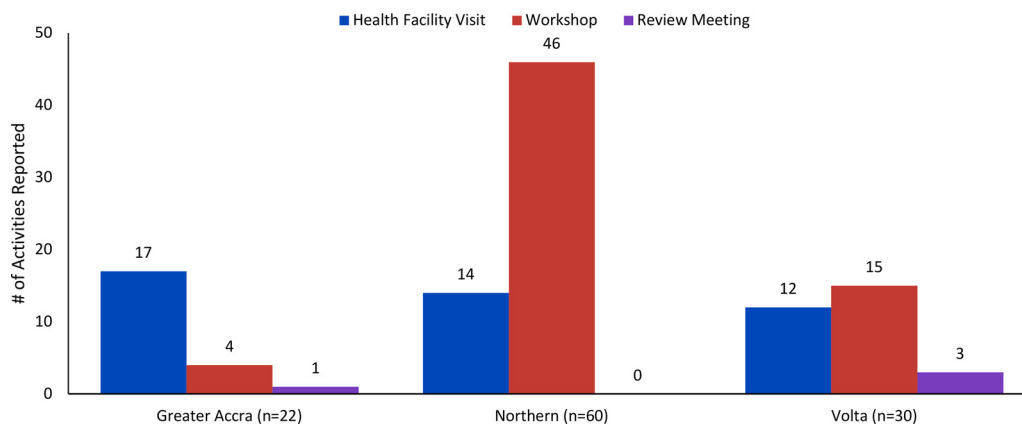
The 2YL baseline health facility survey results enabled us to design the TOT intervention based on representative data, not on the speculation of stakeholders.<sup>3</sup> This information allowed us to address specific 2YL knowledge and practice gaps,

such as communicating with caregivers. Integrating operational skill building in the context of completing technical tasks, rather than developing a separate “management” curriculum, recognized that staff could require both types of skills to complete a single task, such as improving defaulter tracking. Devoting half of the class time to practical components of adult learning theory, enabling them to practice-teach in a supportive environment, and setting clear expectations of the new trainers helped prepare the participants in a very practical way. Hayes’ success factors<sup>11</sup> were a useful check during the training development process.

Most TOT participants reported increased confidence in applying and teaching the technical content, yet this finding is tempered by studies that have shown workers regularly overestimate their ability.<sup>19</sup> This phenomenon could explain the notable percentage of responses that our rubric deemed superior/unlikely. Because of the

**The 2YL baseline health facility survey results enabled us to design the TOT intervention based on real-world representative data.**

**FIGURE.** Summary of 112 Reported Training Activities in Greater Accra, Northern, and Volta Regions by Region and Method, in Ghana 2017



complex nature of the content and our inclusion of mentorship as a component of the intervention, the TOT rubric defined as acceptable if the participants felt less than fully confident at the end of the workshop. Regarding learning engagement, it is important to note that while most participants’ responses were categorized as acceptable by our rubric, the small proportion who reported that they were “often interested but sometimes not” were deemed unacceptable. It may be reasonable to expect adult learners to experience occasional disengagement, and thus care should be taken by training designers when defining their rubrics. We leave it to the reader to determine if it is reasonable to expect that learners will occasionally “tune out.” Finally, we were concerned with the number of unacceptable and red flag responses related to opportunities to practice. These responses were discussed with regional and national leaders in Ghana. The leaders were pleased with the interactivity and requested no major changes to the workshop design.

Regarding the evaluation methods, we found Thalheimer’s<sup>10</sup> performance-focused survey method more actionable than traditional Likert scale workshop satisfaction surveys, as it not only reduces ambiguity for the participant, but it forces the training designer and stakeholders to think more specifically about the performance improvement they expect from the training. The “most useful lesson” group activity was helpful: in addition to providing the master trainers with timely and detailed feedback, the activity provided an interactive means for participants to review the workshop lessons and envision themselves applying what they learned.

Regarding the field activities, although the trainers chose workshops as their primary training method, it was encouraging to see that it was possible for them to teach the 2YL content using small-group meetings at the health facility or one-on-one coaching, both of which occur on the job with minimal disruption to the workflow. The master trainers who observed the DHMT-led workshops noticed a high degree of comfort with the technical content as well as the application of the adult learning principles that were stressed in the workshops. Through the field activity reports, we were able to partially track the follow-through that Hahn et al.<sup>8</sup> and Orfaly et al.<sup>9</sup> recommended.

Based on the participants’ self-reported technical and training confidence, their action plans, and their field reports, the stakeholders considered the TOT a success. The cross-functional team, composed of technical EPI and workforce development experts, supported an intervention that was technically accurate and practical to deploy in Ghana’s setting. Yet none of these factors were as influential as the posttraining actions in the 3 regions: the regional and district teams were open to taking the time to learn new ways of doing their own work and training others in a purposeful way.

We appreciate that all these practices may not be possible in low-resource settings. Still, Pearce et al.<sup>5</sup> suggested that a combination of teaching techniques can help to effectively disseminate content to health workers. We propose, then, that the following combination of factors can support an effective TOT:

**Based on the participants’ self-reported technical and training confidence, their action plans, and their field reports, the TOT was considered a success.**



- Use learning science to inform analysis, design, delivery, and evaluation of the intervention.
- Define specific performance gaps and expected behavior change to inform the content and learning activities.
- Use a variety of components such as those described in Table 2 to build capacity as trainers.
- Spend enough class time to prepare participants for their training role.
- Ensure that the technical content is practical (i.e., activity based) and not just a review of theories or policies.
- Provide instructor materials such as lesson outlines that sketch out how to conduct the lesson.
- Use performance-focused evaluation methods such as Thalheimer's<sup>10</sup> to add rigor to the workshop evaluations.
- Give the trainers specific tasks and expectations, then monitor their field activities.
- Budget for trainer field support and postintervention evaluation.
- Engage regional and local support for the trainers.

### Limitations

With the availability of technology and acceptance of text messaging platforms in even the most remote areas, we think that we could have integrated technology into the design to a greater extent: peer networks and electronic checklists could provide valuable performance support.

Since field activities were reported at the district level without direct oversight of the project team, we were unable to calculate the number of TOT participants who went on to teach. The lack of resources for a field monitoring team also prevented us from conducting a more rigorous evaluation of the participants' impact as a trainer, and we were only able to rely on the learners' perceptions. Additionally, the complete absence of reporting for 2 of the 5 districts in both Northern and Volta regions demonstrates that we cannot know how many activities did occur that were simply not reported. In future efforts, we will engage the trainers earlier in the project to determine a more realistic means for collecting data. We are concerned about sustainability and are looking forward to learning if and how TOT practices continue if external funding and technical support are absent. We also await the findings of the end-of-project evaluation to see if and how performance at the health facility level has improved.

### CONCLUSIONS

Our experience demonstrates how the best practices of adult learning and TOT can support performance-focused training that is applied on the job, although the specifics of the Ghana 2YL initiative should be adapted for local circumstances. We hope the description of methods and tools is specific enough that readers can adapt them for their context. We also believe our findings reinforce the importance of conducting a performance-based baseline assessment and for budgeting resources to enable rigorous monitoring and evaluation. Finally, regardless of the circumstances, strong collaboration and a united purpose such as that demonstrated by the Ghanaian EPI staff at the national, regional, district, and health facility levels created an environment that supported the 2YL TOT.

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ORIGINAL ARTICLE

# Evaluation of the Impact of Immunization Second Year of Life Training Interventions on Health Care Workers in Ghana

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## Key Findings

- After implementing the immunization Second Year of Life capacity-building interventions, quantitative and qualitative data showed that health care workers (HCWs) reported a modest improvement in knowledge, attitudes, and practices in 3 performance problem areas: lack of knowledge on EPI policy; inconsistent data management, quality, and use; and weak communication about vaccination with caregivers.
- Trainers in district health management teams used a variety of teaching methods and delivery techniques to facilitate HCWs' learning and help minimize their forgetting curve.

## Key Implications

- National and subnational leaders should take ownership of the capacity-building needs of their immunization workers and leverage existing mechanisms, such as new hire orientation, supportive supervision visits, and monthly data review meetings to empower their health care workers to perform EPI tasks more proficiently.
- Countries should value budgeting for capacity building of their immunization workforce and for behavior change evaluation to ensure an accurate understanding of capacity-building impact.
- Stakeholders should define their expectations of specific tangible outputs from training that link to a measurable performance objective, instead of broad “refresher” training.

## ABSTRACT

**Introduction:** As part of a suite of training interventions to improve the knowledge and practice of immunization in the second year of life (2YL), training of trainers workshops were conducted with regional and district health management teams (DHMTs) in 15 districts in 3 regions of Ghana. Using adult learning principles, DHMTs implemented several capacity-building activities at the subdistrict and health facility levels, including health facility visits, on-the-job training, and review meetings. The current evaluation investigated whether frontline health care workers (HCWs) reported or demonstrated improvements in knowledge, attitudes, and practices after training interventions.

**Methods:** Quantitative and qualitative methods with a utilization-focused approach guided the framework for this evaluation. A systematic random sample of 115 HCWs in 3 regions of Ghana was selected to complete a competency survey before and after training, which focused on 3 core competency areas—Expanded Programme on Immunization (EPI) policy; communication with caregivers; and immunization data management, recording, and use. Interviews and direct observations by data collectors were done to assess HCWs' knowledge, self-reported attitude, and behavior changes in practices.

**Results:** Of 115 HCWs, 102 were surveyed before and 4 months after receiving capacity-building interventions. Modest but not statistically significant improvements were found in knowledge on EPI policy, immunization data management, and communication skills with caregivers. HCWs reported that they had improved several attitudes and practices after the 2YL training. The most improved practice reported by HCWs and observed in all 3 regions was the creation of a defaulter list.

**Discussion:** Findings of this evaluation provide encouraging evidence in taking the first step toward improving HCW knowledge, attitudes, and practices for 3 core immunization competency areas. The use of learner-focused teaching methods combined with adult learning principles is helpful in solving specific performance problems (such as lack of knowledge of EPI policy).

## INTRODUCTION

The Second Year of Life (2YL) platform promotes vaccinating children aged 12 to 24 months and beyond with recommended vaccines to reduce morbidity and mortality from vaccine-preventable diseases by increasing population immunity during childhood and contributes to disease control and elimination goals.<sup>1,2</sup> The 2YL vaccination platform can serve as a catch-up opportunity for children who have missed vaccine doses

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during the first year of life and enables the administration of booster doses and underutilized or newly introduced vaccines given during 2YL.<sup>2</sup> It can also facilitate health system strengthening via integration of immunization services with other preventative health interventions and programs (e.g., deworming, growth monitoring, and bed net distribution) during the post-infancy period.

The World Health Organization (WHO) recommends a second dose of measles-containing vaccine (MCV2) in the second year of life.<sup>3</sup> WHO's Global Measles and Rubella Strategic Plan 2012–2020 set a milestone of attaining 95% coverage by 2020.<sup>4</sup> High MCV2 coverage is essential to achieving herd immunity within a country and achieving global measles elimination goals. Ghana introduced MCV2 at the 18-month child wellness visit in 2012 as part of their national immunization schedule. During the same year, Ghana also added 2 new vaccines to be given during the first year of life, 2 doses of rotavirus vaccine (6 and 10 weeks) and 3 doses of pneumococcal conjugate vaccine (PCV) at 6, 10, and 14 weeks.<sup>5,6</sup> In 2015, 3 years after introduction, MCV2 coverage was just 63%, while coverage with the last doses of PCV and rotavirus vaccine had reached 88%.<sup>5</sup> The United States Centers for Disease Control and Prevention (CDC) collaborated with Ghana Health Service (GHS) in 2015 to implement multifaceted 2YL interventions. Ghana was selected because of its leadership in the African region in expanding routine vaccination to the 2YL, its low MCV2 coverage and variation in immunization coverage across districts, and its plan to introduce meningococcal A conjugate vaccine (Men A) in 2016. Ghana was the first country in the African region to provide this vaccine during 2YL in the routine immunization schedule.

In mid-2016, CDC and GHS conducted baseline health facility and household surveys in 3 underperforming regions of the country to understand factors associated with poor MCV2 coverage.<sup>5</sup> Survey results indicated that a 9-year absence of EPI staff training, inconsistent supportive supervision and defaulter tracing, weak communication between health care workers (HCWs) and caregivers, and poor documentation of data contributed to the low MCV2 coverage. Additionally, findings revealed coverage inequities across the population for a variety of antigens among districts in the regions surveyed.

Based on the 2016 survey results, CDC recommended that GHS implement various practical strategies (e.g., improving the number, content, and quality of supportive supervision visits, on-

the-job training at health facility level) to improve program performance at subdistricts and health facilities in these underperforming regions. GHS requested CDC to provide technical and financial support on 3 training of trainers (TOTs) workshops for district health management teams (DHMTs). Both institutions worked closely to design, implement, and evaluate these interventions. (Details of these TOTs are provided in the Methods section.) Trained DHMTs then implemented a variety of capacity-building interventions to transfer knowledge and skills related to 2YL immunization to frontline HCWs during the same year. This article describes an evaluation conducted to answer 2 questions:

1. Did frontline HCWs' knowledge of EPI policy, immunization data management and use, and communication with caregivers increase after the DHMTs' interventions?
2. How did frontline HCWs' attitudes and practices regarding 2YL vaccination change after receiving the DHMTs' capacity-building interventions?

## METHODS

### Intervention Overview

GHS and CDC conducted TOT workshops from July through September 2017 in 3 of the most underperforming regions with respect to low MCV2 coverage: Greater Accra Region (GAR), Volta Region, and Northern Region (NR). The TOTs targeted regional health management teams (RHMT) and DHMTs in a total of 15 districts—2 high-performing and 3 low-performing teams per region, based on selected EPI indicators (i.e., coverage of third dose of pentavalent vaccine [Penta 3], first dose of measles and rubella vaccine [MR1], and second dose of measles and rubella vaccine [MR2], and dropout rates). Thirteen of the 15 districts were urban, and the other 2 were both urban and metropolitan (1 in GAR and 1 in NR). In total, the TOTs trained 74 health professionals—24 in GAR, 22 in Volta, and 28 in NR.

The objectives of the TOTs were to improve knowledge and skills at the district and regional levels related to immunization for children in their 2YL and to strengthen participants' ability to train the frontline HCWs in their districts. As described by Traicoff et al.,<sup>7</sup> these TOTs covered adult learning principles (including classroom management), technical (e.g., EPI policies, measles immunogenicity, defaulter tracing), and operational (e.g., best practices of supportive supervision, problem

**In mid-2016, CDC and GHS conducted baseline health facility and household surveys to understand factors associated with poor MCV2 coverage.**

analysis, and prioritization) topics. The authors described in detail the TOTs curriculum design and the activities conducted during and after implementation of the TOTs. DHMTs also received specific guidance on how to effectively plan, implement, and evaluate capacity-building interventions. DHMTs in turn were instructed to transfer their skills and knowledge to frontline HCWs at the subdistrict and health facility levels by implementing several capacity-building interventions, including workshops, health facility visits, on-the-job training, and review meetings. The RHMTs were expected to provide leadership oversight, technical guidance, and support to the DHMTs during the implementation of these interventions.

### Evaluation Approach

Patton's<sup>8</sup> utilization-focused evaluation approach was applied to maximize the use of evaluation findings for improving workforce performance. This evaluation method uses a participatory approach through which evaluators and intended users come together to design and implement the evaluation, analyze the data, and collaboratively review the results to increase the utilization of the findings to improve performance. GHS and CDC staff co-designed an evaluation, met after piloting to rework the data collection tools, and reviewed the results in a moderated discussion. The quantitative component of the evaluation consisted of a survey to assess knowledge of frontline HCWs before and after capacity-building interventions. This component also included a DHMT activity tool to document the scope of their field activities and specific methods/strategies used to deliver the interventions. The competency scaling was developed based on the National Institutes of Health's Proficiency Scale and adjusted to meet the expected competencies of the HCWs within the 3 main training topics (EPI policies, data management, and communication).<sup>9</sup> The qualitative components consisted of interviews with HCWs (i.e., subdistrict/health facility level immunization staff) and participant observations to understand their self-reported behavior changes and to receive feedback on the quality and delivery of the interventions.

### Sample

For each of the 3 participating regions in this evaluation, the total number of targeted frontline HCWs who required interventions varied based on several characteristics as defined by the

DHMTs—length of time working in health care, age, location, and the likelihood of continued years in health care. To be eligible for both intervention and evaluation, HCWs had to be working in 1 of the 15 districts that hosted the TOT workshops. In addition, they had to either be (1) subdistrict HCWs working on immunization services 5 years or less, or (2) newly hired HCWs (in the last 5 years) who did not receive a new hire orientation on immunization services. HCWs planning to retire within the next 5 years were excluded. Based on these criteria, 1,310 HCWs were eligible for training (GAR, 513; Volta, 336; NR, 461) in 15 districts within the 3 regions. Study investigators consulted with a statistician to construct a sample frame from the number of eligible participants. A systematic random sample of 7 HCWs for each of the 15 participating districts was selected from the list of eligible participants, except for in Accra Metro Sub-Metro (equivalent to a district) in GAR. An additional 10 HCWs were added to the GAR sample to account for the much larger number of health facilities in the Accra Metro Sub-Metro areas compared with the other subdistricts. Therefore, 17 HCWs were selected for this district, for a total of 115 HCWs across all 3 regions.

### Data Collection Instruments

A simple DHMT activity report in ODK was developed for the project and was used by the district staff to report for each HCW capacity-building field activity in their respective region, the specific methods/strategies used to facilitate learning, and the topics they taught during each session. The DHMTs submitted this report every time they conducted training or shared knowledge on the 3 core competencies that were covered during the TOT.

We designed a progress analysis survey (PAS) that included quantitative and qualitative closed and open-ended questions aimed at answering the 2 evaluation questions. The questions were designed based on the training curriculum used in the TOT workshops (which was expected to then be adapted for the post-TOT HCW interventions). The PAS included core competencies questions, basic demographic information (age, sex, years in service, and job title), and the date and format of the last 2YL intervention they had received. The questions focused on 3 core competency areas of the TOT curriculum.

- EPI policy: Standard operating procedures around routine and catch-up vaccination, simultaneous injections (i.e., vaccination conducted

**A utilization-focused evaluation approach was applied to maximize use of evaluation findings for improving workforce performance.**

during the same session but different site), decision-making algorithm for when to administer MCV2 or Men A, intervals between vaccines, preventing missed opportunities for immunization, and how to manage adverse events following immunization

- Immunization data management, quality, and use: Accurately documenting data in tally books, child welfare clinic (CWC) registers, child health record booklets, and monthly vaccination reports; updating monitoring charts; and defaulter identification process for defaulter tracing
- Communication: Key immunization messages for caregivers (increasing parents’ awareness of MCV2 and Men A), including what to expect from a 2YL visit, importance of 2YL vaccines, and addressing vaccine hesitancy

GHS EPI experts reviewed the PAS for technical accuracy before piloting it at a health center in GAR. Data collectors practiced with health center staff at the pilot site while one of the primary investigators observed, and then the team (CDC, GHS EPI experts, and data collectors) revised the PAS again for content, clarity of questions, and format. Next, GHS experts validated the revised tool, reviewing it for accuracy on technical content and optimizing it for local context before data collection. Quantitative responses were scored on a Likert scale, adapted from National Institutes of Health’s Proficiency Scale,<sup>9</sup> as follows:

1 = No knowledge. Participant is unable to say anything about the skill or demonstrate any ability to perform the tasks associated with the skill.

2 = Novice (basic knowledge). Participant has a rudimentary understanding of basic techniques and concepts.

3 = Intermediate (practical application). Participant can successfully complete tasks or answer questions in this competency as requested. Help from an expert may be required from time to time, but the participant can usually perform the skills independently.

4 = Advanced (applied theory). Participant can perform the actions associated with this skill without assistance. They can provide guidance, troubleshoot, and answer questions related to this area of expertise and the field where the skill is used.

The data collectors also used the PAS to record observations to understand if and how attitudes and practices around 2YL services had changed. Key observations included participants’

knowledge on how to use the CWC register, the decision-making algorithm for when to administer MCV2 or Men A, availability of data collection reporting tools, presence (or lack of) a monitoring chart at the health facilities, and any changes observed in practice during PAS2. All the observations were noted and recorded in ODK.

### Data Collection

Data collection occurred in 2 phases. The first progress analysis survey (PAS1) was conducted after the TOT workshops (before DHMTs trained HCWs) during November 2017, and the second progress analysis survey (PAS2) occurred during March 2018 after DHMTs implemented a variety of capacity-building interventions with HCWs. The time between PAS1 and PAS2 provided the HCW training participants a chance to practice what they learned during the training. Both PAS1 and PAS2 were administered by trained data collectors and used at both points to assess knowledge of the 3 core competencies. For PAS2, a few questions were added to understand the format and date of the 2YL intervention(s) HCWs recently received, their opinions on the intervention(s), and their self-reported behavior change.

During both surveys, data collectors noted key observations within a structured observation framework while at each collection site, but more extensive field notes about progress or changes since the first visit were encouraged for the second phase. GHS and CDC contracted the Ghana Field Epidemiology and Laboratory Training Program (GFELTP) to collect and analyze the data for PAS1 and PAS2. GFELTP affiliates served as data collectors and received training on the following areas: Android tablet use, how to navigate the LINKS app (i.e., the app used for data collection) and download forms, the basics in Ghana EPI competency standards, key evaluation research questions, and administration of the tool. In addition, data collectors received guidance on the scoring system and definition of key variables. The data collectors were paired up to visit each health facility and administer the survey. They were also assigned to the same sites for both PAS1 and PAS2 to facilitate better observation of behavior and knowledge change. The data collectors were instructed with specific key changes to note during PAS2 data collection (e.g., was the monitoring chart updated, was a data review meeting conducted; observation of improvement in attitudes and practice). We took these measures to minimize potential selection, social desirability, recall, and personal biases.

**Data collection occurred in 2 phases, and the time between phases allowed HCW training participants a chance to practice what they learned in training.**

An electronic version of the PAS was stored in the LINKS app on a dedicated Android tablet supported by Secure Data Kit (SDK). Data collection took 1 week per region, a total of 3 to 4 weeks for each. During data collection, GFELTP affiliates uploaded completed surveys daily to the SDK database and reported field challenges through WhatsApp messaging to ensure rapid support from CDC and GHS staff who assisted with any technical or content-related questions.

### Data Management and Analysis

Collected data were stored on a cloud server; SDK form submissions were added into a database that was continuously backed up on a hard drive in a rolling 7-day window. CDC and GHS staff reviewed the data daily during active data entry/ collection phases. Outliers or questionable survey entries were addressed through conversations with GFELTP and the data collectors who entered the information. CDC and GHS made all combined data available to GFELTP daily during the data entry/ collection phases.

Quantitative data were stored, data quality was checked, and data were initially analyzed for descriptive purposes using Microsoft Excel. The data were then entered into Stata v. 13.0<sup>10</sup> (StataCorp, College Station, TX, 2013) and a Wilcoxon signed-rank test was used to determine if knowledge changes were statistically significant in HCWs' posttraining interventions. All qualitative data, field notes, and observations collected were uploaded into NVivo v. 12 (QSR, 2018) for analysis.<sup>11</sup> Analysis included coding of field notes, observed behaviors, and practice for the expected themes as well as emergent themes. The investigators held several discussion meetings with each other and with stakeholders to review and discuss both quantitative and qualitative analyses and how they informed each other and to decide if additional analyses were needed.

**Eleven of the 15 DHMTs completed activity reports that described a total of 112 capacity-building interventions conducted following the DHMT TOTs.**

### Ethical Clearance

Both CDC and GHS determined that this evaluation was a public health program activity and not human subjects' research.

## RESULTS

### Capacity-Building Interventions Implemented After the TOT by DHMTs

Eleven of the 15 DHMTs completed activity reports that described a total of 112 capacity-

building interventions conducted following the DHMT TOTs. DHMTs reported conducting workshops (n=65), health facility visits (n=43), and review meetings (n=4). Reports from the HCWs themselves in the PAS2 (described below) indicated that they also learned about 2YL via phone calls, learning from peers, and on-the-job training at the health facility level during supervisory visits.

### Evaluation Question 1: Did Frontline HCWs' Knowledge of EPI Policy, Data Management and Use, and Communication With Caregivers Increase After the DHMT Interventions?

#### PAS Survey Characteristics and Demographics

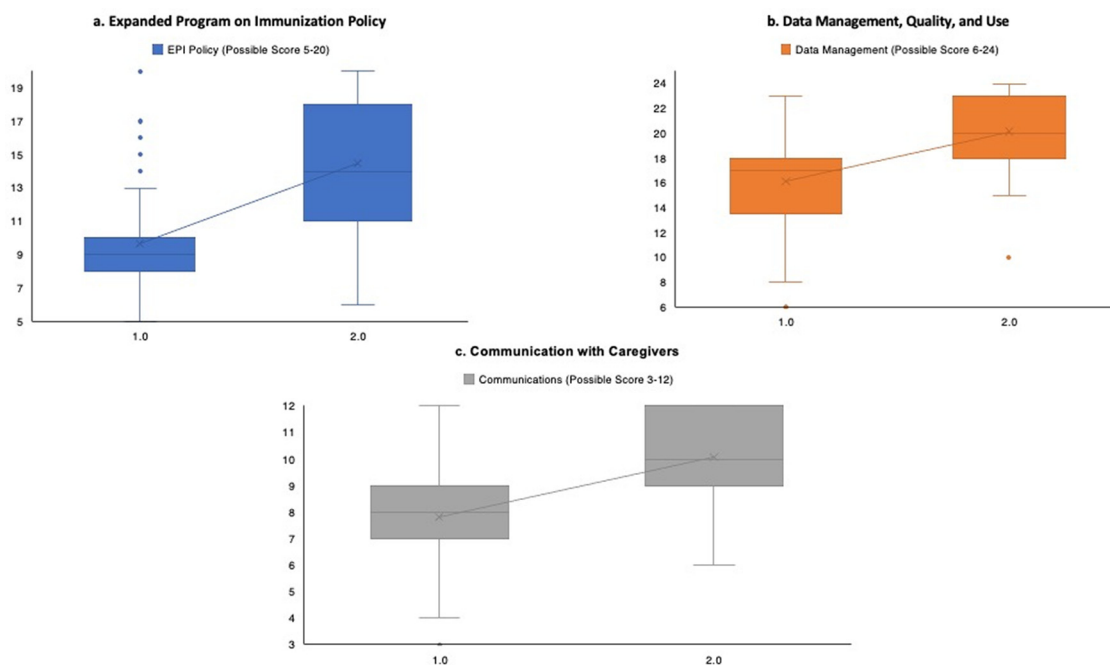
Of the 1,310 HCWs eligible for training, a total of 115 HCWs were included in the sample and all of them were surveyed in PAS1. Of these, 102 (89%) participated in at least 1 capacity-building intervention from their respective DHMT and were surveyed in PAS2. The 13 HCWs who were not surveyed in PAS2 had either not participated in any capacity-building interventions, were on leave, or data collectors were unable to locate them for the survey.

While a total of 102 HCWs were surveyed for both PAS1 and PAS2, we learned that a few DHMTs (primarily in NR) had been so enthusiastic about immediately sharing the skills and knowledge acquired in the TOT that they began implementing capacity-building interventions before PAS1 had been administered. Thus, we present the analyses only for 65 HCWs who were surveyed in PAS1 before capacity-building interventions and in PAS2 after capacity-building interventions. Data are not shown for the 37 HCWs who were included in both PAS1 and PAS2 but were surveyed in PAS1 after already being exposed to at least some capacity-building interventions. Of the total 65 HCWs surveyed at both points in time, the median age of respondents was 30 years (range 25–59 years) and a majority were women (82%). No differences were found in the distribution of demographic characteristics between the 2 groups (65 HCWs included in the analysis and 37 who were not).

#### Knowledge Growth Among the Group (n=65) First Surveyed Before Interventions

For 3 competencies evaluated in the PAS1 and PAS2 using a Likert scale rating of 1–4, there were 5 questions on EPI policy (possible score 5–20); 6 questions on immunization data

**FIGURE.** Knowledge Growth of Health Care Workers in Ghana on (a) Expanded Program on Immunization Policy; (b) Immunization Data Management, Quality, and Use; (c) and Communication With Caregivers, Before and After Capacity-Building Interventions From the First Progress Analysis Survey and the Second Progress Analysis Survey



Abbreviations: EPI, Expanded Program on Immunization; PAS1, first progress analysis survey; PAS2, second progress analysis survey, PAS2.

management, quality, and use (possible score 6–24); and 3 questions on communication with caregivers (possible score 3–12). Of the 3 competencies, national EPI policy recorded the highest increase in knowledge with a mean score increase of 5 points (Figure a). Reviewing individual questions, the largest average increase was 1.09 points for both the catch-up policy for missed immunization and the simultaneous injection policy. Knowledge of the policy on adverse events following immunization had an average increase of 1.05 points, followed by the decision-making algorithm for when to administer MCV2 or Men A (+0.85), and intervals between doses (+0.80).

The data management, quality, and use category averaged a mean score increase of 4.03 points (Figure b). The highest increase in the data management category was knowledge of defaulter tracing (+0.97), followed by monitoring charts (+0.83), monthly reporting (+0.71), and the CWC register (+0.65). Across all 3 competencies, the lowest increase in knowledge was in tally books (+0.42) and child

health books (+0.46). No reduction in knowledge was observed between PAS1 and PAS2.

The communication with caregivers’ competency had the lowest increase in knowledge, with the mean score increasing by 2.2 points (Figure c). Individual questions on what caregivers should expect from the 2YL visit and the importance of the 2YL intervention both increased by 0.77 points, and knowledge about addressing fears and vaccine hesitancy increased by 0.71 points.

None of the demographic characteristics for the 65 HCWs (such as job designation, years of service, location, and number of job duties) were significantly linked to knowledge gained in any competency areas (data not shown). Despite the positive changes in some categories of knowledge, they were not statistically significant in a comparison of the PAS1 and PAS2 test results in all 3 areas combined (Wilcoxon signed-rank test produced a total z score of -0.772 and  $prob > z = 0.44$ ). We found no statistically significant differences in PAS1 and PAS2 when examining each competency score individually (data not shown).



## Evaluation Question 2: How Did the Frontline HCWs' Attitudes and Practices Regarding 2YL Services Change After Receiving the DHMTs' Capacity-Building Interventions?

Results from field observations and qualitative data from the PAS provide insights into behavior changes and practices of the 102 HCWs in all 3 competency areas. When the study investigators asked HCWs about their perspectives on the capacity-building activities they received, they expressed high appreciation and reported knowledge improvement after the training. For example, an HCW from the Volta region stated:

*Formerly if I met a child 17 months old I won't give MR1 [first dose of measles/rubella vaccine], I would wait till 18 months and give MR2 [second dose of measles/rubella vaccine], but now with the help of the training, I will administer MR1 and schedule one-month interval for MR2.*

Similarly, another nurse from GAR reported:

*After learning about policies, I now vaccinate every child I come into contact with regardless of wastage. I have also improved on defaulters tracing.*

When asked about any changes made since 2YL training, HCWs reported that they had changed their attitudes and practices due to the 2YL training. The most improved practice reported and observed in all 3 regions was the creation of a defaulter list. For example, a public health nurse from GAR stated:

*Before the training, [I] didn't trace defaulted eligible children. But after 2YL training, I started tracing the defaulted eligible children through phone calls. . .*

Another HCW from NR stated:

*After the training, we realized school health can actually make a difference in our coverage. We began school health outreaches. We got about 40 children for Men A and MR2. We knew about school health but didn't know it could be helpful.*

HCWs also reported that they changed their immunization data management practices to improve their work. The HCWs reported the importance of data validation (i.e., review data for accuracy and quality) and began to meet monthly for data validation and to check immunization coverage. The largest observed challenge was data management as HCWs across the region continued to struggle with completing reporting forms correctly and health facilities lacked the necessary data management tools (CWC

registers, monitoring charts, tally books, and child health record books). When data management tools were unavailable, some HCWs improvised with personal notebooks, but several lacking the tools also struggled with the ability to do correct calculations or did not know their target population for vaccination.

HCWs also reported improvement in communication practices with caregivers during the vaccination visits due to the 2YL training. A senior nurse from NR stated:

*We now know the importance of effective communication with caregivers so we now spend more time in communicating to them to make them understand us more.*

The HCWs reported that they are more patient with the caregivers and asked their clients for feedback on their one-on-one communication during immunization sessions.

At the end of the activity tool, DHMTs were asked the following 4 open-ended questions for the 112 reported activities:

1. What were the key strengths observed during this activity?
2. What were the key challenges experienced during this activity?
3. Based on what was accomplished today, what are the next steps with this health facility?
4. Any additional comments?

The Table presents examples of key strengths and challenges observed during implemented activities reported by DHMTs.

## DISCUSSION

Overall, findings indicate increased knowledge among frontline HCWs in all 3 competencies (EPI policy; data management, recording, and use; and communication with caregivers) in the 3 months during which DHMTs implemented a range of capacity-building interventions. Although this evaluation was not designed to assess causality or contribution of this training intervention to immunization coverage within the participating districts and regions, this was the only intervention on this subject matter in the 3 regions that was targeted to district and subdistrict HCWs within the specified time period. While knowledge improvements were not statistically significant, it is important to note that determination of the impact of an intervention should not rely solely on a quantitative threshold with an arbitrary *P*-value of <.05. Furthermore, the small sample size for this intervention contributed to inadequate power

**When asked about their perspectives on the capacity-building activities, HCWs expressed high appreciation and reported knowledge improvement after the training.**

**Findings indicate increased knowledge among frontline HCWs in all 3 competencies in the 3 months during which DHMTs implemented capacity-building interventions.**

**TABLE.** Examples of Key Strengths and Challenges Reported by District Health Management Teams in Implementing Capacity-Building Interventions to Improve Knowledge and Practice of Immunization in Ghana

Key Strengths	Key Challenges
HCWs have started school immunization.	Hard to reach communities in the zone
HCWs are conducting defaulter tracing and applying good communicating skills.	Inadequate child welfare clinic register and immunization monitoring chart; no permanent place to display chart
Various viewpoints are brought for discussion—effective participation.	Mothers reluctant to bring their children for vaccination
Good collaboration with the subdistrict is present.	Heavy workload for HCWs
Improvement in data documentation and defaulter tracing (i.e., list of children missing doses of recommended vaccines) is occurring.	Hard getting stationery from the health facility

Abbreviations: HCW, health care worker.

to detect differences in these 3 categories and might be due to exclusion of a good portion of the respondents.<sup>12,13</sup>

The 2YL intervention was custom designed for specific performance problems in the 3 regions, namely lack of knowledge on EPI policy, inconsistent defaulter tracing, poor documentation of immunization data, and weak communication about vaccination with caregivers. “Success” for training interventions is determined by behavior change that leads to better outcomes and solves the performance problem. The evidence of knowledge growth as shown in our quantitative results is supported by many of the qualitative comments from HCWs indicating positive behavior changes following the capacity-building interventions. One interesting finding was the combination of improved knowledge regarding the simultaneous injection policy (i.e., MCV2 and Men A can be given simultaneously) and improved defaulter tracing as seen in field observations and follow-up with HCWs after training. Moreover, although communication seemed to have the least improved score, HCWs reported spending more time communicating with caregivers about vaccination and addressing their concerns. With continued mentorship, peer-to-peer learning, and skill building through various means (e.g., supportive supervision visits or a buddy system), communication between nurses and caregivers will continue to improve over time. These improvements would lead to fewer missed opportunities for vaccination during the 2YL by capturing more unvaccinated children than in the past and ensuring they receive all appropriate vaccinations at the same immunization visit. These practices prevent an accumulation of susceptible (unvaccinated)

children who could potentially sustain disease transmission or cause outbreaks of vaccine-preventable diseases.

The increase of knowledge and self-reported improved behavior changes suggest that various interventions used by the DHMTs to reach HCWs may be promising practices for improving workforce performance. This includes follow-up and postintervention activities, such as supportive supervision visits, on-the-job training, and data review meetings to facilitate learning.<sup>14,15</sup> Changes in practice and knowledge of HCWs could also be due to the effect of spacing learning, whereby the frontline HCWs engaged with these learning materials through a practical application over time in their health facilities.<sup>16</sup> The DHMTs learned how to train HCWs using a learner-focused (i.e., based on expected job duties) and performance-based approach with embedded adult learning principles. The DHMTs used a variety of teaching methods and delivery techniques to facilitate learning, including the application of performance improvement strategies (e.g., group problem analysis, supervisory and interpersonal skills) to understand the underlying causes of workforce performance issues related to EPI identified within the district and health facility levels.<sup>15–18</sup> These factors minimize the forgetting curve for the HCWs: learners tend to forget information learned during training if there are no efforts to apply acquired skills and knowledge.<sup>19,20</sup>

According to Gilbert’s<sup>21</sup> behavior engineering model, clear expectations such as those provided by standard operating procedures and performance feedback have a bigger impact on workforce performance and health systems than improving knowledge. Gilbert’s<sup>21</sup> model also demonstrates that providing HCWs with the

**Increased knowledge and improved behavior changes suggest that interventions used by DHMTs to reach HCWs may be promising practices for improving workforce performance.**

necessary tools has a greater effect on their performance than knowledge and skill. We observed that some workers did not have the tools to record immunization data and had to improvise. While partner agencies facilitated the acquisition of CWC registers with subsequent training interventions for this project, for the long term we recommend that the district staff routinely assess whether subdistrict and health facility staff have a standard set of tools, keep track of the availability of these tools, and report to the regional or national staff about these needs. The national and regional EPI budget should include funds for printing and distribution of these materials to enable national EPI staff to provide these tools to the subdistrict and health facility staff. Lastly, based on field observations and study results some HCWs did not trace defaulters, know their target population for immunization, or master the catch-up policies for missed immunizations and simultaneous injections. This finding is a major concern because every health encounter should be used to identify and reach children with recommended vaccines, especially those who may have missed doses.<sup>22</sup> GHS should leverage existing mechanisms, such as new hire orientation, supportive supervision visits, and monthly data review meetings to empower their HCWs to perform EPI tasks more proficiently. The ownership and continued attention by national and subnational leaders on the capacity-building needs of the immunization workforce will be key to ensure optimal performance of the immunization program. HCWs in Ghana and beyond could benefit from standardized simple quality job aids for immunization topics that could be translated into many local languages.

### Limitations

Due to budget limitations, a small sample was used for this study and focused on just a subset of 5 poorly performing districts in each of the 3 participating regions in the country. The small sample size did not allow for us to conduct multiple comparisons of subgroups and limited the power of the study to detect statistically significant increases in knowledge before and after the intervention. In addition, PAS1 was not administered to a substantial portion of eligible HCWs at the right time, so their exclusion from the analysis further reduced the sample size. Because of the restricted geographic focus, our results are not generalizable for the entire population in Ghana, and we do not know whether these interventions would yield

similar results in other districts. The knowledge score of the HCWs could have been influenced by selection and social desirability biases—the data collectors could have unconsciously or consciously scored certain participants higher to be viewed favorably. Furthermore, all data on training quality and behavior change were self-reported and had the potential for recall and personal biases.

Also, study findings were not compared with district-level immunization performance data to verify the degree of performance improvement after the intervention among key immunization indicators (e.g., dropout rates, coverage). A 2YL endline survey is planned to evaluate the overall impact of various 2YL interventions (including workforce development) on improving immunization coverage and reducing variation in coverage equity among districts surveyed during the 2YL 2016 baseline assessment. This endline survey will address this data gap.

### CONCLUSION

This evaluation offers preliminary encouraging results in taking the first step toward improving HCW knowledge, attitudes, and practices for 3 core immunization competency areas. Following the 2YL interventions we have outlined, HCWs reported an overall increase in knowledge of the EPI policy; the importance of data validation/data review meetings to improve data management, recording, and use; the significance of conducting defaulter tracing; and the need to improve communication with caregivers about vaccination. HCWs also showed improved attitudes and practices in all 3 competency areas. The use of learner-focused teaching methods combined with adult learning principles was helpful in solving specific performance problems (such as lack of knowledge of EPI policy and poor documentation of data) and should be included as a standard practice for future training interventions. The upcoming 2YL endline survey will offer insights into the impact of this workforce development approach for improving immunization coverage in the target geographies.

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ORIGINAL ARTICLE

# Young People’s Experiences With an Empowerment-Based Behavior Change Intervention to Prevent Sexual Violence in Nairobi Informal Settlements: A Qualitative Study

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## Key Findings

- A 6-week behavioral, school-based intervention can contribute to empowering adolescent girls to recognize and resist sexual violence and to exercise agency.
- The intervention can also promote positive, nonviolent masculinities among adolescent boys and encourage rejection of harmful stereotypes.
- Skilled, thoroughly trained local facilitators and interactive, adolescent-friendly relevant content were highlighted by the adolescent participants as key to intervention success.

## Key Implications

- Policy makers should consider integrating empowerment-based, behavioral interventions in standard school curriculums to prevent sexual violence and harmful gender norms.
- Policy makers should adopt legislation that will facilitate the implementation of comprehensive sexuality education that addresses topics such as sexual consent communication and guarantees access to adolescent-friendly sexual and reproductive health services.
- Public health practitioners and implementers should consider expanding similar interventions to include comprehensive sexuality education as well as directly targeting the broader social environments in which adolescents are socialized.
- More research is needed to better understand the longitudinal effects of the intervention and the strategies for sustainable implementation in different contexts.

## ABSTRACT

**Purpose:** Young people in sub-Saharan Africa face one of the world’s highest burdens of sexual violence. Previous impact evaluations indicated that a 6-week empowerment-based behavioral intervention in Nairobi informal (slum) settlements can reduce sexual assault. This qualitative study investigated girls’ and boys’ experiences of the intervention to identify potential mechanisms of change.

**Methods:** We conducted a qualitative study in Nairobi slums with students (aged 15–21 years) who had participated in 2 parallel school-based curriculums called IMPower (girls) and Your Moment of Truth (boys) at least 1 year ago. Data were collected via 10 focus group discussions (5 for boys, 5 for girls) with 6–11 participants in each and 21 individual in-depth interviews (11 boys, 10 girls) that explored participants’ experiences of the intervention and their suggestions for improvement. Findings were analyzed using thematic network analysis guided by empowerment theory.

**Results:** Girls described how the intervention enabled them to recognize and resist sexual assault via verbal and physical strategies for self-protection, negotiate sexual consent, and exercise agency. Boys described increased ability to avoid risky behaviors and “bad” peer groups and to understand and respect consent. Girls also described how the intervention strengthened their self-confidence, and boys said that it boosted positive life values and gender-equal attitudes. Skilled facilitators and interactive and relevant content were highlighted as key to intervention success. Areas of improvement included expanding the curriculum to contain more content on sexual and reproductive health and rights and involving out-of-school youth, parents, teachers, and communities.

**Conclusion:** Findings indicate that a relatively short, behavioral school-based intervention can empower both girls and boys to prevent various forms of sexual violence in a low-income setting where it is endemic. Incorporating multilevel support structures, such as involving communities and families, could further enhance young people’s long-term safety, health, and well-being.

## INTRODUCTION

Gender-based violence (GBV) remains a major global public health problem and human rights violation.<sup>1</sup> Globally, 1 in 3 women reports experiencing physical and/or sexual violence in her lifetime.<sup>2</sup> Multiple, well-established consequences for this violence exist in regards to sexual and reproductive health,<sup>3</sup> physical and

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mental health,<sup>4</sup> and social and economic development.<sup>5</sup> GBV, including sexual violence, begins early in life,<sup>6</sup> with an estimated 1 in 10 girls (120 million) having been forced to perform sexual intercourse or other forms of sexual acts before her 20th birthday.<sup>7</sup> Likewise, according to a 4-country study in sub-Saharan Africa, between 8% and 27% of boys and young men aged 13–24 report ever perpetrating sexual violence,<sup>8</sup> and a global study in poor urban settings found that up to 1 in 10 boys aged 15–19 years reported perpetration of sexual violence against an intimate partner in the past year.<sup>9</sup> Thus, focusing on adolescence as a formative period for shaping attitudes and behaviors linked with both violence exposure and perpetration is both a research priority<sup>10</sup> and central to achieving gender equality in line with Agenda 2030.<sup>11</sup>

Young people in Kenya face one of the world's highest rates of sexual violence and other forms of GBV. National data indicate that 35% and 47% of young women (aged 15–19 and 20–24 years, respectively) have experienced physical and/or sexual violence in their lifetime. Husbands are the most common perpetrators of sexual violence for married women, whereas, for never-married women, the perpetrators are commonly a stranger, friend, or acquaintance.<sup>12</sup> The risk of GBV is especially high in urban informal settlements (slums), which are characterized by high levels of poverty, unemployment, violence, crime, and a lack of health and educational services. According to a recent survey in 2 Nairobi informal settlements, 33%, 23%, and 16% of young women report experiencing psychological, physical, and sexual violence, respectively, in the past year.<sup>13</sup>

In Kenya, sexual violence and other forms of GBV are driven by multiple social-ecological factors,<sup>14,15</sup> including gender norms that undermine the power of girls and women and expect boys and men to adhere to stereotypical masculinity ideals of violence and risk.<sup>15</sup> Empowerment self-defense (ESD) is an interactive feminist training to prevent sexual violence by building verbal, emotional, and physical skills to recognize and resist different forms of GBV through heightened self-esteem and confidence.<sup>16–18</sup> Previous studies in high-income settings indicate that ESD is a promising strategy for reducing sexual assault and coercion against female students on college and university campuses.<sup>17,19,20</sup> In low- and middle-income countries, ESD has primarily been used in primary and secondary schools via an adapted curriculum called IMPower, developed

by the U.S.-based nongovernmental organization No Means No Worldwide.<sup>16</sup> In Kenya and Malawi, IMPower is implemented in Nairobi slum schools by the local nongovernmental organization Ujamaa-Africa, with cluster-randomized evaluations indicating reduced incidence of past-year sexual assault among girls aged 10–19 years.<sup>16,21,22</sup>

As global scholars have noted, the responsibility for GBV ultimately rests with the perpetrator.<sup>23,24</sup> Thus, a comprehensive approach to sexual violence prevention must address underlying gender norms and support the development of nonviolent behaviors among young men as agents of change in bolstering gender equality. In Kenya, IMPower has therefore been combined with a parallel and complementary curriculum called Your Moment Of Truth (YMOT) that works with boys and young men to build positive masculinities and skills for verbal bystander intervention.<sup>25,26</sup> Even though YMOT's effect on sexual violence perpetration has not been evaluated as part of peer-reviewed research, a 2015 evaluation in Nairobi slums found that boys who received the intervention were more likely than the control group to hold gender-equal attitudes and to intervene successfully when witnessing GBV.<sup>26</sup>

To date, no qualitative research has explored if, how, and under which circumstances girls and boys can draw on skills taught by these curriculums to prevent sexual violence. Such research could help provide important insights into the potential mechanisms of change that underlie the intervention in a way that is not elucidated in survey research. In light of findings from a 2020 review conducted by the What Works to Prevent Violence Against Women and Girls Global Program, which indicated that more evidence is needed on the intervention given limitations in previous study designs,<sup>27</sup> qualitative research can help to better understand participants' experiences.

In response to this gap, the current study aims to understand girls' and boys' experiences of this empowerment-based behavioral intervention in schools to prevent sexual violence in Nairobi slums. Focusing on changes in perceived agency and empowerment, we seek to elucidate both positive aspects of the intervention as well as areas for improvement.

## PROGRAM DESCRIPTION

Both the intervention for girls (IMPower) and boys (YMOT) were developed by No Means No and Ujamaa-Africa for the East African context

**The current study aims to understand girls' and boys' experiences of an empowerment-based behavioral intervention to prevent sexual violence in Nairobi slums.**

**We hypothesize that the intervention helps to reduce power over by strengthening girls’ and boys’ power to protect themselves and others; their power within; and their power with.**

via extensive formative work, including focus groups and piloting.<sup>22,26</sup> Both curriculums are implemented simultaneously over a 6-week period and comprise 5 2-hour sessions that are taught in separate complementary classes, followed by a sixth joint session. The girls’ curriculum (IMPower) uses ESD techniques to strengthen girls’ critical reflection and problem-solving skills and to boost their self-esteem and confidence. The curriculum also offers hands-on risk-reduction techniques for recognizing and resisting different forms of sexual harassment and violence, such as boundary setting, diffusion tactics, verbal assertiveness, and negotiation (e.g., name potentially threatening behaviors from abusers), and if needed, different forms of physical self-defense (e.g., bodily weapons) as the last resort. Throughout the intervention, girls disclosing violence or abuse are connected with the Sexual Assault Survivors Anonymous program at each site. The boys’ curriculum (YMOT) is designed to promote positive, nonviolent masculinities and to help boys identify emotions and build skills for nonviolence, seeking consent, and strategies for safe bystander intervention (i.e., interrupting potential violence and harassment).

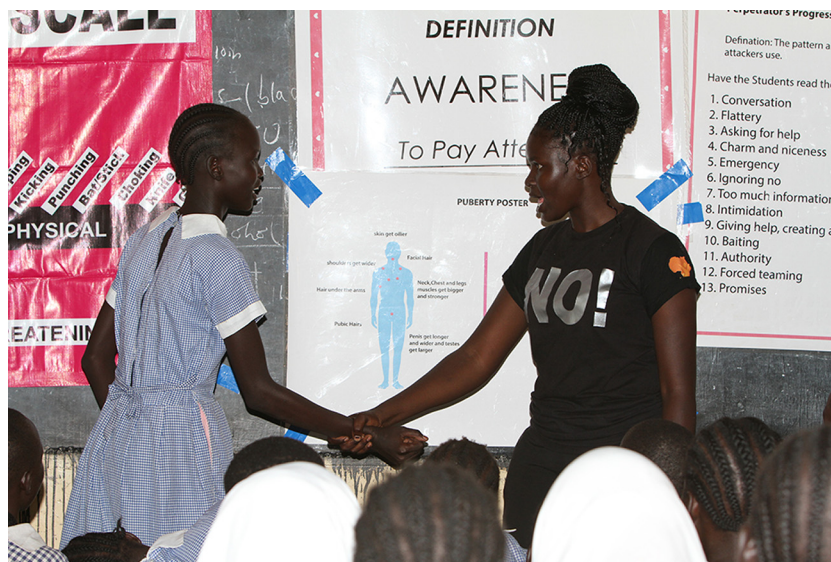
The sessions are designed for ages 10–19 years, but the specific content is age-adapted. A 2-hour refresher session, which is typically attended by at least 80% of program beneficiaries, is given at 6 months and at 1 year after training. Both curriculums are highly participatory and include facilitated discussions, critical reflection, role-play, and

drama. Table 1 provides a detailed description of each session.

The facilitators are carefully selected from the local communities, must be aged 20–30 years, and have at least 2 years’ experience in GBV prevention among young people. Following interviews, selected facilitators undergo a 3-month, 250-hour training by expert instructors, which ends with a rigorous examination, as well as practical demonstrations in a class with adolescents. New facilitators teach alongside an experienced instructor for the first year before facilitating groups independently.

### Theory of Change

The underlying theory of change behind the combined curriculums is that girls who have a sense of control over their bodies and a belief in their rights are more likely to resist sexual violence and to negotiate sex in (wanted) intimate relationships. Furthermore, working with young men to critically reflect on gender norms, consent, and attitudes towards and involvement in violent behaviors is central to reduce perpetration. For the current study, we use VeneKlasen and Miller’s<sup>28</sup> empowerment framework to understand and organize participants’ experiences in light of the theory of change. The framework explains how 4 different manifestations of power affect GBV, with *power over* (an individual/group) referring to the ability of someone (e.g., perpetrators) to dominate others. We hypothesize that the intervention helps to



A female student practicing the wrist grab release in front of her class. © 2018 Peter Omondi/Ujamaa Africa

**TABLE 1.** Intervention Curriculum Themes, With Age-Adapted Content

Girls: Empowerment Self-Defense (IMPower)	Boys: Your Moment Of Truth (YMOT)
<p><b>Session I: Introduction</b> Introduction to the program and girl’s empowerment self-defense, covering a broad range of safety options and goals, including the Assault Continuum, a tool used throughout the intervention to demonstrate different forms of violence ranging from verbal harassment to rape.</p>	<p><b>Session I: Introduction</b> Introduction to the program with facilitators sharing personal stories about important “Moments of Truth” in their lives. The goal is for boys to develop awareness about their own important moments of truth that they might face.</p>
<p><b>Session II: Verbal empowerment skills</b> Verbal skills to prevent violence, including saying “no” in a way that is effective and believable, showing assertiveness, setting boundaries, lying to or tricking potential assaulters, and making a scene to alert others to aggressive acts and behaviors. Understanding how awareness and paying attention can be a powerful line of defense.</p>	<p><b>Session II: Skills to prepare for YMOT</b> Highlighting skills for awareness, how to identify red flags in potential assault situations, and how to use assertive body language and verbal response. Discussion around courage based on personal stories from facilitators and use of role-play to deter physical violence.</p>
<p><b>Session III: Physical empowerment skills (I)</b> Girls are introduced to thinking about their bodies as powerful and equipped with potential tools or weapons (hands, feet, other body parts) that can be used for self-defense against an attacker. Facilitators use role-play to demonstrate scenarios, using concepts such as “What’s Free, What’s Open” where girls learn and practice ways to escape and holds and grabs that minimize power differentials.</p>	<p><b>Session III: Bystander intervention</b> Definition of bystander intervention to interrupt (potential) violent situations in a safe way. Facilitators demonstrate skills using role-play, followed by boys practicing stepping up and trying to recognize or resolve potential conflict.</p>
<p><b>Session IV: Physical empowerment skills (II) and disclosure</b> Focus on self-defense in more extreme situations, with facilitators using mats and strike bags to simulate attack situations and defense. Introduction to disclosure and the importance of telling someone about gender-based violence experiences, and to counter victim blaming. Girls who disclose assault to facilitators are directly linked with the Sexual Assault Survivor Anonymous (SASA) support service.</p>	<p><b>Session IV: Sexual consent</b> Definition and understanding of sexual consent, with facilitators and boys discussing what “counts” as consent, exploring the causes of and myths about rape, and covering basic de-escalation and negotiation techniques.</p>
<p><b>Session V: Advanced empowerment self-defense</b> Skills to de-escalate violence by using language that can help when someone known or a stranger is upset or becoming upset. Girls practice stalling an attacker by using a one-liner that keeps the assailant calm while they plan their next move.</p>	<p><b>Session V: Responsibility for one’s self</b> Boys discuss what it means to be responsible for one’s actions and behaviors and continue practicing utilizing bystander intervention skills.</p>
<p><b>Session VI: Putting it all together</b> Review of key concepts, with girls continuing to practice verbal and physical skills to identify and escape violent/threatening situations and discuss when and how to disclose violence.</p>	<p><b>Session VI: Review of skills and content</b> Review of key concepts, practicing skills via role-play. Boys make public commitments to utilize their new skills and to face their moments of truth.</p>
<p><b>Integrated class for both boys and girls</b> Creates a platform to discuss cross-cutting issues including understanding harmful gender stereotypes, basic instances that require consent, and gender roles and the impact they have on both males and females.</p>	

reduce power over by strengthening girls’ and boys’ *power* to protect themselves and others; their *power within* (e.g., self-confidence, self-efficacy, sense of self-worth); and their *power with*, a collaborative form of power that is achieved through building bridges between individuals to achieve a common goal (e.g., to end GBV in their communities).

**METHODS**

**Study Design and Participants**

We conducted a qualitative study with former intervention participants at 5 schools in 4 Nairobi slums: Kibera, Dandora, Mkuru-Viwandani, and Huruma. Purposive sampling was used to invite participants who were at least 15 years old and who participated in a minimum of 4 curriculum sessions at one of the selected schools, at least 1 year before data collection. Recruitment was

performed by Ujamaa-Africa’s field staff, aided by the research team. Participants were first screened for eligibility by filling out forms in which they indicated interest and availability to participate in either focus group discussions (FGDs) or in-depth interviews (IDIs). When more students than needed were eligible and interested at each school, all papers were put into a closed box from which the study staff made a random selection.

**Data Collection**

Data were collected via a series of FGDs and IDIs in English, Kiswahili, or Sheng (local slang) between January and June 2019. We conducted a total of 10 FGDs (5 with boys, 5 with girls) with 6–11 participants in each group and 21 IDIs (10 girls, 11 boys) (Table 2). Most participants came from schools in Dandora and Mukuru-viwanndani due



**TABLE 2.** Number of Interviews, by Location, Method, and Gender

Location	Gender	Focus Group Discussions	In-Depth Interviews
Kibera	Boys	1 (8 participants)	2
	Girls	1 (8 participants)	1
Dandora	Boys	1 (11 participants)	4
	Girls	1 (10 participants)	5
Mukuru-viwanndani	Boys	2 (8 participants)	4
	Girls	2 (8 participants)	4
Huruma	Boys	1 (11 participants)	1
	Girls	1 (9 participants)	0
Total	Boys	5 (46 participants)	11
	Girls	5 (43 participants)	10

to the ease of accessibility of eligible participants from these sites in school settings. Because adolescents living in Nairobi's informal settlements face similar sexual violence risk factors<sup>29</sup> and because an examination of any potential variation or similarities in participants' experiences of the intervention by location within Nairobi is beyond the scope of the current study, the uneven representation of study participants by location was not viewed as compromising the findings. Interviews were conducted in person by trained data collectors employed by Ujamaa-Africa who had not been part of delivering the intervention but were local to the study area and spoke the language(s). All data collectors underwent a 1-week training in qualitative methods led by experienced researchers at Karolinska Institutet during October 2018, followed by a 4-day refresher training in January 2019. The training covered qualitative methodology, ethics, recruitment, interviewing skills, reflexivity, fieldwork logistics, and transcription.

A set of semi-structured interview guides (piloted in 2 FGDs and 2 IDIs before implementation) were tailored to the type of interview (FDG vs. IDI) and participants' sex, and covered research questions related to participants' overall experiences of the program, impact on sexual violence, agency, gender norms, sexual relationships, and suggestions for improvement. FGD guides were designed to elicit responses around commonly held views on subjects such as gender norms and participants' shared perceptions and experiences of the intervention, while IDIs provided a more private environment for participants to open up about personal experiences including violence. Participants' memorable events were

used to probe for more details on if, and how, they had applied the skills in real life. Participatory methods were used to engage participants, drawing on techniques such as a word-cloud activity (asking participants to describe themselves before and after the intervention) and photo-elicitation (showing pictures of pregnant girls at school with questions around potential causes, consequences, and prevention).

Data collection began with FGDs to update and refine the interview guides and identify themes for further exploration in IDIs. All interviews were matched by gender, with female data collectors interviewing girls and young women and male data collectors interviewing boys and young men, and took place in a private space to ensure participants' confidentiality and privacy. Note-takers took extensive field notes during FGDs, and all data collectors wrote reflective notes after each interview to summarize key themes and context details. Interviews were audio-recorded, transcribed verbatim in Kiswahili/Sheng, and translated into English.

### Data Analysis

Data were analyzed using thematic network analysis,<sup>30</sup> which includes assigning labels (codes) to text segments in the transcripts, followed by the identification of code and categorization into *basic themes*. These were further clustered into categories called *organizing themes* and broader *global themes* that best conveyed the meaning of the data concerning the research questions explored. Transcripts were uploaded into Atlas.ti (Scientific Software, version 8), followed by deductive as well as inductive coding by 2 researchers (PMO,

**Participants related their overall experiences with the program and its impact on their experiences of sexual violence, agency, gender norms, and sexual relationships.**

AK) to create an initial codebook applied to the remaining transcripts, adding new codes as needed. Themes and subthemes concerning the study aims were organized according to the VeneKlasen and Miller empowerment framework.<sup>28</sup> We used several strategies to enhance the credibility of our findings, including double-coding and recoding of transcripts to ensure consistency as well as member checking to confirm emerging themes with interviewing staff.

### Ethical Considerations

Ethical approval was obtained from the National Commission for Science, Technology, and Innovation (NACOSTI) in Kenya. Written informed consent (assent for minors) was sought from all participants. Parental or guardian consent for minors was waived by the ethics board due to the sensitive topics explored, as children might be uncomfortable asking their parents' permission if it may increase their risk of violence and/or affect their ability to seek services.<sup>31</sup> Other protection mechanisms were used to ensure the safety, confidentiality, and privacy of minors, including parental opt-out forms (allowing parents/guardians to object to the participation of their child in the study) and school headteachers witnessing the assent process. In case of violence disclosure, participants were referred to local services for sexual assault survivors. All participants were also provided with written contact information to local child protection and support services, irrespective of violence disclosure or distress.

## RESULTS

The [Figure](#) presents a framework of how the intervention works with girls and boys to prevent different forms of sexual violence based on their experiences and according to the themes identified. Overall, our findings indicate several potential mechanisms of change, including that the intervention helped to strengthen the power to recognize and resist unwanted sexual experiences, communicate sexual consent, and exercise agency among girls and to reduce risky behaviors, avoid "bad" peer circles, and understand and respect sexual consent among boys. Participants' stories also highlighted how the intervention helped them to strengthen their power within—in the form of self-confidence and self-awareness for girls and positive life values and rejection of harmful masculinity norms for boys—and boosted power with their communities (parents, friends, and teachers). Below, we describe girls' and boys'

experiences (using pseudonyms) concerning the different dimensions of power. By including both positive and negative or challenging aspects of the intervention, we reflect on essential implementation elements and end with a summary of participants' suggestions for improvement.

### Power To

Girls described and demonstrated a range of physical skills that they remembered from the curriculum training, such as bodily target areas and using body parts as weapons. They also described psychological skills such as tricks, negotiation, causing a scene to draw attention, de-escalation of potentially violent situations, and consent communication. Recalling situations in which they used curriculum lessons, girls' narratives showed that, by using these skills, they possessed the power to stop sexual assault. Girls described walking in slum alleys to be a particularly vulnerable experience, noting how, for example,

*In the hood now it's even worse, there like you are just passing, sometimes you find the boys seated there, they block your path yes, then they take turns pulling you and you are left hopeless.* —Nuru, female IDI participant

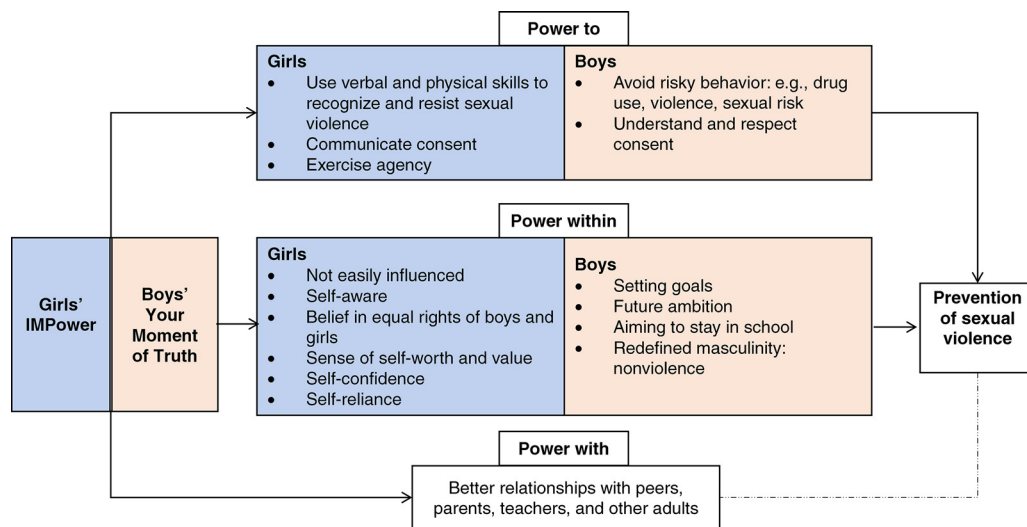
Experiences such as those in the following description aptly demonstrate the use of skills from the curriculum to both recognize and de-escalate such potentially threatening situations.

*You know in the slum, everywhere, there are people sitting everywhere. (. . .) Now the people who sit there, usually smoke "bangi" [marijuana]. When you walk past, you hear them say "niaje" [informal greeting, commonly used by youth] (. . .) if you fail to respond, they all come and stand in front of you. Now, if you act like you want to run away, they will tell you, "We too can run." So you have to stop. So, for me . . . it has happened twice. It was two alleys that I used and experienced something of the sort. I stopped. They said, "Habarĩ"—"mambo" [what's up]. I replied "poa" [cool]. Now, when I stopped, they were startled, they have never seen anyone stop. Most people usually run. I stood. Because there is nowhere you can run to. And I had been told in the [IMPower] training if you notice that someone is big, bigger than you, or if there are many people [potential attackers], you need to first calm down, concentrate, then find out what they want and where they are going (. . .) So I stopped. (. . .) after I responded to all of their questions, they let me be.*—Rhoda, female IDI participant

Girls also told stories of speaking up against unwanted attention and touching, saying that the intervention enhanced their capacity to exercise

**Several potential mechanisms of change were observed, and participants' stories highlighted how the intervention helped them to strengthen their power within.**

**FIGURE.** Themes Identified Related to Potential Mechanisms of Change Through Which the Combined Intervention Curriculums May Empower Girls and Boys to Prevent Sexual Violence



agency to protect and advance their interests in life. They described being firm and forceful and maintaining eye contact whenever they said “no” to someone whose attention was unwelcome.

*I have an uncle who used to come to our place (. . .) he used to pretend it’s playing games with us but instead he is touching one’s breast. So he used to touch me and I became annoyed but there was nothing I could do because he was huge. Now I—this day that we were taught those things by [IMPower], we were taught how you can use your voice and nowadays when he tries to touch me I become harsh, and tell him no with a loud voice, (. . .) with confidence I tell him “Leave me!” and “Do not try to touch me.” — Emily, female FGD participant*

*Before we were taught [IMPower] my “no” was not as firm, it was a weak “no.” So now after learning this we learned how special our bodies are and nobody should mess with them, so now when you say “no” it means exactly that. —Nuru, female IDI participant*

Examples of girls forcefully saying “no,” like the ones illustrated above, were often limited to encounters outside the context of steady relationships. With intimate partners, communicating and negotiating consent was sometimes more vague and complicated, with both boys and girls differentiating between a “hard” and “soft” no.

*Because there is a “no” that shows that one is serious, yes, “NO!” and there are those that say “no” as they*

*draw on the ground, they say “no” [lowers tone]. So, the way I see it, there are two “no’s.” The “no” that shows that you don’t want, serious. You put on a stone face, meaning you don’t want that thing. —Zawadi, IDI female participant*

*I have never been told “no,” but it depends on how that girl says it. When she says it in a low voice, you should know that that “no” means “yes.” But when she stands up and says “No, I don’t want!” in a loud voice, it means that she is serious about rejecting that thing. —Luke, male FGD participant*

Narratives from both male and female participants illustrated a double standard of consent communication in intimate relations, with “no” needing to be qualified, for example, by nonverbal cues versus in unwanted or platonic relations, in which “no” really means “no.” While boys explained that the training had helped them seek and understand sexual consent, they did not automatically interpret a “no” within intimate relationships as simply meaning “no.” For example, boys narrated how it was difficult to believe that a girl was serious about their “no” the first time, but that the training had nonetheless taught them to seek consent and respect (persistent) refusal:

*I wouldn’t believe her at first. If she told me “I don’t want,” I would tell her, “You are just kidding me.” You will eventually give in. But if she refuses, I will respect that, I will tell her it is okay. Because we were*

**Narratives from both male and female participants illustrated a double standard of consent communication in intimate relations, with “no” needing to be qualified.**

*taught by Ujamaa that if a girl says she’s not interested, tell her it’s fine. Leave her alone.* —Faraji, male IDI participant

Stories from male participants further highlighted how the boys’ curriculum works to increase their power to stay away from or quit risky behaviors, such as violence and drugs, that act as risk factors for violence perpetration. After undergoing the training, boys described not only disapproving of violence but also attempting to refrain from it in their daily lives. They further explained how the training had influenced their capacity to make better friendship choices, to leave “bad company” and/or resist peer pressure, and abstain from using drugs altogether. In one IDI, the interviewer asked a participant whether he could talk about a time when he applied what he was taught. The participant responded,

*Bad company. Because I stopped associating myself with, friends who, those friends who, who only think of evil things. And then also. . . using drugs. I mean, I have never indulged in drugs but [the training] has helped me know the dangers, I mean. . . It has helped me learn more about drugs.* —Francis, male IDI participant

The training thus not only encouraged young boys to abstain from vices such as drug use and bad company, but it also appeared to affirm the positive choices that some male participants had already made.

For boys living in slums, resisting peer pressure and choosing to walk away from bad company could be challenging, however, and several male participants described how alternative choices could result in isolation, stigma, and sometimes threats.

*I have lost my friends in school because that day when we were going home, they asked me to join them to do drugs and I refused. They began calling me a snitch because I joined [Ujamaa], but now I am proud (. . .) So even at home, many were angry with me because I refused to do the things that they are doing.* —Nathan, male FDG participant

Despite experiencing some challenges, boys were nonetheless proud of the choices and changes they had made, stating:

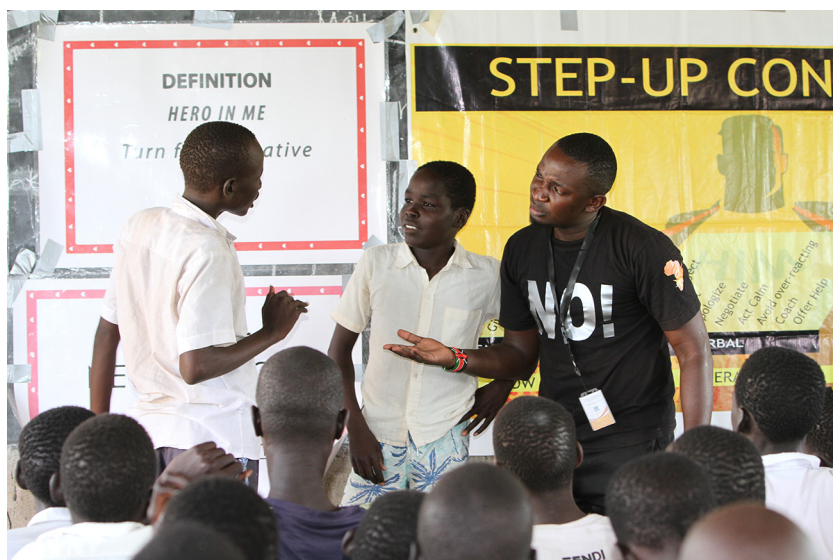
*Not following people. I am not their shadow. When they do something, I do it too. So I do my own things, and life is good.* —Ali, male FDG participant

or acknowledging potential pitfalls which they had avoided,

*I am very happy because if I would not avoid, I would be in a bad place.* —Jesse, male FDG participant

Similarly, applying the learned skills did not come without challenges for girls, as illustrated by one female participant who spoke up against a boy harassing her in class:

**For boys, resisting peer pressure and choosing to walk away from bad company could be challenging, while girls experienced negative responses when standing up for themselves.**



An Ujamaa male instructor leading primary school male beneficiaries in a de-escalation skit. © 2018 Rose Alice/Ujamaa Africa

**Boys described how the curriculum helped to instill positive life values, such as self-discipline, confidence, and having life goals.**

*There are challenges and also good things [with what we learned] because there is a boy in our class, he likes (...) disturbing me, so one day he wanted to touch my breast and I told him, I shouted at him and told him to leave me alone, I shouted at him in front of the class, he felt ashamed in front of them, [and] he began to abuse me in front of them (...) he insulted me with all names (...) I felt bad but [it] also helped me because even those other boys saw I was not that "less" [meaning, not too soft to be intimidated] (...) if they came to me they know I am "fire." And they can't joke with me. —Emily, female FGD participant*

While Emily was verbally harassed for speaking up against the violence that was directed at her, she also described feeling empowered; her act of speaking up deterred future assaults from her classmates. Another female participant, Rhoda, described feeling guilty about drawing public attention to her assailant, which resulted in him being beaten—yet, she acknowledged that the beating was not her fault:

*I was at the bridge, a man walked past me and he touched me—he touched my breasts. So you know, I was there, I picked up a stone, and threw it at him. He was caught by some people who beat him up. But it was not—I mean—as in—I was not happy as he was being beaten up, but I just let it be because it was his mistake. —Rhoda, female IDI participant*

As exemplified in these quotes, girls who described facing repercussions when using self-protection skills from the curriculum did not appear to blame themselves but perceived these skills as useful and empowering despite not always working as intended.

### Power Within

In terms of power within, girls recounted how the curriculum boosted their ambitions and confidence in their human rights and sense of self-worth. They also described having the agency to act and actualize choices and aspirations that they valued, be more self-reliant and assertive, and exercise agency in relation to others.

*You know how boys will—they will—as you walk to the back of the class, they will say things like—"ah wewe! wewe!" ["Hey you! Hey you!" while checking a girl out] (...) I recalled what I was told, that we need to defend at least a fellow girl or help someone when they are in need (...) I stood up and told them that what they were doing was not good, we need to live well like sisters and brothers, and we need to help each other. Then they let her be. —Rhoda, female IDI participant*

**Both boys and girls related how the intervention helped them build better relationships with adults, thereby increasing their "power with."**

Boys described how the curriculum helped to instill positive life values, such as self-discipline, confidence, and having life goals. Boys' narratives further indicated that they disagreed with harmful notions of masculinity, such as sexual aggression, violence, and drug use—emphasizing that a real man should have "self-control," be "responsible," "resist peer pressure," "focus on their education," and "respect" the rights of women and girls.

*You will find that another boy would hit a girl if she did wrong. At times the boys tell me that I am being too soft with the girls and that because I don't hit them when they wrong me, I act like one of them [girls]. This forces me to talk to them and explain that it is not necessary to [use] violence when a girl does something wrong to them because beating up the girl does not resolve anything—it only changes their perception towards you. —Martin, male IDI participant*

However, perceptions on femininity remained largely stereotypical, with boys noting that "good girls" should be "shy, polite, kind, loyal," "clean, humble, and respectful," and "remain [a] virgin," as is evident in the views below by 2 male participants in an FGD.

*According to me, first, a good girl is always shy, polite, kind, loyal. . . .she is supposed to be a virgin because she is a girl not a lady/madam . . . she is supposed to be a virgin, be polite and clean and also be humble and be respectful. —Shem, male FGD participant*

*I'd say, according to me, good girl, as in should behave . . . like . . . like you said "be a good girl" should like. . . . should not be doing some things . . . like . . . bad things. . . things like . . . let's say being a chura [whore] . . . as in "kupenda hio kitu sana" [love sex too much] . . . as in such things. —Charles, male FGD participant*

These findings reveal that while the boys' curriculum may have positively shaped boys' views of nonviolence and positive masculinities, attitudes about gender norms and the roles of women in relationships appear to be complex and deeply ingrained.

### Power With

Both boys and girls told stories of how the intervention helped them build better relationships with adults such as parents, teachers, and guardians, thereby increasing their "power with."

*I mean from that day [when the training began] I stopped being rude. I started respecting people. I mean —let's say when a teacher talks to me, I could respond*

to her/him, unlike how I was before. —Francis, male IDI participant

Boys further described themselves as positively influencing their peers, demonstrating a ripple effect of the training that potentially extends beyond the individual. In so doing, participants inadvertently created environments that could sustain their positive changes.

*My life changed. You find even how I relate to people— You find that I now have friends. I started changing in that I built my relationship with my teachers. Even at home, when my brother is around, we could relate well, we could have a conversation. If there was something we were supposed to do, we would do it together like people who are familiar with each other. —Juma, male IDI participant*

While there were similar stories among girls, we did not identify any concrete examples highlighting how the curriculum led to increased “power with” for girls that, in turn, enabled them to recognize and resist different forms of sexual violence.

**Essential Implementation Elements: Positive Highlights and Potential Improvements Skilled Facilitators and Relevant, Interactive Content**

Both boys and girls emphasized the importance of skilled facilitators, interactive teaching methods, and relevant content. Facilitators were described as being relatable, fun, realistic, and “free,” allowing for self-expression. Girls also highlighted the facilitators’ openness and confidentiality as especially positive, and boys underscored the use of demonstrations with real-life examples in local slang as instrumental.

*It is usually very hard for a boy to express himself when asked a question by the teacher, it is hard to answer the question, it is a must you be in a group of the same gender like now males, so that you can be able to express your points. So when we were there [YMOT training], we were very free. —Mike, male FDG participant*

Participants further described the training as “honest,” “open,” “unique,” and relevant to their daily challenges. Similar to how a male FDG participant noted that “the facilitators were facilitating (...) the reality ... the real thing, something that happens ... around us,” a female participant highlighted how the teaching methods and content of the program felt especially relevant given the prevailing risk of sexual violence in Nairobi slums.

*For me it was enjoyable because the time that we were being taught those teachings there were so many cases of rape, we were hearing that a girl has been raped in school so it was motivating me to come and hear those ways that I can use to defend myself if it was me ... —Daisy, female FGD participant*

**Areas of Improvement**

Participants also discussed several ways to strengthen the intervention curriculums. First, girls and boys alike suggested including additional topics on how to initiate and maintain healthy intimate relationships with partners. For example, Emily, a female FGD participant, stated that the training should focus on “how to manage it (a relationship),” while Francis, a male FGD participant, also explained that:

*... they [the facilitators] should not stop us, they should not tell us that it is wrong to have girlfriends, but they should encourage us on how we can live with girls (...) in a healthy relationship, that you don’t involve yourselves in other things like sex, yes. —Frank, male FDG participant*

Girls pointed out that the subject of contraceptives was missing from the curriculum, and both boys and girls described contraceptives as risky and taboo outside of marriage, highlighting the need to address misperceptions and myths.

*You even find a form 2 girl [approximately 16 years] using family planning and you wonder what for, even the gospel says family planning is for the married, it’s not meant for school-going girls meaning if you use them now as a girl you might end up regretting later in life when the right time comes and you fail to conceive, so it’s not good. —Nuru, female IDI participant*

Challenges such as the lack of female health professionals and difficulty in discussing sexual well-being with health care providers described by one female participant in the quote below also highlighted the need for adolescent-friendly sexual and reproductive health services.

*Where you find your private parts being itchy, you see we were told that if you go the doctor he/she will ask you whether you and your partner used protection and maybe you’ve never even had sex so you will shy away from disclosing it to the doctor about your private parts. (...) around here you find most of these doctors are male and they are not ... My opinion is we get to know its name [of the medication] so that when you’re going to buy you know what you are looking for, you have an*

**Participants noted ways to strengthen the intervention curriculums, such as including information on healthy intimate relationships and sexual and reproductive health services.**

*idea of what to ask for also we should be directed on how to use it, so that when we go a chemist you just buy and go use it. And also prevention measures. —Nuru, female IDI participant*

While some boys reported using condoms and talking more about family planning with their intimate partners following the training, most participants did not discuss safer sex but rather emphasized an aspiration for abstinence to delay or keep off sex completely.

*I have found myself in situations, for instance a girl comes and whines for me and while we dance we get feelings for each other but I tell her that I am not ready to have sex because I know it comes with its consequences like the girl might get pregnant. What would I have done? Again there is HIV/AIDS. Just because of such consequences I choose to back off. —Martin, male IDI participant*

Secondly, boys suggested the need to provide additional support for young men to quit drugs, stating, for example,

*... it is supposed to be like that if you have a problem you can find means to call and tell them am addicted to these what should I do and you help. —Brian, Male IDI participant*

**Boys highlighted the need for community support systems to sustain the changes that they make over time and to also teach boys about their rights.**

They further highlighted the need for community support systems to sustain the changes that young men make over time and to also teach boys about their rights (as boys may, themselves, be victims rather than perpetrators of sexual violence).

*One thing I would like you to see done ... and this thing is always in my mind. Now if, you know most guys who are addicted to drugs are boys who are idle, they are idle, so you find that they start hanging out with people who use drugs. But if this person was busy all the time, it would be nice. So I would love for things to do with sports, try and raise it so that our school can get it (...) you know, those guys, you will find one saying, you know tomorrow I have a game at a certain place, tomorrow I have to be in school by 6. ... so that person will sleep early and he will not do that. Because he will pause to go and exercise a bit and come back. When he returns, it is late. He takes a shower. Now, you see, there is no way that he will interact with drugs. For him to interact with them, he has to really go out of his way. So things to do with sports, I'd love that to be okay. —Mathew, male FGD participant*

*What I would love to see added is the beacon board. That beacon board means ... it means, we as young people ...*

*now like the way girls are talked to like girls ... this beacon board means that we as young boys are treated as young boys, we are taught that yes, as a young boy, these are your rights. —Reuben, male FGD participant*

Third, in terms of delivery techniques, both boys and girls addressed the need for (additional) refresher classes beyond the current 2 (at 6 months and 1 year) stating that they forgot content and skills over time. They also highlighted the importance of confidentiality, with a few girls requesting that boys should not be allowed in their training sessions (there is one mixed-gender session), and some boys wanting private consultations with the facilitators to get personal advice and support.

*Now that you have come again, don't get tired of coming back to our school, because, yes you taught us but you know. ... No one knows it all. ... you have to keep refreshing us ... , So keep coming. —Lucas, male FGD participant*

Finally, participants suggested the expansion of the target population beyond school-going adolescents in urban slums, to reach those out-of-school, including in rural areas. Girls specifically suggested that the training should also target girls who have dropped out of school.

*You forgot to include those girls who have dropped out and also the mothers. (...) you can also talk to them (...) You just look for a meeting point eehhh! —Sandra, female FGD participant*

Additionally, boys noted the importance of involving parents and community elders who can provide more support to young people and parents whom they described to be the "source" of some of the challenges that they face because of stressors that emanate from the home environment or due to parents' ignorance on how to approach the subject of sexuality with their children:

*... we should also include the elders in the community ... so we can know ... so they can know our significance and how they can help us, even those of us who are currently in school.—Charles, male FGD participant*

*Ujamaa should ... also train our parents because it's very hard... There are children who live with... single parents, like ... like me I live with my mother and brother so it's hard to find my mother telling me that ... I stop ... abstain from sex, things like that. They should also train parents about. ... if your child reaches adolescence, you should teach them how these things and these things, how things are ... —Mike, male FGD participant*

## DISCUSSION

This qualitative study sought to understand former participants’ experiences of a school-based sexual violence prevention intervention in Nairobi slums that combines ESD training for girls with positive masculinity and bystander training for boys. To our knowledge, this study is the first qualitative exploration of the potential change processes underlying the intervention and of the challenges that adolescents face when they confront norms of violence and gender. Thus, this study is a critical extension of existing impact evaluations.<sup>16,21,22,25,26,32</sup>

Consistent with the theory of change, our findings show that even a relatively short, focused intervention can, according to former participants, boost their ability to recognize and resist violence and harmful gender norms and enhance their self-confidence and agency to promote safer and healthier behaviors. Girls who had participated in the intervention reported learning tools to negotiate (potentially) threatening situations, mirroring the experiences of girls and young women participating in ESD trainings in Western countries.<sup>17,18,33</sup> A qualitative evaluation with school-aged girls in New Zealand highlighted how an ESD curriculum enhanced girls’ assertiveness and verbal as well as physical skills to resist sexual assault.<sup>18</sup> Based on the experiences shared by girls who participated in the current intervention, the results from our study thus indicate that ESD

approaches can also benefit school-aged girls in low-income, high-risk settings such as Nairobi slum areas.

Our findings add to the growing body of evidence challenging the notion that ESD promotes female victim blaming.<sup>17,18,23,34,35</sup> Female participants described feeling *more* empowered as a result of learning about their rights and using verbal and physical self-defense skills, even in cases when doing so was challenging. In a 2018 review, Hollander<sup>17</sup> stated that such skills remain essential given that “no perpetrator-focused violence prevention strategy has proven effective and where . . . no strategy could ever provide perfect prevention.” While the responsibility for sexual violence prevention falls on the perpetrator, our results confirm that empowering girls’ agency to refuse unwelcome advances and tackle gender norms that perpetuate a sexual double standard, are necessary (though not sufficient) to disrupt the power of perpetrators.<sup>17,23,34</sup>

Working with boys and young men is a core, relatively unique component of the intervention. Consistent with evidence from impact evaluations,<sup>25,26</sup> male participants described rejecting harmful gender stereotypes and expressed lower tolerance for violence, including reducing risky behaviors that often underlie men’s perpetration of GBV, such as substance abuse and delinquency.<sup>36–38</sup> This may be an important contribution of this intervention, given the evidence that many

**Even a relatively short, focused intervention can boost participants’ ability to recognize and resist violence and harmful gender norms, while enhancing their self-confidence and agency.**



An Ujamaa instructor leading a question and answer session in one of the schools. © 2018 Peter Omondi/Ujamaa Africa



**Study findings also elucidate the complexity of changing gender norms and underscore that consent communication in intimate relationships is complex and potentially influenced by gender norms.**

men who perpetrate GBV do so for the first time in their teenage years.<sup>37</sup> In addition, the challenges that some boys experienced while deciding to leave bad company elucidate the complexities associated with quitting gangs in Nairobi slums,<sup>39,40</sup> underscoring the need for post-training support for boys and their communities to ensure that positive life changes are retained.

Our findings also elucidate the complexity of changing gender norms,<sup>41–44</sup> with boys emphasizing (more) support for women's rights while maintaining stereotypical notions, such as female chastity. Furthermore, despite a strong and clear message in the curriculum about sexual consent, narratives from some boys and girls indicate that consent communication in intimate relationships is complex and rooted in norms of token resistance, such as the belief that girls and women say "no" to sex in relationships when they mean "yes."<sup>45</sup> It may be that deeply entrenched gender norms limit the application of curriculum lessons on explicit consent communication to platonic and unwanted relations while affecting consent communication in intimate relations appears to be more difficult. This is an important area to consider for future interventions, especially given that boyfriends account for nearly half of the sexual violence perpetrators against young people aged 10–14 in several of Nairobi's informal settlements.<sup>29</sup> Indeed, research from high-income countries recommends that interventions to improve sexual consent communication among young men should focus more on sexually assertive communication (saying "yes" rather than "no").<sup>46</sup> In addition, one effective ESD program for young women in higher-income settings featured a 3-hour session on relationships and sexuality.<sup>20</sup>

As observed in other successful school-based GBV prevention initiatives, the importance of skilled male and female facilitators who use local slang, know their environment, and serve as role models stood out as a key component.<sup>18,27</sup> The rigorous selection process and training of local facilitators, much longer than that of other interventions,<sup>27</sup> and the careful and continuous training process appear to be critical to building trust among and between facilitators and participants.

Finally, we identified several areas for improvement to optimize intervention design and implementation. These include needs to (1) expand the content on sexual and reproductive health and rights (especially regarding debunking myths on contraceptives) and build the knowledge and capacity of facilitators to understand and deliver comprehensive sexuality education to participants;

(2) address boys' own experiences of sexual violence and other forms of GBV, a reality for many young men and a risk factor for future perpetration<sup>15,38</sup>; and (3) ensure long-term support after training. In particular, the findings highlight the need to target adolescents' broader social environments, given that GBV is a complex phenomenon that is shaped by multilevel forces.<sup>14</sup> The present intervention rests on the individual level, and while it appears to help build participants' "power with" (e.g., via positive adult relationships), more conscious efforts are needed to directly target communities (parents, teachers, and out-of-school youth) and to enhance and emphasize positive behaviors such as sports as alternatives to risky practices. Many of the underlying risk factors for GBV, including child abuse, witnessing violence in the home, and the socialization of inequitable gender norms, have their roots in adolescents' homes and communities.<sup>15,38</sup> Although building individual skills and challenging gender norms is an integral strategy to end GBV,<sup>15,24,37</sup> global evidence indicates the need to integrate this method into multicomponent approaches to achieve sustainable change.<sup>15,24,27,41</sup>

## Limitations

This qualitative evaluation aimed to explore what participants remembered about the intervention at least 1 year after implementation. While we found that participants did recall the intervention skills and discussions, owing to the retrospective nature of the study, we cannot draw conclusions about the impact of the intervention or treat participants' experiences as reflective of all girls and boys exposed to the program. It is also possible that the use of interviewers from the same organization that implemented the program led to socially desirable answers; however, it was crucial that the interviewers knew the intervention as well as local communities and slang to gain participants' trust. We addressed this potential social desirability bias via careful training of the interviewers to solicit both potentially positive and negative experiences, emphasizing the need to learn about challenges encountered by participants. The credibility of our findings is strengthened by the use of a theoretical framework, double-coding of transcripts, and the verification of emerging themes and interpretations with the interviewers.

Despite its limitations, the present study adds novel insights into potential mechanisms of change underlying the effects of interventions aimed at preventing sexual violence in low-income, high-risk communities.

## CONCLUSION

This study fills an important gap in the literature by highlighting participants' experiences with an empowerment-based, behavioral intervention aimed at preventing sexual violence against adolescents in slums, and by contributing to the call for increased evidence on the intervention<sup>27</sup> beyond previous impact evaluations.<sup>16,21,22,25,26,32</sup> Our findings suggest several potential pathways through which this relatively short-term intervention can prevent sexual violence by teaching girls skills to recognize and resist harmful situations, and by working with boys to promote positive, nonviolent masculinities and choices. Our analysis also points to several areas of improvement, including the need to incorporate multi-level support structures to target the root causes of sexual violence and other forms of GBV and enable long-term change and sustainable positive behaviors beyond individual skills, which are not sufficient in challenging high-risk environments. Longitudinal mixed-methods studies are needed to unpack how these processes play out over time. In the meantime, our study illustrates how an intervention aimed at both girls and boys early in the life-course can help address the prevailing high rates of sexual violence in Kenya and other low-income settings, an impact made ever more important by how GBV has increased as an indirect result of the COVID-19 pandemic.<sup>47</sup>

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ORIGINAL ARTICLE

# Income Inequalities in Hepatitis B Vaccination and Willingness to Pay Among Women of Reproductive Age in Hanoi, Vietnam

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## Key Findings

- Most women were willing to pay for the hepatitis B virus (HBV) vaccine and there was no difference in willingness to pay for HBV vaccination between income quintiles.
- The amount willing to pay for the vaccine was different between income levels for prices higher than US\$4.50.

## Key Implications

- Because women from the lowest income quintile had the lowest awareness of the HBV vaccine, efforts on education and awareness of HBV and the vaccine should focus on low-income women.
- Given the high vertical transmission rates of HBV infection, policy makers should prioritize vaccinating women of reproductive age as well as newborns.
- In light of the finding that higher-income women were willing to pay more for the vaccine, adopting a sliding-scale payment system may mitigate challenges with funding and provide opportunities for equitable vaccine access.

## ABSTRACT

**Background:** Hepatitis B virus (HBV) infection is endemic in Vietnam and can be transmitted from mother to child. Vaccination of women of reproductive age (WRA) can reduce this transmission. Because adult HBV vaccination in Vietnam follows a fee-for-service model, research is needed to determine the effect of household income on willingness to pay (WTP) to ensure equitable access to the vaccine.

**Methods:** A cross-sectional study was performed in Hanoi, Vietnam, in April 2018, among WRA. Questionnaires were administered to assess household income, HBV history, vaccination status, vaccine awareness, and WTP for the vaccine. Multivariable logistic and interval regression were performed to assess the impact of household income on WTP for HBV vaccine.

**Results:** This study found that 62.3% of all participants were willing to pay for the HBV vaccine with no differences in WTP across income quintiles. There were significant differences among household income levels in awareness of HBV vaccination and WTP amount beyond US\$4.50 with the lowest awareness and WTP amount among women from the lowest income quintiles.

**Conclusions:** Our data suggest the need to subsidize HBV vaccination for low-income women to ensure more equitable access to HBV vaccination. We propose that a sliding-scale payment method may be an effective strategy in light of limited funding to support vaccination expansion. An education campaign focusing on lower-income households should also be implemented in conjunction with this program. Further research would be required to evaluate consumer acceptance of this payment scheme and to develop an appropriate sliding scale to maximize vaccine uptake.

## INTRODUCTION

Hepatitis B virus (HBV) infection can cause both acute and chronic liver disease. In a small percentage of patients whose immune systems are unable to clear the virus, particularly children aged younger than 6 years old, HBV infection becomes chronic, often leading to cirrhosis and hepatocellular carcinoma.<sup>1</sup> Though increasing availability of HBV vaccination has decreased morbidity and mortality, as of 2015, the World Health Organization (WHO) estimated that 257 million people worldwide are still living with chronic HBV infection with approximately 887,000 annual deaths due to cirrhosis or hepatocellular carcinoma.<sup>1</sup>

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Vietnam has one of the highest rates of HBV infection in the world with 8.8%–19.0% of the general population estimated to be hepatitis B surface antigen-positive (HBsAg-positive).<sup>2–5</sup> The disease is primarily vertically transmitted from mother to child during labor or less commonly, in-utero.<sup>6,7</sup> If infants do not receive HBV immunoglobulin and vaccination at birth, mothers who are HBsAg-positive may transmit HBV infection at rates up to 90%.<sup>8</sup> It is estimated that at least 50% of HBV-positive individuals acquired their infection perinatally or in early childhood.<sup>9</sup> Horizontal transmission of HBV and disease incidence in adulthood is less clearly studied though data have suggested that extrafamilial horizontal transmission is likely high.<sup>10</sup>

Especially in endemic countries, HBV vaccination of neonates is an effective strategy to decrease transmission.<sup>11</sup> In 2006, Vietnam began implementing widespread neonatal vaccination, resulting in a decrease in children who were HBsAg-positive from 3.62% to less than 2% between study periods 2000–2003 and 2008–2011.<sup>12</sup> However, a national study in 2014 found that only 62.8% of children received the birth dose—far from universal coverage.<sup>12</sup> As such, additional approaches should be considered to further decrease transmission rates.

A promising strategy that has been proposed to decrease rates of HBV infection transmission and improve disease control is vaccination of women of reproductive age (WRA).<sup>13</sup> During pregnancy, women are vaccinated to confer immunity to neonates,<sup>14</sup> given the risk of horizontal transmission in adulthood. However, there is a lack of randomized controlled trials on the efficacy of HBV vaccination for WRA to prevent maternal infection and consequently neonatal infection.

Currently, HBV vaccination among adults in Vietnam follows a fee-for-service model, which has worsened health disparities across socioeconomic statuses.<sup>15</sup> Indeed, in other countries that follow a similar model, including China and South Korea, income was found to be the largest contributor to inequalities in HBV vaccination.<sup>16,17</sup> Studies examining the effect of income on HBV vaccination have not been conducted in Vietnam. This study aims to fill this gap by elucidating the role of household income on WRA's willingness to pay (WTP) and the amount they are willing to pay for HBV vaccination in an effort to pursue a more optimized payment scheme and equitable access across all income groups.

**HBV vaccination among adults in Vietnam follows a fee-for-service model, which has worsened health disparities across socioeconomic statuses.**

## METHODS

### Study Design and Sample

We performed a cross-sectional study in Dong Da (urban setting) and Ba Vi (rural setting) districts, Hanoi, Vietnam, in April 2018. In each district, we randomly selected 2 communes—Trung Tu and Phuong Lien communes in Dong Da district and Thuy An and Phong Van communes in Ba Vi district.

Women were invited to participate in this study if they were pregnant or had a child aged younger than 12 months. Other inclusion criteria were residence in the study setting for at least 6 months and willingness to participate in the study. Women were excluded if they had any cognitive impairment or disabilities that might affect their ability to understand and answer the questionnaire. A list of all eligible women in the study sites was compiled with the support of local health authorities. Then, participants were randomly selected using computer software and contacted via phone. If they refused to participate, we invited the next individual on the list. A total of 764 women were contacted to enroll in the study, and no one refused. However, data of only 695 women were included in the study because some participants did not report monthly household income (response rate 91.0%).

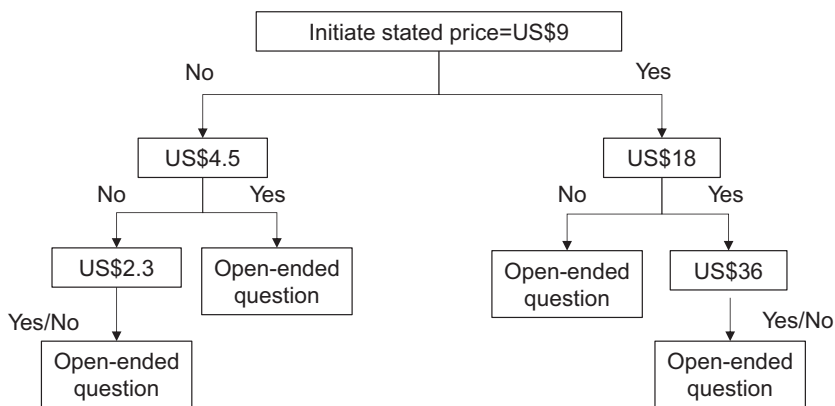
### Ethics Approval

The protocol of this study was reviewed and approved by the Ethics Committee of Hanoi Medical University (Code number:184/HMU-IRB; November 14, 2015). After hearing a one-on-one explanation of the study by trained health care workers at the Hanoi Medical University, all participants gave their verbal informed consent before participating in the study, acknowledging full understanding of the study's purpose, their rights to withdraw from the study at any time, and protection of confidentiality.

### Data Collection and Measurement

Face-to-face interviews were conducted by medical students and health care workers at Hanoi Medical University in 2018. These data collectors were trained extensively regarding study purpose, communication, and interview skills. Moreover, they participated in piloting the structured questionnaire to ensure the consistency of the data collection process. Each interview lasted 20–25 minutes. The questionnaire included questions regarding the following:

**FIGURE 1.** Bidding Process Used During Interviews With Women of Reproductive Age to Determine Willingness to Pay for One Dose of Hepatitis B Vaccine, Hanoi, Vietnam



- Sociodemographic characteristics. We asked participants to report their age, education level, occupation, number of children, and residential setting (urban/rural). Household economic status was divided into 5 quintiles based on total household monthly income.
- HBV history, vaccination awareness, and uptake. We collected information on history of HBV infection, awareness of HBV vaccine, source of general vaccination knowledge, vaccination status against HBV, and willingness to pay for HBV vaccines in the future.
- Willingness to pay for HBV vaccine. We applied a contingent valuation approach through double-bounded dichotomous choice to elicit WTP and the amount participants were willing to pay for 1 dose of HBV vaccine. The bidding process is illustrated in Figure 1. We first informed the women about the HBV vaccine and its effects on HBV prevention. Then, we asked them to state their willingness to pay for the vaccine. We used 200,000 VND (approximately US\$9) for a single vaccine as a first bid. This price was selected based on the actual price for the on-demand vaccination service. Initially, we asked participants about their WTP for the first bid. If they answered “no,” they were asked whether they were willing to pay US\$4.50. If they had answered “yes,” to the first bid, they were asked about their willingness to pay US \$18. At the end of the process, participants were asked the maximum amount they were willing to pay for 1 dose of the HBV vaccine.

### Statistical Analysis

The data were analyzed by STATA version 14.0. Chi-squared and Kruska-Wallis tests were used to examine the difference in various characteristics among 5 household income quintiles. The differences in WTP by income quintile were explored by plotting the percentage of each quintile that was willing to pay a particular value or higher. As the value increases, the curves fall to reflect decreasing proportions of participants willing to pay higher prices. Lorenz curves and Gini coefficients were used to measure the extent of inequality based on the history of HBV vaccination and WTP for the HBV vaccine.

Multivariable logistic and interval regression were then performed to examine the factors associated with WTP and the maximum amount participants were willing to pay for 1 dose of HBV vaccine. These regression techniques were used along with stepwise forward selection strategies. A *P*-value <.2 was employed for variable selection. Statistical significance was determined if the *P*-value <.05.

### RESULTS

Table 1 lists these findings with Q1 corresponding to the quintile with the lowest income and Q5 the highest income. Of 695 participants, the mean age and household monthly income were 27 years and US\$663.20, respectively. Household monthly income, residential setting (urban versus rural), and education level were significantly different between income quintiles (*P*<.05). The lowest quintile had the largest percentage of rural residents, as well as the largest percentage of participants with high school and lower levels of education.

**TABLE 1.** Sociodemographic Characteristics of Participants in Study of Effects of Household Income on Willingness to Pay for Hepatitis B Vaccine, Hanoi, Vietnam, (n=695)

	Income Quintiles					Total	P Value
	Q1	Q2	Q3	Q4	Q5		
Total, n (%)	124 (17.8)	211 (30.4)	131 (18.9)	120 (17.3)	109 (15.7)	695 (100.0)	
Mean age, years	26.8	26.2	28.1	27.6	27.1	27.0	.06
Mean household monthly income, US\$	187.0	389.6	611.6	830.0	1612.8	663.2	<.01 <sup>a</sup>
Married, n (%)	120 (96.8)	204 (97.1)	130 (100.0)	117 (98.3)	108 (100.0)	679 (98.3)	.12
Living in rural area, n (%)	107 (90.7)	151 (72.6)	42 (32.6)	25 (21.4)	14 (12.8)	339 (49.8)	<.01 <sup>a</sup>
Having any children, n (%)	119 (96.0)	192 (91.0)	119 (90.8)	110 (91.7)	101 (92.7)	641 (92.2)	.51
Education, n (%)							
≤ Secondary	48 (38.7)	29 (13.7)	10 (7.6)	5 (4.2)	2 (1.8)	94 (13.5)	<.01 <sup>a</sup>
High	51 (41.1)	85 (40.3)	40 (30.5)	20 (16.7)	19 (17.4)	215 (30.9)	
Vocational training	13 (10.5)	52 (24.6)	27 (20.6)	31 (25.8)	16 (14.7)	139 (20.0)	
University	12 (9.7)	45 (21.3)	54 (41.2)	64 (53.3)	72 (66.1)	247 (35.5)	

<sup>a</sup> Significant at  $P < .05$ .

### The percentage of women who were aware of the HBV vaccine was significantly different across quintiles.

Table 2 shows that 3.2% of participants had a history of HBV infection. The percentage of women who were aware of the HBV vaccine was significantly different across quintiles with the lowest rates in Q1 (86.3%) and the highest in Q5 (98.2%) ( $P < 0.5$ ). Moreover, the percentage of women who had previously received the HBV vaccine was significantly different between quintiles with the lowest rates in Q1 (18.6%) and higher rates in Q5 (40.4%) ( $P < 0.05$ ). Only 1.1% injected 3 doses of vaccine during the pregnancy. People with higher income were more likely to be injected with a higher number of doses ( $P < 0.05$ ). Among all quintiles, 62.3% of women were willing to pay for the HBV vaccine, with a mean maximum amount of US\$10.30. No significant difference was found between quintile groups regarding WTP and the maximum amount.

The Lorenz curves in Figure 2 show that the distribution of previous HBV vaccination was not equalized (Gini coefficient=0.13) when household income was taken into account. On the other hand, the distribution of WTP for the HBV vaccine was approximately equalized (Gini coefficients=0.02) among the various household income levels.

Figure 3 shows the cumulative percentage of participants willing to pay various amounts for HBV vaccination by household income quintiles. Differences between Q1 and Q5 were significant at US\$9, \$18, and \$36.

Table 3 shows that 37.7% of women were not willing to pay for the vaccine. The major reason was “not necessary” (45.2%), following by “no risk of HBV infection” (18.4%), “others” (17.2%), and “already injected” (16.5%). Significant differences between people who were and were not willing to pay for the vaccine were found in education levels; awareness of HBV vaccine; and using school, radio/loudspeaker, Internet, and friends/relatives as sources of information ( $P < .05$ ).

Table 4 reveals that income quintile groups (except Q2 for WTP) were not independent factors associated with previous HBV vaccination, WTP, and the amount willing to pay for HBV vaccine after adjusting for other confounders. Women with university degrees, without spouse/partner, who received vaccine information from newspapers/magazines, and who had heard about HBV vaccination were more likely to have been previously vaccinated against HBV. The source of vaccination information was found to be associated with WTP for the HBV vaccine. Education, marital status, and source of information were associated with the maximum amount participants were willing to pay.

## DISCUSSION

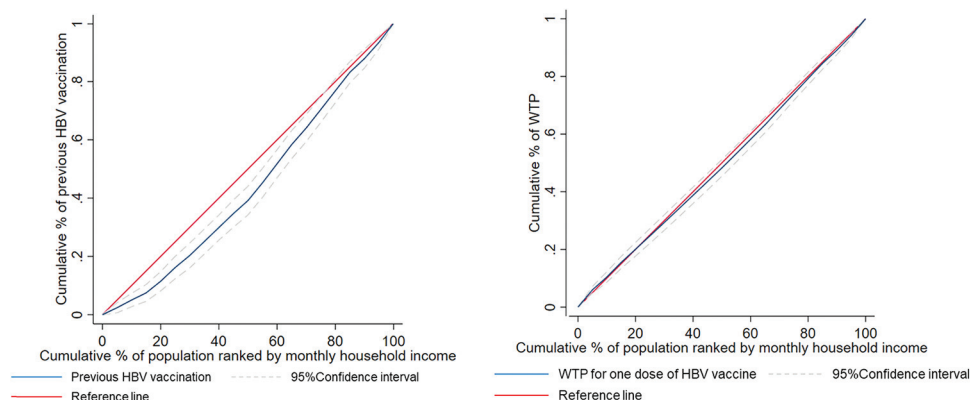
Overall, we found that 62.3% of all study participants were willing to pay for the HBV vaccine, a higher rate than previous studies among Malaysians

**TABLE 2.** Hepatitis B Vaccination Awareness, Uptake, and Willingness to Pay Among Participants in Study of Effects of Household Income on Willingness to Pay for the Vaccine, Hanoi, Vietnam, (n=695)

Characteristics	Income Quintiles					Total	P Value
	Q1	Q2	Q3	Q4	Q5		
History of Hepatitis B virus infection, n (%)	8 (6.5)	7 (3.3)	2 (2.3)	2 (1.7)	2 (1.8)	22 (3.2)	.19
Awareness of Hepatitis B vaccine, n (%)	107 (86.3)	202 (95.7)	121 (92.4)	116 (96.7)	107 (98.2)	653 (94.0)	<.01 <sup>a</sup>
<b>Source of general vaccination information, n (%)</b>							
School	6 (4.8)	11 (5.2)	6 (4.6)	5 (4.2)	8 (7.3)	36 (5.2)	.84
Television	30 (24.2)	70 (33.2)	57 (43.5)	57 (47.5)	43 (39.5)	257 (37.0)	<.01 <sup>a</sup>
Radio or loudspeaker	45 (36.3)	81 (38.4)	23 (17.6)	27 (22.5)	17 (15.6)	193 (27.8)	<.01 <sup>a</sup>
Newspapers/magazines	16 (12.9)	36 (17.1)	41 (31.3)	38 (31.7)	28 (25.7)	159 (22.9)	<.01 <sup>a</sup>
Internet	35 (28.2)	95 (45.0)	82 (62.6)	81 (67.5)	83 (76.2)	376 (54.1)	<.01 <sup>a</sup>
Health workers	79 (63.7)	129 (61.1)	78 (59.5)	51 (42.5)	51 (46.8)	388 (55.8)	<.01 <sup>a</sup>
Friends and relatives	6 (4.8)	18 (8.5)	32 (24.4)	23 (19.2)	30 (27.5)	109 (15.7)	<.01 <sup>a</sup>
Other	8 (6.5)	13 (6.2)	2 (1.5)	5 (4.2)	2 (1.8)	30 (4.3)	.13
History of Hepatitis B vaccination, n (%)	23 (18.6)	71 (33.7)	58 (44.3)	53 (44.2)	44 (40.4)	249 (35.8)	<.01 <sup>a</sup>
Willingness to pay for Hepatitis B vaccine, n (%)	78 (62.9)	123 (58.6)	81 (61.8)	80 (67.2)	70 (64.2)	432 (62.3)	.61
<b>Maximum amount willing to pay for Hepatitis B vaccine</b>							
Mean, US\$	8.0	9.8	9.9	11.0	13.2	10.3	.09
Median, US\$	5.3	6.4	8.5	8.5	8.5	8.5	.09

<sup>a</sup> Significant at P<.05.

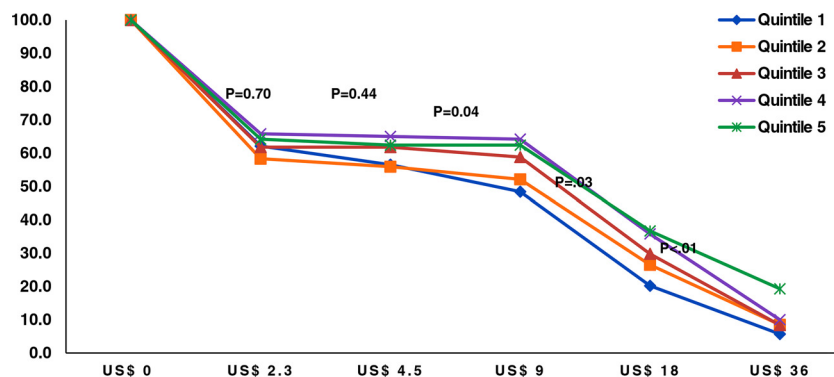
**FIGURE 2.** (a) Lorenz Curve Showing History of Hepatitis B Vaccination Among Women of Reproductive Age, Hanoi, Vietnam, by Monthly Household Income; (b) Lorenz Curve Showing Willingness to Pay for One Dose of Hepatitis B Vaccine Among Women of Reproductive Age, Hanoi, Vietnam, by Monthly Household Income



Abbreviations: HBV, hepatitis B virus; WTP, willingness to pay.



**FIGURE 3.** Cumulative Percentage of Women Willing to Pay Various Amounts for Hepatitis B Vaccine, Hanoi, Vietnam, by Household Income Quintile



**From a cost-effectiveness standpoint, the benefits of vaccinating WRA extends beyond the individual vaccinated to her future children as well.**

**These data demonstrate that the current market price of the HBV vaccine is inaccessible to the majority of low-income women, suggesting the need to subsidize HBV vaccinations for women from low-income households.**

(37.5%) and Chinese Americans in New York City (53.2%).<sup>18,19</sup> Women across the income spectrum were willing to pay for HBV vaccination at similar rates. Among those willing to pay, the mean maximum was US\$10.30, over twice the amount found by a similar study in 2016 (108,600 VND, US \$4.73).<sup>13</sup> When participants were asked how much they were willing to pay, differences between income levels emerged for maximum prices greater than US\$4.50. We found that 50% of women from Q4 and Q5 were willing to pay a maximum price between US\$9–US\$18, whereas 50% of women from Q1 were willing to pay less than US\$9. When the WTP percentage is increased to 60%, women from Q1 were willing to pay between US\$2.30–US\$4.50 and Q5 between US\$9–US\$18.

These data demonstrate that the current market price of the HBV vaccine (approximately US \$9) is inaccessible to the majority of low-income women, suggesting the need to subsidize HBV vaccinations for women from low-income households. Ideally, these subsidizations should be funded through national grants, which is typically more stable than foreign aid—though foreign aid may be considered for short-term assistance. However, due to limitations with both of these funding options, a possible solution could be to create a sliding scale for HBV vaccination based on household income in which high-income women pay an amount greater than the market price to subsidize the cost for low-income women. Given that the average maximum price participants were willing to pay was greater than the current market price, it appears that such a vaccination program among WRA could be financed by the high-

income recipients of the vaccine alone. However, further research would be required to evaluate consumer acceptance of this payment scheme and to develop an appropriate sliding scale to maximize vaccine uptake.

Because HBV is primarily transmitted vertically in Vietnam, we believe that increasing vaccination among WRA would work synergistically with current neonatal vaccination efforts to decrease transmission and confer immunity. This effort is especially important for women in rural or mountainous areas, whereas many as half may deliver their neonates at home,<sup>20</sup> and neonatal vaccination may not be immediately available. With limited resources to dedicate toward a widespread HBV vaccination campaign, the government should prioritize vaccinating WRA given their high risk of disease transmission. From a cost-effectiveness standpoint, the benefits of vaccinating WRA extend beyond the individual vaccinated to all of her future children as well.

At the same time, this vaccination strategy should be paired with an education campaign, given that improved knowledge has previously been demonstrated to be associated with higher WTP.<sup>21</sup> In particular, our data found that women from Q1 had the lowest level of awareness, suggesting that future campaigns should especially focus on low-income women. Information should be distributed through radio programs and over loudspeakers, which are more readily available to all women. Indeed, we found that mediums requiring greater financial investment, such as television, magazines/newspapers, and the Internet, were significantly less used among women in the lowest-income quintiles. Moreover, some studies have found a higher

**TABLE 3.** Characteristics of Participants Who Were and Were Not Willing to Pay for Hepatitis B Vaccines and Reasons for Not Willing to Pay

Characteristics	Not Willing to Pay	Willing to Pay	P Value
<b>Total, n (%)</b>	261 (37.7)	432 (62.3)	
<b>Age, mean (SD), years</b>	27.2 (6.8)	27.0 (5.0)	.92
<b>Household monthly income, mean (SD), US\$</b>	642.8 (550.9)	676.2 (548.6)	.36
<b>Married, n (%)</b>	258 (98.9)	419 (97.9)	.35
<b>Living in rural area, n (%)</b>	122 (48.8)	215 (50.1)	.74
<b>Having any children, n (%)</b>	242 (92.7)	399 (92.4)	.86
<b>Education, n (%)</b>			
≤ Secondary	45 (17.2)	49 (11.3)	.03
High	72 (27.6)	143 (33.1)	
Vocational training	43 (16.5)	94 (21.8)	
University	101 (38.7)	146 (33.8)	
<b>History of hepatitis B vaccine, n (%)</b>	10 (3.9)	12 (2.8)	.44
<b>Awareness of hepatitis B vaccine, n (%)</b>	239 (91.6)	413 (95.6)	.03
<b>Source of general vaccination information, n (%)</b>			
School	20 (7.7)	16 (3.7)	.02
Television	86 (33.0)	171 (39.6)	.08
Radio or loudspeaker	61 (23.4)	132 (30.6)	.04
Newspapers/magazines	57 (21.8)	102 (23.6)	.59
Internet	125 (47.9)	251 (58.1)	<.01
Health workers	134 (51.3)	253 (58.6)	.06
Friends and relatives	31 (11.9)	78 (18.1)	.03
Other	9 (3.5)	20 (4.6)	.45
<b>History of hepatitis B vaccination, n (%)</b>	91 (34.9)	158 (36.6)	.65
<b>Reasons for not being willing to pay</b>			
Not necessary	118 (45.2)		
Unaffordable	7 (2.7)		
No risk of hepatitis B virus infection	48 (18.4)		
Already injected	43 (16.5)		
Others	45 (17.2)		

Abbreviation: SD, standard deviation.

WTP for vaccines against chronic disease with high morbidity and mortality,<sup>22</sup> suggesting that future education campaigns should not only focus on raising awareness of HBV vaccination but also provide further education on HBV's related morbidity and mortality.

The cost of treating HBV and its complications in Vietnam is estimated to total US\$4.4 billion in 2008 alone.<sup>23</sup> Given that HBV prevalence

is projected to increase from 6.4 million cases in 1990 to 8.0 million in 2025,<sup>24</sup> this amount will likely be greater in the coming years. The cost-effectiveness of universal newborn HBV vaccination has been well-studied,<sup>25</sup> and our proposed strategy would operate synergistically to reduce vertical transmission to neonates at a minimal cost to the Vietnamese government. Aside from an initial investment in research,

**TABLE 4.** Factors Associated With Willingness to Pay for HBV Vaccine and Maximum Amount

Characteristic	Previous HBV vaccination		WTP for HBV vaccine		Amount of WTP for one dose of HBV vaccine	
	OR	95%CI	OR	95%CI	Coef.	95%CI
<b>Education</b>						
≤ Secondary	ref		ref		ref	
High	0.99	0.52, 1.88	1.55	0.89, 2.69	6.44 <sup>a</sup>	1.95, 10.93
Vocational training	1.30	0.66, 2.58	1.51	0.81, 2.81	6.62 <sup>a</sup>	1.64, 11.61
University	2.29 <sup>a</sup>	1.16, 4.51	0.89	0.49, 1.62	3.17	-1.65, 7.99
<b>Household monthly income quintiles</b>						
Q1	ref		ref		ref	
Q2	1.73	0.97, 3.10	0.58 <sup>a</sup>	0.35, 0.98	-1.14	-5.24, 2.96
Q3	1.87	0.96, 3.65	0.73	0.40, 1.32	0.36	-4.36, 5.08
Q4	1.56	0.78, 3.11	1.08	0.57, 2.05	1.87	-3.05, 6.80
Q5	1.28	0.62, 2.63	0.89	0.46, 1.70	3.93	-1.19, 9.05
<b>Marital status</b>						
Having spouse/partner	ref		ref		ref	
Other	4.04 <sup>a</sup>	1.06, 15.5	4.69	0.92, 23.89	12.29 <sup>a</sup>	1.76, 22.83
<b>Living area</b>						
Urban area	ref					
Rural area	0.70	0.46, 1.08				
<b>Source of general vaccination information</b>						
School (Yes vs. No-ref)			0.33 <sup>a</sup>	0.16, 0.69	-5.00	-11.03, 1.03
Magazine/Newspaper (Yes vs. No-ref)	1.49 <sup>a</sup>	1.01, 2.20				
Listening to radio or loudspeaker (Yes vs. No-ref)			1.46	0.99, 2.16	3.07 <sup>a</sup>	0.03, 6.11
Internet (Yes vs. No-ref)			1.57 <sup>a</sup>	1.09, 2.28		
Medical staff (Yes vs. No-ref)			1.43 <sup>a</sup>	1.01, 2.01		
Friends and relatives (Yes vs. No-ref)			1.55	0.96, 2.52	3.21	-0.52, 6.94
<b>Ever heard about HBV vaccine</b>						
No	ref		ref			
Yes	4.54 <sup>a</sup>	1.33, 15.49	1.65	0.79, 3.44		

Abbreviations: Coeff, coefficient; CI, confidence interval; HBV, hepatitis B virus, OR, odds ratio; WTP, willingness to pay.

<sup>a</sup> $P < .05$ .

implementation, and education, this vaccination program would be financially self-sustaining, a step toward more equitable health outcomes for decades to come.

### Limitations

Limitations of this study include its cross-sectional nature, which only allowed for us to test for association without insight into

causative relationships—though we were able to correlate some results with a previous study conducted in the same districts in 2016. Another limitation is that this study involves self-reporting, which could predispose participants to recall or social desirability bias. Moreover, while participants do not represent all WRA in Vietnam, we did implement random sampling from both urban and rural environments, ensuring that participants from a variety of backgrounds were included in this survey.

**Author contributions:** XTTL, NTTN, HTL, TTTD, THN, HLTN led this research, including proposal write up, and designed the instrument. XTTL, NTTN, HTL collected and analyzed data. XTTL, NTTN, BXT, CAL, CSSH, RCMH discussed data and wrote the manuscript. All authors read and approved the final manuscript.

**Competing interests:** None declared.

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ORIGINAL ARTICLE

# Mapping the Antimicrobial Supply Chain in Bangladesh: A Scoping-Review-Based Ecological Assessment Approach

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## Key Messages

- This framework proposes a novel method for antimicrobial medicines supply chain mapping using 16 indicators with a focus on access and use in the context of antimicrobial resistance containment.
- Countries, especially low- and middle-income countries, can apply this framework to rapidly assess supply chain gaps and to identify areas for targeted interventions on access and use of antimicrobials.
- Bangladesh's antimicrobial supply chain was profiled, identifying strengths in ensuring access to antimicrobials and gaps in use and regulation.

## Key Implications

- Policy makers, program managers, and Antimicrobial Resistance Containment One-Health Secretariat committees could use this framework to perform a rapid situational analysis (strength, weakness, opportunities, and threats) of the antimicrobial/antibiotic supply chain for human and veterinary medicines at the national level to identify target areas for intervention. This can include policy interventions via restrictions on licensing of certain antibiotics of critical importance to humans, as Bangladesh is doing with colistin. Through an analysis of the brief market dynamics presented here, program managers can make assessments of supply risks.
- Regulators could use the mapping to identify geographical regions with high pharmacy densities for more targeted inspections for medicines quality assurance.
- One-Health Secretariat committees could use professional densities numbers to advocate for more training and capacity building for pharmacists and veterinarians.

## ABSTRACT

**Introduction:** Maintaining access to antimicrobials while preventing misuse is essential to combating the threat of antimicrobial resistance (AMR). The study objectives are to propose a framework of 16 indicators that can be used at the national level to assess the capacity to ensure access and curtail inappropriate use and to profile the antimicrobial supply chain for Bangladesh.

**Methods:** Using a framework based on a rational construct, we assessed the antimicrobial supply chain of Bangladesh, with a focus on key players and products using a scoping review to obtain and describe information on 16 indicators. With players, we mapped linkages, manufacturers' production capacity, and ownership, among others, and demand point characteristics—pharmacy and pharmacist density, pharmacy/medicine outlets dispersion, veterinary clinic/hospitals, veterinarians' density, product quality, and regulation. We assessed product characteristics including listing on the World Health Organization (WHO) Model Essential Medicines List (EML) and WHO Access, Watch, and Reserve (AWaRe) classification of the major (top 10) antibiotics for human use; the proportion of medically important antimicrobials (MIAs) in veterinary use; and pricing. Production capacity and price controls were used to assess access and listing on the WHO EML, AWaRe/MIA classification, and a calculated pharmacy-to-pharmacist ratio to assess use.

**Results:** Bangladesh has a high (98%) local antibiotic production capacity with pricing controls indicating the ability to ensure access. The presence of a high proportion of medicine outlets not under the control of pharmacists (4:1) and the high percentages of WHO Watch (54%) and MIAs (90%) of the major antibiotics are indicators of possible misuse.

**Discussion:** Most of the data used in the framework were publicly available. Bangladesh has the capacity to ensure access but needs to strengthen its ability to regulate the quality of antimicrobials and prevent their inappropriate use through antimicrobial stewardship at the community (medicine outlet) levels to check AMR. There may also be a need for more regulations on licensing of MIAs.

## INTRODUCTION

Antimicrobial resistance (AMR)—the ability of microorganisms to withstand treatment with therapeutic doses of an antimicrobial agent—is a public health emergency requiring concerted global multisectoral strategies aimed at containment through curbing inappropriate use while ensuring access.<sup>1–3</sup> The inappropriate use of antimicrobials includes practices such as self-medication, sale of antimicrobials without prescription, noncompliance with prescribed doses, prescribing

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without reference to sensitivity tests, use of substandard and falsified antimicrobials, and non-therapeutic uses for growth promotion or prophylaxis of medically important antimicrobials (MIAs) in livestock and contributes to AMR in public health.<sup>4–6</sup> Access to medicines within health systems is a 5-dimensional concept comprising availability, affordability, geographical accessibility, acceptability or rational selection and use, and quality.<sup>7</sup> Balancing access with use means that populations get the antimicrobials they need (evidence-based prescribing), when they need them (appropriate use), at the right price, at the right place, and of the right quality. A holistic assessment of national antimicrobial supply chains can help simultaneously identify challenges with access and use.

Maintaining access to antimicrobials through the pharmaceutical supply chain—the network of players and processes through which medical products move from the source to the end-user—needs to be balanced against inappropriate use. For most countries, there are guidelines for medicine use, including formularies and standard treatment guidelines. The World Health Organization (WHO) maintains the Model Essential Medicines List (EML) as a guide for the appropriate selection and use of medicines by nations.<sup>8</sup> Additionally, it introduced the Access, Watch, and Reserve (AWaRe) categorization, which groups antibiotics according to their potential to induce resistance and clinical utility. With veterinary uses, measures to reduce AMR in public health include restrictions in the use of MIAs, which are antimicrobials used in human health, and reduction in the overall use of all antimicrobials.<sup>9,10</sup> These guidelines specify institutional controls on the use of antimicrobials in all sectors as strategies to combat AMR.

A well-developed pharmaceutical supply chain ensures access. In a well-regulated system, the demand points for medicines—the distribution point to the end-user within formal and informal health systems—are manned by professionals with the skill set to ensure supply while preventing misuse or abuse, thus contributing toward balancing access and use.

Bangladesh is a densely populated South Asian country identified as one of several with a high risk for AMR.<sup>11</sup> A systematic review of AMR in Bangladesh conducted in 2018 reveals, for example, that organisms causing urinary tract infections showed high levels of resistance to penicillins (ampicillin and amoxiclav), ranging from 58%–100%.<sup>12</sup> Against the cephalosporins (cefotaxime, ceftazidime, and ceftriaxone), the most commonly used

class of antibiotics, resistance was similarly high at  $\geq 55\%$  in *E. coli* and  $\geq 78\%$  in *Klebsiella* spp.<sup>12–14</sup> Comparative WHO GLASS 2019 data shows *E. coli* isolated from urine samples resistant to ciprofloxacin in 11.5% of patients (n=82,2931) in the United Kingdom to 89.7% (n=394 patients) in Bangladesh.<sup>15</sup> Against ceftriaxone, *E. coli* resistance was 10.1% (n=87,398) in the United Kingdom and 63.9% (n=394) in Bangladesh.<sup>15</sup>

Bangladesh runs a pluralistic health system with 5 parallel systems of medicine: allopathic, ayurvedic, herbal, homeopathic, and *unani*.<sup>16</sup> Regulatory oversight of all 5 systems is provided by the National Medicine Regulatory Agency, the Directorate General of Drug Administration (DGDA).<sup>17</sup> Antimicrobials, classified under the allopathic category, constitute a significant size of the domestic pharmaceutical market. In 2016, antimicrobials (systemic anti-infectives) ranked second in sale volumes (18%) after medicines for alimentary and metabolism or the gastrointestinal tract (36%).<sup>18</sup> The total market size for pharmaceuticals sale was estimated at about US\$2.5 billion in 2018.<sup>19</sup>

There are 3 main pathways for the supply of allopathic medicines in Bangladesh: formal public, formal private, and informal private sector.<sup>20</sup> In terms of intended use and financing, the market for antimicrobials for human use can be structured into 3: antimicrobials for TB, antimicrobials used for maternal and child health, and all other antimicrobials that are licensed by the DGDA and available for sale through both formal and informal private channels. Antimicrobials for TB and maternal and child health are largely supplied for free to the end-user through public and private not-for-profit facilities under the formal public channel with the participation of key development partners and nongovernmental organizations.<sup>20</sup> In addition, outside of these antimicrobials for these specific conditions and cases, the government provides free public health care at all levels from specialized facilities at the tertiary level in administrative divisions to community clinics to make health care geographically accessible. However, utilization is low, with most people (67%) seeking health care, including medicines, in the private sector.<sup>16</sup>

Although there are several studies addressing challenges with access, misuse, quality, AMR, or regulatory governance in LMICs,<sup>21–24</sup> there is as yet no standard method for analyzing or mapping antimicrobial supply chains that addresses both access (including medicines quality) and inappropriate use. There is an urban health atlas mapping health facilities in Bangladesh.<sup>25</sup> However, there is

**Maintaining access to antimicrobials through the pharmaceutical supply chain needs to be balanced against inappropriate use.**

**There is as yet no standard method for analyzing or mapping antimicrobial supply chains that addresses both access and inappropriate use.**

no current comprehensive national-level assessment of the formal and informal antimicrobial supply chain to characterize challenges with the dynamics of access, use, medicine quality, and regulatory governance for the human and livestock sectors in Bangladesh.

As part of a broader One-Health project assessing behavioral, practice, and policy factors contributing to the indiscriminate uses of antimicrobials, including poor-quality medicines, and AMR, in Bangladesh, we have evaluated the National Action Plans on AMR containment in Bangladesh and 7 other LMICs and assessed the integrity of the antimicrobial supply chain in Bangladesh.<sup>26</sup> This study complements this previous body of work. This present study aimed to map the supply chain for human and veterinary antimicrobials, with a focus on the implications for public health. The objectives were to: (1) propose a novel method for antimicrobial supply chain analysis to identify challenges with access and use in the context of AMR, and (2) apply the development to describe/characterize the supply chain for antimicrobials in Bangladesh. While the scope is One-Health, comprising humans and animals, in recognition of the impact of irrational uses of antimicrobials in animals as a driver of AMR, the article focuses on public health implications, in essence on human health.

## METHODS

This study employed a qualitative ecological design with a scoping review methodology to profile the antimicrobial supply chain in Bangladesh. We adopted a 5-tier model of pharmaceutical supply chains consisting of primary manufacturer of active pharmaceutical ingredient (API) (Tier 1), secondary manufacturer of finished pharmaceutical product (FPP) (Tier 2), main distributor (Tier 3), local distributor (Tier 4), and demand point (Tier 5).<sup>27</sup> The scoping review methodology was adopted to enable comprehensive data collection, considering that some of the information sought on these players and processes in the supply chain may not be available as peer-reviewed literature.

We performed an ecological assessment of the supply chain using a constructed framework of 16 selected indicators to characterize: (1) the antimicrobial supply chain, (2) manufacturers, (3) sales and dispensing, or demand, points (4) regulation, and (5) licensed antimicrobial products (Table 1).

To obtain these indicators, we performed a scoping review for information, first for the general pharmaceutical supply chain, and then specifically

for the antimicrobial supply chain as summarized here and detailed in the [Supplement](#).

## Literature and Database Review for Information on the General Pharmaceutical Supply Chain

To scope the general pharmaceutical supply chain in Bangladesh, a search was conducted on 4 databases: Banglajol (a service that provides access to Bangladesh Online Journals), Google Scholar, PubMed, and the DGDA database.

## RESULTS

The medicine supply chain in Bangladesh, based on data from the DGDA dashboard, is complex (Table 2). Overall, for products, there are 43,529 registered drugs from 761 manufacturers distributed through 120,871 retail outlets in the country. In terms of players, for allopathic drugs alone, there are 118,519 wholesale and retail outlets as of March 2020.

Specific supply chain elements are presented and discussed in the following sections.

### Antimicrobial Supply Chain

Figure 1 maps the supply chain network for human and animal use antimicrobials in Bangladesh.

Bangladesh imports APIs for its pharmaceutical industry. Almost all APIs (reported at between 97%–99.5%) are imported from Tier I manufacturers, based mainly in China (40%), India (30%), and Korea (10%),<sup>31</sup> as well as in Vietnam, Europe, United States, and Japan.<sup>19,32</sup> There is only limited domestic API production in 4 pharmaceutical firms: Square, Beximco, Globe, and Gonoshasthaya Pharmaceuticals Limited. There are plans for the establishment of a local API industry in Munshiganj district, 40 km southeast of Dhaka.<sup>33</sup>

There are 3 key player types in the antimicrobial supply chain at Tier II in Bangladesh with different distribution networks and processes: private sector manufacturers and importers; the Global Drug Facility; and the public Essential Drug Company Limited (EDCL). In the for-profit private channel, 78 manufacturers produce antimicrobials for human use, and 44 produce antimicrobials for veterinary use (with overlaps). The supply of TB, HIV, and malaria medicines (antimicrobials) is controlled by international development partners – the Global Drug Facility – and the government of Bangladesh. Procurement is facilitated by the development partners, storage by the

**TABLE 1.** Framework<sup>a</sup> of Selected Indicators Used to Map the Antibiotic Supply Chain in Bangladesh

Element	Indicator		Rationale/Assumption
	Characteristic	Metric(s)	
Supply chain	Linkages	Schematic	Maps product flow from manufacture to use
Manufacturers	Market structure	Market share of the top 10 by value (concentration)	For identification and classification
	Ownership	% local/domestic	Local production supports access <sup>b</sup> (availability)
	Overall production capacity	% supplied locally	
	Source of active ingredients	% sourced locally	
	Specialization in antimicrobial production	Proportion of manufacturers producing the top 10 by volume (%); high/low	Low specialization can protect against shortages and guarantee availability but may be a risk for drug quality
Regulation <sup>c</sup>	Technical capacity	WHO classification of NRA	A WHO Stringent Regulatory Authority of Maturity Level 3 or 4 is a competent NRA able to ensure medicines quality in the supply chain
Demand points	Pharmacy density	No./ 5 km <sup>2</sup> and No./10,000 population	Quantification and dispersion measures of (geographic) access; poor surveillance of a large number of pharmacies can impede product quality
	Pharmacist density	No./10,000 population	A measure of professional capacity to guard against potential misuse
	Veterinary clinic density	No./ 5 km <sup>2</sup>	Geographical accessibility to licensed demand points promotes rational use
	Veterinarian density	No./10,000 population	A measure of professional capacity to guard against potential misuse
	Product quality	Prevalence of SF medicines	A measure of the integrity of the supply chain
Antimicrobial products with market authorization (license)	WHO AWaRe categories	%	High % of Watch and Reserve groups may indicate (potential) misuse
	Medically important antibiotics	%	
	Listing of top 10 in EML	%	Proxy for rational selection and use—the acceptability component of access
	Pricing/price controls	Present/absent	Proxy for access (affordability). High prices may promote misuse through poor adherence

Abbreviations: AWaRe, Access Watch and Reserve classification; EML, Essential Medicines List; NRA, National Regulatory Authority; SF, substandard and falsified medicines; WHO, World Health Organization.

<sup>a</sup>This framework is not intended to be exhaustive.

<sup>b</sup>Access is described here using the 5-dimensional framework of Wirtz et al.,<sup>7</sup> consisting of availability, affordability, geographical accessibility, acceptability, and quality.

<sup>c</sup>Regulation is an overarching feature of the supply chain, not 1 distinct element.

government, and distribution by the government through its facilities. Thus, this system is more regulated. While the EDCL produces and supplies all government facilities, private manufacturers also supply these public health facilities through tenders. The EDCL produces 27 antimicrobials.<sup>34</sup>

Importers of FPP are mainly nonpharmaceutical companies who largely procure medicines intended for veterinary uses. These firms typically also supply animal feed (medicated) and other products for use in the agricultural sector or other industries.



**TABLE 2.** Characteristics of Supply Chain Elements for All 5 Medicine Systems in Bangladesh

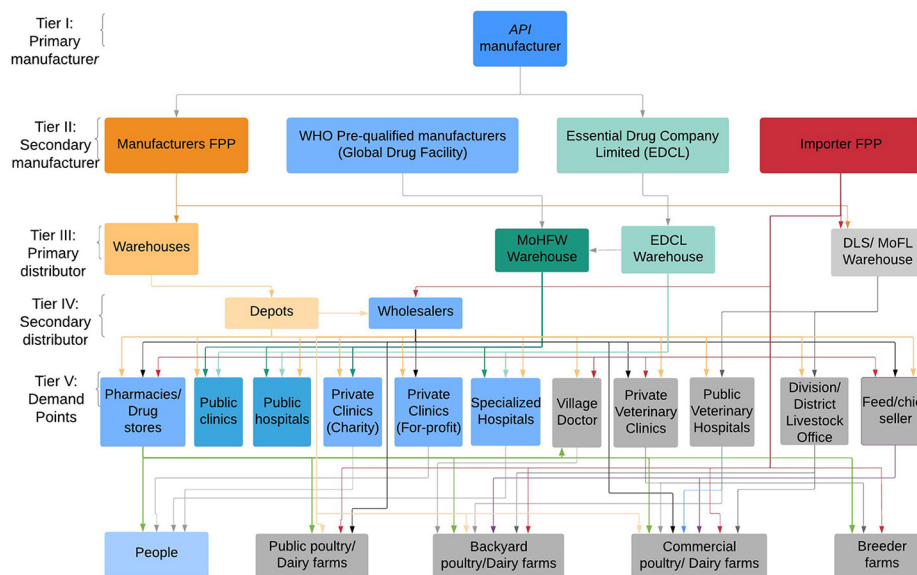
	Allopathic	Ayurvedic	Homeopathic	Herbal	Unani	Totals
Registered drugs	29,813	4,119	2,417	550	6,630	43,529
Generics <sup>a</sup>	3,642	N/A	N/A	N/A	N/A	N/A
Manufacturers	204	202	42	35	278	761
Wholesale pharmacies	1,165	N/A	N/A	N/A	N/A	N/A
Retail outlets	117,354	409	2411	11	686	120,871

Abbreviation: N/A, not applicable or not available.

<sup>a</sup> Generic is defined as an unbranded product.

Source: Directorate General of Drug Administration dashboard (as of February 16, 2020).

**FIGURE 1.** Schematic of the Network Structure of the Antimicrobial Supply Chain for Human and (Terrestrial) Animal Sectors in Bangladesh Illustrating the Flow of Product<sup>28–30,34–46a</sup>



Abbreviations: DLS, Department of Livestock Services; EDCL, Essential Drug Company Limited of Bangladesh; MOHFW, Ministry of Health and Family Welfare, Bangladesh; MOFL, Ministry of Fisheries and Livestock.

<sup>a</sup> At the lower tiers, blue represents the human sector. In general, gray represents the animal sector exclusively, apart from the village doctor. The *palli chikitshak/pallachikitos* or “village doctor” (someone without a medical or MBBS degree) is a term applied to various persons including the “pharmacist,” someone who is regarded as knowledgeable to provide advice and medicines for human and veterinary use, sometimes a licensed medical professional who does locum in a pharmacy/drug store in a “doctor’s chamber” attached to this facility, or a cadre of trained informal health care providers, albeit without authorization to prescribe/dispense antimicrobials outside of the list of over-the-counter drugs. The specialized hospitals represent a mix of public and private hospitals providing advanced care, including TB. Data sources for the animal sector were supplemented by expert knowledge provided by Md. Samad and Tanvir Rahman.

Generally, the key manufacturers in the private sector own their distribution channels (Tiers III and IV). All top 10 manufacturers of human antimicrobials maintain distribution networks, each

with about 16–33 depots, including warehouses, throughout the country for a total of 231 distribution centers for 9 manufacturers; we could find no information about 1 manufacturer.<sup>35–42</sup> Distribution

networks are either an integral part of the manufacturer or subsidiary specialized distribution sister companies. The Ministry of Health and Family Welfare maintains a central medical store as its warehouse, as does the Ministry of Fisheries and Livestock; and EDCL has warehouses at its production facilities. Most wholesalers are located in markets in Dhaka, with the Mitford market hosting the greatest numbers.<sup>43</sup> All manufacturers maintain direct marketing teams to canvas from demand points all over the country.

There are 11 demand points (Tier V) through which people and animals obtain medicines, comprising retail outlets, private and public health care facilities, and sale points for animal medicines including the village doctors (*pallachikitos*), a feature of the rural health care system. The number

of retail outlets (private medicine outlets) is estimated to be about twice the registered drug outlets, or about 200,000.<sup>44</sup> The District Health Information System 2 (DHIS2) health facility registry for Bangladesh lists 23,926 public and private facilities<sup>45</sup>; almost all of which dispense drugs, including antimicrobials, and, thus, under the ambit of the DGDA.

Table 3 summarizes other characteristics of the antimicrobial supply chain, as presented in-depth in the following sections.

### Manufacturers

**Market structure:** Overall, the pharmaceutical market is protected and dominated by domestic brands. Pharmaceutical manufacturing is concentrated, with 10 of the registered 204 allopathic

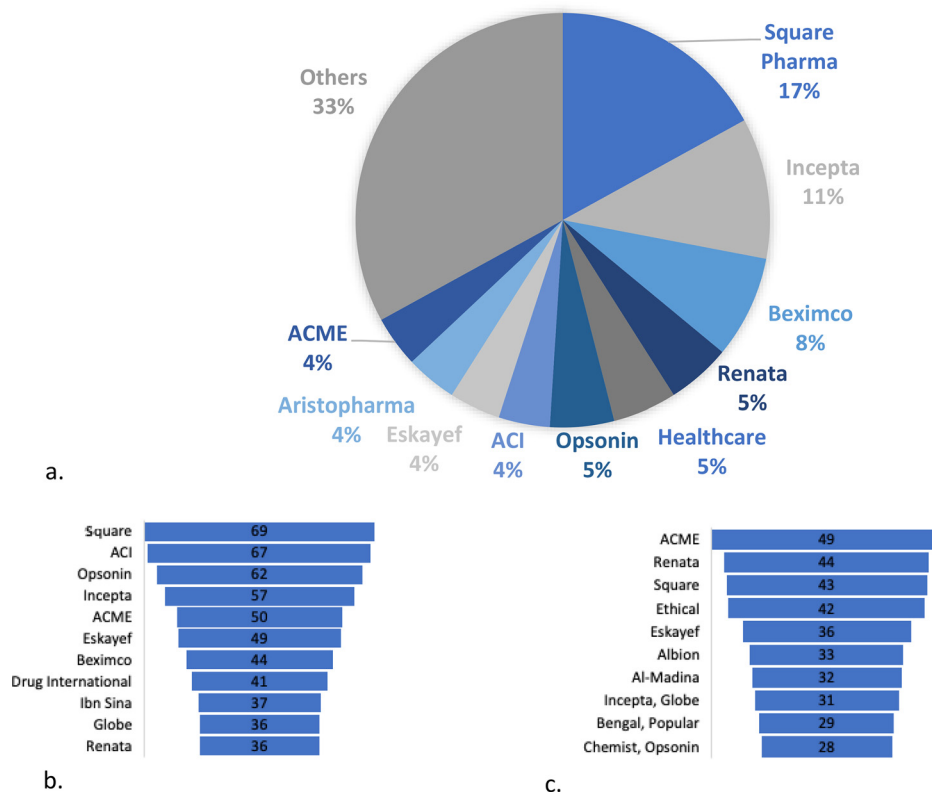
**TABLE 3.** Indicators for Key Elements of the Antimicrobial Supply Chain in Bangladesh Based on the Constructed Framework

	Indicator		
	Characteristic	Metric(s)	Value
<b>Supply chain</b>	Linkages	Schematic	N/A
<b>Manufacturers</b>	Market structure	Top 10 market share by value	≈70%
		CR <sub>4</sub>	255, human sector 178, animal sector
		Ownership	Domestic
	Overall production capacity	Supplied locally	98%
	Source of active ingredients	Local	≤3%
	Specialization in antimicrobial production	Proportion of manufacturers producing the top 10 by volume	38–63%, human sector
			25–84%, animal sector
<b>Demand points</b>	Pharmacy density	No./5 km <sup>2</sup>	<1–7 <sup>a</sup>
		No./10,000 population	7.2
	Pharmacist density	No./10,000 population	1.8
	Veterinary clinics/hospitals density	No.	428 public veterinary hospitals
	Veterinarian density	No./1,000,000 livestock	≈1–2
Product quality	Prevalence of SF medicines	0.04%	
<b>Regulation</b>	Technical capacity	WHO classification of NMRA	Not a stringent regulatory authority
<b>Antimicrobial products with market authorization (license)</b>	WHO AWaRe category “Watch”	Top 10 human use	54%
	Medically important antibiotics	Top 10 (animal use)	90%
	Listing of top 10 in EML	Top 10 (human use)	62%
	Pricing/price controls	Present/absent	Present

Abbreviations: CR<sub>4</sub>, four firm concentration ratio; EML, Essential Medicines List; N/A, not applicable; NMRA, National Medicines Regulatory Authority; SF, standard formulary; WHO, World Health Organization.

<sup>a</sup> Depending on the district, and based on only 30%, or 46,161 currently licensed outlets at the time of the study of 117,354.

**FIGURE 2.** (a) The top 10 pharmaceutical manufacturers by market share in value in Bangladesh, 2018. Top 10 human antimicrobial producers, by proportion of licensed INNs, for: (b) human antimicrobials, (c) animal antimicrobials in Bangladesh<sup>a</sup>



<sup>a</sup>There was a greater similarity between the top 10 manufacturers by market share and the 10 producers of animal antimicrobials (73%, 8/11) than with the top 10 producers of human antimicrobials (46%, 6/13). With human antimicrobials, producers not among the top 10 by value were: Drug International, Ibn Sina and Globe. With animal antimicrobials, these were: Ethical, Albion, Al-Madina, Globe, Bengal, Popular and Chemist. In either sector, human or animal, the difference between market shares by value and volumes suggest diversification or branding among manufacturers.

manufacturers controlling about 70% of the market and 3 controlling one-third by market share (Figure 2). The top 10 are Square, Incepta, Beximco, Renata, Healthcare, Opsonin, ACI, Eskayef, Aristopharma, and ACME. Of these 10, Square has been the market leader for more than 3 decades in terms of sales value, with a market share of 18% in 2018.<sup>46</sup>

The ranking of manufacturers by the number of licensed antimicrobials for human and veterinary use produced reveals a sort of diversification or branding strategy. While most are also in the top 10 by sales values, several of these (ACI, Opsonin, ACME, and Eskayef) produce more antimicrobials by volume, even though their share of the market is only about 4%–5% by sales (Figure 2).

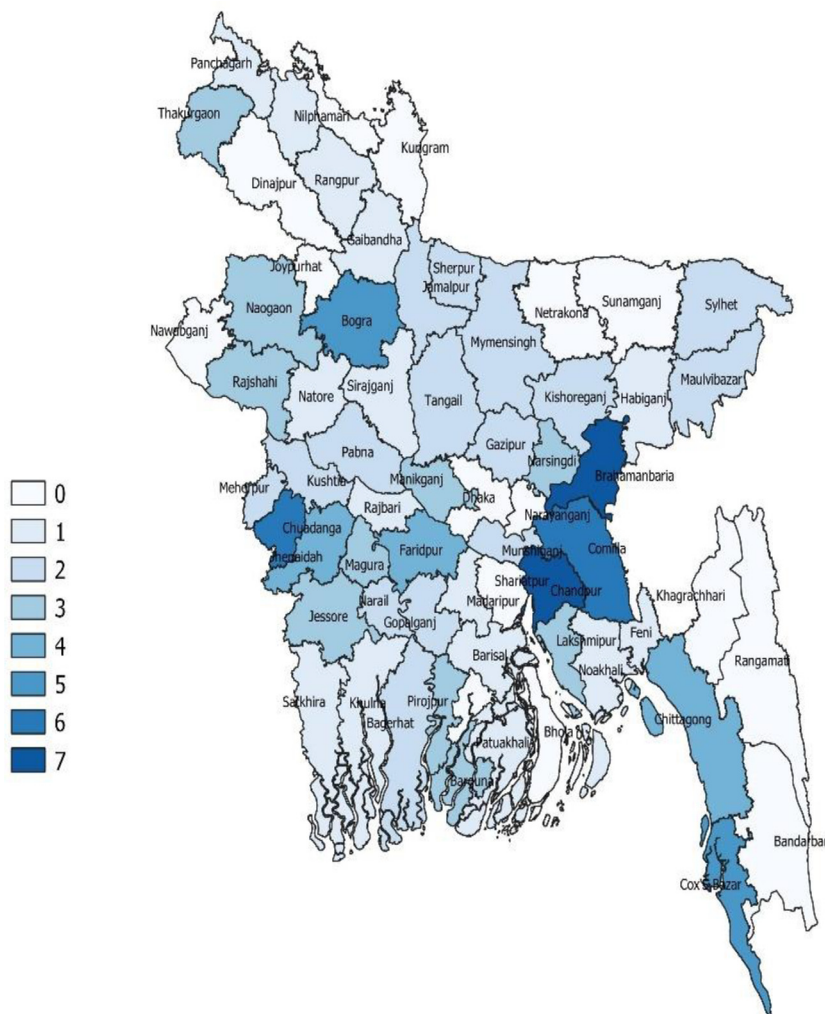
The market for antimicrobial production is oligopolistic, as indicated by a Concentration Ratio of the 4 largest antimicrobial producing firms greater than 60, or  $CR_4 > 60$  (Table 3).

**Ownership:** Manufacturers are mostly (90%) domestic, following divestments by multinational pharmaceutical companies consequent on regulatory changes instituted in the 1980s, with one of the last, Sanofi, scheduled to leave by 2020 and under buy-out consideration by Beximco as of January 2021.<sup>47,48</sup>

**Production capacity:** Bangladesh produces almost all (97%) of its medicines locally, mostly as generics.<sup>19</sup>

**Specialization:** There is low specialization among manufacturers of antimicrobials with high contributions to the overall market. More than 10 different manufacturers produce each of the major

**FIGURE 3.** District-Wise Distribution of Retail Pharmacy Outlets in 64 Districts of Bangladesh<sup>a</sup>



<sup>a</sup>The numbers are number of pharmacies/medicine outlets per 5 km<sup>2</sup>. Numbers refer to currently valid licensed outlets per district as obtained from the DGDA Registration Dashboard as at May 12, 2020. Each of the seven intervals signify a range. For example, 0 indicates 0–1, 1 indicates 1–2 pharmacies per 5 km<sup>2</sup>, etc. Thus, 0 does not necessarily imply the absence of a pharmacy/medicine outlet but means that the pharmacies are more dispersed, or fewer in overall numbers, except for the two districts of Lalmonirhat and Sunamganj, where there did not seem to be any currently licensed pharmacy/medicine outlet, with the Directorate General of Drug Administration database showing license expired for all listed premises, as at the time the study was conducted. Nawabganj is the same as Chapai Nawabganj.

antimicrobials for veterinary use, ranging from 11–37 (25%–84%, n=44); for antimicrobials for human use, this is between 30–49 (38%–63%, n=78). In both sectors, there is a correlation between the number of licensed formulations and the number of producers.

**Demand Point Characteristics**

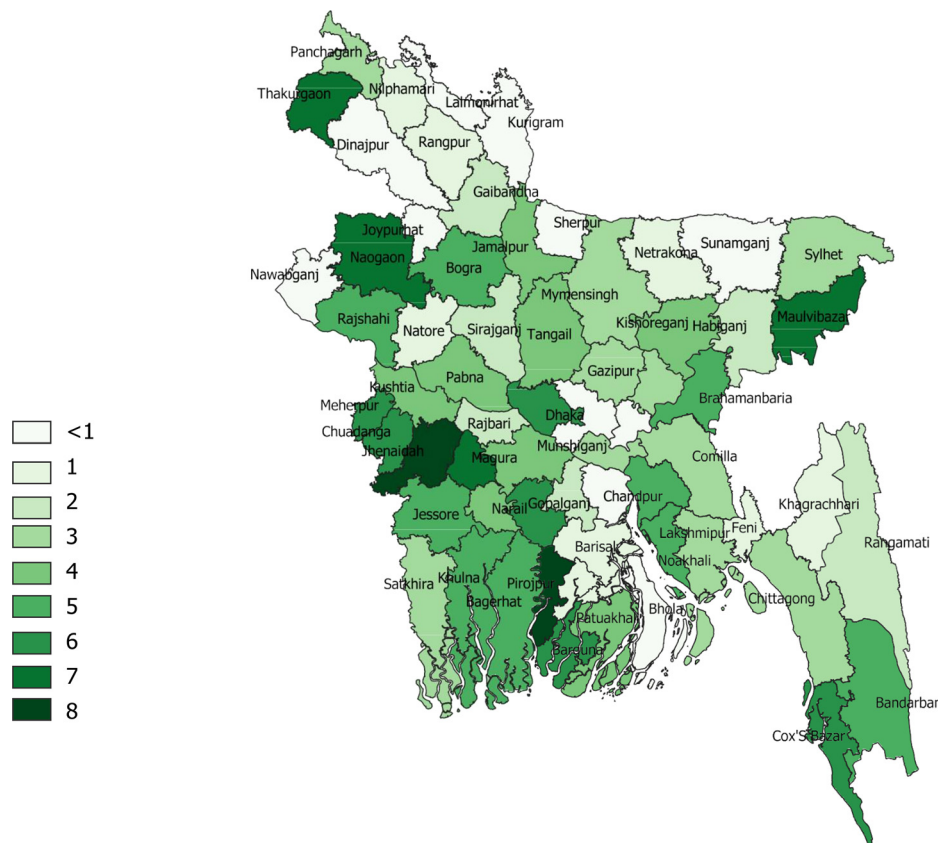
**Pharmacy dispersion:** There is 0.9 retail outlet/drug store per km<sup>2</sup> (117,354 registered allopathic pharmacies on a landmass of 130,170 km<sup>2</sup>).

The subregional (district) distribution of licensed retail outlets, based on the currently licensed total of 46,161 as of May 2020, ranges from <1 up to 7 per 5 km<sup>2</sup> across the 64 districts (Figure 3).

**Pharmacy density:** There are 7.2 retail outlets per 10,000 population (based on 117,354 registered pharmacies for 162 million people). The regional distribution is shown in Figure 4.

**Pharmacist density:** There are 1.8 pharmacists per 10,000 population.<sup>49</sup> Thus, the pharmacy to pharmacist ratio is 7.2/1.8, or 4:1.

**FIGURE 4.** Pharmacy Density Per 10,000 Population at the District Level in Bangladesh<sup>a</sup>



<sup>a</sup>Numbers represent ranges. For example, 1 is a nominal 1 to <2 per 10,000 population, similar to numbers in Figure 3, with <1 suggesting an overall fewer registered pharmacy/medicine outlets per 10,000 population, as at study completion in May 2020.

**Veterinary clinics:** There is 1 public veterinary hospital at each *upazilla* (subdistrict) or county-level with 481 as at 2015.<sup>50</sup>

**Veterinarians’ density:** 1-2 per 0.7 million livestock.<sup>51</sup>

**Medicines quality:** 0.04% prevalence of sub-standard and/or falsified medicines in 2011.<sup>52</sup>

**Regulatory Capacity:** The DGDA is currently not regarded as a stringent regulatory authority.<sup>53</sup>

**Licensed Antimicrobial Products**  
*Antimicrobials for Use in Human Health*

There are 138 unique, or individual, licensed antimicrobials/anti-infectives by international non-proprietary name for human health commercially available as 1,763 products in the Bangladesh National Formulary 2019; the majority (76%, 1,345/1,763) of which are antibiotics. The antibiotics belong to 8 antibiotic classes, with 4 constituting 92% of all antibiotic products in the market (n=1,345).

The most common antibiotic class was cephalosporin (44%, 597/1,345); followed by penicillin (18%, 236/1,345); quinolone/fluoroquinolone (15%, 203/1,345); and macrolide (15%, 200/1,345). The other antimicrobial classes are: carbapenem and monobactam (2%), tetracycline (2%), sulfonamide (2%), and aminoglycoside (1%).

With almost all licensed antimicrobials (99.5%) locally manufactured, imported products were few, with only 8 products, representing 0.5% of all licensed antimicrobial products, imported. For 5 of the imports, there were also domestic alternatives.

The top 10 antimicrobials ranked by number of licensed/commercial formulations are shown in Table 4. These 10 constitute three-quarters (75%, 1,003/1,345) of all licensed antibiotics. Among the 10, cephalosporin was the most common antibiotic class with 4 members (cephradine-cilastatin, cefuroxime, cefixime, and cefpodoxime) constituting more than one third or 37.5% (376/1,003); followed

**TABLE 4.** AWaRe Classification and Listing of the Top 10 Antimicrobials for Human Use by Total Licensed Formulations

Rank	INN	Total Licensed Formulations	WHO (EML)	Pakistan (EML)	India (NF)	AwaRe Class
1	Azithromycin	116	Yes	Yes	Yes	Watch
	Cephadrine-cilastatin	116				Access
2	Cefuroxime	99	Yes	Yes		Watch
3	Cefixime	97	Yes	Yes	Yes	Watch
4	Ciprofloxacin	96	Yes	Yes	Yes	Watch
5	Amoxicillin	84	Yes	Yes	Yes	Access
6	Flucloxacillin	78				Access
7	Nitazoxanide	64				N/A
	Cefpodoxime	64				Watch
8	Metronidazole	60	Yes	Yes	Yes	Access
9	Erythromycin	55		Yes	Yes	Watch
10	Levofloxacin	37	Yes	Yes		Watch
	Cotrimoxazole	37	Yes	Yes	Yes	Access

Abbreviations: AWaRe, Access, Watch, and Reserve classification; EML, Essential Medicines List; INN, international nonproprietary names of pharmaceuticals; N/A, not applicable or not classified; NF, National Formulary; WHO, World Health Organization.

by macrolide (azithromycin and erythromycin) (17%, 171/1,003); penicillin (amoxicillin and flucloxacillin), (16%, 162/1,003); and the fluoroquinolones, ciprofloxacin, and levofloxacin (13%, 133/1,003).

**AWaRe categories:** Most (54%, 7/13) of the top 10 antimicrobials belong to the WHO Watch category, with 39% in the Access category (Table 4). Nitazoxanide, used for the treatment of infective enteritis caused by giardia, is an uncategorized antimicrobial.

**Listing:** Only 62% (8/13) of the top 10 antibiotics were contained in the WHO EML (Table 4). This is comparable to India, with a 54% (7/13) similarity, and Pakistan at 69% (9/13). Flucloxacillin, cephradine-cilastatin, nitazoxanide, and cefpodoxime were not listed in any of these compendia.

**Pricing:** There are price controls with ceilings for all antimicrobials. Prices are published in the compendium.

### Antimicrobials for Use in Animal Health

Of a total of 1,338 products licensed for veterinary use on the DGDA allopathic medicine database (as of March 26, 2020), 61% or 818 were antimicrobials. These were 73 unique licensed antimicrobials consisting of 30 MIAs, which were commercially available as 428 formulations; 32 nonmedically important antimicrobials in 235 formulations; and

11 anthelmintics as 155 formulations. Antibiotics as a percentage of total antimicrobials for animal use was 85% (62/73). Similarly, MIAs as a percentage of total antimicrobials for animal use was 41% (30/73).

With licensed antimicrobials manufactured locally, imports were few or absent. For example, there were no listed imported ceftriaxone or oxytetracycline, and only 10 listed ciprofloxacin products imported from manufacturers in Korea. The antimicrobials imported included unique combinations not manufactured locally, for example, ampicillin+colistin, amoxicillin+colistin, amoxicillin+erythromycin+colistin, and amoxicillin+gentamycin. These products were imported mostly (85%, 11/13) from Korea; then China, and the Netherlands (1 each).

The most common antibiotic classes, comprising over half (55%) of all licensed antibiotics, were: fluoroquinolone (18%, 119/663); tetracycline (17%, 112/663); penicillin (10%, 64/663); and sulfonamide (10%, 64/663).

All but 1 (90%) of the top 10 antibiotics licensed for animal use in Bangladesh were medically important (Table 5).

## DISCUSSION

This ecological assessment profiles the antimicrobial supply chain in Bangladesh for the first time

**TABLE 5.** Selected Characteristics of the Top 10 Antibiotics Licensed for Veterinary Use by Number of Products in Bangladesh

Rank	INN	No. Licensed Products	Antibiotic Class	Medically Important
1	Oxytetracycline	98	Tetracycline	No
2	Ciprofloxacin	67	Fluoroquinolone	Yes
3	Amoxicillin	47	Aminopenicillin/penicillin	Yes
4	Metronidazole	28	Nitroimidazoles	Yes
5	Gentamycin	27	Aminoglycoside	Yes
6	Ceftriaxone	24	Cephalosporin	Yes
7	Sulphamethoxazole + trimethoprim	23	Sulfonamides	Yes
8	Doxycycline	14	Tetracycline	Yes
9	Neomycin	12	Aminoglycoside	Yes
10	Benzyl penicillin + procaine penicillin	11	Penicillin	Yes

Abbreviation: INN, international nonproprietary names of pharmaceuticals.

**The methodology proposed in this study can be used for the comparative evaluation of LMICs antimicrobial supply chains to understand specific challenges to target under national action plans on containing AMR.**

to the best of our knowledge using a novel methodology comprising mapping and the use of indicators to describe access and use in the context of AMR.

The methodology proposed in this study can be used for the comparative evaluation of LMICs antimicrobial supply chains to understand specific challenges to target under national action plans on containing AMR, especially as proxy measures for access and use as contained under strategic objective number 4 in the WHO Global Action Plan on antimicrobial resistance containment.<sup>3</sup> Of the 8 goals listed under this objective, this article covers 6, or 75%, excluding diagnostic laboratories and antimicrobial stewardship considerations. There is no standardized method or approach to antimicrobial supply chain analyses, thereby, preventing any attempt at comparative evaluations. Previous studies in the field have included a variety of methods and reporting styles, informed by study objectives.<sup>21–24</sup> The framework proposed in this study can be applied in the comparative analysis of countries with similar contextual challenges such as in, for example, the WHO South East Asia region.

Bangladesh has the capacity for the local manufacturing and distribution of antimicrobials/medicines, suggesting both commercial availability and geographical access. This capacity sets Bangladesh apart from other LMICs in the same low-income grouping, in terms of local production as a means of improving availability.<sup>54,55</sup> The pharmaceutical industry is the second highest

foreign exchange earner for Bangladesh; exporting to more than 100 countries.<sup>56</sup> In 2015, Bangladesh was granted an exemption under the TRIPS agreement up to 2023, or until graduation from the Least Developed Country status, thus ensuring that its pharmaceutical industry can produce generics or branded generics without regard to patent protection.<sup>57</sup> The concentration of manufacturing among a few suggests consolidation of the pharmaceutical manufacturing industry as an option to improving quality. Interestingly, Bangladesh has a public company manufacturing essential medicines. This is unusual for many countries and could serve as a model for other LMICs.

**Regulatory Capacity Challenge**

Overall, the medicine supply chain in Bangladesh is complex, with implications for effective regulatory oversight, appropriate use, and medicine quality. The DGDA regulates all 5 medicine systems (allopathic, ayurvedic, homeopathic, herbal, and *unani*) with the mandate to control medicine quality, set prices, inspect all premises, and perform postmarketing surveillance. To be able to fulfill all these functions, the DGDA capacity needs to be increased. This is particularly important both in light of the WHO’s finding that poor-quality medicines tend to proliferate in contexts where low regulatory capacity coexists with high demand for medicines and low affordability, and the impact of poor-quality medicines on AMR.<sup>58</sup> A focused study of the DGDA conducted in 2015 highlighted

some challenges it faces, including human capacity and infrastructural,<sup>20</sup> in agreement with the WHO Classification as a nonstringent regulatory agency.<sup>53</sup>

### Sales or Dispensing Points Complexity

The high complexity of Tier V (demand points) is a large challenge for effective surveillance and inspection. This has several implications. The pharmacy density in Bangladesh is higher than in many other countries or regions. For example, at 7.2/10,000 population, this is triple the density in the USA at 2.2/10,000 population<sup>59,60</sup>; double the average density for the European Union, with mean pharmacy density of 3.1/10,000 population; and slightly more than India's with an estimated 5.5/10,000 population in 2018.<sup>61,62</sup> The sheer number of small outlets will require a large human workforce of inspectors to ensure adequate supervision including of good storage and pharmacy practices for antimicrobials. For instance, in a nationally representative study of drug stores, only a third (n=111) had a functional refrigerator required for the proper storage of temperature-sensitive drugs.<sup>60</sup> However, the relatively low spatial distribution (about 1/km<sup>2</sup>) of licensed medicine outlets, suggesting clustering, implies that most could be easily visited for regulatory inspections.

Drug stores outnumber formal providers, illustrating a similar gap in most LMICs.<sup>63</sup> The distribution of retail outlets shows a rural-urban divide. It is estimated that 58% of the drug stores/pharmacies are in the old Dhaka and Chattogram Divisions, both of which contribute to over half of the population of Bangladesh, and are mostly urban areas.<sup>64</sup> Public health facilities are more nationally distributed with a presence at all administrative divisions. For example, community clinics are available at the lowest level of the society; and 1 livestock clinic per *upazilla* or sub-district level.<sup>16</sup> The exact numbers of the *pallachikitos*—a feature of the rural health care system—are unknown. Although antimicrobials are allopathic, all 5 medicine systems in Bangladesh have been known to prescribe/dispense antimicrobials. Controlling use/demand at all these demand points is a second challenge and would require a lot of effort.

There is a shortage of professional capacity (pharmacists) in Bangladesh, with drug stores manned by nonprofessional staff. This gives rise to the third challenge of how to staff this large number of sale points with trained personnel to

ensure Good Dispensing and Pharmacy Practices. An estimated pharmacist density of 1.8 per 10,000 population means that there are only about 29,160 pharmacists for Bangladesh's 162 million people, insufficient to man the over 100,000 registered medicine outlets.<sup>49</sup> In this, Bangladesh is similar to Nigeria (1.3/10,000), and Pakistan (1.6/10,000), but different from India with about 9/10,000.<sup>65</sup> There are 3 classes/grades of persons who can sell medicines in Bangladesh, differentiated on the length of "training" into Grades A, B, and C. Grade A are equivalent to pharmacists in other settings and are those with a University Degree in Pharmacy. Grade B hold a 1-year diploma and may be the equivalent of Pharmacy Technicians. The lowest class, Grade C, requires only an apprenticeship lasting only a few weeks (3–4 months). Sale and dispensing points are characterized by the near-complete absence of Grade A pharmacists, consisting majorly of Grade C "pharmacists."<sup>66</sup> This gap would take time to fill. This is a fundamental weakness in the pharmaceutical supply chain, as evidenced by reports from other countries in the global south where medicine outlets manned by nonprofessionals are significant sources of substandard and falsified medicines.<sup>67,68</sup> With this pharmacy density, Bangladesh is among the bulk of LMICs with less than 5 pharmacists per 10,000 (where this implies, by default, a 1:1 pharmacist: pharmacy ratio), implying a shortage of professional capacity, or a surplus of drug stores.<sup>49</sup>

In the veterinary sector, the 2015 Performance of Veterinary Services Gap Analysis Report for Bangladesh recommends a significant increase in the number of veterinarians over the next 5 years to an estimated 2,130 for the public sector—suggesting a human resource gap in this sector. There is no comprehensive information for the private sector.

Placing all veterinary uses of antimicrobials under a veterinarian is a means of ensuring quality use. In Bangladesh, medicines for use in animals are obtained from a variety of demand points not under the control of a trained veterinarian.<sup>69,70</sup>

In terms of medicine quality, we did not find recent estimates from the DGDA. The reported estimate is from 2011. In contrast, India publishes periodic reports on the substandard and falsified medicines withdrawn from the market.<sup>71</sup> Alternative data sources could be reports from scientific or medicine quality surveys.

Bangladesh has initiated several moves to improve sales and dispensing practices of antimicrobials.

**The high complexity of Tier V (demand points) is a large challenge for effective surveillance and inspection.**



By law, antimicrobials are prescription-only medicines, with only metronidazole included in the over-the-counter list for drug stores. However, this policy is, by and large, not adhered to, not only in Bangladesh but also in other LMICs.<sup>21,23</sup> Recently, it has adapted the Accredited Drug Dispensing Outlet initiative first implemented in Tanzania to create 2-tiers of pharmacies—a model pharmacy staffed by a trained pharmacist, and a lower-level medicine shop without the requirement to be manned by a pharmacist.<sup>72</sup> These are obligated to sell antibiotics only on a prescription basis. However, this concept is not without its challenges.<sup>73–75</sup> Furthermore, there is the plan to mandate antimicrobials to be packaged in red packs—both to create public awareness and to prevent misuse.<sup>76</sup>

### Antimicrobial Products

The high proportion of licensed WHO Watch antibiotics has implications for AMR development and spread. Of the 4 antibiotic classes that make up the bulk of the licensed antibiotic products in Bangladesh, over half belong to the Watch group, including all macrolides and fluoroquinolones and the majority of cephalosporins. This high level of market offering of Watch antibiotics as opposed to the Access group has been observed also in India and Pakistan.<sup>77,78</sup> The target of the AWaRe categorization is 3-fold: achieve an increase in the use of Access antibiotics, the group associated with the lowest potential to induce AMR, to 60% by 2023; decrease the use of Watch antibiotics; and restrict Reserve antibiotics to infections caused by drug-resistant infections.<sup>14</sup> This target may be challenging in contexts with a large proportion of licensed antibiotic products being of the Watch category and with unrestricted access via over-the-counter sales of antibiotics, with implications for antimicrobial stewardship programs.<sup>78</sup>

Similarly disturbing is the extremely high proportion of MIAs which means that a large proportion of licensed antimicrobials for animal use belong also to the human therapeutic arsenal.<sup>9</sup> The usage of these antimicrobials has been correlated with AMR in poultry in neighboring India, for example.<sup>79</sup> The WHO recommends the restriction of all non-therapeutic uses of MIAs for growth promotion or disease prevention in animals. Bangladesh has made recent progress in this area with the de-licensing of most colistin formulations—an MIA ranked as critically important, but we still found combinations containing colistin being imported. This calls for further actions to restrict access. There may also be a

need for more regulations on licensing of other MIAs including critically important antibiotics such as gentamycin, neomycin, ceftriaxone, and ciprofloxacin.

### Limitations

One limitation with the proposed framework is that it does not assess use by the conventional methods such as antimicrobial consumption and point-prevalence surveys which provide standardized measures of inappropriate use. However, these data are unavailable for many LMICs, among other reasons because acquiring primary data via surveillance and point-prevalence studies requires considerable human resources. The indicators assessed provide proxy measures for characterizing antimicrobial supply chains to highlight challenges. We also did not consider in depth the medicine quality aspect of access here as this was outside the scope of this work.

## CONCLUSION

This work presents a novel method for performing supply chain analyses. Using data from Bangladesh as a model LMIC, it maps the supply chain for antimicrobials used in the human and animal sectors in the context of antimicrobial resistance containment to highlight gaps for targeted interventions. In so doing, it also presents, to the best of the authors' knowledge, the first mapping of the supply chain for Bangladesh. This framework can be used to map the antimicrobial supply chain in LMICs.

It represents a lean method of analysis that can supplement ongoing efforts by development, national, and international health authorities to address the urgent threat of AMR. The 16 data types it includes are relatively easy to collect, making the method useful for countries with human capacity and technology constraints to rapidly assess deficits in the supply chain for antimicrobials. Importantly, the proposed method incorporates salient market/economic features such as market structure, specialization, and pricing—often underappreciated or neglected as important components of supply chain analyses. The framework, thus, presents a holistic and efficient tool for antimicrobial/antibiotic supply chain analysis.

Specifically, the methodology proposed in this study, the data collected in the study, and information on the challenges in collecting data not included in the analysis can be used to better inform decisions about interventions (including communities to engage, whether regulatory, private

**The high proportion of licensed WHO Watch antibiotics has implications for AMR development and spread.**

sector, or others) to address the emergence and spread of AMR.

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ORIGINAL ARTICLE

# Trends in National-Level Governance and Implementation of the Philippines' Responsible Parenthood and Reproductive Health Law from 2014 to 2020

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## Key Messages

- The Philippines' Responsible Parenthood and Reproductive Health Law acknowledged reproductive health as a multisectoral initiative. However, national-level implementers of the law had little intersectoral collaboration and focused on specific biomedical programs that were insufficient for remarkably improving reproductive health outcomes.

## Key Implications

- Policy makers must shift away from a health-centric agenda anchored on family planning policy and aim toward holistic life-course interventions.
- National health leaders must secure other sectors' interest in reproductive health rather than rely on weak health-centric leadership based on law alone.
- Government agencies should establish a common narrative to engage different sectors to view reproductive health holistically and contribute multisectoral policy solutions.

## ABSTRACT

In 2012, the Philippines passed the Responsible Parenthood and Family Planning Law, a landmark legislation billed as a multisectoral and rights-based approach to further sustainable human development. This article is part of the first comprehensive evaluation of the implementation of the law by national-level actors. This evaluation is intended to assess the progress of implementers in the conduct of mandates, roles, and responsibilities described in the law and its implementing guidelines. Interviews with key national government officials and data from official documents and literature revealed 3 major trends in governance and implementation from 2014 to 2020. First, despite being a multisectoral policy, performance was siloed within individual units of implementing agencies, with limited interagency coordination. Second, although the law explicitly called for interventions to invest in human capital and address socioeconomic disparities for sustainable human development, performance focused on biomedical and health interventions, particularly in the area of family planning. Third, national-level governance for reproductive health interventions concentrated on programmatic and operational concerns. Overall, this case in the Philippines illustrates that fragmented implementation has contributed to the slow improvement of reproductive health outcomes. This study highlights the challenges of governance and multisectoral coordination to implement multidimensional interventions in a low- and middle-income country, and it provides potential areas for political and administrative reform in reproductive health governance in the Philippines. By creating a common narrative and onboarding multiple sectors, officials can better identify and address structural determinants with holistic policy solutions to improve reproductive health outcomes.

## INTRODUCTION

### Multisectoral Governance for Reproductive Health

Beyond biological health, reproductive health (RH) is tied to access to information and services that enable choices for the well-being of one's self and family.<sup>1</sup> From empowering individual and household decisions, comprehensive RH policies have national impact, facilitating sustainable population growth, human capital investment, and socioeconomic development.<sup>2-4</sup>

To effectively accomplish these goals, the provision of acceptable and affordable RH care services requires an awareness of the social and economic determinants<sup>5-7</sup> affecting gender and interpersonal relations.

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Hence, interventions to address the social determinants of sexual health and RH must acknowledge that individual health outcomes are not solely determined by the health sector but instead require action from multiple sectors.<sup>8</sup>

A critical factor for the success of multisectoral action is governance,<sup>9</sup> which encompasses how activities of different stakeholders with respective responsibilities and resources can be oriented toward a single vision in a process of negotiation, collaboration, and reporting for enforcing accountability.

Governance plays an important role in low- and middle-income countries (LMICs),<sup>10</sup> creating a policy environment conducive to investing in social development without stifling economic growth. Amid the difficulties of this dual role, plans are affected by limited resources and competing political interests.<sup>11</sup> Thus, many LMICs have yet to implement successful multisectoral governance approaches.<sup>9</sup>

### Structure of RPRH Implementation

The Philippines passed the Responsible Parenthood and Reproductive Health (RPRH) Law in 2012, after years of opposition from conservative groups.<sup>12,13</sup> It declared universal access to RH services as integral to the rights to life, health, and sustainable human development.<sup>14</sup>

The wide scope of RPRH envisioned contributions from multiple sectors represented by national government agencies (NGAs) (Supplement). In late 2014, the National Implementation Team (NIT) was created to manage and coordinate interagency RPRH activities.

NIT is chaired by an undersecretary of the Department of Health (DOH), and its members include NGAs, civil society organizations (CSOs), and multilaterals. Keeping with the decentralized system of governance in the Philippines,<sup>15</sup> regional implementation teams, composed of government agencies' regional office staff, were envisioned to mirror NIT's functions at the regional and local government unit (LGU) levels.

### RATIONALE AND OBJECTIVES

This study was part of the first evaluation of the RPRH Law, commissioned by the Philippine DOH. The study objectives aimed to:

- Assess the progress of NGAs across sectors in the conduct of mandates, roles, and responsibilities described in the RPRH Law and its Implementing Rules and Regulations (IRR).<sup>16</sup> Analyses focused on the trends in national-level governance and implementation of the law.

- Provide information on multisectoral governance in an LMIC context, where most multisectoral action for health pertains to communicable diseases, maternal health, and nutrition.<sup>17,18</sup>
- Assess national implementers' performance over 7 years, from the perspective of different sectors, which is especially relevant for overcoming limitations of policy and implementation lags and accounting for externalities that health-sector governance may have on other sectors.
- Present pragmatic recommendations for engaging multiple sectors in health policies.

## METHODS

### Defining Governance

An operational definition of governance was necessary to situate national-level implementers' conduct of their respective mandates and inform the data collection process. Governance<sup>19</sup> refers to the formal structures and processes that promote inclusive participation, responsiveness to people's needs, and accountability among stakeholders. Governance also includes informal processes and power dynamics that facilitate multistakeholder coordination to achieve public goals. Taken together, these formal and informal decisions<sup>20</sup> are the policies that enable the timely and appropriate provision of social services.

### Data Collection and Analysis

Data collection focused on the RPRH activities of agencies involved in NIT. As NIT does not have its own staff, member agencies send representatives for monthly meetings.

Twenty key-informant interviews (KIIs) were conducted with respondents involved in RPRH governance at the national level (Table 1) who held positions within their organizations of program managers or higher (Supplement).

Most interviewees were career bureaucrats who had worked in government for a decade before promotion to their current position. At the time of the study, they had been in their current positions between 1 and 15 years, with a median of 4 years of experience.

KIIs with other implementing agencies were planned, but representatives did not respond to the interview invitation letters. Follow-ups for these agencies were not pursued further due to the onset of the COVID-19 pandemic and the

**Governance refers to the formal structures and processes that promote inclusive participation, responsiveness to people's needs, and accountability among stakeholders.**

**The study assessed the progress of individual NGAs and across sectors regarding conduct of mandates, roles, and responsibilities described in the RPRH Law and its IRR.**

**TABLE 1.** Organizations Included in Key Informant Interviews and Number of Respondents

Organization	Respondents
National Implementation Team	1
Department of Health	6
Commission on Population and Development	4
Department of Social Welfare and Development	2
Philippine Commission on Women	2
Philippine Health Insurance Company	1
Department of Education	1
Department of Interior and Local Government	1
Civil society/private sector	1
United Nations Population Fund	1

The study revealed that implementation activities were siloed, interventions were heavily focused on FP, and implementation tended to be programmatic and operational.

acquired information reaching data saturation.<sup>22</sup> No respondents dropped out of the study.

**Key Informant Interviews**

The KIIs explored how agencies adapted their organizational structures and roles for RPRH activities based on their mandates. NGAs were asked to identify and self-evaluate their performance on RPRH-related activities. Implementing agencies were also asked about their role in NIT and their organizations' participation in NIT meetings. They then enumerated major challenges to accomplishing their mandates and implementing the RPRH Law in general. Interviews were audio-recorded with the consent of participants and transcribed verbatim. In the findings section, we present translated quotes from KIIs and redact portions of the translations that may lead to identification of the respondents. From the transcripts, patterns, trends, similarities, and differences in answers were identified and analyzed independently by 3 researchers using qualitative thematic analysis and synthesized to form an assessment of overall performance.

A review of official documents confirmed whether agencies' mandates were implemented. These included the RPRH Law, IRR (2017 revision), policy issuances after 2013, joint circulars, and executive and administrative orders. Also scoped were the annual accomplishment reports (ARs) published by the NIT secretariat, based on RPRH implementation reports submitted by member agencies. The reports summarize performance, challenges, and recommendations for 5 chosen

key result areas (KRAs) as well as governance and financing. Seventy-one of 79 NIT meeting transcripts from the years 2014 to 2019 were also obtained for analysis.

These data were triangulated with a review of secondary literature. The review included studies that documented or evaluated the activities of implementing NGAs for RPRH. Additional literature validated whether findings from KIIs and official documents were common in the setting of Philippine governance or multisectoral governance. Finally, the literature review also determined best practices and recommendations that may contribute to solving challenges in RPRH governance based on cases from similar contexts.

**FINDINGS**

This section presents 3 interconnected findings.

1. Implementation activities were siloed to individual agencies and compartmentalized to specific programs and policies.
2. Siloed programs and processes, coupled with the historical and political context of the law pushed health-sector activities to the forefront of implementation, leading to a focus on biomedical, particularly family planning (FP), interventions.
3. NIT meetings concentrated on program-specific issues brought up by prominent health-sector agencies, which steered implementation toward being programmatic and operational.

**Siloed and Compartmentalized Performance**

Agencies were generally able to fulfill their mandates; however, these mandates did not require interagency coordination or coordination between different divisions of the same agency. Table 2 qualitatively evaluates the completion of RPRH mandates assigned to NGAs as "not done" (to be implemented), "doing" (some implementation activities), or "done" (completed). Siloed performance was observed both among and within agencies. A significant portion of completed mandates were those that were one-time, straightforward tasks. The majority of these were assigned to DOH, such as the creation of guidelines and standards.

For some agencies, completed mandates aligned with their existing agency functions and could be accomplished without other implementers. An example is the Food and Drug Administration's (FDA's) role in certifying FP commodities for the Philippine National Drug Formulary and Essential Medicines

**TABLE 2.** Completion of RPRH Mandates Listed in RPRH Implementing Rules and Regulations (2017 Revision) by Subsection<sup>a</sup>

Done	Doing	Not Done
<b>DOH Governance: Guidelines</b>		
<b>4.01</b> Service Delivery <b>4.04</b> Informed Choice <b>4.08</b> Care for GBV Survivors <b>4.12, 4.13</b> Policies on Life-Saving Drugs in Maternal Emergencies <b>5.07</b> FP Services at Establishments/Enterprises <b>5.08</b> Mapping Service Delivery Network (SDN) Facilities <b>5.22, 5.23</b> Exempting Private Providers <b>6.01, 6.03-6.05</b> Contracting and Training Health Professionals <b>8.03</b> Procurement of FP <b>10.10</b> LGU Awards/ Recognition <b>14.01</b> Maternal, Fetal, and Infant Death Reviews (M/FIDR)	<b>5.07</b> FP Services at Establishments/Enterprises <b>5.11</b> Match Populations to Facilities in the SDN <b>5.14</b> Assistance to LGUs for Mobile Health Care Services (MHCS) Vehicles <b>5.17</b> Identification of Facilities for Upgrading <b>5.19</b> Support to LGUs <b>5.27</b> Training Counselors of Adolescents <b>6.06</b> Comprehensive Emergency Obstetric and Newborn Care (CEmONC) Curriculum <b>6.07, 6.08</b> Training Barangay (Community) Health Workers <b>10.02</b> Health Promotion Plan <b>12.01</b> <b>except section h</b> DOH duties	<b>5.13</b> Standards of MHCS <b>5.18, 5.20</b> M&E for LGU Fund Utilization and SDN <b>6.02</b> Determine number of Skilled Health Professionals <b>10.06</b> M&E for New Health Promotion Plans
<b>DOH Governance: Non-Guidelines</b>		
<b>5.09, 5.10</b> Mapping Health Facilities and Priority Populations in the SDN <b>8.02</b> Budget to Procure FP <b>9.03, 9.04</b> Funds for Health Facilities and Public Awareness	<b>6.10</b> Technical Assistance to Engage Private Providers in LGUs <b>14.07</b> M/FIDR Panel <b>15.03</b> Streamline Reporting	<b>8.07, 8.10</b> Monitoring System for Procurement <b>12.01-h</b> RH Bureau in DOH
<b>DOH Service Delivery</b>		
<b>4.11</b> Life-Saving Drugs in Maternal Care Emergencies <b>4.15</b> Maternal and Newborn Health Care in Crisis Situations <b>5.21</b> Assist Private FP Services <b>7.02, 8.01, 8.08</b> FP Logistics <b>13.02</b> RPRH in Anti-Poverty <b>15.01</b> Reporting Requirements	<b>4.05-4.07</b> Access to FP (including minors) <b>4.09</b> PWD-RH Programs <b>4.10</b> Responding to Unmet Need <b>5.02, 5.05</b> RH Care in SDN <b>5.12</b> MHCS <b>6.09</b> SBCC Materials <b>10.01</b> Health Promotion	
<b>Other Implementers</b>		
<b>5.10</b> Identify Priority Populations in the SDN ( <b>DSWD</b> ) <b>12.03, 12.04</b> Duties ( <b>DSWD</b> ) <b>7.04, 7.05, 7.08, 7.12</b> RH Product Certification ( <b>FDA</b> ) <b>7.06</b> Harmonize Standards ( <b>FDA</b> ) <b>9.06-9.08</b> Financing RH ( <b>PhilHealth</b> ) <b>10.07, 12.04</b> CSO Participation ( <b>Cross-Cutting</b> ) <b>11.02</b> Curriculum Development ( <b>DepEd</b> )	<b>4.02, 5.03, 5.15, 5.16, 8.09, 10.05</b> Service Delivery ( <b>LGUs</b> ) <b>5.07</b> FP Services at Establishments/Enterprises ( <b>Department of Labor and Employment</b> ) <b>9.01, 9.02</b> Appropriations ( <b>Cross-Cutting</b> ) <b>10.04</b> NGAs Assist DOH <b>10.08, 10.09</b> Health Promo in NGAs' Programs ( <b>Cross-Cutting</b> ) <b>9.05</b> Funding for RPRH Education ( <b>PRC/CHED/TESDA/DepEd</b> ) <b>11.01, 11.05, 11.06</b> Provision of RPRH Education ( <b>DepEd</b> )	<b>4.14</b> Integrate RH in Health Professional Curriculum ( <b>PRC/CHED/TESDA</b> ) <b>6.11-6.13</b> Pro-Bono Services Requirements ( <b>PhilHealth</b> ) <b>7.07</b> Guidelines for FP Product Requirements ( <b>FDA</b> ) <b>7.09, 7.10</b> Post-Marketing Surveillance Unit ( <b>FDA</b> ) <b>11.04</b> Training Educators ( <b>DepEd</b> )

Abbreviations: CHED, Commission on Higher Education; CSO, civil society organization; DepEd, Department of Education; DOH, Department of Health; DSDVW, Department of Social Welfare and Development; FDA, Food and Drug Administration; FP, family planning; GBV, gender-based violence; LGU, local government unit; M&E, monitoring and evaluation; NGA, national government agency; PhilHealth, Philippine Health Insurance Corporation; PRC, Professional Regulation Commission; PWD, persons with disabilities; RH, reproductive health; RPRH, Responsible Parenthood and Reproductive Health; SBCC, social and behavior change communication; TESDA, Technical Education and Skills Development Authority.

<sup>a</sup>Sources: RPRH Implementing Rules and Regulations (2017 revision), annual accomplishment reports, key-informant interviews, and review of official documents and secondary literature.



**Despite the multidimensional nature of RPRH, FP received disproportionately more efforts and resources from RPRH implementers than did any other element.**

List. Similarly, Philippine Health Insurance Corporation (PhilHealth), with its core function of benefit package development,<sup>23</sup> fulfilled its mandate of having packages and case rates covering HIV/AIDS, breast and reproductive tract cancers, menopause-related conditions, and long-acting and permanent contraception.

In contrast, although few mandates explicitly mention overlap between the roles of 2 or more agencies, these made up most of the partial or incomplete accomplishments. An example is the compartmentalized co-management of the national FP program (NFFP) supply chain. In the backend, DOH is responsible for procuring FP commodities but has not yet established a computerized procurement tracking system. This contributes to delays in the FDA's overseeing the adherence of FP suppliers to proper handling, storage, and distribution and the conduct of post-marketing surveillance. The Commission on Population and Development's (POPCOM's) and LGUs' roles in FP distribution are the front-end components of the program's service delivery network. However, weak coordination with DOH has led to recurring supply-demand mismatches between procurement and distribution. In 2018, the Commission on Audit<sup>24</sup> found excessive procurement and overstocking of FP commodities, with many undelivered and expired. Their investigation found that DOH's poor inventory management was caused by weak and inefficient coordination within DOH central office units and between DOH central office and regional offices.

Within agencies, initiatives whose entire project cycle was handled by a sole implementing unit were mostly completed. For instance, the conduct of maternal, infant, and fetal death reviews fell under the oversight, evaluation, and support functions of the DOH Safe Motherhood Program.

However, compartmentalization within individual agencies has also contributed to incomplete accomplishments. DOH has still not been able to formulate annual monitoring and evaluation (M&E) plans, targets, and resources for its national multimedia campaigns, given that 3 separate bureaus are responsible for various inputs such as the technical content, material design, and M&E indicators. Another example is the rollout of the Department of Education's (DepEd's) comprehensive sexuality education curriculum, which the DepEd respondent rated only 40% implemented after 5 years of work. Because each change to the curriculum requires approval from 4 bureaus, implementation experienced significant delays. Both DOH and DepEd respondents said bureaucratic

delays were an inefficiency that hindered agency performance.

### Biomedical and FP Focus

Despite the multidimensional nature of RPRH, FP received disproportionately more efforts and resources from RPRH implementers than did any other element. FP has been brought up in almost every single NIT meeting, while the next most frequent elements are raised only half the time (Table 3). Moreover, FP programs are nationwide in scope with sustained implementation. As a result, other RPRH elements received less attention. For instance, the Mental Health Act of 2018 did not prompt discussions around Element 12 leading up to and following its passage.

The preponderance of FP may be partially attributed to the 5 KRAs chosen by NIT in 2015. These focused implementations on maternal, neonatal, and child health and nutrition, FP, adolescent sexual and reproductive health, violence against women and children, and sexually transmitted infections and HIV/AIDS. As such, most programs and initiatives reported in the annual ARs fell under RPRH elements corresponding to the 5 KRAs chosen by NIT (Supplement).

Although FP did not have the greatest number of unique programs, all 4 programs are regularly implemented in hundreds of sites throughout the country. Family counseling sessions are a requirement for those seeking marriage and applying for social welfare programs.<sup>25</sup> Businesses are also required to provide FP services to operate. In contrast, adolescent sexual and reproductive health has the most reported programs (Elements 4, 7, 11), but the majority of these were one-off events such as forums, competitions, seminars, and modules. FP programs are also explicitly required by the RPRH Law, whereas programs in other KRAs predate the RPRH Law and were created in response to pre-existing laws.

Even before the KRAs, FP came to the forefront of RPRH implementation and multi-agency efforts as implementers felt this area faced the most challenges. While other RPRH programs had longstanding support from elected officials, FP had a long history of controversy. Years of struggling to pass the law were due to the provisions related to FP. Just 4 days after the signing of its IRR in 2013, a Supreme Court status quo ante order delayed its implementation over a year, calling into question the constitutionality of FP services.<sup>26</sup> From 2015 to 2017, the Supreme Court imposed a temporary restraining order on the

**TABLE 3.** NIT Agenda by RPRH Element and Frequency in 71 NIT Meetings From 2014 to 2018<sup>a</sup>

RPRH Element	Frequency
1 Family planning	60
2 Maternal, neonatal, child health, and nutrition	32
11 Adolescent reproductive health (RH) education in formal and nonformal settings (i.e., comprehensive sexuality education)	30
4 Adolescent youth and RH guidance and counseling	27
3 Proscription of abortion and management of abortion complication	15
7 Sexuality and RH education and counseling	14
6 Violence against women and children and gender-based violence	12
5 Sexually transmitted infections, reproductive tract infections, and HIV/AIDS	11
8 Breast and reproductive tract cancers and other gynecological conditions and disorders	3
9 Male responsibility and involvement and men's RH	2
10 Prevention, treatment, and management of infertility and sexual dysfunction	1
12 Mental health aspect of reproductive care	0

Abbreviations: NIT, National Implementation Team; RPRH, Responsible Parenthood and Reproductive Health.

<sup>a</sup>Source: NIT Meeting Transcripts 2014–2018.

certification of contraceptive products by the Food and Drug Administration (FDA) and the procurement, distribution, and use of the progestin subdermal implants.<sup>27</sup> The current FP-centric approach taken by implementers was bolstered by support from the Office of the President in 2017<sup>28</sup> and renewed in 2019<sup>29</sup> to fully implement NFFP as part of the country's medium- and long-term development plans,<sup>30</sup> cementing FP's place as the linchpin of RPRH implementation.

*We don't feel the weight of other programs because the NIT meetings rarely touch on them. They are so focused on family planning. I attended 1 forum. Another attendee asked me why they always talk about family planning. So, I just answered, FP is a big problem because a large sector is against it. —Respondent 10*

National implementers' focus on FP from the days of lobbying for the law, overcoming legal obstacles, and capitalizing on current executive support have made the DOH, Commission on Population and Development (POPCOM), DepEd, PhilHealth, and CSOs the most visible actors for RPRH. Interviews with NGA representatives found that even among NGAs, RPRH is considered DOH's responsibility, and DOH is viewed as the leader of implementation.

However, deferring to the health sector emphasized a biomedical view for RPRH implementation. One anecdote from the KIIs highlighted the focus on and insufficiency of biomedical interventions to reduce adolescent pregnancy and

maternal mortality. Instead, social determinants directly influenced young mothers' health outcomes. Although some adolescent mothers were children of doctors, they delayed seeking medical care and informing their parents. A failure to address underlying determinants such as parental education, sensitivity training for health workers, and male responsibility in RH diminished the effectiveness of fertility management programs. This reality stands in contrast to the paradigm that population management alone can address all RH issues, which is still espoused in national policy.

*So mainly it's about family planning. . . that is because of the mandate of the president. The president is connecting family planning with poverty alleviation. So, it's not just a health concern, but about alleviating poverty. On teenage pregnancy, to be declared by the president as a national social emergency, it is still related to family planning. The president is also saying that in his State of the Nation Addresses. —Respondent 11*

The prominence of biomedical discussions has failed to secure the buy-in of NGAs outside the health sector to play a bigger role in RPRH implementation. This is exemplified by the absence of their agencies in NIT meetings and low attendance from higher-level decision makers.

### Programmatic and Operational Concerns

National RPRH governance has focused on service delivery, specific programs, and micro-operational

**TABLE 4.** Annual Trends and Issues Identified in RPRH Implementation<sup>a</sup>

Area	Issues	Years Identified				
		2014	2015	2016	2017	2018
Cross-cutting	No overall plan or a single agency solely in charge of nationwide implementation	●	●	●	●	●
	Weak M&E and data management	●	●	●	●	●
	Weak link between demand generation and service provision; weak logistics system	●	●	●	●	●
	Limited scope and scale of service delivery through public sector	●	●	●		●
	Capacity-building efforts of NGAs like DOH are limited to public sector	●	●	●		●
	Uncertainty of RPRH budget; limited absorptive capacity for incremental budgets	●	●			
	Low utilization of RPRH benefits; lack in clarity for reimbursements and guidelines	●	●	●	●	●
MNCHN	Limited access to services and stagnant/high MMR and IMR due to preventable causes	●	●	●	●	●
	Poor newborn, infant, child health and nutrition		●	●		●
FP	High unmet need varying across population groups; LGU difficulty operationalizing FP SDN	●	●	●	●	
	Variable training standards and requirements for FP licensing or accreditation; few HHR in facilities for competing priorities		●			
	Legal barriers to providing FP (i.e., TRO)		●	●		
	Impractical FP targets and planning, including resolution of bottlenecks				●	●
ASRH	Lack of clear legal authority and evidence-based technical guidelines to direct ASRH programs and strategies		●	●	●	●
	Unavailability of routinely collected age and sex disaggregated data on health service utilization		●	●		●
	Delay in adoption of CSE in K-12; limited IEC on ASRH for parents; ineffective awareness campaigns to raise demand for ASRH services			●	●	●
	High unmet need of adolescents; minors need parental consent to access FP services; lack of youth-friendly treatment centers; stigma					●
VAWC	Laws with dated or discriminatory content; gaps in local policies to address VAWC or GBV		●		●	●
	Inadequate research and monitoring for GBV- and gender-responsive services		●			●
	Lack of comprehensive package of services for survivors (psychosocial, legal, and support)		●			●
	Unaddressed cases and slow access to justice		●	●		●
	Lack of service provider capability (barangay VAW desks, WCPU in hospitals)		●			●
	Prevention of VAWC is not a priority					●

Continued

**TABLE 4.** Continued

Area	Issues	Years Identified				
		2014	2015	2016	2017	2018
STI-HIV/AIDS	Continuing growth of HIV epidemic; rising cases among children (vertical transmission)		●		●	
	Limited access to HIV/STI services and info		●	●		●
	Lack of data and research on HIV		●	●		
	Lack of laws to protect key populations from discrimination and stigma				●	

Abbreviations: ASRH, adolescent sexual and reproductive health; CSE, comprehensive sexuality education; DOH, Department of Health; FP, family planning; GBV, gender-based violence; HHR, health human resources; IEC, information, education, and communication; IMR, infant mortality rate; LGU, local government unit; M&E, monitoring and evaluation; MMR, maternal mortality rate; NGA, national government agency; RPRH, Responsible Parenthood and Reproductive Health; SDN, service delivery network; STI, sexually transmitted infection; TRO, temporary restraining order; VAW, violence against women; VAWC, violence against women and children; WCPU, women and child protection unit.

<sup>a</sup>Sources: Annual accomplishment reports 2014–2018.

concerns above multisectoral governance and leadership. Persistent challenges and recommendations identified in the annual ARs (Table 4) and KIIs highlighted the absence of legal, financial, and M&E mechanisms to support agencies' initiatives across all KRAs. For specific KRAs, governance challenges in planning, priority setting, coordinating, and combating stigma were brought up only in later years. Recommendations given to address these issues remained siloed within individual programs and agencies. Moreover, the KRA-based annual ARs lacked systematic evaluation of progress against the IRR, which operationalizes the contents of the law. Thus, while the law and IRR were congruent, implementation reflected in the annual ARs was not congruent with either.

**NIT Challenges in Governance**

Despite being aware of these challenges, NIT has not been able to steer NGAs toward higher-level governance functions for a decentralized government. NIT meetings instead focused on reviews and revisions for specific policies (70%), FP logistics and inventory issues (58%), and DOH's RPRH communication and health promotion programs (51%), which could be handled by program managers within NGAs (Table 5). The meeting agenda over the years also underscored the biomedical approach to RPRH employed by national-level planners.

Four obstacles may exacerbate NIT's difficulties performing its multisectoral governance functions.

1. Some of the recurring agenda could have been addressed within 1 or 2 agencies outside NIT, such as CSOs' requesting funding via

agreements with individual agencies. Most glaring are the regular updates on the stock of FP commodities, which could be resolved with a transparent tracking system made available to all NFFP supply chain co-managers.

2. Attempts to foster multisectoral coordination did not have a strategic preplanned meeting agenda; instead, each NIT meeting picked up from the content of the previous meeting. Thus, although 17 meetings broached NGA budgets for RPRH, these did not result in convergence budgeting or a unified financial plan because a clear output was not envisioned or expected.
3. NIT and NGAs did not have the tools to enforce their national-level plans. From 2015 to 2018, 17 meetings were devoted to the "Sorsogon issue," when a mayor of Sorsogon City restricted the distribution of FP devices in health facilities and limited the FP counseling sessions to natural methods. NIT found that it did not have the necessary investigation mechanisms and protocols to hold the local chief executive accountable. However, new NIT guidelines such as assigning an investigatory body, standards for LGU noncompliance, and appropriate sanctions or responses did not result from these discussions.
4. NIT members also do not have the means to hold each other accountable for meeting their respective targets and to foster more inter-agency collaboration. Two factors induce compartmentalization: (1) because NIT does not have its own independent staff, each NGA represents itself and finds it difficult to bring

**Persistent challenges and recommendations that were identified highlighted the absence of legal, financial, and M&E mechanisms to support agencies' initiatives across all KRAs.**

**Four obstacles may exacerbate NIT's difficulties performing its multisectoral governance functions.**

**TABLE 5.** NIT Agenda and Their Frequency of Discussion<sup>a</sup>

Agenda: Areas of RPRH Implementation	2014 (n=3)	2015 (n=12)	2016 (n=21)	2017 (n=16)	2018 (n=13)	2019 (n=6)	Total (n=71)
Policy reviews and revisions • 19 on proscription on abortion and management of complications (DOH AO 2018-03) • 5 on requiring an ambulance for hospital licensing (DOH AO 2018-01) • 5 on PhilHealth accreditation of stand-alone FP clinics (Circular 2018-05)	2	4	17	10	10	5	48
FP logistics Supply chain management issues (e.g., stock-outs), use of remaining progestin subdermal implants given SC TRO, and inventory counts	—	8	11	7	11	4	41
RPRH communication and health promotion National FP Conference, events, DOH-HPCS presentations on communication plan	—	3	9	10	11	3	36
Monitoring and evaluation FP Form 1, Annual report, data requests	—	8	15	6	4	1	34
Legal restrictions - SC-TRO	—	—	3	13	9	—	25
CSO funding Process of accreditation of grant funding	—	—	4	6	10	5	25
Capacity building for health care providers Training for FP, MNCHN, interpersonal communication and counseling; Accreditation of Training providers	—	3	4	6	5	5	23
Accreditation of health care providers Standardized certification programs and accreditation of CSOs and private providers	—	3	4	6	5	5	23
RPRH service delivery Various discussions on quality and access	1	4	3	6	8	—	22
PhilHealth claims/reimbursements	—	4	5	6	3	3	21
RPRH budget DOH budget cuts, augmentation, convergence budgeting	—	3	7	4	2	1	17
Sorsogon “Pro-Life City” (LGU issue)	—	4	9	2	2	—	17
ASRH technical working group NIT organizational challenge: Functionality and leadership	—	9	—	5	2	—	16
Regional implementation teams Organizational challenge: Functionality, reporting issues	—	1	8	—	4	2	15
Service delivery network PhilHealth facility accreditation and issues on DOH facility standards (e.g., need for ambulance)	—	5	5	1	2	—	13
Quantity of health care providers Deployments for nurses and family health associates	—	1	4	1	6	—	12

Abbreviations: AO, administrative order; ASRH, adolescent sexual and reproductive health; CSO, civil society organization; DOH, Department of Health; FP, family planning; HPCS, Health Promotion and Communication Service; LGU, local government unit; MNCHN, maternal, neonatal, and child health and nutrition; NIT, National Implementation Team; PhilHealth, Philippine Health Insurance Corporation; RPRH, Responsible Parenthood and Reproductive Health; SC, Supreme Court; TRO, temporary restraining order.

<sup>a</sup>Source: NIT meeting transcripts 2014–2018.

up their shortcomings, leading to a lack of corrective action taken even when governance issues are raised, and (2) because each agency sets its implementation targets and reports its accomplishments,<sup>31</sup> the M&E system prioritizes success indicators, rather than accounting for how different agencies' programs interface together or how they translate in LGU implementation.

Although implementers can formally issue a joint memorandum circular that may integrate the functions of and split accountability between 2 or more NGAs, these were not maximized. Of the 104 reported RPRH policy infrastructures in the annual ARs, only 2 were joint memorandum circulars; both included the DOH as a signatory.

### Absence of NIT Leadership

The 4 obstacles highlight the absence of clear leadership within NIT. Although the position of chair was assigned to the secretary of health, the pivotal role was initially passed to a former secretary of health who was a private individual at the time. The chair prioritized NGAs' meeting their program targets and promoted the involvement of CSOs; however, a macro-operational view of RPRH was overlooked in the process. Only later was the position taken on by a DOH official. This set the tone for NIT's prevailing operating procedure: NIT is expected to resolve programs' operational issues as they are raised rather than proactively set the multisectoral agenda. Consequently, there is a dearth of attention to and effort for building integrated interventions and the investments required to implement them, which some respondents observed.

*The idea of creating the NIT was good. It should be an avenue for the stakeholders to come in together to provide recommendations . . . But what really happens, it became a venue for partners to air their rants, their complaints, their concerns. So, it doesn't seem like a recommendatory policy body. —Respondent 17*

Current operations stand in contrast to NGAs' united effort in the past to lift the status quo ante order and temporary restraining order. Meeting minutes indicate that together, health-sector NGAs, multilaterals, and CSOs advocated for RPRH, provided RH services, and mobilized civil society's demand for RH until the law and its mandates were declared constitutional. Thus, NIT shows great potential as a venue for stewardship for the full and holistic implementation of the law; however, this outcome has not yet been realized given its focus on specific

complaints. The most blatant example of micro-operational thinking is that implementers have still been unable to produce the mandated comprehensive package of RPRH services. Various RPRH services are still demarcated by the units that pilot them, translating to how they are presented as an individual NGA's accomplishment in the annual ARs. Subsequently, this mindset obscures absent services needed in the bigger picture. However, some RPRH implementers have become aware of this problem and the need for multi-agency collaboration that understands the interplay of different programs.

*It seems like even if this element is connected to reproductive health, more often than not, we do not see the connection. I observe we deal on matters separately so when you say reproductive health, the discussion is confined to them [health agencies]. But for the other elements, we also admit that we sometimes view them without the health lens when actually we should also see, for instance, eliminating violence against women by access to reproductive health. —Respondent 2*

As more implementers shifted to a multisectoral perspective for RH, NIT initially intended to develop a concrete multisectoral implementation plan in 2020. However, their strategy meetings were stalled due to the COVID-19 pandemic.

## DISCUSSION

Based on results presented in the Findings section of this article, we chose the Centers for Disease Control and Prevention policy process (Box) to guide the explanation and interpretation of the governance trends in this section.

The study sought to present and explain trends in national-level implementers' governance activities to facilitate the implementation of the Philippines' RPRH Law. It found that implementation focused on the success of specific programs without a clear plan for integrated services to improve the country's RH outcomes. These programs were heavily skewed toward FP and other biomedical interventions handled by the health sector. Thus, despite the multisectoral nature of RH, implementation efforts and responsibilities were siloed within NGAs and the units that pilot them.

However, policy implementers in the Philippines have begun to recognize RPRH is multisectoral. As a country in the first decade of implementing a national RH policy, the Philippines' challenges to improve RPRH performance are not unique. Governance issues remain major challenges in RH implementation worldwide, particularly among LMICs, and these issues reinforce compartmentalized performance.<sup>32</sup>

**The study revealed a dearth of attention to and effort for building integrated interventions and the investments required to implement them.**

**Despite the multisectoral nature of RH, implementation efforts and responsibilities have been siloed within NGAs and the units that pilot them.**

**BOX.** The Centers for Disease Control and Prevention Policy Process

The process (Figure) includes agenda setting and planning activities before policy implementation; its focus on stakeholder engagement and collaboration is appropriate given the multi-agency nature of RPRH implementation.

In the problem identification phase, decision makers first agree on the main issue to be addressed, including which populations are most affected, the scale and scope of the issue, and its causes. The framing of the problem narrows the menu of solutions to be considered in the policy analysis phase. The goal of this second phase is to identify, evaluate, and compare different policy solutions according to their (1) effectiveness, defined by how well they respond to the needs of the affected; (2) efficiency, defined as how benefits can be maximized and costs minimized; and (3) feasibility, defined by whether resources are sufficient.

The strategy and policy development phase refers to making the policy actionable, planning for partnerships, and finalizing the form, language, and policy content so the policy is formally and informally accepted. In policy enactment, approval for implementation is obtained from individual and organizational stakeholders.

Finally, the policy implementation phase involves carrying out the main activity or service as well as performing governance functions: establishing the structures, processes, and environment for the sustainability of implementation. These functions comprise educating stakeholders, improving operations and systems, channeling human and financial resources, and constantly monitoring to hold each implementer accountable. At each phase, evaluations determine whether activities answer the policy problem.

Lessons learned from other LMICs' attempts to coordinate multisectoral action can provide possible governance solutions to improve RH outcomes and promote human development in the Philippines and other neutral policy settings, where there are no clear conflicts of sectors' objectives.

**Sector-Based Framing**

Siloed implementation may be traced to the problem identification phase of RPRH implementation, where implementers painted the issue as the responsibility of discrete NGAs rather than a problem requiring multi-agency solutions. Thus, RPRH programs are inserted wherever they align with existing NGA functions rather than as a part of a prepared multisectoral strategy.

In framing the problem, implementers turned to the language of the RPRH Law and IRR; however, these documents do not provide a concrete vision for multisectoral coordination. Although the rules of the RPRH-IRR Drafting Committee identified NIT agencies, local-government coalitions, and CSOs as its members, mandates were more detailed for DOH tasks while tasks of other agencies remained vague. This finding implies that siloed, DOH-focused implementation predated the drafting of the IRR and was not addressed by it. RPRH policy problems are thus framed by individual NGAs and the sectors they represent, which limits policy solutions to a sector's expertise. Subsequently, agencies unilaterally design, plan, and implement policies to fulfill their mandates without consulting with or studying the effect of other agencies' RPRH policies.

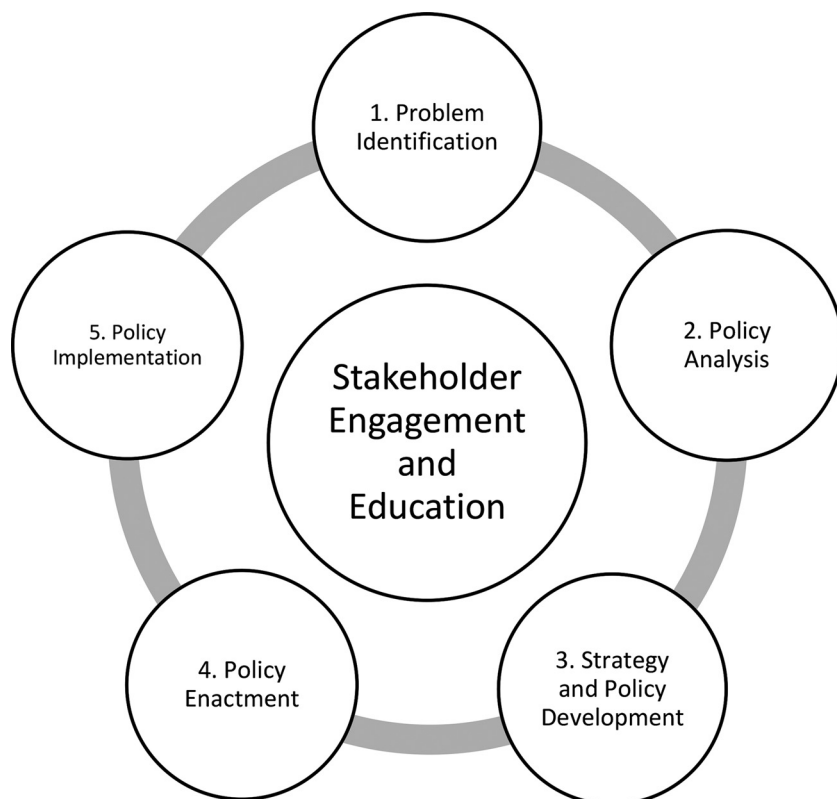
Non-health sector implementers often are unaware of the extent of the problem,<sup>9</sup> and a siloed

understanding of the problem can hinder coordinated efforts that benefit multiple sectors. In 2013, Ethiopia attempted a multi-agency National Nutrition Program.<sup>33</sup> Although each sector agreed that undernutrition, food insecurity, and micronutrient deficiencies were pressing issues, the sectors disagreed about their causes, leading to different priorities for advocacy and budget allocation, leading to a lack of multisector plans.

Concurrently, NGAs have vested interests in their own sectors and agencies' performance. The prevailing tendency to prioritize one's own sector was also observed in Zambia,<sup>34</sup> where the government's maize industry protections may factor into low dietary diversity and the absence of integrated nutrition programs requiring the cooperation of the agricultural and economic sectors.<sup>35</sup> NIT does not face competing sectoral interests to the same extent. Nonetheless, agencies' weak coordination is coupled with a reluctance to disclose their implementation shortcomings. As was found in the KIIs, NGA representatives feel they must defend the image of their agency in NIT. Such an environment prevented constructive feedback for perennial agenda items such as the NFFP supply chain. DOH was not incentivized to streamline coordination among its units, and waste could have been avoided by clearly delineating the roles of each agency to cover all necessary activities across the supply chain while having a transparent monitoring and tracking system accessible to all implementers. Thus, limitations of the RPRH Law and reliance on health sector leadership have failed to provide a case for investing in what is still perceived as a health issue, over the inclination toward their own sectors' concerns.

**Siloed implementation may be traced to the problem identification phase of RPRH implementation.**

**FIGURE.** The Centers for Disease Control and Prevention Policy Process<sup>21</sup>



However, the creation of a single compelling narrative can engage different sectors and maintain continuity despite leadership changes. Peru’s<sup>34</sup> national nutrition programs successfully achieved their targets because of the narrative to eradicate under-5 malnutrition by 5% in 5 years. The 2006 advocacy campaign was so popular among Peruvians that officials across agencies, parties, and presidential terms were inclined to focus on nutrition.

Multisectoral framing in policy planning more accurately responds to the problems faced by health systems.<sup>9</sup> Other sectors’ involvement in public health policies become more apparent when considering the social determinants of health,<sup>36</sup> which highlights that the nonmedical context of people’s daily lives influences their health outcomes. By making clear how each agency understands a problem and can contribute to a solution, a holistic approach to policy making can be undertaken.

**Health-Centric Policy Options**

Of the 5 health-centric KRAs, FP deliberately received the most attention from implementers to

compensate for the political challenges FP programs faced. Preoccupation with these legal battles<sup>37</sup> may have hampered attempts to comprehensively build a multisectoral strategy beyond FP. The emphasis on biomedical programs and FP may be analyzed according to the issues faced by public administrators during the policy analysis and strategy development phases.<sup>21</sup>

FP is a national priority at multiple levels of governance (e.g., Office of the President, NIT, NGAs), and the continual discussion of a particular agenda primes strong opinions and decisions in favor of engaging with the issue.<sup>38</sup> Although fertility management can indeed aid in improving health outcomes, a predisposition to FP interventions precludes exploring how other RPRH elements can supplement them and address other RH policy problems.

The prominence of FP interventions exemplifies the biomedical paradigm, in which “clinical interventions take on aggressive forms and emphasize short-term results,”<sup>39</sup> based on the premise that the body can be treated independently of

**By making clear how each agency understands a problem and can contribute to a solution, a holistic approach to policy making can be undertaken.**



**NIT's leadership role is fundamental to engaging with different sectors, and effective leadership can coordinate stakeholders and overcome opposition and resource deficits.**

**Through empowering non-health sectors in NIT, more holistic policy options for RH can be devised for the needs of the Philippine RH context.**

one's context.<sup>40</sup> Consequently, nonmedical and preventive interventions, which address the impacts of the individual's socioeconomic, political, and environmental context, are viewed as less legitimate. Such a paradigm individualizes the issues that may be caused by systemic or structural inequalities, and poor social, economic, and health outcomes are attributed to individual failure.

Although many countries' development paradigms once relied heavily on managing fertility through biomedical interventions, a focus on the quality of life afforded each citizen emerged following the 1994 Cairo Declaration on Population and Development.<sup>41</sup> Since then, countries that famously prescribed population control, like China,<sup>42</sup> have begun to focus on improving social services while easing restrictions on family size.

Thailand's decentralized government<sup>43</sup> also faced difficulties providing integrated and coordinated RH services across sectors.<sup>44,45</sup> This situation changed in 2017 when the government recognized that underlying factors such as better education, better jobs, and higher income, especially among women, led to greater gains in reducing the total fertility rate than their NFFP alone could have achieved.<sup>46</sup> Thai RH policy then shifted to providing a better-quality life to those born by basing their success and impact indicators on human rights and the social determinants of RH, similar to the United Nations Population Fund's demographic dividend index,<sup>47</sup> which integrated various human capital inputs for health, employment, youth rights, and education to track African states' progress toward sustainable development.

Should the Philippines employ a similar index, various RPRH can be connected congruent with the vision of the RPRH Law and IRR. The index can provide objective annual benchmarks to hold NIT members accountable, while also engaging with non-health sectors.

Through empowering non-health sectors in NIT, more holistic policy options for RH can be devised for the needs of the Philippine RH context. Meaningful participation of different sectors can provide expert information on solutions that may not have been apparent to a sector alone.<sup>21</sup> Some examples include reforming the private insurance market in the state of California in the United States to automatically include comprehensive maternity benefits for any health care plans.<sup>48</sup> US federal policy also integrates health care, criminal justice, and social work policies to address sexual and partner violence.<sup>49</sup> As more studies highlight the vulnerability of disadvantaged groups to poor

RH outcomes,<sup>50-52</sup> understanding the dynamics of one's socioeconomic, political, and community context is more relevant than ever.

### Weak Leadership for Implementation

In RPRH implementation, NIT serves as the coordinating body for RPRH activities. However, persistent governance challenges in planning, financing, monitoring, and accountability, may be attributed to the structure and activities of NIT during the policy enactment and policy implementation phases.

NIT's leadership role is fundamental to engaging with different sectors. Effective leadership can coordinate stakeholders and overcome opposition and resource deficits. For instance, health interventions to control noncommunicable diseases are often met with pushback from the food, tobacco, or alcohol industries.<sup>9</sup> However, in Turkey, Brazil, and Norway,<sup>9</sup> stewardship catalyzed policy creation, united different sectors to pressure industries, and eventually shifted the policy environment to produce better health outcomes.

Effective leadership is tied to 3 accomplishments<sup>21</sup>:

1. Outcomes and goals must be made clear to all stakeholders. Since LGUs are ultimately responsible for RPRH service delivery, local chief executives need to be educated and empowered.
2. Policy makers must identify the necessary resources for implementation. These include not only the financial and human resources needed to execute the programs but also the policy infrastructure to support changes made to systems that ensure the sustainability of implementation.
3. Implementers must designate who is involved and what each actor's responsibilities are in a concrete plan, which includes having a clear leader, definite roles for each implementer, and plans with opportunities for collaboration in mind.<sup>53</sup>

To address such challenges, NIT can reform its structure. The present NIT structure is flat, with no agencies having authority over others. One alternative model would appoint a dedicated full-time NIT executive team to create guidelines and incentives, while serving as an objective arbiter holding members to their benchmarks. Historically, POPCOM operated under such an arrangement, before its functions were diminished during its

subsumption into DOH and later back to the National Economic Development Authority.<sup>54–56</sup>

Another model involves restructuring NIT into management teams<sup>57</sup> or committees. Currently, NIT has technical working groups, each composed of different agency representatives; however, meeting transcripts reveal an absence of their contribution to NIT operations. Future research may explore optimal arrangements for NIT technical working groups, coordinated by the chair, as the main driver for NIT's governance activities.

Such reforms within NIT will facilitate multi-agency policy integration, changing administrative practices and institutional culture and assimilating RH into different policies.<sup>58</sup> Policy integration weaves RH into all levels of an agency's agenda (vertical integration) and across sectors (horizontal integration). Rather than aiming to create 1 policy executed by each actor, the goal is to study the relationships of each agency's policies and how they can address the issue together.

As evidenced in NIT, however, many LMICs face the barrier of the traditional hierarchical structure of state organizations,<sup>9</sup> which tends to value vertical authority over horizontal partnerships. Through horizontal planning and communication, NGAs can veer away from program-specific operational challenges toward creating formal partnerships and identifying areas where multisectoral dimensions can be added to pre-existing policies, programs, and indicators.<sup>59</sup> Planning also promotes accountability,<sup>60</sup> which fosters ownership and commitment to carrying out NGAs' roles.

Together, these trends may have contributed to slow improvements in RH outcomes despite the law's passage. In 2015, the country failed to meet its Millennium Development Goals for reducing maternal mortality, lowering HIV/AIDS incidence, and eradicating poverty.<sup>61</sup> Currently, the country stands to once again fail to meet its Sustainable Development Goals as the maternal mortality ratio remained at 121 maternal deaths for every 100,000 live births in 2017,<sup>62</sup> Philippine HIV infections are one of the fastest growing in Asia,<sup>63</sup> and the poorest Filipino women are 5 times more likely than the richest income quintile to have begun childbearing in their teenage years.<sup>64</sup>

### Limitations

The results of this research should be considered in light of 3 limitations. Because the study focused on national-level governance, the scope of KIIs was limited to national-level implementers. The

impact of NGAs on subnational government units' RPRH activities could not be assessed, and due to the sudden outbreak of COVID-19 disease, interviews with every single implementing agency were not pursued. Given the focus on trends in governance, KIIs also did not cover the specifics of each RPRH program and policy and governance of discrete programs such as supply chains in depth, as those warrant separate nuanced studies. Nonetheless, data collection for the KIIs had reached a point of saturation and common themes could be identified from the interviewees' responses. Moreover, other data collection techniques such as official document reviews and literature searches were employed when necessary to provide more context for NGAs' tasks, policies, and programs. Despite religious groups' visible presence in the history of the law, their noninvolvement in national governance for its implementation precluded them from the scope of this study. Additionally, their role in the law's implementation at the national level was not mentioned in our interviews or reviews of documents such as the annual ARs. Although some religious groups may aid in the implementation of the law at the community level, their involvement was beyond the national-level scope of this study.

Except for NIT meeting transcripts, document reviews included only published documents, reports, and policies. Of the official documents, quantitative success indicators reported by NGAs were not analyzed. Rather, as the first study to assess national-scale RPRH performance, the study was focused on trends in performance to identify major areas for administrative reform.

Finally, given the nature of this study as part of the first review of RPRH implementation, literature on multi-agency RPRH efforts in the Philippines was scarce. As such, the study looked for parallels of multisectoral action for health in other LMICs. The study also revealed gaps in prior literature on comprehensive multisectoral RH policies, particularly in LMICs, as most pertained to nutrition programs.

### CONCLUSION

As more developing countries formally recognize the need for multidimensional interventions to improve the lives of their citizens, multisectoral governance becomes ever more crucial to create strategies and enforce commitments across government agencies. While comprehensive studies on multisectoral policies in LMICs are scarce, those on RH are even more so. This study sought

**Reforms within NIT will facilitate multi-agency policy integration, changing administrative practices and institutional culture and assimilating RH into different policies.**

to extend the literature as part of the first evaluation of the Philippines' RPRH Law.

The Philippines' implementation of the RPRH Law presents a case of a country in the first decade of implementing a multisectoral initiative for sustainable human development. Agencies' viewing only the interests and interventions under the purview of their respective sectors has limited interagency collaboration. Although RH is multidimensional, historical focus on the law's fertility management aspect has skewed policy options toward biomedical interventions. Despite having an interagency coordinating body, NIT has not reached its full potential, including creating a multi-agency strategy for RPRH implementation. Faced with a lack of formal mechanisms to facilitate multi-agency coordination, NGAs' implementation of the law is fragmented, biomedical, and programmatic and has not led to remarkable changes in the country's RH status.

In light of these challenges, policy makers have begun to acknowledge the importance of an integrated and coordinated response to modern RH issues.

Although multisectoral governance challenges are complex, experiences from other LMICs can illuminate possible actions to address them. Creating a single compelling narrative to frame the policy issue can emphasize the multidimensional nature of the problem and identify structural causes, which may not straightforwardly relate to health. Including different sectors' expertise, through horizontal integration and communication, broadens policy solutions and provides more benefits to populations. Developing a single multisectoral index to benchmark each implementer's annual progress can promote accountability. Finally, appointing a dedicated RPRH lead while assigning sector representatives to committees may be a more effective model of governance that promotes planning and accountability.

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## ORIGINAL ARTICLE

# Negative Incentives for Noninstitutional Births Are Associated With a Higher Rate of Facility-Based Births in the Eastern Visaya Region, Philippines

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## Key Findings

- Negative incentives to prohibit noninstitutional deliveries were significantly associated with higher facility-based delivery rates.
- No significant association was found between positive incentives and the facility-based delivery rate.

## Key Implications

- Along with introducing penalties for noninstitutional deliveries, investing limited resources to make a vehicle available at the barangay level could effectively address these barriers and increase the facility-based delivery rate.

## ABSTRACT

In the Philippines, the “no home-birthing policy” implemented in 2008 has encouraged local governments to endorse ordinances that prohibit noninstitutional deliveries (NIDs). The Philippines’ social insurance scheme has also enabled them to provide incentive payments to women who deliver at birthing facilities (BFs). This study evaluated whether these positive and/or negative incentives were associated with an increased facility-based delivery (FBD) rate and examined challenges in implementing those incentive measures in the Eastern Visaya Region of the Philippines. Cross-sectional data were collected regarding delivery locations during 2017, and barangay-level data were collected regarding positive and negative incentives and the characteristics of 4,371 barangays in the region. Multivariate logistic regression analysis, using “ordinance with nonmonetary sanction” as the reference category, indicated that no ordinance to prohibit NIDs was significantly associated with a lower FBD rate (odds ratio [OR]: 0.90,  $P=.013$ ), and ordinance with low cash penalty (OR: 1.37,  $P<.001$ ) and high cash penalty (OR: 2.52,  $P<.001$ ) had higher FBD rates. Positive incentives were not associated with FBD rates (OR: 1.02,  $P=.563$ ). The FBD rate was also significantly associated with urban barangay status (OR: 1.45,  $P<.001$ ), availability of a vehicle (OR: 3.19,  $P<.001$ ), availability of public transportation to a government BF (OR: 1.25,  $P<.001$ ), and distance to the most accessible government BF (OR: 0.89,  $P<.001$ ). Substantial proportions of barangays had no vehicles available for transportation (34.1%) or no available vehicles and no public transportation to a government BF (5.5%). Although negative incentives for NIDs could motivate pregnant women to seek FBD, local governments in the Philippines should be aware of barriers that limit access to government BFs in underserved barangays before introducing those negative incentives. Above all, barangay-level investments in making a vehicle for transporting pregnant women might help address these barriers and increase the FBD rate.

## INTRODUCTION

Access to quality maternal care throughout pregnancy is the key to reduce preventable mortality and morbidity among pregnant women.<sup>1</sup> In particular, facility-based deliveries (FBDs) are considered a crucial contributor to improving the maternal mortality ratio in low- and middle-income countries (LMICs).<sup>2–4</sup> In the Philippines, the Department of Health (DOH) issued the Maternal, Newborn and Child Health and Nutrition (MNCHN) Strategy in 2008 to reduce maternal mortality

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**Despite studies of positive and negative incentives, little has been studied about the effects of such incentives on the facility-based delivery rate in the Philippines.**

by primarily promoting FBDs.<sup>5</sup> The strategy was further updated by the MNCHN Manual of Operations, which was released in 2011 and contained a key statement on the prohibition of deliveries assisted by traditional birth attendants (TBAs).<sup>6</sup> It particularly highlighted that deliveries assisted by TBAs contributed to the 3 delays, namely delays in identification of complications, referral, and management of complications, and led to maternal and neonatal deaths.<sup>6</sup> These documents have been interpreted as a “no home-birthing policy” and have generated controversy regarding their appropriateness, especially in underserved small villages that are known as barangays.<sup>7,8</sup> The documents resulted in several local governments endorsing ordinances to prohibit home-based deliveries assisted by TBAs and often to penalize TBAs and/or pregnant women who participate in noninstitutional deliveries (NIDs).<sup>7</sup> The penalties indicated in the ordinances were either cash payments or nonmonetary sanctions such as a reprimand by authorities. Some ordinances simply prohibit home-based deliveries without specifying penalties.

The Philippines has a social insurance scheme (PhilHealth) with a Maternal Care Package that covers essential health services during the prenatal period and throughout all stages of labor, normal delivery, and the immediate postpartum period. Cases that involve a normal delivery are reimbursed at rates of 8,000 Philippine pesos (PHP) for accredited primary care facilities and 6,500 PHP for hospitals.<sup>9</sup> Local governments with jurisdiction over those facilities may decide to direct a portion of the reimbursed amount to the women as a cash incentive to promote FBDs.

Individual- and community-level factors that affect FBDs have been examined in LMICs, and these factors are related to the local sociodemographic, socioeconomic, and cultural situation.<sup>10–14</sup> A study by Bohren et al.<sup>14</sup> indicated that key barriers to FBD include traditional and familial influences, distance to the facility, cost of delivery, low perceived quality of care, and fear of discrimination during FBD.<sup>14</sup> In the Philippines, a study based on the 2013 National Demographic Health Survey<sup>15</sup> revealed that the FBD rate might be influenced by the child’s birth order, the mother’s religion, and the subjective distance to the closest health care facility.<sup>16</sup> Another study revealed that a woman’s choice of FBD might be influenced by the involvement of the husband and other people in the decision regarding delivery location.<sup>17</sup>

Financial incentives and penalties have also been used to promote maternal care service

utilization and FBDs in LMICs. A systematic review by Murray et al.<sup>18</sup> identified various studies that examined how demand-side financing or positive incentives influenced women’s decision to seek the services of a skilled birth attendant. A few studies also examined the impacts of the penalties or negative incentives that were applied to TBA-assisted deliveries.<sup>19,20</sup> A qualitative study in the Philippines also examined mothers’ and service providers’ views regarding the effects of financial incentives and penalties on the FBD rate.<sup>21</sup> Despite these studies of antecedents that focused on the positive and negative incentives, to the best of our knowledge, little has been studied about the effects of those incentives on the FBD rate in the Philippine context. In addition, few studies have quantitatively examined the association between the negative incentive for NID and the increase of the FBD rate in LMICs.

This study evaluated the association between local governments’ policies regarding positive and negative incentives to promote FBD and pregnant women’s decisions to seek FBDs and NIDs in the Eastern Visaya Region of the Philippines. The study also examined challenges in implementing those incentives and policy measures that might be useful for increasing the FBD rate in the region.

## ■ METHODS

### Target Areas and Facilities

The Eastern Visaya Region is 1 of the 17 regions in the Philippines, with a population of 4,440,150 people. The region is composed of 6 provinces that are subdivided into 143 cities/municipalities and then into 4,390 barangays.<sup>22</sup> The region’s total land area is 23,234.8 km<sup>2</sup>, which accounts for 7.7% of the national land area.<sup>23</sup> The per capita gross domestic product (GDP) in the Eastern Visaya Region was 73,995 PHP or US\$1,404 in 2018, while the national average per capita GDP was 163,474 PHP or US\$3,102.<sup>24</sup>

Institutional delivery takes place at birthing facilities (BFs), which are categorized as hospitals, infirmaries (quasi-hospitals that do not satisfy the DOH’s hospital standards), or birthing homes (primary care facilities that satisfy the DOH’s standard for BFs). As of December 31, 2016, the Eastern Visaya Region included 46 hospitals (23 government and 23 private hospitals), 38 infirmaries (28 government and 10 private centers), and 127 birthing homes (104 government and 23 private centers).<sup>25–27</sup> Each barangay has a barangay health station (BHS), which is the most peripheral health facility that provides primary health care

services, including antenatal care. Functional BHSs are staffed with a full-time or part-time rural health midwife (RHM) or a nurse, although some BHSs are considered nonfunctional because adequate staff are not available. All the women in the region were exempted from paying for delivery services at government facilities during the study period because of the devastation caused by Typhoon Haiyan in 2013, indicating that the user fee payment is less likely to be a barrier to FBD for pregnant women in this study.<sup>28</sup>

### Data Collection

Cross-sectional data of deliveries in 2017 were collected between February and May 2018 from the 4,390 barangays in Eastern Visaya Region. The 1,568 temporary staff who had been hired and assigned at the barangay level under the DOH's deployment program (Nurse Deployment Program: 1,465 individuals, Universal Health Coverage Implementor Deployment Program: 103 individuals) were trained to serve as data collectors.<sup>29</sup> The collected data were compiled at the municipality/city level and submitted to the DOH research team in Manila; data of 19 barangays were not submitted. Thus, the present study included data of 4,371 barangays, which were entered into a database for analysis.

A questionnaire form was used to collect 3 types of data at the barangay level.

First, delivery-related statistics were gathered. FBDs and NIDs that involved each barangay's residents were identified between January 1 and December 31, 2017. In principle, the BHS-level prenatal registers are filled out by RHMs or nurses in charge of the barangays. The prenatal register is updated each time barangay health workers (BHWs) identify a new pregnant client, when BHWs conduct house-to-house visits for pregnancy tracking in their barangays, when a registered pregnant woman makes a prenatal visit or gives birth, or when a non-registered woman gives birth at a facility located within the barangay. Information of NIDs and deliveries that occur at private facilities and government facilities in other municipalities/cities is supposed to be relayed to the RHMs or nurses in charge and retrospectively reflected on the BHS-level prenatal registers. However, in reality, the BHS-level prenatal registers have 3 issues: (1) they often fail to record information regarding deliveries by pregnant residents that occur in other municipalities/cities, (2) they occasionally do not include pregnant residents who did not seek antenatal care at the BHS, and (3) they include nonresidents who delivered at a facility located

within the barangay. Therefore, to meet the purposes of the study, a register that only considered deliveries by residents in their own barangay was introduced to guide the barangay-level calculations of FBDs and NIDs.<sup>30</sup> Information gaps regarding pregnant residents who did not appear in the prenatal registers were filled based on the recall of the RHMs or nurses in charge of the barangays, as well as in consultation with BHWs who were familiar with the household statuses of barangay residents from their periodical house visits.

Second, missed delivery cases were accounted for. To estimate the chance of missed delivery cases in the barangays, the RHMs or nurses in charge were asked to answer the following question: "Have you ever come across a woman among the barangay residents whose pregnancy status you were not aware of during the prenatal period, but became aware of the pregnancy history only when a newborn child was brought to you for immunization or other services?" If the answer was "yes," they were additionally asked to give the number of such cases they observed in 2017.

Third, barangay characteristics were recorded. The RHMs or nurses in charge of the barangays were consulted to answer the following questions: (1) "Did pregnant women in this barangay receive any incentive payments for FBDs during 2017?" and (2) "Was there a local ordinance or policy supported by a written official order to prohibit NIDs that was effective during 2017?" In connection with the second question, the type and cash amount of the penalties were also asked. Additional information was collected regarding whether the barangay was classified as urban or rural; whether an RHM or a nurse was deployed at the BHS (full-time/part-time or none); what was the most accessible government BF; whether a vehicle was available for transporting pregnant women; and whether a government BF was accessible via public transportation (or walking). A vehicle was considered available if (1) the barangay owned a functional ambulance/vehicle, (2) an ambulance/vehicle owned by the municipality/city/province would pick up pregnant women within the barangay, (3) the barangay had an official memorandum of agreement with private health care facilities to use their ambulance/vehicle, or (4) the barangay had an official memorandum of agreement with owners of personal vehicles or tricycles. The distance from the barangay centroid to the most accessible government BF was also calculated for each barangay.

**Cross-sectional data of deliveries in 2017 were collected between February and May 2018 from the 4,390 barangays in Eastern Visaya Region.**



## Data Analysis

The barangay-level dataset was reorganized to generate a new individual-level dataset of deliveries during the study period that were coded as FBDs (a value of 1) or NID (a value of 0); all the delivery cases in the new dataset inherited the variables of the barangay characteristics. A multivariate logistic regression analysis was performed with the binary status of FBD as the outcome variable and the barangay's characteristics as the explanatory variables. The barangay's characteristics used in the logistic regression model included (1) providing incentive payments for FBDs, (2) local ordinance to prohibit NIDs, (3) urban or rural barangay status, (4) an RHM or nurse deployed (full-time/part-time or none), (5) vehicle availability, (6) public transportation availability, and (7) distance to the most accessible government BF. Among these variables, the local ordinance to prohibit NIDs was treated as a categorical variable with the following categories that were dummy coded: (1) yes, nonmonetary sanction or penalty not specified, (2) yes, with low cash penalty, (3) yes, with high cash penalty, and (4) no. All the other variables were treated as binary variables, except the distance to the most accessible government BF, which was treated as a continuous variable. Odds ratios (ORs) of each variable were calculated with 95% confidence intervals (CIs) and *P*-values. The variance inflation factors were also calculated to detect the presence of multicollinearity in the model. Additionally, we analyzed the vehicle availability at the barangay level by its ownership.

**Multivariate logistic regression analysis revealed that FBD was significantly associated with barangays prohibiting NIDs.**

## Ethical Considerations

The study protocol was exempted from review by the Research Ethics Review Committee of Eastern Visayas Health Research and Development Consortium, as it was considered low-risk research that did not involve direct contact with human subjects. Client-level data were de-identified during the data aggregation process. No direct contact was made with pregnant women throughout the study period.

## RESULTS

During the study period, we identified 74,414 deliveries in the 4,371 barangays of the Eastern Visaya Region. The deliveries included 65,842 FBDs, 6,016 NIDs, and 2,556 deliveries at unknown places. When we only considered deliveries in known locations, the regional FBD rate was 91.6% (Table 1). In addition, during the immunization service provided in the 4,371 barangays in the

study period, 4,228 delivery cases that had not previously been reported by the BHWs were identified.

Table 2 shows the characteristics of the 4,371 barangays. The results indicated that 43.2% of the barangays provided incentive payments for FBDs and 77.6% had implemented a local ordinance or policy supported by a written official order to prohibit NIDs. The vast majority of barangays were rural (97.3%) and 10.4% of barangays had nonfunctioning BHSs (i.e., no staff to provide routine maternal care). A vehicle was considered available for transporting pregnant women in 65.9% of the barangays, and most barangays (91.3%) had available public transportation to government BFs. However, 5.5% of the barangays did not have an available vehicle or public transportation. The median distance from the barangay centers to the most accessible BF was 4.06 km (range: 0–39.4 km, interquartile range: 5.54 km). Among barangays that provided incentive payments for FBD, the mean value was 1,239 PHP (range: 10–8,000 PHP, standard deviation: 541 PHP). Concerning the penalties for the first-time offense of NIDs, 20.6% either indicated nonmonetary sanction or did not specify any penalty in the orders, 28.5% indicated cash penalty amounts ranging between 200 and 1,000 PHP, and 28.5% between 1,200 and 10,000 PHP. The orders were supported by city, municipality, and/or barangay-level ordinances.

Multivariate logistic regression analysis revealed that FBD was significantly associated with barangays prohibiting NIDs. When using “yes, nonmonetary sanction or no specific penalty” as the reference category, FBD was negatively associated with barangays without an ordinance to prohibit NIDs (OR: 0.90, 95% CI: 0.83–0.98), *P*=.013) and positively associated with low cash penalty (200–1,000 PHP) (OR: 1.37, 95% CI: 1.26–1.49, *P*<.001) and high cash penalty (1,200–10,000 PHP) (OR: 2.52, 95% CI: 2.29–2.78, *P*<.001). Moreover, FBD was not associated with barangays providing an incentive payment for FBDs (OR: 1.02, 95% CI: 0.96–1.09, *P*=.563) (Table 3). In addition, FBD was associated with urban barangay status (OR: 1.45, 95% CI: 1.27–1.67, *P*<.001), availability of a vehicle for transporting pregnant women (OR: 3.19, 95% CI: 3.00–3.39, *P*<.001), availability of public transportation to government BFs (OR: 1.25, 95% CI: 1.13–1.39, *P*<.001), and distance (km) to the most accessible government BF (OR: 0.89, 95% CI: 0.89–0.90, *P*<.001) (Table 3). Running a regression using the interaction term between the ordinance and distance, we found that the directions of the associations between FBD and all the other variables, including the ordinance and

**TABLE 1.** Distribution of Deliveries That Occurred During 2017 Among Pregnant Women Residing in 4,371 Barangays in the Eastern Visaya Region, Philippines

Province	Total Deliveries	FBD Cases	NID Cases	Delivery Place Unknown	Delivery Place Known	
					Total	FBD Rate, %
Biliran	3,458	3,365	80	13	3,445	97.7
Eastern Samar	7,757	7,014	537	206	7,551	92.9
Leyte	31,958	30,196	760	1,002	30,956	97.5
Northern Samar	10,488	8,002	2,037	449	10,039	79.7
Samar	14,585	11,295	2,558	732	13,853	81.5
Southern Leyte	6,168	5,970	44	154	6,014	99.3
Total	74,414	65,842	6,016	2,556	71,858	91.6

Abbreviations: FBD, facility-based delivery; NID, noninstitutional delivery.

the distance, unchanged from the regression result without the interaction term. The variance inflation factors calculated for each variable ranged between 1.02 and 1.84 (mean: 1.30), indicating a negligible level of multicollinearity.

Table 4 shows details of the vehicle availability at the barangay level by ownership. Among the 4,371 barangays, 7.0% had a functional ambulance/vehicle, 64.2% had access to an ambulance/vehicle owned by the municipality/city/province, 3.0% had an agreement with private facilities to use an ambulance/vehicle, and 2.0% had an agreement with personal vehicle owners.

## DISCUSSION

Our study found that ordinances to prohibit NIDs, even with nonmonetary sanctions such as reprimand or without specific penalties, were significantly associated with higher FBD rates. It also revealed that the penalty amount indicated in the ordinances was positively associated with the FBD rate. However, the study results indicated no significant association between positive incentives and the FBD rate. In addition, the FBD rate was higher in barangays that had urban status, vehicles available to transport pregnant women, public transportation available to government BFs, and were located a shorter distance to the most accessible government BF.

Several studies have examined whether positive incentives influence FBDs in LMICs,<sup>18</sup> although there is less information regarding whether cash payments contingent on FBD influence the birth location. This study focused on such an unstudied area and revealed that positive incentives were not significantly associated with the FBD rate, which may

suggest that the contingent payment of cash incentives is not effective at motivating women to use BFs for FBDs. However, the cross-sectional nature of this study highlights the importance of caution when interpreting the causality of this relationship. For example, local governments may be aware of low FBD rates in their areas, which could motivate them to provide incentive payments for FBD in an attempt to improve their FBD rate. Thus, a longitudinal study is needed to clarify the effects of positive incentives on the FBD rates in the Philippines.

Several studies have also examined the effects of penalties on FBDs,<sup>19–21</sup> although we are not aware of any studies that have quantitatively identified an association between negative incentives and FBDs. Thus, our study serves to fill the knowledge gap regarding this relationship in the Philippines, which in 2008 implemented a no home-birthing policy<sup>5</sup> that had been locally endorsed in 3,320 barangays (>75% of the Eastern Visaya Region) by 2017. Apparently, the association between negative incentives and FBDs could be explained by pregnant women’s behavioral patterns to avoid penalties. However, a qualitative study conducted in the Eastern Visaya Region of the Philippines also indicated stigma, shame, and fear borne in the culture at the barangay level out of the ordinances prohibiting NIDs as significant contributors to driving the women toward FBDs.<sup>21</sup> Despite the novelty of our study findings, some areas still need to be further researched. First, our study dataset did not provide information about how many women among those who engaged in NIDs were aware of the existence of ordinances and the penalty amounts. The FBD

**Ordinances to prohibit NIDs, even with nonmonetary sanctions such as reprimand or without specific penalties, were significantly associated with higher FBD rates.**

**TABLE 2.** Characteristics of the 4,371 Barangays That Were Included in the Study Looking at Incentives and Institutional Deliveries in Eastern Visaya Region, Philippines, 2017

Questionnaire Items	No.	%
Pregnant women receiving any incentive payment for FBDs		
Yes	1,848	43.2
No	2,433	56.8
Missing	90	—
Existence of a local ordinance or policy supported by a written official order to prohibit NID		
Yes, nonmonetary sanction or no specific penalty	881	20.6
Yes, with low cash penalty (200–1,000 PHP)	1,218	28.5
Yes, with high cash penalty (1,200–10,000 PHP)	1,221	28.5
No	957	22.4
Missing	94	—
Barangay classification		
Urban	119	2.7
Rural	4,252	97.3
Assignment of a full-time or part-time RHM or nurse for routine maternal care services in the barangay		
Yes	3,741	89.6
No	436	10.4
Missing	195	—
A functional vehicle available to transport pregnant women		
Yes	2,812	65.9
No	1,453	34.1
Missing	106	—
Public means of transport to a government BF available		
Yes	3,936	91.3
No	376	8.7
Missing	59	—

Abbreviations: BF, birthing facility; FBDs, facility-based deliveries; NID, noninstitutional delivery; PHP, Philippine pesos; RHM, rural health midwife.

**The results imply that the no home-birthing policy helped lower NID rates and increased FBD rates, but penalties for NIDs could be inappropriate.**

rate could have been more significantly associated with the ordinances and the penalty amounts among women who were aware of their existence and the amounts. Second, we were unable to provide information about how many NID cases were actually ordered to pay a fine. It is particularly interesting to understand to what extent the existence of ordinances is effective as a deterrent to NIDs even without levying a fine. In addition, in this region, negative incentives were associated with a higher FBD rate, while positive incentives did not influence FBDs. There is no straightforward explanation to support this finding; however, this result might be

justified by the prospect theory proposed by Kahneman and Tversky,<sup>31</sup> which states that losses cause a greater emotional impact on an individual than does an equivalent amount of gain.

The study results imply that the no home-birthing policy helped lower the NID rates and increased the FBD rates. Nevertheless, concerns remain regarding the appropriateness of levying penalties for NIDs. Especially for indigent individuals, the cash penalty that ranges up to 10,000 PHP could be catastrophic. The Gabriela Women’s Party, a Filipino organization that advocates for women’s issues, also expressed concern that the no home-birthing

**TABLE 3.** Logistic Regression Analysis to Measure the Associations Between Facility-Based Delivery and the Characteristics of 4,371 Barangays in the Eastern Visaya Region, Philippines

	Odds Ratio	95% CI	P value
Incentive payment provided for FBD	1.02	0.96, 1.09	.563
Ordinance to Prohibit NID			
No	0.90	0.83, 0.98	.013
Yes, nonmonetary sanction or no specific penalty	(Reference)		
Yes, with low cash penalty (200–1,000 PHP)	1.37	1.26, 1.49	<.001
Yes, with high cash penalty (1,200–10,000 PHP)	2.52	2.29, 2.78	<.001
Urban barangay	1.45	1.27, 1.67	<.001
RHM/nurse available (full-time or part-time)	1.07	0.95, 1.20	.298
Vehicle available	3.19	3.00, 3.39	<.001
Public transportation to government BF	1.25	1.13, 1.39	<.001
Distance to the most accessible government BF, km	0.89	0.89, 0.90	<.001

Abbreviations: BF, birthing facility; CI, confidence interval; FBD, facility-based delivery; NID, noninstitutional delivery; PHP, Philippine pesos; RHM, rural health midwife.

**TABLE 4.** Details of Vehicle Availability at the Barangay Level by Ownership, in the Eastern Visaya Region, Philippines (N=4,371)

	No.	%
Barangay having a functional ambulance/vehicle		
Yes	302	7.0
No	3,998	93.0
Missing	71	—
An ambulance/vehicle owned by the municipality/city/province available		
Yes	2,757	64.2
No	1,538	35.8
Missing	76	—
Barangay having an agreement with private facilities to use an ambulance/vehicle		
Yes	130	3.0
No	4,135	97.0
Missing	106	—
Barangay having an agreement with personal vehicle owners		
Yes	84	2.0
No	4,190	98.0
Missing	97	—

policy may even result in an increase in the incidence of maternal and infant deaths by presenting a case of a pregnant woman in labor who tried to walk and cross a river and died before

reaching the nearest BF.<sup>7</sup> The present study also identified several barriers to FBDs in underserved barangays, which should be considered and addressed before prohibiting NIDs

and financially penalizing women who seek them.

One of the barriers to increasing FBDs was the accessibility of the BFs, as 34.1% of the barangays did not have a vehicle available to transport pregnant women and 5.5% of the barangays did not have an available vehicle or public transportation that would allow women to access a government BF. Furthermore, the distance from the center of some barangays to the most accessible BF was >30 km in some instances. Moreover, logistic regression analysis revealed that a higher FBD rate was significantly associated with vehicle availability, public transportation availability, and a shorter distance to a BF, with vehicle availability being a very strong determinant (OR: 3.19). These results have 2 policy implications. First, measures that penalize NIDs should be implemented with caution, as they may be unethical in barangays where the lack of a vehicle or public transportation makes the BF difficult to access. Second, with limited resources, investing in a vehicle to transport women to a BF might be an appropriate measure to increase the FBD rate, given that it is likely simpler and more realistic than improving public transportation availability or shortening the distance to a BF. Despite the cross-sectional nature of the study, our interpretation of the causal relationship between the FBD rate and the vehicle availability could be supported by a systematic review study conducted in LMICs, in which the poor availability of transportation was identified as a crucial factor in women's decision to deliver at a facility.<sup>14</sup> To increase the FBD, it would be ideal for all the barangays to have a functional vehicle; however, with the limited barangay budget composed of the Internal Revenue Allotment from the national government and nominal revenues at the barangay level,<sup>32</sup> it may not be realistic. In fact, we found in our study that only 7.0% of the barangays owned a functional vehicle. An alternative and realistic measure could be to provide a vehicle at the municipality, city, and provincial levels as evidenced in our study results that a majority of the barangays with a vehicle available to transport pregnant women made such an arrangement.

Interestingly, the FBD rate was not significantly associated with the local availability of an RHM or nurse, even though 10.4% of the barangays did not have staff to support the BHS. In this context, pregnant women in the Philippines are required to visit an RHM or nurse for antenatal care at least 4 times during the prenatal period.<sup>33</sup> However, women in barangays with nonfunctional BHSs would need to visit another barangay for their

antenatal care, which is likely associated with an economic burden and a decreased likelihood of compliance with the antenatal care requirement. Further studies are needed to understand how understaffing at the barangay level influences outcome indicators, such as antenatal care coverage, and the results might be of interest to policymakers.

### Limitations

This study has several limitations. First, the study's cross-sectional nature precludes a conclusion regarding the causality of the relationships between the FBD rate and the other variables. Second, the study primarily identified deliveries based on prenatal registers that were maintained at the BHSs, and missing data or missed deliveries are possible, especially in barangays with poor pregnancy tracking. The number of missing data represented by "delivery place unknown" in our study was 2,556, which accounted for 3.4% of the total deliveries. In addition, during the immunization service in 2017, health workers found 4,228 missed deliveries that occurred in 2016 or early 2017. Assuming that the same level is applied to the study period and that a majority of the missed cases were captured during the immunization visits, the missed deliveries could account for around 5.7% of the total deliveries. We cannot exactly identify reasons for the missing data and the missed deliveries; however, they may presumably include pregnant women using private facilities, BHWs' insufficient performance or deployment in conducting the pregnancy tracking, and urbanized society with attenuated neighbor relations that make it difficult for the BHWs to identify residents' pregnancy and delivery statuses.

### CONCLUSION

The findings from this study suggest that negative incentives for NIDs might help increase the FBD rate at the barangay level, although positive incentives were not associated with an increase in the FBD rate. Nevertheless, the appropriateness of the no home-birthing policy must be carefully assessed, as we identified several barriers that may reduce access to BFs and limit the FBD rate in underserved barangays. These barriers include the nonavailability of a vehicle or public transportation to help pregnant women visit BFs, as well as long distances to the nearest BF. Therefore, local governments in the Philippines should be aware of these barriers when planning or implementing penalties for NIDs. Above all, with limited resources, investing in a vehicle to transport pregnant women

to BFIs might be an effective and realistic measure to address these barriers and increase the FBD rate.

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# Readiness to Provide Antenatal Corticosteroids for Threatened Preterm Birth in Public Health Facilities in Northern India

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## Key Findings

- Most of the 37 public health facilities in northern India that we assessed were not readied for providing quality care for threatened preterm birth and ensuring the safe use of antenatal corticosteroids (ACS).
- Deficiencies were identified in areas of evidence-based practices, competent workforce, actionable health information system, physical resources, and communication.
- The existing ACS guidelines were not up-to-date with current evidence and were not disseminated or implemented uniformly across facilities.
- Attention to accurate gestational age estimation and the quality of childbirth and preterm care were inadequate in all the facilities.

## Key Implications

- Increasing uptake of ACS for threatened preterm birth without providing adequate-quality maternal and newborn care and meeting essential preconditions outlined by World Health Organization recommendations will not improve preterm outcomes.
- Facility-level actions are needed for the safe and effective use of ACS in support of the delivery of quality care.

## ABSTRACT

**Introduction:** In 2014, the Government of India (GOI) released operational guidelines on the use of antenatal corticosteroids (ACS) in preterm labor. However, without ensuring the quality of childbirth and newborn care at facilities, the use of ACS in low- and middle-income countries is potentially harmful. This study assessed the readiness to provide ACS at primary and secondary care public health facilities in northern India.

**Methods:** A cross-sectional study was conducted in 37 public health facilities in 2 districts of Haryana, India. Facility processes and program implementation for ACS delivery were assessed using pretested study tools developed from the World Health Organization (WHO) quality of care standards and WHO guidelines for threatened preterm birth.

**Results:** Key gaps in public health facilities' process of care to provide ACS for threatened preterm birth were identified, particularly concerning evidence-based practices, competent workforce, and actionable health information system. Emphasis on accurate gestational age estimation, quality of childbirth care, and quality of preterm care were inadequate. Shortage of trained staff was widespread, and a disconnect was found between knowledge and attitudes regarding ACS use. ACS administration was provided only at district or subdistrict hospitals, and these facilities did not uniformly record ACS-specific indicators. All levels lacked a comprehensive protocol and job aids for identifying and managing threatened preterm birth.

**Conclusions:** ACS operational guidelines were not widely disseminated or uniformly implemented. Facilities require strengthened supervision and standardization of threatened preterm birth care. Facilities need greater readiness to meet required conditions for ACS use. Increasing uptake of a single intervention without supporting it with adequate quality of maternal and newborn care will jeopardize improvement in preterm birth outcomes. We recommend updating and expanding the existing GOI ACS operational guidelines to include specific actions for the safe and effective use of ACS in line with recent scientific evidence.

## INTRODUCTION

Globally, prematurity is a leading cause of death among children under the age of 5 years.<sup>1</sup> In India, about 13% of babies are born preterm, which amounts to 3.5 million babies annually. Of these, 10% die due to complications of preterm birth and many of the survivors experience learning disabilities and hearing and vision problems.<sup>2,3</sup>

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**ACS benefits can only be achieved with appropriate selection of patients and the provision of minimum standards of maternal and newborn care.**

The use of antenatal corticosteroids (ACS) during preterm labor is acknowledged as one of the most effective interventions to improve preterm birth outcomes. ACS use has been widely studied in high-income countries where most facilities are equipped with adequate childbirth and preterm care and have the ability to estimate accurate gestational age. In a recent review of trials done mostly in high-resource settings, ACS use was associated with a reduction in respiratory distress syndrome (34%), intraventricular hemorrhage (45%), necrotizing enterocolitis (50%), and newborn mortality (31%).<sup>4</sup> A lower rate of intensive care admissions (10%) and reduced cost of care (36%) are additional benefits of ACS.<sup>3,5</sup> However, little evidence-based research is available on ACS use from low- and middle-income countries (LMICs) such as India.

In June 2014, the Government of India (GOI) published the *Use of Antenatal Corticosteroids in Preterm Labour (Under Specific Conditions by ANM): Operational Guidelines*.<sup>6</sup> This was a pragmatic approach for India, where many women give birth at home or in facilities without advanced newborn care and without comprehensive emergency obstetric care. Although the primary focus of the operational guidelines was to empower auxiliary nurse midwives (ANMs) to provide ACS, the document was also intended for use by medical officers and staff nurses. In February 2015, the Antenatal Corticosteroid Trial,<sup>7</sup> a multicenter trial of ACS use in 6 LMICs (including 2 sites in India) reported increases in newborn mortality and serious maternal infections with ACS use. Imprecise estimation of gestational age, inadequate newborn care, poor availability of postpartum maternal care, and poor assessment of imminent preterm birth have been proposed as factors that contribute to the increased mortality and morbidity with ACS use in LMICs.<sup>6-9</sup> These findings raised international concern regarding the benefits versus risks of using ACS in peripheral settings in LMICs. Different authors have emphasized the need for adequately powered trials for establishing the safety and efficacy of ACS use in resource-limited settings.<sup>3,8-10</sup>

The World Health Organization (WHO) provided recommendations on threatened preterm birth in 2015, specifying essential preconditions for ensuring safe use of ACS.<sup>11</sup> These preconditions include accurate assessment of gestational age, preterm birth imminent within 7 days, absence of evidence of maternal infection, and availability of adequate childbirth care and adequate preterm newborn care. Based on these guidelines, the WHO ACTION-I trial was undertaken to establish the safety and efficacy of ACS between 26 and

34 weeks of gestation in resource-limited settings, including India.<sup>12</sup> In this multicountry trial, strict inclusion criteria were followed for selecting secondary/tertiary facilities and participants, and the findings of a low incidence of neonatal deaths and maternal infection provided reassurance about the benefits of dexamethasone in low-resource settings. Further, these findings re-emphasized that the benefits of ACS can only be achieved if WHO standard criteria are adopted for the appropriate selection of patients and if minimum standards of maternal and newborn care are provided.

Health systems are also challenged by the resources required to adequately support the provision of ACS for threatened preterm birth. Two different multicountry analyses in 2015 and 2018 identified major bottlenecks in leadership and governance, health service delivery, health financing, health information system (HIS), essential medicine and technologies, community ownership, and partnership that hinder the uptake of ACS.<sup>13,14</sup>

This study was conducted in India to assess the current utilization and clinical practice of ACS use in threatened preterm birth at the health facility level. We assessed the training, knowledge, and attitudes of all levels of providers of obstetric care. The findings are intended to inform policy makers regarding facility readiness, recommend essential actions to support implementation, and catalyze the revision of the GOI operational guidelines to ensure safe and effective use of ACS.

## **METHODS**

To undertake this study, the role of key stakeholders including policy makers, professionals, and state representatives was critical. The Ministry of Health and Family Welfare, Child Health Division, GOI, established a project advisory group to approve the study framework and approach and review findings and current evidence to expand the scope of national operational guidelines for safe and effective use of ACS in threatened preterm birth. Representation included the Ministry of Health and Family Welfare, Global Alliance to Prevent Prematurity and Stillbirth, Haryana State Department of Health officials, Indian Council of Medical Research, National Neonatology Forum-India, Norway-India Partnership Initiative, Society for Women and Child Health, United Nations Children's Fund (UNICEF), United States Agency for International Development, and leading Indian medical faculty.

### **Study Design**

A cross-sectional mixed-methods study was conducted in government health facilities in Hisar

and Ambala districts of Haryana, India. The study assessed the facilities' process of care and readiness for using ACS in threatened preterm birth. Health care providers (HCPs) were interviewed using a semistructured questionnaire to assess their knowledge and attitudes regarding ACS administration and evidence-based practices for ACS administration. Women were interviewed using a semistructured questionnaire to identify mothers' perspectives on accessing care during preterm labor and their level of communication with HCPs.

### Study Sites

The selection of study districts was based on a purposeful selection process in consultation with the project advisory group to include 1 National Health Mission's high-priority district (HPD) and 1 non-HPD. HPDs were identified based on process/outcome indicators for maternal health, child health, and family planning.<sup>15</sup> Hisar as an HPD and Ambala as a non-HPD were selected with the concurrence of the Government of Haryana and respective district health authorities.

### Study Facilities and Population

Health facilities for assessment were selected in consultation with the local district health authorities based on the provision of delivery services and distance from district hospitals. All health facilities within the study districts had been classified according to the level of care. The primary health care centers (PHCs) and sub-centers (SCs) were classified as primary care facilities, and community health centers (CHCs), subdistrict hospitals (SDHs), and district hospitals (DHs) were classified as secondary care facilities. A total of 37 health facilities, including 25 primary care (8 PHCs and 17 SCs) and 12 secondary care facilities (8 CHCs, 2 SDHs, and 2 DHs), were included in the study.

For the facility assessment component of the study, 17 SCs were excluded from 37 health facilities in the study districts because they were not providing delivery services.

For assessment of knowledge and attitudes regarding the safe use of ACS, a total of 88 HCPs involved in ACS administration, including medical doctors, staff nurses, and ANMs, were selected through convenience and purposive sampling.

To assess the care-seeking behavior of preterm delivered mothers who received ACS, 19 women up to 4 weeks postpartum and aged 15 years or older who delivered a preterm newborn were identified from clinical record registers.

HCPs involved in ACS administration were invited by trained field investigators to participate in

the study through scheduled interviews. Eligible women were approached at the time of discharge. In addition, at the primary facilities, interviewers contacted health extension workers twice weekly to identify women who met the study criteria and had delivered at home. The health extension workers then informed these women either by telephone or in person about the interviewer's visit. Consenting women were interviewed either immediately at a designated area of the health facility that was quiet and private, or at a more convenient time at the woman's home. To avoid possible coercion, no financial incentives were provided. Inclusion criteria for facilities and participants are presented in Table 1.

### Study Framework

For a comprehensive assessment of ACS use, a framework for this study was developed from the *WHO Standards for Improving Quality of Maternal and Newborn Care in Health Facilities*.<sup>16</sup> The study framework includes the 7 domains from the WHO standards for the facility process of care, and ACS use was assessed using 5 study instruments (Table 2).

### Study Instruments

Quantitative data were collected by using (1) a facility assessment tool; (2) a semistructured questionnaire for HCPs; (3) a clinical verification checklist and a case history extraction form; (4) a semistructured questionnaire for mothers; and (5) HIS indicator report summary. Data collection instruments were developed through a multistep process. Based on the study framework and the *WHO Recommendations on Interventions to Improve Preterm Birth Outcomes*,<sup>11</sup> the scope of each tool was defined, and questions were drafted by the research team to include essential preconditions for facility readiness to provide ACS. These preconditions included accurate assessment of gestational age, preterm birth imminent within 7 days, absence of evidence of maternal infection, and availability of adequate childbirth care and adequate preterm newborn care. We also included all interventions from the 2015 WHO document that were related to the care of women with threatened preterm birth.<sup>11</sup> The WHO-recommended interventions and resulting study framework used by the research team for assessment of clinical care elements are shown in the Box. The instruments were pilot-tested, and they were then further refined in terms of flow and content based on the feedback. The interviews were conducted orally by a trained research associate with a clinical background.

**TABLE 1.** Study Tools, Inclusion Criteria, Facility/Participants, and Sample Size to Assess Use of ACS in Threatened Preterm Birth Public Facilities in Northern India

Study Tool	Inclusion Criteria	Facility Level/Participant	Sample Size
Facility assessment	District hospital, subdistrict hospital, community health center, primary health center, or subcenter in the study districts providing delivery services	District hospital	2
		Subdistrict hospital	2
		Community health center	8
		Primary health center	8
Health care provider interview	Health care providers involved in administration of ACS (medical doctor, staff nurse, or auxiliary nurse midwife)	Specialist doctor	6
		Medical officer	19
		Staff nurse	46
		Auxiliary nurse midwife	17
Clinical verification	Hospital records related to administration of ACS	District hospital	17
		Subdistrict hospital	5
Maternal care pathway	Women up to 4 weeks postpartum, aged 15 years or older, delivered preterm, and received at least 1 dose of ACS	District hospital	13
		Subdistrict hospital	6
HIS indicator extraction	Indicators related to ACS from facility reporting records	District hospital	2
		Subdistrict Hospital	2
		Community health center	8
		Primary health center	8

Abbreviations: ACS, antenatal corticosteroids; HIS, health information system.

**TABLE 2.** Study Instruments Mapped to Study Framework Domains to Assess Use of ACS in Threatened Preterm Birth in Public Facilities in Northern India

Framework Domain	Facility Assessment	Provider Interview	Clinical Record Verification	Maternal Recall Interview	HIS Indicator Report
Evidence-based practices	X	X	X		
Competent, motivated personnel	X	X			
Physical resources	X				
Actionable information system	X	X	X		X
Effective communication		X		X	
Respect and dignity		X		X	
Functioning referral system	X	X		X	

Abbreviations: ACS, antenatal corticosteroids; HIS, health information system.

**Data Entry and Analysis**

The data were entered digitally using XLSForms and hosted on a server using KoBoToolbox.<sup>24</sup> Quantitative data were analyzed in STATA 15.1,<sup>25</sup> and descriptive statistics were applied.

**Ethics Approval and Consent of Participants**

This project was reviewed and approved by the institutional review boards of the PGIMER, Chandigarh India (No. IEC-08/2016-491), and Project Concern International (No. 21).

**BOX.** Framework for Assessment of Clinical Care Elements

**Evidence-based care:** Practices assessed by focusing this domain to threatened preterm birth care in line with the *WHO Recommendations on Interventions to Improve Preterm Birth Outcomes*.<sup>11</sup>

- Availability of guidelines for ACS use: Availability in print/digital format of the national ACS guideline: *Use of Antenatal Corticosteroids in Preterm Labour Under Specified Condition by ANM: Operational Guidelines*.<sup>6</sup>
- Gestational age assessment: Different methods used by health care providers for estimation of gestational age such as use of fundal height, last menstrual period, and use of ultrasound. The most accurate estimate is from ultrasound scan before 24 weeks of gestation.<sup>17</sup>
- Identification of imminent preterm birth: Birth anticipated within 7 days (i.e., preterm labor, PPROM, severe preeclampsia/eclampsia, and antepartum hemorrhage).
- Adequate obstetric care: The basic emergency obstetric care services were assessed based on availability of drugs (parenteral antibiotics, magnesium sulfate, and oxytocin for management of infections, preeclampsia, and hemorrhage, respectively), manual removal of retained placenta, removal of retained products of conception, assisted vaginal delivery, and resuscitation with bag and mask of nonbreathing neonate. The comprehensive emergency obstetric care services were assessed based on obstetric surgery with anesthesia and blood transfusion availability.
- Adequate newborn care: Newborn care was assessed based on availability of newborn care corner, newborn stabilization unit, and special newborn care unit at the prescribed public health facilities and practices for thermal care; safe oxygen delivery; feeding support and infection management.
- Infection prevention and management in mother and newborns: This was assessed based on prescribed infection prevention interventions and clinical practices during antenatal, intranatal, and postnatal periods.<sup>18</sup>

**Competent and motivated workforce:** Availability of trained health care providers and their knowledge and attitude about providing adequate preterm care.

- Availability and training requirements: Availability of trained health care providers (specialists, medical officers, staff nurses, and auxiliary nurse midwives) as per Indian Public Health Standards.<sup>19-23</sup>
- Indications of ACS: ACS is indicated in preterm birth for gestational age 24 to 34 weeks expected within 7 days with one of the following: preterm labor, PPROM, severe pre-eclampsia/eclampsia, and antepartum hemorrhage.
- Preconditions: ACS use is recommended only when the following conditions can be met: threatened preterm birth between 24 and 34 weeks of gestation with accurate assessment of gestational age, preterm birth is considered imminent within 7 days, no clinical evidence of maternal infection, availability of adequate childbirth care (including the capacity to recognize and safely manage preterm labor and birth), and adequate preterm newborn care (including resuscitation, thermal care, feeding support, infection treatment, and safe oxygen use).
- Clinical parameters: Gestational age, fetal heart sounds, imminent preterm birth, cervical dilatation, PPROM, evidence of vaginal bleeding, and evidence of maternal infection.
- Signs of true labor: Regular uterine contractions, descent of presenting fetal part, and evidence of cervical shortening/dilatation.
- Minimum and maximum gestational age for ACS use: Minimum age is 24 weeks of gestation and maximum age is 34 weeks of gestation.
- Conditions that put woman at risk of preterm birth: Preterm labor, PPROM, severe pre-eclampsia/eclampsia, and antepartum hemorrhage.
- Route and dose of ACS administration: Administered intramuscularly and dose of dexamethasone is 4 doses of 6 mg at 12-hour intervals.
- Authority for ACS use by providers and existing supervision and monitoring practices.

**Actionable information system:** Availability of standard forms, review of completeness and accuracy of case sheets and registers of mothers who had received ACS and use of this data to improve care of mother and newborn. Documentation of ACS specific indicators as mentioned in Government of India 2014 ACS operational guidelines.

**Physical resources:** Availability of adequate physical environment, medicines, and equipment required for threatened preterm care.

**Effective communication:** Communication or counseling by health care providers and availability of IEC material on threatened preterm birth.

**Respect and preservation of dignity:** Communication or counseling by health care providers and availability of IEC material on threatened preterm birth.

**Functioning referral system:** Presence of an existing referral mechanisms for timely identification and safe referral with documentation of relevant information.

Abbreviations: ACS, antenatal corticosteroids; ANM, auxiliary nurse midwife; CPAP, continuous positive airway pressure; IEC, information, education, and communication; PPROM, preterm premature rupture of membranes.

Letters of support were secured from all district offices and facilities where data were collected. We obtained written consent from potentially eligible and interested participants

in their preferred language. We also informed them that their participation would be voluntary and there would be no professional or personal consequences or benefits of

**TABLE 3.** Facility Readiness Practices and Resources for ACS Use in Threatened Preterm Birth as Reported by Health Care Providers in Public Facilities in Northern India

Clinical Services		District Hospital, % (N=2)	Subdistrict Hospital, % (N=2)	Community Health Center, % (N=8)	Primary Health Center, % (N=8)
Evidence-based practices					
Adequate gestational age assessment	Ultrasound fetal biometry	100	100	87.5	100
	Fundal height	100	100	87.5	87.5
	Advise for USG <24 weeks	100	100	100	100
Adequate obstetric care <sup>a</sup>	Parenteral antibiotics for maternal infection	100	100	100	100
	Parenteral magnesium sulfate for pre-eclampsia	100	100	100	100
	Parenteral oxytocic drugs for hemorrhage	100	100	100	100
	Manual removal of retained placenta	100	50	87.5	100
	Removal of retained products of conception	100	100	100	75
	Assisted vaginal delivery	50	100	50	50
	Resuscitation with bag and mask	100	100	100	100
	Obstetric surgery with anesthesia	100	100	NA	NA
	Blood transfusion facility	100	100	NA	NA
	Protocol for threatened preterm birth	0	0	0	0
	Adequate preterm care	Measure labor room temperature	100	100	100
Measure postnatal unit temperature		0	0	12.5	12.5
Kangaroo mother care		100	50	37.5	25
Physical resources					
Essential medicine and functional equipment	Dexamethasone	100	100	100	100
	Oxytocin	100	100	100	100
	Magnesium sulfate	100	100	100	100
	Parenteral antibiotics	100	100	100	100
	Antihypertensives	100	100	100	87.5
	Antipyretics	100	100	100	87.5
	Oxygen	100	100	87.5	100
	Thermometer	100	100	75	100
	Ultrasound	100	50	0	0
	Fetoscope	50	50	100	75
	Dipstick for urine protein	100	50	100	75
	Phototherapy lights	100	100	75	62.5

Continued

**TABLE 3.** Continued

Clinical Services	District Hospital, % (N=2)	Subdistrict Hospital, % (N=2)	Community Health Center, % (N=8)	Primary Health Center, % (N=8)
Pulse oximeters	100	100	75	50
Radiant warmers	100	100	100	75
Oxygen tubing	100	100	100	75
Oxygen blender	50	0	0	0
Nasogastric tube	100	100	100	87.5
Container and cup	50	50	50	50
Wall suction	50	50	25	62.5
CPAP	50	0	0	0

Abbreviations: ACS, antenatal corticosteroids; CPAP, continuous positive airway pressure; NA, not applicable; USG, ultrasonography.  
 °Basic emergency obstetric care and comprehensive emergency obstetric care.

**TABLE 4.** ACS Guidelines Awareness, Training, and Knowledge Among Health Care Providers

	Specialist, n (%) N=6	Medical Officer, n (%) N=19	Staff Nurse, n (%) N=46	ANM, n (%) N=17
Aware of 2014 Government of India ACS guidelines	4 (66.6)	10 (52.6)	3 (6.5)	6 (35.2)
ACS-related training attended	1 (16.6)	3 (15.7)	3 (6.5)	1 (5.8)
Minimum gestational age for ACS use	3 (50)	5 (26.3)	16 (34.7)	11 (64.7)
Maximum gestational age for ACS use	3 (50)	42.1 (8)	18 (39.1)	9 (52.9)
Correct route of administration	5 (83.3)	14 (73.6)	42 (91.3)	14 (82.3)
Correct dose of dexamethasone	2 (33.3)	8 (42.1)	25 (54.3)	41.1 (7)
Indications for ACS	1 (16.6)	0	2 (4.3)	1 (5.8)
Essential preconditions for ACS use	2 (33.3)	4 (21.1)	0	0
Ascertaining true labor	3 (50)	10 (52.6)	23 (41.3)	0
Conditions for risk of preterm birth	1 (16.6)	3 (15.7)	7 (15.2)	3 (17.6)
Critical parameters before ACS administration	0	1 (5.2)	0	0

Abbreviations: ACS, antenatal corticosteroids; ANM, auxiliary nurse midwife.

participation. Mothers were given the option to read or hear their consent form according to their literacy level. No financial incentives were provided.

**RESULTS**

A total of 25 PHCs and 12 secondary health care facilities were included in the study. A total of 88 HCPs and 19 mothers were interviewed (Table 1). Additionally, 23 clinical verification cases and HIS indicators extraction assessments for the last 6 months were studied.

**Evidence-Based Practices**

Table 3 describes the facility readiness practices and resources for ACS use in threatened preterm care as defined in the 2015 WHO Recommendations on Interventions to Improve Preterm Birth Outcomes.<sup>11</sup> Emphasis on early ultrasound at <24 weeks of pregnancy to estimate gestational age in the form of an advisory or guideline was lacking at all levels. However, HCPs were using ultrasonography, last menstrual period, or fundal height for estimation of gestational age. Fundal height was being routinely used in 90% (18 out of 20) of the health

facilities for gestational age estimation and 70% (14 out of 20 facilities) had a job aid for using fundal height for gestational age estimation. Among HCPs, 88% (n=78) reported using last menstrual period as a method for estimation of gestational age, 82% (n=72) reported using ultrasonography, and 65% (n=57) reported using fundal height.

Basic emergency obstetric care services were reported to be available across all the facilities but a few SDHs, CHCs, and PHCs lacked services including manual removal of retained placenta, removal of retained products of conception, and assisted vaginal delivery. Comprehensive emergency obstetric care services were available at DHs and SDHs in both districts. However, none of the facilities had a comprehensive protocol for identification and management of conditions that put a woman at risk of threatened preterm birth such as severe preeclampsia and eclampsia, premature preterm rupture of membrane, antepartum hemorrhage, and spontaneous preterm labor. Most of the facilities were using partograph for monitoring of labor.

Newborn care corner, newborn stabilization unit, and special newborn care unit were present as prescribed by GOI guidelines.<sup>26</sup> The availability of protocols for neonatal resuscitation, safe oxygen delivery, thermal regulation, feeding, and infection prevention were not uniform across facilities. The 2014 GOI operational guidelines had not been disseminated to the facilities.

### Competent and Motivated Workforce

The second subdomain assessed the knowledge and motivation of the workforce to provide adequate preterm care. All facilities reported a shortage of health care staff especially of physician specialists at CHCs, SDHs, and DHs and medical officers at DHs, SDHs, and PHCs. Only 23 out of 46 nurses (50.0%) and 8 out of 17 ANMs (47.1%) were trained in facility-based integrated management of neonatal and childhood illness. Among HCPs, ACS-related training was attended by 1 out of 6 specialists (16.6%), 3 out of 19 medical officers (15.7%), 3 out of 46 staff nurses (6.5%), and 1 out of 17 ANMs (5.8%). The details of ACS-related knowledge about the clinical requirement for ACS use are presented in Table 4.

The HCPs' attitudes regarding the effectiveness of ACS and its safety and their confidence in ACS use were measured using Likert scales. A disconnect was observed between knowledge and attitude among all the HCPs; although

HCPs reported they were confident about using ACS, their knowledge of essential clinical requirements was poor. This disconnect was observed more among ANM and staff nurses (Figure 1). In both study districts, a disconnect between attitude and knowledge was observed among all cadres. All cadres reported being confident regarding indications for ACS, identification of signs of preterm labor, and identification of conditions that put women at risk of preterm birth, but they scored poorly on knowledge assessment on these parameters/domains.

### Decision for ACS Administration

A total of 76 of 88 HCPs (86.4%) reported that decisions for ACS administration were made mainly by doctors; 29 of 88 HCPs (32.9%) reported that the decision was made by staff nurses; and 7 of 88 HCPs (7.9%) reported that the decision was made by ANMs.

### Supervision or Monitoring of HCPs

None of the facilities had a routine audit or supportive supervision strategy in place to ensure safe and effective use of ACS.

### Physical Resources

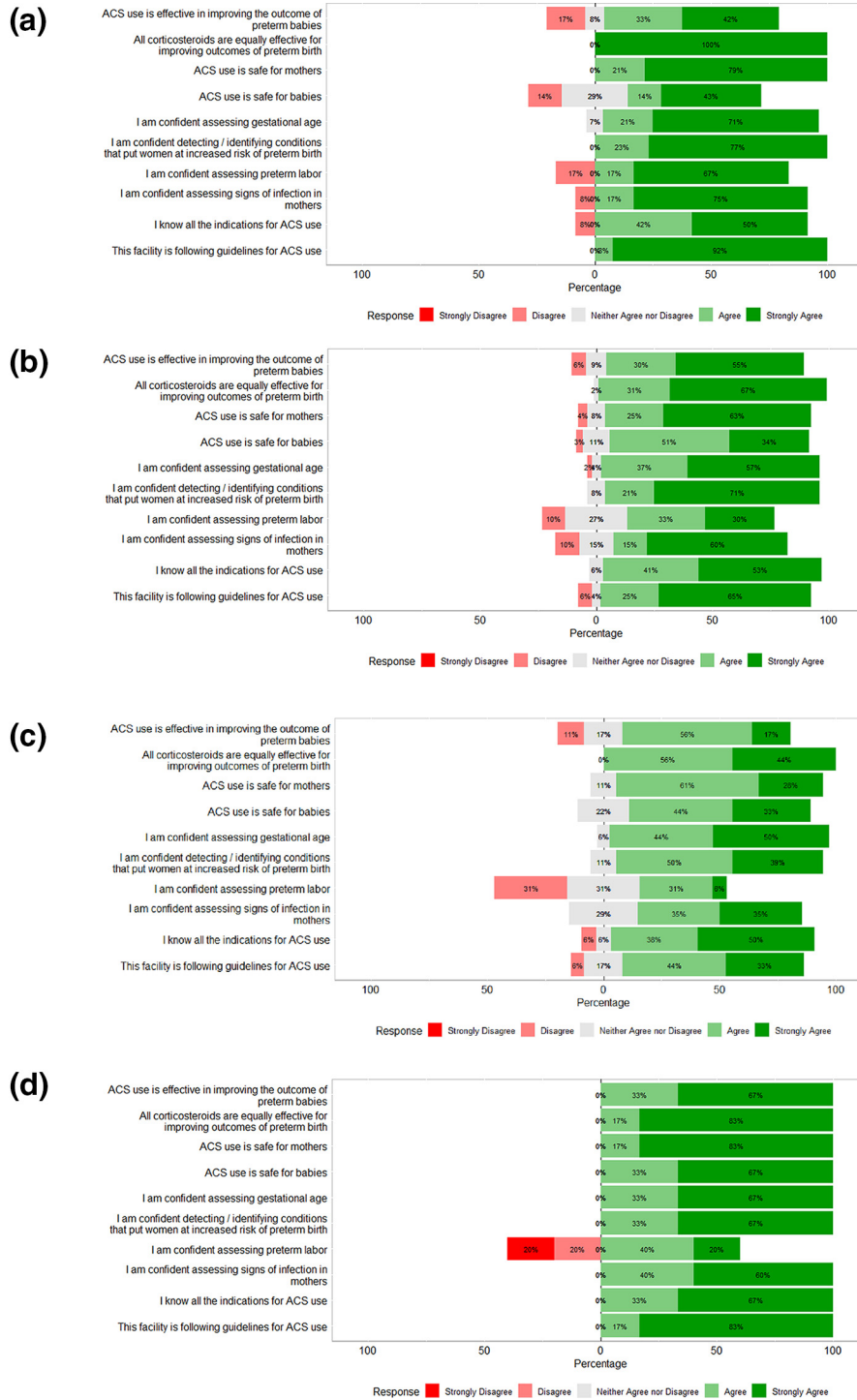
Dexamethasone, oxytocin, magnesium sulfate, and parenteral antibiotics were available in most of the facilities, except dexamethasone in 1 CHC and 1 PHC in the past 6 months. However, antihypertensives, oxygen, and antipyretics were not available at some of the facilities. Ultrasound machines were available only at DHs and 50% of the SDHs. The necessary equipment for thermal regulation, oxygen delivery, and feeding were either unavailable or nonfunctional at the time of facility assessment. The remaining equipment, such as blood pressure machine, stethoscope, and baby weight scale, were available in all health facilities. All facilities had a continuous water supply and power backup.

### Actionable Health Information System

The clinical record documentation of 19 mothers who had received ACS in health facilities was assessed. Of these mothers, 79% were given ACS between 24 and 34 weeks, and 21.1% were given ACS after 34 weeks. In all the cases, ACS-specific indicators as per the 2014 guideline were not recorded or monitored. Moreover, indicators on the quality of ACS use, such as administration beyond 34 weeks and use of ultrasound for

**A disconnect was observed between knowledge and attitude; although HCPs reported confidence about using ACS, their knowledge of essential clinical requirements was poor.**

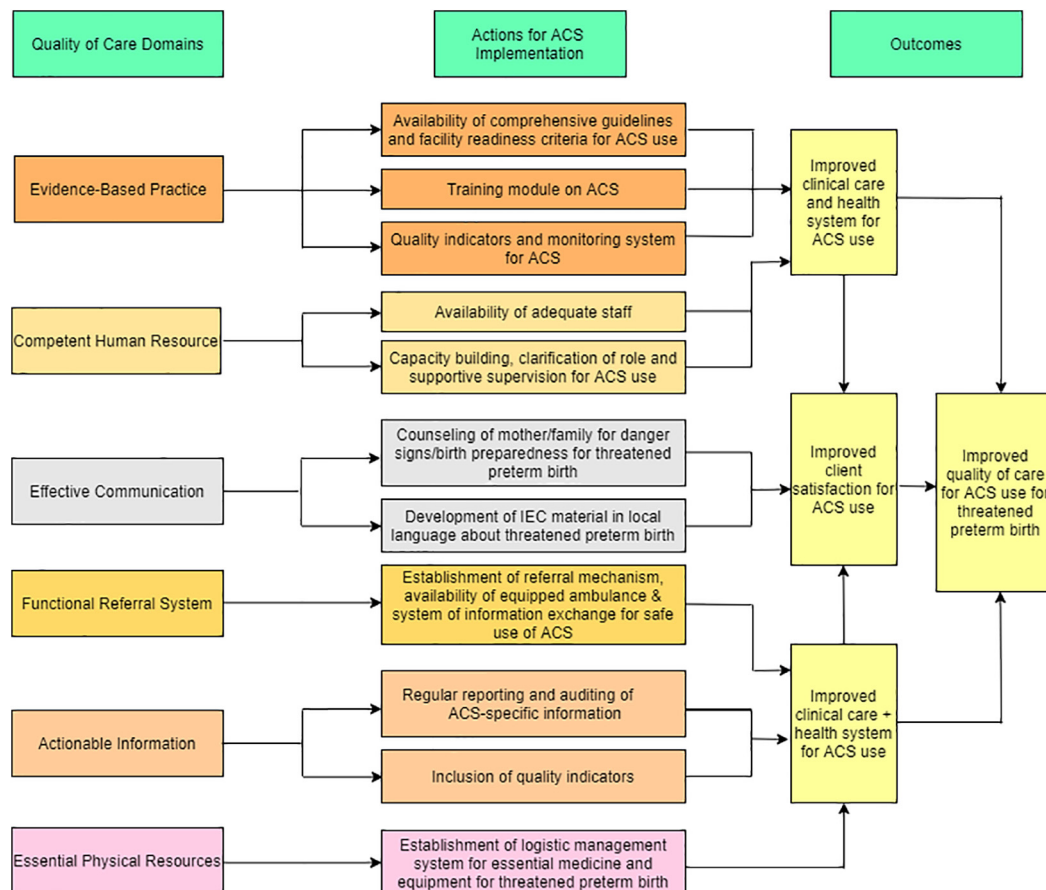
**FIGURE 1.** Attitudes of Health Care Providers Regarding Antenatal Corticosteroids Administration (a) Auxiliary Nurse Midwives; (b) Nurses; (c) Medical Officers; (d) Physician Specialists



Abbreviations: ACS, antenatal corticosteroids.



**FIGURE 2.** Proposed Actions and Outcomes for the Safe and Effective Use of Antenatal Corticosteroids for Threatened Preterm Birth



Abbreviations: ACS, antenatal corticosteroids; IEC, information, education, and communication.

gestational age estimation, were lacking in the existing guidelines. Moreover, these facilities lacked monitoring of ACS-specific facility readiness in terms of existing infrastructure, human resources, clinical practices, and documentation of relevant information.

### Communication, Respect, and Dignity

We interviewed 19 mothers who had a preterm delivery in the previous 1 month and those who had received ACS in an SDH or DH regarding their experiences with the care provided. More than two-thirds (68.4%) of the mothers were informed about recognizing true labor, and 4 out of 19 mothers (21.2%) were informed about the risk of preterm labor. The newborn's condition was explained to 58% of the mothers, and 16% were informed

regarding ACS before administration. Although danger signs of pregnancy were printed on the antenatal maternal child protection card, ACS-specific information in the vernacular language was not available.

### Functioning Referral System

Out of 19 women, 11 were referred for care. Eleven women were referred by an HCP and 8 others reached secondary care facilities on their own. The reasons for referral were pain, bleeding, leakage, and weakness. Referrals were made mainly to DHs that the patient could reach within 30 to 60 minutes using the state ambulance services. Eleven mothers were provided an ambulance for referral. Referral slips were given to 9 women. A separate referral card was made for newborns in all DHs, 1 out of 2 SDHs (50%), 6 out of 8 CHCs (75%), and 3 out

8 PHCs (37.5%). The documentation of information about ACS use on referral slips/cards was poor.

## ■ DISCUSSION

This study is the first systematic analysis of facility process of care in the context of the 2014 GOI guidelines to provide ACS for threatened preterm birth in public health facilities. Our findings suggest that most of the facilities were not equipped for providing quality care for threatened preterm birth and ensuring safe use of ACS. The facilities that were deficient in the quality of care domains of evidence-based practices, competent workforce, actionable information, physical resources, and communication and respect failed to fulfill the preconditions outlined in the 2015 WHO recommendations.<sup>11</sup> Overall, the study facilities lacked monitoring of ACS-specific facility readiness.

In comparisons across levels of facilities, DHs were better equipped with infrastructure and trained human resources. The reported use of different methods (ultrasonography, last menstrual period, and fundal height) by HCPs for estimating gestational age indicates the need to emphasize the importance of standardizing the accurate estimation of gestational age by ultrasonography within 24 weeks of pregnancy. Although most of the facilities were using a partograph for monitoring labor, the completion of the form was not assessed. The basic emergency obstetric care packages in SDHs, CHCs, and PHCs need to be strengthened in the guidelines. A comprehensive protocol for the identification and management of threatened preterm birth should be developed, tested, and implemented in the health facilities.<sup>11,13,14</sup>

Similarly, ACS clinical knowledge was better among doctors at the secondary care level and poorest among ANMs. But there is a shortage of doctors, especially physicians and specialists at CHCs, SDHs, and DHs and medical officers at DHs, SDHs, and PHCs. Therefore, a cadre-specific training curriculum updated with the latest evidence on identification and management of threatened preterm birth should be in place to train HCPs based on their assigned level of facility. Additionally, to address the shortage of health care staff, regular recruitment should be in place to ensure continuous service delivery. Periodic audits and supportive supervision should also be in place to sustain the quality of care. Decision for ACS administration should only be made either by a medical officer or a staff trained in the management of threatened preterm birth. Health systems can be further strengthened to provide timely ACS

at secondary-level facilities through strict monitoring of the supply of ACS and by adequate inventory management. The necessary equipment for thermal regulation, oxygen delivery, and feeding should be made available or made functional.<sup>27–29</sup> A regular audit should be in place for the availability of equipment and medicines essential for providing threatened preterm birth care.

Timely referral with details of the diagnosis, investigations, treatment given (i.e., ACS time and dose), and reason for referral of the mother as well as the newborn can facilitate appropriate and prompt decision making and improve maternal and newborn outcomes.<sup>30</sup> Communication and counseling at the time of referral and treatment constitute an important aspect of health care delivery, build confidence in the health system, and improve patient satisfaction. This need was reflected in the present study because mothers were not informed about labor signs, danger signs, the need for ACS administration, and newborn condition. The availability of information, education, and communication material in vernacular language will help patients and caregivers to be aware of and communicate danger signs or conditions leading to preterm labor and indications for use of ACS.

This assessment of facility readiness to provide ACS for threatened preterm birth was aligned with the WHO quality of care framework, in contrast to previously published assessments.<sup>13,14,31</sup> In 2014, the WHO completed a multicountry assessment limited to the coverage of ACS.<sup>28</sup> Other studies have looked at systematic targeted approaches to the strengthening of health systems, with a focus on overcoming specific bottlenecks for the highest impact interventions.<sup>13,32</sup> In one multicountry assessment, policy makers were interviewed to assess compliance with WHO recommendations for use of ACS.<sup>14</sup> In a multicountry analysis of 11 countries (including 3 sites in India) in 2015, 9 countries documented major bottlenecks in health system building blocks under ACS-specific health service delivery, HIS, and essential medicines.<sup>13</sup> These mainly included lack of clear guidelines and training; limited capacity in gestational age estimation and identification of threatened preterm birth; shortage of HCPs at high cadre and discrepancies between cadres who were prescribing authority and cadres who were care providers; deficiency in data on ACS coverage, use, and outcome; lack of critical reviews of ACS use in clinical audits; lack of national essential medicines listing; delays due to referral; and lack of supervision, mentoring, and quality improvement

**Our findings suggest that most of the facilities were not equipped for providing quality care for threatened preterm birth and ensuring safe use of ACS.**

systems.<sup>13</sup> A policy implementation analysis of ACS use in 7 sub-Saharan African countries highlighted a lack of emphasis on essential preconditions for ACS use such as accurate estimation of gestational age, critical window period of 24–34 weeks for ACS administration, identification of threatened preterm birth, and contraindications for ACS use.<sup>14</sup> Another study on quality of maternal and newborn care in public health facilities (DHs, PHCs) in Bihar reported gaps in structural capacities such as availability of basic infrastructure, essential equipment and supplies, and adequate staff.<sup>33</sup> Similar to the present study, findings from Latin America on knowledge of HCPs regarding ACS use reported the need to improve knowledge on the indication, benefits, and dose regimen of ACS.<sup>34</sup> A recent review from LMICs concluded that ACS risks and benefits may change if the health system is too weak to support preterm deliveries and subsequent preterm care.<sup>35</sup> The principle of “Do No Harm” has been invoked by authors assessing ACS use in LMICs.<sup>10,14</sup> An editorial emphasized an urgent need for advocacy for the safe use of ACS by maternal and newborn health experts.<sup>10</sup>

In 2020, WHO published a multicountry double-blind randomized trial in Bangladesh, India, Kenya, Nigeria, and Pakistan to assess the safety and efficacy of dexamethasone in women in hospitals in low-resource countries who were at risk for early preterm birth.<sup>12</sup> The study provided robust evidence that ACS for threatened preterm birth in facilities that met the 2015 WHO recommendations for ACS use only under certain conditions, including the accurate assessment of gestational age, imminent preterm birth, the absence of maternal infection, and adequate care for childbirth and preterm newborns resulted in significantly lower risks of neonatal death alone and stillbirth or neonatal death without an increase in the incidence of possible maternal bacterial infection. For ensuring the safe and effective use of ACS in threatened preterm birth, facility readiness to meet the preconditions outlined by the 2015 WHO guidelines is an essential prerequisite.<sup>11</sup> The existing 2014 GOI guideline should be updated with recent evidence and expanded to emphasize accurate gestational age estimation, ACS-specific readiness for infrastructure, human resources, clinical practices, and monitoring indicators. Assessments based on a quality of care framework for essential processes for providing care in facilities may prove beneficial in quality improvement activities targeting ACS use.<sup>36</sup> A quality improvement initiative for ACS use

comprising a technical update followed by an audit of and feedback on ACS data led to an increase in ACS coverage, knowledge score, and confidence of HCPs, as well as a complete recording of ACS data in the Philippines and Cambodia.<sup>37</sup> Our study identified the need for establishing a quality improvement and monitoring system for ensuring appropriate use of ACS in line with the 2015 WHO recommendations.

Suggested actions for ensuring safe and effective use of ACS include (1) expanding the scope of existing guideline from preterm labor to threatened preterm birth; (2) developing facility readiness criteria; (3) regular training and audit of HCPs; (4) expanding existing indicators on ACS coverage to indicators on the quality of ACS use; (5) developing efficient logistic management; (6) strengthening of existing referral system; (7) improving counseling practices of HCPs; and (8) developing information, education, and communication material on preterm birth care in the local language and engaging mothers/family in childbirth care/process (Figure 2).

### Limitations

For this assessment of the readiness of facilities to provide ACS, we followed the WHO quality of care framework<sup>16</sup> with an emphasis on clinical requirements<sup>11</sup> from a provider/facility viewpoint with observational validation when possible. Additional elements of the analysis focusing on the experience of care included the perspectives of preterm delivered mothers were more cursory. For this report, the focus was specifically on providers of ACS services and their clients (preterm-delivered women) and not on facility-in-charges or other facility staff.

We did not include the tertiary care level because the national guidelines are generally implemented by individual states up to the district level. The 2014 GOI guideline did not stratify the strategies for ACS use at respective primary, secondary, and tertiary care levels and did not include the facility readiness for safe and effective use of ACS.

Tertiary care centers that are referral centers do not follow specific guidelines, and treatment is physician specific based on the condition of the patients. Most of these centers are either medical colleges or advanced institutes that have trained staff, and they are well equipped in providing very advanced maternal and newborn services.

Another limitation of this study is the generalizability of the finding to other states in India. Moreover, private health facilities were not included in the study. However, this study can be replicated in other states and the findings can be used for the expansion of existing guidelines. The

**For the safe and effective use of ACS in threatened preterm birth, facility readiness to meet the preconditions outlined by the 2015 WHO guidelines is an essential prerequisite.**

data presented on evidence-based practices were self-reported by HCPs and could not be verified by observation.

## CONCLUSIONS

Health facilities at primary and secondary levels lack facility readiness to provide quality of care for threatened preterm birth and safe use of ACS for threatened preterm birth. This study suggests a need to strengthen the existing health system by improving advocacy for ACS programs and quality of health care delivery, training of HCPs, and developing an actionable information system. Merely increasing uptake of any single intervention<sup>38</sup> such as ACS without supporting it with adequate quality of maternal and newborn care and meeting essential preconditions in line with the 2015 WHO recommendations<sup>11</sup> will not result in improving preterm outcome. Such improvement requires functioning health facilities and integrated planning and delivery of efficient, effective, and quality care to mothers and children<sup>39</sup> based on up-to-date national policy and guidelines for ACS use that are evidence-based and directed at all levels of facilities and cadres of HCPs.

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ORIGINAL ARTICLE

# Care Around Birth Approach: A Training, Mentoring, and Quality Improvement Model to Optimize Intrapartum and Immediate Postpartum Quality of Care in India

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## Key Findings

- Adopting an integrated implementation framework that combined training, mentoring, and quality improvement processes to improve the quality, equity, and dignity of care during the intrapartum and immediate postpartum periods, the Care Around Birth approach addressed key drivers of maternal and newborn mortality.
- The approach refocused energy on facility-based quality processes that are currently central to efforts in reducing mortality and achieving Sustainable Development Goal targets.

## Key Implications

- Integrated implementation frameworks need to be aligned to the resources available and tailored to the ecosystem in which health programs operate.
- Facility-level ownership and accountability by optimizing the engagement of health staff remain the fulcrum for any improvement effort. This however needs to be adequately supported by district and state-level health systems.

## ABSTRACT

**Background:** With the highest risk of maternal and newborn mortality occurring during the period around birth, quality of care during the intrapartum and immediate postpartum periods is critical for maternal and neonatal survival.

**Methods:** The United States Agency for International Development’s Scaling Up Reproductive, Maternal, Newborn, Child, and Adolescent Health Interventions project, also known as the Vriddhi project, collaborated with the national and 6 state governments to design and implement the Care Around Birth approach in 141 high caseload facilities across 26 high-priority districts of India from January 2016 to December 2017. The approach aimed to synergize evidence-based technical interventions with quality improvement (QI) processes, respectful maternity care, and health system strengthening efforts. The approach was designed using experiential training, mentoring, and a QI model. A baseline assessment measured the care ecosystem, staff competencies, and labor room practices. At endline, the approach was externally evaluated.

**Results:** Availability of logistics, recording and reporting formats, and display of protocols improved across the intervention facilities. At endline (October–December 2017), delivery and newborn trays were available in 98% of facilities compared to 66% and 55% during baseline (October–December 2015), respectively. Competency scores (> 80%) for essential newborn care and newborn resuscitation improved from 7% to 70% and from 5% to 82% among health care providers, respectively. The use of partograph in monitoring labor improved from 29% at the baseline to 61%; administration of oxytocin within 1 minute of delivery from 35% to 93%; newborns successfully resuscitated from 71% to 96%; and postnatal monitoring of mothers from 52% to 94%.

**Conclusion:** The approach successfully demonstrated an operational design to improve the provision and experience of care during the intrapartum and immediate postpartum periods, thereby augmenting efforts aimed at ending preventable child and maternal deaths.

## INTRODUCTION

Three recent global reports prioritize the importance of quality health services, the impact of not providing quality care to clients, and necessary measures to improve it.<sup>1–3</sup> Although poor quality of care has an impact

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across all dimensions of the health systems, possibly nowhere is it more acute than during the intrapartum and immediate postpartum periods. The World Health Organization (WHO) estimates that 303,000 mothers and 2.7 million newborn infants die annually around the time of childbirth and that many more are affected by preventable illnesses. Further, some 2.6 million babies are stillborn each year.<sup>4-5</sup> Hence, the time of childbirth and the period immediately after birth are particularly critical for maternal, fetal, and neonatal survival and well-being. In addition, a United Nations report estimated that providing high-quality care during childbirth could prevent approximately 113,000 maternal deaths, 531,000 stillbirths, and 1.3 million neonatal deaths every year at an estimated cost of \$4.5 billion per year (\$0.9 per person).<sup>6</sup>

In line with global trends, maternal and newborn mortality remains a major challenge in India. Though the maternal mortality ratio and the neonatal mortality rate have seen an appreciable decline over the past 2 decades,<sup>7-8</sup> 32,000 maternal and 640,000 newborn deaths still occur every year in the country.<sup>9-10</sup> Most of these deaths occur during the period around birth, but efforts to improve access to care, such as Janani Suraksha Yojna (a Safe Motherhood scheme), have not resulted in a concomitant decline in mortality.<sup>11-12</sup> Thus, it is imperative that India focuses on quality of care at and around the time of birth for the mother and baby dyad. Although the Government of India has undertaken multiple efforts toward improving the quality of care through various national policy initiatives, the real challenge is translating operational guidelines and plans to on-the-ground implementation.<sup>13-16</sup>

## ■ VRIDDHI PROJECT

Prioritizing the need to improve access, utilization, and quality of care, in 2013, the Government of India launched the Reproductive, Maternal, Newborn, Child, and Adolescent Health (RMNCH+A) Strategy.<sup>17</sup> To facilitate focused planning and implementation, the strategy identified 184 underperforming districts as high-priority districts. Overall, within each state, 25% of the poorest-performing districts were identified. The tribal predominant districts and those affected by insurgent and rebel groups were also selected. Thus, the strategy primarily aimed to address geographical inequity by prioritizing districts that had traditionally performed suboptimally. Further, the strategy obtained

technical assistance from partner agencies to support its rollout and implementation. Thus USAID, through the Vriddhi Scaling up RMNCH+A Interventions) project (hereafter referred to as the project), implemented by IPE Global in collaboration with the national Ministry of Health and Family Welfare (MOHFW), supported 26 high-priority districts in the states of Delhi, Haryana, Himachal Pradesh, Jharkhand, Punjab, and Uttarakhand.

## ■ CARE AROUND BIRTH APPROACH INTERVENTION

Aligning with global priorities, WHO's Quality of Care framework for maternal and newborn health, and national guidelines,<sup>18</sup> the project designed and implemented the Care Around Birth approach, a strategic intervention to improve clinical practices. This approach combines essential evidence-based technical interventions and health system strengthening efforts through quality improvement techniques to improve the quality of care at and around the time of birth. The intervention was implemented from January 2016 to December 2017 in 141 high caseload public health facilities across these 26 high priority districts in the 6 states and reached 463,713 mothers and 458,152 newborns.

The intervention, which was externally evaluated, included building a robust and scalable model and catalyzing and measuring the change (Figure 1).<sup>19</sup>

### Building a Robust, Scalable Implementation Model

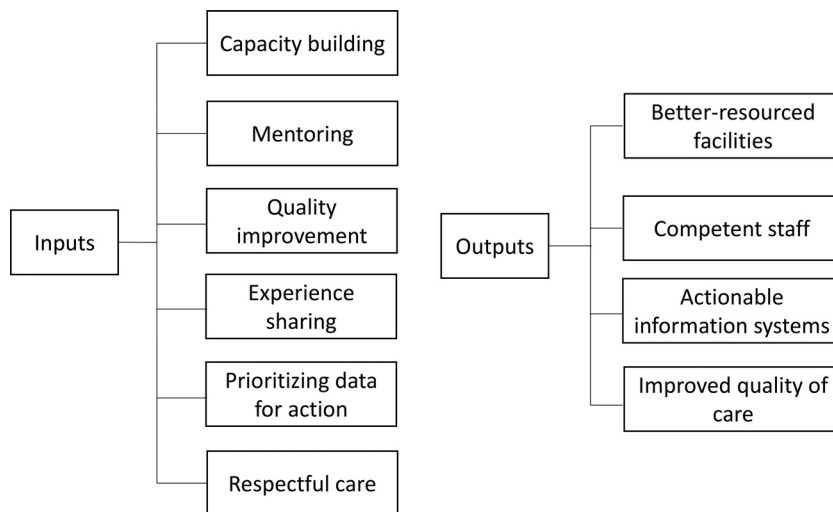
Because implementation was planned across 6 states that varied considerably in sociodemographic and health parameters, adequate time was spent on designing and conceptualizing the approach (Table 1).

The project team engaged in multiple rounds of discussions to comprehensively define the scope and spectrum of the intervention including the geographical reach, the identification of facilities, the care practices to be supported, and the measurement indicators to be tracked. The team developed a robust and comprehensive assessment framework for establishing baselines across the facilities. Then, we finalized the care practices to be strengthened, tailored the technical intervention package to be delivered using adult learning principles, adapted the quality improvement (QI) processes for implementation at scale, and envisioned an actionable management information

**The Government of India has made efforts to improve the quality of care through various national policy initiatives, but the challenge of translating operational guidelines and plans to on-the-ground implementation remains.**



**FIGURE 1.** Care Around Birth Approach Framework to Improve Quality of Care in 6 States in India



system. The preparatory phase also included training of the project team on all the components. The design phase culminated in advocacy workshops across the 6 states led by the respective state governments to disseminate the baseline findings, develop facility improvement plans, and initiate the implementation phase of the approach.

**Catalyzing Change**

The Care Around Birth approach integrated training, mentoring, and QI aspects to potentiate change. Identifying staff competencies as a major barrier to implementation of quality, high-impact interventions at scale, the approach included capacity building to ensure that health workers were not only well-trained on clinical, programmatic, and managerial aspects but also competent to provide high-quality services.

**Experiential Trainings**

A participant-centric, experiential training package based on adult learning principles was designed to address the knowledge and practice gap and help facility staff overcome barriers in translating their knowledge into action.<sup>20</sup> The training content was adapted from relevant national guidelines and focused on delivering high-impact technical interventions to mothers and newborns during childbirth to manage complications, giving clear guidance on processes and protocols. Overall, the trainings improved

competency on 14 technical interventions, including monitoring the progress of labor; active management of the third stage of labor; essential newborn care, newborn resuscitation, postnatal monitoring of mothers and newborns, management of postpartum hemorrhage and pre-eclampsia/eclampsia, kangaroo mother care, assisted feeding of low birth weight babies, use of antenatal corticosteroids for preterm labor, management of maternal and newborn sepsis, and the prevention of mother-to-child transmission of HIV. The trainings followed the sequence of birth to promote seamless care for mothers and newborns. Simulation-based drills were used to build competencies for managing complications with cross-cutting issues of health systems strengthening, documentation, labor room organization, and respectful maternity care (RMC) integrated into the package.

The training methods included simulations, demonstrations, case studies, role playing, and other participatory methods. The choice of methods was guided by factors enabling spontaneous participation of all participants; building on participants’ experiences, views, and beliefs; encouraging peer learning; and allowing for self-assessment of knowledge and skills. The training session flow was adapted to fulfill these criteria and included the following:

- Establishing a learning need: Sessions always started with establishing a learning need by allowing participants to realize the gap in

**The Care Around Birth approach included capacity building to ensure that health workers were not only well-trained on clinical, programmatic, and managerial aspects but also competent to provide high-quality services.**

**TABLE 1.** Health and Sociodemographic Indicators Across Intervention States Included in Care Around Birth Approach Intervention

Indicator	States						India
	Delhi	Haryana	Himachal Pradesh	Jharkhand	Punjab	Uttarakhand	
MMR (SRS MMR bulletin 2014–16)	NA	101	NA	165	122	201	130
NMR (SRS statistical report 2015)	14	24	19	23	13	28	25
Infant Mortality Rate (SRS statistical report 2015)	18	36	28	32	23	34	37
Total Fertility Rate (SRS statistical report 2015)	1.7	2.2	1.7	2.7	1.7	2	2.3
Sex ratio at birth (SRS statistical report 2015)	869	831	924	902	889	844	900
<b>The below indicators are cited from NFHS 4 (2015–2016)</b>							
Women age 20–24 years married before age 18 years, %	14.3	19.4	8.6	37.9	7.6	13.8	26.8
Current use of a modern method of family planning, %	48.6	59.4	52.1	37.5	66.3	49.3	47.8
Unmet need for family planning, %	15	9.3	15.7	18.4	6.2	15.5	12.9
Mothers who had antenatal check-up in the first trimester, %	63	63.2	70.5	52	75.6	53.5	58.6
Mothers who had at least 4 antenatal care visits, %	67.9	45.1	69.1	30.3	68.5	30.9	51.2
Mothers who had full antenatal care, %	39	19.5	36.8	8	30.7	11.5	21
Institutional births, %	84.4	80.4	76.4	61.9	90.5	68.6	78.9
Institutional births in public facility, %	55.5	52	61.6	41.8	51.7	43.8	52.1
Births delivered by cesarean delivery, %	26.7	11.7	16.7	9.9	24.6	13.1	17.2
Births in a public health facility delivered by cesarean delivery, %	26.5	8.6	16.4	4.6	17.8	9.3	11.9
Children aged 12–23 months fully immunized (BCG, measles, and 3 doses each of polio and DPT), %	68.8	62.2	69.5	61.9	89.1	57.6	62
Children under age 3 years breastfed within 1 hour of birth, %	28	42.4	41.1	33.1	30.7	27.8	41.6
Children under age 6 months exclusively breastfed, %	49.6	50.3	67.2	64.8	53	51.2	54.9
Children aged younger than 5 years who are stunted (height-for-age), %	31.9	34	26.3	45.3	25.7	33.5	38.4
Children aged younger than 5 years who are wasted (weight-for-height), %	15.9	21.2	13.7	29	15.6	19.5	21
Pregnant women aged 15–49 years who are anemic (<11.0 g/dl), %	46.1	55	50.4	62.6	42	46.5	50.4
Women having a bank or savings account that they use, %	64.5	45.6	68.8	45.1	58.8	58.5	53
Women having a mobile phone that they use, %	66.6	50.5	73.9	35.2	57.2	55.4	45.9
Women aged 15–24 years who use hygienic methods of protection during their menstrual period, %	90.7	78.3	84.3	49.6	84.4	69.9	57.6

Abbreviations: DPT, diphtheria, pertussis, tetanus vaccine; MMR, maternal mortality rate; NFHS, national family health survey; NMR, neonatal mortality rate; SRS, Sample Registration Survey.

Definitions: Maternal Mortality Ratio: The number of maternal deaths during a given period per 100,000 live births during the same period.

Neonatal Mortality Rate: The number of neonatal deaths (deaths during the first 28 days of life) per 1000 live births.

Infant Mortality Rate: The number of infant deaths (deaths during the first year of life) per 1,000 live births.

Total Fertility Rate: The number of children who would be born per woman (or per 1,000 women) if she/they were to pass through the childbearing years bearing children according to a current schedule of age-specific fertility rates.

Sex Ratio at Birth: The number of girls born for every 1,000 boys born.

Unmet need for family planning: The percentage of women of reproductive age, either married or in a union, who have an unmet need for family planning.

Women with unmet need are those who want to stop or delay childbearing but are not using any method of contraception.

**QI efforts were built into the model and were optimized as the fulcrum for maintaining and sustaining changes over the intervention period.**

knowledge or practice. This was done through structured questions and answers, writing cards, and demonstrating existing practices.

- **Building on existing knowledge:** Participants' responses were valued, and facilitators provided additional new information only after summing up the group's inputs. This helped to build upon existing knowledge and further highlighted the learning need.
- **Learning by observation:** The correct practice was demonstrated by the facilitator; the participants observed the demonstration and were encouraged to note differences from their current practice.
- **Doing, observing, and critiquing:** All participants were given an opportunity to practice individually under supervision in small groups. In addition to the group and facilitator, all co-participants observed the practice. This further added to the learning experience.
- **Sharing problems, challenges, and solutions:** This step allowed participants to reflect on what they had learned and visualize challenges and issues in implementing the new practice, the process facilitated by peer-to-peer learning. At this stage, problems related to larger systemic issues such as supplies, infrastructure, etc., which were beyond the scope of the training, were also listed to be discussed subsequently with district and state authorities.
- **Performing the new skill:** At the end of each session, participants demonstrated their newly learned skills and made commitments to continue the practice.

The trainings were centralized, held at the district level over 2 days, and were followed by planned, structured, and low-density, high-frequency on-site training sessions at health facilities to ensure saturation of all health care providers at the intervention facilities. The trainings were facilitated by the project team, which included professionals with relevant experience in maternal and child health.

### **On-Site Mentoring**

The project team conducted post-training follow-up facility visits to mentor and support health care providers, resolve doubts, and facilitate practice to boost confidence and enable local problem solving.<sup>21</sup> Drills and checklists were introduced to maintain a high level of preparedness among staff to handle maternal and newborn complications. Job aids and notes were provided to labor room

staff to remind them of actions and interventions, and peer-to-peer learning opportunities were created by highlighting good practices. The consistent emphasis on data for action during the mentoring visits helped tailor the visits to the specific needs of the health workers and facilities, enabling improved record maintenance and inculcating the practice of evidence-based care.

### **QI Processes**

The momentum for change was sustained by introducing QI processes at the facility level.<sup>22</sup> QI efforts were built into the model and were optimized as the fulcrum for maintaining and sustaining changes over the intervention period. The project facilitated the process of institutionalizing QI in health facilities by forming QI teams and using a data-driven approach to problem solving. Core members of the QI teams included facility managers, gynecologists, pediatricians, and head staff nurses. Auxiliary members, such as pharmacists, storekeepers, and accountants were included according to the improvement aim identified. QI processes enabled the teams to start addressing challenges as a group, and these teams instituted at facilities took up facility-level unresolved issues, identified bottlenecks, brainstormed to find viable solutions, fixed responsibilities and timelines, and eventually accelerated change. The teams usually met monthly to identify gaps based on service statistics, suggest ideas for change, and track progress. Initial handholding support and coaching were provided by project staff. QI teams developed and tested ideas using the plan-do-study-act approach for continual improvements to service quality.<sup>23</sup>

### **Experience-Sharing Platforms**

The facility-level QI efforts were complemented by district- and state-level experience-sharing platforms, which brought together facility staff at the district or state levels to share learnings, challenges, and solutions. This further facilitated peer-to-peer engagement and also served as a way to acknowledge good performers.

### **Imbibing RMC**

To prioritize RMC, the project team ensured a provider-centric RMC framework that included institutionalizing RMC practices during various components of care. The project team identified RMC as integral to its outcomes, both in project design and implementation, and undertook a situational analysis in select public health facilities to understand their readiness to provide RMC. The

**FIGURE 2.** Job Aids to Encourage Providers to Practice Respectful Maternity Care at Intervention Facilities in 6 States in India



project team aimed to improve the experience of care at the intervention facilities by including RMC practices within the training curriculum, engaging with health care providers on it during mentoring visits and QI meetings, and developing job aids for display at the intervention facilities (Figure 2).

**Measuring Change**

Data management and usage were built on USAID’s Collaborating Learning and Adapting framework, which ensured that the intervention was coordinated with other parallel efforts, grounded in a strong evidence base, and iteratively adapted.<sup>24</sup> Data systems were set up during the conceptualization and design phase and evolved during the implementation phase to ensure data-based decision making. The systems were built upon existing government systems, and relevant and appropriate process level indicators were incorporated. The overall effort included standardizing labor room registers and case sheets, regular review of records with emphasis on complete and accurate recording, internal data validation processes including data review, on-site data validation, and triangulation of data from multiple sources to meet requirements at the facility, district, and state levels. The government staff working at the facility and district levels were involved in this process, and data management processes were

strengthened at the intervention facilities during the mentoring visits by the project staff.

**METHODS**

**Selection of Intervention Facilities**

Identification of intervention facilities was based on the line-listing of public health facilities that had reported at least 1 delivery through the health management information system for the year 2013–2014. More than 1,400 health facilities in the 26 districts had reported deliveries during the year. These facilities were then enlisted by the district. An average of 5–7 high caseload facilities—accounting for close to 70% of the institutional delivery load in public health facilities in the district—were identified for the intervention. Except for 2 primary health centers in Himachal Pradesh, all of the intervention facilities were either district hospitals, first referral unit community health centers, non-first referral unit community health centers, referral hospitals, or subdivisional hospitals. Operationally, 69 intervention facilities were L2 and 72 L3 level facilities<sup>25</sup> (Table 2).

**Baseline Assessment**

From January to February 2016, a baseline assessment was conducted across all intervention facilities.

**TABLE 2.** Categorization of Health Facilities in India Included in Care Around Birth Approach Intervention Implemented in 6 States

Type and Level of Facility	Population Served	Beds	Human Resource (Also Calculated Based on Caseload)	Maternal Health Services	Newborn Care	Family Planning Services
Subcenters, Level 1  Primary health care center, not operational 24x7, Level 1	5,000 people or 3,000 in remote areas  30,000 or more people (20,000 in remote areas)	1–2 inpatient/observation beds  6 inpatient/observation beds	<ul style="list-style-type: none"> <li>• 2 auxiliary nurse-midwives</li> <li>• 1 part-time female sweeper</li> </ul>	<ul style="list-style-type: none"> <li>• Identification and referral for danger signs</li> <li>• Pregnancy testing and counseling</li> <li>• Antenatal care</li> <li>• Intranatal care</li> <li>• Normal deliveries by skilled birth attendant (Partograph, active management of the third stage of labor, etc.)</li> <li>• Pre-referral management for obstetric emergencies (Eclampsia, postpartum hemorrhage, shock)</li> <li>• Postnatal care— 24–48 hours stay post-delivery</li> <li>• Immediate newborn care – drying, warming, skin-to-skin contact</li> <li>• Initiation of breastfeeding</li> <li>• Postpartum contraceptive counseling</li> </ul>	<p><b>Newborn Care Corner</b></p> <ul style="list-style-type: none"> <li>• Essential newborn care including resuscitation</li> <li>• Zero day immunization (OPV, BCG, Hepatitis B; as per Government of India schedule), Inj. Vit. K</li> </ul> <p><b>Care of normal newborn</b></p> <ul style="list-style-type: none"> <li>• Breastfeeding/ feeding support, thermo-regulation, and asepsis</li> </ul> <p><b>Care of sick newborn</b></p> <ul style="list-style-type: none"> <li>• Identification, stabilization, and initial management of complications (sepsis, low birth weight/ premature babies, etc.) before referral and prompt referral of “sick” newborn</li> <li>• Referral services</li> </ul>	Counseling and provision of spacing methods including interval intrauterine device
Primary health care center operational 24x7, Level 2  Non-first referral unit - community health care center, Level 2	30,000 or more people (20,000 in remote areas)  120,000 people in urban areas or 80,000 people in remote areas	6 inpatient/observation beds  30 bedded	<ul style="list-style-type: none"> <li>• 1–2 Medical officers (on-call after outpatient department hours)</li> <li>• Minimum 4 staff nurses/auxiliary nurse-midwives each for labor room and maternity ward</li> <li>• 2 Lab technicians (for round-the-clock service delivery)</li> <li>• Sweeper–3 for labor room (preferably female) and maternity ward HR for NBSU</li> </ul>	<p><b>All services listed in facilities above in Level 1, plus the following:</b></p> <ul style="list-style-type: none"> <li>• Assisted vaginal deliveries</li> <li>• Management of complications other than those requiring referral to L3 including blood transfusion or surgery</li> <li>• Episiotomy and suturing</li> <li>• Stabilization of obstetric emergencies and referral to L3 wherever required</li> <li>• Antenatal steroids for preterm labor</li> <li>• HIV screening</li> <li>• 48 hours stay postdelivery</li> <li>• Comprehensive abortion care</li> </ul>	<p><b>NBSU (Newborn Stabilization Unit)</b></p> <p><b>All newborn care services those in Level 1, plus the following:</b></p> <p><b>Care of sick newborn</b></p> <ul style="list-style-type: none"> <li>• Identification and Management of LBW infants <math>\geq</math> 1800 gm with no other complications</li> <li>• Phototherapy for newborns with hyperbilirubinemia</li> <li>• Management of newborn sepsis</li> <li>• Stabilization and referral of sick newborns and those with very low birth weight</li> </ul>	<p><b>All Services provided in Level 1, plus the following:</b></p> <p>Female sterilization including post-partumsterilization, male sterilization (conventional and no-scalpel vasectomy)</p>

Continued

**TABLE 2.** Continued

Type and Level of Facility	Population Served	Beds	Human Resource (Also Calculated Based on Caseload)	Maternal Health Services	Newborn Care	Family Planning Services
				<ul style="list-style-type: none"> <li>• Case management of sexually transmitted infection</li> <li>• Antibiotics for pre-term or premature rupture of membranes for prevention of sepsis of newborns</li> </ul>		
First referral unit community health center, Level 3	120,000 people in urban areas or 80,000 people in remote areas	30 bedded	Specialists including gynecologist/ emergency obstetric care, anesthetist/LSAS, pediatrician	<p><b>All services listed in facilities above in Level 1 and 2, plus the following:</b></p> <ul style="list-style-type: none"> <li>• Comprehensive management of all obstetric emergencies, e.g., PIH/eclampsia, sepsis, PPH, retained placenta, shock, obstructed labor, severe anemia</li> <li>• Cesarean delivery and other surgical interventions</li> <li>• Blood bank/storage center</li> <li>• Blood grouping and cross-matching</li> <li>• Link ART/ART at district hospital</li> </ul>	<p><b>Sick newborn care unit</b>  <b>All newborn care services those in Level 1 and 2, plus the following:</b>  <b>Care of sick newborn</b></p> <ul style="list-style-type: none"> <li>• Identification and management of LBW infants <math>\geq</math> 1800 gm</li> <li>• Management of all sick newborns (except those requiring mechanical ventilation and major surgical interventions)</li> <li>• Follow-up of all babies discharged from the unit and including of high-risk newborns</li> </ul>	<p><b>All services provided in Level 1 and 2, plus the following:</b></p> <ul style="list-style-type: none"> <li>• Laparoscopic sterilization</li> <li>• Postpartum intrauterine device insertion</li> </ul>
Subdistrict hospital / referral hospital, Level 3	100,000 - 500,00 population	31–50 bedded for small population (100,000) – 51–100 beds for large population (500,000)	Medical officers Staff nurse, cleaning staff, counselor, lab technician 1 certified sonologist (on call after routine hours) HR for SNCU			
District hospital, Level 3	All population in the district (35,000 to 3,000,000)	300 beds for 1,000,000 people population; As the population increase the recommended beds increase to a maximum of 500 beds				

Abbreviations: ART, antiretroviral therapy; LSAS, lifesaving anesthetic skills; HR, human resources; SNCU, sick newborn care unit; LBW, low birth weight; OPV, oral polio vaccine.

The assessment included 748 data parameters on the labor room environment, staff competencies, and practices. While the labor room environment was assessed through a structured checklist based on MOHFW’s maternal and newborn health toolkit, competency assessment was conducted using a mix of vignette, knowledge, and simulation-based tools. Of the 1,410 staff nurses and auxiliary nurse-midwives (ANMs) posted at the intervention facilities during the assessment, 427 providers, identified based on 8-hourly duty shifts, were included in the assessment. Practices for a set of predetermined indicators at the intervention facilities were reviewed through facility-level labor room registers and case sheets with October–December 2015 serving as the reference period.

While the labor room records were reviewed fully, case sheet-based records were assessed through a random sample of case sheets with 10 sheets for each of the 3 months at district hospitals and 5 at community health centers and other facilities (Supplement 1). The results of the baseline assessment were subsequently collated and analyzed using an Excel-based tool.

### Development of Intervention Package and Management Information System

Using the baseline assessment findings, the project team developed technical packages for the intervention. The 14 interventions were split

into 2 groups: 1 set of interventions was required for all deliveries, and another set of interventions was used to build competencies for managing maternal and newborn complications. In 2016, the trainings aimed at improving competencies for monitoring the progress of labor, active management of the third stage of labor, essential newborn care, newborn resuscitation, and postnatal monitoring of mothers and newborns. The remainder of the interventions were rolled out in 2017. Similarly, establishing a management information system (MIS) involved identifying a set of standardized indicators to track the progress of the intervention through an Excel-based data entry tool.

### Implementation

The implementation was staggered with the first set of interventions rolled out through a series of district and on-site low-density, high-frequency training sessions between March and May 2016. Post-training monthly mentoring visits by district-level project officers were initiated from June 2016 to provide on-job handholding and supportive supervision. Facility QI platforms were established beginning October 2016. Similarly, trainings for the second set of interventions were conducted between February and April 2017.

The monthly MIS capturing key indicators was introduced at the facilities with efforts initially focused on streamlining data capture at facilities followed by ensuring regularity and completeness in data maintenance (Supplement 2).

### Endline Assessment

An independent external evaluation of the first set of interventions in the “Care Around Birth” approach was conducted by the Center for Operations Research and Training between November 2017 and February 2018. The assessment was conducted across a sample of 51 intervention facilities (the sample size was calculated using WHO’s Service Availability and Readiness Assessment’ technique) and included facility assessment; competency assessment of staff nurses/ANMs; in-depth interviews with staff nurses/ANMs, medical officers, district and state officials, and beneficiaries; and direct observation, of deliveries. Overall competency assessments and in-depth interviews were conducted with 195 staff nurses/ANMs, 77 medical officers, and 33 district and 8 state officials. Direct observation of 399 deliveries was conducted to

determine essential practices, and 392 beneficiaries were interviewed to assess their experience with care and provision of services. Weights were then applied to the sample to generalize the findings to the intervention universe of 139 facilities, as 2 facilities (the primary health centers) had closed during the intervention period. Quantitative data were collated on CPro and analyzed on SPSS, while the qualitative data were audio-recorded, transcribed, and coded thematically (Supplement 3).

### Data Management and Analysis

Data for the current paper have been analyzed at several levels: (1) labor room amenities and competency scores during the baseline assessment and external evaluation; (2) trends in essential maternal and newborn practices during the intervention period cumulatively and with facility and state-level differentials; and (3) provision and experience of care during the external evaluation. While aggregate level alterations over time were undertaken from the cumulative data of the 6 states, monthly records at each facility level were used to distinguish the variation in improvement over time. To compare the difference in the performance of the indicators at baseline and different phases of the intervention, Chi-square tests were performed. Each phase of the intervention was compared with its previous phase to examine whether the change in percent observed was significant or not. To compare the performance among levels of the facility and states scores were calculated for the pre and during intervention periods for each indicator. As the distribution of observations was skewed during both periods, median values were calculated to provide a better representation of the shift in improvement. Furthermore, provision and experience of care were estimated in percentage improvement.

### Ethical Clearance

As the model included facilitating the on-the-ground implementation of interventions included in the national service delivery package for maternal and newborn health, ethical clearance was not sought before implementation. However, Institutional Review Board clearance was obtained for conducting the endline assessment (No.EC –CORT/1730), and each respondent involved in the in-depth interviews provided their oral or written consent.

## ■ RESULTS

We present the results from the first set of interventions.

### Labor Room Environment

The labor room environment was assessed across a set of indicators during the baseline and endline assessments, which included the availability of amenities, recording formats and protocols, infection control practices, and biomedical waste management. Improvement was observed across almost all of the indicators during the intervention (Table 3).

### Service Provider Competency

While most health care providers scored less than 50% for all the components during the baseline, after the intervention, competency improved across all of the components with maximum improvement observed for the use of the partograph, active management of the third stage of labor, essential newborn care, resuscitation, and newborn vaccination (Table 4).

*The good aspect of this project was skill enhancement. Skills have been enhanced which will stay with us. Staff who have been trained and posted at facilities will remain there and will train the new staff.* —Former Chief Medical Health Officer, Mandi, Himachal Pradesh

### Labor Room Practices

Practices in the labor rooms were monitored through on-site mentoring visits and collection of monthly maternal and newborn health-related datasets. These include the following:

- a. Maternal care during delivery: oxytocin administered within 1 minute of delivery, filled partograph, postpartum monitoring within 6 hours and at discharge, and average number of times mothers monitored during their stay at the facility.
- b. Essential newborn care and resuscitation: temperature recorded at birth, breastfeeding initiated within 1 hour of birth, delayed cord clamp, administration of vitamin K1, monitoring within 1 hour and within 6 hours, average number of times monitored after birth, and rates for birth dose vaccination.

Changes across these indicators were analyzed across 5 time periods: Period 1: October–December 2015 (baseline), Period 2: January–May 2016 (the baseline data collection and training period), Period

3: June–September 2016 (post-training mentorship period), Period 4: October–December 2016 (post-initiation of QI efforts by establishing QI teams and continued mentorship), Period 5: January–September 2017 (implementation with on-site mentoring and concurrent QI efforts) and Period 6: October–December 2017 (implementation and endline assessment).

An upward trend was seen across all maternal and newborn indicators over the intervention period indicating improvement in care practices (Figures 3, 4, 5 and Table 5 and Table 6). Statistically significant differences were seen across the intervention phases. For deliveries with filled partograph, it is seen that while period 2 did not differ much from period 1 which is the base period, period 3 when post-training mentorship was introduced marked a significant increase in partograph use (Table 5). Again, it was during period 5 with QI and on-site mentoring that the indicator saw a significant increase after which it did not change much for the subsequent period 6. Likewise, taking delayed cord clamping as another example, a significant difference in the practice was observed during periods 3, 4, and 5 after which the increase was not significant at period 6 (Table 6). It is evident that while performance for most of the indicators improved after training, the maximum impact was observed after mentorship, establishment of QI teams, and organization of QI meetings.

Moreover, apart from a few indicators like resuscitation and newborn vitals monitoring that had fluctuations during the intervention period, other indicators had an improved trajectory all through the intervention period.

Comparison of care practices of facility levels reveals that while district hospitals had satisfactory performance of certain indicators like oxytocin administration, vitals monitoring, vitamin K1 administration, breastfeeding and resuscitation at base period, first referral unit community health centers, non-first referral unit community health centers, 24x7 primary health centers had negligible practice of oxytocin administration or resuscitation and therefore, improvements seen in the indicators among these facilities were comparatively higher. There was hardly any practice of temperature recorded at birth or delayed cord clamping in most facilities but after the intervention, these practices rose above 90% (Table 7). Delhi, Jharkhand, and Uttarakhand states, which had very low levels of practice for most maternal and newborn indicators at baseline, made substantial improvement during the intervention period (Table 8). Comparatively, Haryana had started with fairly higher levels of practice of

**Health care provider competency improved across all of the components.**



**TABLE 3.** Labor Room Environment in Health Facilities Included in Care Around Birth Approach Intervention in 6 States in India

Indicator	Baseline (n=141)	External Assessment (n=139)
<b>Amenities available in labor room</b>		
Attached functional toilet facility in labor room	74.5	79.9
LR has 24x7 running water facility	90.8	100.0
LR has 24x7 Electricity supply with functional power backup that includes an inverter or generator	80.1	96.3
A functional refrigerator	60.3	90.9
<b>Availability of equipment/furnishing</b>		
Mackintosh with each labor table	70.2	93.9
Functional Kelly's pad on each labor table	41.1	78.9
Modular light for conducting deliveries	48.2	57.1
Functional wall clock with second hand/digital clock in labor room	90.1	97.9
Wall-mounted thermometer for measuring room temperature	61.0	85.9
Functional hemoglobinometer with reagents and lancet	34.8	70.5
Functional suction apparatus in labor room	35.5	83.8
Functional oxygen cylinder in labor room or central oxygen supply	75.2	92.4
Functional pulse oximeter in labor room	16.3	63.7
Newborn resuscitation bag	81.6	97.8
Pediatric stethoscope	22.7	67.8
Baby weighing scale	95.0	100.0
Radiant warmer	89.4	100.0
Radiant warmers have dedicated stabilizers	9.9	62.9
<b>Type of trays available</b>		
Delivery tray	66.0	98.0
Episiotomy tray	39.7	91.1
Baby tray or newborn tray	55.3	98.0
Medicine tray	51.1	97.1
Emergency drug tray	61.7	100.0
Postpartum intrauterine device tray	56.0	94.4
<b>Display of protocols</b>		
Active management of third stage of labor	64.5	94.8
Antepartum hemorrhage before 20 weeks	42.6	89.7
Antepartum hemorrhage after 20 weeks	41.8	93.8
Management of postpartum hemorrhage	67.4	98.6
Eclampsia	56.0	98.6
Breastfeeding	39.7	78.6
Kangaroo mother care	33.3	72.7
Newborn resuscitation	63.8	98.6
Handwashing	63.8	94.6

*Continued*

**TABLE 3.** Continued

Indicator	Baseline (n=141)	External Assessment (n=139)
Preparation of 1 liter bleaching solution	40.4	94.8
Infection prevention	46.1	88.1
<b>Availability of recording formats</b>		
Referral register (out)	85.8	96.5
Maternal death record register	31.9	74.6
LR sterilization register	19.1	62.6
Handing over/taking over register	37.6	86.2
Discharge register	42.6	85.3
Postpartum intrauterine device/family planning register	72.3	96.4
Postnatal care register	16.3	76.5
<b>Hand hygiene and antisepsis</b>		
Handwashing facility at point-of-use (sink with running water)	94.3	98.0
Elbow operated taps	46.1	87.8
<b>Material for personal protection</b>		
Masks	75.9	98.0
Sterile gloves	95.7	100.0
Gowns/aprons	84.4	97.9
Shoe covers	33.3	70.4
Caps	59.6	86.1
Utility gloves and gum boots for housekeeping staff	23.4	84.8
Personal protective kit for delivering HIV-positive patients	35.5	57.2
<b>Environment control of patient care areas</b>		
Staff is trained to prepare cleaning solution (0.5% chlorine solution) as per standard procedure	73.8	100.0
External footwear is restricted	42.6	87.1
<b>Biomedical waste management</b>		
Color-coded bins at point of waste generation	88.7	98.0
Functional needle cutters	94.3	100.0
Puncture-proof box	57.4	92.3
Disinfection of sharp objects before disposal	56.0	100.0
Instruments dipped in 0.5% chlorine solution immediately after use	76.6	100.0

partograph usage, vitals monitoring, delayed cord clamping, temperature recorded at birth, and successful resuscitation. Hence, the difference in improvement for these indicators is marginal.

## Endline Assessment Results

### Provision of Care

While monitoring the progress of labor using a partograph was done in 75% of deliveries

observed during the endline assessment, 100% of women were administered oxytocin after birth with 99% receiving it within 1 minute of delivery. After delivery, newborns were kept in skin-to-skin contact with mothers in 86% of observations; breastfeeding was initiated within 1 hour of birth in 96% of cases; injection of vitamin K1 was administered to 97% of newborns; 99% of newborns were weighed at birth; and temperature

**TABLE 4.** Service Provider Competency in Health Facilities Included in Care Around Birth Approach Intervention in 6 States in India

Indicator	Baseline, % (n=424)			External assessment (n=1,176)		
	<50%	51%–80%	80%+	<50%	51%–80%	80%+
Use of partograph	65	22	13	7	59	34
Active management of third stage of labor	15	52	33	8	31	62
Essential newborn care	66	26	7	2	28	70
Newborn resuscitation	68	27	5	1	17	82
Newborn vaccination	23	11	66	6	1	93
Postnatal monitoring	41	51	8	30	38	32
Infection prevention	40	54	6	18	39	43

was recorded for 88% of newborns observed. Health care providers used sterile disposable gloves during all the deliveries that were observed, 85% of health care providers practiced handwashing before examining the newborns, and protocols for safe disposal of placenta were followed in 99% of observations. Privacy was maintained in 84% of observations, and birth companions were allowed inside labor rooms in 78% of cases.

**Experience of Care**

Almost all the respondents reported the delivery room to be clean, and 84% reported the toilets to be clean. A majority of respondents (93%) reported availability of running water in the facility, 81% reported drinking water to be available; and 72% received free meals at the facilities. Regarding breastfeeding, 86% had initiated breastfeeding within the first hour after birth and 81% reported receiving necessary support for initiating breastfeeding. A majority (87%) reported that the nurse and/or doctor had checked them and/or the newborn during the postnatal period. Clients also reported that they had received information/counseling from providers, which included information on postpartum family planning (51%), hygiene and handwashing (44%), and the continuation of exclusive breastfeeding (41%) for the first 6 months. Clients were also provided with counseling information that applied to mothers, such as eating regular meals (23%) and drinking fluids regularly (18%), and to newborns, such as not applying anything to the cord stump (17%) and monitoring for danger signs. Nearly half (49%) of clients stated that they were able to ask health care providers questions about their own and their newborn’s health when needed. Regarding services provided at the facilities, 67% of clients were “satisfied” and

31% were “very satisfied,” with 97% of clients stating that the health care providers were supportive.

*I am very happy with the services here and the nurses talk very nicely to me. They also explain everything and make me feel comfortable.* —Client, district hospital, Muktsar, Punjab

Although a preliminary analysis of facility data indicated a reduction in perinatal mortality, the duration of the intervention limited any definitive statistical analysis.

**DISCUSSION**

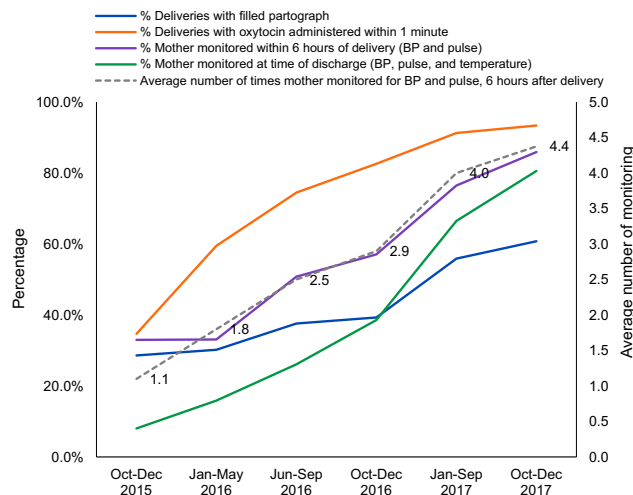
With the global transition to the Sustainable Development Goals framework, multiple efforts have been undertaken for improving and optimizing the quality of care across the health care delivery system.<sup>1,22,26–29</sup>

The Care Around Birth approach adds to the existing body of evidence by potentiating efforts to improve the quality of health care delivery systems using a training, mentoring, and QI model in resource-constrained and poor-performing districts in India.

In a relatively short period of 2 years, this approach has been able to demonstrate improvements. Possible factors include addressing and streamlining implementation challenges through an inclusive problem-solving approach with attention to detail, comprehensive planning for end-to-end solutions, clear messaging, and role clarity. The approach ensured a high level of engagement from the government counterparts at all levels that generated ownership, which is in line with available literature.<sup>29</sup> Implementing the approach demonstrated that optimizing the use of existing resources for driving and sustaining

**The Care Around Birth approach adds to the existing body of evidence by potentiating efforts to improve the quality of health care delivery systems using a training, mentoring, and QI model in resource-constrained and poor-performing districts in India.**

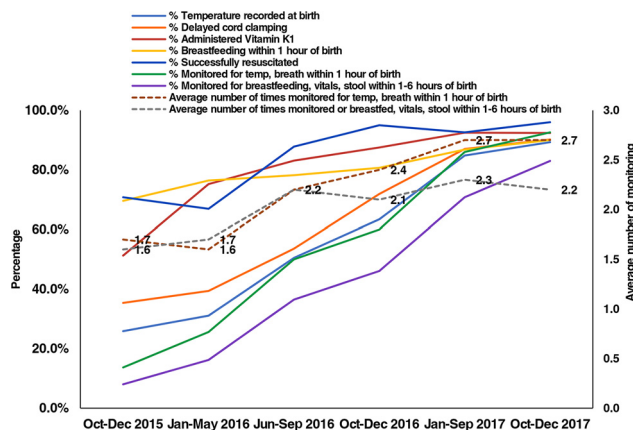
**FIGURE 3.** Improvement in Maternal Care During Delivery During Intervention to Improve Quality of Care in 6 States in India<sup>a</sup>



Abbreviation: BP, blood pressure.

<sup>a</sup>Dotted lines are represented on right side Y-axis due to different unit scale.

**FIGURE 4.** Improvement in Essential Newborn Care and Resuscitation During Intervention to Improve Quality of Care in 6 States in India

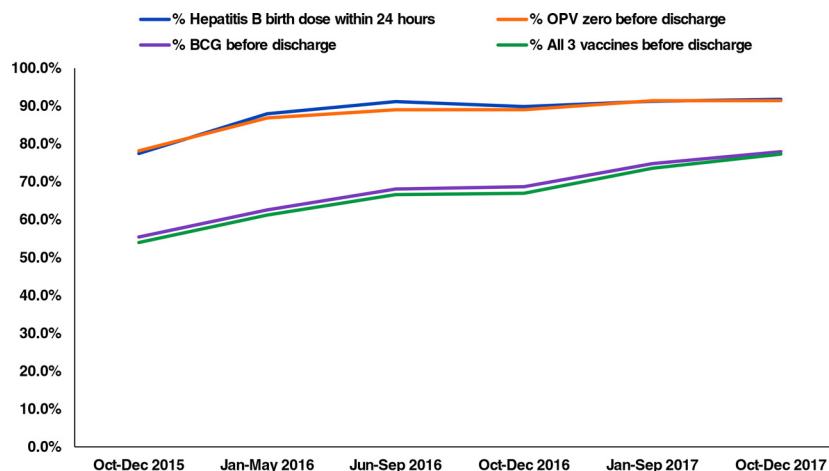


change with continued advocacy for long-term goals, including improvement in infrastructure and human resources, should be the way forward for any health intervention. Further, the fact that the approach was implemented in 26 districts across 6 states with variable resources and levels of service delivery enabled the project team to learn and gain insights into the nuances of

implementation, understand the need for improvisation for improvement, and ensure that mechanisms were built-in to sustain and scale complex and integrated interventions.<sup>30-31</sup>

By designing the training package according to the sequence of events in the labor room and post-natal wards, the approach integrated maternal and newborn care and helped health care

**FIGURE 5.** Improvement in Newborn Vaccination During Intervention to Improve Quality of Care in 6 States in India



Abbreviation: OPV, oral polio vaccine.

**TABLE 5.** Maternal Care During Delivery in Health Facilities Included in Care Around Birth Approach Intervention in 6 States in India

Indicators <sup>a</sup>	October-December 2015	January-May 2016	June-September 2016	October-December 2016	January-September 2017	October-December 2017
Deliveries with filled partograph, %	28.6	30.2	37.6 <sup>c</sup>	39.3	55.9 <sup>c</sup>	60.8
Deliveries with oxytocin administered within 1 minute, %	34.7	59.5 <sup>c</sup>	74.5 <sup>c</sup>	82.6 <sup>c</sup>	91.3 <sup>c</sup>	93.4
Mothers monitored within 6 hours of delivery (BP and pulse), %	33.0	33.1	50.8 <sup>c</sup>	57.1 <sup>b</sup>	76.5 <sup>c</sup>	85.9 <sup>b</sup>
Mothers monitored at the time of discharge (BP, pulse, and temperature), %	8.0	15.9 <sup>b</sup>	26.1 <sup>c</sup>	38.6 <sup>c</sup>	66.5 <sup>c</sup>	80.6 <sup>c</sup>
Average number of times mother monitored for BP and pulse; 6 hours after delivery	1.1	1.8 <sup>b</sup>	2.5 <sup>c</sup>	2.9 <sup>b</sup>	4.0 <sup>c</sup>	4.4

Abbreviation: BP, blood pressure.

<sup>a</sup> t-test for difference in percentage between subsequent phases.

<sup>b</sup> P<.01.

<sup>c</sup> P<.001.

providers recognize the importance of managing both the mother and the newborn together as 1 unit and ensured competencies for both maternal and neonatal care. The integration of interventions and operational strategies in the approach is in line with recent evidence that suggests while single interventions are unlikely to achieve reductions in maternal, newborn, and child mortality, combining interventions is more effective in improving health care practices.<sup>29,32</sup>

The approach adopted a staggered implementation framework where different capacity-building measures were initiated and implemented over 2 years. While the baseline assessment helped provide a thorough understanding of the intervention facilities, the initial round of short, centralized, and facility-based low-density, high-frequency trainings not only refreshed provider competency but also helped saturate facilities with trained health care providers thereby negating the potential

**TABLE 6.** Essential Newborn Care, Resuscitation and Newborn Vaccination in Health Facilities Included in Care Around Birth Approach Intervention in 6 States in India

Indicators <sup>a</sup>	October-December 2015	January-May 2016	June-September 2016	October-December 2016	January-September 2017	October-December 2017
Temperature recorded at birth, %	25.9	31.1	50.5 <sup>c</sup>	63.4 <sup>c</sup>	84.8 <sup>c</sup>	89.3
Delayed cord clamping, %	35.4	39.4	53.6 <sup>c</sup>	71.9 <sup>c</sup>	87.0 <sup>c</sup>	90.2
Administered Vitamin K1, %	51.3	75.2 <sup>b</sup>	83.1 <sup>b</sup>	87.5	92.5 <sup>b</sup>	92.4
Breastfeeding within 1 hour of birth, %	69.6	76.4 <sup>b</sup>	78.2	80.7	86.8 <sup>b</sup>	90.0
Successfully resuscitated, %	70.8	66.9	87.8 <sup>c</sup>	95.0 <sup>c</sup>	92.6	96.0
Monitored for temperature, breathing within 1 hour of birth, %	13.7	25.6 <sup>b</sup>	50.0 <sup>c</sup>	60.0 <sup>c</sup>	86.0 <sup>c</sup>	92.6 <sup>b</sup>
Monitored for breastfeeding, vitals, stool within 1–6 hours of birth, %	8.0	16.2 <sup>b</sup>	36.5 <sup>c</sup>	46.1 <sup>c</sup>	70.8 <sup>c</sup>	83.0 <sup>c</sup>
Average number of times monitored for temp, breath within 1 hour of birth	1.7	1.6	2.2 <sup>c</sup>	2.4 <sup>c</sup>	2.7 <sup>c</sup>	2.7
Average number of times monitored for breastfeeding, vitals, stool within 1–6 hours of birth	1.6	1.7 <sup>b</sup>	2.2 <sup>c</sup>	2.1	2.3 <sup>b</sup>	2.2
Administered hepatitis B vaccine birth dose within 24 hours, %	77.5	88.0 <sup>b</sup>	91.2	89.9	91.3	91.8
Administered OPV 0 before discharge, %	78.2	86.8 <sup>b</sup>	89.0	89.0	91.4	91.4
Administered BCG before discharge, %	55.4	62.5 <sup>b</sup>	68.1	68.7	74.8 <sup>b</sup>	77.9
Administered all the three vaccines before discharge, %	53.9	61.2 <sup>b</sup>	66.6	66.9	73.6 <sup>b</sup>	77.3

Abbreviations: BP, blood pressure; OPV, oral polio vaccine.  
<sup>a</sup> Test for difference in percentage between subsequent phases.  
<sup>b</sup> P < .01.  
<sup>c</sup> P < .001.

impact of variable service provider competencies. The mentorship visits immediately after the trainings helped sustain the gains, improved the availability of equipment and logistics at the facilities, and engendered trust and mutual respect between the project staff and health care providers at the intervention facilities. The subsequent introduction of QI approaches through facility teams then transferred ownership to health care providers, which ensured accountability and local problem solving. It was also evident that this staggered implementation not only built the capacity of the health system to absorb and inculcate change but also ensured facility readiness to adopt QI approaches, which usually tend to work better in areas with increased levels of resources than in low-resource settings.<sup>30</sup>

Data-driven decision making and facility-based QI teams formed the fulcrum of the approach.

While robust measurement, collation, and triangulation of data enabled the intervention facilities to adopt a comprehensive approach to improvement, the QI efforts utilized this data to address issues at the facility level. The dual approach of combining quantitative data through the MIS and qualitative data through the QI meetings demystified various implementation challenges and issues. The approach also differed from the traditional plan-do-study-act approach by using predefined data elements across a set of indicators to foster improvements rather than addressing 1 improvement aim at a time. This possibly helped faster improvement across the facilities and countered the narrative of QI approaches failing due to lack of leadership, financial, organizational, and system support.<sup>33</sup> However, the success of the QI approaches was differential, with some

**By designing the training package according to the sequence of events in the labor room and postnatal wards, the approach helped health care providers recognize the importance of managing both the mother and the newborn together as 1 unit.**

**TABLE 7.** Facility-Level Comparative Assessment of Maternal and Newborn Indicators Before and During Care Around Birth Approach Intervention in 6 States in India

Indicators <sup>a</sup>	Pre-intervention Phase (October 2015-May 2016)					Intervention Phase (June 2016-December 2017)				
	District Hospital (n=27)	Subdistrict Hospital/RH (n=25)	CHC-FRU (n=25)	CHC-non FRU (n=48)	24×7 PHC (n=14)	District Hospital (n=27)	Subdistrict Hospital/RH (n=25)	CHC-FRU (n=25)	CHC-non FRU (n=48)	24×7 PHC (n=14)
<b>Maternal Care</b>										
Deliveries with filled partograph, %	13.0	27.0	2.0	26.0	21.0	43.5	68.5	67.0	81.0	88.5
Deliveries with oxytocin administered within one minute, %	63.5	0.0	0.0	62.5	0.0	97.0	98.0	99.0	98.0	100.0
Mother monitored within 6 hours of delivery (BP and pulse), %	70.0	65.0	68.0	40.0	68.0	95.0	93.0	95.5	100.0	94.0
Mother monitored at the time of discharge (BP, pulse, and temperature), %	0.0	0.0	0.0	0.0	0.0	40.0	46.5	50.0	82.0	87.0
Average number of times mother monitored for BP and pulse, 6 hours post-delivery	0.55	0.40	0.45	0.40	0.35	2.25	3.35	2.65	3.50	4.20
<b>Essential Newborn Care and Resuscitation</b>										
Temperature recorded at birth, %	0.0	0.0	0.0	0.0	0.0	87.5	98.0	96.0	98.5	100.0
Delayed cord clamping, %	0.0	0.0	0.0	7.0	0.0	92.0	96.0	94.5	96.0	99.0
Administered Vitamin K1, %	95.0	99.0	85.0	96.5	82.5	98.5	99.0	99.0	99.0	98.0
Breastfeeding within 1 hour of birth, %	93.5	99.0	97.5	99.0	95.5	90.5	96.0	97.0	98.0	98.0
Successfully resuscitated, %	76.0	42.5	0.0	61.5	0.0	97.0	100.0	100.0	100.0	100.0
Monitored for temp, breath within 1 hour of birth, %	0.0	0.0	0.0	0.0	0.0	82.0	84.0	93.0	98.0	93.0
Monitored for breastfeeding, vitals, stool within 1–6 hours of birth, %	0.0	0.0	0.0	0.0	0.0	58.0	70.0	67.0	87.0	66.0
Monitored for temperature, breathing, and feeding at discharge, %	0.0	0.0	0.0	0.0	0.0	30.0	41.0	47.0	73.0	60.0
Average number of times monitored for temperature, breathing within 1 hour of birth	0	0	0	0	0	1.2	2	1.9	2.4	2.25
Average number of times monitored for breastfeeding, vitals, stool within 1–6 hours of birth	0	0	0	0	0	1	1.3	1.4	1.1	1
<b>Newborn Vaccination</b>										
Administered hepatitis B vaccine birth dose within 24 hours, %	93.0	98.0	97.0	96.5	97.5	95.0	97.0	97.0	98.0	98.0
Administered OPV zero before discharge, %	94.0	99.0	96.0	96.0	98.0	95.0	97.5	96.5	97.0	98.0
Administered BCG before discharge, %	87.5	72.0	45.0	85.5	22.5	94.0	81.0	79.0	91.0	80.0
Administered all the 3 vaccines before discharge, %	86.0	68.0	45.0	84.0	22.5	92.0	79.0	77.5	88.0	78.0

Abbreviations: 24×7 PHC, primary health center operating 24 hours a day/7 days a week; BP, blood pressure; CHC-FRU, first referral unit community health care center; CHC-non-FRU, non-first referral unit-community health care center; OPV, oral polio vaccine; RH, referral hospital.

<sup>a</sup>Data for 2 HSCs has not been included in the analysis.

interventions demonstrating preferable results compared to others.

Though overall improvements were noted inter-state and inter-facility, variations in results were observed during the implementation. These variations are attributable to the overall performance of health systems in the states and point toward the need for comprehensive improvements at the systems level for sustained gains.

The approach prioritized high caseload facilities, however, engagement of the L1 facilities through a pared-down version of basic obstetric and newborn care could have led to improvements in quality of care across all levels, as well as possibly a more optimal distribution of caseload. Similarly, the interventions targeting maternal and newborn complication management including management of postpartum hemorrhage and pre-eclampsia/eclampsia, kangaroo mother care, assisted feeding of low birth weight babies, use of antenatal corticosteroids for preterm labor, management of maternal and newborn sepsis, and the prevention of parent to child transmission were implemented for less than a year and did not provide enough time for measurement and evaluation, moreover the relatively short implementation period might have limited sustainability of efforts. The approach also did not strengthen referral pathways.

Although the approach did not measure motivation among staff, it can be presumed that improving the experience of care for beneficiaries is directly proportional to not only the competency but also the motivation level of health care providers. As there was hardly any increase in staff strength at the intervention facilities during the implementation period, improved results are a marker of both better competency and accountability of the facility staff. Hence, all interventions should identify health care providers as important stakeholders and ensure sustained capacity building through a multipronged approach to build competencies and enhance motivation and self-confidence among them. Also, while most of the training packages focus on improving clinical competencies, health care providers should acquire skills in time management, team building, and interpersonal communication. These skills are essential to health care providers, especially those in high-caseload facilities with low human resource capacity. Though the approach had these aspects incorporated in the clinical training modules, soft skills trainings should be designed and implemented for health care providers.<sup>34</sup>

It is increasingly recognized that all women need and deserve respectful care and that RMC

should be promoted as a critical element of strategies to improve the utilization and quality of maternity care.<sup>35-36</sup> The approach aimed to improve RMC by integrating it into overall health system strengthening efforts. Contrary to multiple studies, which point to care being compromised due to mistreatment and disrespectful care during childbirth,<sup>37-38</sup> the current intervention reported good levels of satisfaction among clients. While this may be due to low levels of expectation, integrating RMC into the overall efforts to improve the labor room environment, competencies, and service delivery mechanisms and targeting health care providers to incorporate respectful care practices into their scope of work might well be responsible for the better experience of care by beneficiaries. This is in line with recent evidence that shows that improving the quality of care by promoting RMC needs to not only address interactions between the woman and the provider but also make improvements at the health-systems level. Thus, RMC should not be considered as an isolated intervention but rather as a critical component for providing good-quality care for mothers and newborns within health systems.<sup>39</sup>

Sustained advocacy at the state level helped to mobilize financial resources to address larger systemic issues through annual program implementation plans with states providing funds for labor room strengthening, setting up skill labs, and training health care providers. In addition, efforts were made to build ownership by ensuring that government staff and program officers were identified to serve as focal points for reviewing progress and addressing challenges at the state, district, and facility levels and developing a pool of state-level trainers to ensure continued scale up to other facilities and districts across the states. Moreover, the partnership with the state governments helped to sustain and ensure a contextualized scale up of the approach. Some states like Punjab and Delhi scaled up the initiative statewide, but others undertook both intra- and inter-district scale-ups. Learnings from the approach, specifically those related to facility-level QI initiatives and RMC, were then integrated into the national labor room and maternity operation theater QI initiative, LaQshya, with the project supporting a national program management unit based out of the MOHFW for program rollout and implementation across the country and focused support to LaQshya implementation across 7 states through dedicated state units. A substantial number of the Care Around Birth facilities were also designated as LaQshya facilities and received state and national certifications in due course.

**The approach differed from the traditional plan-do-study-act approach by using predefined data elements across a set of indicators to foster improvements rather than addressing 1 improvement aim at a time.**



**TABLE 8.** Interstate Comparative Assessment of Maternal and Newborn Indicators Before and During Care Around Birth Approach Intervention in 6 States in India

Indicator <sup>a</sup>	Pre-Intervention Phase (October 2015-May 2016)						Intervention Phase (June 2016-December 2017)					
	Delhi (n=8)	Haryana (n=32)	Himachal Pradesh (n=16)	Jharkhand (n=42)	Punjab (n=18)	Uttarakhand (n=25)	Delhi (n=8)	Haryana (n=32)	Himachal Pradesh (n=14)	Jharkhand (n=42)	Punjab (n=18)	Uttarakhand (n=25)
<b>Maternal Care</b>												
Deliveries with filled partograph, %	0.0	90.0	64.5	15.5	0.0	0.0	71.0	96.0	86.5	56.5	44.0	59.0
Deliveries with oxytocin administered within 1 minute, %	9.0	91.0	0.0	44.0	0.0	17.5	100.0	99.0	100.0	97.0	99.0	99.0
Mothers monitored within 6 hours of delivery (BP and pulse), %	100.0	91.0	60.0	0.0	80.0	0.0	100.0	100.0	95.0	100.0	90.0	83.0
Mothers monitored at the time of discharge (BP, pulse, and temperature), %	0.0	0.0	0.0	0.0	0.0	0.0	100.0	69.5	58.0	80.0	23.0	41.5
Average number of times mother monitored for BP and pulse; 6 hours after delivery	1.85	1.65	0.50	0.00	0.45	0.00	3.50	5.35	3.10	2.30	2.70	2.40
<b>Essential Newborn Care and Resuscitation</b>												
Temperature recorded at birth, %	0.0	100.0	100.0	0.0	0.0	0.0	88.5	100.0	100.0	92.5	87.0	82.5
Delayed cord clamping, %	0.0	100.0	100.0	0.0	0.0	0.0	90.5	99.0	100.0	92.0	88.0	93.0
Administered Vitamin K1, %	67.5	92.5	100.0	96.5	62.0	73.0	96.0	95.5	100.0	99.0	99.0	99.0
Breastfeeding within 1 hour of birth, %	6.5	98.5	100.0	98.0	98.0	0.0	83.5	97.5	100.0	97.5	91.5	91.0
Successfully resuscitated, %	0.0	85.5	0.0	96.0	0.0	0.0	100.0	100.0	88.0	98.5	92.0	88.0
Monitored for temp, breath within 1 hour of birth, %	100.0	9.0	0.0	0.0	0.0	0.0	100.0	93.0	91.0	93.0	76.0	93.0
Monitored for breastfeeding, vitals, stool within 1-6 hours of birth, %	100.0	0.0	0.0	0.0	0.0	0.0	100.0	71.0	73.0	76.0	51.5	48.0
Monitored for temperature, breathing and feeding at discharge, %	0.0	0.0	0.0	0.0	0.0	0.0	93.0	50.0	57.5	74.0	21.0	39.5
Average number of times monitored for temp, breath within 1 hour of birth	0.3	0.2	0	0	0	0	1.3	2.2	2.3	2.1	1.45	2.45
Average number of times monitored or breastfeeding, vitals, stool within 1-6 hours of birth	0.3	0	0	0	0	0	1.5	1	1	1	1.45	1.3
<b>Newborn Vaccination</b>												
Administered hepatitis B vaccine birth dose within 24 hours, %	95.5	97.0	98.0	94.0	97.0	75.0	95.0	97.0	99.0	97.0	98.0	94.0
Administered OPV 0 before discharge, %	99.0	97.0	100.0	94.0	96.0	76.5	95.0	97.0	99.0	96.0	98.0	95.5
Administered BCG before discharge, %	34.0	91.0	95.5	84.0	20.0	0.0	93.0	95.0	97.0	86.0	77.0	19.5
Administered all the 3 vaccines before discharge, %	34.0	90.0	89.0	81.0	10.0	0.0	92.0	93.0	96.0	83.5	77.0	21.5

Abbreviations: BP, blood pressure; OPV, oral polio vaccine.

<sup>a</sup>Data for 2 HSCs in Himachal Pradesh has not been included in the analysis for the intervention phase.

### Limitations

While the “Care Around Birth” approach demonstrated impact at scale, it did have certain limitations. The difference in the methodology for the baseline assessment and external evaluation might have a bearing on the overall impact, moreover, the absence of control districts did not allow

for comparative assessment. Both the provision and experience of care were measured only during the endline and hence results need to be interpreted cautiously as there might have been a Hawthorne effect.<sup>40</sup> In addition, though the approach presumably demonstrated a decline in mortality rates these aspects need to be further studied.

## CONCLUSION

Overall, the Care Around Birth approach has demonstrated impact at scale. It is envisaged that subsequent efforts in this field will gain insights from the approach to comprehensively address key drivers of maternal and newborn mortality.

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ORIGINAL ARTICLE

# A Mixed-Methods Process Evaluation: Integrating Depression Treatment Into HIV Care in Malawi

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## Key Findings

- Early evaluations of integrating a depression management program using antidepressants and psychotherapy into HIV clinics in Malawi found that depression screening, diagnosis, and treatment initiation were successfully integrated.
- A follow-up evaluation found that treatment over time was not delivered as intended, clinic staff had mixed attitudes regarding program acceptability, and the program was not sustained.
- Antidepressants and problem-solving therapy were acceptable evidence-based depression treatments for patients, but clinic staff found delivering these treatments challenging given constrained human resources and infrastructure.
- Delivery challenges included difficulties identifying and reassessing patients, negative attitudes, lack of integration into the electronic medical records system, medication stock-outs, staff and space availability, cost of transport, generally low retention, and reliance on study staff.

## Key Implications

- Program managers need to invest in program supervision, build and maintain the capacity of providers, integrate into existing electronic medical records systems, and ensure the availability of psychotherapy counselors to more effectively integrate depression treatment into HIV care in these types of settings.

## ABSTRACT

**Background:** Depression is highly prevalent among people living with HIV in Malawi. Depression can undermine engagement in HIV care and worsen HIV morbidity and mortality. The Ministry of Health integrated a pilot depression management program into HIV care at 2 clinics. This program included a measurement-based care protocol for prescribing antidepressants and an adapted Friendship Bench psychotherapy protocol for providing problem solving. Early evaluations indicated successful integration of the initial stages of training and depression screening, diagnosis, and treatment initiation. This follow-up mixed-method investigation contextualizes our previous findings and shares insights from the implementation experience.

**Methods:** We conducted a mixed-methods process evaluation drawing on both patient clinical data and qualitative interviews with patients and clinic staff. We focus on the following implementation outcomes: fidelity, acceptability, and sustainability.

**Results:** Although fidelity to depression screening and treatment initiation was high, fidelity to the follow-up treatment protocol was poor. Antidepressants and problem-solving therapy were acceptable to patients, but clinic staff found delivering treatment challenging given constrained human resources and infrastructure. The program was not sustained after the project. Key identified needs included substantial support to supervise the implementation of the program, continue to build and maintain the capacity of providers, integrate the program into the electronic medical records system, and ensure the availability of Friendship Bench counselors.

**Conclusions:** Although initial steps were successful, sustained integration of this depression treatment program into HIV care in this setting met greater challenges. Implementation science studies that support both implementation and evaluation should recognize the potential for clinical implementers to rely on evaluation staff for clinical support and consider distancing evaluation staff from the actual program implementation. Further research is needed to test enhanced implementation strategies for integrating evidence-based mental health interventions into existing health care systems in a sustainable fashion, particularly in low-resource settings.

## INTRODUCTION

The burden of depression is high among people living with HIV, particularly in sub-Saharan Africa (SSA).<sup>1</sup> Depression hinders engagement in HIV care and antiretroviral therapy (ART) adherence, which ultimately

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**HTC counselors and ART providers were trained to conduct depression screening of patients newly receiving ART and to refer them for antidepressants or counseling as needed.**

**The impact of health innovations depends not only on their effectiveness, but also how well they are adopted, implemented, and maintained over time.**

predict HIV clinical morbidity and mortality.<sup>1–6</sup> Despite the deleterious impact of untreated depression, low levels of investment in mental health care persist across the globe and especially in resource-limited settings such as SSA.<sup>7</sup> Fortunately, interventions to address the burden of depression among people living with HIV are being developed,<sup>8,9</sup> with several specifically for SSA or other settings with limited psychiatric infrastructure and human resources.<sup>10–15</sup>

To address the burden of depression among people living with HIV, the Malawi Ministry of Health (MOH) implemented a pilot task-shifting program that integrated depression management into ART initiation at 2 clinics in Lilongwe, Malawi.<sup>16,17</sup> As part of this program, existing clinic-based staff provided 2 evidence-based depression treatment interventions: measurement-based care (MBC) antidepressant prescription<sup>10,15,18</sup> and the Friendship Bench problem-solving therapy.<sup>14,19</sup> Early assessments of program delivery demonstrated the feasibility of integrating depression screening into ART initiation and starting patients on antidepressants or Friends Bench therapy.<sup>17,20</sup> Despite the proven efficacy of these treatment models, the initial program evaluation found that the treatment program did not improve retention, viral suppression, or depression remission.<sup>20</sup>

The ultimate impact of health innovations depends not only on their effectiveness, but also on their reach and the extent to which they are properly adopted, implemented, and maintained over time.<sup>21</sup> In this manuscript, we first describe how the program was designed. We then present a mixed-methods process evaluation investigating the extent to which the treatment program was delivered with fidelity at treatment initiation and over time, deemed acceptable by providers and patients, and sustained after the conclusion of the program evaluation. This mixed-method investigation allows us to contextualize our previous findings<sup>17,20</sup> and share insights from the implementation experience.

## PROGRAM OVERVIEW

The pilot program integrated depression screening and treatment into ART initiation at 2 semi-urban primary-level health facilities in Lilongwe, Malawi. The intervention launched at Clinic A in November 2017 and at Clinic B in April 2018. These public facilities provide services free of charge and encompass an ART clinic or department. Approximately 25 nurses and clinicians provide ART services at each site, although staff

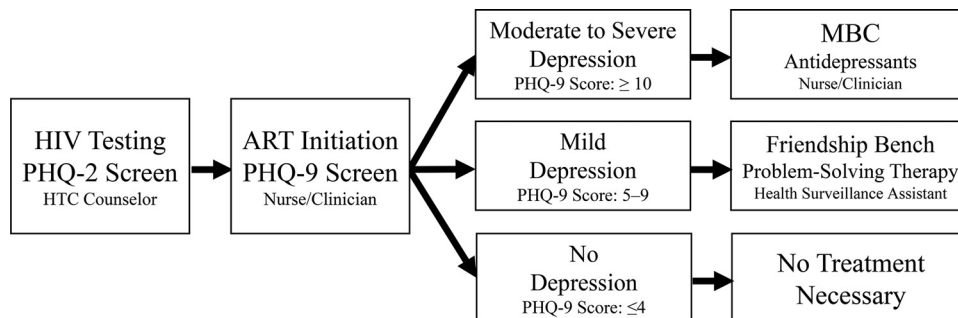
turnover is high. Only 1 facility employs a psychiatric nurse who does not regularly offer psychiatric services. Private mental health care specialists irregularly offer mental health clinic days at the facilities. Otherwise, patients can be referred to the psychiatric department at the district hospital. Further details on the health facilities are available in previous publications.<sup>17</sup>

HIV testing and counseling (HTC) counselors and ART providers were trained to conduct depression screening of patients when they were newly initiating ART by using the Patient Health Questionnaire-9 (PHQ-9), a 9-item screening questionnaire that has been widely used in the region.<sup>22–26</sup> HTC counselors screened patients who tested positive for HIV with the first 2 questions of the PHQ-9 (the Patient Health Questionnaire-2 [PHQ-2]) that screen for depressed mood and anhedonia. ART providers completed the remaining 7 questions of the PHQ-9 with any patients who endorsed either of the symptoms captured by the PHQ-2 (Figure 1).

For patients with moderate to severe depression (PHQ-9 score  $\geq 10$ ), ART providers were trained to treat them with antidepressants (amitriptyline or fluoxetine) using MBC (Figure 1). MBC is a resource-efficient, task-sharing model for prescribing antidepressant management in nonpsychiatric settings that has demonstrated safety, feasibility, and acceptability when adapted for HIV care and delivered by nonspecialists in Cameroon, Tanzania, and Uganda.<sup>10,15,18</sup> The pharmacies at the health facilities were instructed to stock amitriptyline and fluoxetine, 2 antidepressants that are considered “essential medicines” under Malawi’s Essential Health Package and are meant to be freely available for patients at health facilities.<sup>27,28</sup> ART providers were instructed to discuss the available antidepressants with the patient and jointly decide on the patient’s best option. When patients returned for ART care, ART providers were then meant to reassess patients’ depressive symptoms, evaluate their response to the depression treatment, and prescribe antidepressants as necessary. The study staff hung posters in the ART clinic rooms that provided an overview of the MBC protocol and detailed how to use PHQ-9 scores and adverse-effect tolerability to guide changes in dosage or type of antidepressant (Supplementary Material 1). A standard course of antidepressants should consist of at least 3 consecutive months of antidepressant prescription with dosage adjustments as necessary.

For patients with mild depression (PHQ-9 score 5–9), ART providers were trained to refer

**FIGURE 1.** Algorithm Used by Providers for Screening and Managing Patients With HIV for Depression Who Were Newly Initiating Antiretroviral Therapy, Malawi



Abbreviations: ART, antiretroviral therapy; HTC, HIV testing and counseling; MBC, measurement-based care; PHQ, Patient Health Questionnaire.

them to clinic-based community health workers (called health surveillance assistants [HSAs]) who were trained to provide Friendship Bench problem-solving therapy (Figure 1). Friendship Bench therapy is an adaption of problem-solving therapy or patient-centered counseling developed in Zimbabwe that teaches patients how to identify triggers and effectively manage stressful life events by learning or reactivating problem-solving skills.<sup>14,19</sup> The Friendship Bench protocol planned for referred patients to receive at least 6 counseling sessions, with adequate treatment comprising at least 6 sessions within the first 6 months. While Friendship Bench counselors were instructed to encourage patients to return weekly for Friendship Bench therapy, patients set their own appointments in line with the protocol’s patient-centered approach. While 8 HSAs at each site were trained in the Friendship Bench protocol, these HSAs continued to be responsible for fulfilling their previous duties. The responsibilities of a clinic-based HSA vary but may include activities such as following up with patients who have dropped out of care or managing community outreach vaccination campaigns. The study also employed 1 Friendship Bench counselor at each site who attended the same Friendship Bench training as the HSAs. The study-employed counselors were meant to provide backup support for the HSAs trained in the Friendship Bench protocol. Additionally, to address counseling space limitations, the study built covered shelters at both sites as a dedicated space for the Friendship Bench therapy.

Throughout the program implementation, the study coordinator held bimonthly meetings at

each site to support clinic staff and leadership deliver the program. However, the study staff were otherwise not meant to assist in the provision of daily clinical care and were only meant to consent patients and abstract their clinical data. Before the conclusion of the program evaluation, the study coordinator worked with the health facility staff and leadership to transition ownership of the program entirely to the health facilities. As such, the HIV providers were to continue screening and treating patients according to the Friendship Bench and MBC protocols after the conclusion of the study evaluation. Previous publications provide further details on the program design,<sup>16</sup> implementation,<sup>17</sup> and impact.<sup>20</sup>

## METHODS

### Clinical Data

After the launch of the intervention, all nonpregnant adults newly initiating ART were exposed to the program and eligible to participate in the program evaluation. Between April 2017 and November 2018 at Clinic A and between April 2018 and November 2018 at Clinic B, study staff approached potential participants during the ART initiation process to invite them to allow their clinical data to be used in the program evaluation. Study staff abstracted sociodemographic information as well as data on depression and HIV care from consenting participants’ clinical records over a 13-month period, starting at ART initiation. Again, further details on enrollment in the program evaluation, clinical data abstraction, and the measures captured have been previously published.<sup>16,20</sup> Only participants with elevated

**Before the program evaluation concluded, ownership of the program transitioned to the health facilities.**



A shelter dedicated for Friendship Bench therapy that was built at one of the program sites in Lilongwe, Malawi. © 2018 Steven Mphonda/University of North Carolina Project-Malawi.

depressive symptoms (PHQ-9  $\geq 5$ ) at ART initiation are included in this mixed-methods process evaluation. All statistical analyses were performed using STATA IC 14.

### Qualitative Data

In-depth interviews were conducted between June and December 2018 with the following objectives: (1) explore providers’ and patients’ attitudes toward and experiences with the depression treatment intervention; (2) understand barriers and facilitators to integrating depression treatment into HIV care; and (3) prepare for the long-term sustainability of the program after the conclusion of the program evaluation. The qualitative interviews were conducted with a convenience sample of patients returning for ART care. Patients were eligible to participate if they had previously been identified with depression at ART initiation and either referred to the Friendship Bench or prescribed antidepressants. Additionally, a convenience sample of ART providers, Friendship Bench counselors, and clinic leadership were also interviewed. Before data collection, study staff met with the administrators at both health centers and drew up a list of staff. The study coordinator or interviewer approached staff and leadership at the clinic to schedule interviews. The study staff identified eligible patients returning for ART services and invited these patients to participate. An effort was made to interview a range of men and women because prior research showed that attitudes toward depression and the provision of mental

health care may vary by the gender of both providers and patients.<sup>29–31</sup> The research team developed semistructured interview guides based on the study objectives. Interviews were conducted in either Chichewa (the local language) or English, based on participants’ preference, by a Malawian woman with a background in qualitative research and HIV care services. All interviews were held at the respective health facility in a private location. The interviews were audio-recorded, transcribed, and translated into English (if necessary). The research team reviewed transcripts as they became available and provided feedback to the interviewer throughout the data collection process.

After reviewing the transcripts, the author (MS) drafted a thematic codebook that would address the study objectives and capture emerging themes evident from her initial review of the transcripts.<sup>32,33</sup> MS then met with research team members to review and finalize the codebook. Two coders (MS and CM) coded a subset of the same transcripts and resolved any discrepancies to ensure consistency in their use of the codes using NVivo (Version 12). Coding was treated as an iterative process, and the coders met several times throughout to discuss the addition, definition, and appropriate use of the codes that emerged from the data. Upon completion of coding, the coders executed queries in NVivo and reviewed coded data related to the key aspects of program implementation, depression treatment initiation and treatment over time, acceptability, and sustainability. The coders

**Interviews were conducted to explore attitudes towards the depression treatment intervention and the barriers and facilitators to integrating the treatment into HIV care.**

created detailed summaries relevant to each code, took inventory of the emerging principal themes, and observed any variation across participant groups. While synthesizing these findings, MS met with the study team to ensure accurate interpretation of the interviews.

### Implementation Outcomes

We defined the implementation outcomes in line with Proctor and colleagues' conceptualization of implementation science research outcomes<sup>34</sup> and Carroll and colleagues' framework for implementation fidelity.<sup>35</sup> Fidelity is the degree to which this program was implemented as intended or the adherence to the program protocol. Acceptability is the perception among stakeholders and consumers—in this case, health facility staff, leadership, and patients—that the program is agreeable or satisfactory based on their knowledge, experience, and comfort with the program's content and complexity. Sustainability is defined as the extent to which the program is maintained within the health facilities' ongoing operations after the conclusion of the program evaluation. We assess each of these outcomes in the following manner.

#### Fidelity

We examined adherence to the program treatment protocol in terms of content, coverage, frequency, and duration<sup>35</sup> by using clinical data to determine whether patients initiated the correct depression treatment (content) based on their depressive severity (coverage) and whether these patients continued to attend Friendship Bench therapy sessions or receive antidepressants (frequency) over their first 6 months in care (duration). Data from the qualitative interviews explain and contextualize the quantitative fidelity measures.

#### Acceptability

We used data from the qualitative interviews to explore participants' views toward treatment delivery and its impact on patient outcomes. We specifically considered providers' comfort with the depression treatment options, their opinions about the complexity of the program, and structural impediments to program delivery. Additionally, patients' and providers' experiences with the program's effect on patient health outcomes were also reviewed.

#### Sustainability

We examined screening rates soon after the study stopped enrolling participants in the program

evaluation (from February to May 2019) and then again in December 2019. We also used discussions with clinic staff and leadership about maintaining the program to help understand these findings.

### Ethical Considerations

We obtained approval from both the Malawi MOH's National Health Science Research Committee (NHSRC) institutional review board (IRB) and the Biomedical IRB of the University of North Carolina at Chapel Hill. All participants who agreed to participate in the study provided informed consent. Qualitative study participants were given a travel reimbursement equivalent of 10 USD (7,000 MK).

### RESULTS

We first describe the characteristics of the study participants and then assess fidelity, acceptability, and sustainability. Fidelity was examined at treatment initiation and over time for both the MBC protocols and Friendship Bench protocols. Of note, themes presented in the fidelity section may reflect participants' comfort with the program and its overall complexity, and these factors may overlap with the program's acceptability.

#### Participant Characteristics

Of the 936 patients who enrolled in the program after the launch of the intervention, 211 were depressed at the time of ART initiation (Table 1). A convenience sample of 14 of these 211 patients were interviewed. Of these 14 patients, 11 were prescribed antidepressants and 3 started Friendship Bench therapy at ART initiation. In light of the delayed launch at Clinic B, a small number of participants had depression at Clinic B; thus all of the interviewed patients were from Clinic A. Twelve clinic staff were also interviewed.

#### Fidelity

##### Measurement-Based Care

The clinical data demonstrate that ART providers successfully prescribed antidepressants at a therapeutic dose in nearly all (96%) cases of moderate to severe depression, achieving high fidelity to the MBC protocol (Table 2). Based on the qualitative interviews, ART providers appeared knowledgeable about the depression treatment protocol and how to appropriately triage patients based on their PHQ-9 scores. The interviews suggested that providers deviated from guidance to discuss the antidepressant options with patients and jointly decide on the best antidepressant. It seemed that providers

**Implementation outcomes were defined by fidelity to the program protocol, acceptability to stakeholders and consumers, and sustainability of the program itself.**

**The clinical data demonstrate that ART providers successfully prescribed antidepressants at a therapeutic dose to nearly all patients with moderate to severe depression.**



**TABLE 1.** Characteristics of Participants With Depression at the Time of ART Initiation

	Clinical Data Patients (N=211)	Qualitative Data	
		Patients (N=14)	Providers (N=12)
Sex, no.			
Female	89	6	7
Male	122	8	5
Age <sup>a</sup> , mean (range)	34.0 (19–65)	36.1 (23–47)	34.2 (26–46)
Health facility, no.			
Clinic A	116	14	6
Clinic B	174	0	6
Marital status <sup>b</sup> , no.			
Married	n/a	6	n/a
Single	n/a	0	n/a
Separated	n/a	7	n/a
Employment, no.			
Employed	n/a	12	n/a
Self-employed	n/a	0	n/a
Unemployed	n/a	1	n/a
Position, no.			
ART provider	n/a	n/a	6
Friendship Bench counselor	n/a	n/a	4
Leadership	n/a	n/a	2
Professional experience			
Years at clinic, mean (range)	n/a	n/a	4.9 (0.7–11)
Years as clinician, mean (range)	n/a	n/a	8.7 (4–15)

Abbreviations: ART, antiretroviral therapy; n/a, not applicable.

<sup>a</sup>Age missing (n=3) and excludes leadership.

<sup>b</sup>Marital status and employment missing (n=1).

were most comfortable prescribing amitriptyline and the decision around which antidepressant to prescribe was almost entirely governed by what was in stock. As heard from one ART provider:

*We just prescribe the antidepressants that are in stock at that time, but the first choice is amitriptyline. If amitriptyline is not available, then we give that patient the other antidepressant.* —ART provider

Leadership and ART providers felt that providers were more familiar with amitriptyline and that it was easier for patients to take. Patients take amitriptyline daily, while they initially take fluoxetine every other day.

The provision of MBC over time was challenging. This challenge was partially due to waning

retention over the first 6 months of care. Figure 2 uses clinical data to show that by the first follow-up appointment (month 1) only around three-quarters of participants attended an ART appointment and by month 6 only around a third of participants attended an ART appointment. Among those who did come to follow-up HIV care appointments, providers often failed to reassess these patients with the PHQ-9, which would have guided depression management, or to continue providing appropriate depression treatment to those who were rescreened.

The qualitative interviews helped explain why it was difficult to identify depressed patients returning for care and to reassess those patients for depression. ART providers felt that the process

**The qualitative interviews helped explain why it was difficult to identify depressed patients returning for care and to reassess those patients for depression.**

**TABLE 2.** Initiation of Depression Treatment Prescribed by ART Providers

	Mild Depression (PHQ-9 score 5–9)* N=156, no. (%)	Moderate to Severe Depression (PHQ-9 score ≥10) N=55, no. (%)
Counseling by ART provider	15 (10)	2 (4)
Friendship Bench	134 (86)	0 (0)
Antidepressant	0 (0)	41 (75)
With counseling by ART provider	0 (0)	8 (15)
With Friendship Bench	2 (1)	4 (7)
None <sup>a</sup>	5 (3)	0 (0)
Of those who start antidepressant	N=2	N=53
Type		
Amitriptyline	1 (50)	37 (70)
Fluoxetine	1 (50)	16 (30)
Dose		
Subtherapeutic	0 (0)	0 (0)
Therapeutic	2 (100)	53 (100)

Abbreviations: ART, antiretroviral therapy; PHQ-9, Patient Health Questionnaire-9.

<sup>a</sup> Includes 4 patients with missing baseline treatment.

of identifying patients with depression and confirming the diagnosis with the PHQ-9 took a lot of time and significantly added to their workload, especially in light of the general shortage of staff and high patient caseload. For context, study staff timed the PHQ-9 administration, and ART providers took about a minute per question. That said, clinic leadership admitted:

*[ART providers] said they get tired and they don't even ask the PHQ because they know that "this will take much of my time." But if we had more personnel more people seeing patients that would have been better.*  
—Clinic leadership staff person

Identifying patients was also difficult because the program was not integrated into the electronic medical records (EMR) system. Providers had to look for stickers on the patients' health passports that signaled they had previously been diagnosed with depression. If providers noticed the sticker, they would then manually search for the patient's file, reassess the patient with the PHQ-9, and then provide appropriate treatment. It was difficult for providers to determine when a patient no longer needed to be assessed or had completed their depression treatment. One ART provider ventured:

*There wouldn't be a problem if depression questions were in the electronic system.* —ART provider

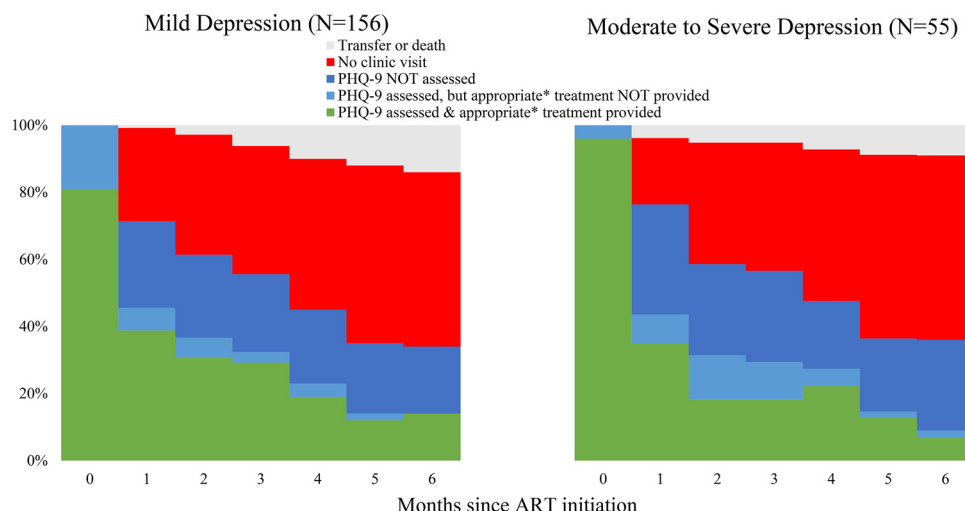
As an extension of these issues, ART providers often had a poor attitude toward the program. This phenomenon was summarized by clinic leadership,

*The workload [is problematic] when you are alone in the ART room and you need to screen those people, so sometimes people may be annoyed, [thinking] "I should screen this one, but this will delay me."* —Clinic leadership staff person

Other interviewed ART providers echoed this sentiment. As a result, ART providers often relied on the study staff to identify patients with depression returning for care, and the accuracy of the follow-up PHQ-9 assessments may have been compromised.

Few of those with moderate to severe depression received antidepressants continuously for the recommended minimum 3 months based on analysis of the clinical data (Table 3). Only 6 participants received at least 3 consecutive months of the same antidepressant. Switching the type of antidepressant prescribed was common; of the 30 individuals who were prescribed antidepressants at least twice, 40% (n=12) changed antidepressants at least once. Providers also failed to

**FIGURE 2.** Depression Treatment Engagement of Patients With HIV, by Depressive Severity, Malawi



Abbreviations: ART, antiretroviral therapy; PHQ, Patient Health Questionnaire.

\* Appropriate treatment is operationalized as attending a Friendship Bench session, or having completed 6 Friendship Bench sessions for those with mild depression, or being prescribed antidepressants among those with moderate to severe depression.

**The qualitative interviews provided insight into the barriers to achieving the recommended duration of antidepressant prescription.**

increase the dose of antidepressants for any of the patients when indicated by persistent elevated symptoms as dictated by the MBC protocol.

The qualitative interviews provided insight into the barriers to achieving the recommended duration of the antidepressant prescription. The main challenge was rooted in identifying patients returning for care, as previously described. While prescribing antidepressants added to ART providers' workload, providers were much more concerned about the time it took to identify and rescreen patients. When asked specifically about the added workload of prescribing antidepressants, one ART provider responded:

*The issue is just the time to ask the PHQ only, the time to ask the PHQ is what troubles us.* —ART provider

Additionally, antidepressant stock-outs were common, as noted by an ART provider:

*It's very rare whereby you have both [antidepressants] available . . . , sometimes you find that the one [the patient started taking] is not available so we switch them.* —ART provider

These reports from the clinics show that switches in antidepressant prescription were not due to side effects or lack of effect, but necessitated

by stock-outs. Ensuring that staff were properly trained on the MBC protocol was also challenging, due to high staff turnover and/or rotation through clinic departments and staff availability to attend the original trainings or the supervision sessions. Clinic leadership spoke to these needs:

*The training was just one day, so most people were not familiar with the dosages so they need to be reminded here and there. Of course, there are debriefing meetings that are done on Thursdays, but still not everybody attends. So prescribing is difficult just because people forget the dosage of the medication.* —Clinic leadership staff person

This feedback highlights the complexity of MBC and a need for ongoing support and training. From a patient perspective, actually taking antidepressants appeared largely acceptable. While some providers were concerned about the added pill burden, patients mostly found the antidepressants both tolerable and acceptable.

**Friendship Bench**

The clinical data demonstrate that nearly all (86%) of cases of mild depression correctly started the Friendship Bench therapy that same day, achieving high fidelity to the Friendship Bench protocol.

**TABLE 3.** Duration of Antidepressant Provision to Patients With Moderate to Severe Depression at Baseline (N=55)

	Moderate to Severe Depression (PHQ-9 score ≥10), no. (%)
Months of antidepressant prescription	
0	2 (4)
1	23 (42)
2	14 (25)
3	7 (13)
≥4	9 (16)

Abbreviation: PHQ-9, Patient Health Questionnaire-9.

However, the study-employed Friendship Bench counselor provided over half of the initial Friendship Bench therapy sessions (Table 2). As noted by one ART provider,

*Most of the time they [Friendship Bench counselors] are in the field, so we refer them to the [study-employed counselor].—ART provider*

This statement suggested that the clinic-based Friendship Bench counselors were often unavailable, resulting in heavy reliance on the program-employed counselor.

The clinical data revealed that although almost all patients with mild depression at ART initiation started the Friendship Bench, few participants received consistent Friendship Bench therapy over their first 6 months in care (Table 4). The original Friendship Bench therapy protocol was designed to be administered over the course of 6 consecutive weekly sessions. None of the patients completed this ideal “full course” in their first 2 months of care. Only 13 patients completed at least 6 Friendship Bench sessions within their first 6 months of care. The study-employed Friendship Bench counselor provided over half of the follow-up sessions.

The qualitative interviews help explain the challenges to achieving the recommended number of Friendship Bench sessions. Both patients and providers reported that scheduling weekly Friendship Bench sessions was almost impossible for patients because the cost of transport was prohibitive, clinic wait times were long, and patients would have to take off work. For this reason,

patients often chose to schedule their Friendship Bench appointments monthly in conjunction with their ART appointments. As described by one Friendship Bench counselor:

*Some [challenges] are transport ... we [Friendship Bench counselors] give dates and ART give their dates. ... So the person weighs the cost ... Many are prioritizing coming for [ART] medications rather than just coming for the Friendship Bench.—Friendship Bench counselor*

Beyond highlighting the complexities of attending follow-up Friendship Bench sessions in light of constrained resources, this quote also hints at a disconnect between the ART and weekly depression care for patients on Friendship Bench therapy.

The same staffing challenges that impeded initiating Friendship Bench therapy were also raised for providing therapy over time. The Friendship Bench counselors were not always available owing to their competing responsibilities as community health workers, and they felt their workload had substantially increased. While the Friendship Bench counselors strove to share the added workload, the clinics often relied heavily on the program-employed Friendship Bench counselor, as previously described. Friendship Bench counselors felt the provision of the Friendship Bench therapy was hampered by the sheer number of patients who defaulted or failed to attend follow-up sessions. They were frustrated by their inability to adequately trace patients in light of phone numbers not working, difficulties locating patients’ residences, and limited funds for airtime or transport.

The qualitative interviews also suggest patient discomfort may have played a role in poor continued engagement in Friendship Bench therapy. Interviewed Friendship Bench counselors believed it was important to develop rapport with patients, create an environment where patients felt comfortable speaking openly, and maintain patient privacy. Patients echoed this sentiment, both as a concern and as something they appreciated about the Friendship Bench therapy. As an extension of this, clinic staff and leadership raised concerns about the availability of confidential spaces. One Friendship Bench counselor noted that other patients were often nearby the Friendship Bench shelters and “when the client sees that, they feel that when we tell them that what we are going to discuss is confidential, we cheat on them because people are passing by.”

**Both patients and providers reported that scheduling weekly Friendship Bench sessions was almost impossible for patients.**

**TABLE 4.** Duration of Friendship Bench Therapy Provided to Patients With Mild Depression at Baseline (N=1 56)

	Mild Depression (PHQ-9 Score 5–9), <sup>a</sup> no. (%)	
	Within the first	
	2 months	6 months
Friendship Bench sessions attended		
0	20 (13)	20 (13)
1	64 (41)	59 (38)
2	32 (21)	19 (12)
3	37 (24)	13 (8)
≥4	3 (2)	45 (29)

Abbreviation: PHQ-9, Patient Health Questionnaire-9.  
<sup>a</sup>Includes 4 patients with missing baseline treatment.

This suggests that the open, outdoor nature of these shelters may not be conducive to the provision of depression counseling in this setting.

### Acceptability

The qualitative interviews show that nearly all patients, staff, and leadership believed both MBC and the Friendship Bench helped improve patients’ mental health, relieve their depressive symptoms, and prevent risk of suicide. In contrast, the previously published quantitative evaluation found that the treatment program did not demonstrably improve retention in HIV care, viral suppression, or depression remission 6 months after ART initiation.<sup>20</sup> In the qualitative interviews, ART providers cited patients’ reduced PHQ-9 scores as proof of the effectiveness of both antidepressants and the Friendship Bench. The Friendship Bench counselors attributed the program’s perceived success to its focus on teaching patients to identify their own problems and solutions. Some patients described the specific ways their respective depression treatment helped them. For example, patients believed treatment allowed them to calm their thoughts and to eat and sleep regularly. As heard from one patient taking antidepressants:

*I am able to talk normally and I do not have any anxiety/depression. I am now able to chat with my friends, just like the way life should be.* —Patient

While this patient believed taking antidepressants helped manage their anxiety and depression, other patients demonstrated a lack of understanding of depression, their respective depression

treatment, and its intended purpose and effect. Patients expressed a reverence for the medical field, often stating that they believed their treatment worked simply because the doctors told them it would. Finally, both Friendship Bench counselors and ART providers recognized that depressed patients may struggle to accept their HIV diagnosis and to take their ARTs consistently. For example, a Friendship Bench counselor and an ART provider commented

*Because of the counseling session, it helped the people . . . and now they are taking the medications consistently . . . this person is coming to collect drugs and their outlook [toward their] status has changed.*—Friendship Bench counselor

*Taking antidepressants has helped our friends with depression . . . to take their ARVs [antiretrovirals] adherently because when they are depressed they don’t even take the ARVs.* —ART provider

These descriptions demonstrate that clinic staff perceive that depression treatment supports ART adherence and engagement in HIV care.

### Sustainability

The clinical data suggest the program was not sustained. After enrollment into the program evaluation ended, the rate of screening dropped sharply (Table 5). By December 2019, 6 months after the study staff had complete data abstraction, ART providers had completely stopped screening patients newly initiating ART.

These quantitative findings are partially in contrast with staff attitudes toward sustainability

**Nearly all patients, staff, and leadership believed screening and treatment helped improve patients’ mental health, relieve their depressive symptoms, and prevent risk of suicide.**

**The clinical data suggest the program was not sustained and were partially in contrast with staff attitudes toward sustainability.**

**TABLE 5.** Screening Rates During and After Enrollment Into the Program Evaluation

	PHQ-2 Screening, <sup>a</sup> %	Complete PHQ-9 Screening, <sup>b</sup> %
Program enrollment period (Apr. 2017–Nov. 2018)	91.8	90.5
Brief follow-up period (Feb. 2019–May 2019)	25.1	58.8

Abbreviations: PHQ-2, Patient Health Questionnaire-2; PHQ-9, Patient Health Questionnaire-9.

<sup>a</sup> Among all new antiretroviral therapy initiators.

<sup>b</sup> Among those who endorse the PHQ-2.

identified in the qualitative interviews. The staff generally expressed a belief that they would continue to screen and manage depression after the study staff left the facilities. As heard from one ART provider,

*It will continue, because it's our job as health workers to assist those people, because if we don't assist, then who will? It's like most people will not be taking the ARVs.*  
—ART provider

In fact, only 2 ART providers directly expressed any skepticism toward the sustainability of the program:

*Because there are people who are supporting [us] but if they can move out, it is when the true picture of their [providers'] attitude can be seen.* —ART provider

These ART providers acknowledged that the clinics receive a lot of support from the study staff and that challenges to sustainability may become evident after they leave. However, clinic staff and leadership did suggest certain resources would be key to supporting the sustainability of the program. These included increasing the number of trained staff, particularly Friendship Bench providers; offering refresher trainings and opportunities for continued learning; providing ongoing supervision; maintaining the stock of antidepressants; and having space for providing screening and counseling.

## DISCUSSION

This mixed-methods evaluation of an integrated depression treatment program found that, while early stages of training, depression screening, diagnosis, and treatment initiation were successfully integrated,<sup>17</sup> treatment was not delivered as intended over time, clinic staff had mixed attitudes regarding the acceptability of the program, and sustainability was lacking. Over time, both ART providers and Friendship Bench counselors struggled to provide continued depression treatment owing to

difficulties identifying and reassessing patients, negative attitudes, lack of integration into the EMR system, medication stock-outs, staff and space availability, cost of transport, and generally low retention. Further, program implementation relied heavily on study staff. While the quantitative program evaluation did not find that program exposure improved HIV care or depression outcomes,<sup>20</sup> interviewed patients and clinic staff generally found the depression treatment both acceptable and helpful. The program was not sustained after the evaluation concluded, potentially because of limited staff, training, infrastructure, and supply of antidepressants.

During the study, clinics failed to deliver Friendship Bench therapy with fidelity to the program protocol, particularly in regards to the low frequency of attended sessions over the 6-month duration of follow-up.<sup>35</sup> The original Friendship Bench therapy protocol ideally called for 6 weekly therapy sessions, although patients were meant to set their own follow-up appointment dates. Similar to our findings, various evaluations of the original Friendship Bench therapy program in Zimbabwe suggest low patient engagement may not be uncommon. The pilot evaluation found that only 30% of participants completed 6 sessions in the first 6 weeks,<sup>14</sup> the randomized control trial found around 40% completed 6 sessions over a 6-month period,<sup>12</sup> and a mixed-methods longitudinal study over a 5-year period found nearly half of patients only attended 1 session, with only around 6% receiving 4 or more sessions.<sup>36</sup> We found that scheduling weekly appointments was challenging for patients, often because of the prohibitive cost of transport and time spent at the clinic. Patient follow-up was also difficult for providers, in light of limited resources and challenges in contacting patients. The mixed-methods evaluation of the Friendship Bench in Zimbabwe also noted the lower-than-expected appointment attendance and follow-up challenges, which were attributed to the lack of incentives for Friendship

**Early stages of training, depression screening, diagnosis, and treatment initiation were successfully integrated; however, problems were apparent in the program delivery over time.**

Bench counselors to follow up with patients.<sup>12</sup> While the Friendship Bench is a promising approach to providing evidence-based psychosocial therapy, further investigation of how best to engage patients over time is needed.

Providers managed to accurately identify patients with moderate to severe depression and started them on the correct dose of antidepressants, but fidelity to the MBC protocol over time was hampered by stock-outs, ART providers' level of comfort with fluoxetine and increasing dosages, difficulties identifying depressed patients, lack of integration into the EMR system, and negative attitudes. These findings support previous conclusions around the feasibility of integrating screening and treatment initiation into ART.<sup>17,20</sup> However, the challenges related to the provision of care over time are unsurprising because the providers are already overburdened and were expected to engage with the depression treatment program without additional incentives. A literature review on health systems facilitators and barriers to integration of HIV and chronic disease services found that successful integration programs have adequate, appropriately skilled, incentivized health care workers; supportive institutional structures; dedicated resources; and strong leadership and political will or support for the program.<sup>37</sup> However, ensuring such a comprehensively supportive environment is particularly challenging in resource-limited settings. Furthermore, very few studies have been conducted on task-shifting programs that use algorithm-guided protocols for antidepressant prescription in the region, and those that have been conducted often do not rely on existing staff or incentivize the staff involved in the research.<sup>10,15</sup> Further research that seeks to evaluate and compare integrated models of care for the provision of antidepressants is urgently needed to ensure the mental health needs of people living with HIV are met.<sup>39</sup>

Designing implementation science studies to evaluate programs that can readily (and rapidly) be adopted and integrated into routine care in the public sector is challenging.<sup>39,40</sup> To assess such a depression treatment intervention, our program was intentionally designed to rely almost entirely on existing clinical staff and systems. Similarly, the evaluation was deliberately designed to influence the provision of care as little as possible. However, the study staff likely significantly supported both patients and providers involved in the program. The program-employed Friendship Bench counselors provided a significant proportion of the therapy sessions, suggesting a lack of

effective task-shifting to existing community health workers. The study coordinator supervised and engaged clinic staff and assisted in supply-chain management to ensure the availability of antidepressants. The evaluation staff may have acted as "expert peers" by helping patients navigate clinical care, likely as a result of engaging patients in the consent process.<sup>17</sup> Further, study staff helped providers identify depressed patients returning for care, thus artificially inflating the number of patients that would have been reassessed or would receive ongoing depression treatment. The lack of sustainability further suggests that the study staff were integral to the program implementation. Implementation science studies that support program implementation and program evaluation may need to take into account how the relationship between the evaluating team and the clinic staff may affect the implementation of the study itself.

Several key recommendations have emerged from this experience. As implemented, depression screening, diagnosis, and treatment initiation were successfully integrated into HIV care<sup>17</sup>; however, integrating follow-up treatment into HIV care in this setting was not feasible. Some of the implementation challenges appeared to be more immediately remediable and could be addressed through simple solutions such as the following:

- HTC counselors could administer the entire PHQ-9 at ART initiation. This would partially address the added burden of administering the PHQ-9 at ART initiation placed on ART providers, who are still well-positioned to determine a final diagnosis and provide appropriate treatment.
- The facility pharmacists could ensure an adequate supply of antidepressants through improved communication and coordination with central medical stores. This would allow providers to defer the choice of medication to the informed patient and prevent unnecessary and inappropriate switching of antidepressants.
- Friendship Bench appointments could be routinely scheduled on the same day as ART follow-up visits to alleviate the patient-side travel and resource burden and also allow the ART providers to consistently reconnect patients in Friendship Bench therapy to the counselors.

Resolving other challenges would require a fundamental change in the program design or substantially more resources than are currently available in the Malawian public health system.

**Some of the implementation challenges appeared to be more immediately remediable and could be addressed through simple solutions.**

Nevertheless, the clinics would have benefitted from substantially more support, such as the following potential facilitators:

- The presence of a salaried, on-site coordinator or champion employed by the Ministry of Health would increase the likelihood of more faithful implementation. Such an individual would be well-positioned to foster clinic ownership of the program and provide the ongoing supervision and training that are needed to effectively build and sustain mental health care capacity.
- Integration into the EMR system is critical. This integration would help ensure that screening is completed and that returning patients are reassessed and reinforce mental health capacity building and intervention delivery with fidelity.
- Finally, successful implementation requires a dedicated, clinic-based Friendship Bench counselor. Task-shifting to an already overburdened cadre of community health workers is an ineffective means of providing depression services.

### Limitations

Findings from this evaluation should be considered in light of limitations due to the program and evaluation design. First, neither the program nor the evaluation design was guided by a formal implementation science framework. However, both were designed in congruence with the key principles of implementation science, using methods that would promote the systematic uptake of evidence-based practices (e.g. the Friendship Bench and algorithm-based care) into routine care.<sup>41,42</sup> We drew from various implementation science frameworks for this process evaluation to help ground our mixed-methods approach in implementation science theory.<sup>21,35</sup> A small convenience sample of health care facility staff and patients from the program sites participated in the interviews. Notably, patients were still engaging with HIV care and may have had different opinions about the program than those lost to follow-up. Thus, the attitudes captured here may not be generalizable to all the patients exposed to the program.

In addition, all the patient participants were from Clinic A owing to the small number of individuals with depression identified at Clinic B after the launch of the intervention. While the shorter study period at Clinic B is largely responsible for the small number of depressed individuals, Clinic B also had a slightly lower prevalence of

depression than Clinic A. Given the generally low retention rates, the study team decided to sample patients from Clinic A to achieve the target qualitative sample within the study period. However, this sampling decision does raise the potential for sampling bias, and it limited our ability to explore potential facility-level characteristics that could have been associated with the implementation success or failure.

Further, as the main objective of the study was to evaluate a program at the sites where participants worked or received care, it is possible that participants' responses were subject to social desirability bias. The use of mixed-methods approaches is particularly useful for evaluating implementation outcomes,<sup>21</sup> and in this case, the qualitative interviews helped to contextualize and provide nuanced information around the program's shortcomings.

### CONCLUSION

This mixed-methods evaluation of a depression treatment program using antidepressants and psychotherapy in HIV clinics in Malawi found that although the early stages of integration and treatment initiation were successful,<sup>17</sup> follow-up care was not delivered as intended, clinic staff had mixed attitudes regarding the acceptability of the program, and the program was not sustained. While these challenges may be responsible for the program's lack of impact on retention, viral suppression, and depression remission,<sup>20</sup> even the suboptimal depression treatment was appreciated by both patients and providers. This experience suggests that, while integrating depression screening, diagnosis, and treatment initiation in HIV care appeared feasible,<sup>18</sup> without substantial support to supervise the implementation of such programs, continue to build and maintain the capacity of providers, integrate the program into the electronic medical records system and ensure the availability of psychotherapy counselors, the depression management aspects of this program may not be entirely appropriate or feasible in this setting. This process evaluation helps explain the shortcomings of the program implementation and provides valuable insight into how it could be improved. Further, similar mixed-methods exercises could be incorporated into more routine quality-improvement activities and offer potential insights into patient-, provider-, and system-level challenges to the delivery of evidence-based interventions. Moving the field of implementation science forward, we recommend that a conscious effort be made in study and program design to distance evaluation staff from the program implementation itself. Further research is also



needed to test enhanced implementation strategies for integrating evidence-based mental health interventions into existing health care systems, particularly in low-resource settings.

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ORIGINAL ARTICLE

# Prioritizing Health-Sector Interventions for Noncommunicable Diseases and Injuries in Low- and Lower-Middle Income Countries: National NCDI Poverty Commissions

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## Key Findings

- National Noncommunicable Disease and Injury (NCDI) Poverty Commissions were established in 16 low- and lower-middle-income countries (LLMICs) to define local NCDI epidemiology, determine an expanded set of priority NCDI conditions, and recommend cost-effective, equitable health-sector interventions.
- Commissions prioritized an average of 35 health-sector interventions estimated to cost an additional US\$4.70–US\$13.70 per capita or approximately 9.7%–35.6% of current total health expenditure (0.6%–4.0% of current gross domestic product).
- Commissions demonstrated positive outcomes in understanding NCDIs of poverty, informing national planning and implementation of NCDI health-sector interventions, and improving governance and coordination for NCDIs.

## Key Implications

- Policy makers should use findings from the National NCDI Poverty Commissions to provide evidence-based, locally driven determination of priorities to guide health-sector policies, programs, and investments for NCDIs.
- External financing will be required to bridge the gap in financing for NCDIs to achieve universal health coverage in LLMICs.

## ABSTRACT

Health sector priorities and interventions to prevent and manage noncommunicable diseases and injuries (NCDIs) in low- and lower-middle-income countries (LLMICs) have primarily adopted elements of the World Health Organization Global Action Plan for NCDs 2013–2020. However, there have been limited efforts in LLMICs to prioritize among conditions and health-sector interventions for NCDIs based on local epidemiology and contextually relevant risk factors or that incorporate the equitable distribution of health outcomes. The *Lancet* Commission on Reframing Noncommunicable Diseases and Injuries for the Poorest Billion supported national NCDI Poverty Commissions to define local NCDI epidemiology, determine an expanded set of priority NCDI conditions, and recommend cost-effective, equitable health-sector interventions. Fifteen national commissions and 1 state-level commission were established from 2016–2019. Six commissions completed the prioritization exercise and selected an average of 25 NCDI conditions; 15 conditions were selected by all commissions, including asthma, breast cancer, cervical cancer, diabetes mellitus type 1 and 2, epilepsy, hypertensive heart disease, intracerebral hemorrhage, ischemic heart disease, ischemic stroke, major depressive disorder, motor vehicle road injuries, rheumatic heart disease, sickle cell disorders, and subarachnoid hemorrhage. The commissions prioritized an average of 35 health-sector interventions based on cost-effectiveness, financial risk protection, and equity-enhancing rankings. The prioritized interventions were estimated to cost an additional US\$4.70–US\$13.70 per capita or approximately 9.7%–35.6% of current total health expenditure (0.6%–4.0% of current gross domestic product). Semistructured surveys and qualitative interviews of commission representatives demonstrated positive outcomes in several thematic areas, including understanding NCDIs of poverty, informing national planning and implementation of NCDI health-sector interventions, and improving governance and coordination for NCDIs. Overall, national NCDI Poverty Commissions provided a platform for evidence-based, locally driven determination of priorities within NCDIs.

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## ■ BACKGROUND

Noncommunicable diseases and injuries (NCDIs) are a major contributor to morbidity and mortality in low- and lower-middle-income countries (LLMICs).<sup>1</sup> The World Health Organization (WHO) Global Action Plan for Prevention and Control of Noncommunicable Diseases (NCDs) 2013–2020 emphasizes 4 behavioral risk factors (tobacco use, unhealthy diets, physical inactivity, and harmful use of alcohol) in the context of 4 disease groups (cardiovascular diseases, diabetes, cancer, and chronic respiratory diseases), subsequently expanded to include air pollution and mental health disorders.<sup>2,3</sup> However, there is increasing evidence that this framework does not adequately represent the diverse and comprehensive set of risk factors and NCDIs com-

prising the disease burden in LLMICs.<sup>4,5</sup> The conditions comprising this burden in resource-constrained settings are diverse, and infectious diseases and conditions related to poverty comprise a large component of associated risk factors.<sup>6,7</sup> These conditions not only result in a large burden of disease in LLMICs, but due to younger population demographics, delays to diagnosis, and limited service availability, they tend to occur earlier and more severely in these populations.<sup>8</sup> Prolonged chronicity of these conditions along with dependency on out-of-pocket payments for NCDI services result in dramatic impoverishment and productivity losses as compared to other disease areas.<sup>9,10</sup>

To date, NCDI strategic plans and frameworks in LLMICs have been largely influenced by elements of the existing global action plan and monitoring framework.<sup>11</sup> Efforts to adapt or contextualize the WHO Global Action Plan for Prevention and Control of NCDs to the national burden of NCDI conditions or health system capacities in LLMICs have been inadequately prioritized or resourced.<sup>11–13</sup> Interventions proposed to avert the burden of NCDIs have focused on primary and secondary prevention of conditions due to behaviorally mediated risk factors and have not frequently considered a broader range of NCDIs and their associated risk factors.<sup>11</sup> Furthermore, these interventions have been largely evaluated and selected based on measures of cost-effectiveness and feasibility within resource-constrained environments and have not traditionally included measurements of equitable distribution of health outcomes at country-level.<sup>14</sup>

The *Lancet* Commission on Reframing Non-communicable Diseases and Injuries for the Poorest Billion (“*Lancet* NCDI Poverty Commission”) was established to assess the nature of the NCDI burden among the poorest billion people in the world, assure that sustainable financing is not a bottleneck to NCDI prevention and treatment among the world’s poorest, and expand the NCD movement and the global health agenda to urgently address NCDIs among the poorest billion.<sup>5</sup> The *Lancet* NCDI Poverty Commission additionally aimed to work with stakeholders in a diverse group of countries to develop actionable pro-poor pathways for expansion of NCDIs interventions. To achieve these objectives, the *Lancet* NCDI Poverty Commission established and supported national and subnational NCDI Poverty Commissions in countries with high rates of extreme poverty.

In this article, we first describe the structure and analytic framework used by the national NCDI Poverty Commissions (termed “commissions”). We then provide a synthesis of the

**Efforts to adapt or contextualize the WHO Global Action Plan for Prevention and Control of NCDs to the national burden of NCDI conditions or health system capacities in LLMICs have been inadequately prioritized or resourced.**

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characteristics, findings, and recommendations reported by the commissions. Lastly, we report results of a semistructured survey and qualitative interviews conducted with key informants from the commissions regarding short-term outcomes of the commissions in 11 thematic areas corresponding to major objectives of the *Lancet* NCDI Poverty Commission framework.

## METHODS

### Commission Establishment and Capacity Building

The *Lancet* NCDI Poverty Commission was established in 2015 and supported administratively and technically by a central secretariat at the Program in Global NCDs and Social Change at Harvard Medical School. The measure used by the *Lancet* NCDI Poverty Commission to assess poverty was a global multidimensional poverty index based on indicators of living standards and education obtained through routine and standardized household surveys.<sup>15,16</sup> The “poorest billion” were defined as households with deprivations in at least 5 of the 8 indicators included in this modified index.

Key individuals active in clinical, research, programmatic, or governance aspects of the NCDI health sector response from a diverse representation of this group of countries were invited to review the analytic framework developed for the *Lancet* NCDI Poverty Commission and propose adaptations to reflect national objectives (detailed in Analytic Approach). The *Lancet* NCDI Poverty Commission then invited the Ministry of Health of each key informant’s respective country to formally nominate and commission a national group of multisectoral experts in NCDIs to undertake an analytic and consultative process with technical, financial, and administrative support from the *Lancet* NCDI Poverty Commission secretariat.

From January to December 2016, 10 countries were invited to apply for support to establish an NCDI Poverty Commission (Round I). Five additional countries and 1 subnational region (Chhattisgarh State, India) were invited to establish commissions from October 2018 to September 2019 (Round II). Each Ministry of Health nominated 1 to 2 chairpersons to lead the commission, a coordinator to administer commission activities and communications, and approximately 20–30 multisectoral experts in the area of NCDIs, including policy makers, clinicians, researchers, patient group advocates, health economists, and health-sector planning experts.

All national commissioners were invited to participate in a series of 6 online “Knowledge

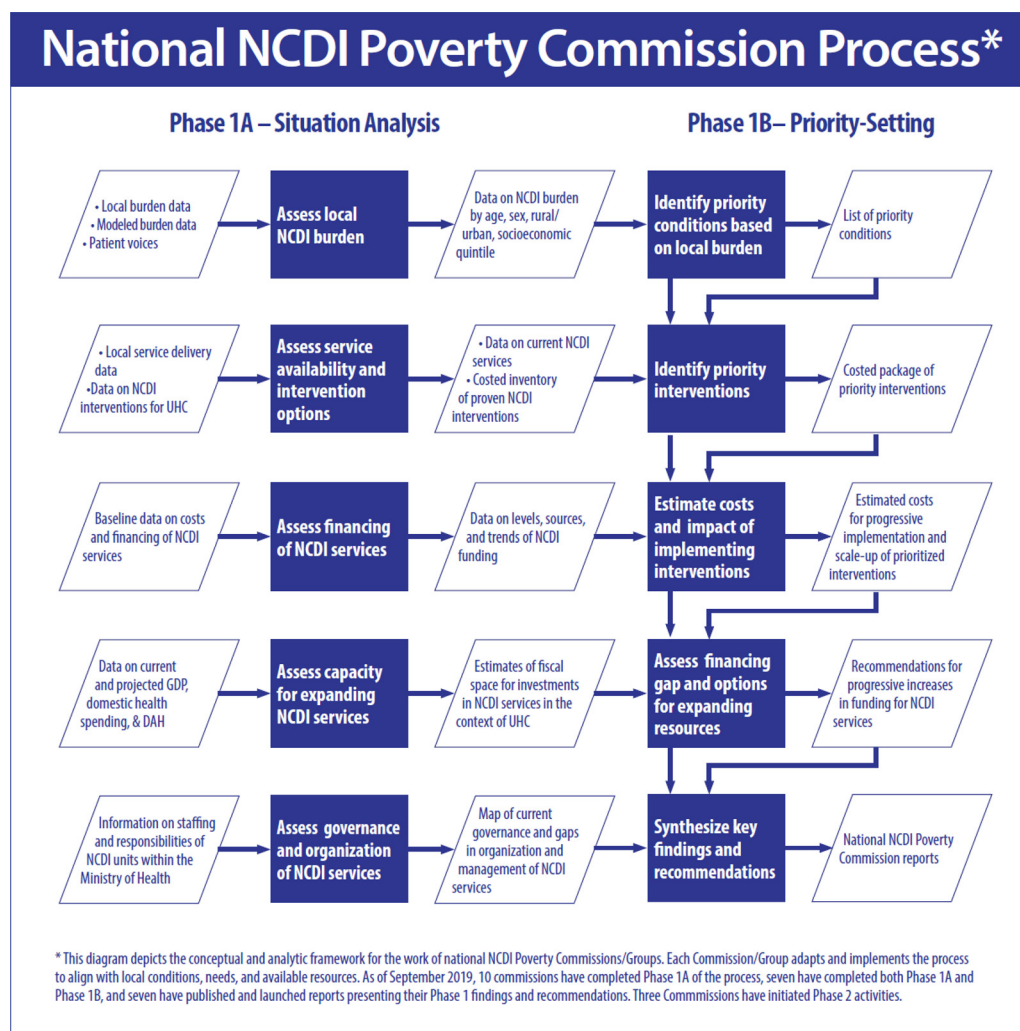
Exchange” teleconferences jointly organized by the *Lancet* NCDI Poverty Commission and the World Bank. These teleconferences consisted of didactic presentations from global experts and participatory discussions facilitated by commission leads.<sup>17</sup> Subregional meetings in East Africa (Kigali, Rwanda, March 2018) and Southern Africa (Maputo, Mozambique, June 2018) and a 4-day workshop entitled “The NCDI Poverty Commission Initiators’ Workshop” (Dubai, United Arab Emirates, 2018) were held to foster collaboration and knowledge sharing among commissions.<sup>18</sup>

### Analytic Approach by Commissions

An analytic framework to achieve national commission objectives was developed (Figure 1). Phase 1A focused on aggregating a range of available data related to the burden of disease, service availability, financing, and governance of NCDI services in each country (Supplement Table 1). Descriptive statistics regarding population demographics were obtained from the Global Burden of Disease study (GBD) 2017 and World Bank World Development Indicators.<sup>1,19</sup> Data regarding health expenditures were obtained from national health accounts compiled and available from the WHO Global Health Expenditure Database and human resources from the WHO Global Health Workforce Statistics.<sup>20,21</sup>

In Phase 1B, national commissions convened a set of deliberations and meetings to review the available evidence in NCDIs and make recommendations for local policy. This prioritization exercise was structured using the principles of priority setting established by the WHO Consultative Group on Equity and Universal Health Coverage.<sup>22</sup> To develop a list of priority NCDI conditions, the commissions analyzed and ranked NCDI conditions in several dimensions, including the burden of disease, severity, and disability, using data from the GBD study.<sup>23</sup> The overall burden of disease of each condition at the national level was measured by disability-adjusted life-years (DALYs). Severity was calculated using the average years of life lost (YLLs) per death, and disability was calculated by years lived with disability (YLDs) per prevalent case. The age-standardized DALY rate per 100,000 population was compared for each condition to high-income country rates as a reference standard. A total of 190 NCDI conditions from the GBD database were analyzed using these 4 metrics, and a summary score was provided to each condition according to an average of the ranking quartiles. Each of the 4 metrics

**FIGURE 1.** National Noncommunicable Diseases and Injuries Poverty Commission Analytic Framework



Abbreviations: DAH; developmental assistance for health; GDP, gross domestic product; NCDI, noncommunicable diseases and injuries; UHC, universal health coverage.

was weighted according to its relative importance as determined by each commission. The 50 conditions with the highest priority summary scores were then reviewed by a subcommittee of the national commission. Commissioners then selected conditions that they believed (1) contribute significantly to adverse health and economic consequences in their respective country, (2) could be feasibly and effectively controlled in their local context, and (3) were aligned with or complementary to existing national policies and strategic plans.

Information regarding evidence-based and cost-effective health-sector interventions was

obtained from the Disease Control Priorities Project, which produced model lists of essential health-sector interventions and essential intersectoral health policies for the Disease Control Priorities, 3<sup>rd</sup> Edition (DCP3) publication. DCP3 recommended 21 packages consisting of a total of 218 health-sector interventions to achieve essential universal health coverage (EUHC) in LLMICs based on key intervention metrics, including cost-effectiveness, financial risk protection, and equity scores (Supplement Table 2).<sup>24</sup> The 65 interventions pertaining to NCDI conditions recommended as part of EUHC were reviewed by

**TABLE 1.** Key Characteristics of States and Countries With Established National Noncommunicable Diseases and Injuries Poverty Commissions

Country	Demographics			Finances <sup>20</sup>			Human Resources <sup>21</sup>		Commission Characteristics		
	Population (millions) <sup>1</sup>	Percent Living in Poorest Billion <sup>16,c</sup>	Population Living in Poorest Billion (millions) <sup>1,5,16</sup>	Gross Domestic Product per Capita (US\$), 2017	Current Health Expenditure per Capita (US\$), 2017	General Government Health Expenditure per Capita (US\$), 2017	Physicians per 10,000 Population (year)	Nurses/Midwives per 10,000 Population (year)	Month and Year of Commission Establishment <sup>a</sup>	Number of Commissioners	Priority Setting Conducted as of July 2020
Afghanistan	32.9	25.1	8.3	569.9	67.1	3.4	2.8 (2016)	1.8 (2017)	April 2018	22	No
Chhattisgarh State, <sup>b</sup> India	27.7	15.8	4.4						March 2019	20	No
Ethiopia	102.9	81.5	83.8	721.2	25.3	6.3	0.8 (2018)	7.1 (2018)	Aug 2016	18	Yes
Haiti	11.8	39.0	4.6	776.0	62.4	7.4	2.3 (2018)	6.8 (2018)	Dec 2016	28	Yes
Kenya	48.3	38.9	18.8	1595.2	76.6	32.7	1.6 (2018)	11.7 (2018)	Nov 2016	25	Yes
Liberia	4.7	48.3	2.3	694.0	56.6	9.7	0.4 (2015)	5.3 (2018)	Jan 2017	23	Yes
Madagascar	26.1	65.2	17.0	448.4	24.7	11.6	1.8 (2014)	1.5 (2018)	July 2019		No
Malawi	17.2	48.5	8.3	334.4	32.3	9.9	0.4 (2018)	4.4 (2018)	Nov 2016	23	Yes
Mozambique	30.0	65.1	19.6	426.4	21.1	6.3	0.8 (2018)	6.8 (2018)	June 2017	14	Yes
Nepal	29.9	12.6	3.8	862.8	47.9	10.7	7.5 (2018)	31.1 (2018)	Nov 2016	20	Yes
Rwanda	12.6	49.2	6.2	748.7	49.2	16.9	1.3 (2018)	12.0 (2018)	March 2017	17	No
Sierra Leone	7.8	62.2	4.9	494.8	66.4	9.1	0.3 (2011)	2.2 (2016)	Aug 2018	38	Yes
Tanzania	54.0	56.2	30.4	930.4	33.9	14.7	0.1 (2016)	5.8 (2017)	Sept 2016	7	Yes
Uganda	39.1	58.4	22.8	621.0	38.9	6.0	1.7 (2017)	12.4 (2018)	Jan 2019	26	Yes
Zambia	17.4	46.7	8.1	1513.3	67.6	26.1	11.9 (2018)	13.4 (2018)	Aug 2018	22	Yes
Zimbabwe	14.7	28.6	4.2	1659.9	110.1	56.9	2.1 (2014)	19.3 (2018)	Aug 2018	25	Yes
Total or Averages <sup>c</sup>	477.0	51.9	247.4	826.4	52.0	15.2	2.4	9.4		328	

<sup>a</sup> Date of endorsement by formal communication from Ministry of Health or first official commission meeting, whichever came first.

<sup>b</sup> State-level indicators not available from sources listed.

<sup>c</sup> Average of “percent living in poorest billion” is weighted average. All other averages are unweighted averages.

the national commissioners and evaluated for (1) alignment with stated NCDI priority conditions; (2) feasibility and desirability in the national context, and (3) cost-effectiveness, financial risk protection, and equity scores as assessed by DCP3.<sup>25</sup> Commissions conducted customized deliberative processes to select a final set of interventions. Several commissions also considered additional interventions suggested by commissioners using locally available data (not included in costing estimates). In Ethiopia, the commission considered an expanded set of 235 interventions consisting of DCP3-recommended interventions as well as locally customized interventions.<sup>26</sup>

The commissions estimated the costs of their recommended interventions using methods and

data that built on the cost modeling done for DCP3.<sup>27</sup> In brief, costs were estimated as a function of: (1) the number of beneficiaries requiring each intervention (derived from GBD incidence, prevalence, or population estimates); (2) unit costs for each intervention (derived from published literature and extrapolated to different countries based on variation in labor and capital costs); and (3) proportion of the population “covered” by the intervention. Each intervention was assigned a current coverage, estimated from existing data sources or expert opinion (from the commissioners) if local data were not available. The commissions then assigned a feasible target coverage for each intervention within a timeframe of 5 to 10 years. Finally, the total annual cost of

**TABLE 2.** Baseline National NCDI Poverty Commission Findings on the Proportion, Severity, Diversity, and Expenditure on NCDIs<sup>a</sup>

	Estimated Burden of NCDIs <sup>1</sup>			General Government Health Expenditure on NCDIs (2017) <sup>20</sup>		External Health Expenditure on NCDIs (2017) <sup>20</sup>	
	% DALYs from NCDIs	% NCDI DALYs Occurring Before Age 40 years	% NCD DALYs not due to 5x5 Conditions <sup>b</sup>	% General Government Health Expenditure on NCDs	% General Government Health Expenditure on injuries	% External Health Expenditure on NCDs	% External Health Expenditure on injuries
Afghanistan	55.2	61.8	46.3	38.4	2.5	8.8	4.8
Chhattisgarh State, India <sup>c</sup>	62.3	37.4	41.9				
Ethiopia	40.2	59.7	53.4	19.5	5.3	0.7	0.1
Haiti	63.3	51.8	41.5	20.6	7.7	4.8	5.7
Kenya	43.4	53.1	52.3	4.3	3.2	0.9	0.6
Liberia	37.6	56.4	54.1	17.8	1.3	8.6	0.6
Madagascar	38.9	55.1	45.0				
Malawi	36.2	58.0	51.4	11.4	8.9	7.2	5.6
Mozambique	33.5	59.1	50.2				
Nepal	68.6	36.4	41.5	50.5	1.1	13.5	1.4
Rwanda	49.5	57.1	53.2				
Sierra Leone	33.9	60.2	54.2				
Tanzania	43.4	61.9	56.8	12.9	2.1	2.2	0.5
Uganda	36.9	62.9	51.7	26.0	4.0	1.8	0.3
Zambia	37.5	60.6	53.6	12.9	8.6	12.9	
Zimbabwe	42.5	50.5	40.1				
<b>Average (unweighted)</b>	<b>45.2</b>	<b>55.1</b>	<b>49.2</b>				

Abbreviations: DALY, disability adjusted life year; NCDI, noncommunicable disease and injury.

<sup>a</sup> Gray boxes indicate national health account data is unavailable or not disaggregated for NCDIs.

<sup>b</sup> 5x5 conditions refers to Global Burden of Disease categories of cardiovascular diseases, diabetes, cancer, chronic respiratory diseases, and mental health disorders.

<sup>c</sup> State-level indicators not available from sources listed.

implementing each intervention at the additional coverage increment was calculated as the product of (1), (2), and (3). The commission in Ethiopia used an alternative method to estimate the cost of prioritized recommendations based on bottom-up costing through the use of the One Health tool, described in greater detail elsewhere.<sup>26</sup>

In each country, findings and recommendations were synthesized and disseminated to national stakeholders. The target audience for commission recommendations included government officials (national and subnational level), clinical leaders, implementation partners, donors, patient advocacy groups, local media, and the general public. Dissemination occurred through the publication of findings and recommendations, public launch events, media coverage, social

media, advocacy meetings, and the NCDI Poverty website (Supplement Table 1). To further enhance awareness and local understanding of these conditions, commissions were additionally invited to develop video documentary narratives of young individuals living with severe NCDIs in populations of extreme poverty. Patients were selected for the documentary narratives as determined by each commission.

### Design and Methodology of Evaluation

From April to November 2019, the *Lancet* NCDI Poverty Commission Secretariat conducted a 2-part evaluation to understand how commissions influenced national-level dialogue and policies. This evaluation consisted of a semistructured



**Across 16 countries and states, 60.2% of the NCD DALYs were associated with NCD conditions other than those comprising the 4 disease categories in the global NCD action plan.**

online survey and phone-based qualitative interview. Each of the commissions in Round I was invited to nominate a key informant (generally a commission chair or coordinator) to complete the online survey. Respondents were asked a series of open-ended questions related to their respective commission's work in 11 thematic areas corresponding to major objectives of the *Lancet* NCDI Poverty Commission framework.<sup>5</sup> The survey was administered through the Qualtrics platform without time limitation. Respondents were encouraged to consult with other members of their national commissions in developing their responses to the online survey.

After completing the online survey, respondents were invited to participate in a follow-up interview in which the respondent could provide in-depth, detailed elaborations on survey responses.

Online and interview responses were entered into Dedoose version 8.3.35. Each transcript was coded independently by the 2 researchers. The number of respondents reporting positive outcomes on the online survey or interview was tabulated by thematic area.

The online survey and qualitative interviews were approved by the Harvard University Longwood Medical Area Institutional Review Board. All participants were provided a standardized consent form and asked to provide consent before beginning the data collection. Consent was provided electronically for the online survey and verbally for the interviews.

## ■ RESULTS

### Commission Countries and Characteristics

In Round I, commissions were established in 9 countries including Afghanistan, Ethiopia, Haiti, Kenya, Liberia, Malawi, Mozambique, Nepal, and Tanzania (Table 1). In Rwanda, a research group was formed to undertake this analysis rather than a formal commission. In Round II, commissions were established in an additional 5 countries including Madagascar, Sierra Leone, Uganda, Zambia, and Zimbabwe, and 1 subnational region (Chhattisgarh State, India). Two countries (Rwanda and Zambia) opted to not use the nomenclature of "commission" formally and instead used the terms "group" and "task force", respectively. Although formally established, the commission in Madagascar had not yet begun activities as of July 2020. Twenty-two individuals were nominated as commissioners or official group participants for each commission. As of July 2020, 7 commissions had completed the prioritization exercise and cost estimation analysis (Phase 1B) and an additional 5 commissions were in

the process of completing this analysis. Additionally, 80 patient narratives were developed in video documentary format across 5 countries representing a range of NCDI conditions, including type I diabetes, rheumatic heart disease, chronic kidney disease, breast cancer, cervical cancer, neuroblastoma, childhood leukemia, schizophrenia, and disability due to traumatic injury.<sup>28</sup>

### Commissions' Findings of NCDI Burden of Disease and Expenditure (Phase 1a)

On average across the 16 countries and states, 45.2% of DALYs were attributed to NCDIs (range 33.5–68.6%; Table 2), and 55.1% of DALYs due to NCDIs occurred before age 40 years (range: 36.4–62.9%). Additionally, 60.2% of the NCD DALYs across this group of countries were associated with NCD conditions other than those comprising the 4 disease categories included in the global NCD action plan (cardiovascular diseases, chronic respiratory diseases, diabetes, and cancer). When considering an expanded "5 by 5" framework that includes mental health and substance use disorders, 49.2% of NCD DALYs were from other conditions. In terms of injuries, 73.7% of DALYs due to injuries across this set of countries were due to injuries other than road traffic injuries (data not shown here).

Ten of the 15 countries (not including Chhattisgarh state) had available estimates for domestic government and external expenditures for NCDs and injuries. In these countries, the proportion of government health expenditure for NCDIs as a proportion of general government health expenditures ranged considerably, from 4.3%–50.5% for NCDs and 1.1%–8.9% for injuries. The proportion of external expenditures was consistently lower for NCDIs, from 0.7%–12.9% for NCDs and 0.1%–5.7% for injuries. In Liberia, 74.7% of expenditures for NCDIs were out-of-pocket, exceeding the proportion of out-of-pocket expenditure for other disease areas, such as malaria (60%), TB (48%), HIV/AIDS (30%), and reproductive, maternal, neonatal, child, and adolescent health (19%).<sup>29</sup> In Ethiopia, 68% of expenditures for NCDIs were out-of-pocket.<sup>26</sup>

### Commissions' Recommendations on Prioritization for NCDI Conditions and Health-Sector Interventions (Phase 1b)

As of July 2020, 7 commissions completed a prioritization exercise for NCDI disease conditions and health-sector interventions (Unpublished Haiti NCDO Poverty Commission report).<sup>26,29–33</sup> The

commission in Ethiopia conducted a prioritization exercise for an expanded set of NCDI health interventions but not for disease conditions. Prioritization exercises had also been initiated in Mozambique, Sierra Leone, Uganda, Zimbabwe, and Zambia, though they were not yet completed and subsequently not included here. After compiling and analyzing data on the burden, severity, disability, and equity metrics from GBD, and undergoing a commission review and validation, the 6 commissions that had completed the process and had prioritized among NCDI conditions selected between 14 and 48 conditions for prioritization (Table 3). Overall, 75 of 211 total NCDI conditions were selected by at least 1 commission. Fifteen conditions were selected by all 6 commissions. These conditions included asthma, breast cancer, cervical cancer, diabetes mellitus type 1, diabetes mellitus type 2, epilepsy, hypertensive heart disease, intracerebral hemorrhage, ischemic heart disease, ischemic stroke, major depressive disorder, motor vehicle road injuries, rheumatic heart disease, sickle cell disorders, and subarachnoid hemorrhage. An additional 12 conditions were selected by at least 4 of the 6 commissions.

Six commissions considered 65 health-sector NCDI-focused interventions recently recommended as a package for EUHC. Thirty-two interventions were selected by a majority (>/=4) of the commissions, including 18 that were selected by all commissions (Table 4). Among these 32 interventions, 19 targeted the health center level, 6 targeted first-level hospitals, 4 at referral/

specialty hospitals, 2 for population-level mass media messages, and 1 at the community level. These interventions included 4 surgical “packages” at various levels of the health system and packages for palliative care and rehabilitation services. Of the 18 interventions selected by all commissions, 17 were recommended as “high-priority” EUHC interventions by DCP3. The commission in Ethiopia conducted the prioritization exercise considering all 235 health-sector interventions they had identified and selected 90 interventions as high-priority. Including the commission in Ethiopia, the annual cost across the 7 commissions of the prioritized interventions at the target intervention coverage assigned by each commission ranged from US\$4.70–US\$13.70 per capita. This amount of per capita expenditure ranged from 9.7% (Haiti) to 35.6% (Tanzania) of the most recently reported total health expenditure per capita and from 0.6% (Ethiopia) to 4.0% (Malawi) of gross domestic product per capita at the time of the respective analyses.

**The annual cost across the 7 commissions of the prioritized interventions at the target intervention coverage assigned by each commission ranged from US \$4.70–US\$13.70 per capita.**

### RESULTS OF EVALUATION

Responses were received from each of the 9 commissions formally established in Round 1. Findings were categorized according to the 3 overall NCDI Poverty Commission objectives: “Understanding NCDIs of Poverty,” “Planning and Implementation of NCDI Interventions,” and “Governance and Coordination for NCDIs” (Figure 2). Respondents

**TABLE 3.** Results of National NCDI Poverty Commissions Prioritization of NCDI Conditions and NCDI Health-Sector Interventions

	Number Of Prioritized Conditions	Number Of Recommended Interventions	Incremental Intervention Coverage Increase, %	Annual Incremental Expenditure to Provide Target Coverage for Recommended Interventions (mil US\$)	Annual Incremental Cost per Capita to Provide Target Coverage Of Recommended Interventions (US\$)	Percentage of Current Total Health Expenditure per Capita, %	Percentage of Current Gross Domestic Product per Capita, %
Ethiopia <sup>a</sup>	N/A	90	30	550	4.70	16.8	0.6
Haiti	36	36	25	69.1	6.44	9.7	0.8
Kenya	14	34	20-70	520.1	11.97	17.1	0.7
Liberia	19	33	30	29.5	9.21	13.8	2.1
Malawi	38	54	0-50	236.7	13.70	34.2	4.0
Nepal	25	23	30	250.2	8.76	22.0	1.4
Tanzania	48	53	30	702.9	12.26	35.6	1.3

Abbreviation: N/A, not applicable; NCDI, noncommunicable disease and injury.

<sup>a</sup>In Ethiopia, the commission considered an expanded set of 235 interventions consisting of DCP3-recommended interventions as well as locally customized interventions.

**TABLE 4.** Most Commonly Selected Conditions and Corresponding Prioritized Health Sector Interventions by 6 Commissions Conducting Prioritization Exercises by Both Disease Conditions and Health Sector Interventions (Displaying Conditions and Interventions Selected by  $\geq 4$  Commissions)

Disease Condition Category	Selected Condition (No. of Commissions)	Corresponding Health Sector Intervention (No. of Commissions)
Cardiovascular	Hypertensive heart disease (6) ischemic heart disease (6) ischemic stroke (6) intracerebral hemorrhage (6) subarachnoid hemorrhage (6)	Long term management of ischemic heart disease, stroke, and peripheral vascular disease with aspirin, beta blockers, angiotensin-converting enzyme inhibitors, and statins (as indicated), for secondary prevention (6) Mass media messages concerning healthy eating or physical activity (6) Use of aspirin in case of suspected myocardial infarction (6) Medical management of acute heart failure (6) Medical management of chronic heart failure with diuretics, beta-blockers, ace-inhibitors, and mineralocorticoid antagonists (6) Opportunistic screening for hypertension for all adults, with treatment decisions guided by absolute cardiovascular disease risk (4) Screening and management of hypertensive disorders in pregnancy (4)
	Rheumatic heart disease (6)	Secondary prophylaxis with penicillin for rheumatic fever or established rheumatic heart disease (6) Treatment of acute pharyngitis in children to prevent rheumatic fever (6) Heart failure interventions as above cardiovascular disease
	Congenital heart anomalies (4)	No specific interventions
Diabetes	Diabetes (type 1 and 2) (6)	Prevention of long-term complications of diabetes through blood pressure, lipid, and glucose management as well as consistent foot care (6) Screening for diabetes in pregnant women (6)
Respiratory	Asthma (6) Chronic obstructive pulmonary disease (5)	Mass media messages concerning use of tobacco and alcohol (6) Low-dose inhaled corticosteroids and bronchodilators for asthma and for selected patients with chronic obstructive pulmonary disease (5) Management of acute exacerbations of asthma and chronic obstructive pulmonary disease using systemic steroids, inhaled beta-agonists, and, if indicated, oral antibiotics and oxygen therapy (5) Tobacco cessation counseling and use of nicotine replacement therapy in certain circumstances (4)
	Breast cancer (6)	Treat early stage breast cancer with appropriate multimodal approaches, including generic chemotherapy, with curative intent, for cases that are referred from health centers and first-level hospitals following detection using clinical examination (6) Palliative care and pain control services <sup>a</sup> (5)
	Cervical cancer (6)	Treatment of early-stage cervical cancer (6) Opportunistic screening for cervical cancer using visual inspection or human papillomavirus DNA testing and treatment of precancerous lesions with cryotherapy (5) School-based human papillomavirus vaccination for girls (5)
	Non-Hodgkin lymphoma (5)	Treat selected early-stage childhood cancers with curative intent in pediatric cancer units/hospitals (6)
Sickle cell disease	Sickle cell disease (6)	In settings where sickle cell disease is a public health concern, universal newborn screening followed by standard prophylaxis against bacterial infections and malaria <sup>a</sup> (6)
Chronic kidney disease	Due to glomerulonephritis (4) Due to hypertension (4)	Treatment of hypertension in kidney disease, with use of angiotensin-converting enzyme inhibitors or angiotensin receptor blockers in albuminuric kidney disease (5)

*Continued*

**TABLE 4.** Continued

Disease Condition Category	Selected Condition (No. of Commissions)	Corresponding Health Sector Intervention (No. of Commissions)
Liver cirrhosis	Cirrhosis due to hepatitis B virus (5) Alcoholic cirrhosis (5)	Mass media messages concerning use of tobacco and alcohol (6)
Acute abdominal conditions	Paralytic ileus and intestinal obstruction (4)	Basic first-level hospital surgical services <sup>a</sup> (6) Expanded first-level hospital surgical services <sup>a</sup> (4)
Epilepsy	Epilepsy (6)	Management of epilepsy using generic anti-epileptics (6)
Mental health	Depression (5) Anxiety (4)	Management of depression and anxiety disorders with psychological and generic antidepressant therapy (6) Management of schizophrenia using generic anti-psychotic medications and psychosocial treatment (5) Management of bipolar disorder using generic mood-stabilizing medications and psychosocial treatment (4)
Injuries	Motor vehicle road injuries (6) Pedestrian road injuries (4) Burns (4)	Basic outpatient surgical services <sup>a</sup> (4) Basic first-level hospital surgical services <sup>a</sup> (6) Expanded first-level hospital surgical services <sup>a</sup> (4) Specialized surgical services <sup>a</sup> (6) Basic rehabilitation services <sup>a</sup> (5)

<sup>a</sup> Indicates a set of interventions.

provided key contextual information on successes achieved and challenges experienced by the national commissions (key aspects highlighted in Supplement Tables 3 and 4). Most respondents reported that their respective commissions improved their understanding of NCDI epidemiology in relation to poverty (n=7). However, only a minority of respondents reported improvements in understanding of gaps in current NCDI service delivery (n=2) or household expenditures and impoverishment by NCDIs (n=2). All country respondents indicated that their respective commissions had informed the development of national NCDI plans or strategies, and most reported provision of valuable evidence for health system planning (n=7) and contribution to defining essential health service packages (n=6). Several respondents reported contributions by their respective commissions for health insurance benefits packages (n=3) and the design of innovative or integrated services platforms (n=2). There was a strong theme of commissions supporting the governance of coordination of NCDIs, with most respondents indicating that their commissions altered perceptions of NCDIs by key policy makers (n=8), catalyzed the formation of broader coalitions for NCDIs (n=6), and enhanced capacity of the Ministry of Health in their NCDI response (n=7).

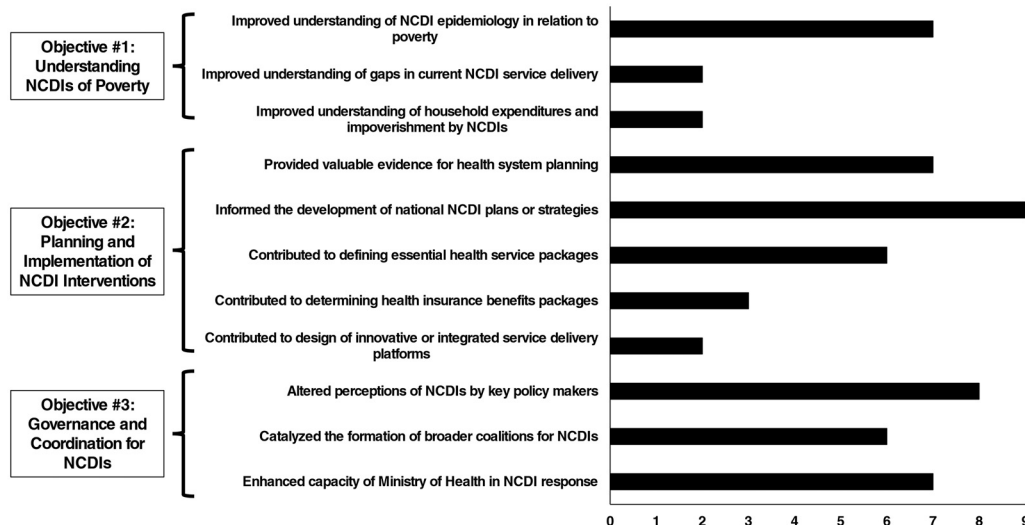
## DISCUSSION AND NEXT STEPS

We have described the establishment, structure, and findings of national- and state-level NCDI Poverty Commissions established in 16 LLMICs with significant populations living in extreme poverty. The NCDI Poverty Commissions represent a coordinated effort to quantify the comprehensive burden of NCDIs and provide evidence-based recommendations on health-sector interventions to strengthen NCDI services under commitments to UHC.

Current expenditure on NCDIs reported by the commissions varied widely by country, though these findings may be subject to high variability and low reliability of national health accounts.<sup>34</sup> The commissions estimated that to implement the prioritized health-sector NCDI interventions for a substantial target population would require an additional US\$4.70–US\$13.70 per capita, or approximately 9.7%–35.6% of current total health expenditure (or 0.6%–4.0% of current gross domestic product). The commissions in Malawi and Tanzania established more expansive criteria for selecting health-sector interventions to drive dialogue and advocacy for health system expansion and investment. Commissions in Nepal and Kenya opted for a more targeted approach to selecting interventions to focus advocacy on key interventions currently lacking in their respective

**The NCDI Poverty Commissions represent a coordinated effort to quantify the comprehensive burden of NCDIs and provide evidence-based recommendations on health-sector interventions to strengthen NCDI services under commitments to UHC.**

**FIGURE 2.** Frequency of National Noncommunicable Diseases and Injuries Poverty Commissions Reporting Key Outcomes in Evaluation Surveys and Qualitative Interviews, by Thematic Area (n=9)



Abbreviation: NCDI, noncommunicable diseases and injuries.

health systems. The overall EUHC health benefits package was previously estimated to cost US\$79 per person at 80% population coverage in low-income countries, representing an additional investment of 8.0% of the 2015 gross national income.<sup>27</sup> Interventions to reduce mortality from NCDIs comprised at least 37.6% of these EUHC estimated costs, not including substantial costs of interventions targeting the reduction of disability from NCDIs. The interventions prioritized and costed by the commissions represent a more conservative incremental intervention coverage target (i.e., 30%) and focus on a smaller subset of NCDI interventions, though still include a wide range of medical, surgical, mental health, palliative care, and rehabilitation services, as well as indirect costs for laboratory services, infrastructure, administration, and management.

A recent analysis by the *Lancet* NCDI Poverty Commission showed that this level of additional expenditure for NCDIs may be possible within domestic financing under conditions of strong economic growth, increased tax revenues, and greater proportional allocation of government expenditures to health consistent with recent targets.<sup>5,35</sup> However, such conditions may be unlikely in most LLMICs, particularly in the context of severe economic challenges incurred during the coronavirus disease (COVID-19) pandemic, and

external development assistance will be required to finance this critical set of interventions.

Most commissions identified opportunities to integrate prioritized health-sector interventions into existing platforms to improve efficiencies and facilitate operationalization. Decentralization may rely on training and task optimization for nurses and other mid- to low-level cadres of the health workforce, and clustering of services based on intervention properties.<sup>36,37</sup> Further efforts to more accurately define additional interventions within national contexts are needed to inform the development of essential health service packages, health insurance coverage schemes, and national financing priorities. Intersectoral policies were not explicitly prioritized and costed by the commissions and require further consideration given their vital role in the prevention of NCDIs.

The urgent need for strong integrated health systems to mitigate and address the adverse effects of NCDs in LLMICs has been magnified by the COVID-19 pandemic.<sup>38,39</sup> NCDI Poverty Commissions provide an opportunity for local definition and accountability for a context-specific and locally relevant NCDI agenda under rapidly evolving epidemiology and health system constraints. National commissioners highlighted the impact of these commissions in changing the traditional perceptions and framing of NCDIs with a

**The urgent need for strong integrated health systems to mitigate and address the adverse effects of NCDs in LLMICs has been magnified by the COVID-19 pandemic.**

focus on severe conditions affecting poor, rural populations at young ages. The priority-setting process utilized in this analytic framework was additive and contributory to national strategic and operational planning efforts and packages of essential services, core components to health system readiness, and achievement of commitments to UHC. The commissions provided a productive forum for policy makers to meet with academic and implementing stakeholders to critically analyze and consider available data and formulate evidence-based recommendations. National commissioners highlighted the role of commissions in strengthening in-country public-sector capacity in the response to NCDs and expanding perceptions of NCDs by key policymakers. Evaluation of a group of these commissions demonstrated substantial contributions of the commissions in informing national efforts in strategic and health system planning for NCDs as well as the understanding and capacity of key governance structures for the NCD response at a national level.

The collective experience of the commission processes and findings presented here has informed the establishment of the NCDI Poverty Network.<sup>40</sup> The NCDI Poverty Network aims to catalyze technical and financing partnerships to improve the understanding, awareness, investment, and outcomes for individuals living with NCDs in settings of extreme poverty. National commissions will further assess the current availability and organization of these interventions in both public and private-sector facilities, with a particular focus on integrating and optimizing human resource availability and capacities. In addition, national commissions will play a key role in defining, piloting, and scaling potential facility-based delivery models for severe conditions impacting younger populations, such as “PEN-Plus.”<sup>41</sup> The NCDI Poverty Network will aim to promote cross-border collaboration for an expanded NCDI agenda, build programmatic and research capacity, and establish global financing partnerships to support the availability and coverage of NCDI interventions. These will be necessary steps to fulfill national commitments to UHC for populations facing the double burden of extreme poverty and disproportionately suffering from the physical and economic consequences of a highly diverse array of NCDs.

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ORIGINAL ARTICLE

# Animal Source Food Social and Behavior Change Communication Intervention Among Girinka Livestock Transfer Beneficiaries in Rwanda: A Cluster Randomized Evaluation

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## Key Findings

- A social and behavior change communication (SBCC) intervention was associated with increased odds of children consuming cow's milk 2 or more times per week.
- For approximately half of the children, frequency of cow's milk consumption was limited by inadequate household milk production or sale of the milk produced.
- SBCC did not influence the percentage of households that kept or sold their milk, demonstrating that SBCC alone is not enough to change nutrition outcomes in households with poor food security.

## Key Implications

- Community health workers successfully implemented the intervention and the SBCC messages have been incorporated into the recently revised national CHW counseling cards.
- SBCC for this target population should be implemented for a longer period and tailored to discuss financial management and dietary choices with a limited budget. Accompanying training or other activities to assist households that receive cows are needed to ensure adequate cow's milk production for home consumption.
- High levels of severe food insecurity in this population may have limited the potential of the SBCC to improve dietary diversity and more substantially improve frequency of cow's milk consumption.

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

## ABSTRACT

Animal source foods (ASFs), including cow's milk, contain essential nutrients and contribute to a healthy diet, but frequency of intake is low among children in low- and middle-income countries. We hypothesized that an ASF social and behavior change communication (SBCC) intervention implemented by community health workers (CHWs) would increase child milk consumption and dietary diversity in households that received a cow from the Government of Rwanda's Girinka livestock transfer program. We tested the 9-month SBCC intervention among children aged 12–29 months at baseline in administrative cells randomly assigned to the intervention or control. Most mothers in the intervention group were exposed to CHWs' home visits (90.7%) or community-level activities (82.8%). At endline, more mothers in the intervention group compared with the control group knew that cow's milk was an ASF (90.1% vs. 81.7%,  $P=0.03$ ) and could be introduced to children at 12 months (41.7% vs. 18.7%,  $P<0.001$ ). More mothers in the intervention group compared with the control group knew they should feed their children ASFs (76.2% vs. 62.1%,  $P=0.01$ ) and give them 1 cup of cow's milk per day (20.6% vs. 7.8%,  $P<0.001$ ). Children's consumption of fresh cow's milk 2 or more times per week increased in the intervention group, although not significantly (8.0 percentage points,  $P=0.17$ ); minimum dietary diversity was unchanged. Children in the intervention group had increased odds of consuming cow's milk 2 or more times per week if their mothers recalled hearing that children should drink 1 cup of cow's milk per day during a CHW's home visit [odds ratio (OR) 2.1, 95% confidence interval (CI) (1.1, 3.9)] or a community activity [OR 2.0, 95% CI (1.2, 3.5)]. Approximately half of the children had no milk during the past week because their households produced too little or sold what was produced. In poor households receiving a livestock transfer, strategies to further tailor SBCC and increase cow's milk production may be needed to achieve larger increases in children's frequency of milk consumption.

## INTRODUCTION

Animal source foods (ASFs), including milk, are a rich source of energy, protein, and micronutrients

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and can contribute to a healthy and diverse diet in young children.<sup>1</sup> Yet consumption of ASFs by young children in low- and middle-income countries (LMICs) is limited. Based on recent nationally representative data from countries in East and Southern Africa, only 49% of children aged 6–23 months consumed at least 1 ASF on the day before the survey and 19% consumed dairy, which are the lowest prevalence estimates across LMIC regions.<sup>2</sup>

Consumption of ASFs by young children in LMICs is influenced by several different factors, including affordability, accessibility, child's age, perceived nutritional value, taste preferences, and sociocultural factors (e.g., food prohibitions, preferential food allocation, child feeding styles).<sup>3–5</sup> Livestock ownership is also related to ASF consumption by children, in part, because it increases ASF accessibility and income.<sup>6–9</sup> In sub-Saharan Africa, children in livestock-owning or pastoral households are more likely to consume ASFs than those in non-livestock-owning households,<sup>5,10–12</sup> and children in families that received a livestock transfer or participated in a livestock production program also consume more ASFs than those that have not participated in such programs.<sup>13–16</sup> However, in nonpastoral, livestock-owning households in sub-Saharan Africa, consumption of ASFs is suboptimal because livestock are kept for selling or are considered monetary assets or because consumption of staple foods uses fewer resources, so it is prioritized over ASF consumption.<sup>17–21</sup>

One of the pathways through which agriculture programs, such as livestock transfers, can have an impact on the consumption of nutritious foods, such as ASFs, and child nutritional status is the “own production to consumption” pathway.<sup>22,23</sup> This pathway is based on the theory that household food production leads to consumption of ASFs, leading to better nutrient intake and positive nutritional outcomes, including for children. Food production, expenditures, and consumption can be influenced and increased by social and behavior change communication (SBCC),<sup>23–25</sup> including group sessions, home visits, community meetings, and mass media. Child consumption of ASFs and subsequently their nutritional status are increased in households where SBCC is incorporated into livestock production interventions.<sup>23,26</sup>

The Government of Rwanda's One Cow per Poor Family Girinka program is a presidential initiative started in 2006 to provide an exotic or cross-bred dairy cow to households with low socioeconomic status that do not already own cattle.<sup>27</sup> Economic eligibility for the program is based on the government's *Ubudehe* or socioeconomic classification categories, which are updated every 3 years.<sup>28</sup> The goals of the

Girinka program are to increase social cohesion and integration and to improve income, food security, and nutrition in poor households. Previous evaluations showed the economic benefits of the Girinka program,<sup>29,30</sup> but the nutrition benefits are less clear, despite the program being implemented in a context with high stunting prevalence (38%) and low milk consumption (21%) among young children.<sup>31</sup> The Girinka program does not include a nutrition education or SBCC component promoting the consumption of home-produced milk.

To address this gap, we conducted a cluster-randomized trial to test an SBCC intervention to increase cow's milk consumption among Girinka households with a young child. The study aimed to evaluate whether training community health workers (CHWs) to conduct community and household SBCC activities promoting cow's milk consumption would increase milk consumption and dietary diversity among young children in households that had received a cow through the Girinka program.

## METHODS

### Study Overview

This cluster-randomized controlled trial was designed to test the impact of an SBCC intervention to promote the consumption of ASFs, especially cow's milk, on maternal ASF knowledge and awareness and on child milk consumption and dietary diversity in households that had received a cow from the Girinka program. The trial was registered at ClinicalTrials.gov (NCT03455647).

The study was conducted in Nyabihu and Ruhango Districts, Rwanda. The districts were selected in consultation with the Ministry of Local Government to include districts with a high prevalence of childhood stunting and poverty.<sup>31,32</sup> Districts in Rwanda are subdivided administratively into sectors, which are further divided into cells. Cells typically contain 5–7 villages, but they can range from 4 to 12 villages.

### Sample Selection and Sample Size

We randomly assigned administrative cells in the 2 districts to intervention or control. Nyabihu had nutrition programs in different parts of the district, whereas Ruhango had nutrition programs operating throughout the district. Therefore, randomization in Nyabihu was stratified by ongoing nutrition programs. The existing nutrition programs in the counties did not specifically promote ASF or cow's milk consumption by young children. In both districts, the randomized cells were balanced on total population size.

**This study tested the impact of an SBCC intervention promoting consumption of ASFs on maternal ASF knowledge and on child milk consumption and dietary diversity.**

**Child consumption of ASFs and subsequently their nutritional status are increased in households where SBCC is incorporated into livestock production interventions.**

We obtained lists of households that had received a cow through the Girinka program from district and sector animal resources officers. Households were eligible for enrollment at baseline if they received a Girinka cow in 2017 or earlier or a Girinka calf in 2016 or earlier, the animal was still alive, the mother was 18–49 years of age and had a child who was 12–29 months of age, and the biological mother lived with the child.

Our target was 4 households per cell. However, because we had challenges finding enough eligible households and many cells had fewer than 4 eligible households, we included up to 9 households per cell. If a cell contained more than 9 eligible households, the data collection team randomly selected from among those that were eligible.

We calculated sample sizes for 2 child outcomes—minimum dietary diversity (consumption of  $\geq 4$  food groups in the past 24 hours) and milk consumption in the past 24 hours—based on a comparison of the changes in these parameters between baseline and endline. Minimum dietary diversity required a larger sample size (Supplement Table 1), so it was used as the sample size for the study. To detect a 15-percentage point difference between groups in the prevalence of minimum dietary diversity<sup>33</sup> (i.e., at endline: control 29% and intervention 44%) with 80% power and  $\alpha=0.05$ , required 208 households per group, assuming an average cluster size of 4 households per cell, an intracluster correlation of 0.10, and a design effect of 1.3. We added 10% to the sample to account for attrition, resulting in 229 households per group and a total baseline sample size of 458.

### Intervention

The SBCC intervention was known as *Gabura Amata Mubyeyi* in Kinyarwanda, which translates to “Parents, Give Milk” in English. The intervention was developed based on formative research and guided by the theory of change shown in Figure 1. The theory of change posits that appropriate and effective SBCC on ASF consumption from CHWs reaches mothers and increases their knowledge. Mothers are concerned about child nutrition and are willing and able to adopt the recommended practices. They increase the child’s consumption of home-produced milk from their Girinka cow, which in turn increases child dietary diversity and may contribute over the long term to increases in child growth directly or through improved dietary diversity. In this analysis, we measured the effects of the intervention on the intermediate outcomes in the own-production pathway indicated in bold boxes in Figure 1. The theory of change also shows an

alternate pathway to increased dietary diversity and growth through the purchase of ASFs.

The intervention and SBCC materials were designed in collaboration with the National Child Development Agency, which coordinates nutrition activities in Rwanda. The SBCC materials consisted of counseling cards, a poster, and a brochure translated into Kinyarwanda. The counseling cards were designed using the same style as the Rwanda maternal, infant, and young child nutrition counseling cards. The messages from the SBCC materials related to this analysis are shown in the Box. Rwanda does not have food-based dietary guidelines, so the recommendation in this study to give children 1 cup of milk per day was based on the Rwanda Agriculture Board’s One Cup of Milk per Child program.<sup>34</sup> This quantity of milk is low compared with the U.S. Department of Agriculture dairy recommendations for children 12–23 months (1 2/3 to 2 cups) and 2–3 years (2 to 2 1/2 cups).<sup>35</sup> The recommendation to introduce cow’s milk to the child’s diet at 12 months is based on evidence that cow’s milk can result in occult blood loss from infants’ gastrointestinal tracts<sup>36</sup> and the inability of infants’ kidneys to handle the high levels of protein, sodium, and potassium in cow’s milk.<sup>37</sup>

Community and environmental health officers, who supervise CHWs, were trained to train CHWs to use the SBCC materials and conduct household and community SBCC sessions. The household visits were specifically targeted at households included in the intervention arm of the study. The community sessions were offered to all community members in the intervention cells. The intervention was implemented from February to October 2019 and was designed as an addition to CHWs’ usual activities. CHWs were asked to visit households in the SBCC intervention group monthly and conduct community SBCC sessions monthly. At the time of this study, SBCC materials specifically promoting ASF consumption were not available to CHWs through the government or its implementing partners. In the 2 study districts, only CHWs in the intervention group had copies of the *Gabura Amata Mubyeyi* SBCC materials. CHWs work within their own administrative cells, so the possibility of the intervention being inadvertently implemented outside the target cells was very low.

### Data Collection

Experienced enumerators were trained to conduct the baseline and endline surveys. The training

**The SBCC intervention was known as *Gabura Amata Mubyeyi* in Kinyarwanda, which translates to “Parents, Give Milk” in English.**

**TABLE 1.** Participants’ Individual and Household Characteristics at Baseline

	Intervention (N=234), Mean±SE or %	Control (N=228), Mean±SE or %	P Value
No. of household members	5.9±0.1	5.8±0.1	.96
Age of mother, years	33.7±0.4	32.8±0.5	.20
Age of father, years	40.1±1.1	37.6±1.0	.00
No. of children	3.5±0.1	3.4	.78
Age of index child, months	19.6±0.4	19.9±0.4	.97
Sex of index child, % male	46.6	46.9	.71
Marital status of mother			.76
Single	23.2	29.4	
Married	72.1	66.7	
Widowed	2.1	1.8	
Separated/divorced	2.6	2.2	
Index mothers who are household heads, %	5.6	6.6	
Mother’s occupation			.74
Farmer	95.7	92.5	
Housewife	0.4	1.3	
Jobless	1.7	2.2	
Other	2.1	3.9	
Mother’s education			.06
Informal education, never attended school	12.0	14.9	
Lower primary (1–4)	36.8	36.4	
Upper primary (5–8)	39.3	37.7	
Any secondary or higher	12.0	11.0	
Father’s occupation			.42
Farmer	90.6	87.5	
Jobless	0.0	1.6	
Other	7.4	11.0	
Father’s education			.68
Informal education, never attended school	13.6	14.1	
Lower primary (1–4)	33.3	28.1	
Upper primary (5–8)	43.9	45.3	
Any secondary or higher	9.1	12.5	
Household assets: land, ha	0.1±0.0	0.1±0.0	.41
Household domestic asset index <sup>a</sup>	9.1±0.6	10.1±1.0	.36
CASHPOR housing index <sup>b</sup>	5.0±0.2	5.2±0.2	.03
Household food insecurity access category			.98
Food secure	13.7	17.0	

*Continued*

**TABLE 1.** Continued

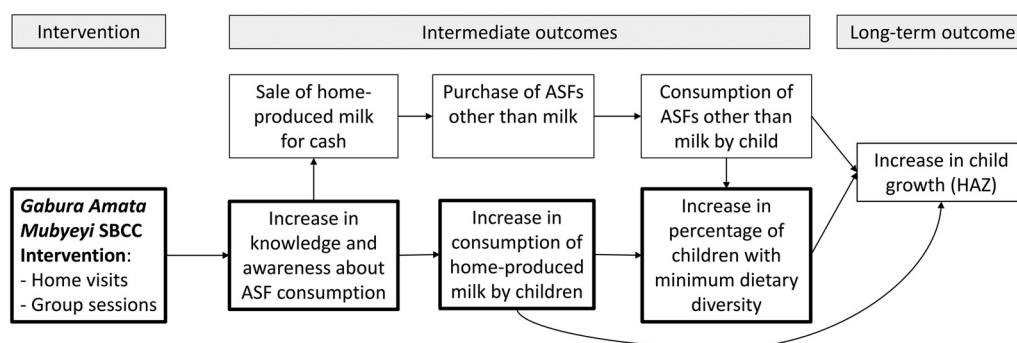
	Intervention (N=234), Mean ± SE or %	Control (N=228), Mean ± SE or %	P Value
Mild food insecurity	0.9	0.4	
Moderate food insecurity	22.2	20.1	
Severe food insecurity	63.2	62.5	

Abbreviation: SE, standard error.

<sup>a</sup>Household domestic asset index was calculated for all movable assets including livestock, so that each asset was assigned a weight then adjusted for age. Higher asset scores indicate higher socioeconomic status.

<sup>b</sup>The CASHPOR housing index captures quality of housing by using roof, wall, and floor materials as a proxy for measuring poverty. CASHPOR scores below 5 indicate very poor housing and scores from 5 to 9 indicate poor housing.

**FIGURE 1.** Theory of Change for the *Gabura Amata Mubyeyi* Social and Behavior Change Communication Intervention to Promote Consumption of Cow’s Milk Among Children, Rwanda



Abbreviations: ASF, animal source food; HAZ, height-for-age z-score; SBCC, social and behavior change communication.

**BOX 1.** Key Messages in the *Gabura Amata Mubyeyi* Social and Behavior Change Communication Materials

Importance and benefits of animal source foods (ASFs) and milk consumption for children aged 1–3.5 years:

- Milk is rich in calcium needed for bone formation and has fat and protein needed for children to grow well.
- ASFs provide multiple micronutrients simultaneously. For example, food such as liver contains iron and vitamin A.

Appropriate quantities of ASFs and cow’s milk to be consumed by children aged 1–3.5 years:

- Children aged 6–11 months should be fed at least 1 portion of ASFs, such as eggs, meat, fish, or chicken, to meet their daily nutrient needs, in addition to continued breastfeeding.
- Children 1 year and older should drink at least 1 cup (240 mL) per day or eat at least 1 portion of other ASFs.
- Mothers who are not breastfeeding their children should seek advice from community health workers or health providers on introducing ASFs and cow’s milk to their young children.

Appropriate time to introduce cow’s milk and ASFs to young children:

- Children aged 6 months should be given breast milk and introduced to ASFs such as meat, poultry, fish, and eggs, but not cow’s milk.
- Children aged 12 months should be introduced to cow’s milk into their daily diet.
- A child should continue to be breastfed even after cow’s milk is introduced. Breast milk protects a child from illnesses and reduces the risk of malnutrition.
- Household cow’s milk production should be used primarily to feed children and mothers at least 1 cup of milk each per day to improve maternal and child nutrition.



Three Stones International coordinator training community health workers. © 2019 Jean Claude Gasangwa/ Three Stones International

covered screening and enrollment, consent procedures, review of the questionnaire on paper and in Open Data Kit (ODK), and a pilot. Enumerators collected the data at the participants’ households using tablets with the questionnaire programmed in ODK. Completed interviews were reviewed by the field supervisor and uploaded to a secure server. The baseline survey was conducted in batches in April–May, July–August, and October–November 2018 as the lists of Girinka participants were received. The bulk of the endline survey was conducted from January–March 2020; 6 participants had their interviews in July 2020 because of travel restrictions related to COVID-19.

The questionnaires were developed in English then translated into Kinyarwanda. They included questions on child diet and feeding practices from the World Health Organization (WHO) infant and young child feeding questionnaire,<sup>38</sup> including the types of fluids and foods the child consumed in the past 24 hours (24-hour recall). The questionnaire also collected information on the frequency of the child’s consumption of cow’s milk and other ASFs in the past 7 days (7-day recall), maternal knowledge and awareness related to milk, participation in nutrition activities conducted by CHWs, household food insecurity, livestock ownership, household milk production, and socioeconomic characteristics. Maternal ASF knowledge questions were asked without providing response options, whereas maternal awareness was gauged by asking women if they had

ever heard about specific practices. Questions on general exposure to home visits and community activities conducted by CHWs were asked to participants in both study groups at baseline and endline. The endline questionnaire also included questions on intervention exposure for participants in the intervention group only. Intervention exposure questions were posed in a yes/no format, except for questions about the numbers of home visits or community activities attended.

### Data Analysis

Several variables in this study were calculated or derived from the data. Child dietary diversity was calculated using the WHO infant and young child feeding indicator guidelines.<sup>38</sup> We did not use the updated dietary diversity indicator that includes breast milk because part of our study population was  $\geq 24$  months at baseline and most children were  $\geq 24$  months at endline and no longer breast-feeding. Household food insecurity access categories were calculated using guidelines from the FANTA project.<sup>39</sup> The household domestic asset index was calculated for all movable assets including livestock, using guidelines by Njuki et al.<sup>40</sup> Each of the assets was assigned a weight, which was then adjusted for the age of the asset. Higher asset scores indicate higher socioeconomic status. The household land asset was calculated as total agricultural land parcels owned by the household in square meters. A CASHPOR housing index that

captures the quality of housing in terms of roof, wall, and floor materials was used as a proxy for measuring poverty.<sup>40</sup> CASHPOR scores below 5 indicate very poor housing and scores from 5 to 9 indicate poor housing.

We used longitudinal random effects regression models with robust standard errors in Stata (MP, version 16.0) to account for clustering at the level of the cell and estimate difference-in-difference for the impact of the SBCC intervention on child milk consumption (24-hour recall and 7-day recall) and minimum dietary diversity. We calculated unadjusted difference-in-difference estimates and performed an analysis adjusted for factors that could influence the outcomes (child's age, child's sex, current breastfeeding status, mother's educational status, and mother's marital status). We calculated the average means or percentages across districts by study group for outcome, socioeconomic, and other variables and used regression models to evaluate the difference in means.

## ■ RESULTS

### Study Participants and Characteristics

The flow of study participants is shown in Figure 2. Less than 5% of participants in both study groups were lost to follow-up between baseline and endline. The main reason for loss to follow-up was families moving away from the area or traveling at the time of endline data collection.

At baseline, fathers in intervention households were older ( $P<.001$ ) and intervention households had a slightly lower mean CASHPOR housing index ( $P=.03$ ) than control households (Table 1). We found no statistically significant differences in other individual and household characteristics of participants in the 2 study groups. In both groups, households contained approximately 6 members on average. Mothers' mean age was approximately 33 years and children's mean age was 19 months. About three-quarters of mothers' had a primary-level education or lower. Households in both groups had very small landholdings and few domestic assets and were living in houses classified as very poor or poor. More than 60% were classified as having severe food insecurity.

Most children in both study groups were still breastfed at baseline (intervention 86.3%, control 83.8%), whereas few children continued to be breastfed at endline (intervention 15.3%, comparison 13.7%). Current breastfeeding status did not differ significantly by study group at baseline or endline. Mean meal frequency was low at baseline (intervention  $2.6\pm 0.4$ , control  $2.6\pm 0.4$ ), remained

similar at endline (intervention  $2.6\pm 0.4$  meals, control  $2.4\pm 0.4$  meals), and did not differ significantly by study group at either time point.

### Exposure to CHW Activities and *Gabura Amata Mubyeyi*

CHWs in both study areas continued with their usual home visits and community nutrition activities throughout the intervention period, while CHWs in the intervention areas also implemented the additional *Gabura Amata Mubyeyi* intervention components. More than 70% of mothers in both study groups reported that they had been visited at home by a CHW in the past 6 months and more than 75% had contact with a CHW in the community to discuss nutrition in the past 6 months (Supplement Table 2). Difference-in-difference estimates were 9.0 percentage points higher for CHW home visits ( $P=.02$ ) and 10.3 percentage points higher for contact with a CHW in the community ( $P=.03$ ) in the intervention group compared with the control group.

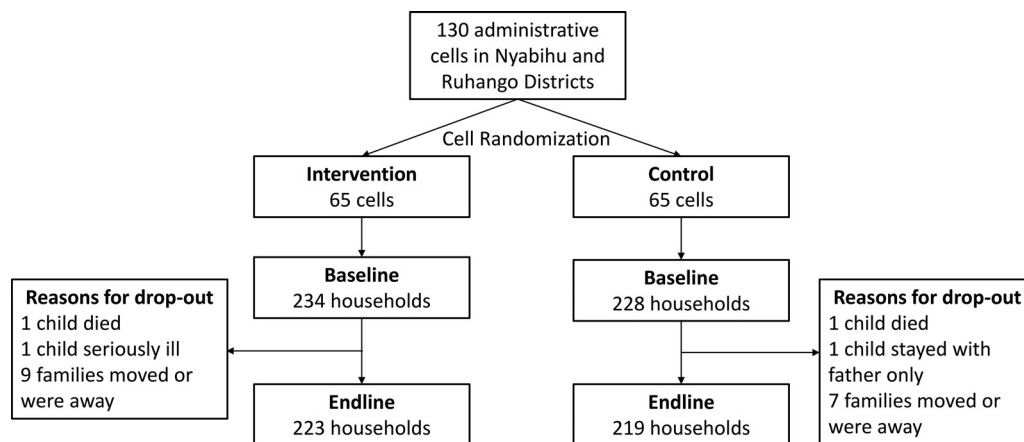
Table 2 shows exposure to the *Gabura Amata Mubyeyi* SBCC intervention among mothers in the intervention group. Ninety percent of mothers in the intervention group were visited at home by a CHW to discuss *Gabura Amata Mubyeyi* and they had an average of  $5.3\pm 5.1$  visits. Eighty-three percent of mothers in the intervention group participated in community activities in which the CHW discussed ASFs or milk, and CHWs discussed these topics during community activities an average of  $5.9\pm 4.6$  times during that period.

### Impact on Mothers' Knowledge and Awareness

At endline, more mothers in the intervention group compared with the control group were able to name the ASFs, for instance, milk (90.1% vs. 81.7%,  $P=.03$ ), fish (61.0% vs. 50.7%,  $P=.04$ ), and eggs (82.1% vs. 70.8%,  $P=.01$ ), and more knew that children should not start to receive cow's milk until 12 months of age (41.7% vs. 18.7%,  $P<.001$ ) (Table 3). Mothers in the intervention group also had greater awareness than mothers in the control group that they should feed their child ASFs (76.2% vs. 62.1%,  $P=.01$ ), feed the child 1 cup of cow's milk per day (20.6% vs. 7.8%,  $P<.001$ ), and introduce cow's milk at 12 months of age (35.9% vs. 11.0%,  $P<.001$ ). We found no differences between the study groups in mothers' knowledge of the number ASFs a child should consume daily, main nutrients in cow's milk, and quantity of cow's milk that a child should drink daily.

**At endline, more mothers in the intervention group could name the ASFs, and more knew that children under 12 months should not receive cow's milk.**

**FIGURE 2.** Study Flow Diagram for Participants Involved in a Social and Behavior Change Communication Intervention to Promote Consumption of Cow’s Milk Among Children, Rwanda



**TABLE 2.** Intervention Participants’ Exposure to *Gabura Amata Mubyeyi* Activities Conducted by Community Health Workers

	Home Visits (N=223), % or Mean ± SD	Community Activities (N=223), % or Mean ± SD
Mother participated in <i>Gabura Amata Mubyeyi</i>	90.7 (n=195 <sup>a</sup> )	82.8 (n=178 <sup>b</sup> )
CHW used <i>Gabura Amata Mubyeyi</i> educational materials	82.0	90.4
Type of educational materials used		
Counseling cards	64.2	66.9
Brochure	88.7	0.0
Poster	18.2	0.0
Topics CHW discussed		
Importance of animal source foods for children and mothers	90.3	98.3
Children should drink 1 cup of cow’s milk per day	74.4	77.8
Introduce cow’s milk at 12 months	73.4	79.4
No. of home visits or community activities during which CHW talked about these topics	5.3 ± 5.1	5.9 ± 4.6

Abbreviation: CHW, community health worker.

<sup>a</sup>Of the mothers who participated in *Gabura Amata Mubyeyi* home visits.

<sup>b</sup>Of mothers who participated in *Gabura Amata Mubyeyi* community activities.

### Household Milk Use

Nearly half of the households in both groups reported that they never used the milk produced by their cow either because the production is too low and they leave the milk for the calf or the cow has not calved (intervention, 42.3% baseline, 48.4% endline; control, 42.5% baseline,

49.8% endline). Among households that used the milk from their cow, 58%–75% kept all their morning milk and 79%–87% kept all their evening milk, indicating that an important portion of the households sold some or all of their milk, especially milk collected in the morning (Supplement Table 3). The percentage of households that kept



**TABLE 3.** Differences in Mothers’ Knowledge and Awareness Related to Milk and Other Animal Source Foods at Endline

	Intervention (N=223),%	Control (N=219), %	Difference, %	P Value
Types of food considered to be ASFs				
Milk	90.1	81.7	8.4	.03
Meat (beef, goat, chicken, pork)	91.0	84.5	6.6	.07
Fish	61.0	50.7	10.3	.04
Eggs	82.1	70.8	11.3	.01
No. of types of ASFs a child should eat daily				
0	5.4	3.7	1.7	.44
1	10.3	14.2	-3.8	.26
2 or more	74.9	73.1	1.8	.74
Main nutrients in cow’s milk				
Calcium	4.0	5.5	-1.4	.48
Protein	31.4	27.4	4.0	.36
Fat	5.4	7.3	-1.9	.45
Carbohydrates	18.4	13.2	5.1	.18
Quantity of cow’s milk a child should drink each day				
1 cup or more	87.0	88.1	-1.1	.77
Age when a child is old enough to receive cow’s milk				
12 months or older	41.7	18.7	23.0	.00
Awareness				
Feed the child ASFs	76.2	62.1	14.1	.01
Feed the child 1 cup or 240 mL of cow’s milk every day	20.6	7.8	12.9	.00
Introduce cow’s milk at age 12 months	35.9	11.0	24.9	.00

Abbreviation: ASF, animal source food.

**Children were more likely to consume cow’s milk at least twice per week if their mothers recalled hearing that children should drink 1 cup of cow’s milk per day.**

or sold their milk did not differ by study group. Among households that reported keeping some or all of their milk, mean milk production in both groups was approximately 1 L of milk at baseline and 1.5 L at endline (data not shown). We found no difference in milk production by group at either time point.

**Impact on Children’s ASF Consumption, Milk Consumption, and Dietary Diversity**

Approximately half of children in both study groups had not consumed fresh cow’s milk during the past week at endline. Among children who consumed fresh milk, the difference-in-difference estimate for consumption of fresh cow’s milk 2 or more times per week was 8.0 percentage points higher in the intervention group compared with

the control group, although the difference was not statistically significant (adjusted  $P=.17$ ) (Table 4). Children in the intervention group had increased odds of consuming cow’s milk 2 or more times per week if their mothers recalled hearing that children should drink 1 cup of cow’s milk per day during a CHW’s home visit (odds ratio [OR] 2.1, 95% confidence interval [CI] 1.1, 3.9) or a community activity (OR 2.0, 95% CI 1.2, 3.5).

The intervention was not associated with children’s ASF consumption (24-hour recall), dairy consumption (24-hour recall), fresh cow’s milk consumption (24-hour recall), or minimum dietary diversity. ASF consumption and dairy consumption decreased in both groups from baseline to endline, whereas fresh cow’s milk consumption (24-hour recall) increased by 21.1% in the

**TABLE 4.** Impact of *Gabura Amata Mubyeyi* on Children’s Animal Source Food (ASF) Consumption, Milk Consumption, and Dietary Diversity

	Baseline (T1)		Endline (T2)		Intervention (T2 – T1) <sup>a</sup>	Control (T2 – T1) <sup>a</sup>	DiD Impact Estimate <sup>a</sup>	P Value	Adj. P Value
	Intervention (N=234), %	Control (N=228), %	Intervention (N=223), %	Control (N=219), %					
ASF consumption (24-hour recall) <sup>b</sup>	55.6	47.8	40.8	36.5	-14.7	-11.3	-3.5	.63	.68
Dairy consumption (24-hour recall) <sup>c</sup>	44.0	36.4	31.4	26.0	-12.6	-10.4	-2.3	.86	.94
Fresh cow’s milk consumption (24-hour recall)	9.4	7.5	30.5	25.1	21.1	17.7	3.4	.95	.84
Fresh cow’s milk consumption (7-day recall)									
Never	54.7	56.6	48.0	51.6	-6.7	-5.0	-1.7	.77	.73
1 time per week	2.6	0.4	2.2	6.4	-0.3	6.0	-6.3	.02	.02
2 or more times per week	42.7	43.0	49.8	42.0	7.0	-1.0	8.0	.20	.17
Minimum dietary diversity	51.3	44.3	47.1	40.2	-4.2	-4.1	-0.1	.99	.99

Abbreviations: ASF, animal source food; DiD, difference-in-difference.

<sup>a</sup> Percentage point difference.

<sup>b</sup> ASF consumption includes meat, poultry, fish, eggs, and dairy, including fresh and powdered milk.

<sup>c</sup> Dairy consumption includes fresh and powdered milk, yogurt, and cheese, but very little yogurt or cheese was consumed by children in this study (see Supplemental Figure 1).

intervention group and 17.7% in the control group. The specific types of ASFs consumed by the children in both study groups at baseline and endline are shown in Supplement Figure 1. Dietary diversity was 3.4±0.1 food groups in the intervention group and 3.3±0.1 in the control group at baseline; it did not change significantly from baseline to endline.

## DISCUSSION

In this study, we designed an SBCC intervention that was implemented by CHWs who promoted the consumption of ASFs, especially cow’s milk, among children in households that received a cow through the Girinka program in 2 districts of Rwanda. We detected impacts of the intervention on mothers’ ASF knowledge and awareness and an increased odds of more frequent milk consumption among children whose mothers were exposed to the intervention, but no effects on the prevalence of milk consumption during the past 24 hours or minimum dietary diversity. We hypothesized that the intervention would work through the own-production pathway and that increased maternal knowledge would lead to increased consumption of household-produced milk and subsequently to increased dietary diversity. The most likely explanations for the lack of

impacts of the intervention on nutrition outcomes were the low milk production of the cows and the high level of food insecurity and poverty among the participants, which led to competing needs for household resources. Cows in nearly half of the households were not productive enough for the household to use the milk, and up to 40% of households with enough milk sold some or all of it. This finding suggests that milk is an important source of income for these families and SBCC alone may not modify milk use patterns in Girinka households at current levels of milk production. This aligns with results from other studies showing that SBCC is not sufficient to change nutrition outcomes in households with poor food security.<sup>41,42</sup> It is also congruent with agriculture-nutrition pathways indicating that income and sufficient resources for food expenditures are needed for agricultural programs to have nutrition impacts.<sup>22,25</sup>

This study demonstrated that it is feasible for government health staff to train and supervise CHWs to implement an ASF SBCC intervention. Mothers in the intervention group reported frequent contacts with CHWs as part of this intervention both through home visits and community activities related to nutrition. CHWs used the SBCC materials and transmitted the key messages.

**The lack of impacts of the intervention on nutrition outcomes was likely due to low milk production and high levels of food insecurity and poverty.**

These activities resulted in increases in some aspects of maternal knowledge and awareness related to milk. Mothers in both study groups had high levels of knowledge about some topics, including which foods constitute ASFs, the number of ASFs that should be eaten daily, and the quantity of milk that should be given to a child daily. Maternal knowledge about giving children 1 cup of milk per day most likely came from the Rwanda Agriculture Board's One Cup of Milk Per Child program, which has provided milk to school children since 2011.<sup>34</sup> Mothers' knowledge and awareness about introducing cow's milk at 12 months was lower before the intervention than for other topics and it increased during this study.

We found several notable changes in children's dairy consumption in both study groups during this study. Children's fresh cow's milk consumption in the past 24 hours increased greatly from baseline to endline, while dairy consumption decreased. The increase in fresh cow's milk consumption in both study groups may be partly related to differences in the timing of data collection at baseline and endline. Baseline data were collected across long rains, long dry season, and short rains, whereas endline data were collected during the latter part of short rains, when fodder is more plentiful. However, the differences in mean milk production from baseline to endline were small. The change in type of milk consumed by children from baseline to endline was more likely related to their use of a locally produced fortified maize-soy blend containing milk powder (known as *Shisha Kibondo*), which is provided for free at health facilities to low-income families with children <24 months.<sup>43,44</sup> Most of the children in our study were <24 months at baseline, so *Shisha Kibondo* accounted for the majority of their milk, dairy, and ASF consumption at baseline. As the children grew and no longer received *Shisha Kibondo*, their consumption of fresh cow's milk increased and accounted for most of their dairy and ASF consumption. The shift away from *Shisha Kibondo* consumption also explains why ASF and dairy consumption decreased over time. Children in both study groups had a higher prevalence of dairy consumption compared with children aged 6–23 months in the Rwanda Demographic and Health Survey<sup>31</sup> and to children among livestock-owning households in Tanzania.<sup>11</sup> However, given that all households in this study had a cow, children's milk consumption was still low, with no milk consumption being reported for about half of the children during the past week. Interestingly, most children in this study either received fresh cow's milk

2 or more times per week or not at all, which may indicate that when households have fresh milk available, they do give it to children.

### Strengths and Limitations

The strengths of this study were a cluster-randomized design and a well-designed SBCC intervention based on formative research. This study also had several limitations. The intervention was originally planned for 12 months but had to be shortened because of challenges in getting approvals from various government agencies. Our baseline data were collected in batches over several months because we received lists of potentially eligible households at different times and needed to collect data before the children were no longer eligible. As a result, our baseline and endline data were not collected during the same time of year. However, the difference in timing of data collection did not appear to be related to milk production because we found no differences in milk production between study groups. To stay within budget constraints, our study was powered for a 15-percentage point difference. This explains why the 8-percentage point higher frequency of weekly milk consumption detected in this study was not statistically significant and indicates that future studies should use a smaller percentage point difference to estimate the sample size needed to detect between group differences in milk consumption and dietary diversity.

### CONCLUSION

In conclusion, this study found effects of an ASF SBCC intervention on maternal knowledge and awareness related to milk consumption, and intervention exposure was associated with increased odds of children's milk consumption 2 or more times per week. Although we hypothesized that the SBCC intervention would increase milk consumption through the own-production pathway, more than half of the households in this study either had inadequate production for human consumption or sold their milk. This finding indicates that interventions to increase household milk production, influence decision making around retention of milk for home consumption, and influence how the proceeds of milk sales are used for household nutrition could be impactful, as was shown in an agriculture-nutrition program in Burkina Faso.<sup>45</sup> Insufficient milk production by Girinka cows and the need for some households to sell their milk also suggests that the Girinka program may need to add other components or supporting activities that would assist households to increase

milk production and/or to keep more of the milk that they produce. It also indicates that SBCC may need to be tailored to support increased ASF consumption through the agriculture-nutrition “income” pathway. The messages would need to focus on cost-effective ways to improve children’s diets with the income from cow’s milk sales and potentially on increasing women’s control over resources and decision making related to food purchases. Finally, the low levels of knowledge on some ASF topics at endline, despite large differences between groups (e.g., introducing milk at 12 months), indicate that a longer duration SBCC intervention may be needed to increase knowledge and modify social norms. This process is already underway as the National Child Development Agency has incorporated the *Gabura Amata Mubyeyi* messages into the recently revised national CHW counseling cards and is training CHWs on their use.

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**Author contributions:** VLF designed the study, contributed to intervention design, led the analysis, and drafted the manuscript; EO designed the study, contributed to intervention design, contributed to the analysis, and contributed to the manuscript; LI oversaw data collection and contributed to the manuscript; M-AS, AUf, AUw designed and implemented the intervention and contributed to the manuscript; AOB performed the analysis and contributed to the manuscript; EN contributed to the manuscript; and CN contributed to the study design and the manuscript.

**Data availability:** The data from this study will be made publicly available on the Harvard Dataverse by December 31, 2021.

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## En français

**Intervention de communication sur le changement social et comportemental par rapport à l'aliment d'origine animale parmi les bénéficiaires du transfert de bovins Girinka au Rwanda: une évaluation randomisée en**

### Principaux résultats

- L'exposition à l'intervention était associée à une probabilité accrue que les enfants consomment du lait de vache 2 fois ou plus par semaine.
- Environ la moitié de la fréquence de consommation de lait de vache chez les enfants était limitée par une production ou une vente inadéquate du lait produit par les ménages.

- La CCCS n'a pas eu d'influence sur le pourcentage de ménages qui ont gardé ou vendu leur lait, démontrant ainsi que la CCCS seule ne suffit pas à modifier les résultats nutritionnels dans les ménages ayant une faible sécurité alimentaire.

#### Implications Clés:

- Les agents de la santé communautaire (ASC) ont mis en œuvre avec succès l'intervention et les messages de la CCCS ont été intégrés dans les cartes nationales de conseil des ASCs récemment révisées
- CCCS pour cette population cible devrait être mise en œuvre pour une période plus longue et adaptée pour discuter de la gestion financière ou des choix alimentaires avec un budget limité. Une formation d'accompagnement ou d'autres activités visant à aider les ménages qui reçoivent des vaches sont nécessaires pour assurer une production adéquate de lait pour la consommation domestique.
- s niveaux élevés d'insécurité alimentaire grave dans cette population peuvent avoir limité le potentiel de la CCCS d'améliorer la diversité alimentaire et d'améliorer plus considérablement la fréquence de la consommation de lait de vache.

#### RÉSUMÉN

Les aliments d'origine animale, y compris le lait de vache, contiennent des nutriments essentiels et contribuent à une alimentation saine, mais la fréquence de consommation est faible chez les enfants dans les pays à revenu faible ou intermédiaire. Nous avons émis l'hypothèse qu'une intervention de communication sur le changement de comportement et social (CCCS) mise en œuvre par les agents de santé communautaires (ASC) lors des visites mensuelles à domicile et des activités au niveau communautaire augmenteraient la consommation de lait par les enfants et la diversité alimentaire dans les ménages qui ont reçu une vache du programme de transfert de bétail Girinka du gouvernement du Rwanda. Nous avons testé l'intervention CCCS sur 9 mois dans une cohorte d'enfants âgés de 12 à 29 mois au départ dans des cellules administratives aléatoirement affectées aux groupes d'intervention ou témoin. La plupart des mères du groupe d'intervention ont été exposées aux visites à domicile par les ASCs (90,7 %) et aux activités communautaires (82,8 %). À la fin de l'intervention, plus de mères dans le groupe d'intervention comparé au groupe témoin savaient que le lait de vache était un aliment d'origine animale (90,1 % contre 81,7 %,  $P = 0,03$ ) et qu'il pouvait être introduit aux enfants à 12 mois (41,7 % contre 18,7 %,  $P < 0,001$ ). Plus de mères dans le groupe d'intervention comparé au groupe témoin savaient qu'elles devraient nourrir leur enfant d'aliment d'origine animale (76,2 % contre 62,1 %,  $P = 0,01$ ) et leur donner une tasse de lait de vache par jour (20,6 % contre 7,8 %,  $P < 0,001$ ). La consommation de lait de vache frais par les enfants 2 fois ou plus de fois par semaine a augmenté dans le groupe d'intervention, mais pas de manière significative (8,0 points de pourcentage,  $P = 0,17$ ); la diversité diététique minimale n'a pas changé. Les enfants du groupe d'intervention avaient une probabilité accrue de consommer du lait de vache 2 fois ou plus par semaine si leur mère se souvenait d'avoir entendu dire que les enfants devaient boire une tasse de lait de vache par jour lors d'une visite à domicile d'une ASC [odds ratio (OR) 2,1, intervalle de confiance (IC) 95 % (1,1, 3,9)] ou d'une activité communautaire [OR 2,0, IC à 95 % (1,2, 3,5)]. Environ la moitié des enfants n'ont pas eu de lait au cours de la dernière semaine parce que leur ménage produisait peu de lait ou vendait ce qui était produit. Dans les ménages pauvres qui reçoivent un transfert de bétail, des stratégies visant à adapter davantage la CCCS et à augmenter la production de lait de vache peuvent être nécessaires pour obtenir une augmentation plus importante de la fréquence de la consommation de lait chez les enfants.

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ORIGINAL ARTICLE

# Qualitative Review of Organizational Responses to Rumors in the 2014–2016 Ebola Virus Disease Outbreak in Liberia and Sierra Leone

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## Key Findings

- During the 2014–2016 Ebola virus disease outbreak in Liberia and Sierra Leone rumors were identified and managed using formal and informal approaches, most often through interpersonal communication rather than mass media. Rumor management approaches included Community Led Ebola Action, Community Led Total Sanitation, drama performances, Ebola treatment center/unit-based approaches, radio, leveraging community leaders as information sources, and organizational change.
- EVD responders often identified and responded to rumors even when this was not part of their professional role.
- Several rumors were addressed through improvement or changes in the outbreak response.

## Key Implications

- Program managers involved in rumor identification and management programming should consider the role of staff members who have direct contact with the public but who do not have specific communication responsibilities.
- Rumors provide vital information about public perception of outbreak response and issues that may require remediation.

## ABSTRACT

**Introduction:** Rumors and misperceptions were a persistent challenge in the response to the 2014–2016 Ebola Virus Disease (EVD) outbreak in West Africa. This study aimed to document organizational approaches to identifying and addressing rumors and provide practical recommendations for future outbreaks.

**Methods:** We conducted semistructured interviews with 34 individuals who participated in the EVD response in Liberia and/or Sierra Leone. Interviews focused on the general organizational approach and organizational response to specific rumors. Interviews were recorded and transcribed verbatim.

**Results:** Most respondents reported that rumors were considered an organizational priority and their importance increased over time. Formal rumor identification systems using community-level reporters were described in Liberia and Sierra Leone as well as varied informal systems. A wide range of approaches was used to address rumors including Community Led Ebola Action, Community Led Total Sanitation, drama performances, Ebola Treatment Center/Unit-based approaches, radio, leveraging community leaders as an information source, and organization change. Interpersonal and community-led approaches were described most often. Staff whose professional roles did not involve rumor management reported informally addressing rumors with colleagues and beneficiaries. Rumors reflecting valid concerns with the EVD response, such as potential infection in health care facilities, were addressed through organizational change and improvement.

**Discussion:** Interpersonal and community-led approaches were considered effective by participants and hold promise for future outbreaks. Informal systems developed at Ebola Treatment Centers/Units highlighted how these facilities may be utilized as an information hub. Professionals who interact with beneficiaries, especially local staff, are likely to address rumors informally and organizations may benefit from considering local staff an asset in rumor management. Rumors alerted responders to issues in the EVD response, but this may not be the most efficient mechanism to receive and address concerns.

## INTRODUCTION

The 2014–2016 Ebola Virus Disease (EVD) outbreak in West Africa was devastating. In Guinea, Liberia, and Sierra Leone there were 28,616 confirmed, probable, and suspected EVD cases and 11,310 deaths.<sup>1</sup>

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Although numerous risk and emergency communication manuals, guidance, and trainings existed at the start of the outbreak, persistent communication challenges highlighted gaps in these approaches.<sup>2</sup> A coordinated response to the outbreak did not begin until approximately 6 months after the first human contact with the Ebola virus<sup>3</sup> and inadequate and inappropriate communication early in the outbreak proved counterproductive.<sup>4-6</sup> Early messaging, for example, overemphasized the importance of bushmeat in transmission while underemphasizing the comparatively higher risk of human-to-human transmission.<sup>7,8</sup>

Rumors, misperceptions, and community resistance presented significant obstacles in controlling EVD spread.<sup>4,5</sup> Rumors, defined as “unverified and instrumentally relevant information statements in circulation that arise in contexts of ambiguity, danger, and potential threat,”<sup>9</sup> can be problematic, but are an expected and adaptive response to frightening and ambiguous situations.<sup>10</sup> Information is necessary for planned action and when it is unavailable or not trusted, people may come together to pool information in an attempt to develop a reasonable understanding of a situation.<sup>9-11</sup> Rumors are not traditionally viewed as an information source but do reflect fears, hopes, and concerns of the populations in which they circulate. As such, they can be an invaluable resource for informing communication approaches and outbreak response.

This study aimed to capture the range of approaches used to identify and address rumors during the 2014–2016 EVD outbreak in Liberia and Sierra Leone. Guinea was excluded because the interview guide drew on rumors previously identified in Liberia and Sierra Leone, and rumor data were not available for Guinea.

Although program descriptions describing formal organizational responses to rumors exist,<sup>4,5,12,13</sup> this study sought to describe both informal and formal approaches used by EVD responders in a variety of roles, locations, and organizations to identify and address rumors to provide practical recommendations for rumor identification and management in future outbreaks. Rumors continue to be of interest in public health as illustrated by their impact on the ongoing COVID-19 pandemic.<sup>14,15</sup> To better understand how to identify and manage rumors, it is important to identify lessons learned from previous outbreaks and encourage innovation. In particular, studying informal rumor identification and management techniques practiced by EVD responders with direct community contact can provide unique insights into bottom-up approaches to identifying and addressing rumors.

## METHODS

This was a cross-sectional qualitative study.

The study was reviewed and approved by the Tulane University Social-Behavioral Institutional Review Board. Participants provided oral informed consent.

### Sample

Participants were recruited via Facebook and Twitter posts on the lead author’s personal pages, the lead author’s professional networks, and the CORE Group, Global Alliance for Nursing and Midwifery, and Healthcare Information for All listservs. Snowball sampling was used to reach the target sample size of 30 to 50 or until saturation was reached.

Thirty-four individuals who participated in the EVD response in a professional capacity in Liberia or Sierra Leone participated in the study. Of these, 16 participants worked in Sierra Leone, 14 worked in Liberia, and 4 worked in both countries. Twenty participants were international staff and 14 were local staff. Individuals aged younger than 18 years and/or unable to communicate in English were excluded.

### Data Collection

First, participants completed a short survey about the organizations they worked with during the EVD response. The survey was available on the Health Insurance Portability and Accountability Act (HIPAA)-compliant Johns Hopkins University instance of Qualtrics.

Then, participants completed semistructured interviews on organizational response to common rumors about EVD. Interviews were conducted in person, by phone, or via their preferred digital platform (e.g., Skype, WhatsApp, Zoom). Interviews conducted via Skype and Zoom were audio-recorded using platforms’ integrated recording capacity. All other interviews were recorded via QuickTime Player version 10.5 on a laptop computer. Audio recordings were labeled with a participant code and transcribed verbatim.

Data collection took place between September 24, 2019, and June 24, 2020.

### Data Analysis

Survey data were downloaded from Qualtrics and analyzed in Microsoft Excel. Interview transcripts were analyzed in Dedoose version 8.3.21 using individual-level thematic content analysis based upon an a priori analysis plan (Table 1). Two

**Studying informal rumor identification and management techniques can provide unique insights into bottom-up approaches to addressing rumors.**



**TABLE 1.** Analysis Plan for Semistructured Interview Responses of Participants Who Were Asked About Their Organization’s Response to Rumors During the 2014–2016 Ebola Virus Disease Outbreak

Interview Topics	Analytic Questions
Ebola virus disease responder background and experience	MICRO <sup>1</sup> : What is the background of this participant? MICRO: What perspective does this participant have regarding rumors? MACRO <sup>2</sup> : How does this participant’s background correspond to her perception of rumors?
General organizational approach to rumors	MACRO: What is the range of organizational approaches to rumors?
Organizational response to specific rumors	MACRO: What is the range of organizational responses to specific rumors?

<sup>1</sup> Refers to analytic questions that focus on the individual participant.  
<sup>2</sup> Refers to analytic questions that focus on trends amongst all participants.

**Formal rumor identification systems in Liberia and Sierra Leone used a national network of community-level individuals reporting rumors.**

coders reviewed the first 20 interview transcripts to develop a codebook based on emerging themes. Each transcript was coded by 1 coder and reviewed by a second coder who identified code discordance. Coders discussed discordant codes until reaching consensus. Participants were not provided with a rumor definition but were rather asked how they defined rumors. This was an intentional approach to allow participants to describe their experience based on their own understanding of rumors and how they were addressed.

**RESULTS**

**Participant Background and Rumor Perception**

Of participants who completed the organizational characteristics survey (n=30), 17 worked for 1 organization during the outbreak, 11 worked for 2 organizations, and 2 worked for 3 or more organizations. In total, participants reported working at 40 organizations (Table 2).

The professional and educational backgrounds of participants varied and included international development, emergency response, public health, and clinical care, with international development and public health being the most common. Many participants had experience in multiple areas.

**Organizational Response to Rumors  
Rumor Priority**

At an organizational level, the importance of identifying and addressing rumors varied. Some participants reported a high-priority level but also described how the priority level varied between departments. Several participants indicated that

rumors were a low priority in their organizations. Increasing priority of rumors over time emerged as a common theme. Table 3 presents illustrative quotes regarding rumor priority.

**Rumor Identification**

Of the 34 participants, 13 described a formal rumor identification system. Formal systems described in Liberia and Sierra Leone consisted of a national network of community-level individuals reporting rumors via mobile phone. Additionally, a few participants also mentioned formal systems reviewing mass media to identify rumors. However, although the formal systems were national, several participants were unaware of their existence.

Many participants discussed how organizations identified rumors with informal or ad hoc methods, most often through in-person communication between staff and community members. In some cases, staff members who were told about rumors worked in social mobilization or communication roles, although in some cases local staff were asked about rumors even if their professional role did not include any formal communication responsibilities. For example, a local staff working with an international nongovernmental organization focused on creating business opportunities described how he was frequently asked about rumors. Some participants also described other systems used to identify rumors of EVD cases but not other types of rumors. Table 4 presents illustrative quotes regarding the rumor identification processes.

**Rumor Management**

Participants described a wide range of rumor management approaches using interpersonal communication and mass media channels. Participants

**TABLE 2.** Characteristics of Organizations Employing Interview Participants Who Were Asked About Their Organization's Response to Rumors During the 2014–2016 Ebola Virus Disease Outbreak, by Country

Organizational Characteristic	Liberia	Sierra Leone
Organization type	n=17	n=23
Bilateral cooperation organization	1	0
Governmental organization	1	3
International nongovernmental organization	11	18
Local nongovernmental organization	0	2
United Nations agency	1	0
Other	3	0
Number of in-country employees	n=17	n=23
<10	2	1
10–25	2	2
26–50	5	2
51–100	3	3
101–500	5	5
>500	0	9
Don't know/not sure	0	1
Number of total employees	n=13	n=20
26–50	0	2
51–100	3	0
101–500	1	0
>500	8	10
Don't know/not sure	1	8
Not applicable	0	0
National headquarters location	n=13	n=20
Capital city	11	17
Other	2	3
Participation in national coordination structure <sup>a</sup>	n=17	n=23
Case management	6	19
Epidemiological/surveillance	6	14
Laboratory	2	9
Social mobilization	9	21
Contact tracing	5	N/A <sup>b</sup>
Special staff	4	N/A <sup>b</sup>
Logistics	N/A <sup>b</sup>	11
Burials	N/A <sup>b</sup>	7
Psychosocial	N/A <sup>b</sup>	18
Other	8	7
Don't know/not sure	1	0

<sup>a</sup> Organizations participated in multiple coordination structures.

<sup>b</sup> Organization structure did not exist in this country.

**TABLE 3.** Participant Quotes Regarding Rumor Priority From Interviews on Organizational Response to Rumors During the 2014–2016 Ebola Virus Disease Outbreak in Liberia and Sierra Leone

Theme	Quote
High priority	Rumors were super important, and they were considered a fundamental bedrock of everything that they were doing. —International staff, Sierra Leone
Priority variation within organization	I think we really dropped the ball at the [Ebola Treatment Center]. I mean, it's embarrassing because . . . it should have been really at the top of my mind, but it wasn't. I was so busy doing other ETC stuff. I wasn't thinking about laying any kind of groundwork or trying to track rumors around the ETC. —International staff, Sierra Leone
Low priority	As far as I remember - they were not particularly concerned in having an approach to do with addressing the rumors. —International staff, Sierra Leone
Changing priority over time	I don't think anyone really knew what a huge problem they would be until after the peak of the outbreak. I don't I don't think we understood how much of a barrier they would be. I mean we started hearing rumors in probably May or June of that of 2014, but I don't I just don't think any of us foresaw what a barrier they would be to health seeking behaviors. And so before then I don't think we took them seriously, to be quite honest. Or not seriously enough. I think there was a lot of, like, laughing them off at the Ministry level and in the technical working groups. —International staff, Liberia

emphasized that using multiple communication channels was vital to ensure that people in remote or isolated areas were reached, as well as the importance of different complementary approaches (e.g., radio, community meetings, drama) that allowed for wide distribution of information as well as gave people opportunities to ask questions and raise concerns.

Interpersonal communication approaches were discussed most often and were generally implemented at the community level. In Sierra Leone, one such approach was a participatory methodology called Community-Led Ebola Action. One participant described how this approach was used to address fears and rumors about personal protective equipment and ambulances. Participants described a similar approach that was used country-wide and coordinated through a consortium. Another international staff member in Liberia discussed how Community-Led Total Sanitation, the approach on which Community-Led Ebola Action was based, was adapted for community engagement in Lofa County, Liberia. Community-Led Ebola Action<sup>16</sup> and Community-Led Total Sanitation<sup>17,18</sup> have previously been described in detail in the literature. These approaches emphasize the capacity of communities to develop their own solutions to challenges that meet scientific standards for outbreak control as well as the importance of demystifying situations and objects that cause fear. Another community engagement approach used musical and drama performances. Participants also discussed the importance of listening to questions and

concerns from the community, gathering accurate information, and sharing that information with the community to close the communication loop.

Informal interpersonal communication efforts were also frequently discussed, especially those that took place in the Ebola treatment center/unit (ETC/ETU) context. Another international staff member working at an ETC/ETU described a more formal approach to using downtime to provide education and reduce misinformation. Although this approach used interpersonal communication to start, it later expanded to mass media. These approaches illustrated the potential for the ETC/ETU to be a setting for information sharing and addressing rumors.

Radio was the most common medium for mass media approaches, but billboards, posters, and social media were also mentioned. Interactive radio programs were generally seen to be the most effective mass media efforts. One international staff member working in Liberia and Sierra Leone and described other radio programming and efforts to work with journalists to reduce and address rumors.

Consistent messaging was discussed as a key attribute to both mass media and interpersonal communication approaches. In Sierra Leone, participants described a standard messaging guide that was produced by a Social Mobilization Action Consortium, while in Liberia participants reported that official messaging was centrally approved. Although consistent messaging was considered important to effective communication,

**Community-level communication approaches emphasize communities' capacity to develop solutions to challenges that meet scientific standards for outbreak control and help demystify situations and objects that cause fear.**

**TABLE 4.** Participant Quotes Regarding Rumor Identification From Interviews on Organizational Response to Rumors During the 2014–2016 Ebola Virus Disease Outbreak in Liberia and Sierra Leone

Theme	Quotation
Formal System – Community Level Worker Network	You know, we had a network of . . . over 10,000 people. If you put the religious leaders, the social mobilizers, the traditional healers together that we are working with . . . With the social mobilizers, we had we developed a system of communication. . . . On a daily basis the mobilizers were able to share . . . rumors. The things we hear from the communities as they [were] engaging the community . . . So we are getting those. I will not say close to real time, but on a daily basis we are able to actually collect that information. —Local staff, Sierra Leone
	We would work with Community Health volunteers who would send via [short messaging system] the specific rumor that they heard and that would track the [global positioning system] coordinates. And so then what would happen is we could say ‘okay, this 1 specific rumor came from this specific village on this specific day,’ and then we could alert our social mobilizers as well as the Ministry contacts that we had about that specific rumor. —International staff, Liberia
Formal System – Mass Media	That was a separate pillar that was led that was co-led by the Ministry of Information and they really . . . were more responsible for gathering some of that misinformation that was spreading . . . through the media, through . . . some of those channels. And so both that pillar, and the social mobilization pillar would bring that information to those daily Situation Room meetings where it was discussed then with the wider . . . response teams. —International staff, Liberia and Sierra Leone
Informal System	I mean it was it was an everyday thing where . . . I mean most of the time when I would do the work, people would confront us and talk to us about these rumors. And, you know. But we knew exactly what it is. And then we knew where the rumors came from. —Local staff, Liberia
System to Identify Ebola Virus Disease Case Rumors	The rumors . . . [we] will get the call from community-level. At times they too come from stakeholders [and] at times it will come from our partners that were working with the [nongovernmental organizations]. They will bring the information to us and then we would investigate the rumors and then if it is true then we do investigation and then if necessary, we can collect samples. —Local staff, Sierra Leone
	[It] . . . was like, ‘Oh if you hear that there is Ebola, you need to report to authorities.’ There was even a toll-free line where you could call . . . so that a response team could come and address to that case. —International staff, Sierra Leone

several participants also discussed how initial messaging about the high likelihood of death from EVD was actually counterproductive and caused people to hide EVD cases. This illustrated the importance of considering the potential unintended effects of messaging.

A common theme in participants’ discussions of both interpersonal and mass media rumor management approaches was the importance of delivering information through trusted sources. The first step described for identifying trusted sources in communities was entering a community in a culturally appropriate way. One international staff member working in Sierra Leone discussed the need to be cautious in entering communities; approaches that worked in some communities may not work in others. After entering a community, participants discussed approaches to identifying trusted community members and then using those people to share information as community members may be more likely to accept information from a trusted source.

While the majority of rumor management approaches discussed were focused on communication, several participants also provided examples of organizational changes. For example, several participants discussed how family access to the ETC/ETU was increased over time and decreased rumors. Some organizational changes were made in direct response to a rumor. For example, bags used for safe burials were modified to allow family and friends to see the face of the deceased in response to rumors that these bags were filled with rocks, which illustrated the importance of transparency in reducing rumors.

Several participants discussed how traditional beliefs could affect communication and rumor management. One international staff member working in Sierra Leone described how this appeared to contribute to the persistence of the rumor that EVD was not real. In contrast, a local staff member also working in Sierra Leone described how they took traditional beliefs into account to lead to desired health behaviors. This contrasting

approach illustrated that traditional beliefs, even those that are inconsistent with the biomedical explanation of disease, may not be inconsistent with behavior change goals.

Another theme that emerged in several interviews was how to address rumors that the participants felt were based on truth, at least in part. Participants mentioned rumors of people profiting from EVD, chlorine being dangerous, nepotism in ETC/ETU hiring, and health workers transmitting EVD as having some basis in truth. Participants generally indicated that when addressing these rumors the best approach was to acknowledge the element of truth. Table 5 presents interview quotations for emergent rumor management themes and summarizes the key insights for rumor management approaches.

**Organizations can use their internal communication structures to encourage staff members to report rumors and provide the necessary information and skills to respond to them.**

**A common rumor in Sierra Leone was that health workers were spreading EVD.**

### Organizational Response to Specific Rumors

A common rumor in Sierra Leone was that health workers were spreading EVD. Participants mentioned identifying the rumor in several different ways.

Five of the 9 participants who discussed this rumor believed that there was some truth to this rumor, but several believed the fears may have been overstated. Despite participants believing that there was some element of truth to the rumor, they also recognized that it was very damaging and led to the stigmatization of health workers and decreased health-seeking behavior.

The primary approach to addressing this rumor was organizational change and improvement of infection prevention and control procedures. As 1 participant put it:

*You can't message your way out of something like that.*—International staff, Sierra Leone

Interpersonal communication approaches and mass media campaigns were also used to complement organization change efforts. Table 6 presents illustrative quotes describing the organizational response to this rumor.

## DISCUSSION

Rumor identification systems using mobile phones and large networks of social mobilizers appeared to be effective for gathering rumors, but interviews seemed to indicate that there was limited awareness of these systems. This indicates a need for improved coordination and communication about rumor identification and management efforts. It is also worth considering how information from rumor identification systems can be used to improve outbreak response. While rumors and misinformation

are often considered within the purview of communications, rumors are also an important information source regarding how operations can be improved. This was illustrated by the operational changes that several organizations made in response to rumors in the community.

It also was a consistent theme that EVD responders heard and responded to rumors even if this was not part of their professional role. This was especially common among local staff. This presents a potential risk as staff members may respond in a way that exacerbates a negative rumor but also presents an opportunity. Organizations can use their internal communication structures to encourage staff members to report these rumors and provide the necessary information and skills to respond to them. For example, it could be beneficial to allocate a portion of time during staff meetings to discuss questions, concerns, and rumors that staff are hearing from the communities they work with. Alternatively, an organization could appoint a focal person to which that community feedback could be directed. Social and behavior change training (effective communication, facilitation, negotiated behavior change, etc.) could be beneficial to prepare staff members to respond to rumors. These efforts should take into account existing workloads and be cognizant of situations where this would cause an undue burden on staff members.

The use of mass media messaging and interpersonal communication at a community level to address rumors is not a new idea. Many EVD responders discussed how the 2014–2016 EVD outbreak was a learning experience and that both mass media and interpersonal communication approaches steadily improved as the outbreak went on. However, this type of approach may underutilize rumors as an information source. The results of this study illustrate how rumors highlighted issues within the response that were later addressed, but this process was ad hoc as there was not a structure in place for community members to share rumors or feedback directly with those who could address their concerns.

Despite this challenge, numerous examples of how community feedback was used to improve the outbreak response were described. One of the most striking examples was the rumor that health workers were spreading EVD. This rumor was perceived by several EVD responders as having some basis in truth and is supported by evidence of nosocomial transmission during the outbreak in Sierra Leone.<sup>19,20</sup> As such, the primary response to this rumor was no communication or messaging, but rather improving infection prevention and control

**TABLE 5.** Participant Quotes and Key Insights Regarding Rumor Management From Interviews on Organizational Response to Rumors During the 2014–2016 Ebola Virus Disease Outbreak in Liberia and Sierra Leone

Theme	Quotation	Key Insights
Use of multiple approaches and channels	I think what is important is having a combination of all these channels so that you're sure you're reaching people even the remotest areas of the country. So although you know committee meetings are better because you can have conversations, people can ask questions, and you respond but in terms of creating awareness and making sure you reach as many people as possible, I think a combination of all these channels was quite important. Because there's also posters that are put out there, so for those that way are able to read in order to get that information and based on what they've seen on posters, for example, they, during committee meetings, they could go ask more questions or based on what they would have heard on the radio, when they come face-to-face with a health worker, they have an opportunity to ask questions. —International staff, Sierra Leone	Importance of using multiple complementary channels to disseminate information
Community Led Ebola Action	You have the community champions. You have those to follow up so they were also used because the mobilizers during those triggering were able to listen to the communities to get the community perspective about how they could also protect themselves and keep themselves safe because honestly speaking I think most times we think the communities do not have . . . a scientific explanation to how they are able to prevent or protect themselves against diseases like Ebola and that. But if you engage the communities, really and you sit with them you discuss then you realize that they also have some explanations and some ideas on how they would be able to do it and that meets scientific standards. —Local staff, Sierra Leone	Communities are capable of developing their own solutions that meet scientific standards
	People . . . were resisting because of the PPE (personal protective equipment) people are putting on. . . . During the community engagement we had a session where you have community [members] who were actually encouraged to wear PPE . . . . You have Community leaders all using the ambulance and . . . so people were going to the ambulance so that the community that we serve will see that's okay. 'Okay, my fear was able to actually go into the ambulance and nothing happened.' So it means though that was able to kind of demystify some of the myths around the use of ambulance and the PPE that people were afraid that were leading to some of . . . [that] resistance. —Local staff, Sierra Leone	Demystifying situations or objects that cause fear can help reduce rumors.
Community Led Total Sanitation Adaptation	[It] was a like a way of bringing community members together in groups and addressing like their fear and their perceptions and their experiences and stories they'd heard and all those kind of like listening to all of that and then giving them the actual information and kind of addressing directly those, you know, maybe misconceptions that they had or clarifying if they were correct ones and then helping them to figure out what they need to do. —International staff, Liberia	It is important to listen to community questions and feedback, gather appropriate information, and communicate back with the community to close the loop.
Drama performance	We didn't just go and perform but we created a stage that will reduce the number of rumor because people ask questions that they feel somebody told them, and we wrote those questions down and we communicate[d] their back with our sponsor, like UNICEF, right . . . and they will send the real information. —Local staff, Liberia	
Ebola Treatment Center/ Unit-based approaches	But I suppose the nice thing was that we had really great relationships with the Ebola Treatment Center staff and they were there, you know every day, so you had time to like just sit and shoot the sh** with them and if they were like 'this is what I'm hearing,' then you had time and space to just be like, 'okay, let's talk about why the, you know, physiology of Ebola isn't actually related to, you know, kind of airborne spread like, so let's kind of talk about that. So kind of trying to defeat those rumors on a very one-to-one personal kind of basis. —International staff, Sierra Leone	The Ebola Treatment Center / Ebola Treatment Unit was a useful setting for information sharing and addressing rumors.

Continued

**TABLE 5.** Continued

Theme	Quotation	Key Insights
	<p>We started this whole training curriculum where you know, they [local staff] . . . would take responsibility and sign up for topics and then go research it and then teach their peers about that particular topic, and then we included the foreign staff and stuff, and, and tracked it. So we treated it like, almost like an education degree that was informal. . . . The nursing team also started a weekly radio show where they had like call in questions . . . The local . . . Ebola Treatment Unit team, that was a way that they wanted to be available to answer questions. It was so cool. They did, I remember, they did . . . topics at different times, like one was about fever, and then they would talk about Tylenol, and talk about what a fever is doing for someone's body, and it was linked to [the] . . . curriculum that we set up with our foreign nursing staff. —International staff, Liberia</p>	
Radio	<p>I think in terms of addressing rumors, the best way was usually through interactive programs. So whether you have an interactive program on radio, TV, or at a community level, programs where people can ask questions and answers are provided. I think those were the best in terms of addressing rumors, because sometimes the rumor is spread about a particular issue and then you respond with a messaging without getting to hear from the people who are spreading the rumors, but I think the best ones always platforms that give people an opportunity to ask questions and get responses. —International staff, Sierra Leone</p>	Interactive radio programs were perceived to be the most effective.
	<p>Radio dramas that were that were done at that time trying to remember the name of it. Mr. Plan-Plan or something like that, but there were you know some radio dramas and radio programming that were that were broadcast that would touch on addressing some of those some of those rumors. There were the journalist trainings. So to make sure that, you know, journalists were reporting more accurately. So there are a couple other things that that were being done at that time as well that, you know, would help to provide more accurate information, which would hopefully then reduce the number of rumors . . . And you know, maybe one thing to add is that you know, I think there was a real sense of wanting to be very careful about not repeating the rumor. So, you know by addressing the rumor you're really kind of just accelerating that accurate information rather than repeating the rumor in a way that's you're telling people that it's not true. So that's something that you know where people were really careful not to do. Because I didn't want to exacerbate that that rumor. —International staff, Sierra Leone and Liberia</p>	Journalist training can help prevent rumors by increasing accuracy of media reports.
Centrally approved messaging	<p>It was the kind of feeding up from the ground and then feeding back down. Kind of changing up the message guides like every couple of weeks or every month to ensure that they had. That they were kind of addressing the most current rumors. —International staff, Sierra Leone</p>	Messaging was centrally approved in Liberia and Sierra Leone.
	<p>So if the information came from Central Ministry because Central Ministry is responsible to do the IEC/BCC (information education communication/behavior change communication) had been approved. So if that was done, it came down to the county, from the county to the district, and then to your community that needed the information. —Local staff, Liberia</p>	
Ineffective messaging	<p>But at first, it was just like, it kill[s] you, you will die. It will kill you. But later on now the message change[d] . . . On the message side we change that, look, when you have this, you can get to the treatment center. You'll be treated and you can survive. People became relaxed. But during the early stages a lot of people ran away. —Local staff, Liberia</p>	It is important to consider potential unintended effects of messaging.
Community entry strategies	<p>If you just show up with you know and have, you know, PPEs you know with chlorine sprayers and start giving messages, if you're lucky, the best thing . . . is they won't listen to you. The other thing is . . . run you out of the village. —International staff, Liberia</p>	Community entry is a sensitive process that needs to be done carefully and in a culturally appropriate way.

*Continued*

**TABLE 5.** Continued

Theme	Quotation	Key Insights
	<p>If you go to a village that you know is infested, you call the Elder, like the Big Chief. Have him call his people because there were no mobile phones in order to make an appointment . . . Having called the elders, called the people, and tell them look we're coming back the next day because we're doing it from town to town. Like we spend a whole week out of town because you actually make appointments. Like, look we coming back tomorrow, Saturday at 4 o'clock. Let other people be here. We got a bundle of good news for you. —Local staff, Liberia</p>	<p>Entry strategies vary, so it is important to gain an understanding of the community leadership structure before entering.</p>
	<p>In some of the chiefdoms that we worked in, the paramount chiefs were very well respected, and they were sort of the purveyors of a lot of trust, and a lot of trying to you know, if you wanted access to the community you had to go through them. I know that there were some communities that we worked in or that we worked with that was the opposite, is that the Paramount Chief was not seen as being legitimate. It was somebody who was put in place because they were, you know, somebody's father or brother or connected somebody who is already powerful, and so the community actually didn't trust them. —International staff, Sierra Leone</p>	
<p>Community leaders as information source</p>	<p>You have to go you have to drill down deeper and find out who in each community is already an accepted source of information and whether they are knowledgeable about the issue, whether it's Ebola or an earthquake or whatever . . . All communities have some natural leaders. Some of them are either formally appointed like the village Chief or Council of some kind or you have just individuals who are recognized by other members of the community as having skills of organizing people of putting together trainings or those kind of things. —International staff, Liberia</p>	<p>Communities may be more likely to accept information from a trusted source in the community rather than from an outsider.</p>
	<p>And if there is any new information you share with people . . . so that it comes from the trusted source first. Otherwise, if you try to counter it, it's difficult. With misinformation, you just continue to provide accurate information. Probably through trusted channels in the community. So like religious leaders, traditional leaders, and mobilizers who are residing in the communities . . . You may be able to use those people to provide information to the populace regarding rumors. —Local staff, Sierra Leone</p>	
<p>Organizational change</p>	<p>One of the things that was changed in the short time I was there, was the opening the possibility for the family to see the people inside the treatment center, with quite a distance but being able to communicate with them. And the other thing that was, I think, quite important was also . . . opening the possibility in the treatment center, to see the dead body from the distance. —International staff, Liberia and Sierra Leone</p>	<p>Increasing family's ability to communicate and see their loved ones in the Ebola Treatment Center / Ebola Treatment Unit increased trust and reduced rumors.</p>
	<p>I do think actually the changes that were made at the treatment centers to increase a patient's ability, family's ability to see the patients I think that that has a huge impact, on trust and rumors, I think in a lot of ways probably more so than communication. —International staff, Liberia</p>	
	<p>The burial team . . . [was] hearing rumors about how you know, the body bags that they were using were, you know, the bodies weren't in it. They were taking the bodies out. I think again there were rumors around harvesting organs and other things. And that . . . that they were filling those bags up with rocks. And so what [organization] did was they . . . [made] part of the body bags . . . a see-through screen basically so that you could at least see the face of the body. —International staff, Liberia and Sierra Leone</p>	<p>Increasing transparency, where possible, may reduce rumors.</p>
<p>Traditional beliefs</p>	<p>Strong support of traditional beliefs and the fact that there was a really strong tradition in the spirit world allowed for alternative explanations for what was happening [that] did not involve germ theory. And trying to convince a population that doesn't have a high scientific background, that viruses exist and that this is how you pass the virus from one person to another. And . . . just not realizing viruses exist but that they can kill people,</p>	<p>Although traditional beliefs may lead to a rejection of the biomedical explanation of disease, it is possible to accept these beliefs and incorporate them into behavior change communication.</p>

Continued



**TABLE 5.** Continued

Theme	Quotation	Key Insights
	<p>and that your traditional, really important practices of your community like making sure people are buried properly and taking care of loved ones in the home, are putting you and your family at risk too. I think that the biggest issue with the sustained rumor was lack of scientific education combined with strong traditional beliefs that provided a really solid counter-narrative to what was going on. —International staff, Sierra Leone</p> <p>We have a discussion with stakeholders. And then we explain to them that what they are calling voodoo, medically we call it an illness. It can be carried by illness. So we educate them. At times we tell them that, ‘okay, the names are different.’ We tell them for example, if we’re talking to religious leaders, we tell them . . . ‘there are many names people call God. So that’s the same medically there are many ways what you call witchcraft is what we call a sickness. So this sickness we need to . . . investigate it and tell you what the exact sickness is and then we can give medication and the person will be okay.’ For example, when we had the outbreak here in my own community, they said . . . a witchcraft plane had a crashed. So as a result many people were dying. So we accepted the fact. We told them ‘okay, yes what you call a plane crash is what we call medically Ebola.’ So it’s like we buy the idea so that they can accept us and there we have a deal where we explain to them. We give them the right information. That’s when we will have an agreement and then they will listen to us and then we work as a team because [for] community infection you need community intervention so that at the end of the day you are able to achieve your aims. —Local staff, Sierra Leone</p>	
Addressing rumors with element of truth	<p>I would default to saying that it’s unhelpful to reject or disagree with those narratives that people are making money in the response because it is true. And if they’re rejected, if the response given to those individuals is, “No, no, like, you know, it’s nothing to do with that. That’s not why we’re here and you’re wrong,” then I think it makes it a lot more difficult to convey and convince them of other . . . It doesn’t present yourself as a trustworthy source of information. I suppose is the best way to put it. —International staff, Sierra Leone</p> <p>I mean, chlorine’s a corrosive gas, like it’s real . . . and they used it . . . And in fact the new guidelines for spraying of chlorine, do not include spraying because aerosolized chlorine (A) does not actually kill the virus, and (B) it gets it into your lungs and it can cause some pretty harmful effects on the lungs, especially for people who’ve been working in treatment centers or on decontamination teams, whatever and they’re constantly inhaling the sh** . . . A lot of people would say ‘oh, we don’t like the chlorine’ and I’d be like, ‘well, this is the protocol.’ And I think the logic that I had at the time was you’re more likely to die of Ebola than you are chlorine poisoning. Or like, you know, it’s a long-term impact. What we’re trying to do is stop you from dying today. —International staff, Sierra Leone</p>	When rumors have an element of truth, it is best to acknowledge it.

procedures in ETC/ETUs and health centers. Rumors that indicated mistrust of ETC/ETUs were seen by most EVD responders as being understandable given that in the early part of the outbreak family members or friends often went to the ETC/ETU and were never seen again. Increasing access to ETC/ETUs and modifying burial practices to allow safe family participation was perceived by participants to successfully reduce rumors, but more importantly, led to a more compassionate response that respected the humanity of those affected by the outbreak.

**Limitations**

This study had several limitations. EVD responders working with large international nongovernmental organizations were overrepresented in the sample due to the use of snowball sampling and the author’s own professional network. The lead author had worked in Sierra Leone during the 2014–2016 EVD outbreak, which resulted in higher levels of interconnection between participants who had worked in Sierra Leone and may have contributed to more similar opinions among

**TABLE 6.** Participant Quotations Regarding Organizational Response to Rumors of Health Workers Spreading Ebola Virus Disease in Sierra Leone

Theme	Quotation
Rumor identification	<p>I remember hearing it even before I was in Sierra Leone. I remember reading news stories. —International staff, Sierra Leone</p> <p>It was during the Monday morning meetings when I went to Kenema. So the SMAC team who was talking about this during the Monday morning meetings. —International staff, Sierra Leone</p> <p>Working in surveillance, I just remember seeing that there were some communities that were reluctant to report and I started asking the community members when I would go out for a certain case investigations with a surveillance team and then ask the surveillance team why they weren't speaking, why they weren't reporting, and they would tell me it was 1 of those 2 reasons, [that health care workers spread EVD or chlorine is deadly]. —International staff, Sierra Leone</p>
Element of truth in rumor	<p>I don't think that there's an impossibility that people who went into an Ebola Treatment Center and were negative didn't pick up anything while they were in the Ebola Treatment Center and then get sick because they were there. I do think as well that there is a truth to the fact that some health care workers were treating patients at home and not necessarily in full [infection prevention and control] procedures and because they were treating people at home then they themselves might have gotten sick and could have potentially then passed it on to other people if they were treating them as well . . . I think that it's not that there was no truth to the fact that health care workers can spread Ebola. I think that the rumor that health care workers were spreading Ebola to the extent that that was being feared was probably not true. If somebody was treating somebody and got sick and then continued to treat people while they were themselves sick, yes, they could absolutely have spread Ebola, but usually when people get sick, then they're too sick to continue being clinicians and not always, obviously, but most of the time I think that people are not necessarily able to provide medical care at that point. —International staff, Sierra Leone</p>
Negative effects of rumor	<p>During the time of Ebola, people were afraid to go to the hospital, people were afraid to go to the health centers. And so in Sierra Leone health workers were victims. So health workers were kicked out of their places that they are living . . . Landlords gave notice to health workers 'we want you no more, you are kicked out of your home Because if you are a health worker, you might have Ebola, and you might infect us.'" —Local staff, Sierra Leone</p>
Rumor management: organizational change	<p>You can't do an SBC campaign until you actually fix the [infection prevention and control] problem. So a big part of it is you've actually got to just make the [infection prevention and control] better at the level of the health facility and then you can start to bring people in and say let's go for a tour of this facility. Why don't you participate in an evaluation of the infection prevention and control of the facility, use the rumor phone call line to let us know if people are not wearing gloves or if they're reusing needles, you know, ask people to sort of be agents like have some kind of they have to be agents of making it better I think a lot of the time. It's about working with health care workers to understand that [infection prevention and control] is not an optional but it's also a way of keeping them safe from sickness. I think you've really got to attack it on both supply and demand side if you want to get some measure of trust back into health system or in a Health service. —International staff, Sierra Leone</p> <p>I think we just got to make a better . . . response. Right? I think one way to beat those types of rumors . . . is to put up results that show that essentially protect people and doesn't exacerbate the issues that we're all talking about. So I feel like that's really the only way to do that, the only way to really truly build trust after trust has been broken through a number of different things where it's rumors that have truth but are damaging nonetheless would be to build trust through proving that we can do this right. Which is can we reduce health care worker infections and nosocomial infections? When persons that are believed to be sick interact with health care workers and response workers as well. —International staff, Sierra Leone</p>
Rumor management: interpersonal communication	<p>We hire people from the communities educated about . . . Ebola, and they go out and talk to their people telling - giving them the right information about the virus, right information about how to . . . and so that you keep yourself safe. So we are doing the IEC: information, education, and communication, through them. Where we mobilize communities, we explain to them about tell them about the rumors that people are talking about because of communities first talk about the rumors, what they are hearing . . . we asked them about their information on the virus, on the outbreak, and they tell us what they know, where they had got the idea in from other people, and on what they are saying. We give them the right information, we give them posters, we give them</p>

*Continued*

TABLE 6. Continued

Theme	Quotation
Rumor management: mass media	<p>flyers, we show them videos that we would use about the outbreak. And we would get most of the people convinced that the rumors that they were hearing were not. . . . So this was one of the way that we are tackling about rumors. —Local staff, Sierra Leone</p> <p>They tried to hold up people who were survivors and people who were Ebola champions to show what their contribution had been in terms of fighting Ebola and the fact that basically that they were to be trusted and they highlighted a lot of the Ebola response workers and the health care workers in that, which was really cool. —International staff, Sierra Leone</p>

those participants. No incentive was provided for participating in the study so it is likely that participants were motivated primarily in their own interest in the topic, which may have led to some sampling bias. To encourage openness and honesty in participant interviews, participants were not asked to provide the name of the organization(s) they worked with. However, as organization names are not included in the data, it is not possible to take into account duplication in the organizations represented. The data were also limited due to the long amount of time that had passed between the EVD outbreak and the time of interviews.

### CONCLUSION

This study provides an overview of how rumors affected the 2014–2016 EVD response at an organizational level. While participants believed rumors had a clearly negative impact on health-seeking behavior, they were also instrumental in improving the EVD response. This study illustrates that rumors should be a key consideration in outbreak responses from the start of an outbreak response and should be considered in all aspects of the response, not only as an issue to be addressed via communication.

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**FIELD ACTION REPORT**

# Using mHealth to Improve Timeliness and Quality of Maternal and Newborn Health in the Primary Health Care System in Ethiopia

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## Key Findings

- The Last Ten Kilometers 2020 Project (L10K 2020) designed a user-friendly mobile health (mHealth) solution that bridged communication gaps between health care workers and health extension workers and improved quality services for women across the pregnancy continuum of care delivery in Ethiopia.
- Findings from routine monitoring and usability assessment showed that the mHealth application facilitated real-time information exchange with supervising health facilities in the primary health care system, as well as timely identification and registration of pregnant women, thereby increasing uptake of maternal health services across the continuum of pregnancy, childbirth, and postnatal stages.

## Key Implications

- Engaging with health sector stakeholders at all levels when developing, testing, and deploying the mHealth solution can effectively cultivate ownership and ensure skills and knowledge transfer at all levels.
- Using a cocreation strategy to develop an mHealth solution will help ensure the smooth handover and scalability of the model and build local capacity.
- Vigilance in consistently mitigating the challenges related to mHealth infrastructure, such as mobile data capacity, electricity, and internet connectivity, will reduce usage disruption, and bolster users' confidence in the app's capabilities.

## ABSTRACT

The Last Ten Kilometers 2020 Project (L10K 2020) designed a strategy for piloting, implementing, and scaling a mobile health (mHealth) digital solution to improve the quality of community-level maternal and child health service delivery in Ethiopia. L10K 2020 first conducted a landscape assessment to design a context-appropriate smartphone-based mHealth solution for the Health Extension Workers and tablets for their supervisors and the midwives managing the same clients at the health center level. These applications included multiple modules and packages including client registration and appointment management; follow-up and notifications; digital job aids for each of the maternal and child health program packages (for Health Extension Workers only); and referral and client tracking systems.

Findings from the process evaluation of the mHealth app usage and user experience indicated that the application was user-friendly and facilitated real-time information exchange, defaulter tracing, referral, and feedback systems. It improved the timely identification and registration of pregnant mothers. Adherence to treatment protocols also increased in all domains across the pregnancy continuum of care.

L10K 2020 has developed a user-friendly model for implementing mHealth solutions at the community level through stakeholder engagement across levels when developing, testing, and deploying the applications, which was critical to effectively cultivating ownership as well as skills and knowledge transfer at all levels. To replicate and scale this model, context-based scoping, resource analysis, and mapping are essential to determine the infrastructure, cost, time, risks, and key stakeholders involved throughout the implementation of the intervention. During implementation, vigilance in consistently mitigating the challenges related to mHealth infrastructure, such as mobile data capacity, electricity, smartphones and tablets, solar chargers, and internet connectivity, is critical for continued success.

## BACKGROUND

Mobile health (mHealth) refers to the use of wireless technology and devices (smartphones and tablets) to enhance access to information and improve the delivery of basic health care services.<sup>1,2</sup> Over the past 3 decades, a range of digital technologies have emerged for sharing and generating health and medical information,

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and the fields of mHealth and digital health have expanded globally.

Real-time access to reliable and accurate information to deliver consistent and high-quality health care is in high demand.<sup>3</sup> Globally, the application of mHealth solutions in the public health sector has contributed to improvements in the delivery of quality health care.<sup>4,5</sup> mHealth applications are widely acknowledged as a way to transform how clients and health providers exchange health information,<sup>4</sup> and they present the opportunity to improve the quality and timeliness of maternal and child health services and strengthen referral linkages, particularly in under-resourced health systems.<sup>4,6-11</sup>

Ethiopia achieved most of the Millennium Development Goals for health<sup>12</sup> through well-coordinated and extensive efforts made by the government, community, and implementing partners through the health extension program (HEP) and the expansion of primary health care services. The government and its partners have prioritized mobile technology as a potential solution to revitalize Ethiopia's HEP and the country's overall primary health care system.<sup>6,13</sup> In collaboration with the Ministry of Health (MOH), the Last Ten Kilometers 2020 Project (L10K 2020), implemented by JSI Research and Training Institute, Inc., designed an mHealth strategy to complement the existing MOH interactive voice response (IVR) system. This system allows Health Extension Workers (HEWs) to call and record information and send/review their activity reports to a centralized database system.

The primary aim of the L10K 2020 initiative was to improve delivery, timeliness, and quality of maternal and child health services by leveraging existing mHealth technology to support service provision and strengthen linkages within the primary health care units (PHCUs) (i.e., health centers and their catchment health posts). The specific objectives included the following:

1. Improve timeliness and coverage of reproductive, maternal, newborn, and child health (RMNCH) services
2. Improve the quality of RMNCH services
3. Improve referral care (number/proportion of cases referred from health post level to health centers) for RMNCH services by linking the health extension application with health center focal person application and by leveraging information communication technology (ICT)

Once the mHealth initiative was designed in line with MOH's vision, policies, and strategies, L10K 2020 designed incubation sites for learning to field test the initiative in Mirab Azernet woreda of Southern Nations, Nationalities, and People's Region (SNNPR) followed by expansion to other 3 rural districts: Dembecha (Amhara), Shebe Sombo (Oromia), and Werai Leke (Tigray).

This article outlines L10K 2020's experience introducing the mHealth strategy for improving RMNCH care. Specifically, it:

1. Describes the mHealth solution design and implementation process
2. Documents the mHealth solution usability and usage across the continuum of care
3. Examines the role of the mHealth solution in enhanced RMNCH service delivery
4. Describes the contribution of the mHealth solution to the electronic community health information system (eCHIS)
5. Documents lessons learned and challenges

To organize this article, we reviewed all project documents including the mHealth program plan, reports, findings from routine monitoring, and the implementation process evaluation. Process evaluation included a review of design, scoping, development, deployment, troubleshooting, application usage monitoring, and feedback systems used in the implementation of mHealth programs. We also reviewed the support and engagement of the health sector.

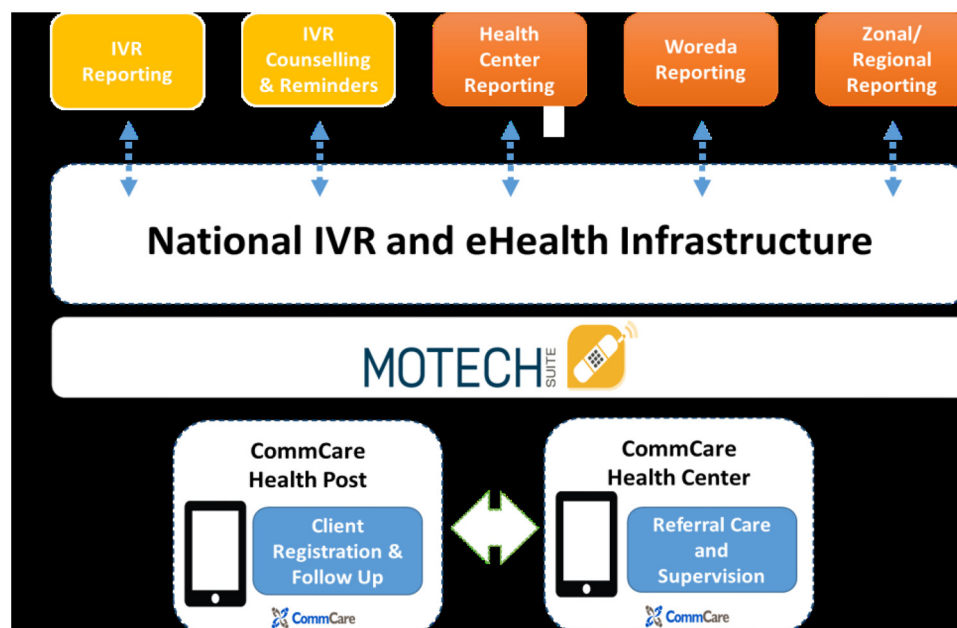
## ■ MHEALTH SOLUTION DESIGNING PROCESS

### Landscape Assessment

In 2015, L10K 2020 conducted a landscape assessment to investigate the local context and to propose a feasible technological architecture (Figure 1) aligned with L10K 2020 program objectives and opportunities as related to MOH objectives. The assessment covered the ICT infrastructure of the pilot sites, including mobile penetration for HEWs; mobile and data network coverage of health centers, health posts, and villages; availability of electricity or solar power for health centers and health posts for charging of devices; review of the national strategies related to eHealth and the key components of the health information system, including the community health information system, electronic health management system, the District Health Information System (DHIS2), and the MOH IVR

**The initiative aimed to improve delivery, timeliness, and quality of maternal and child health services and to strengthen linkages within PHCUs.**

**FIGURE 1.** Proposed Technology Architecture for mHealth Initiative in Ethiopia



Abbreviations: IVR, interactive voice response; mHealth, mobile health.

system. Core strengths and challenges in the existing system were identified through interviews, workflow observation, and document review. Midwives, HEWs and their supervisors, health information technicians, and program managers in the primary health care system were interviewed in the pilot woredas. The assessment findings showed that all the health centers in the proposed intervention areas of mHealth had mobile networks with mobile data networks and access to electric power. While 91% of the health posts had both mobile network and mobile data (internet) network coverage, only 25% and 12% of them had electric and solar power coverage, respectively. The findings of the landscape assessment were used as inputs to set the requirements and recommendations for the project implementation.

### mHealth Solutions Designing

Based on the findings of the landscape assessment and prior in-country use of the technology, CommCare\* was identified as an appropriate plat-

form for leveraging existing national efforts such as IVR and the electronic health information system infrastructure (Table 1). This platform could also support future MOH goals. Through a series of discussions, MOH agreed on the use of CommCare as a platform for the initiative with the expectation that implementation would complement the existing IVR system, support the national eHealth strategy, and be interoperable with the national health management information system (HMIS).

The electronic platform we chose is interoperable with the district health information software (DHIS2) platform on which Ethiopia’s HMIS is built, and it complies with a range of industry-recognized standards.

To launch the mHealth initiative, Dimagi—the technology partner of this initiative—drew upon global experience to develop the following mobile applications to the local context:

- HEW app: Supports HEWs in registration, prioritization, referral, and follow-up of RMNCH service delivery and provides automated job aids.

**The CommCare platform leveraged existing national efforts and could also support future MOH goals.**

\*CommCare ([www.commcarehq.org](http://www.commcarehq.org)) is an open source, easily customizable, and widely adopted mobile platform that supports frontline workers (FLWs) to track and support their clients with registration forms, checklists, SMS reminders, and multimedia in low-resource settings. CommCare was used as solution based on prior use in the country and opinion of experts that it can be easily customized to fit in to MOHs future plan. As such we would like to acknowledge that it is the product of Dimagi.

**TABLE 1.** Summary of Objectives of the mHealth Initiative in Ethiopia With Corresponding Technology Components

Health Objectives	Technology Components
1. Improve timeliness and coverage of RMNCH services provided by health posts	Leverage electronic platform for automated reminders and follow-up notifications and alerts
2. Improve the quality of RMNCH services provided by health posts	Leverage electronic platform for mobile electronic job aids (e.g., checklists) for Health Extension Workers
3. Improve referral care for RMNCH clients to health centers	Leverage electronic platform for improved data and referral workflow

Abbreviation: RMNCH, reproductive, maternal, newborn, and child health.

- Health center app: Allows midwives and health workers at the health center level to confirm referrals from HEWs for RMNCH services in the catchment area and share information with HEWs related to referral feedback, information about clients that received services at the health center without notifying the HEWs, and delivery notifications.
- HEW focal person app: Used by supervisors of the HEWs who are health care professionals based at the health center to provide remote technical and programmatic support and follow-up. The HEW focal application is uploaded on a smartphone with a mobile data network. The primary role of the HEW focal person/supervisor is to provide technical support to the HEWs on the HEP packages. Thus, the HEW focal person app was designed based on that person’s roles and responsibilities as described in the HEP implementation manual. The HEP focal person also provides support on HEW app operation, including troubleshooting and maintenance of the devices that need repair.
- Client notification (short message service [SMS]-based): Notifies clients of appointment reminder messages in local languages to their mobile number.

### Application Modules

Each HEW was provided a smartphone with the mHealth application to register new clients and track existing clients across the continuum of care (Figure 2). Once logged in, the HEW selects the relevant service or views the list of clients with pending appointments. If a client is not on the list, the HEW initiates a new registration for the client. If a client bypasses the health posts and goes to the health center for services, midwives or health workers in the maternal and child health unit register the client using a tablet-based application,

which automatically sends a notification to the HEWs at the health posts with the necessary information, including types of services provided, due date, and place of next appointment.

Since the initiative was implemented in the 4 bigger regions of the country, the interface was developed in different local languages including Amharic, Affan Oromo, and Tigrigna.

### Reminder, Follow-Up Alert, and Notification

Before the introduction of the mHealth platform, HEWs used a paper folder and tickler box systems to track client appointments for each service type. With the paper-based system, it was cumbersome to trace clients who missed appointments. The mobile applications complement this system by facilitating communication between clients and service providers at different levels because both providers can access updated information on the same client.

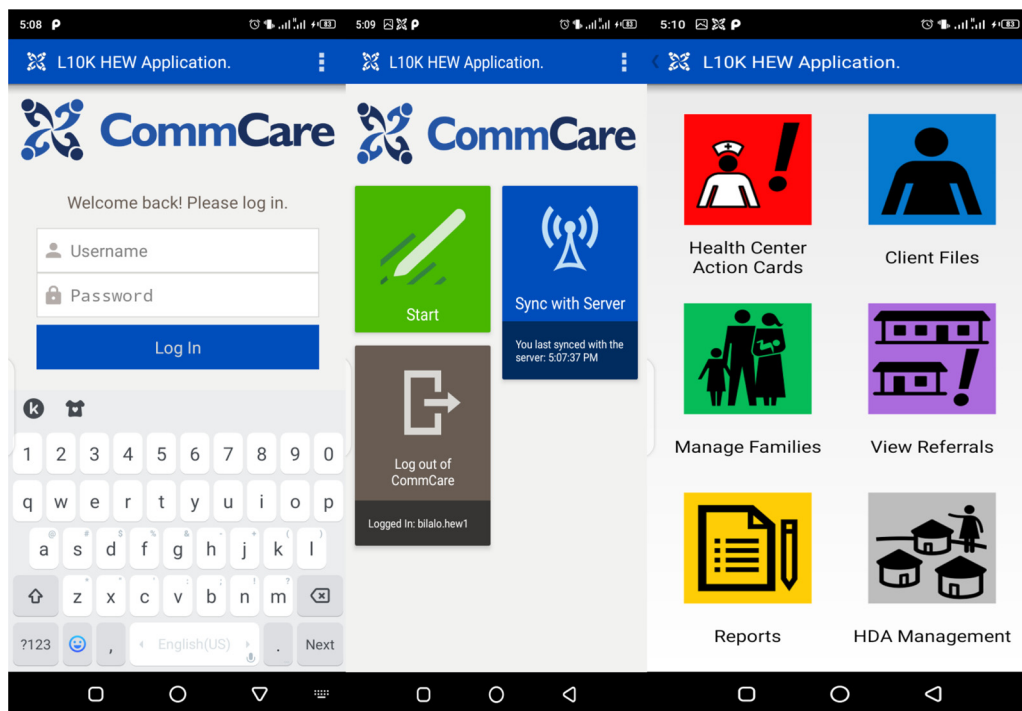
The RMNCH service registration system at the health center triggers mobile notifications for HEWs for the services that require visits at home or the health facility. When a woman or a child receives services at the health facility, their basic information is entered into a database and they are assigned to a specific HEW for follow-up. This information can be entered using a smartphone. These features work online and offline, but whenever a device can connect to the internet, the information is synced to the server. The HEW is then notified of the client who needs a follow-up visit. RMNCH clients (who have mobile phones and registered in the app), HEWs, and midwives receive these notifications via SMS or as an alert through the application on their mobile phones.

If a HEW misses a visit to her RMNCH client at home or health facility level, the system triggers alerts and notifications to be sent to both the

**The mobile application complements the system by facilitating communication between clients and service providers.**



**FIGURE 2.** Health Extension Workers CommCare-Based mHealth Application in Ethiopia for Client Registration and Tracking, Screenshots



Abbreviations: HDA, Health Development Army; HEW, Health Extension Worker; mHealth, mobile health; L10K 2020, Last Ten Kilometers 2020 Project.

HEW and her supervisor about an overdue visit. Notifications and alerts related to the appointment (i.e., due or missed), referral, and births are sent using the mobile app and SMS at both the health center and health post levels.

### **Electronic Job Aids for HEWs**

Job aids and counseling tools were automated for HEWs to ultimately replace the paper-based tools used during household visits and instead use mobile functions such as voice, video or audio clips, and images to enhance the quality and effectiveness of counseling on RMNCH services. Initially, both the paper-based and automated job aids and tools were used simultaneously until the automated system was fully functional. The automated job aids include workflow and protocol support through checklists and decision support; multimedia content played through phones to strengthen counseling and education; and educational messages that could be played through IVR to strengthen counseling and education (Figure 3).

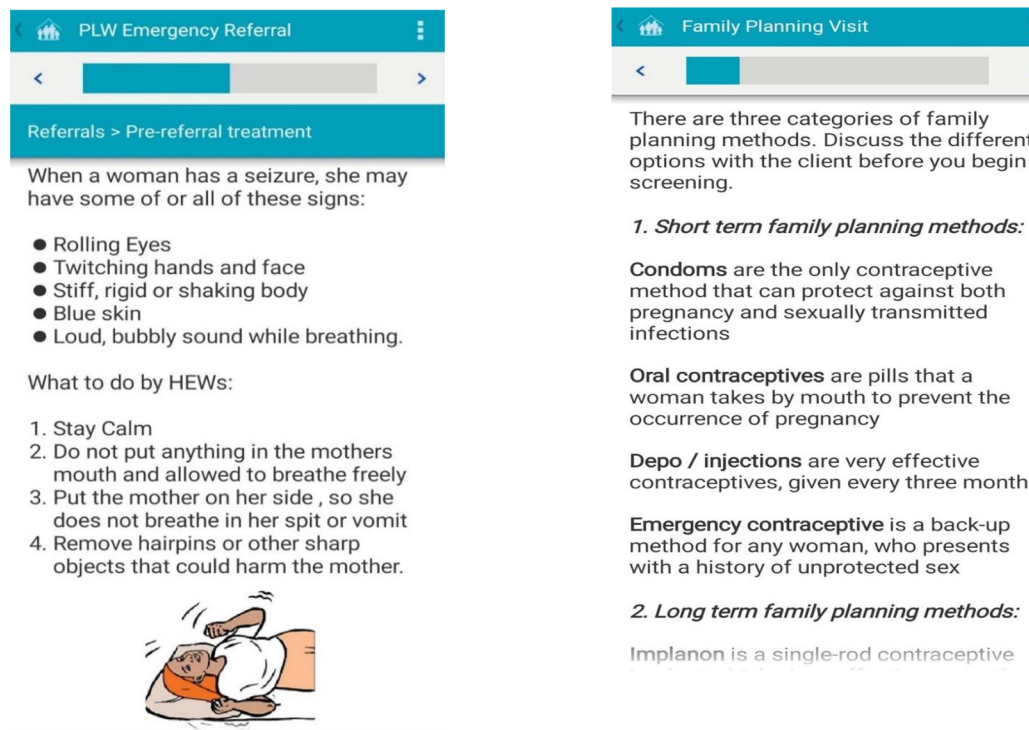
**The referral process was automated through the mobile application to strengthen communication and ensure completed referrals.**

### **Referral and Tracking**

Before the introduction of the mHealth platform, HEWs used to provide a paper-based referral slip, which a client would take to the health center. Health center staff would then write a counter referral or feedback slip with relevant information regarding services delivered and any follow-up care needed. This process was automated through the mobile application to strengthen communication and ensure completed 2-way referrals among different providers and facilities.

To strengthen referral care for mothers and newborns identified with complications during antenatal care (ANC), and postnatal care (PNC) or other visits, a closed user group system was created for HEWs and health centers to be able to call one another within the closed user groups to discuss a case under their care. Contact addresses of caregivers (mobile app users) were registered during the installation of the app with the possibility of updating changes. The providers can give a call and SMS when additional information is needed. Anyone within the closed user group can see

**FIGURE 3.** Sample Screenshots of the Electronic Job Aids Included in the CommCare-Based mHealth Application in Ethiopia



Abbreviations: HEW, Health Extension Worker; mHealth, mobile health; PLW, pregnant and lactating women.

ongoing activities and can call others in the group at no cost to themselves. This has enabled more direct communication between health center staff and HEWs.

When a HEW refers a client to the health center designated for health post/HEW using the app, the app automatically triggers a notification to the health center with the necessary referral information, including the planned visit date. If the client is late on the due date, health workers can communicate to the client and/or HEWs with the contact’s address registered in the app. Once the client arrives, the health center application is updated by health workers with the services delivered and whether any follow-up care is required from the HEW. This information is also available on the HEW apps as referral feedbacks and used to track referral status.

### IMPLEMENTATION

The mHealth platform was developed over 3 phases to achieve the full scope of L10K 2020 and MOH programmatic objectives (Figure 4). The health

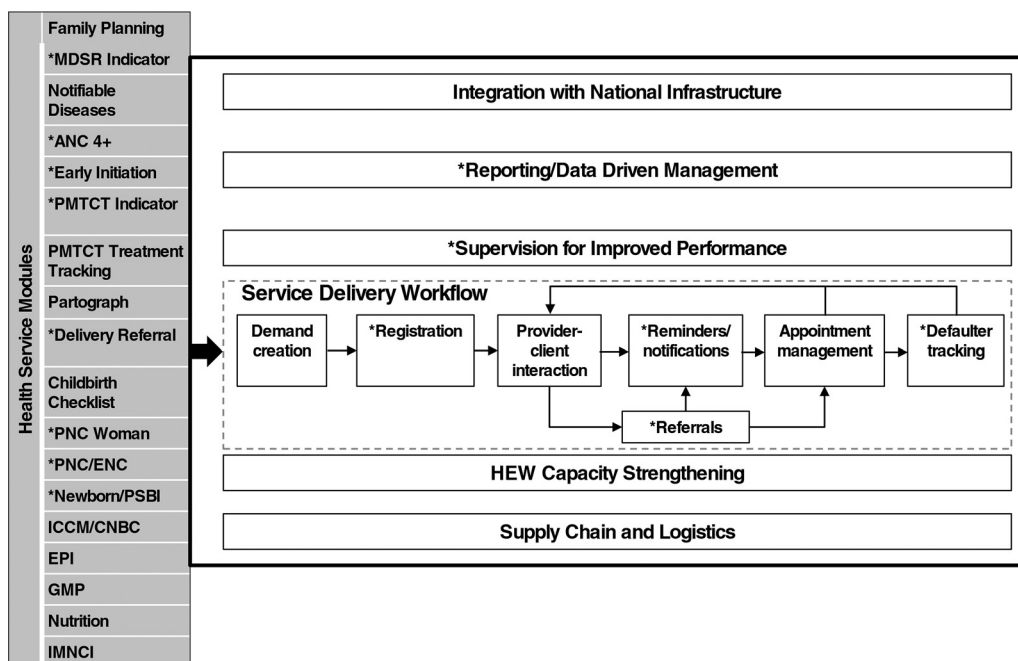
services prioritized by MOH are shown on the left, while the activities the platform is capable of supporting are on the right.

The phased release approach intended to test the application with the highest priority health interventions:

**Release 1:** This phase focused on quickly developing and releasing the highest priority modules while building organizational capacity for supporting and scaling the technology. The highest priority modules and activities were ANC, delivery, and PNC service recording, referral, and notification. The mobile tool was designed to meet programmatic needs while responding to the context of users and project stakeholders, the workflows required, and the constraints of the operating environment. Release 1 was developed and pilot-tested in Mirab Azernet Woreda in SNNPR with a population of 59,289 (based on the 2007 population and housing census of Ethiopia); 4 health centers, 19 health posts, and 35 HEWs.

**Release 2:** This phase refined and expanded the L10K 2020 priority modules from Release 1 and included the development of the second set

**FIGURE 4.** Health Service Modules Prioritized by the Ethiopia Ministry of Health (Left) and the CommCare Platform (Right)



Abbreviations: ANC, antenatal care; CBNC, community-based newborn care; ENC, essential newborn care; EPI, Expanded Program for Immunization; GMP, growth monitoring and promotion; HEW, Health Extension Worker; iCCM, integrated community-based case management of common childhood illnesses; IMNCI, integrated management of newborn and childhood illnesses; MDSR, maternal death surveillance and response; PNC, postnatal care; PMTCT, prevention of mother-to-child-transmission (of HIV); PSPI, possible serious bacterial infection.

of modules. The subset of modules in the second release included family planning, nutrition, child vaccinations, and maternal tetanus toxoid vaccinations. The pilot was expanded into 3 additional woredas with a total population of 426,159 according to the 2007 national census in 3 different regions, namely, Dembecha, Shabe Sombo, and Weire Leke and Medebay Zana woredas in Amhara, Oromia, and Tigray regions, respectively. These woredas have a total of 18 health centers, 84 health posts, 159 HEWs, and 203 mobile users.

**Release 3:** The module in this phase included integrated community case management and community-based newborn care. In addition to designing these programmatic modules, the team integrated feedback from Releases 1 and 2 to improve the usability of the system.

### Training and Material Distribution to mHealth Users

Midwives, HEWs, and their supervisors based at the health centers providing support to HEWs in

the intervention woredas received in-depth mHealth training (Table 2). The training provided orientation on smartphones and tablets, key application features, how to install and uninstall the application, logging in and out, syncing data, the application menu, settings, and navigational functionality. Through demonstration, exercises, and testing, the training focused on using the app to register clients, navigate existing client records, record services, use automated job aids for counseling, create referrals and give feedback, monitor performance, trace defaulters, and track reports. Case scenarios for every application module were designed as practical exercises, with 1 trainer per 5 trainees to provide intensive coaching and support during the practical sessions.

L10K 2020 distributed 308 smartphones to midwives, HEWs, and their supervisors after the training as per the number of HEWs at the health post level but only 1 communal smartphone was distributed to each health center irrespective of the number of midwives. Power banks and solar

**TABLE 2.** Number of mHealth App Users Trained in the Pilot Sites of L10K 2020, Ethiopia, May to December 2017

Region	HEWs and HWs Trained on mHealth			Total
	Training of Trainers	HEWs	Midwives and HEP Supervisors	
Amhara	5	58	40	103
Oromia	5	47	31	83
SNNP	6	35	28	69
Tigray	5	88	40	133
Total	21	228	139	388

Abbreviations: HEP, Health Extension Program; HEW, Health Extension Worker; HW, health worker; mHealth, mobile health; L10K 2020, Last Ten Kilometers 2020 Project.

chargers were also provided for lower-resourced facilities based on findings from the landscape assessment.

### Reporting, Supervision, and Performance Monitoring

Supervision and performance digital reports were made available to the HEWs and supervisors through the mobile app (Figure 5).

Regular service delivery reports can be generated using the app reporting modules, which were developed to be compatible with HMIS platforms. The app allows HEW supervisors and midwives to see real-time health post performance reports in their catchment through their mobile phones or tablets. These reports were regularly reviewed and discussed with the HEWs to provide immediate feedback and ensure timely action using the mHealth apps.

Weekly and monthly reports (e.g., workers’ activity, daily form submission, completion time), key indicators by facility (e.g., ANC and PNC coverage), and individual-level performance reports for HEWs, focal persons, and midwives were developed and used for routine performance monitoring through the app. App usage was remotely monitored at the national level with a biweekly feedback system for PHCUs and woreda health offices for service provision.

### Troubleshooting

Troubleshooting is a logical and systematic problem-solving approach rather than simply trying things at random. In the mHealth initiative, operational processes for troubleshooting technical issues with the application and with mobile devices were established to manage mobile and app-related problems. Mobile device and application-related bugs were

regularly tracked by HEW supervisors. Observations from routine monitoring visits and the usability assessment showed that the most common problems faced by users include malfunctioning charging equipment, phone app crash and lock-out, hardware damage, and mHealth app software uninstalling. A troubleshooting guide was developed and training was provided for HEP supervisors and health sector health information technicians and other program staff at the PHCU and woreda levels. These health workers were able to address most of the common problems using the troubleshooting guide and with remote support from L10K 2020’s regional and central teams. The L10K 2020 teams also provided ad hoc and routine onsite support and supervision to end-users.

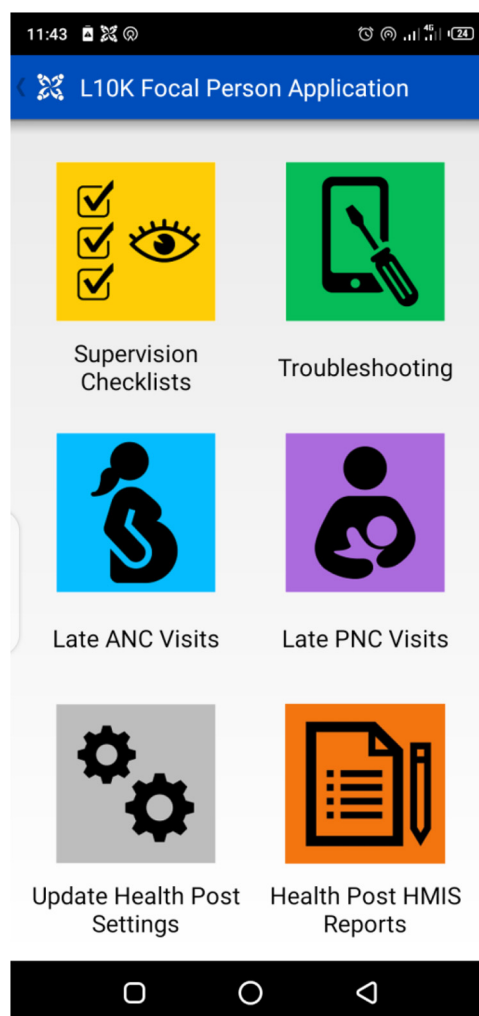
### ■ USABILITY AND CONTRIBUTION OF MHEALTH INITIATIVE ON RMNCH SERVICE DELIVERY

L10K 2020 conducted a process evaluation after a year of implementation to identify the implementation strengths and common challenges users faced when adopting the L10K 2020 mobile app system. The study employed purposive sampling techniques to select high- and low-performing app users in the study sites. The study participants include 20 HEWs, 8 midwives, and 6 HEW supervisors.

mHealth app usage and user experiences were evaluated by reviewing system data and key informant interviews of the 34 users. mHealth app usability assessment was also conducted through interviews with the 20 HEWs.

Of 20 HEWs that participated in the usability assessment, 19 preferred the electronic mHealth app over the paper-based client tracking system.

**Nearly all the HEWs interviewed on their experience using the mHealth app preferred the app over the paper-based tracking system.**

**FIGURE 5.** Health Extension Workers (HEWs) Supervisor/Focal Person mHealth Application Screenshots

Abbreviations: ANC, antenatal care; HMIS, health management information system; mHealth, mobile health; PNC, postnatal care.

**Box 1** highlights specific benefits as reported by end-users.

*Using the paper-based system was difficult to address all eligible clients for services. It was also challenging to access information about pregnant women who received services at the health center and higher health facilities [through self-referral]. Now, we can trace defaulters and follow clients easily, provide timely services, and access information about the clients who bypass our health posts through application notifications and referral linkages. It also saved our time and effort because we are not expected to go to each village for notifying clients about each visit. Instead, we can send a message or call the client or Women's Development Army member using the mobile phone. —HEW, 24 years old, Oromia*

The major challenges (**Box 2** includes details) that were collected from end-users through routine reports, field visits, and evaluation were reported to the project management as part of the project's monitoring and follow-up and for timely decision making to correct problems. One of the challenges was the high turnover of trained HEWs and health workers. About half of the HEWs trained on the mHealth app left their duty station for different reasons including resignation, education opportunities, or transfer within a year of the implementation period. There were also very few health information technicians to handle the fluctuating demand for ICT support to fix mobile devices and mHealth application bugs. Users

worried about losing their mobile devices, and fear of damage or loss meant they sometimes left the devices at home during a community visit. From a total of 308 smartphones distributed for mHealth users, about 7 (3%) tablets were reportedly lost, and 86 (28%) were damaged within the first year of pilot implementation.

Each health center received a single mobile device that needed to be used across multiple service delivery points (i.e., ANC, delivery, PNC, child health), which limited usage by health facility staff. As a result, health center app users—especially midwives who used communal devices—used different strategies to reduce clients' waiting time during service provision such as through exchanging the device based on caseload across the different service delivery points, assigning a focal person to register cases using the app, transferring cases from registration book to the app, doing a daily audit of clients that received services, and re-recording missed data in the app.

HEWs reported that although solar chargers and power banks were provided for low-resource health posts, they did not always work.

*It is difficult to have the risk of mobile device or tablet loss. We [also] have no power source at the health post and usually, we send the mobile devices through another person for charging to the nearby town. We also travel a long distance alone for outreach services or home visits with two mobiles, including our phones. In such a situation, we worried a lot not to lose them . . . and we usually left the mobile device at home though it is very important for our work. —HEW, 30 years old, Tigray*

### Usability of the mHealth Solution

Sixteen of the 20 HEWs who used the mHealth app reported that it was easy and enjoyable to use and they understood its intent, purpose, and potential for impact in their job. HEWs who were engaged in the usability study rated core features of the application as “easy” to “very easy” after being asked to simulate application use in real-life situations. Despite the majority of users (80%) having no prior experience with smartphones or apps in their personal lives, users were generally confident in finding the app on the phone and completing basic form navigations. This suggests that a user's lack of familiarity with smartphone technology is not necessarily a key barrier to increasing app usage.

Many mHealth users also demonstrated a general understanding of how the app could improve the efforts of HEWs and health centers in case

#### BOX 1. Benefits Reported in Using the mHealth App in Ethiopia

- Facilitates remote performance tracking and monitoring
- Enhances quality and timely care for clients
- Provides reliable, quality, and on-time data for action
- Supports access client's previous and current clinical information
- Strengthens 2-way referral linkages, notifications, and feedback systems with the primary health care unit system
- Provides dynamic job aids to improve clinical skills and client counseling
- Promotes early pregnancy identification and tracking clients in their reproductive, maternal, newborn, and child health care

#### BOX 2. Challenges Reported in Using the mHealth App in Ethiopia

- Work overload when using the app and the existing paper-based recording system
- Fear of theft and loss of phones and tablets
- Burden of carrying multiple high-value devices
- Shortages of phone and tablets require sharing devices across service delivery points
- Delays in repairing or replacing equipment
- Use of mobile devices for other purposes (e.g., video recording, installing other mobile apps), which can affect the app's functionality
- Delays in reporting nonfunctional device/app and untimely maintenance
- Interruptions of mobile data connection and unavailability of consistent mobile airtime

management. HEWs demonstrated high literacy levels and general comfort in reading text questions and counseling guides on the small phone screen. Many users also demonstrated intuitive ease in playing the audio recordings associated with counseling messages.

### Standardized and Quality Service Delivery

mHealth users reported that they used the app as a job aid and a comprehensive tool to record and send data, monitor services, and exchange referral and reminder messages and notifications. HEWs explained that they used the mHealth application as a job aid and counseling guide during service provision. They reported that they believed clients' adherence to the pregnancy continuum of care improved as a result of standardized care and counseling services. mHealth application users also described the app as a useful tool that helped them improve interactions, linkages between facilities, and timely exchange of real-time

**Despite 80% of users having no prior experience with smartphones or apps, users were generally confident in finding the app on the phone and completing basic form navigations.**

information and achieve higher quality provision of standardized services.

*mHealth enables us to have real-time information and deliver quality and timely services for pregnant and post-natal women. The paper-based system takes time and extra effort to get the previous history of the clients about specific services, but this mHealth app enabled us to access all types of information about the clients. We used it as a checklist for our services. This simplified our routine job more than ever on the provision of standardized care for clients. —HEW, 26 years old, Oromia*

### Improved Linkage and Real-Time Information Exchange at the PHCUs

The mHealth strategy bridged communication gaps between health care workers and HEWs. It assisted HEWs to more easily identify pregnancy danger signs and complications, leading to more timely referrals through the app's electronic forms.

Users reported that the mHealth app helped HEWs and health workers to exchange information and to monitor each client's appointment dates, location, and types of RMNCH services. The app also helped them to easily identify and trace defaulters and bring them back into care.

*With a paper-based system, it was difficult to know and retrieve late users for RMNCH services, especially the areas with scattered populations and challenging topography, but now we can trace them and can provide services per the schedule. It also supports us to pay attention to when services need to be scheduled services and improved our interaction with clients to improve the coverage of MNCH. —HEW, 28 years old, Amhara*

### Pregnancy Registration and Adherence to Treatment Protocols and Continuity of Care

Early identification and registration of pregnant women is a critical entry point to providing focused ANC, delivery, and PNC services. At the beginning of the mHealth initiative, the majority of the pregnant women were registered by HEWs in the third trimester and or later. Data from the mHealth app showed an increase in pregnant mother registration by the HEWs in the first and second trimesters at mHealth PHCU pilot sites as a result of case referrals and notification through the app (Figure 6).

Key indicators of the continuum of maternal and child care services such as ANC, delivery assisted by a skilled birth attendant, and PNC services showed a good level of adherence to RMNCH

care-seeking in the implementation period. Among births registered in mHealth apps, 83% of clients were able to receive PNC, with 28% of these clients receiving it within 2 days of giving birth. This better coverage in the implementation period as compared with the previous trend in the woreda might be due to the use of the mHealth apps for birth notification and a reminder that improves the tracking system for services in the pregnancy continuum of care. The below quote corroborates this finding.

*The app helped us to remotely follow HEW performance. We have access to see all client information in our catchment area who registered in the app, such as clients' due dates for ANC, delivery, and PNC. We can identify clients who are late in receiving those services, the reason for the delay, and take timely corrective measures by discussing with the HEW. Our coverage has improved as a result of our close follow-up through the app and gives us room to quickly fix problems. —HEW supervisor, 24 years old, Amhara*

In Ethiopia, most women discontinued receiving care at the postpartum stage.<sup>6,13</sup> Most women were receiving PNC services after receiving delivery care, and this could be due to the program effect (Figure 7).

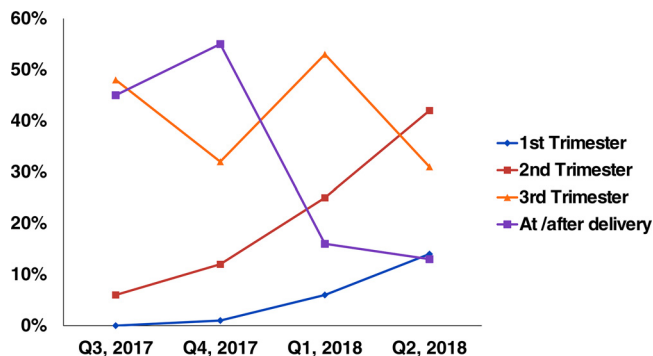
## MHEALTH APP USED AT SCALE FOR ECHIS PROGRAM

The mHealth app was designed to be incorporated into the envisioned eCHIS plan of the country's health system. Realizing the learning from the implementation of the mHealth initiative and its potential and wide applicability, the MOH took over the mHealth platform including the development of further programmatic modules and ongoing maintenance for large-scale implementation of the national eCHIS. L10K 2020 worked with MOH to adapt the existing mHealth tools to meet the requirements of the eCHIS and is supporting MOH to scale up the eCHIS to 8,000 more HEWs by 2025 to improve the coverage and quality of primary care through data-based performance. The eCHIS application digitizes the existing paper-based, manual family folder, and service workflows to record and report household member health and related data. The system captures data on the HEP and other community-level services. Improving HEP performance and community health outcomes was one of the objectives of the system.

**The mHealth strategy bridged communication gaps between health care workers and HEWs and helped HEWs to more easily identify pregnancy danger signs and complications.**

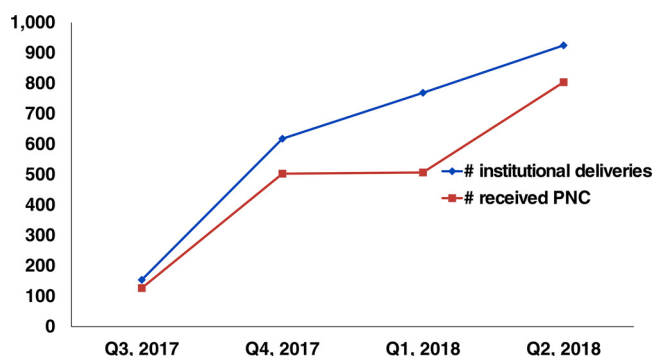
**Realizing the mHealth initiative's potential and wide applicability, the MOH took over the mHealth platform, including developing further programmatic modules and maintenance for large-scale implementation of the national eCHIS.**

**FIGURE 6.** Increased Early Pregnancy Registration as a Result of the App at L10K 2020 mHealth Pilot Project Sites in Ethiopia, July 2017–June 2018



Abbreviations: mHealth, mobile health; L10K 2020, Last Ten Kilometers 2020 Project.

**FIGURE 7.** Trends of Delivery and Postnatal Care in mHealth Pilot Sites in Ethiopia, 2017–2018



Abbreviations: mHealth, mobile health; PNC, postnatal care.

L10K 2020 and Dimagi provided technical support to MOH experts on the deployment and integration process of the mHealth platform to eCHIS. MOH officials and L10K 2020 experts developed a plan to install a locally hosted instance of the mobile platform to run the eCHIS application and build the capacity of local experts to effectively hand over the integration of the eCHIS system. Major activities accomplished by L10K 2020 during the transition to eCHIS included: (1) local installation of the mobile platform, (2) capacity building of local experts on server set-up and use of the front-end features, and use and customization of the mobile android application; and (3) content review of the eCHIS family folder module. L10K 2020 facilitated national and regional master technical and management training of

trainers, supported cascading of the training to end-users, and procured and distributed approximately 1,150 tablets for eCHIS end-users at health posts. As of March 2020, the eCHIS app had been implemented at 1,386 health posts in 134 agrarian woredas, with the MOH planning to scale it nationwide.

**LESSONS LEARNED**

L10K 2020’s health sector stakeholder engagement across levels when developing, testing, and deploying the mHealth applications was critical to effectively cultivating ownership as well as ensuring skills and knowledge transfer at all levels. Smooth handover and fully-scaled government use depended on a sound, cocreated strategy to sustainably build local capacity, develop clear operational troubleshooting and ICT-supported guidance



**The landscape assessment was the most important factor in understanding opportunities, resources, and barriers affecting planning and benchmarking toward maximizing the use of the app and integrating it with the eCHIS vision.**

tools, and iterating implementation based on experience. The landscape assessment was the most important factor in understanding opportunities, resources, and barriers affecting planning and benchmarking toward maximizing the use of the app and integrating it with the nascent eCHIS vision.

Despite the numerous benefits of the mHealth initiative, continued success will require vigilance in consistently mitigating the following challenges:

- There was a critical shortage of infrastructure such as mobile data capacity, electricity, smartphones and tablets, and solar chargers to effectively leverage the benefits of mobile technology. Gaps identified through routine monitoring include delayed distribution of mobile cards, delayed replacement of damaged or lost mobile devices, and failure in timely reporting of nonfunctional devices or apps.
- mHealth app implementation at the intervention sites was strained by technology infrastructural challenges such as limited data transfer capacity due to weak internet signal, particularly for the variety of mobile devices used among end-users.
- Protracted and widespread internet connectivity interruption due to a national mobile data blackout during several months of piloting the mHealth initiative affected the quality and timely information exchanges within the PHCUs.
- HEW supervisors and program managers were not closely monitoring the service delivery data entered into the application or using these data to make decisions.

Hence, addressing these issues would reduce individual usage disruptions and engender users' confidence in, reliance upon, and consistent use of the app's sound capabilities. Also, creating ownership and close monitoring while integrating with the existing system is a much-needed effort because the use of mHealth tools by itself could not incentivize the health system.

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SHORT REPORT

# Translating Implementation Experiences and Lessons Learned From Polio Eradication Into a Global Health Course: Insights From an International Consortium

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## Key Findings

- Using international collaborations to develop educational materials is an effective approach to obtaining a wealth of information, perspectives, and context and to facilitating local and global ownership and uptake of the educational materials.
- While these collaborations can involve challenges for curriculum design, content development, and team cohesion, in-person meetings and early recognition of institutional hierarchies can mitigate challenges and enhance team strengths.

## Key Implications

- Collaborations should plan for and adjust approaches for hierarchies ahead of time and ensure significant in-person meeting time to make the most of international collaboration.

## ABSTRACT

Lessons learned from one global health program can inform responses to challenges faced by other programs. One way to disseminate these lessons is through courses. However, such courses are often delivered by and taught to people based in high-income countries and thus may not present a truly global perspective. The Synthesis and Translation of Research and Innovations from Polio Eradication (STRIFE) is a consortium of 8 institutions in Afghanistan, Bangladesh, the Democratic Republic of the Congo, Ethiopia, India, Indonesia, Nigeria, and the United States that seeks to carry out such a transfer of the lessons learned in polio eradication. This short report describes the collaborative process of developing content and curriculum for an international course, the learnings that emerged, the barriers we faced, and recommendations for future similar efforts. Various parts of our course were developed by teams of researchers from countries across South Asia and sub-Saharan Africa. We held a series of regional in-person team meetings hosted in different countries to improve rapport and provide a chance to work together in person. The course content reflects the diversity of team members' knowledge in a variety of contexts. Challenges to this effort included team coordination (e.g., scheduling across time zones); hierarchies across and between countries; and the coronavirus disease (COVID-19) pandemic. We recommend planning for these hierarchies ahead of time and ensuring significant in-person meeting time to make the most of international collaboration.

## INTRODUCTION

The knowledge amassed in the process of implementing a global health initiative can enhance frameworks for prevention, care, and treatment for a broader range of health conditions. Lessons learned from one program can profoundly shape the response to the challenges faced in other programs. For example, lessons learned from the HIV/AIDS epidemic have been leveraged to address noncommunicable diseases<sup>1</sup> and Ebola-related stigma.<sup>2</sup> However, widespread uptake of key public health lessons (both positive and negative) does not occur passively; the knowledge gained from one initiative will not automatically transfer to another without active strategies.<sup>3–5</sup> Public health practitioners tend to produce narratives that validate their work, but more complex accounts that integrate an understanding of

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politics and history are key to truly replicating solutions to global health problems.<sup>6</sup>

A major way of delivering this knowledge is through education, using courses that explore the complexities of lessons learned in ways that allow knowledge gained in one program to benefit others. Courses with a global perspective, however, are often taught by and for residents of high-income countries, leaving out those in low- and middle-income countries (LMICs) who are most in a position to act on lessons learned.<sup>7</sup> Massive open online courses (MOOCs) are a powerful way to reach a global audience, but most MOOCs on major platforms are developed by academics based in high-income countries, a reflection of the resources required to launch them.<sup>8</sup> If a MOOC is truly to reach a global audience, we felt that the lessons and experiences that go into its creation and the expertise around teaching reflected in its instructors should be similarly global. Further, many students across the globe would be best reached not by MOOCs, but by in-person courses taught by local experts. Hence, our course was designed by a global team that could deliver both MOOCs and in-person content to reach students in a variety of public health contexts across the world.

The Synthesis and Translation of Research and Innovations from Polio Eradication (STRIPE) project is a collaboration of researchers from 8 countries (Afghanistan, Bangladesh, the Democratic Republic of the Congo [DRC], Ethiopia, India, Indonesia, Nigeria, and the United States) working to collect, synthesize, and disseminate lessons learned from polio eradication activities (Table 1), with advice from a technical advisory committee (TAC) composed of various global stakeholders.<sup>9</sup> The scale of polio eradication, a global initiative that has been carried out in more than 200 countries and currently has a budget of more than \$1 billion a year, has resulted in a wealth of experiences in varied contexts that can be adapted by other health initiatives. Polio lessons are especially relevant for mass vaccination programs aiming to eliminate or eradicate a disease, and there are many direct lessons for coronavirus disease (COVID-19) control efforts as well as measles elimination efforts. But many topics are more broadly relevant: global agenda setting, data collection and management, social mobilization, and human resource management, to name a few.

We aim to bring the lessons and experiences from the polio eradication effort into academic and training programs for various global health audiences and thus facilitate the active transfer of tacit knowledge from polio to global health actors,

students, and other health initiatives. We used mixed methods to collect lessons learned from diverse stakeholders who have been involved in the planning and implementation of polio eradication activities at the global level and national and sub-national levels in the 7 partner countries.<sup>9</sup> We are disseminating our findings through a variety of channels. This article focuses on our global health course, which explores lessons learned from polio eradication through the lens of implementation science. The goals of the course mirror the goals of implementation science more broadly—to bring the findings of research into routine practice to improve health services.

The course is available online, free of charge, and as several MOOCs hosted on the project website and FutureLearn (a digital education platform), enabling global online access. The course is also being delivered in person by the STRIPE consortium members across the world. The course materials, including lecture recordings and PowerPoint slides, are freely available for use by instructors who wish to integrate this material into existing courses. This short report describes the collaborative process of developing the course with academic partners from institutions across both LMICs and high-income countries, and it outlines our lessons learned from such collaborative processes.

## ■ THE PROCESS OF CREATING AN ADAPTABLE COURSE WITH GLOBAL REACH

The experiences of polio eradication have relevance across a wide range of global health theory and practice, from global alliance building to surveillance systems to community engagement to health equity. We determined the topics to include in our course during a 2-day consortium-wide meeting held in April 2019, in Baltimore, Maryland, USA, where researchers from all consortium institutions came together to present and discuss initial findings from our research. Before the meeting, we listed potential topics to be covered in the course, drawing both on the global health literature<sup>10</sup> and preliminary data emerging from our project. We then completed a consensus-building exercise during the meeting to determine which of these topics we should include. The consortium agreed on a final set of 10 knowledge domains (Table 2).

We felt strongly that this course should be driven by experienced researchers and educators based in the domains described in the course who

**This article focuses on our global health course, which explores lessons learned from polio eradication through the lens of implementation science and ultimately to bring the findings of research into routine practice to improve health services.**

**TABLE 1.** Synthesis and Translation of Research and Innovations From Polio Eradication Project Consortium Partner Institutions

Partner Institution and Country
1. [REDACTED], Afghanistan
2. BRAC James P. Grant School of Public Health, BRAC University, Bangladesh
3. School of Public Health, University of Kinshasa, the Democratic Republic of the Congo
4. School of Public Health, Addis Ababa University, Ethiopia
5. Indian Institute of Health Management Research University, India
6. Faculty of Medicine, Public Health and Nursing, Gadjah Mada University, Indonesia
7. College of Medicine, University of Ibadan, Nigeria
8. Johns Hopkins Bloomberg School of Public Health, USA

The process of international collaboration across contexts facilitated diverse participation but was logistically challenging.

were familiar with the diverse educational contexts in which the course would be taught. We also decided that, given the interdisciplinary nature of implementation science and relevance for diverse global health programs, each knowledge domain in the course should teach relevant core competencies in implementation science.<sup>11</sup> This decision led to a process of international collaboration across contexts, which facilitated diverse participation but was logistically challenging. The Figure presents the overall timeline of this process.

### Team Development

At our initial meeting in April 2019, we distributed a brief survey asking consortium researchers to identify topic areas from the course in which they had expertise, interest in developing curriculum, and substantial familiarity with the data from our research project. We used the results of the survey to form “teaching teams” for each topical area, which were then tasked with working together to develop the curriculum for that topic. We sought to achieve gender and geographical representation (i.e., members from both Asian and African countries) in each team. This was the first point in the overall project when individuals from different countries were asked to work extensively together and not just with others within their country teams. Each teaching team was assigned a facilitator from Johns Hopkins University (JHU) who had knowledge of that learning domain and expertise in curriculum development.

### Regional Meetings

We held 3 regional meetings to facilitate curriculum development. The first meeting was held in

Dhaka, Bangladesh, in June 2019, following the Global Conference on Implementation Science and Scale-up. Members from each of the consortium institutions were invited to attend; in addition to JHU members, 4 of the 7 partner institutions were represented (from Bangladesh, India, Indonesia, and Nigeria). During this meeting, we discussed course design, expected outputs, and proposed timelines for completing drafts of lectures and case studies. Teaching teams met to discuss their knowledge domains, develop outlines for the lectures, brainstorm potential case studies based on their data, and divide tasks among team members. We shared this information with partners who could not be present for feedback.

The second regional meeting was held in early August 2019 in Ibadan, Nigeria. Before the meeting in Nigeria, teaching team members submitted draft lectures. In addition to providing feedback on these lectures, attendees also reviewed 1 case study, which prompted discussion on how to change existing draft cases. The teams set the next set of deadlines in preparation for the final regional meeting.

The third regional meeting was hosted in Yogyakarta, Indonesia, in late August 2019. At this meeting, we discussed our varied experiences with the case-based learning method. Small groups met to review drafts of lectures, outline major revisions, and identify gaps where additional research data needed to be incorporated. This meeting was attended by collaborators from Afghanistan, Bangladesh, India, Indonesia, and the United States.

### Validation

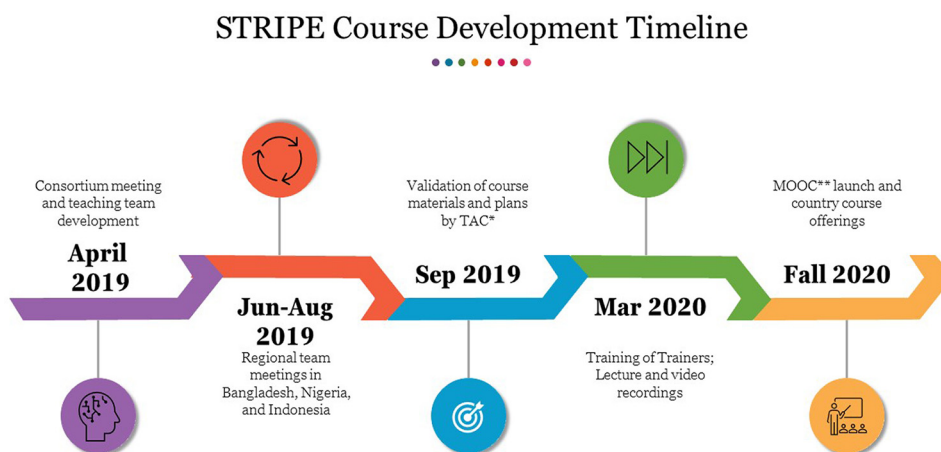
Each teaching team finalized their lecture materials, accompanying teaching notes, and case studies in preparation for a TAC meeting in September 2019. The TAC is composed of individuals representing faculty from schools of public health, Ministries of Health, and nongovernmental organizations in low-, middle-, and high-income countries, as well as experts representing core Global Polio Eradication Initiative partners (World Health Organization, United Nations Children’s Fund, Bill & Melinda Gates Foundation, U.S. Centers for Disease Control and Prevention, Rotary International). At the meeting, TAC members provided useful feedback on key lessons learned to include and highlight in the course (e.g., to highlight specific experiences relevant for the lecture content, redescribing content to appeal to a diverse global audience). TAC members subsequently reviewed the course material relevant to each of their areas of expertise.

**TABLE 2.** Knowledge Domains Included in Global Health Course on Polio Eradication

Global Health Knowledge Domains	Domain Overview <sup>a</sup>
1. Global alliances	History of the global polio eradication alliance and its trajectory. Provides strategies for alliance building, focusing on how approaches differ depending on health systems, structures, and political contexts.
2. Policy engagement and influence	Defines policy engagement and its importance in global disease control programs. Explores the importance of process, stakeholders, and contexts in considering policy engagement approaches.
3. Field epidemiology and outbreak response	Explores surveillance as a decision support system for planned as well as outbreak responses.
4. Data for decision making	Explores various data collected through polio eradication activities and how they are interpreted to support program decision making. Considers factors that influence the quality of data.
5. Health communications and behavior change	The role of health communications for behavior change and the key principles in designing communication tools, focusing on how they are adapted and refined across different phases of a program and across contexts.
6. Community engagement	Importance of community engagement in health programs and strategies for engaging communities. Considers its key role in long-term health programming and trust building.
7. Planning and management	Considers key elements of planning and management, including microplanning and monitoring.
8. Health commodities, logistics, and supply	Importance of and best practices in logistics management for public health programs, especially large-scale and multicountry programs.
9. Human resources for health	Considers who polio workers are and the challenges they face in achieving disease control, as well as critical factors to consider in acquiring, training, and deploying appropriate health care workers.
10. Health equity and social justice	Describes social determinants of health and how global disease control programs shape global equity and equality. Considers the impact on hard-to-reach populations.

<sup>a</sup>Materials for all domains can be found here: <https://stripe.jhu.edu/learning-hub/global-health-course/>.

**FIGURE.** Synthesis and Translation of Research and Innovations From Polio Eradication (STRIFE) Course Development Timeline



MOOC, massive open online course; TAC, technical advisory committee.

## Training of Trainers

A final meeting was held in Baltimore in March 2020, attended by collaborators from Afghanistan, Bangladesh, DRC, Ethiopia, Nigeria, and the United States, while members from India joined remotely. During the meeting, we discussed and finalized course structure and flow, identified course assignments and activities, and shared strategies on teaching techniques for the on-site course. In addition, lectures and discussions for the MOOC were recorded with support from Johns Hopkins Bloomberg School of Public Health's Center for Teaching and Learning (CTL). CTL provides training, instructional design services, recording studios, and support for online course development—the sort of MOOC infrastructure found most often at well-resourced institutions.

Subsequently, CTL along with the JHU team formatted and standardized all course materials, including lecture slides, recordings, and case studies, and then packaged the materials both to distribute online and to meet the needs of individual country team's in-person iterations of the course.

## ■ DESIGNING CURRICULUM AND DEVELOPING CONTENT

One major challenge in developing a course to be taught in so many different settings to many diverse groups of learners is that the background knowledge of those learners will vary widely. To engage and reach a diverse student body, we aimed to create an adaptable course that instructors could tailor both to their region and their students' experience levels. Hence, for each major topic listed in [Table 1](#), we developed 2 lectures summarizing some major lessons learned from polio in that area. One lecture is appropriate for students with little or no background in the topic in question and uses polio examples to illustrate key basic concepts. For example, the introductory lecture on human resources for health covers basic concepts in the area through the example of the polio workforce. A second lecture in each topic area delves deeper into more complex lessons learned applicable to other health programs. It is designed to be used as a stand-alone lecture for advanced students or as a follow-on to the basic lecture in each topical area. This second lecture has many more opportunities for student reflection, engagement, and application to other health programs. For example, the second lecture on human resources for health explores issues of gender, incentive structure, and lethal violence, all of which have been complex issues for polio eradicators in

many contexts. Thinking through these issues has direct utility for the design and implementation of other health programs. The MOOCs include both the basic and the advanced material, so that less experienced learners have the background they need, while more experienced learners can access key information.

All lectures draw on core learning themes and competencies in implementation science. We paired each lecture with readings to extend knowledge—open-access readings for the MOOCs and a broader range for in-person courses. We also developed case studies for each topic area that dig deeper into implementation challenges in a particular context. They provide students a chance to apply and extend the material presented in lectures, or they can be used alone with more advanced students or in other contexts. Both the lectures and the case studies include a range of perspectives shared with us during the research we did for this project, from global-level policymakers to frontline workers. [Table 3](#) provides links to access each MOOC in addition to a description, the core learning themes, and competencies addressed.

## ■ INTERNATIONAL ACADEMIC COLLABORATIONS: RICH AND REWARDING

The process of working collaboratively with colleagues across the world facilitated diverse perspectives and learning exchanges within the consortium, which was apparent from the very early days of our collaboration. For example, during the first regional meeting in Bangladesh, small groups worked on developing lecture outlines for each module. As the policy engagement group discussed potential material, 2 members shared how their unique Ministry of Health governance structures either hindered or supported priority setting for polio.

As our familiarity with each other deepened over multiple in-person meetings, these conversations also deepened. By the time we met to record course material for the MOOC, we had thoughtful and insightful conversations about complex topics including corruption; international influence and aid; community opposition to externally funded health programs; and implementing health programs in settings characterized by complex violence. The opportunity to have these conversations across such a breadth and depth of expertise and perspective was a valuable experience for many of us that we were able to transfer to course materials including a series of short video discussions. These video discussions are in the MOOCs and also available separately online for classroom use ([Tables 2](#) and [3](#)).

**One major challenge in developing a course for many different settings and diverse learners is that the background knowledge of the learners will vary widely.**

**TABLE 3.** Global Health Polio Eradication Core Course Themes and Implementation Research Competencies for Each Massive Open Online Course<sup>a</sup>

Modules	Course Themes	Implementation Research Competencies
<b>I. Planning and Managing Health Programs: Promoting Quality, Accountability, and Equity</b>		
<ul style="list-style-type: none"> <li>– Planning and management</li> <li>– Health commodities, logistics, and supply</li> <li>– Human resources for health</li> <li>– Health equity and social justice</li> </ul>	<ul style="list-style-type: none"> <li>– Reaching hard-to-reach populations</li> <li>– Importance of politics</li> <li>– Potential and demands of eradication programs</li> </ul>	<ul style="list-style-type: none"> <li>– Understanding the interventions, their mechanisms, and emerging implementation challenges</li> <li>– Building an effective team</li> <li>– Applying ethical principles in conducting implementation research</li> </ul>
<b>II. Building Alliances in Global Health: From Global Institutions to Communities</b>		
<ul style="list-style-type: none"> <li>– Global alliances</li> <li>– Policy engagement and influence</li> <li>– Health communications and behavior change</li> <li>– Community engagement</li> </ul>	<ul style="list-style-type: none"> <li>– Importance of context</li> <li>– Relationship between vertical programs and health systems</li> <li>– Power of engagement</li> </ul>	<ul style="list-style-type: none"> <li>– Understanding contexts (health systems, implementing organizations, and communities)</li> <li>– Identifying and engaging relevant stakeholders</li> <li>– Leveraging required resources for conducting implementation research</li> <li>– Communicating and advocating effectively throughout the implementation research process.</li> </ul>
<b>III. Collecting and Using Data for Disease Control and Global Health Decision Making</b>		
<ul style="list-style-type: none"> <li>– Field epidemiology and outbreak response</li> <li>– Data for decision making</li> </ul>	<ul style="list-style-type: none"> <li>– Promise and limits of technology</li> <li>– Importance of incentives</li> </ul>	<ul style="list-style-type: none"> <li>– Formulating appropriate implementation research questions</li> <li>– Determining applicable study design and methodology</li> <li>– Conducting research in a robust and rigorous manner</li> <li>– How to use information from implementation research</li> </ul>

<sup>a</sup>The three massive open online courses are available at: <https://www.futurelearn.com/partners/stripe>.

Beyond topical discussions, learning about and incorporating teaching methods and styles from different institutional contexts constituted an interesting and valuable exercise. For example, at the meeting in Indonesia, we had discussions about the very different ways many of us had previously used case studies in the classroom. These discussions gave all of us, no matter how extensive our previous experience, new tools to use in our teaching going forward.

### ■ INCORPORATING PRACTITIONERS' PERSPECTIVES

The majority of consortium members currently hold academic positions. Although many of us have worked on polio eradication in various capacities in the past, none of us currently have a full-time job within polio eradication. This carries with it an attendant limitation; although we have all been involved in this current research project on polio eradication, most of us are less familiar with the specifics of day-to-day polio work, even within our own countries, than people who are working full time on

polio eradication activities. Thus, we found the experience, review, and contributions of the TAC extraordinarily valuable. TAC members were often able to provide additional insight into the topics we covered in the course, as well as additional resources to share with students.

Our positions as academics do carry an advantage. We are free to discuss difficult and politically sensitive topics in ways that those who work for United Nations agencies and governments would not be able to. Thus, in our course, we were able to openly delve into complex and thorny issues such as the power relations of international aid; the politics of international and local agenda setting; and the ethical trade-offs involved in the goal of eradication. Some of these issues were captured in the video discussions included as part of the MOOC.

### ■ COORDINATING A COLLABORATIVE PROCESS

In addition to being rewarding, our collaboration across countries and continents also bore challenges. Time differences, poor internet connectivity in many



areas, and distance made scheduling calls and setting deadlines difficult. As we were on different sides of the world, regular scheduling and follow-up were of foremost importance to maintain a cohesive approach, yet such scheduling and follow-up were challenging. Team members needed to speak to each other regularly to ensure all materials were consistent, built on one another, and met the learning objectives; yet these conversations were often difficult to have online.

Our final meeting happened just as COVID-19 was beginning to spread globally; partners from 6 countries met together in Baltimore, but those of us in India attended via Zoom, an online teleconferencing tool. It was of course not quite the same as being in the same room, especially since the meeting took place in what in India was the middle of the night. Yet we made this collaboration work by the commitment of partners across the world investing their time and energies on advancing the project.

## ■ FORMULATING INTERNATIONAL TEAMS

**Each teaching team was created to have geographic and gender representation in addition to expertise, interest, and experience, but other factors also needed consideration.**

One critical issue we did not consider when we developed our international teaching teams was that these collaborations were layered on top of existing hierarchies. As described earlier, each teaching team was purposefully created to have geographic and gender representation in addition to expertise, interest, and experience with the topic. However, as teams began to develop materials, it was clear that in some countries, particularly in Asia, our assumption that everyone worked entirely independently was not correct. For example, high-ranking professors occasionally delegated the responsibility for producing lecture materials or case studies to lower-ranked staff in their own countries, even though the latter individual had not attended the teaching team calls. Also, some lower-ranking professors were uncomfortable sharing materials developed with other people on their teaching team until it had been vetted by their in-country superiors. These decisions, while all understandable, made working across countries more challenging. This was especially true where people were working on multiple teaching teams. In the future, we would consider these dynamics more carefully at the outset and plan for them.

Another related issue is that we had many high-ranking and busy professors on our teams and fewer people with substantial time to devote to course development. As a result, sometimes there were many people providing ideas and

direction but fewer people to produce content. In practice, this situation meant that we benefited from a wealth of knowledge and valuable feedback but suffered from a shortage of people incentivized to carry out those edits in content production, editing, writing, and so on. This issue would be easy to fix with some advance planning—for example, hiring staff to carry out some of these tasks for teaching teams would have been valuable.

Unique teaching styles, borne out of contextual experience, also complicated the collaborations. Some draft lecture materials were full of text while others utilized imagery. Some members were familiar with the development and use of teaching notes or case-based approaches while others were not. These diverse approaches sometimes made creating cohesive content more difficult. Ultimately, we feel that this diversity of background enriched the course, but again, making materials standardized was labor-intensive.

Because the teams were funded through subcontracts with JHU, yet another hierarchy existed within the consortium. The course development was managed by JHU faculty who made major decisions about course content and direction. This circumstance added another layer of hierarchy and was unfortunately a different dynamic than if the project had been managed and run out of one of the LMIC institutions in our consortium. One benefit of centering the project at JHU was access to resources. For example, we had access to CTL, a global leader in instructional design for different audiences that has a wealth of experience in creating aesthetic and accessible online content. But this particular hierarchy mirrored larger power differentials globally and at times created tension. Having the administration of the course centered in one of the LMIC institutions rather than at JHU would have potentially alleviated some of these issues.

## ■ RECOMMENDATIONS

Academic collaborations across countries are well worth the challenges outlined, but anticipating and considering how to mitigate some of these issues ahead of time would be helpful. Of note, hierarchies both between senior and junior faculty and between primary and sub awardees should be considered and planned for at the outset. Wherever possible, in-person international meetings should be held to facilitate collaboration, motivate team members, and facilitate relationship development/maintenance. Investing in developing team rapport helps to foster a collective understanding, allows for nuanced exchange of ideas and approaches, and results in

greater cohesion and depth of thought in the output. We also recommend providing substantial staffing support to execute the insightful ideas of senior faculty. This infusion of human resources is needed throughout the process, from conceptualization to curriculum design and to content development and delivery.

## CONCLUSIONS

Using international collaborations to develop educational materials is an excellent approach to obtaining a wealth of information, perspectives, and context. This approach is particularly important in implementation science where context is king. While exceptionally valuable, these collaborations can be challenging to organize, and in-person meetings are needed to keep materials cohesive. Hierarchical contexts, both within each country and across consortium members, should be considered in the planning phases and this may mean adjusting expectations and workload balances.

Overall, though, the benefits of collaborating to build a course across countries and contexts were enormous. All of us learned an extensive amount from our colleagues about health program implementation in contexts ranging from the remotest corners of DRC to the center of Jakarta, Indonesia. Not only did this lead to rich course material, but it also led to the formation of new collaborations across continents that many of us hope to build on throughout our careers.

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**SHORT REPORT**

# An International Virtual Classroom: The Emergency Department Experience at Weill Cornell Medicine and Weill Bugando Medical Center in Tanzania

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## Key Messages

- Specialty graduate medical education and training typically follows an apprenticeship model that requires in-person teaching and instruction, which because of the COVID-19 pandemic, can be challenging in regions with travel restrictions and strict lockdown guidelines. In areas that have few specialty-trained local providers, it presents a circular conundrum: creating training programs requires faculty; having faculty requires creating training programs.
- The bidirectional partnership established between the emergency medicine departments of Weill Cornell Medicine and Bugando Medical Center demonstrates a collaborative approach to telemedicine and e-learning that is sustainable and encourages long-term engagement. Our approach of incorporating telecommunications into academic collaborations may remediate problems that have reduced the effectiveness of other traditional forms of educational connection between high-income countries and low- and middle-income countries, including lack of sustainability and reduced engagement over time.
- Although this technology was used in the context of emergency medicine graduate education, the benefits of this approach can easily be extrapolated to strengthen a wide variety of international collaborations.

## ABSTRACT

Emergency medicine (EM) is rapidly being recognized as a specialty around the globe. This has particular promise for low- and middle-income countries (LMICs) that experience the largest burden of disease for emergency conditions. Specialty education and training in EM remain essentially an apprenticeship model. Finding the required expertise to educate graduate learners can be challenging in regions where there are low densities of specialty providers.

We describe an initiative to implement a sustainable, bidirectional partnership between the Emergency Medicine Departments of Weill Cornell Medicine (WCM) in New York, NY, USA, and Bugando Medical Center (BMC) in Mwanza, Tanzania. We used synchronous and asynchronous telecommunication technology to enhance an ongoing emergency medicine education collaboration.

The Internet infrastructure for this collaboration was created by bolstering 4G services available in Mwanza, Tanzania. By maximizing the 4G signal, sufficient bandwidth could be created to allow for live 2-way audio/video communication. Using synchronous and asynchronous applications such as Zoom and WhatsApp, providers at WCM and BMC can attend real-time didactic lectures, participate in discussion forums on clinical topics, and collaborate on the development of clinical protocols. Proof of concept exercises demonstrated that this system can be used for real-time mentoring in EKG interpretation and ultrasound technique, for example. This system was also used to share information and develop operations flows during the COVID-19 pandemic. The use of telecommunication technology and e-learning in a format that promotes long-term, sustainable interaction is practical and innovative, provides benefit to all partners, and should be considered as a mechanism by which global partnerships can assist with training in emergency medicine in LMICs.

## EMERGENCY MEDICINE AS A GROWING SPECIALTY

In the United States, emergency medicine (EM) was recognized as a specialty in 1979.<sup>1</sup> Since that time the specialty has developed rapidly; now, more than 30 countries formally recognize the specialty. In countries where EM is new, residency training programs and certifications in EM are being developed.<sup>2</sup> The expansion of this specialty has particular promise for low and middle-income countries (LMICs), as they bear a disproportionate burden of emergency conditions compared to high-income countries (HICs).<sup>3</sup>

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In sub-Saharan Africa, in particular, it has been shown that starting EM training programs can dramatically reduce hospital-wide mortality.<sup>4-6</sup>

Specialty graduate medical education and training typically follows an apprenticeship model, where the principles of clinical care are acquired through longitudinal contact over years with experienced specialists who provide instruction grounded in the clinical realities of their specialty.<sup>8,9</sup> This often requires in-person teaching and instruction, which can be challenging in regions where there are low densities of specialty providers. Building graduate programs where there are few specialty-trained local providers presents a circular conundrum: to create the required training programs, faculty are needed; to have faculty, training programs must be created.

In Africa, medical education partnerships between HICs and local institutions have tended to focus on creating educational infrastructure. This has corresponded to increased support for undergraduate medical education in sub-Saharan Africa and a concomitant increase in medical school capacity.<sup>10,11</sup> Despite efforts to expand public health and research capacity with the help of international funding, support for the specialty training after medical school has not developed at the same pace.<sup>12,13</sup> Lack of clinical mentorship and educational support have been identified as critical limitations to specialty education in sub-Saharan Africa.<sup>14,15</sup>

EM education opportunities in Tanzania are currently limited, and when present, they are in the early stages of development. In Tanzania, the first and only EM residency program was established in 2010. The nation of Tanzania has a population of 44 million people and a total of 35 EM-trained specialists.<sup>7</sup> The majority of emergency departments (EDs) are staffed by providers with little to no formal EM training so potential trainees often have to look for positions in other countries for formal training.<sup>7</sup> Development of further residency programs would require “buy-in” and regulatory approval from the national government which has not occurred to date. In the context of these limitations, we hope that our collaborative efforts can help support the efforts of the EM-trained Bugando Medical Center (BMC) staff in Mwanza, Tanzania, to build EM knowledge among local providers.

Much of the current academic literature on this topic, particularly those that examine clinically oriented partnerships between the United States and African medical centers, indicates that there have been ongoing issues with maintaining

and sustaining connection. Several studies discuss the subsequent lack of consistent training for African providers and overall inconsistent U.S. partnership presence for African programs.<sup>16,17</sup> Although programs such as the Medical Education Partnership Initiative have attempted to address the disparities, there are still many examples where partnerships between HICs and LMICs are less beneficial or even harmful.<sup>18-20</sup> Electronic learning (e-learning) and other types of remote education have gained new prominence in the setting of the coronavirus disease (COVID-19) pandemic.<sup>21,22</sup> It may be that some of these same tools, coupled with partnerships between specialty faculty in HICs and LMICs, may be a method to address this lack of clinical mentorship and support.

## ■ USING E-LEARNING TO PROMOTE EM TRAINING

E-learning platforms have previously been proposed as a mechanism to expand access to medical education in sub-Saharan Africa.<sup>23-25</sup> In theory, e-learning can allow self-directed education that mitigates the limited availability of specialists.<sup>24,25</sup> However, in many cases, e-learning programs have not lived up to expectations and have been criticized for poor organization and misalignment with local conditions and priorities.<sup>24</sup> Barriers to effective e-learning have included difficulties associated with obtaining the required electronic resources, integrating curriculum, and motivating participants to initiate and sustain their engagement.<sup>26-28</sup> It may be possible to address some of these e-learning shortcomings in the context of HIC/LMIC medical partnerships by using electronic communications media to foster the same relationships and longitudinal connection that occurs with traditional face-to-face instruction. This same ongoing engagement could also be dynamically structured to help ensure that educational content remains aligned with local needs and priorities.

The timing may be opportune for telecommunication use in global specialty medical educational partnerships. In the United States, as well as in many other parts of the world, telemedicine care delivery systems, including provider-to-provider consultations and direct patient care, have become part of mainstream practice.<sup>29-31</sup> As this type of care grows, providers and graduate medical educators become more comfortable with telecommunication technology and the use of this technology in education increases.

**Lack of clinical mentorship and educational support have been identified as critical limitations to specialty education in sub-Saharan Africa.**

**Barriers to effective e-learning have included difficulties associated with obtaining the required electronic resources, integrating curriculum, and motivating participants to initiate and sustain their engagement.**

EM at Weill Cornell Medicine (WCM) in New York is an example of an academic department where the delivery of telemedicine care and remote e-learning have developed together.<sup>32–34</sup> In this context, we felt it would be of interest to the greater community to share the way we have used these telecommunication technologies to support the collaborative relationship between the EDs of WCM and BMC. Here, we describe our initiative to implement a sustainable, bidirectional partnership using both synchronous and asynchronous telecommunication to support EM training and use this technology to enhance traditional models of clinical education. We hope that this work may suggest a useful avenue for other global partnerships.

## ■ WCM AND BMC EM DEPARTMENT COLLABORATION

WCM and BMC have a decades-long history of cooperation beginning in the 1980s (Box).<sup>35</sup> In recent years, both institutions have seen rapid development within their EM programs with BMC creating a formal ED in 2017 and WCM establishing an academic Department of EM in 2018.<sup>36,37</sup>

In 2018, a collaboration between BMC and WCM EM departments began with a bidirectional exchange of personnel for both clinical electives and research. In addition, a 2-month standard rotation at BMC was developed for WCM Pediatric EM fellows. In 2019, 2 BMC EM specialists participated in a 1-month observership at WCM, and a 4-week elective at BMC was established for senior EM WCM residents.

While rotating at BMC, WCM residents and fellows participated in oversight of patient care and deliver lectures on common clinical presentations. Through these educational opportunities, WCM and BMC have jointly developed department

protocols to streamline patient care for common chief complaints.

## Developing the Internet Infrastructure to Promote Educational Exchange

In fall 2019, BMC and WCM EDs jointly decided to strengthen and establish systematic interactions between the departments by developing Internet capacity that would allow for more regular educational exchange. It was felt that building this technology capacity would allow for organic development of educational programming. A stakeholder assessment at BMC indicated that Internet infrastructure was limited; total Internet for the institution, including clinical services for the 900-bed hospital, had a bandwidth of 10Mbps, and this limited bandwidth was subject to frequent service outages. In addition, materials needed to facilitate telecommunication, such as laptops and webcams, were not widely available.

To increase Internet capacity, an “always-on” high-speed Internet connection was considered the preferred solution. A cabled connection was not available in the region. As an alternative, BMC faculty suggested using the existing 4G cellular service. This led to the development of a system (detailed below) that included a 4G antenna mounted on the roof, a cable connection to the ED’s ground floor location, and a cell signal repeater, as well as a multiband 4G router to achieve 24 Mbps download and 15 Mbps upload speed.

Building and maintaining Internet capacity was paid for using departmental funds from WCM EM. Equipment included a wireless router device that uses a SIM card, the same type of SIM card used in a cellular phone. Trials of several wireless service providers in Mwanza indicated that the fastest service was available from the local Tanzanian Vodacom Company. The SIM card solution provided relatively inexpensive Internet,

Through bidirectional exchange opportunities, WCM and BMC have jointly developed department protocols to streamline patient care for common chief complaints.

### BOX. Background of Weill Cornell Medicine and Bugando Medical Center Collaboration

WCM was established as a medical school in 1898 and has been affiliated with New York- Presbyterian Hospital since 1913.<sup>37</sup> A formal residency for EM training was established at New York-Presbyterian Hospital and WCM in 2003, and the division of EM transitioned to the Department of EM in 2018. The Department has over 80 EM board-certified faculty caring for 150,000 patients a year and is home to the WCM Center for Virtual Care, a center chartered to promote development and education in telemedicine.<sup>38</sup>

BMC was built by the Catholic Church and opened in 1971. In 2003, the Catholic University College of Health and Allied Sciences (CUHAS) opened the first medical college in western Tanzania at the same location. WCM established a formal affiliation with CUHAS and BMC in 2003. Since its establishment, over 1,000 Tanzanian physicians have graduated from CUHAS. BMC is the zonal referral hospital for the Lake Zone of Tanzania, with a catchment population of 18 million people. The ED has an annual volume of 35,000 patients with varied acuity. The BMC ED is staffed by 3 EM specialist physicians supervising 33 entry-level physicians and 22 nurses in clinical care.<sup>36</sup>

albeit with the drawback that the available data is “capped” (after a given amount of data is transmitted, the card must be “recharged”). Comparison of readily available “hotspot” SIM card modems sold by the same company with a multiband SIM card router (a router that makes use of signals from more than 1 cell tower and more than 1 frequency at a time) indicated faster connection speed with the multiband router. A rooftop antenna, coaxial cable, and a multiband 4G signal repeater, along with the multiband SIM card router, were purchased from eBay and Amazon in the United States, where the equipment was less costly. The resulting connection allowed 24 Mbps download speed, 15 Mbps upload speed, and a latency of 30–40 milliseconds. In addition to the connection equipment, funding was also made available for 2 laptop computers, a camera, and microphone equipment to allow for video conferencing through the Zoom application. The (Table) indicates initial start-up costs of equipment in addition to ongoing costs.

### Establishing a Collaborative Educational Exchange

We intended to build adequate Internet capacity first, then mutually determine what types of collaboration made the most sense for the 2 departments; this remains an iterative process. To date, we have used synchronous and asynchronous software platforms to support joint conferences, lectures, and the sharing of medical education resources.

WCM EM faculty provide real-time Zoom lectures on a variety of topics, including EKG interpretation, toxicology, pediatric drowning, and ultrasound instruction. These lectures occur once a month (late night United States time, morning East Africa time). With BMC faculty input, these sessions are designed for the needs of clinical learners in Mwanza. Based on this guidance, these lectures emphasize the development of clinical protocols and systematic care approaches. To allow for off-hours exchange of educational materials, WCM EM didactic lectures on clinically relevant topics including burn care, facial trauma, pediatric drowning, and chest pain have been recorded and placed on a shared hard drive to be viewed at individuals’ convenience. BMC staff have also attended the weekly WCM EM didactic conferences in real-time via Zoom. Additionally, we performed “proof of concept” interactions where U.S.-based faculty members guided BMC providers in real-time ultrasound acquisition.

We have also established WhatsApp messaging groups between WCM and BMC clinicians that support asynchronous questions and feedback on clinical topics. For example, a WhatsApp group dedicated to EKG interpretation, where de-identified EKGs are posted by BMC ED clinicians. All members of the group can respond with guidance on interpretation or pose additional clinical questions. Other WhatsApp messaging groups also allow for discussing, scheduling, providing updates on departmental news, and supporting real-time troubleshooting.

We continue to develop and expand our implementation of this technology to provide further clinical support. Additional collaborations include the Helping Children Survive initiative to train both BMC ED staff as well as BMC Department of Pediatrics staff in Pediatric Emergency Assessment Recognition and Stabilization that is adapted to a resource-limited setting. BMC has also incorporated a structured note template for pediatric admissions to create a local clinical information network. Research collaboration is ongoing on topics such as the evaluation and impact of delayed referrals for trauma patients and the examination of ED point-of-care ultrasound to improve outcomes among patients with heart failure. When not directly present with one another, these research teams maintain communication through WhatsApp, email, and Zoom meetings.

BMC faculty conduct real-time (afternoon East Africa time, morning New York time) Zoom lectures to WCM learners on clinical cases in Mwanza that involve pathologies and presentations that are uncommon in HIC settings, and therefore educationally valuable for the WCM residents. The clinical cases are incorporated into the WCM EM residency curriculum. These joint conferences, conducted monthly, explore clinical concepts relevant to both departments with shared presentations and discussion of teaching points to illustrate the practice of EM in different clinical environments.

In March 2020, given that the pandemic epicenter was currently in New York City and estimated to peak in eastern Africa in the coming months, colleagues from BMC sought clinical operations guidance to prepare themselves for a COVID-19 outbreak in western Tanzania. The WCM ED clinical operations team conducted a 90-minute Zoom conference for BMC colleagues describing triage, screening procedures, and infection control mechanisms in clinical areas. In June 2020, the BMC ED team presented via Zoom their

**WCM EM faculty provide real-time Zoom lectures on a variety of topics, including EKG interpretation, toxicology, pediatric drowning, and ultrasound instruction.**

**TABLE.** Telecommunication Equipment and Costs

Equipment	Description	Cost, US\$
Two Hewlett Packard 15.6" laptops	Computers	1,062.62
Indmire laptop battery for Hewlett Packard Pavilion	Extra laptop battery	42.49
Logitech high-definition pro webcam	Webcam	60.97
Two Owl conference room cameras	Voice activated, swiveling cameras (one for BMC, one at WCM) (purchased refurbished)	1,398.00
Innogear upgraded adjustable microphone stand	Desktop Microphone Stand	12.99
UHF wireless microphone	USB Microphone/UHF microphone with USB receiver for laptop	31.99
Two Lysignal outdoor/indoor wall mount directional panel antenna 698 to 2700 MHz	Antennas to distribute 4G signal in department	39.98
OB directional log-periodic antenna	Antenna able to receive 4G signal on roof (purchased used)	50.00
Cellphone signal booster	Cell signal repeater kit, to boost 4G signal within Department after signal delivered to ground floor by cable.	287.78
Teltonika RUT950 mobile 4G/LTE dual SIM slot modem with 802.11n wireless router	Multiband sim card wireless router	214.98
Wilson Electronics 75 ft. coax cable	Cable to connect ground floor to roof	62.64
Wilson Electronics 55 ft. coax cable	Cable to connect signal booster to indoor antennas	53.77
Ancable N-Type male to dual 2 N Type female 3-way splitter	Cable connection material	11.99
Ancable 2-pack premium N type ohm barrels adaptor coupler	Connectors for cell signal booster	8.99
<b>Total set-up cost</b>		<b>3,339.19</b>
Bandwidth expense	Recurring Sim recharge for 90GB of data (approximate)	approx. 40/month

Abbreviations: BMC, Bugando Medical Centre; USB, universal serial bus; WCM, Weill Cornell Medicine.

**The long-term impact and benefits of global EM collaborations depend on building and maintaining partner involvement through ongoing, bidirectional interaction.**

experiences of establishing and caring for patients in their ED-based COVID-unit. Many of their clinical protocols were developed based on WCM experiences from the surge earlier that year. Tanzania has subsequently experienced a second resurgence of COVID cases that has limited WCM’s ability to send personnel to Tanzania. However, our established telecommunication channels and sustained relationship have enabled us to offer continued educational and clinical support in the form of Zoom lectures and clinical guidance.

**DISCUSSION**

Traditional global health EM collaborations have often focused on short-term, in-person experiences, sending individuals from HICs to LMICs for a time-limited rotation or to oversee project implementation. Although sustainability is increasingly a central criterion in global health initiatives, resources are not always directed toward infrastructure to

maintain these efforts beyond the individuals’ physical presence.<sup>39,40</sup> Frustration with such discontinuities can lead to a disproportionate benefit to HICs while leading to LMIC participant disillusionment, posing obstacles to future collaborative relationships.<sup>41,42</sup> The long-term impact and benefits of global EM collaborations depend on building and maintaining partner involvement through ongoing, bidirectional interaction. We described a telecommunications approach that has the potential to mitigate discontinuity and be a model for remote academic partnerships between international EDs. Although there were start-up costs and effort required to establish the necessary technologic infrastructure, these investments in money and effort are relatively small compared to the expense and time required for round-trip travel between Mwanza and New York City.

Even before the onset of the COVID-19 pandemic, we felt that the increasing familiarity with electronic communication might make the time

right to explore the use of these tools as part of our international collaboration. Events associated with the pandemic have strengthened our conviction on this point.<sup>43</sup> The impact of the pandemic has demonstrated that global mobility is fragile. Travel restrictions and quarantine guidelines underscore the importance of establishing systems for partnerships that can be maintained outside of recurrent physical presence. Telemedicine technology allows us to continue specialty medical education initiatives even at long distances. The use of this technology in the context of EM graduate education has become common, and its benefits can easily be extrapolated to strengthen a wide variety of international collaborations.<sup>44</sup> A combination of asynchronous and real-time communication also alleviates the numerous shortcomings that have been described for e-learning as a sustainable approach to global education.<sup>24,26</sup> The increasing availability of high-speed Internet in many areas of the globe, coupled with the prospect of increased Internet availability that may occur following the deployment of low earth orbit satellite networks, will continue to reduce the technical obstacles to this type of collaboration.<sup>45</sup>

### Limitations

There are some limitations to this approach. Synchronous interactions can be challenging to schedule due to the time difference between our sites (7 or 8 hours, depending on U.S. Daylight Savings Time). Scheduling lectures at different mutually agreed upon times rather than 1 recurrent time means that both partners equally bear potential inconveniences, but the fact remains that the time difference creates inconveniences for both parties. One potential advantage to the time difference is that it allows individuals with different clinical schedules—like nocturnists—an opportunity to participate. Asynchronous techniques like the WhatsApp groups and the recorded lectures have also been useful in overcoming time difference obstacles.

While we report preliminary anecdotal success with this initiative, further research is needed to assess the effectiveness of the approach in global graduate medical education. We are in the process of obtaining formal feedback for joint conferences and lectures in reaching educational graduate medical education milestones for both WCM and BMC participants.<sup>46,47</sup> In the meantime, we plan to expand our collaborative projects through the creation of a WhatsApp toxicology consult group, allowing for asynchronous discussion of toxicology

principles. Our ultimate goal is to use this technology as a mechanism to support the establishment of an EM residency program at BMC while simultaneously broadening the exposure of US residents to pathology not frequently encountered during their training.

Although we have used this technology specifically for education, there is also potential to develop these telecommunication tools to support virtual clinical teaching in the direct care of patients. Currently, however, there are only preliminary regulations regarding the provision of remote clinical care across international borders. These remain broad without the necessary specificities to the local health care environment. Without these, questions regarding legal and ethical guidelines to providing direct patient care in other international health care systems remain unanswered and limit the clinical support we can provide.

**There is potential to develop these telecommunication tools to support virtual clinical teaching in the direct care of patients.**

### CONCLUSION

Telemedicine is a practical and innovative way to expand specialty training in EM in LMICs and establish bidirectional partnerships between HIC and LMIC academic departments. Our approach of incorporating telecommunication into academic collaborations could remediate problems that have reduced the effectiveness of e-learning and other traditional forms of educational connection between HIC and LMIC, including lack of sustainability and limited engagement over time. We seek to implement a working relationship between distant partners that more closely approximates real-time, long-term in-person interactions. Integrating modalities of telemedicine into a learning environment aligns the experience with other proven graduate medical educational methodologies.

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# Implementation of GeneXpert for TB Testing in Low- and Middle-Income Countries: A Systematic Review

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## Key Messages

- In low- and middle-income countries (LMICs) that have a higher burden of TB, the necessity for improved and rapid diagnostic testing, such as Xpert MTB/RIF that detects both TB and rifampicin resistance, has been limited by resource-related implementation challenges.
- Identifying and responding to the implementation-related barriers and enablers in Xpert testing programs across LMICs can help improve public health outcomes, which in this review were negatively impacted by barriers that were identified.
- We found that across the studies included in the review, an integrated and coordinated approach was required for implementing Xpert TB models of care into different health settings, but in LMICs, this approach can be associated with a lack of integration and coordination.
- When deciding on a particular implementation approach, the existing context of a health setting and the expertise and needs of key stakeholders (for example, clinicians, laboratories, and government) should be considered.
- Reporting of Xpert programs against an implementation science framework can increase learning across geographically diverse settings and thereby support improvement in program design.

## ABSTRACT

**Introduction:** Current evidence indicates that the impact of GeneXpert for diagnosing TB in low- and middle-income countries (LMICs) has not demonstrated equivalent outcomes when compared to Xpert evaluations in upper-middle-income countries. Challenges associated with implementation are possible contributing factors preventing this innovative diagnostic technology from achieving more significant public health outcomes. This review aimed to assess the use of implementation science frameworks when reporting the enablers and barriers for the implementation of GeneXpert for diagnosing TB in LMICs.

**Methods:** We conducted a qualitative systematic review of the peer-reviewed literature using PubMed, Medline, and Scopus. Eligible articles were those published between January 2010 and March 2020 that identified enablers and barriers to GeneXpert implementation, as well as the implementation approach delivered in an LMIC.

**Results:** Eleven studies were included in the review. Implementation barriers were found to be relatively consistent across studies and included patient-level factors, human resources, material resources, service implementation, service coordination, and technical operations. Few studies (n=5) identified enabling factors in the implementation of Xpert for TB testing. Identified enablers included strategies such as active case finding, expanding diagnostic algorithms, and daily transport of samples. The public health impact of Xpert TB testing interventions was commonly influenced by implementation barriers (n=4). Of the 11 studies, only 3 reported against an implementation framework.

**Conclusion:** This review identified a commonality in implementation barriers and enablers that influenced the overall public health impact of GeneXpert. With greater transparency of these barriers and enablers, program planners can promote a more collaborative approach and adapt interventions. It is recommended that program planners use implementation science frameworks when conducting research and publishing. This will build an evidence base focused on implementation and thereby support programs to address implementation barriers and include enabling factors in program design.

## INTRODUCTION

An estimated 10 million people were affected by TB globally in 2019, with the total number of deaths reaching 1.2 million people,<sup>1</sup> down from 1.5 million people in 2018.<sup>2</sup> Although TB is prevalent in all countries, the distribution shows a significant burden in low- and middle-income countries (LMICs). It is estimated that up to two-thirds of global incident cases are found

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in only 8 countries, 5 of which are classified as LMICs.<sup>1</sup> In 2019, the highest proportion of new cases (44%) occurred in Southeast Asia.<sup>1,3</sup>

In addition, approximately half a million cases of rifampicin-resistant TB were diagnosed in 2019.<sup>1,4</sup> Of these cases, 78% had multidrug-resistant TB (MDR-TB).<sup>1</sup> It has also been estimated that up to one-third of global TB cases and more than three-quarters of MDR-TB cases are undetected,<sup>3</sup> equating to upward of 3.3 million people globally living with active TB who are unaware of their status and remain undiagnosed.<sup>5</sup>

The global public health response to TB is guided by the World Health Organization (WHO) *End TB Strategy*<sup>2,6</sup> and the Sustainable Development Goals.<sup>2</sup> Both of these strategic documents prioritize TB as a health issue, aiming to achieve a 95% reduction in TB deaths and 90% reduction in the incidence rate by 2035.<sup>6</sup> Achieving these goals will require a high level of collaboration between regional, national, and international stakeholders working in partnership across a range of interventions targeting TB risk factors and priority populations.<sup>7</sup> These often include interventions that aim to reduce the time to diagnosis, provide more effective contact tracing, improve treatment adherence and outcome, enhance collaborative partnerships with HIV-specific programs, and prevent TB transmission.<sup>3</sup>

Case detection interventions are an ongoing challenge,<sup>5</sup> often due to restrictive testing algorithms that reduce access to testing among people with presumptive TB who fall outside the scope of the algorithm. However, in resource-limited settings, removing these restrictions comes with significant cost implications.<sup>8</sup> Therefore, no single intervention will result in achieving the global TB elimination targets.<sup>7</sup> Modelling undertaken to predict the impact of a variety of interventions indicates that improvements in diagnostic testing will make a substantial contribution.<sup>7</sup> Earlier detection of TB and MDR-TB allows cases to be promptly triaged into appropriate treatment and care, leading to improved patient outcomes.<sup>3,9</sup> When comparing point-of-care testing approaches with more conventional laboratory-based testing procedures, the longer timeframe for delivery of laboratory results is often cited as a reason for disengagement from the treatment pathway,<sup>10</sup> with recent estimates suggesting only 56% of diagnosed MDR-TB cases worldwide are treated successfully.<sup>2</sup>

In 2010, the WHO recommended the use of the Xpert MTB/RIF (Cepheid, Inc., Sunnyvale, CA), a test that simultaneously detects *Mycobacterium tuberculosis* (MTB) and rifampicin-resistant TB (RIF)

strains, as the initial diagnostic for people presumed to have MDR-TB or HIV-associated TB in high-incidence countries.<sup>3,11</sup> These recommendations have since expanded to all people with presumed TB while acknowledging resource implications within resource-limited settings.<sup>12</sup> The Xpert advances a health system's ability to diagnose and respond to TB as it has improved sensitivity in comparison to sputum smear microscopy.<sup>5</sup> Studies indicate that Xpert can detect TB in a large number of people that routine testing services cannot detect.<sup>13</sup> Therefore, new models of care are possible due to this rapid diagnostic technology that returns results within 2 hours.

Since the recommendation of Xpert, the number of programs using this new diagnostic technology to improve access to testing services has increased significantly.<sup>14</sup> By 2017, 23 million testing cartridges had been procured for use across 6,659 Xpert machines located in 130 countries.<sup>11,15</sup> However, requirements for specialist staff, temperature control, and a continuous power supply, as well as the high cost of purchasing the machine and ongoing testing cartridges, restrict the installation of Xpert in many locations.<sup>11</sup>

The challenges associated with implementation differ significantly between high-income and low-income countries.<sup>5,16</sup> The impact of new diagnostic testing interventions is often dependent on the functioning of the overall system in which the intervention is being introduced, as well as the operational implementation of the Xpert program.<sup>7,17,18</sup> In LMICs, implementation challenges often impact the effectiveness of Xpert, with many failing to achieve the expected outcomes demonstrated by Xpert evaluations in upper-middle-income countries.<sup>5</sup> This includes indicators such as a reduced timeframe to deliver test results to patients or successfully transitioning newly diagnosed cases into quality treatment and care.<sup>14,17,19</sup> As countries begin to scale up Xpert-based interventions, understanding how contextual factors influence program impact is critical.<sup>20</sup>

*Implementation research is the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and hence, to improve the quality and effectiveness of health services and care.<sup>21</sup>*

Furthermore, it explores the impact that implementation has on outcomes and identifies sustainable improvements.<sup>22</sup> This approach recognizes that challenges often experienced in real-world health settings impede meaningful outcomes for interventions that were previously proven effective

**Case detection interventions are an ongoing challenge, often due to restrictive testing algorithms that reduce access to testing among people with presumptive TB who fall outside the algorithm's scope.**

**As countries begin to scale up Xpert-based interventions, understanding how contextual factors influence program impact is critical.**

**With a higher burden of TB in LMICs, implementation research in this setting can advance understanding of how the challenges of implementation impact effectiveness.**

in research studies.<sup>23</sup> For this reason, sharing knowledge from across Xpert sites is needed to improve real-world implementation and program outcomes.<sup>13</sup> With a higher burden of TB in LMICs, implementation research in this setting can advance understanding of how the challenges of implementation impact effectiveness.

This review aimed to assess the use of implementation science frameworks when reporting the enablers and barriers for the implementation of Xpert for the diagnosis of TB in LMICs. The specific objectives were to (1) identify approaches to implementing Xpert in LMICs, (2) determine the barriers and enablers across the identified Xpert testing programs, and (3) assess the use of implementation science frameworks in Xpert programs in LMICs.

## **■ METHODS**

This qualitative systematic review was developed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement, which ensures transparency in the formulation of findings.<sup>24</sup> The data analysis consisted of de-identified, publicly available data and therefore is exempt from ethics approval.

### **Eligibility Criteria**

The PICOS (population, interventions, comparisons, outcomes, and study design) was used to frame the research question. The population was limited to LMICs as defined by the World Bank classification of low-income economies or lower-middle-income economies.<sup>25</sup> This was in recognition of the unique challenges associated with implementing Xpert within this setting.<sup>5,16</sup> Within this population setting, interventions that used the Xpert technology for TB testing in public or private sector facilities were included. In the data analysis process, a comparison of implementation approaches used across the included studies was undertaken. Therefore, a within-study comparison group was not required to meet eligibility. The outcome variables of interest were the identified enablers and barriers to implementation, as well as the implementation approach.

As the Xpert was recommended for use by the WHO in 2010, articles were limited to those published from January 1, 2011, to March 31, 2020. Included studies were peer-reviewed and published in English where the full-text article was available. Articles were excluded if they were not single country reviews and if they did not specify the implementation approach as well as identifying

barriers and/or enablers to the implementation approach. Further to this, articles focused on the implementation of Xpert for TB in closed population settings, such as prisons or pediatric clinics, multi-country reviews, and interventions occurring under a research trial were also excluded.

### **Search Strategy and Study Selection**

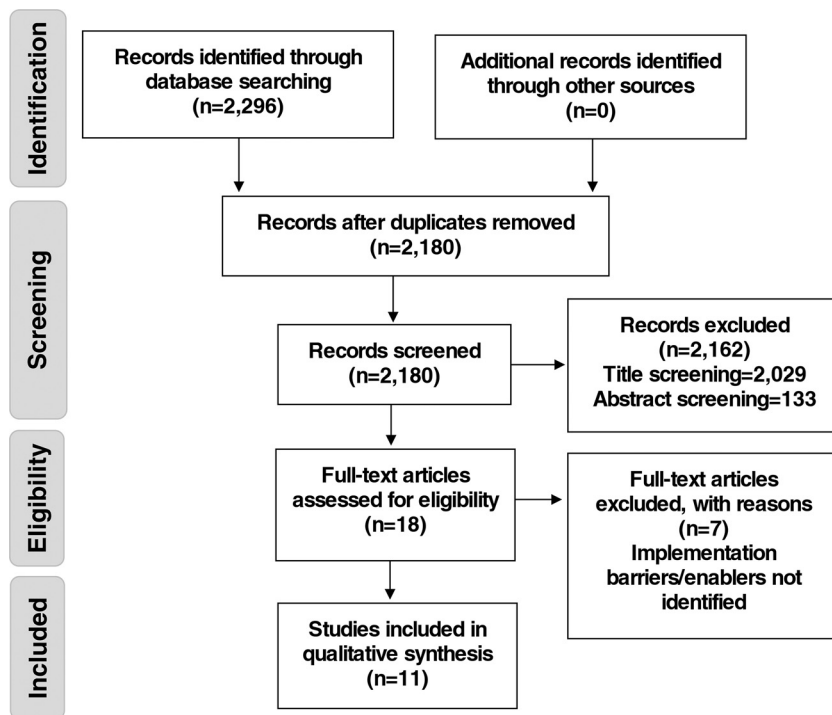
To identify relevant literature, PubMed, Medline, and Scopus databases were searched over 3 weeks beginning April 4, 2020. Search terms included the keywords “implementation,” “GeneXpert OR Xpert” and “Tuberculosis OR TB.” The preliminary search was performed in PubMed.

In total 2,296 articles were initially identified. Articles were extracted to EndNote X9.3.2 and 116 duplicates were removed. All articles identified underwent a review to assess relevance against the eligibility criteria. This review process occurred in stages, which initially involved screening the article titles (excluding 2,029 records). Then, the abstracts of the remaining 151 articles were assessed to identify those suitable for full-text review. In completing this process, a further 133 articles were excluded. This resulted in 18 articles undergoing an eligibility assessment involving a full-text review. A total of 7 articles were excluded as they did not address the barriers and/or enablers in the implementation of the intervention. A second full-text review process was then completed involving all 3 authors, who assessed the remaining articles against the eligibility criteria and mutually agreed on the final selection of studies for the data extraction process. A total of 11 articles were included in the review (Figure).

### **Data Extraction and Analysis**

Data were independently extracted from selected articles and transferred into an Excel spreadsheet to maintain consistency. Before the data extraction process, variables for extraction were agreed upon among all authors. The final variables included author, year, country of implementation, implementation approach (i.e., the characteristics of how an intervention is implemented, for example, a hub-and-spoke model or a point-of-care model), health setting, testing algorithm, public health impact, as well as the identified barriers and enablers to implementation and use of an implementation framework. The hub-and-spoke model was characterized by a centrally located laboratory performing the TB testing using the Xpert machine and returning the results to the community health clinic that initially collected

**FIGURE.** PRISMA Flow Chart for Study Selection on Implementation of GeneXpert for TB Testing in Low- and Middle-Income Countries



Abbreviation: PRISMA, Preferred Reporting Items for Systematic reviews and Meta-Analyses.

the sputum sample. The point-of-care model involved the installation of the Xpert machine at health centers where sputum samples were collected and tested.

## RESULTS

### Study Characteristics

The final 11 articles were published between 2015 and 2020, with Xpert implementation occurring in Asia (n=5) and Africa (n=6). More details on the characteristics of the 11 studies are summarized in Table 1.

### Implementation Approaches

Among the studies included in this review, the hub-and-spoke implementation approach for Xpert was used more often (n=6)<sup>15,26-30</sup> than the point-of-care model (n=5).<sup>31-35</sup> As part of the hub-and-spoke model, varying approaches to the transportation of samples between the laboratory and clinic were identified, which included transportation by a health care worker,<sup>30</sup> employed drivers,<sup>26,28</sup> and informal

couriers.<sup>27</sup> The return of results to the clinic that collected the patient sputum sample most commonly occurred via the same transport network, while a study in Uganda examined the use of SMS to return results directly to the clinic and patient.<sup>15</sup> Of the remaining interventions implementing the point-of-care model, one had 2 distinct arms involving differing approaches in active case finding of symptomatic people.<sup>35</sup> This included health workers actively seeking sputum samples from hospital patients or community-based screeners referring symptomatic people attending private health clinics to a TB testing center with an Xpert machine installed.

### Health Setting

For the hub-and-spoke models (n=6), the Xpert machine was installed at a combination of high level facilities such as regional (n=2), district (n=3) and urban (n=1) public hospitals (n=4),<sup>15,26,28,29</sup> or dedicated national TB diagnostic laboratories (n=2).<sup>27,30</sup> Information relating to the possible collocation of TB laboratories within hospitals was not provided. The majority of the spokes in these

**TABLE 1.** Characteristics of Studies on Implementation of Xpert for TB Testing in Low- and Middle-Income Countries

Author (Year)	Country	Implementation Approach	Health Setting	Testing Algorithm	Public Health Impact
Cattamanchi et al. <sup>15</sup> (2020)	Uganda	Hub-and-spoke model: Testing ‘hubs’ linked to 3–5 microscopy unit ‘spokes’ Monitoring of results centralized through National TB Reference Laboratory.	Regional or district public hospital for testing, with community health center for sample collection	Any person with presumed TB.	Nearly 4-fold increase in confirmed MDR-TB from 2009–2017 Increase in TB CNR from approximately 41,000 cases pre-2010 to 57,756 cases in 2017
Cowan et al. <sup>26</sup> (2015)	Mozambique	Hub-and-spoke model: Xpert installed in 4 public hospitals in 4 districts. Transportation network established from select health centers to transfer samples for testing.	District and urban public hospital for testing. Urban and remote health centers for sample collection	Two-step algorithm for people suspected of having pulmonary TB. GeneXpert testing occurs after 2 separate smear-negative results using smear microscopy.	Increase in diagnosis of bacteriologically confirmed pulmonary TB by 69%
Sikhondze et al. <sup>27</sup> (2015)	Swaziland	Hub-and-spoke model: 23 Xperts installed in 19 TB diagnostic laboratories. Community health sample transportation covers 78% of country. NGO covers the remaining regions.	TB diagnostic laboratories for testing	Not stated.	Not stated.
Nalugwa et al. <sup>28</sup> (2020)	Uganda	Hub-and-spoke model. 249 Xpert machines in 227 of 1500 TB diagnostic units. Motorcycle riders employed by Central Public Health Laboratories transport samples from community health centers.	Regional or district public hospital testing hub, with community health center for sample collection	At time of study, Xpert testing available to PLHIV, health care workers, contacts of DR-TB, pregnant women or breastfeeding mothers, prisoners, patients from refugee camps, and diabetics.	Not stated.
Newtonraj et al. <sup>29</sup> (2019)	India	Hub-and-spoke model: Xpert installed at the Intermediate Reference Laboratory in a government hospital for chest diseases in Puducherry district. Samples are received from 27 designated microscopy centers in medical colleges or district-level hospitals.	Centralized testing in Intermediate Reference Laboratory within government hospital for chest diseases. Sample collection from district hospitals.	Initial diagnostic for extra-pulmonary, pediatric, and HIV-associated TB. Xpert is also an add-on test for sputum microscopy negative patients.	CNR reduced from 118 to 97 per 100,000 population between 2010 and 2017
Rendell et al. <sup>30</sup> (2017)	Mongolia	Hub-and-spoke model: 3 Xpert machines installed across the country. Samples collected at community TB clinics and results returned using several paper-based delivery options.	Testing available at the National TB Reference Laboratory, the Regional Diagnostic and Treatment Centre, and a northern province hospital. Samples collected at community/district level TB clinics.	All smear-negative pulmonary TB cases, patients with presumed TB diagnosed with HIV, patients with presumed MDR-TB, and all smear-negative new cases aged 15–35 years	Number of diagnosed cases increased from 2,783 in 2012 to 3,209 in 2015
Gidado et al. <sup>31</sup> (2018)	Nigeria	Point-of-care model: 176 Xperts installed at clinics that meet necessary installation requirements. Test results monitored centrally, as well as the procurement of supplies.	Primary, secondary, and tertiary facilities	Not stated.	Not stated.
Hoang et al. <sup>32</sup> (2015)	Vietnam	Point-of-care model: Xpert installed in TB units of district health center in 35/63 provinces. Provinces chosen based on known prevalence of MDR-TB and/or HIV.	TB units in district health centers	Presumptive MDR-TB cases, defined as belonging to a risk category including TB treatment non-converters; contact of a person with MDR-TB; person coinfecting with TB/HIV; >1 month using TB drugs.	37.8% of estimated presumptive MDR-TB patients tested 75% of identified MDR-TB patients completed treatment and cured.

Continued

TABLE 1. Continued

Author (Year)	Country	Implementation Approach	Health Setting	Testing Algorithm	Public Health Impact
Joshi et al. <sup>33</sup> (2018)	Nepal	Point-of-care model: Xpert installed in 26 health facilities under TB Reach Project and operated by either government or NGO. In 2014, all machines donated to government. Samples collected from patients for smear microscopy, and an additional sample collected for Xpert testing, where available.	Government health facilities such as District Public Health Office laboratory, hospital and primary health centers located throughout the country	Targeted to specific populations as per WHO recommendations, including children aged younger than 15 years, PLHIV, severe forms of TB, and in presumptive MDR-TB.	Xpert diagnosed 28% of the total bacteriologically confirmed TB cases in 2015/2016.
Mustapha et al. <sup>34</sup> (2015)	Nigeria	Point-of-care model: Xpert implemented at 22 sites by NGO in partnership with government. Governance oversight by the National TB Control Program in the form of an advisory committee.	10 secondary health facilities, 10 tertiary hospitals, 2 private health facilities	Targeted to specific risk groups, including PLHIV with presumptive TB, those with poor response/relapse to TB treatment, contact of known MDR-TB case, TB cases at risk of resistance.	Not stated.
Awan et al. <sup>35</sup> (2018)	Pakistan	Two-pronged point-of-care approach: A “private-public mix model” with an Xpert installed at the TB lab of 6 public hospitals and 1 private site participating in Programmatic Management of Drug-Resistant TB. Active case finding occurred among outpatients and in wards of hospitals. The second “social business model” introduced Xpert at 3 TB centers for testing, with community screeners identifying symptomatic patients from nearby private-sector clinics and referring them to TB clinics.	Public and private hospitals and private community clinics	Initial diagnostic for people with presumptive TB.	43% increase in diagnosed DR-TB83.2% of TB cases found in the public-private mix model.

Abbreviations: CNR, case notification rate; DR-TB, drug-resistant TB; MDR-TB, multi-drug resistant TB; NGO, nongovernmental organization; PLHIV, people living with HIV.

studies were community-level primary health clinics (n=4)<sup>15,26,28</sup> or a TB community clinic (n=1).<sup>30</sup> For the point-of-care implementation models, the Xpert was installed at health settings defined as primary health care sites (n=2),<sup>31,33</sup> secondary-level facilities (n=2),<sup>31,34</sup> dedicated TB units/public health office (n=3)<sup>27,32,33</sup> and hospitals (n=4).<sup>31,33–35</sup> Two studies located an Xpert in a private health facility.<sup>34,35</sup>

### Testing Algorithm

The testing algorithm that determined eligibility for an Xpert test varied across all interventions. Although the majority used Xpert as an initial diagnostic for their targeted population (n=6),<sup>15,28,29,33–35</sup> 3 studies

implemented Xpert as a secondary diagnostic after smear-negative microscopy or a combination of both.<sup>26,29,30</sup> Across all studies, the broadest testing algorithm was defined as any person with presumptive TB (n=2).<sup>15,35</sup> The remaining studies provided Xpert testing to a combination of people deemed to be within an at-risk category, such as people living with HIV,<sup>28,33,34</sup> children aged 15 years or younger,<sup>33</sup> people with presumptive MDR-TB,<sup>32,33</sup> a contact of a known DR/MDR-TB case,<sup>28,32,34</sup> TB cases at risk of resistance,<sup>32,34</sup> health workers,<sup>28</sup> pregnant women or breastfeeding mothers,<sup>28</sup> prisoners,<sup>28</sup> refugees,<sup>28</sup> and diabetics.<sup>28</sup> One study limited the testing algorithm to cases of presumptive MDR-TB, as the intervention was focused on identifying MDR-TB cases.<sup>32</sup> Two studies did not indicate the testing algorithm used,



both of which primarily focused on the technical use of the Xpert machine and identifying the cause of error in results.<sup>27,31</sup>

### Public Health Impact

Seven of the 11 studies outlined some form of public health impact achieved by the implementation of Xpert.<sup>15,26,29,30,32,33,35</sup> Three studies assessed the Xpert within a continuum of care and highlighted treatment-related public health impacts within the cohort of TB cases detected by Xpert.<sup>15,26,32</sup> For example, the primary outcome identified by Hoang et al.<sup>32</sup> was the successful treatment of 75% of the identified MDR-TB cases, having tested 31.2% of the estimated MDR-TB cases nationally. This study, along with the Nepalese study,<sup>33</sup> framed the Xpert specific implementation impact as the proportion of national cases identified by Xpert. A limited number of studies (n=5) identified a measurable public health impact relating directly to TB testing using Xpert.<sup>15,26,29,30,35</sup> These included an increase in the identified cases of TB (n=3),<sup>15,30,35</sup> DR-TB (n=1)<sup>35</sup> or MDR-TB (n=1),<sup>32</sup> and 1 study saw a decline in the TB case notification rate from 118 to 97 per 100,000 people between 2010–2017<sup>29</sup> (see Table 1).

### Implementation Barriers

The barriers were allocated into the following 6 categories: patient-level factors, human resources, material resources, service implementation, service coordination, and technical operations (Table 2). Of the total (n=28) barriers identified, 43% (n=13) were found to have occurred in multiple studies.

The greatest number of barriers were categorized as service implementation factors (n=7). However, the most cited barrier was a service coordination factor (n=8) involving the lack of communication/referral pathways between staff in laboratories and health centers.<sup>27–30,32–35</sup> The second most common barrier related to inadequate and/or inconsistent staff training, which was identified relatively equally by studies in both Africa (n=3)<sup>26,28,34</sup> and Asia (n=4).<sup>29,30,32,35</sup>

Overall, the hub-and-spoke model generated the most commonly occurring barriers. Of the studies that implemented this approach, Cowan et al.<sup>26</sup> was the only study that did not identify communication barriers between the testing laboratory and the clinic collecting patient samples. Further to this, delays in patient notification of

results were also a common barrier associated with the hub-and-spoke model (n=5).<sup>15,26,28–30</sup>

### Implementation Enablers

Five studies<sup>15,30,32,33,35</sup> identified enabling factors in the implementation of Xpert for TB testing, including strategies such as taking an active case-finding approach,<sup>35</sup> expanding diagnostic algorithms,<sup>35</sup> and the daily transport of samples<sup>15</sup> (Table 3). Of the studies that identified enablers, only 2 highlighted more than 2 factors.<sup>30,35</sup> Of the enablers identified, the single factor highlighted by more than 1 study was the addition of human resources to support the implementation of a new program.<sup>30,35</sup> For the study conducted in Mongolia, this corresponds with the identified barrier that relates to the workload capacity of laboratory staff.<sup>30</sup> Further enablers have a correlation with an identified barrier; for example, Uganda stated the daily transport of samples as an enabling factor, while also identifying inconsistent and/or delayed transportation of samples as a barrier to successful implementation.<sup>15</sup>

### Implementation Science

Of the studies included in this review, only 3 reported being guided by a structured reporting framework,<sup>27,30,33</sup> and only 1 was specifically for implementation studies.<sup>33</sup> These included the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE),<sup>27</sup> the Consolidated Criteria for Reporting Qualitative Research,<sup>30</sup> and the Standards for Reporting Implementation Studies (StaRI).<sup>33</sup>

## DISCUSSION

This review aimed to assess the use of implementation science frameworks when reporting approaches to implementing Xpert in LMICs and determining the barriers and enablers across the identified Xpert testing programs. The review found 7 of the 11 identified studies outlined some form of public health impact achieved by Xpert, which included treatment success (n=3)<sup>15,26,32</sup> and an increase in identification of active cases (n=3).<sup>15,30,35</sup> Mostly consistent barriers to implementing Xpert were reported across all the identified studies. This highlights a commonality of implementation barriers across geographically dispersed Xpert interventions in LMICs. In contrast, less than half of the studies articulated enabling factors in the implementation of Xpert for TB testing in LMICs. More consistent and transparent reporting using implementation science frameworks will

**Of the enablers identified, the single factor highlighted by more than 1 study was the addition of human resources to support the implementation of a new program.**

**The greatest number of barriers were categorized as service implementation factors; however, the most cited barrier was a service coordination factor.**

**TABLE 2.** Identified Barriers to Implementing Xpert TB Testing in Studies in Low- and Middle-Income Countries

Barriers	India	Mongolia	Mozambique	Nepal	Nigeria	Pakistan	Swaziland	Uganda	Vietnam
<b>Patient-level factors</b>									
Distance to testing sites <sup>29,33,35</sup>	X			X		X			
Cost of testing in private health clinics <sup>35</sup>						X			
<b>Human resources</b>									
Inadequate/inconsistent staff training on testing processes/guidelines, and/or limited awareness of availability <sup>26,28-30,32,34,35</sup>	X	X	X		X	X		X	X
Low self-efficacy and confidence that Xpert improves outcomes <sup>15</sup>								X	
Workload capacity in laboratories <sup>15,30</sup>		X						X	
High staff turnover <sup>15,31,32</sup>					X			X	X
Initial struggle with English software (since rectified) <sup>26</sup>			X						
<b>Material resources</b>									
Inadequate power supply <sup>15,26,27,31,33,35</sup>			X	X	X	X	X	X	
Poorly equipped labs (e.g., limited space for patient assessment; no ventilation, workbench, air conditioning, and/or refrigerator) <sup>15,26,34</sup>			X		X			X	
Inappropriate storage of cartridges <sup>31</sup>					X				
<b>Service implementation</b>									
Geographically dispersed TB laboratories <sup>35</sup>						X			
Transportation of sputum samples (e.g., inconsistent/delays in availability of deliveries; improper packaging/temperature control during transport) <sup>15,32,34,35</sup>					X	X		X	X
Inability to track/follow up with patients testing positive <sup>15</sup>								X	
Determining an appropriate testing algorithm <sup>26</sup>			X						
Failure to identify eligible cases for screening <sup>30,32</sup>		X							X
Limitations to accessing updated and clear standard operating procedures/internal audits <sup>27,32</sup>							X		X
Poor quality samples collected <sup>27,29,30,32</sup>	X	X					X		X

Continued

TABLE 2. Continued

Barriers	India	Mongolia	Mozambique	Nepal	Nigeria	Pakistan	Swaziland	Uganda	Vietnam
Service coordination									
Supply chain for procurement of cartridges, reagents, and/or medicines resulting in lack of supplies <sup>15,26,30,32-35</sup>		X	X	X	X	X		X	X
Lack of referral pathways/communication between staff and health centers (e.g., referral pathways and transfer of results) <sup>27-30,32-35</sup>	X	X		X	X	X	X	X	X
Insufficient oversight from national body/remote monitoring <sup>15,26</sup>			X						X
Delays in notification of results <sup>15,26,28-30,34</sup>	X	X	X		X			X	
Limited ability to track positive cases and confirm treatment <sup>26,28,35</sup>			X			X		X	
Technical operations									
Xpert maintenance (e.g., frequency of maintenance not always implemented as required; poor understanding of routine maintenance in dusty, non-temperature-controlled labs) <sup>26-28,31,33,35</sup>			X	X	X	X	X	X	
Failure of calibration and required replacement <sup>26</sup>			X						
Lack of timely replacement of damaged modules <sup>33</sup>				X					
Module malfunction <sup>28,31</sup>					X			X	
Limited internet connectivity <sup>26,31</sup>			X		X				
Local repair options limited <sup>30</sup>		X							

improve access to information that supports improved public health outcomes for real-world Xpert interventions in LMICs.<sup>13</sup>

### Implementation Approach

In this review, we found an integrated and coordinated approach was required when implementing Xpert models of care into a health setting.<sup>5,28</sup> This was particularly apparent in the implementation of the commonly used hub-and-spoke model. In high-income countries, this model of care is considered ideal for maximizing efficiencies and effectiveness for services that require advanced medical equipment, such as the Xpert.<sup>36</sup> However, in LMICs the hub-and-spoke model was found to be associated with the greatest number of barriers, highlighting a lack of integration and service coordination. Therefore, when deciding on a particular implementation approach, the existing context of a

health setting and the expertise and needs of key stakeholders (e.g., clinicians, laboratories, and government) should be considered.<sup>37</sup>

Recommendations to enhance integration and coordination included supporting continuous quality improvement of systems, as well as procuring and maintaining appropriate equipment, strengthening supply chains, having reliable specimen referral networks, suitable laboratory information systems, and proper laboratory training for staff.<sup>37</sup> This is reinforced by Rendell et al.,<sup>30</sup> indicating that the mere introduction of Xpert does not automatically “guarantee a natural fit into the [existing] program environment.”<sup>30</sup> There is a need for more consistent, transparent, and collaborative information sharing regarding the suitability of strategies to support the implementation and integration of Xpert programs at the local level.<sup>37</sup>

**TABLE 3.** Identified Enablers of Implementation of Xpert TB Testing Studies in Low- and Middle-Income Countries

Enablers	Country
Daily transport of samples <sup>15</sup>	Uganda
SMS communication of results to health centers <sup>15</sup>	Uganda
Collecting monthly performance feedback from staff for quality improvement purposes <sup>15</sup>	Uganda
Clear guidelines in local language <sup>30</sup>	Mongolia
Purchase of uninterruptable power supply <sup>30</sup>	Mongolia
Access to external experts <sup>30</sup>	Mongolia
Peer learning for professional development <sup>30</sup>	Mongolia
Consistent process of confirming of results between referring site and laboratory after sample sent <sup>32</sup>	Vietnam
Laboratory personnel understood Xpert to be superior to smear microscopy <sup>33</sup>	Nepal
Active case finding approach <sup>35</sup>	Pakistan
Expanded diagnostic algorithm <sup>35</sup>	Pakistan
Additional human resources <sup>30,35</sup>	Pakistan, Mongolia
Close collaboration <sup>35</sup>	Pakistan
Supervisory visits to improve maintenance and stock procurement <sup>35</sup>	Pakistan

Abbreviation: SMS, short message service.

### Barriers to Greater Public Health Impact

Across all the identified studies, 2 main barriers to the identification of active TB cases were identified, the underutilization of Xpert and the inadequate identification of eligible patients. These barriers frequently resulted from a lack of communication/referral pathways between health centers and laboratories (n=8)<sup>27–30,32–35</sup> and inadequate or inconsistent training to support staff awareness and knowledge of testing and/or testing processes (n=7).<sup>26,28–30,32,34,35</sup> Restricted testing algorithms were also likely to have affected the identification of eligible patients, as this adds a level of complexity in triage that requires specific staff training, which was lacking; therefore, staff were not adequately identifying eligible patients. Furthermore, the underutilization of Xpert was exacerbated when stocks of material resources such as sputum cups for sample collection were not maintained; 7 studies had periods of downtime due to inadequate supplies.<sup>15,26,30,32–35</sup> These barriers are also reflected in multicountry reviews that analyzed quarterly reports and machine data.<sup>13</sup>

As the Xpert allows for the timely turnaround of test results, a secondary public health impact of Xpert is the immediate initiation of treatment to prevent onward transmission.<sup>33</sup> However, in this review, 8 studies identified a delay in either

samples being delivered for testing (n=4)<sup>15,32,34,35</sup> or a delay in the notification of test results (n=6).<sup>15,26,28–30,34</sup> Accordingly, a delay in the notification of results reduces the opportunity to improve treatment initiation.<sup>16,26</sup> In examining the difference in time to treatment between patients diagnosed by Xpert and those diagnosed under the previous smear microscopy system, several studies (n=2) found that an Xpert diagnosis resulted in a longer time to treatment or loss to follow-up.<sup>13,26,28</sup> These outcomes are often noted as the result of operational challenges associated with program implementation.<sup>17</sup> With consistent reporting of barriers that inhibit the integration of Xpert into the existing health system, the overall public health impact of Xpert implementation in LMICs can be improved.<sup>16</sup>

### Implementation Enablers

In this review, only 5 studies specifically identified enablers for the implementation of Xpert for TB testing in LMICs.<sup>15,30,32,33,35</sup> Identifying improvements to implementation was a theme across 3 studies.<sup>15,31,33</sup> Gidado et al.<sup>31</sup> suggested that strategies for improved functionality of Xpert machines should be prioritized over the installation of new machines. Secondly, Cattamanchi et al.<sup>15</sup> reported on the practical benefit of highlighting enabling factors to improve implementation, reporting quality improvement

**Two main barriers to the identification of active TB cases were identified, the underutilization of Xpert and the inadequate identification of eligible patients.**

**Sharing of knowledge via standardized reporting provides valuable information that supports the ongoing integration of Xpert for TB testing in LMICs.**

initiatives that positively impacted outcomes along the TB treatment and care cascade including SMS communication for the delivery of Xpert results, and implementing a process to gather monthly performance feedback from health center staff.<sup>15</sup> Accordingly, sharing of knowledge via standardized reporting provides valuable information that supports the ongoing integration of Xpert for TB testing in LMICs.<sup>13</sup> In the longer term, consistent reporting and communication of the enabling factors to improve implementation will contribute to systemic improvement in the public health impact of Xpert as programs are scaled up across LMICs.<sup>20,38,39</sup>

### Implementation Science

Implementation frameworks such as the Standards for Reporting Implementation Studies (StARI) and the Consolidated Framework for Implementation Research (CFIR) were developed with the knowledge that effective interventions are often found to be ineffective when implemented in a real-world context.<sup>40,41</sup> This is often due to the central role that context plays in understanding how factors such as the social, cultural, economic, political, legal, and physical environment may affect the intervention.<sup>22</sup> For programs to improve public health impact, there is a need for the continued development of tools and strategies that support successful implementation.<sup>42</sup> The similar or recurring barriers being experienced across LMIC Xpert interventions indicate the need for more consistent and transparent reporting methods to facilitate knowledge-sharing. Consistent reporting through implementation frameworks will increase understanding of the most effective implementation approaches and contextual influences and enable the scaling up of Xpert interventions.<sup>20,22</sup> Therefore, an increase in the use of implementation frameworks for planning and evaluation of Xpert programs has the potential to improve outcomes achieved by Xpert programs and accelerate the translation of research into policy and practice.<sup>42</sup>

### Limitations and Strengths

This review had several limitations. We searched 3 databases and restricted our search to English language publications. Further, of the studies included in this review, only 3 reported being guided by a structured reporting framework<sup>27,30,33</sup> and only 1 was specifically for implementation studies.<sup>33</sup> Also, not using the word “program” or “programmatic” may have reduced the number of search results. However, this review had several

strengths including being guided by PRISMA, as well as the articles for inclusion being appraised by the lead author and 2 co-authors.

## CONCLUSION

With a higher burden of TB in LMICs, implementation research can advance understanding of implementation barriers and enablers. This study demonstrates the commonality of these barriers across geographically dispersed Xpert interventions in LMICs. With greater transparency of these barriers and enablers, program planners can promote a more collaborative approach and adapt interventions to reduce the impact of implementation barriers. To build the evidence base and in turn improve the implementation and effectiveness of Xpert, it is recommended that programs use implementation science frameworks when conducting research and disseminating findings. Wider use of these frameworks will provide valuable insight and support the ongoing improvement of TB programs in LMICs.

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