

Evaluation of a Systems Analysis and Improvement Approach to Optimize Prevention of Mother-To-Child Transmission of HIV Using the Consolidated Framework for Implementation Research

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Background: Despite large investments to prevent mother-to-child-transmission (PMTCT), pediatric HIV elimination goals are not on track in many countries. The Systems Analysis and Improvement Approach (SAIA) study was a cluster randomized trial to test whether a package of systems engineering tools could strengthen PMTCT programs. We sought to (1) define core and adaptable components of the SAIA intervention, and (2) explain the heterogeneity in SAIA's success between facilities.

Methods: The Consolidated Framework for Implementation Research (CFIR) guided all data collection efforts. CFIR constructs were assessed in focus group discussions and interviews with study and facility staff in 6 health facilities (1 high-performing and 1 low-performing site per country, identified by study staff) in December 2014 at the end of the intervention

period. SAIA staff identified the intervention's core and adaptable components at an end-of-study meeting in August 2015. Two independent analysts used CFIR constructs to code transcripts before reaching consensus.

Results: Flow mapping and continuous quality improvement were the core to the SAIA in all settings, whereas the PMTCT cascade analysis tool was the core in high HIV prevalence settings. Five CFIR constructs distinguished strongly between high and low performers: 2 in inner setting (networks and communication, available resources) and 3 in process (external change agents, executing, reflecting and evaluating).

Discussion: The CFIR is a valuable tool to categorize elements of an intervention as core versus adaptable, and to understand heterogeneity in study implementation. Future intervention studies should apply evidence-based implementation science frameworks, like the CFIR, to provide salient data to expand implementation to other settings.

Key Words: Consolidated Framework for Implementation Research (CFIR), option B+, Africa, PMTCT, systems analysis and improvement, quality improvement

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INTRODUCTION

Prevention of mother-to-child-transmission (PMTCT) cascade is inherently complex, crossing multiple biological phases for women–infant pairs and multiple services within the health sector. Barriers to accessing PMTCT of HIV services occur at every step of the PMTCT cascade. Facility-level barriers include human resources shortages, lack of service integration, lack of ongoing mentoring, and poor patient–provider interactions.^{1–4} Stigma may also play a role in preventing PMTCT service access, although the stigma is probably beyond the reach of health facilities. Option B+, lifelong combination antiretroviral therapy (ART) for all HIV-positive pregnant or breastfeeding women, presents advantages in the ease of prescribing a fixed-dose

combination regimen without the need for CD4 testing.⁵ However, Option B+ also presents obstacles; for example, a sizable proportion of women may refuse or default from ART or receive no antiretroviral medication at all, putting them at risk of increased MTCT.^{6–10} Formative research on Option B+ conducted by the authors in Mozambique found that only 52% of women returned for drug pick-up at 30 days, and only 38% returned at 90 days.¹¹ Integrating all steps of the PMTCT cascade into a holistic process is a priority to maximize PMTCT access and its population-level benefits.⁶

Effective, affordable, and scalable delivery strategies are needed to improve PMTCT service delivery, including approaches to maximize initiation of ART before the onset of HIV symptoms, lifelong adherence to ART, and retention of women and infants in care beyond the postpartum period. Implementation science (IS) seeks to understand the magnitude, causes, and solutions to close gaps between what is known to be efficacious and what is done in real-world settings.^{12,13} Given the gap between demonstrated efficacy of PMTCT strategies to prevent infant HIV infections and the suboptimal provision of PMTCT services in many settings in sub-Saharan Africa, IS is uniquely positioned to identify and address barriers to effective PMTCT provision by using real-world data to generate effective, contextually appropriate solutions for sub-Saharan Africa. The National Institute of Health and the President's Emergency Plan for AIDS Relief's PMTCT Alliance was launched to provide a platform to enhance communication and collaboration between researchers, policy makers, and program implementers testing practical solutions to PMTCT service gaps and was integral in prioritizing the use of IS methods and tools in HIV research.¹⁴

The Systems Analysis and Improvement Approach (SAIA) trial was a cluster randomized trial that used tools, methods, and approaches from systems engineering to address persistent implementation challenges in PMTCT.^{15–17} Study details have previously been published.^{18,19} Briefly, 36 facilities in 3 countries (Mozambique, Kenya, and Côte d'Ivoire) were stratified by country and patient volume and randomized 1:1 to receive SAIA (intervention arm) or usual care (control arm). The study intervention was a 5-step, iterative process that used systems engineering theory to guide staff and facility-level managers to improve PMTCT services using 3 tools: (1) The PMTCT Cascade Analysis Tool (PCAT) tracked drop-off across each step of the PMTCT cascade using routine data. Its maximizing function quantified what retention would be if drop-off were eliminated across each step to identify the step that would yield the largest gains if targeted for improvement.²⁰ (2) Process flow mapping of the PMTCT cascade provided staff with a holistic picture of services and sectors involved in service provision at their facility to identify workflow inefficiencies to target and modifications to test. (3) Last, classic Continuous Quality Improvement (CQI) tools were used to iteratively implement and evaluate facility-level improvement strategies.

Facilitation of future scaling of the SAIA intervention depends on first understanding factors critical to successful implementation and separating core (eg, essential and non-modifiable) intervention components from those that are adaptable to new practice environments. The SAIA trial

design embedded an IS framework to capture this implementation data, to take advantage of the varied settings and countries, and to guide future SAIA application.

Although IS lacks a standard definition, all definitions recognize the importance of transdisciplinary approaches to solve implementation challenges.¹² Meta-frameworks—like the Consolidated Framework for Implementation Research (CFIR)—go beyond assessing intervention effectiveness, to identify contextual influences that explain the heterogeneity of implementation success across settings using multidisciplinary theories, including those from psychology, organizational change, and sociology.²¹ Across 38 constructs, the CFIR provides a guide to identify interventions' core and adaptable components, which supports efforts to scale-up effective interventions. Distinguishing core and modifiable components optimizes contextual fit, and ensures effective implementation of interventions' core components. The CFIR has been applied to interventions to promote healthy eating and physical activity in Australian childcare centers, weight management among Veteran's Affairs in the United States, and tobacco control guidelines in Vietnam.²² To our knowledge, the CFIR has not previously been applied to PMTCT services in either high or low and middle-income country (LMIC) settings.^{23,24}

This article aims to use the CFIR to: (1) to define the core intervention and adaptable peripheral components of the SAIA; and (2) identify contextual influences that explain the heterogeneity in SAIA's implementation success across 3 country settings.

METHODS

This qualitative study was nested within a 2-arm, 1:1 cluster randomized trial designed to assess the SAIA intervention effectiveness in 18 intervention and 18 control facilities, across study countries.^{18–20,25} This article presents results from focus group discussions (FGDs) and key informant interviews (KIIs) conducted at 6 of the 18 intervention sites (Fig. 1), as well as FGDs with in-country study teams. FGD and KII questions used the CFIR as a guiding framework.

Study Setting

The SAIA intervention was implemented from February to December 2014 in Mozambique, Kenya, and Cote d'Ivoire; these countries were selected to provide implementation data from heterogeneous settings because of differences in health sector design, varying levels of resource investments, and HIV burden.

Mozambique

Study facilities were selected from Dondo and Nhamatanda districts and Beira City, located along the populated Beira corridor in Sofala province. Sofala has an estimated adult HIV prevalence of 15.5%, although higher in densely populated, urban areas.²⁶ The Mozambique National Health Service has a broad network of health facilities, and is the principal provider of formal health services in Sofala,



FIGURE 1. Map of SAIA study health facilities with FGDs and KIs (n = 6).

providing more than 98% of outpatient services.²⁷ The Ministry of Health uses a mixed approach for PMTCT; including option B + in facilities with capacity to offer ART, and option A in remaining facilities.

Kenya

Study facilities were selected from Nairobi and Coast province, with estimated adult HIV prevalences of 8.6% and 11.1%, respectively.²⁸ PMTCT services in Kenya are provided through public and private not-for-profit health facilities. High volume facilities typically offer option B+, whereas lower volume facilities offer option B or A.

Côte d'Ivoire

Study facilities were located in 3 northern regions of Côte d'Ivoire (Gbêké, Hambôl, Poro-Tchologo-Bagoue) with

estimated adult HIV prevalence of 4.4, 4.4, and 2.5%, respectively.²⁹ PMTCT services in Côte d'Ivoire are provided primarily through public sector health facilities. Option B, universal ART for all pregnant and breastfeeding women, was adopted as national policy in November 2012; roll out began at study clinics in March 2013.

Procedures and Analysis

Aim 1: Define the Core Intervention and Adaptable Peripheral Components of the SAIA

After presenting and discussing overall and country-specific results at the end-of-study meeting in August 2015, country teams participated in a 3-hour review of core and adaptable intervention components in their countries. Guided by the global study team, consisting of the principal

investigator, study manager, and postdoctoral fellow, and using CFIR as a framework, each country study team reviewed and shared their findings, including their country-specific ranking of SAIA activities as essential or adaptable. Data sources included field notes, implementation assessment forms, and secular trend reporting forms used throughout the implementation period, as well as transcripts and synthesis notes from end-of-study FGDs and KIIs. After team presentations by study staff from each country, analysis focused on qualitative content of the “intervention” and “implementation process” domains.³⁰ Consensus across study countries surrounding core and adaptable intervention components for the SAIA were obtained through cross-checking country-specific rankings. Activities ranked essential across all 3 settings were ranked highest, followed by activities carried out and ranked essential across 2 countries.

Aim 2: Identify Contextual Influences that Explain the Heterogeneity in SAIA’s Implementation Success

Two health facilities per country (Fig. 1), one high performing and another low performing, were selected to participate in facility-level, endline FGDs in December 2014. Performance was determined by in-country study staff based primarily on fidelity to the intervention, as study outcomes were not yet available; subsequent analysis of trial outcomes confirmed study staff’s assessments. Fidelity was assessed based on study staff’s extensive experience with each facility during frequent follow-up visits during the 9-month intervention period, and was corroborated by data available in December 2014. For example, high-performing sites tested 12 microinterventions on average during the study period (range, 5–23), whereas all low-performing sites tested 7 microinterventions over the study period. In these 6 facilities, workers engaged in PMTCT services (nurses, midwives, and doctors from antenatal care, maternity, postpartum or pediatric HIV services, pharmacists and laboratory technicians) were invited to participate in facility-level, endline FGDs in December 2014. Open-ended interview guides were developed based on 4 of the CFIR domains and subdomain constructs; data on the other domains (outer setting) were gathered prospectively by study staff monitoring secular events. Separate KIIs were conducted with PMTCT leadership and carried out with SAIA study teams, to gather data on the implementation process using the same questions as the FGDs.

FGD and KII data were recorded, transcribed, and analyzed using qualitative content analysis following a deductive approach,²⁵ using the CFIR as a guiding framework.^{24,30} For each country, analysis was performed by 2 authors in a stepwise, iterative process. After reviewing transcripts, notes, secular trend reports, and written summaries, each pair of analysts independently coded facility-level transcripts for each CFIR construct.^{31,32} Coding was compared across pairs, and differences were discussed to agree on final coding. Once country-level case memos were refined and finalized, 3 analysts, with input from a qualitative expert, assigned ratings for each construct within each facility. Using a rating process previously applied to the CFIR, ratings reflect the positive or negative influence (valence) and the strength of each construct.²⁴ Constructs were coded as missing too much data

to discern a pattern (M), not distinguishing between high and low implementation (0), or weakly (+1/–1) or strongly (+2/–2) distinguishing low to high implementation performance. Findings were then used to develop recommendations of best practices to facilitate high performance and highlight challenges and lessons learned from lower-performing facilities across the 3 countries.

RESULTS

Aim 1: Define the Core Intervention and Adaptable Peripheral Components of the SAIA

Intervention Core Components

Across the 3 countries, SAIA core components included flow mapping and CQI. Flow mapping was reported as essential to identify system bottlenecks as well as promote team building, which encouraged sustainability of the SAIA intervention given staff absences and/or turnover. At facilities with successful implementation, flow mapping was based on “walk throughs” by multiple health workers, where they traced patient steps from first antenatal care visit through early infant HIV diagnosis. Subsequent creation and refinement of maps and team-level discussion uncovered discrepancies in service delivery, promoted better systems understanding among staff, and supported more accurate problem identification.

CQI provided health care teams with a defined methodology to identify, implement, and evaluate system-level improvements to mitigate bottlenecks identified through flow mapping and cascade analysis. Coordination across sectors, especially during the SAIA introduction phase, promoted broader systems-level thinking across the care team.

Intervention Adaptable Periphery

The PCAT was described as a core component in both Mozambique and Kenya—which had larger health facilities with greater patient flows and higher HIV prevalence—but not in Cote d’Ivoire where the PCAT was described as overly complex and nonessential for its significantly lower HIV burden. In all countries, stakeholders requested the PCAT be transferred to a mobile platform that could be managed independently by health care workers, as computer access and literacy was limited.

Implementation Process Core Components

For successful implementation, respondents reported site supervision should occur weekly over the first month followed by monthly check-in meetings to clarify questions and allow for independent implementation by the health care team (with periodic monitoring). Monthly use of the PCAT was described as most effective, as it aligned with routine data collection periods. Despite challenges in using the PCAT in computer access and/or literacy, it was well received in Mozambique and Kenya, particularly in larger facilities with higher HIV prevalence, as it identified inefficiencies across multiple PMTCT services points. In smaller facilities in these countries, the PCAT was most helpful during the postpartum

period to assess uptake of polymerase chain reaction testing and initiation of infant ART.

The format of CQI—with planning, engagement, execution, and reflection phases—provided critical space for facility teams to consider their findings from systems analysis tools (eg, flow mapping and cascade analysis), brainstorm solutions, and encourage continual use of the tools for benchmarking ongoing process improvement. Successful implementation of CQI required participation of and communication between multiple PMTCT service sectors. Finally, ensuring adequate meeting and workspace facilitated CQI implementation.

Successful innovations were those that reinforced existing Ministry of Health protocols, required low written outputs, and promoted democratic engagement across the health care team. Higher-performing facilities whose iterative changes targeted health service reorganization proved more effective and sustainable over time. Finally, the presence of external change agents (study nurses) ensured ongoing prioritization of systems analysis and improvement efforts in low-resourced facilities.

Implementation Process Adaptable Periphery

At larger, urban sites with high patient flow and HIV prevalence, SAIA implementation was reported to have improved with externally supported community health workers, whose presence countered staffing shortages. Study managers reported investments in team building and sensitization to study objectives were necessary for initially resistant facilities. In smaller, more peripheral facilities with limited infrastructure, availability of extra support for minor rehabilitation or infrastructure improvements (eg, air conditioning) improved participation in the intervention. Depending on facility resources and needs, the role of external change agents varied, from facility-based community health workers to district, provincial, or study supervisors. Likewise, periodicity and regular use of different components of the SAIA varied depending on needs, concerns, and facility resources; in some facilities, all 3 tools (flow mapping, PCAT, and CQI) were used monthly, whereas in others, all 3 were used initially and then only CQI was subsequently used.

Aim 2: Identify Contextual Influences That Explain the Heterogeneity in SAIA's Implementation Success

Of the 34 CFIR constructs assessed (Table 1), 5 strongly distinguished high and low-performing facilities: (1) networks and communication, (2) available resources, (3) external change agents, (4) execution, and (5) reflection and evaluation. Further explanation of each construct is described below. Supportive quotations are noted in Figure 2. Six constructs weakly distinguished high-performing from low-performing facilities: (1) intervention source, (2) relative advantage, (3) complexity, (4) tension for change, (5) relative priority, and (6) goals and feedback.^{31,32} Supportive quotations are located in Figure 2, Supplemental Digital Content, <http://links.lww.com/QAI/A827>. Six constructs were mixed across facilities, and 12 constructs

reported insufficient data to assess. Implementation success varied across countries and settings, and were published previously.¹⁹ The following section briefly describes strongly distinguishing constructs; additional quotes for each construct are in site-specific memos (see Files 3–7, Supplemental Digital Content, <http://links.lww.com/QAI/A827>).

Strongly Distinguishing

Networks and Communication

Formal and informal communications within the facilities differed notably between performance categories. In high-performing facilities, roles were clearly communicated across sectors, which ensured that planned innovations were implemented and evaluated. Lower-performing facilities worked to develop accountability systems, but with less success, potentially because of human resource constraints.

Available Resources

Resource availability, including physical space, laboratory supplies, and human resources, strongly distinguished high-performing from low-performing facilities. Although most facilities reported some resource challenges, higher-performing facilities were more nimble at finding solutions to resource challenges or selected innovations requiring few additional resources. Lower-performing facilities had chronic staffing and infrastructure challenges, undermining improvement efforts.

External Change Agents

Study teams were not perceived to affect staff engagement in Mozambique, but were associated with performance in Kenya and Cote d'Ivoire. At the high-performing facility in Kenya, "...all health staff...appreciated the study staff for work well done," whereas the lower-performing facility did not mention the study team. In Cote d'Ivoire, the higher-performing facility appreciated the organization, time management, and availability of the study team. The lower-performing facility, meanwhile, complained of long meetings that failed to acknowledge high workloads.

Executing

Facility staff in Kenya did not mention if SAIA implementation went according to plan. In Mozambique, the high-performing facility reported that facility staff always attended monthly meetings, and study nurses respected meeting start and stop times. At the low-performing facility, staffing changes required on-the-job training to ensure SAIA continuity. At the high-performing facility in Cote d'Ivoire, 4 of 5 interventions were successful and have been routinized into service delivery; no significant absences occurred. At the low-performing facility, although many of the interventions were successful, "*none of the interventions are continued.*"

Reflecting and Evaluating

The SAIA encourages reflection and evaluation through updating flow maps and the PCAT, and iterative CQI. However, stimulating reflection was challenging, and was a strongly distinguishing construct between high-performing

TABLE 1. Ratings Assigned to CFIR Construct by Site

	Low Performers			High Performers			
	Mozambique	Kenya	Cote d'Ivoire	Mozambique	Kenya	Cote d'Ivoire	
Intervention characteristics							
Intervention source	+1	+1	-1	+2	+2	+1	*
Evidence strength and quality	+1	M	M	+2	M	+1	
Relative advantage	+2	-1	+1	+2	M	+2	*
Adaptability	+2	+1	M	+2	+1	M	
Trialability	+1	+1	M	+1	M	+2	
Complexity (reverse rated)	+1	+1	-1	-1	+2	+1	*
Design quality and packaging	M	M	M	+1	M	X	
Cost	M	M	M	M	M	+1	
Inner setting							
Structural characteristics							
Structural characteristics	+2	M	-2	M	M	M	
Networks and communication	+1	+1	-1	+1	+2	+1	†
Culture	+2	+1	M	+2	+2	+1	
Implementation climate							
Tension for change	0	-2	+1	+1	0	+2	*
Compatibility	+1	M	M	+2	+1	M	
Relative priority	-1	-1	+1	+2	M	X	*
Organizational incentives and rewards	M	M	M	M	M	M	
Goals and feedback	+1	M	X	+2	M	+1	*
Learning climate	+2	M	M	+2	+1	+1	
Readiness for implementation							
Leadership engagement	+1	+2	+1	+1	+2	+2	
Available resources	-2	-2	-2	+1	-1	-1	†
Access to knowledge and information	+2	+1	X	+2	+1	X	
Individuals							
Knowledge and beliefs about the innovation	+1	+2	+1	+1	+2	+1	
Self-efficacy	+2	M	+1	+2	+2	+1	
Individual stage of change	+1	M	M	X	M	M	
Individual identification with organization	+2	M	-1	M	M	M	
Other personal attributes	M	M	-1	M	+1	M	
Process							
Planning	+1	+1	-1	+1	+2	M	
Engaging							
Opinion leaders	M	M	+1	M	M	M	
Formally appointed internal implementation leaders	+1	M	M	+2	+2	+1	
Champions	M	+1	M	M	+1	M	
External change agents	+2	M	+1	+2	+2	+2	†
Key stakeholders	M	+1	M	M	M	+2	
Innovation participants	M	M	M	M	M	+2	
Executing	-2	M	-1	+2	M	+2	†
Reflecting and evaluating	-2	+1	X	+2	+1	+1	†

*Construct weakly distinguishes between low and high implementation effectiveness.
 †Construct strongly distinguishes between low and high implementation effectiveness.
 M, missing; X, mixed result.

and low-performing facilities. At weaker facilities, although the health care team was supportive, staff shortages limited reflection and evaluation.

DISCUSSION

To our knowledge, this is the first study to apply the CFIR to research conducted in LMICs to determine (1) the

core versus adaptable elements of an intervention, and (2) the correlates of a successful implementation of an IS intervention. Flow mapping and CQI were integral to the SAIA, whereas the PCAT was not essential. We found that 5 CFIR constructs (networks and communication, available resources, external change agents, executing, and reflecting and evaluating) were strongly associated with implementation success.

Supporting quotations from focus group discussions and interviews

Networks and Communication

"The Administration was very keen in making follow up in the assignments given. A duty roster was made especially in relation to working during the weekends as well as to remind all staff of the upcoming meetings." (Kenya – High)

"They discussed HIV activities and the study activities during their monthly site staff meeting. There was at least one meeting where the doctor, midwife and community health worker sat down together to look at patient charts and make sure they were up to date. However, as time went on, these meetings were held with less regularity outside of the study team site visit." (Côte d'Ivoire – Low)

Available Resources

"[W]e had the problem with not enough tubes to draw blood in ANC and maternity. Because the head nurse was there, she saw we had a shortage...spoke with the district...got more tubes so we can draw blood where it is best for the women." (Mozambique – High)

"There was lack of privacy with regard to reactive mothers but currently, there is privacy." (Kenya – High)

"They said they felt ready to begin the first intervention because it was just a reorganization of the patient flow - they didn't need any equipment or supplies or extra rooms to do it. All it required was a little more work from site staff." (Côte d'Ivoire – High)

"There were times when it was difficult to decide on an intervention because of site staff scheduling conflicts (maternity leaves) and the number of midwives that would be available at any given time to devote to an intervention." (Côte d'Ivoire – Low)

"The infrastructure is terrible. The ANC is provided in a converted kitchen—there are not windows and there is no privacy. If we had better infrastructure and more staff we could do so much better." (Mozambique – Low)

External Change Agents

"[Study] staff tended to come when it wasn't too busy (in the afternoons) and meetings took about 1 hour. They liked the frequency of the visits (monthly) and site staff were generally available for the meetings." (Côte d'Ivoire – High)

"Follow-up visits by [study] staff were reported to take about two hours, but 'at least two times it was longer than that.' It was occasionally difficult to balance [study] site visits and normal patient workload." (Côte d'Ivoire – Low)

Executing

"When one person can't come from a sector, a substitute would come. Most of the visits lasted about an hour. Coming once a month is good. It is the multiple interactions that make it work." (Mozambique – High)

"Today, none of the interventions are continued, though they reported several of them were successes." (Côte d'Ivoire – Low)

Reflecting and Evaluating

"[T]he collaborative approach of brainstorming interventions was positive...[T]he monthly interviews...helped them process the needs and progress of the site." (Côte d'Ivoire – High)

"...[I]t wasn't always obvious where [they] should intervene [to make improvements.]" (Mozambique – Low)

FIGURE 2. Supporting quotations from FGDs and interviews.

As the CFIR and IS are relatively new, few studies exist with which to compare our results. In the analysis by Damschroder's 2013 of a hospital-based weight-management program in the United States, 6 of 10 constructs strongly associated with performance were related to inner setting; in our study, 2 of the 5 constructs strongly correlated with performance were related to inner setting (networks and communication and available resources), whereas the other 3 were related to process (external change agents, executing, and reflecting and evaluating).²⁴ Available resources were not strongly distinguishing in Damschroder's study, but it is not surprising that resources—or more specifically, methods to overcome resource scarcity—are more critical to implementation in resource-constrained settings. Analyses of implementation of other interventions in LMICs are warranted to explore this hypothesis and identify which types of resource

scarcity (eg, human resources, infrastructure, supplies) are most limiting to implementation.

Leadership engagement (a subconstruct of inner setting) was crucial to implementation, although not coded as a strong success predictor. Of the 18 facilities randomized to the intervention, only 1 facility did not implement it, because of resistance from the lead nurse. Despite repeated attempts by study staff to engage in a dialog with her, she remained adamant in her opposition, and the entire nursing staff followed her example. Therefore, although leadership engagement did not emerge in the analysis as a correlate of success, this was because of the fact that leaders were already relatively supportive in all 17 facilities that implemented the intervention.

This study demonstrates the utility of the CFIR to analyze study implementation and understand which aspects

of the intervention and the implementation process worked well and why.³³ In our application, it yielded insights into how to implement the SAIA intervention if it is to be scaled-up. Of the 5 constructs that strongly distinguished between performance categories, 3 are directly modifiable: external change agents, executing, and reflecting and evaluating, highlighting the importance of well-trained, supportive study staff (external change agents), the benefit of implementing the intervention according to plan (executing), and the value of ongoing feedback (reflecting and evaluating). In the SAIA, ongoing feedback was built into all 3 tools and every follow-up visit. In the future, the SAIA could be improved by systematically collecting process indicators related to specific innovations (eg, wait times) to strengthen facilities' ability to reflect and evaluate on the intervention in real time (and to identify best practices to spread to other facilities). The 2 less modifiable constructs—networks and communication and available resources—can be optimized if facility leadership is supportive of the intervention. Several respondents noted that leaders promoted successful implementation by strengthening communication, procuring resources, and assigning responsibilities, all of which promoted successful implementation, as has been observed in other studies.^{24,34}

The conclusions of this analysis are strengthened by the diversity of study countries and the diversity of study facilities within those countries. We evaluated SAIA implementation across a range of settings, which allows us to generate more robust inferences. We used CFIR, an evidence-based, standardized meta-framework, to guide data collection and analysis, which will facilitate comparisons with future analyses of a scaled-up SAIA, or with other studies applying the CFIR. To maximize accuracy of classifications, analysts independently coded each construct and reached consensus on final ratings.

This study does have limitations. Because of staff and resource availability, we were not able to conduct FGDs with each of the 18 health facilities randomized to the intervention. However, we purposely selected facilities for FGDs to maximize representativeness given available resources.

The National Institutes of Health/President's Emergency Plan for AIDS Relief/PMTCT Implementation Science Alliance enriched this study in a number of ways. By specifically supporting IS research in PMTCT, the Alliance has generated evidence that goes beyond individual-level interventions to develop and test real-world, facility-level interventions that may provide more practical, scalable models to reduce MTCT. Furthermore, participation in the Alliance provided opportunities to engage with policymakers, implementers, and implementation researchers that introduced participants to frameworks and research tools that go beyond assessing effectiveness, to provide practical answers to the "why" and "how" that is essential to take to scale Alliance interventions.

To maximize the utility of our findings, future intervention studies should apply evidence-based IS frameworks like the CFIR to provide salient implementation data to support implementation in other settings, including in PMTCT. Given the importance of inner setting and the

implementation process, and the likely heightened importance of available resources, further applications of the CFIR are needed in LMIC settings.

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