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Option B+ in Mozambique: Formative Research Findings for the Design of a Facility-Level Clustered Randomized Controlled Trial to Improve ART Retention in Antenatal Care

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Introduction: With the rollout of "Option B+" in Mozambique in 2013, initial data indicated major challenges to early retention in antiretroviral therapy (ART) among HIV-positive pregnant women. We sought to develop and test a pilot intervention in 6 large public clinics in central Mozambique to improve retention of mothers starting ART in antenatal care. The results from the formative research from this study described here were used to design the intervention.

Methods: The research was initiated in early 2013 and completed in early 2014 in each of the 6 study clinics and consisted of (1) patient flow mapping and measurement of retention through collection of health systems data from antenatal care registries, pharmacy registries, ART clinic databases, (2) workforce assessment and measurement of patient waiting times, and (3) patient and worker individual interviews and focus groups.

Results: Coverage of HIV testing and ART initiation were over 90% at all sites, but retention at 30-, 60-, and 90-day pharmacy refill visits was very low ranging from only 5% at 1 site to 30% returning at 90 days. These data revealed major systemic bottlenecks that contributed to poor adherence and retention in the first month after ART initiation. Long wait times, short consultations, and poor counseling were identified as barriers.

Conclusions: Based on these findings, we designed an intervention with these components: (1) workflow modification to redefine nurse tasks, shift tasks to community health workers, and enhance patient tracking and (2) an adherence and retention package to systematize active patient follow-up, ensure home visits by community health workers, use text messaging, and intensify counseling by health staff. This intervention is currently under evaluation using a stepped wedge design.

Key Word: Option B+, ART retention, Mozambique, Africa, implementation science

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INTRODUCTION

Throughout sub-Saharan Africa, losses along the prevention of mother-to-child transmission (PMTCT) cascade for HIV-positive pregnant women and their infants are a persistent obstacle to eliminating HIV in children and ensuring appropriate care for HIV-positive women during their childbearing years.[1–10] In 2013, the WHO issued new universal, lifelong antiretroviral therapy (ART) (Option B+) guidelines for pregnant and breastfeeding women in countries with generalized epidemics and high repeat pregnancy rates to streamline the care cascade for HIV-positive pregnant and breastfeeding women, potentially increasing ART uptake and reducing loss to follow-up (LTFU).[6,11,12] Retention in ART services is essential for effective PMTCT in the short term and vital for the health of the mother over her lifetime.

Malawi's early experience with Option B+ demonstrated great gains in ART enrollment for HIV-positive pregnant and breastfeeding women, leading to a more than 7-fold increase in ART start over the first 12 months of Option B+ rollout.[13] Estimates of LTFU after ART initiation ranged from 0% to 58%, with most losses occurring within 3 months.[13,14] A cohort comparison study by Tenthani et al involving more than 28,000 women in Malawi reported a marked increase in PMTCT uptake and significantly shorter interval to ART start after the implementation of Option B+ as well as an 87% retention in care at 6 months, comparable to the pre-Option B+ baseline in this setting.[15] However, concerns remain about retention-in-care for women who start

ART in Option B+ programs, particularly in the postpartum period. Tenthani et al reported that women starting ART while pregnant were 5 times less likely to return to a clinic after their initial ART visit than those starting ART for their own health. Women initiating ART on the day of diagnosis were almost twice as likely never to return to care as pregnant patients who started ART after a delay.[14] Focus group discussions (FGDs) in Uganda and Malawi revealed patient concerns about side effects and adherence when initiating lifelong ART with a high CD4 count.[11] These data raise concern about whether Option B+ programs adequately counsel women regarding a lifelong commitment to ART.[16]

As Option B+ is rolled out broadly in sub-Saharan Africa, there is a pressing need to understand factors that influence retention and adherence.[17,18] The study described here sought to design and test an intervention to improve early retention in Option B+ programming in central Mozambique. The intervention was conducted in Manica and Sofala Provinces where HIV prevalence is higher than the national rate of 11.5%[19] (16% and 18% for women, 15% and 13% for men, respectively)[19] and an estimated 18% among pregnant women in 2009[20] in both provinces. Under-five mortality is estimated at 114/1000 live births in Manica and 105/1000 births in Sofala,[19] whereas pediatric HIV infection contributes to 16% of child mortality.[21] In 2010, approximately 178,000 women attended a first antenatal care (ANC) visit in both provinces, and 164,000 were tested for HIV; 5829 (6% of ANC first visits) tested positive in Manica and 9364 (12%) in Sofala.[22]

By 2012, there was 90% ANC coverage and nearly 95% HIV testing coverage in first ANC visits, and less than 25% of eligible mothers started ART.[23] In 2013, the Ministry of Health (MOH) began its national rollout of Option B+ services to streamline PMTCT services and increase ART coverage.[24] Maternal and child health (MCH) nurses were trained to manage ART through the postpartum period. In the new treatment cascade, women who test positive in their first ANC visit are started on ART (tenofovir + lamivudine + efavirenz, *single-tablet* daily fixed-*dose* combination) either in that same visit or within 7 days. The patient returns to the ANC services for medication refills every 30 days. In the postpartum period, the patient's ART file is transferred to postpartum care and child-at-risk care in the same facility.

By 2014, 62 sites in Manica and 70 sites in Sofala were implementing Option B+.[24] First ANC visit coverage has remained consistently very high at well over 90% at most sites in Sofala and Manica; 97% of those with first ANC consults were also tested for HIV. At most sites, over 90% of those testing positive also initiated ART in the new Option B+ strategy. Despite these high coverage levels, poor retention in the first 3 months remained a challenge.

We conducted formative research at 6 large public health facilities to inform the design of a pilot facility-level intervention to improve patient retention in the context B+. The formative research constituted the first phase of an intervention study that also included a second phase in which the intervention would be introduced and evaluated. The public National Health System is characterized by significant workforce shortages and resource limitations. Formative research therefore centered on identifying constraints and resources already available to develop an intervention that, if successful, could be scaled up within the limitations of the health system. Health workers were enlisted to both identify challenges and participate in the design of the intervention to ensure feasibility within health systems constraints as well as solicit health worker buy-in.

METHODS

Study Setting and Design

The intervention study is a clustered (facility-level) randomized controlled trial using a stepped wedge design[25] to test the effectiveness of a new Option B+ intervention approach to improve early retention in ART care among HIV-positive pregnant women, as compared with the standard MOH approach rolled out nationally in 2013.[26] The intervention was implemented in 6 high-volume health centers providing PMTCT and ART services in the Mozambican National Health System. These health centers serve communities along the highly populated Beira highway and railway transport corridor that passes through Sofala and Manica provinces, from the port city of Beira on the Indian Ocean to the Zimbabwe border. The 6 sites were selected in collaboration with the Provincial Health Directorates of Manica and Sofala from a pool of high patient volume sites along the corridor. Intervention sites include 3 in Sofala Province (Macurungo, Munhava, and Dondo) and 3 in Manica Province (Nhamaonha, 1° de Maio, and Gondola). All are public facilities in the National Health System that provide the full range of PMTCT services, including HIV testing, access to CD4 testing (4 of 6 sites transfer samples to a central lab), and ART. ANC services at health centers are staffed by elementary and mid-level MCH nurses and 1 elementary midwife.

The study was conducted in 2 phases. In phase 1, extensive mixed methods formative research was conducted over a 12-month period at the 6 health facilities.[27] Data were gathered to identify inefficiencies and bottlenecks in the current Option B+ care cascade, guide identification and prioritization of key workflow modifications, and develop an enhanced adherence and retention package. For phase 2, a stepped wedge design would be used to step in the intervention at the 6 study sites and then evaluated. Phase 2 results will be reported elsewhere.

Data Collection

During the first year of the project, researchers conducted mixed methods formative research at the 6 sites to determine how to best adapt the Option B+ model to the 6 facilities. Data were gathered from February to September 2013. Option B+ was initiated in all 6 sites in July 2013 providing an opportunity to collect data before and after Option B+ rollout. The research consisted of the following major activities.

Patient Flow Mapping

Researchers mapped current patient flow patterns in the PMTCT treatment cascade and links to ART services at each

of the target sites to produce current flow charts.[28] Health systems data (number of monthly ANC visits, new ANC enrollees, new ANC enrollees tested for HIV, CD4 tests ordered and received, and patients started on lifelong ART) were collected for each site to identify LTFU in the treatment cascade and ART initiation rates. These data were gathered from ANC registries, pharmacy registries, and ART clinic databases. Together with health workers and clinic directors, new future flow maps were created for each site to demonstrate new pathways required to improve patient flow. To measure waiting and consultation times at each facility, researchers were stationed at health facilities, then observed women and measured waiting time from the moment they joined the waiting line at ANC until the final time they entered the ANC consult room.

Workforce

Patient volume in ANC and outpatient ART services, staffing levels, patient waiting times, and patient flow were examined for each site to identify workforce-related bottlenecks. Staffing levels and training needs required to manage new patient flows were identified for each site and incorporated into new patient flow mapping.

Materials and Medications

Flow and adequacy of key testing materials (HIV and CD4 testing materials), laboratory monitoring resources and medications required for ART and other HIV care were examined for each health unit by assessing pharmacy and facility records, and stockout patterns.

Patient and Health Worker Perspectives

FGDs were conducted both with ANC patients (1 FGD per site with 5–10 participants), and with health workers (1 per site with 6–9 participants) including nurses and counselors at ANC services, pharmacy, and outpatient services at each site. The FGDs sought to (1) elicit perceptions of ART provision to pregnant women, (2) solicit engagement in development of new Option B+ procedures, and (3) identify key challenges to providing treatment. Researchers conducted 49 in-depth individual interviews (IDIs) with health workers (8 at 5 sites, and 9 at 1 site) to support development of new pilot Option B+ protocols. Respondents included MCH nurses, counselors, *activistas*, laboratory technicians, pharmacists, and facility clinical directors. IDIs focused on descriptions of patient flow, perceived challenges to retention, and identification of feasible improvements. The focus groups and IDIs were conducted by trained interviewers using open-ended, semistructured interview guides. Notes were taken by trained note-takers then reviewed and coded in Excel spreadsheets by the research team to identify key themes, barriers to B+ implementation, and suggestions for improvement.

Ethical Approval

The study protocol was approved by the Mozambique Ministry of Health National Health Bioethics Committee and the University of Washington Institutional Review Board.

RESULTS

The formative research centered on generating facility-specific data on patient volume and flow in ANC services, workforce, stockouts, wait times, and ART retention to develop profiles of each site to guide intervention design.

Work and Patient Flow Mapping

Facility data were collected from ANC registries, pharmacy registries, and ART clinic databases from July through September 2013, when Option B+ was rolled out at all 6 sites by the MOH. Additional data were collected from January to September 2013 to provide monthly estimates of other ANC service coverage (Table 1). In both provinces, HIV testing rates were high (97%–100%). HIV prevalence among the ANC patients was consistently higher in Sofala Province compared with Manica. The monthly average of women testing HIV-positive at their first visit ranged from 23 in Gondola to 46 in Munhava. Researchers observed 233 patients in first ANC visits across the 6 facilities (ranging from 37 to 40 at each site) to measure waiting times and time spent in consultations with MCH nurses. In many cases, women were going into and out of the consult room as they went to laboratory and waited for results. Researchers measured all of the time that the woman was outside of the consult room as wait time. Facility waiting time averages varied from about 1.5 hours to over 7 hours, and consultation times from 7 minutes to 25 minutes. Current flow maps were developed for each health facility (see example in Fig. 1) to provide a foundation for identifying bottlenecks in patient flow and to contribute to development of modified future flow maps for the intervention.

Researchers sought to determine the early ART retention rates at each site. Although some preliminary data were gathered from July to September 2013, the best quality data that describe ART retention through pharmacy pickups before the intervention were gathered during baseline data collection in May/June 2014 (Fig. 2). In the baseline cohort, 141 women initiated ART across all 6 sites, ranging from 11 to 44. Each 30-day refill period was given a 25- to 32-day window to be counted as a timely refill. The data show sharp declines at the first refill, followed by steady declines afterward leading to very poor retention by 90 days that ranged from 5% to 32% across the 6 sites.

Workforce

Researchers collected data on formally allocated staff for each site listed by district managers as "active" for that year, that is, not still in training or retired. The Mozambique Public National Health System suffers from an extreme health worker shortage that runs across all facilities (64.5 medical doctors, nurses, and MCH nurses per 100,000 population in 2011, *well* below the WHO minimum acceptable health worker density threshold of 230/100,000).[29] The 6 sites in this study were no exception. Although the 6 sites generally met the MOH criteria and thresholds for workforce allocation, the scale-up of ART has added workload to overburdened staff as evidenced by the time motion data collected here.[30] Within these constraints, there was some notable variation. Nhamaonha had no current physician, but reported the highest first ANC visits among the 6 sites. In Mozambique,

TABLE 1. Monthly Antenatal Care Services Coverage in 6 Study Sites

ANC Services Coverage (Monthly July–September 2013)	Sofala Province			Manica Province		
	Munhava	Macurungo	Dondo	1° de Maio	Nhamaonha	Gondola
HIV testing coverage						
No. of first ANC visits	268	170	194	317	333	469
No. and % tested HIV	260 (97)	170 (100)	194 (100)	308 (97)	323 (97)	455 (97)
No. and % HIV positive	46 (17)	31 (18)	35 (18)	32 (10)	37 (11)	23 (5)
Other (January–September 2013)						
% with 4 ANC visits	51	57	53	44	11	37
% TT (second dose + booster)	65	71	84	100	30	65
% IPT (2 or more doses)	47	59	69	18	10	7
% syphilis test	56	59	7	90	24	28
Waiting times (patients)	n = 40	n = 36	n = 37	n = 40	n = 40	n = 40
Avg (H)	5:42	1:46	1:24	7:04	1:37	2:34
Min (H)	3:25	0:02	0:06	4:46	0:46	0:20
Max (H)	6:41	4:51	4:08	7:21	2:36	4:03
Time w/MCH nurse						
Avg (H)	0:17	0:25	0:16	0:08	0:07	0:09
Min (H)	0:04	0:07	0:06	0:06	0:03	0:02
Max (H)	0:42	1:27	1:15	0:36	0:36	0:33

TT, Tetanus Toxoid; IPT, Intermittent preventive treatment.

the "*tecnico*" category is similar to a physician's assistant trained in the several categories listed in Table 2. Both Munhava and Primeiro de Maio had larger numbers of new MCH nurse cadres. Notably, more MCH nurses had been trained in Option B+ in Sofala than in Manica. ART had been integrated through B+ training into ANC services at all 6 sites by mid-2013. At several sites, community health workers (mostly HIV-positive) known in Portuguese as *activistas*, had been employed at the facilities by international non-governmental organizations (NGO) to support patient

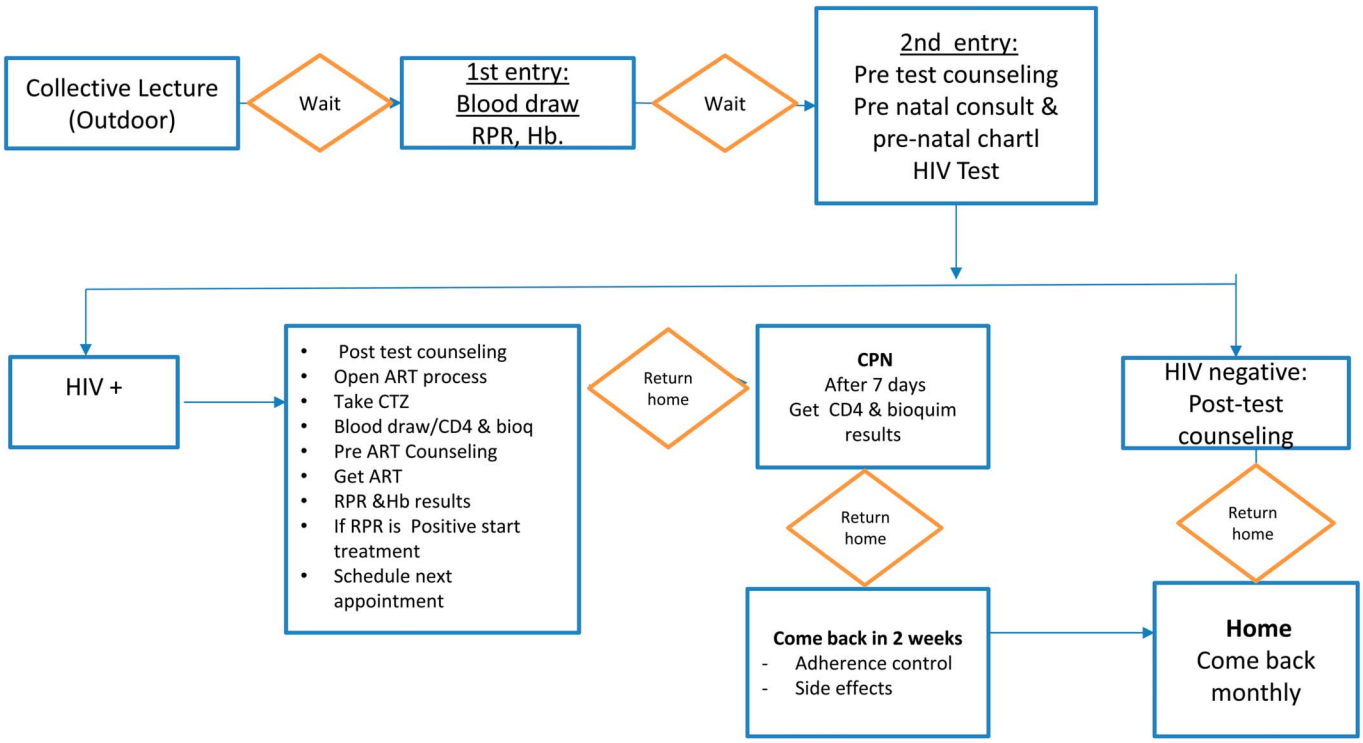

FIGURE 1. Patient flow in ANC at Munhava.

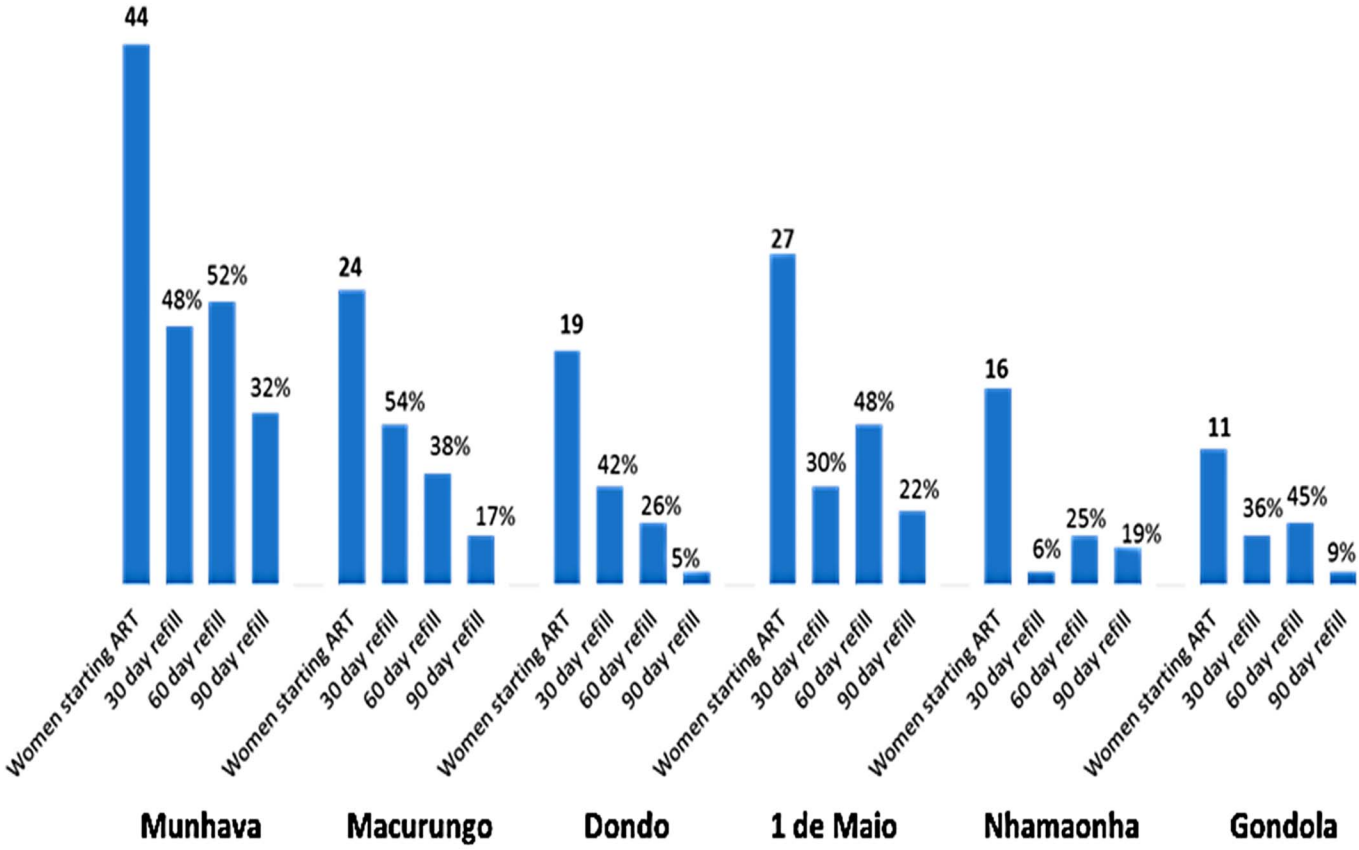

FIGURE 2. Proportion of women starting ART returning for 30-, 60-, and 90-day pharmacy refills.

follow-up, including home visits and counseling. In some instances, *activistas* provided support to MCH nurses in shuttling patients and moving files between services. The MOH had also adopted a facility-based mothers peer support approach across the country known in Portuguese as *Maes para Maes* (MpM), or mothers for mothers. MpM groups had been established at all sites but were only active in several.

Files and Documentation

The flow of patient files was tracked in each of the 6 sites. MCH nurses used an array of registries and patient files for each patient. In ANC, this included an ANC registry and ANC card. Mothers who test HIV-positive were entered into an ART registry, an ART patient file was opened, and a pharmacy form called a *FILA* (in Portuguese, a *Ficha Individual de Levantamento de ARV*, or individual antiretroviral (ARV) pickup record) was filled out and used to record pharmacy refills. The research team found that across the 6 facilities a range of 10%–30% of *FILAS* (median 23.5, IQR 9.0) were missing for mothers who started ART in ANC, making it difficult to follow-up with possible defaulters. There was confusion among some nurses about how ART

TABLE 2. Workforce at 6 Study Sites (2013)

	Sofala Province			Manica Province		
Workforce Categories	**Munhava**	**Macurungo**	**Dondo**	**1° de Maio**	**Nhamaonha**	**Gondola**
Physician	1	1	3	1	0	2
Tecnico—general medicine	4	2	4	3	3	3
Tecnico—pharmacy	1	1	3	4	1	3
Tecnico—laboratory	1	1	1	2	0	2
MCH nurse—midlevel	13	7	4	2	1	3
MCH nurse—basic	4	7	3	11	5	4
MCH nurse—elementary	3	1	0	6	2	1
Number of nurses trained in B+	7	6	5	3	3	3
Activistas	Yes	Yes	Yes	Yes	No	No
Maes para Maes active	No	Yes	Yes	Yes	Yes	No

files and *FILAS* were to be transferred to postpartum care after delivery. Most sites did not have adequate filing cabinet space to properly archive the growing ART files and *FILAS*.

Laboratory Tests and Medications

ANC services maintain their own stocks of HIV tests and ARVs. There were no stock cards used in ANC, so MCH nurses were asked how many days in the previous 3 months they experienced stockouts (Table 3). With the exception of Munhava, no sites reported extended stockouts of over 1 month of ARVs for ART. HIV test stockouts were rare; however, occasional stockouts of azidothymidine and nevirapine for infant prophylaxis were reported. A lengthy national stockout of syphilis rapid tests had added waiting time at each site because mothers were now asked to have blood taken for rapid plasma reagin (RPR) testing before regular ANC consultations (Fig. 1). In general, stockouts of key HIV-related commodities were not reported as a major bottleneck to care.

Patient Interviews

Six FGDs, 1 at each target site, were conducted with women who tested positive for HIV in ANC services and had participated in facility peer support groups (FGD size: Munhava 5, Dondo 7, Nhamaonha 9, Macurungo 10, 1° de Maio 10, Gondola 10). Patient FGDs can be summarized in 3 categories of recurrent themes that emerged across all 6 focus groups.

Community Context: Stigma

FGD participants reported high HIV/AIDS stigma in their communities that created incentives to hide their status from family, friends, and male partners. Lack of male partner involvement and engagement in ANC was cited as a major barrier to women's follow-up with care because of fear of domestic violence and abandonment after testing positive. Participants also reported a pattern of misinformation in the community that included that ARVs are dangerous during pregnancy, ART is ineffective, and pregnancy is proof of a negative HIV status. Continued poor quality of counseling at most sites did little to rectify this misinformation.

Barriers to ART Uptake, Adherence, and Follow-up

According to participants, many pregnant women are not emotionally or socially prepared to be HIV-positive for life and continue ART. Despite their fears, many women consult their male partners before deciding to initiate and/or continue ART. Many HIV-positive pregnant women seek care in more than 1 ANC facility and obtain multiple HIV tests in hopes of possibly receiving an HIV-negative test that could provide hope that their initial test was a false positive. Long wait and short consultation times were reported as barriers and disincentives, and poor counseling contributed to confusing messages about HIV, ART, and how to navigate health services.

Peer Support Groups

The *MpM* peer support groups were reported to be highly valued because of the peer support and advice they provide and the testimony that other members offer about the efficacy of ART. Many women in the groups tell stories of reproductive loss (pregnancy termination and infant mortality) that are conversion moments leading to acceptance of their HIV+ status. Women are encouraged to continue in care by stories of peers who tell of great persistence and triumph despite the violence, need for secrecy, and the many social and clinic barriers care they face. However, sustainability of the peer support groups had been tenuous because provision of resources to support meetings, including snacks and educational materials, ebbed and flowed with NGO support.

Health Worker Interviews

Individual interviews were conducted with 49 health care workers (HCWs) across the 6 sites with 7–9 interviews per site. One FGD with HCWs was conducted at each site to identify major challenges to Option B+ implementation (7–9 participants per site). The following issues were identified by coders as key themes across all 6 FGDs.

Clinic Context and Preparation for Implementation of Option B+

For most HCWs, especially MCH nurses, the new Option B+ approach means more tasks for them and a higher patient volume workload. As a result, most HCWs believe they are significantly overworked and underappreciated, yet continue to work hard to deliver quality services under difficult conditions. Preparation for Option B+ across the 6 sites had been uneven, inadequate, and interpreted differently by different participants. The MOH B+ trainings often excluded key participants and undermined the team mentality instrumental for success.

Health workers cited the lack of basic human resources, functioning technology and other infrastructure, and reliable

TABLE 3. ANC Test and ARV Stockouts in Days in Previous 3 Months (2013)

	Sofala Province			Manica Province		
Test or Medication Stockout	**Munhava**	**Macurungo**	**Dondo**	**1° de Maio**	**Nhamaonha**	**Gondola**
Determine	0	0	n/k	0	0	0
Unigold	7	0	n/k	0	0	0
NVP	0	0	0	6	0	0
AZT	0	0	1	0	14	14
ART	26	0	n/k	0	0	0

AZT, azidothymidine; NVP, Nevirapine.

stocks of consumables as impediments to implementation of B+. At several sites, "Adherence Committees" had been established with support from an Italian NGO, CUAMM (*Collegio Universitario Aspiranti Medici Missionari*), that brought together nurses, activists, and clinicians regularly to review patient follow-up and identify defaulters. HCWs at those sites indicated that the committees were very valuable in following up with patients on ART. None of the sites conducted regular chart review of mothers starting ART.

Human Resource Shortages and Workflow Issues

Understaffing of maternal child health nurses led to gaps in services and patient tracking, inefficient patient flow, and little follow-up of defaulters. Challenges with registries constituted a barrier to implementing B+. The complexity of the forms and the lack of a universal national identification number had made it difficult to track individuals. Health workers indicated that improper, incomplete, and misplaced registries and patient files are common, which impedes patient tracking. Good practices for patient file organizing and tracking exist but need to be streamlined and universally implemented. The roles and tasks of nurses, receptionists, and counselors are all in need of redefinition and clarification in relation to the B + approach.

Activistas are an integral and vital addition to the workforce that allows Option B+ to function. Their roles are multiple and flexible but not clearly understood by all relevant staff or well defined to assure accountability and quality. Many *activistas* and some nurses reported that they already use their own cell phones to text patients for follow-up and suggested that SMS and calls were very effective for patient tracking. They asserted that more systematic use of SMS texting and calls to patients could improve retention.

DISCUSSION

Given the considerable resource constraints experienced by the public system in Mozambique, a scalable intervention would have to rely on systems improvements sustainable within these limitations. The formative research process used an implementation science approach to assessing health system performance that relied on a range of quantitative and qualitative data collection activities. Through the work and patient flow mapping and analysis of the HIV care and treatment cascade for pregnant women at the 6 sites, bottlenecks and process gaps were identified. The qualitative component of the formative research was essential to assess both health staff and patient experiences within the work flow and patient flow to complement quantitative data analysis and help explain bottlenecks and drop-offs in the care cascade. This approach could provide a critical first step toward improving PMTCT and reducing LTFU in many settings.

These techniques allowed the researchers to isolate key points in the workflow and patient flow that could be targeted to improve the key outcomes related to retention in care. Importantly, the implementation science approach in the formative work allowed researchers to carefully identify existing resources that could be more effectively deployed, and systematically recognize constraints and opportunities for improving implementation. The formative work allowed researchers to compare quantitative data collected from health facilities with qualitative interviews to identify key gaps in work and patient flow that the proposed intervention could target. Drawing on these data, an intervention was then designed that focused on those key points in the workflow and patient flow that could be adjusted to optimize patient retention within real-world constraints.

The proposed intervention included 2 core components. First, a model for workflow modification, specification, and clarification was developed to define specific tasks for each MCH nurse to optimize patient flow efficiency, coordinate patient tracking, and reduce workload. Job aids were developed to clarify process flows and support improved use of registries. The intervention allocated *activistas* to each site (where gaps existed) to support filing documentation, calling/texting patients, and conducting home visits. Together with facility staff, future process flow maps were outlined for each site to include the components of the intervention and illustrate the modified work and patient flows. Supportive supervision processes using principles of continuous quality improvement were developed and job aids designed and posted. Supervision checklists were created and provided to clinical directors and MCH nurses at each health facility to ensure quality in registry and patient file data collection, patient tracking processes, registries properly filled out, and patient follow-up conducted.

The second intervention component consisted of an adherence and retention package. The model includes monthly clinical chart reviews coordinated by the clinical director and MCH nurses. "Adherence Committees" created at each site, consisting of MCH nurses and *activistas*, who meet weekly to review patient adherence and coordinate follow-up strategies. The Committee would conduct monthly health facility ANC and ART data reviews to troubleshoot and resolve bottlenecks in patient flow. Because many health staff and activists reported that they already used cell phones for patient follow-up, an SMS texting protocol was developed to define content and timing of messages. Two cell phones were provided to each site with funding for text messaging.

The intervention included modified messaging for first counseling sessions, with repeat counseling for each visit in the first 30 days and subsequent visits. Content included partner notification and testing, side effects, ART, and ANC process, with dissemination of intensified counseling messages to peer support groups. MpM group leaders were trained in the new messaging, and modest material support and snacks were provided for MpM weekly meetings.

The core components were reviewed by provincial health MCH directors and health workers at the sites to confirm feasibility and fit. The core components would comprise already existing tools and basic resources in need of systematization and more consistent application within and among health facilities. Provincial health authorities provided final approval to initiate the intervention through a stepped wedge design. The intervention was designed to rely on minimal infusion of external resources to ensure sustainability and scalability. The costs would include health staff training, cell phones and funds for texting, stipends for 2 *activista*s per site, bicycles for *activistas*, snacks for MpM

groups, and modest additions to office supplies, including filing cabinets and job aids.

The formative research phase of the larger intervention allowed researchers to tailor the intervention to context, constraints, and opportunities posed at the 6 health facilities. The methods also helped researchers evaluate both the commonalities among sites but also heterogeneity of challenges and context. However, there were limitations and challenges to this formative work in a "real-world" health system setting. MOH policy continued to evolve as the research was conducted. Option B+ was initiated during the formative stage, which then required researchers to readjust data gathering plans to best assess the B+ rollout. Because the formative work captured the initial B+ rollout, there may have been adaptation and modification at the sites over subsequent periods before the study intervention itself was initiated. The formative research data will also be used to compare performance and activities before and after the intervention is initiated. After the formative period, specific baseline data were collected for measurement of intervention impact. However, a comprehensive process evaluation was designed to track and evaluate intervention implementation. The evaluation used in-depth focus groups and interviews with patients and health workers at quarterly intervals that will allow some comparison with the formative research interviews.

Given the sometimes volatile, variable, and unpredictable context in which implementation research is often conducted in health systems settings, the experience described here suggests that formative research is an essential component of implementation science efforts to strengthen health systems.

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