HIV and AIDS   Social and Behavioral Science Research (SBSR)

1-1-2021

Optimizing maternal and child health outcomes through use of multidisciplinary 'IMPROVE' teams in Lesotho

Appolinaire Tiam

Vincent Tukei

Lauren Greenberg

Shannon Viana

Heather Hoffman

See next page for additional authors

Follow this and additional works at: https://knowledgecommons.popcouncil.org/departments_sbsr-hiv

Part of the Public Health Commons

Recommended Citation

Authors

Appolinaire Tiam, Vincent Tukei, Lauren Greenberg, Shannon Viana, Heather Hoffman, Laura Guay, Ramatlapeng Thabelo, Tsietso Mots'oane, and Matsepeli Nchephe

report

JANUARY 2021

Optimizing Maternal and Child Health Outcomes Through Use of Multidisciplinary "IMPROVE" Teams in Lesotho

Appolinaire Tiam
Vincent Tukei
Lauren Greenberg
Shannon Viana
Heather Hoffman
Laura Guay
Ramatlapeng Thabelo
Tsietso Mots'oane
Matsepeli Nchephe

PEPFAR

USAID
FROM THE AMERICAN PEOPLE

BOPHELO
MINISTRY OF HEALTH

Elizabeth Glaser
Pediatric AIDS Foundation
Fighting for an AIDS-free generation

PROJECT
SOAR
SUPPORTING OPERATIONAL AIDS RESEARCH

Project SOAR (Cooperative Agreement AID-OAA-A-14-00060) is made possible by the generous support of the American people through the United States President's Emergency Plan for AIDS Relief and the United States Agency for International Development (USAID). The contents of this report are the sole responsibility of Project SOAR and the Population Council and do not necessarily reflect the views of PEPFAR, USAID, or the United States Government.

Through operations research, Project SOAR will determine how best to address challenges and gaps that remain in the delivery of HIV and AIDS care and support, treatment, and prevention services. Project SOAR will produce a large, multifaceted body of high-quality evidence to guide the planning and implementation of HIV and AIDS programs and policies. Led by the Population Council, Project SOAR is implemented in collaboration with Avenir Health, Elizabeth Glaser Pediatric AIDS Foundation, Johns Hopkins University, Palladium, and The University of North Carolina.

The Population Council confronts critical health and development issues—from stopping the spread of HIV to improving reproductive health and ensuring that young people lead full and productive lives. Through biomedical, social science and public health research in about 50 countries, the Council works with our partners to deliver solutions that lead to more effective policies, programs, and technologies to improve lives worldwide. Established in 1952 and headquartered in New York, the Council is a nongovernmental, nonprofit organization with an international board of trustees.

The Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) is a nonprofit organization that seeks to end HIV/AIDS globally in children, youth, and families. Founded in 1988, EGPAF supports activities in 19 countries worldwide. In collaboration with local partners, EGPAF advances research and innovation, advocates for global and local policies and resources, optimizes integrated service delivery programs, and builds global, national, and local capacity through tailored technical assistance to sustain a high-quality, locally-owned response to end the HIV/AIDS epidemic.

Cover photo credit: Elizabeth Glaser Pediatric AIDS Foundation

Optimizing Maternal and Child Health Outcomes Through Use of Multidisciplinary "IMPROVE" Teams in Lesotho

Appolinaire Tiam[1], Vincent Tukei[1], Lauren Greenberg[1], Shannon Viana[1], Heather Hoffman[2], Laura Guay[1,2], Ramatlapeng Thabelo[3], Tsietso Mots'oane[3], Matsepeli Nchephe[3]

[1]Elizabeth Glaser Pediatric AIDS Foundation (EGPAF)

[2]George Washington University

[3]Lesotho Ministry of Health

ACKNOWLEDGMENTS

TABLE OF CONTENTS

ACRONYMS

ANC	Antenatal care
ART	Antiretroviral therapy
ARV	Antiretroviral
CHW	Community health worker
CI	Confidence interval
EGPAF	Elizabeth Glaser Pediatric AIDS Foundation
FGD	Focus group discussion
GEE	Generalized estimating equation
HASI-P	HIV/AIDS Stigma Instrument—PLWA
HCW	Health care worker
HIV-ASES	HIV Adherence Self-Efficacy Scale
HR	Hazard ratio
IMPROVE	Integrated Management Team to Improve Maternal-Child Outcomes
IRB	Institutional Review Board
LTFU	Loss to follow-up
LENASO	Lesotho Network of AIDS Service Organizations
MCH	Maternal and child health
MDT	Multidisciplinary team
MOH	Ministry of Health, Lesotho
MTCT	Mother-to-child HIV transmission
m2m	mothers2mothers
NUL	National University of Lesotho
PHDP	Positive health, dignity, and prevention
PHQ	Patient health questionnaire
PMTCT	Prevention of mother-to-child HIV transmission
PNC	Postnatal care
SD	Standard deviation
VHW	Village health worker
VL	Viral load

EXECUTIVE SUMMARY

Critical progress has been made in reducing mother-to-child HIV transmission globally, yet pregnant and postpartum women continue to struggle with barriers to health services, poor retention and adherence, and health system challenges that compromise health outcomes for mothers and babies.

The "Integrated Management Team to Improve Maternal-Child Outcomes" (IMPROVE) intervention is a comprehensive, evidence-based strategy to improve maternal and child health (MCH) outcomes through patient-centered, participatory service delivery and multidisciplinary management teams (MDT). The intervention includes three key approaches: (1) multidisciplinary, integrated management teams of facility- and community-based health care and lay workers, (2) Joint Positive Health Dignity, and Prevention (PHDP)-focused counseling for patients and skills-building training and job aids for health workers, and (3) increased early community-based counseling and support for patients.

Using a participatory approach, each intervention health facility created its own MDT from the different cadres of staff whose responsibilities involved care and follow-up of pregnant and breastfeeding mothers at the health facility and in the community. The composition of the MDT varied from facility to facility; however, it generally consisted of nurses from the MCH and prevention of mother-to-child transmission (PMTCT) clinics, counselors and ART nurses, midwives, key laboratory and pharmaceutical staff, village health workers (VHW), LENASO focal persons, and mothers2mothers (m2m) staff who worked in the community and in the facility. The goal was to establish a patient-centered system for regular communication and coordination between facility-based teams (MCH/PMTCT service providers) and community teams (VHW, LENASO, and m2m).

To introduce the concept of PHDP-focused counseling, the investigators conducted a training of trainers (TOT) that included key individuals identified from the intervention health facilities. Thereafter, the TOT trainees carried out on-site joint trainings of the MDT and all the involved cadres. Participatory training workshops included group activities, role plays, and presentations to identify unique challenges encountered by women as they navigate through the facility systems. Each MDT identified barriers to better service delivery at their facility and in the community. Identified barriers and gaps in service delivery were turned into action items for the MDT. Refresher trainings were held as the need arose.

Job aids created by the investigators and the Ministry of Health (MOH), with input from the MDTs, were distributed to all cadres involved in the IMPROVE intervention to ensure consistent messaging for women.

To provide early community-based support to antenatal care (ANC) attendees, one to two home visits were conducted soon after the first ANC visit. Women were allowed to choose how they wanted to be followed and to choose the members of the team to visit them.

The study was conducted in Lesotho, a country with a generalized HIV epidemic and the second highest HIV prevalence worldwide.

METHODOLOGY

The IMPROVE study is a mixed methods study that evaluated the effectiveness of the IMPROVE intervention on MCH and HIV/PMTCT outcomes and health seeking behavior in a prospective cohort of HIV-positive and HIV-negative pregnant/postpartum women and their infants, compared to a similar cohort of women receiving routine care alone. The qualitative component of the study, led by investigators from the National University of Lesotho (NUL), assessed HCW attitudes toward the feasibility and acceptability of integrating the IMPROVE package in routine services and compared study women's satisfaction with PMTCT/MCH services in intervention and control facilities. Finally, a costing component, led by Avenir Health, was conducted to estimate incremental costs associated with the IMPROVE intervention and to identify key cost drivers. Two hospitals in Maseru district and four mid to high volume health facilities that were within the referral areas of each hospital were randomly allocated to intervention (6 facilities) or control arms (6 facilities). Between July 2016 and November 2017, a cohort of 614 HIV-positive and 390 HIV-negative women were enrolled during their first ANC visit and prospectively followed until 12–24 months after delivery (study end July 2019). Qualitative interviews and focus group discussions were conducted by the NUL with a subset of study women, facility-based HCWs, and lay health workers to evaluate patient satisfaction with services received and the feasibility and acceptability of integrating this intervention into routine national systems of care. For the costing component, data on service delivery—types of services offered at the site, number of patients or patient visits by service, and total number of patients or patient visits—were collected from summary registration forms and cross-referenced with MoH's District Health Information Software (DHIS2). Financial and cost data were collected in local currency and categorized by component.

KEY FINDINGS

The multidisciplinary teams strengthened communication and coordination across all cadres of health care and lay workers and led to improved delivery of services.

The multidisciplinary teams identified gaps in the delivery of services within their facilities and jointly developed solutions to enhance patient care, improve implementation of Ministry of Health (MOH) policies and tools, and decrease duplication of efforts.

Improved clinical outcomes were observed for HIV-positive women in the intervention arm compared to women in the control arm, but not all changes were sustained over time.

HIV-positive women in the intervention arm had more antenatal clinic visits (p=0.026) and were more likely to deliver in a health facility (92%) than women in the control arm (85%, p=0.025). HIV-positive women in the intervention arm were less likely to have their pregnancy end in a

stillbirth (p=0.015), though this was not seen with HIV-negative women. HIV-positive women in the control arm were 1.6 times more likely to be lost to follow-up by the end of the study, with retention in care for 18.3 months vs 19.8 months for women in the intervention arm, but this difference did not reach statistical significance (p=0.072). HIV-positive women in the intervention arm were significantly more likely to maintain > 95% adherence to ART by pill count at all visits compared to women in the control arm (77% vs. 66%, p=0.003). More than 90 percent of women achieved viral suppression (<1,000 copies/mL) with no difference between the two arms. The high proportion of women with viral suppression in the control group limited our ability to detect a difference between arms. HIV-positive women in the intervention arm were significantly more likely to have an undetectable viral load at 12 months after delivery (83%) than women in the control arm (72%, p=0.037); however, this did not persist in the smaller group of women who were followed to the 24-month endpoint.

HIV-negative women in the intervention arm were retained in care longer and were more likely to be retested for HIV prior to delivery.

HIV-negative women were retained for an average of 17.3 months vs. 16.8 months in the control arm (p<0.001), with women in the control arm three times more likely to be lost to follow-up (LTFU) by the end of the study (HR 3.1 95% confidence interval [CI]: 1.8–5.3). HIV-negative women in the intervention arm were significantly more likely to have a repeat HIV test prior to delivery compared to women in the control arm (AOR 1.95 (95% CI: 1.23–3.08) but both groups had over 80 percent repeat testing within the 12 months after delivery.

Regardless of HIV infection status, women in the intervention arm were significantly more likely to report consistent use of a modern method of contraception.

Consistent use of modern contraceptive methods over the study period was reported by 42 percent of HIV-positive women in the intervention arm vs. 30 percent in the control arm and 48 percent vs. 34 percent among HIV-negative women in the intervention and control arms, respectively. Women in the intervention group (HIV-positive and negative combined) were 1.62 (95% CI: 1.05–2.5) times more likely to report consistent use of a modern method of contraception than all women in the control group. While this represents some improvement in the intervention group, this is still far below the expected family planning needs of this population.

Low rates of depression and experienced stigma were observed in both arms.

Reported symptoms of moderate to severe depression during ANC were relatively low, with HIV-negative women significantly more likely to report moderate to severe depression than HIV-positive women (14% vs. 8%, p=0.036). Depression was reported in less than 10 percent of women in the two years after delivery, with no difference by study arms.

While few HIV-positive women reported experiencing stigma, women in all groups reported fearing that they would face stigma if they tested positive or if others found out about their HIV status. HIV-positive women in the control arm were consistently more likely to report fearing that they

would be treated badly at work or school, experience break-up of their relationship, become a social outcast, or lose their friends through the 18-month study visit, but there were no longer any significant differences in study arms by the 24-month visit. Among HIV-negative women, women in the control arm were significantly more likely to report fearing that they would experience outcomes such as loss of job/livelihood, poor treatment at work or school, or becoming a social outcast if they were to test positive for HIV and others found out at 6 weeks and 6 months postpartum, but no differences in study arms were seen by 12 months postpartum.

HIV-positive women in both arms reported high levels of ART treatment self-efficacy; in contrast, HIV-negative women reported much lower levels of confidence in their own ability to negotiate and implement HIV prevention measures, particularly around correct and consistent use of condoms.

Study women in the intervention arm were more satisfied with the health services they received, while HCWs felt the IMPROVE intervention was feasible and acceptable and improved their communication with patients and delivery of services. HCWs in the intervention arm recommended that the IMPROVE intervention be incorporated as a national standard within routine service delivery.

When asked questions about satisfaction with the information and the counseling and services received, for both HIV-positive and HIV-negative women the ratings were significantly higher among women in intervention facilities than those in control facilities in almost all of the areas. In the qualitative interviews, study women in the control arm reported long waiting times and fragmented services, while in the intervention arm, women reported that services were well-coordinated with few delays. HCWs in the intervention arm felt they provided better care to patients after implementing IMPROVE interventions, due to improvement in their knowledge, interdisciplinary care, attitudes, and communication with women. HCWs felt the IMPROVE intervention should continue and recommended it be incorporated in national service delivery.

The cost of the IMPROVE intervention, especially the integrated approach for FP, PMTCT, and pediatric ART, is not prohibitive, and has the potential to improve coordination of care at relatively low cost to existing services.

The total average unit cost for each of the services provided in the intervention arm was relatively higher than the total average unit cost in the control arm. The percentage cost differences between the arms were significantly higher for ANC services (35%), but only slightly higher for the other services—FP (8%), PMTCT (5%), postnatal care (PNC) (15%), and pediatric ART (8%). Scaling up the intervention, however, would not require a significant amount of financial support or significant human resources. With a relatively low cost and potential for overall improvement in coordinated care, it is worth exploring the expansion of the IMPROVE intervention beyond PMTCT programming, and to adapt it to additional health areas and care models.

CONCLUSION AND RECOMMENDATIONS

The IMPROVE interventions were designed to be relatively easy to implement in routine care settings with existing staff and minimal additional resources. We found that it was acceptable, feasible, and adaptable across a range of facilities in Maseru District. Introducing multidisciplinary teams with joint training of all cadres of facility and community personnel who support pregnant and postpartum women on using a patient-focused approach to MCH/PMTCT service delivery led to improved services and provider-patient relationships that benefitted both patients and staff and led to some improved health outcomes. While there were improvements seen in the intervention group, several of the outcomes still did not reach MCH/PMTCT goals, highlighting areas where gaps remain and additional efforts are needed to design and evaluate effective interventions to address them. Overall implementation of the IMPROVE interventions was found to be an effective strategy to enhance MCH/PMTCT service delivery and improve provider-patient interaction and patient outcomes.

There are several important recommendations based on the findings from the IMPROVE study that could improve program implementation and achieve better overall MCH and HIV outcomes for women and children in Lesotho. These recommendations are also consistent with both MOH and PEPFAR priorities that include improving the quality of HIV prevention and care services, the retention of HIV-positive patients in care, facility and community linkages, the integration of services, and efficiencies in program implementation.

- After consultations with the MOH and other stakeholders including the AIDS Development Partners (ADP) forum and technical working groups (TWGs), we recommend that the IMPROVE interventions be integrated into routine service delivery throughout Lesotho. It requires minimal additional costs to existing services and has the potential to improve coordination of care, even beyond MCH/PMTCT services.
  - This should include taking advantage of the strong MDT leaders in the IMPROVE intervention facilities to contribute to an updated program design and training of new MDT leaders across Lesotho.

- Existing staff trainings should be modified to include a patient-focused, PHDP-principled approach coupled with joint rather than vertical trainings according to the cadre of staff.

- Based upon our findings of low HIV prevention self-efficacy among HIV-negative women, health services should provide additional support to HIV-negative women in negotiating protective behaviors.

- Given the significant number of women who live outside the catchment area of the facility where they receive services or who move during pregnancy and the postnatal period, better systems for follow-up of all women regardless of where they live or move between facilities within a district and between districts are needed to ensure (and document) that they continue to access the necessary health services in their new location.

The IMPROVE intervention resulted in a better understanding of inefficiencies at the service delivery level in Lesotho and helped to spark conversations around the importance of patient-centered care and efficient, low-cost methods of improving both facility- and community-based care models. Several lessons learned from the implementation of the IMPROVE interventions

across the study facilities can inform the design of a nationwide program for scale up to achieve even better outcomes than found in the study. Evaluation after the scale-up of these interventions across Lesotho will be important to determine the effectiveness of this program on improving MCH and HIV/PMTCT outcomes, including population-based community evaluation of health seeking behaviors, family uptake of HIV testing and HIV care services, and HIV-free survival in children after all HIV exposure has ceased.

INTRODUCTION

Critical progress has been made in reducing mother-to-child HIV transmission (MTCT) worldwide with the rollout of prevention of mother-to-child HIV transmission (PMTCT) services and introduction of lifelong maternal antiretroviral therapy (ART). Yet in 2018, approximately 160,000 children (ages 0–14 years) were newly infected with HIV (UNAIDS 2019). MTCT is largely preventable with maternal ART use during pregnancy and breastfeeding; however, barriers to service uptake, poor maternal retention and adherence, and health system challenges continue to contribute to vertical HIV transmission and compromise health outcomes for mothers and their HIV-exposed children.

Pregnant and postpartum HIV-positive women face a complex set of barriers to PMTCT services, including stigma, poor knowledge of HIV and ART, and lack of partner/family support (Buregyeya et al. 2017; Gourlay et al. 2013; Hodgson et al. 2014; Knettel et al. 2018; Ngarina et al. 2013; Sariah et al. 2019; Turan and Nyblade 2013). With the introduction of Option B+ (lifelong ART) for pregnant and breastfeeding women, access to PMTCT services has improved, yet retention rates among women enrolled in PMTCT are lower than those for the general population of adults in HIV care (Knettel et al. 2018). Loss to follow-up (LTFU) and poor ART adherence are particularly high within the first three months of ART initiation and during the postpartum period (Cichowitz et al. 2019; Clouse et al. 2013; Knettel et al. 2018; Nachega et al. 2012). Women who are newly diagnosed with HIV during antenatal care (ANC), those initiating ART on the same day as diagnosis, those with high CD4 cell counts or asymptomatic infections, and those diagnosed at a young age are more at risk of LTFU and poor adherence (Hodgson et al. 2014; Knettel et al. 2018; Mutevedzi, Lessells and Newell 2013; Ware et al. 2013; Watt et al. 2019). Possible explanations for the poor retention include the stress of caring for an infant, postpartum emotional challenges, and stigma related to HIV disclosure (Gourlay et al. 2013; Knettel et al. 2018; Ngarina et al. 2013).

Health system barriers also affect PMTCT uptake and retention, including poor communication and coordination between PMTCT and other health services and between different cadres of providers, negative health care worker (HCW) attitudes, and inadequate counseling and support at ART initiation and across the cascade (Clouse et al. 2013; Colvin et al. 2014; Gourlay et al. 2013; Knettel et al. 2018; Psaros et al. 2015). Strategies shown to improve PMTCT retention, such as the use of peer counselors, community health workers (CHWs), and support groups, have now been widely implemented in maternal and child health (MCH) services, yet LTFU continues to remain high in PMTCT programs (Colvin et al. 2014; Futterman et al. 2010; Kim et al. 2012; Lewycka et al. 2013; Rotheram-Borus et al. 2014; Vrazo et al. 2018). A combination intervention, which addresses challenges at behavioral, social, and structural levels, could be effective in improving service uptake, retention, and ART adherence.

High rates of HIV sero-incidence among pregnant and postpartum women in sub-Saharan Africa are further barriers to elimination of MTCT. Yet, counseling and support for primary prevention among HIV-negative pregnancy women (PMTCT prong 1) are almost non-existent in PMTCT

programs, and rates of retesting, particularly in the postpartum period, are also low (Goga et al. 2015; Hamilton et al. 2017; Nungu et al. 2019; Rogers et al. 2016). In addition, focused efforts to reduce unplanned pregnancies (PMTCT prong 2) and increase access to family planning are often lacking (Kanyangarara, Sakyi and Laar 2019; Rucinski et al. 2018).

DESCRIPTION OF INTERVENTION

The "Integrated Management Team to Improve Maternal-Child Outcomes" (IMPROVE) intervention is a comprehensive, evidence-based strategy to improve HIV and maternal and child health (MCH) outcomes through patient-centered, participatory management teams.

Figure 1 The IMPROVE intervention

Multidisciplinary Integrated Management Teams

- Health facility-based clinicians and facility- and community-based lay health workers met regularly to coordinate patient-focused, outcome-oriented PMTCT/MCH services to all women with immediate defaulter follow-up.

Joint enhanced Positive Health, Dignity, and Prevention (PHDP)-focused counseling, skills-building training, and job aids

- Patient-centered counseling skills-building to facilitate self-efficacy, support partner disclosure, provide screening and referral for depression, and provide linkages to community-based services.
- Joint training and improved job aids for all health cadres (nurses, counselors, lay health workers) together to facilitate a team approach and ensure high quality, consistent messaging.

Increased early community-based counseling and support

- All ANC attendees received 1 to 2 additional home or community visits at 2–7 days and/or 9–14 days after first ANC visit, with particular attention to HIV-positive women to minimize immediate and early LTFU.

The IMPROVE intervention uses a multidisciplinary team approach to care, which has been associated with improved patient care and outcomes across a range of health services (Basta et al. 2017; Epstein 2014, Mitchell, Tieman, and Shelby-James 2008; Prades et al. 2015; Sherer et al. 2002). Multidisciplinary teams can help to ensure patients receive a full range of care and support services for successful management of complex conditions. In resource-limited settings, multidisciplinary teams may also facilitate task shifting and coordination among health cadres. This could be particularly relevant for facility-level integration of MCH and PMTCT services, where ANC services and ongoing HIV prevention and care services may not be effectively linked

after delivery. In the IMPROVE intervention, MCH providers (health care workers [HCWs] and lay facility and community workers) were trained in problem solving techniques and conducted a group mapping exercise to optimize the efficiency of patients' flow within the facilities and to identify gaps and potential strategies for ensuring patient follow-up and continuity from facility to community. Enhanced counseling, skills-building training, and job aids were also introduced to strengthen the multidisciplinary teams' ability to provide patient-centered care with consistent messages across all staff cadres. Patient-centered care practices are associated with better HIV treatment uptake, adherence, and viral suppression (Holtzman, Brady, and Yehia 2015; Thompson et al. 2012; U.S. Department of Health and Human Services 2017). Individualized, patient-focused counseling, community-based support for pregnant and postpartum women, and support for partner disclosure, are key strategies to improve patient retention and adherence. Early community-based counseling and support was also included in the intervention to minimize early LTFU. Figure 2 shows the conceptual framework for the IMPROVE intervention.

Figure 2 Conceptual Framework for the IMPROVE Intervention
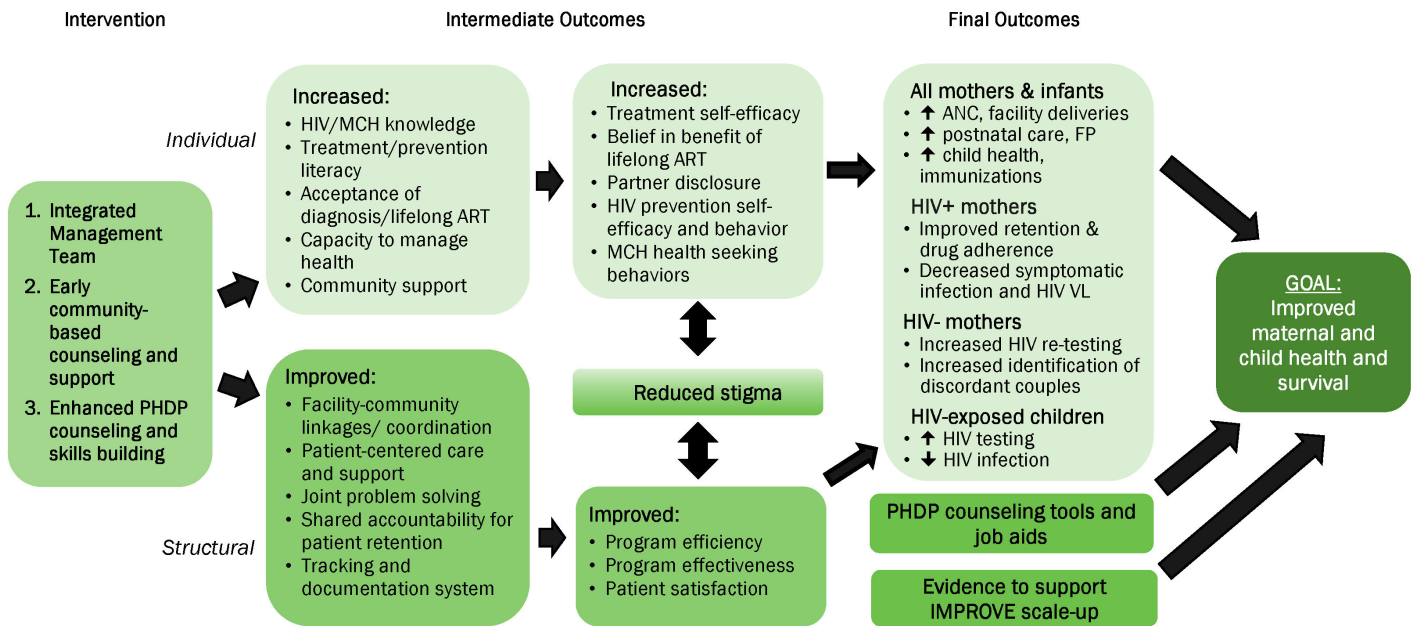
HIV IN LESOTHO AND THE GOVERNMENT RESPONSE

Lesotho is among the countries with the highest HIV burdens worldwide with an estimated prevalence of 23.6 percent among adults aged 15–49 years (UNAIDS 2019). The estimated prevalence among pregnant women is even higher at 25.9 percent (Government of Lesotho 2017).

In April 2013, Lesotho transitioned from Option A to Option B+ (lifelong ART) for PMTCT. The Lesotho Ministry of Health (MOH) has introduced several interventions to reduce LTFU at facility and community levels among people living with HIV and among pregnant women, in particular; however, interventions are led by different stakeholders and are often not well coordinated. For example, community outreach activities are led by three different groups of lay health workers: (1)

village health workers (VHWs), (2) HIV-specific community health workers (CHWs) managed by the Lesotho Network of AIDS Service Organizations (LENASO), and (3) mothers2mothers (m2m). This approach has led to poor coordination of services, duplication of efforts across partners, and a concentration of services in certain areas of the community. The IMPROVE study was designed to create a more structured system for providing improved services.

METHODOLOGY

OBJECTIVES

Primary

1. Evaluate the effect of the IMPROVE intervention on retention in HIV care, viral suppression, and adherence to ART at 12–24 months postpartum in a prospective cohort of HIV-positive pregnant/postpartum women and their infants compared to a cohort of HIV-positive women receiving routine care alone.

2. Evaluate the effect of the IMPROVE intervention on repeat HIV testing by 12–24 months postpartum in a prospective cohort of HIV-negative pregnant/postpartum women compared to a cohort of HIV-negative women receiving routine care alone.

3. Evaluate the effect of the IMPROVE intervention on targeted MCH health seeking behaviors (e.g., facility delivery, child immunization) in both HIV-positive and HIV-negative women compared to women receiving routine care alone.

4. Determine the costs associated with the IMPROVE package of interventions for both HIV-positive and HIV-negative women compared to HIV-positive and HIV-negative women receiving routine care without the IMPROVE intervention.

Secondary

1. Assess additional MCH outcomes (e.g., ANC attendance, infant mortality, maternal mortality); other HIV prevention indices (e.g., disclosure, knowledge of partner status, identification of discordant couples); unintended pregnancy prevention indices (e.g., use of modern contraceptives, repeat pregnancy, fertility intentions); and other indices of HIV care (e.g., timing of infant diagnosis, number of infected infants) among HIV-positive and HIV-negative women receiving the IMPROVE intervention versus those receiving routine care alone.

2. Compare depression, experienced stigma, and self-efficacy among both HIV-positive (treatment self-efficacy) and HIV-negative women (HIV prevention self-efficacy) in the intervention and control facilities.

3. Compare pregnant/postpartum women's attitudes toward lifelong ART (HIV-positive only), acceptability of the IMPROVE intervention (intervention facilities only), and satisfaction with PMTCT/MCH services among both HIV-positive and HIV-negative women in intervention and control facilities.

4. Assess HCW, counselor, and VHW attitudes toward the feasibility and acceptability of integrating the IMPROVE package in routine services.

5. Evaluate the costs of the IMPROVE intervention on retention in HIV care, viral suppression and adherence to ART, HIV retesting, and uptake of family planning and child immunizations at 12–24 months postpartum in a prospective cohort of pregnant/postpartum women and their

infants compared to a similar cohort of women and infants receiving routine care without the IMPROVE intervention.

STUDY DESIGN

This mixed methods study utilized a cluster-randomized design with 12 facilities in Maseru District assigned to implement either: 1) the IMPROVE intervention or 2) the national standard of care. Health facilities were categorized by type of facility (hospital or health center), hospital catchment areas, and type of support (government or Christian Health Association of Lesotho) to ensure even distribution between arms. The two hospitals in the district along with four mid to high volume health facilities within each of their referral areas were randomly allocated to the intervention or control arms. This was to minimize potential cross contamination if a health facility and the hospital that received that facility's referrals were randomly allocated to different arms.

The IMPROVE intervention included creation of health facility-based multidisciplinary integrated management teams (MDT), joint training of the team on PHDP-focused counseling, use of job aids, and increased early community-based counseling and support for ANC attendees. With initial guidance from the study team, each intervention health facility created its own MDT from the different cadres of staff whose responsibilities involved follow-up of pregnant and breastfeeding mothers at the health facility and in the community. To create the teams, health facility and community staff met to identify individuals to be trained as members of the multidisciplinary team. The composition of the MDT varied from facility to facility; however, in general it consisted of nurses from the MCH and PMTCT clinics, counselors and ART nurses, midwives, key laboratory and pharmaceutical staff, VHWs, LENASO focal persons, and m2m staff who worked in the community and in the facility. A participatory approach that involved several meetings among the different cadres that care for women at the facility and in the community was employed during the development of the teams. The goal was to establish a patient-centered system for regular communication and coordination between facility-based teams (MCH/PMTCT service providers) and community teams (VHW, LENASO, and m2m). Each health facility determined the total number of staff that formed the MDT, defined the roles and responsibilities of the team members, and determined the frequency of MDT meetings. During the meetings, the MDT identified gaps in linkage of patients between facility and the community and vice-versa and identified and addressed challenges in communication among the different stakeholders.

To introduce the concept of PHDP-focused counseling, the investigators conducted a training of trainers (TOT) that included key individuals identified from the intervention health facilities. Thereafter, the TOT trainees carried out on-site trainings of the MDT in all the intervention health facilities. This included training all cadres of facility and community personnel that support pregnant/postpartum women together to facilitate a more coordinated and effective system for the delivery of services and facility-community linkages. These participatory training workshops, which included group activities, role plays, and presentations, were held at the health facilities to identify unique challenges encountered by women as they navigate through the facility systems. During the trainings, each MDT identified barriers to better service delivery at their facility and in the community. Identified barriers and gaps in service delivery were turned into action items for the MDT. Refresher trainings were held as the need arose.

To support consistency of counseling messages across facility and community-based service providers, the IMPROVE study team together with the PMTCT and Health Education units of the MOH worked collaboratively to develop and refine short PMTCT "key message" job aids. The job aids comprised linked pocket-sized cards of individualized counseling scripts tailored to women who were HIV-negative, newly diagnosed with HIV, initiating ART, already on ART, or in an HIV-discordant relationship. The brief messages were intended to improve women's engagement and retention in care, self-efficacy to adhere to ART, support for partner HIV status disclosure, screening and referral for depression, and linkage with other clinical and community-based services. All intervention MCH and PMTCT facility and community-based providers were trained on the use of the job aids during the joint trainings.

To provide early community-based support to ANC attendees, one to two home visits were conducted by a member of the MDT after the first ANC visit. Women were allowed to choose how they wanted to be followed and to choose the members of the team to visit them. A Ministry of Health tracking tool was used for documentation of any follow-up carried out at the facility or in the community.

Between July 2016 and November 2017, a cohort of 614 HIV-positive and 390 HIV-negative women were enrolled during their first ANC visit and prospectively followed until 12–24 months after delivery (study end July 2019). Qualitative interviews with a subset of study women and focus group discussions (FGDs) with HCWs and facility- and community-based lay health workers were conducted by the National University of Lesotho investigators to evaluate service delivery experiences and the feasibility and acceptability of integrating this intervention into routine national systems of care. A cost analysis component was also conducted by Avenir Health to estimate incremental costs associated with the IMPROVE intervention.

Data gathering activity #1: Cluster randomized IMPROVE trial

Procedures

Pregnant women attending their first ANC visit at a study health facility were eligible for enrollment in the study and followed until 24 months postpartum. Inclusion and exclusion criteria include:

Inclusion criteria

- Pregnant woman attending first ANC visit at a study facility
  - There was no age restriction for study enrollment as young pregnant women in Lesotho are consider emancipated. Parental permission was not needed for eligible participants under 18 years of age.
- HIV status known at time of enrollment
- Residing in a study facility catchment area
- Willing and able to provide informed consent

Exclusion criteria

- Pregnant women attending second or later ANC visits

- Attending care at study facility temporarily

- Significant medical or psychological condition that would preclude active study participation

- Inability to provide informed consent

After obtaining written informed consent, pregnant women were enrolled into either the IMPROVE intervention arm or control arm depending on the facility she attended. After the enrollment visit, women/infants were seen by study staff for study specific visits during ANC; delivery; and 6 and 14 weeks and 6, 9, 12, 18, and 24 months postpartum. At each visit, participant interviews were conducted and maternal and child medical record and laboratory data were abstracted. Participant-specific data were entered into the electronic database on tablets using a unique study identification number. Dried blood spot specimens for maternal study viral load determinations from HIV-positive women were collected at enrollment, delivery, and 12 and 24 months postpartum. Specimens were transported to the National Reference lab in Maseru and stored in the freezer until batched and sent by ground to the National Institute for Communicable Diseases in Johannesburg, South Africa for testing. Data from HIV-negative women included medical history, service utilization, HIV risk and prevention behavior, and HIV re-testing data.

Access to the CliniOps cloud-based database was controlled through an individual password-protected log-in requirement with differential levels of access as needed for study staff and investigators in Lesotho and the US. Data were exported into analytical programs such as STATA or SAS for analysis.

Assessments of self-efficacy, stigma, and depression were conducted through interviewer-administered questionnaires every six months for all women using the following questionnaires.

- Self-efficacy (HIV Treatment Adherence Self-Efficacy Scale [HIV-ASES] questionnaire) (Johnson et al. 2007); HIV prevention self-efficacy questionnaire

- Depression (Patient Health Questionnaire (PHQ-9) (Kroenke, Spitzer, and Williams 2001)

- Stigma (5-item HASI-P; 9-item anticipated stigma score) (Holzemer et al. 2007)

Sample size calculations

The targeted sample size was ~310 HIV-positive and 200 HIV-negative women in each arm to measure the effect of the intervention on the primary endpoints. The sample selected was estimated to allow us to determine the effect of the intervention with 80 percent power at 0.05 significance level, including adjustment for a design effect of 1.5 and a study LTFU of 20 percent (nQuery Advisor 4.0).

Primary endpoints

HIV-positive women: For the primary endpoint of retention in care at 12–24 months, we have the power to detect a minimum of 15-percentage point increase from an estimated proportion of 60 percent in the standard care arm to 75 percent in the intervention arm with a sample size of 310

HIV-positive women in each arm. With this sample size we will also be able to detect an increase in adherence or viral suppression from an estimated rate of 70 percent in the standard care arm to 85 percent in the intervention arm.

HIV-negative women: For the primary endpoint of the rate of HIV retesting between 12-24 months postpartum, with 200 HIV-negative women per arm, we have the power to detect a 20-percentage point increase from an estimated 40 percent in the standard arm to 60 percent in the intervention arm.

All women: For the MCH care seeking behaviors, both cohorts of study women will contribute to the analysis of the effect of the intervention, separately and combined. For the primary endpoint of complete immunization of the child by 12 months, the combined sample size of 510 women in each arm will allow detection of a 15-percentage point increase if the standard care arm is at least 60 percent coverage (full immunization coverage in Maseru district DHS 2014). This sample will also be sufficient to detect a 15-percentage or more increase in the primary endpoint of proportion of facility deliveries from a standard of care rate of 70 percent or more.

Data analysis

To summarize key indicators related to primary or secondary study objectives, we calculated descriptive statistics (frequency tables, mean/median/range) for these indicators. Intervention arm was determined by the site at which a participant was enrolled; while some participants did receive services at other sites during the follow-up period, most women continued to receive care at the same site for the duration of the study. Analyses are generally stratified by HIV status. We used the Rao-Scott chi-square test and the t-test to assess differences in characteristics and outcomes between groups and generalized estimating equations for multivariable analysis, accounting for clustering by study site. Odds ratios (ORs) were adjusted for baseline characteristics identified a priori: maternal age, marital status, and education. We used Kaplan-Meier curves and a Cox proportional hazards model to assess differences in retention in care, where participants were considered lost to follow up if they did not complete all expected study visits and did not withdraw early from the study.

Data gathering activity #2: Qualitative interviews and focus groups

Procedures

A subset of 65 women (19 HIV-negative and 46 HIV-positive) attending their 18- or 24-month study visit participated in the qualitative component of the study. Six FGDs were conducted with facility-based HCWs and lay health workers (based in facilities or communities) who were providing MCH/PMTCT services in the IMPROVE intervention (24 participants) and control (18 participants) arms. The EGPAF study team identified participants scheduled for their 18- or 24-month visits during the data collection period. Women were informed of the qualitative component of the study and referred to the National University of Lesotho (NUL) research assistants for potential enrollment. Similarly, the study nurses identified the lay health workers and facility-based HCWs who met the inclusion criteria and referred them for potential participation in the FGDs.

The qualitative research assistants explained the purpose and objectives of the study to the participants, read the informed consent text, and asked for permission to record the discussions. The research assistants obtained and documented verbal consent to join the study from all participants. A copy of the informed consent text was offered to study participants. All participants were interviewed in the participant's language of choice using interview and focus group discussion guides available in English and Sesotho.

Data collection process

The research assistants conducted all interviews for study women in private areas in the selected study facilities. However, some women were followed up at their homes and workplaces at the convenience of participants. The discussions were in Sesotho for all participants with discussions audio recorded. For the focus group discussions, given the diverse work location for participants, transportation was provided to a central location. HCWs utilized both languages (Sesotho and English), depending on preference. The lay health worker groups mostly used Sesotho.

Analysis

The data transcriptions and translations were performed by research assistants under the supervision of the NUL investigators. The R Software (RQDA package) was used to create codes, categorization, and mappings. All generated codes were subjected to review by the research team and defined, with an emphasis on achieving clarity and explicit guidance for code application. Upon convergence, the team was comfortable with the code definitions and coding was done on a sample narrative of extracts. The results of the coding were subjected to consistency checks on text segmentation and code application with periodic checks for intercoder agreement.

Data gathering activity #3: Costing component

Procedures

The cost evaluation of facility-based delivery of IMPROVE services began in November 2018. Data collection instruments were designed to collect data from multiple sources including facility, district, and national health staff and patient forms. After an initial pilot-testing period, adjustments were made to data collection forms to reflect availability of aggregate patient service delivery and cost data. These data were collected from interviews with staff at the facility, district, and national levels of the MOH and their implementing partners by a team of Maseru-based costing consultants. Data on service delivery—types of services offered at the site, number of patients or patient visits by service, and total number of patients or patient visits—were collected from summary registration forms and cross-referenced with MoH's District Health Information Software (DHIS2). The cost data were categorized by the following cost components:

1. **Clinical staff costs:** These are defined as the estimated time facility-based clinical providers reported spending with the average patient through specific stages (registration, triage, counseling and testing, consultation, adherence counseling, pharmacy, etc.) during a visit by type of service (ANC, FP, PMTCT, PNC, and pediatric ART). The costs are then calculated by multiplying the reported time spent by the average salary of providers by cadre, the average number of staff providing services at each stage of care by staff cadre, and the estimated number of visits per year for each type of service.

2. **Laboratory costs:** These include the cost of lab commodities (test kits, lab tests, etc.) and the estimated time, reported by lab staff, spent conducting lab tests (blood draw, running test, interpreting test) for each type of patient by service. It also includes the average cost of transporting samples from facilities to testing laboratories (based on national average sample transportation costs). As with clinical staff costs, lab staff costs are then calculated by multiplying the reported time spent running each type of test (HIV, dried blood spot) by the average salary of staff and the estimated number of tests per patient per year for each type of service. Lab testing occurs at either one of three of the 12 study facilities or at the National Reference Laboratory. Costs were collected from all three facilities, as well as from the National Reference Laboratory. As such, the time spent by lab staff and salary of staff cadres who performed lab services were averaged across these three sources and applied to each of the 12 facilities.

3. **Support staff costs:** These are defined as time spent by facility-based staff who do not provide direct clinical services to patients but whose work supports these services at the facility (for example, night guard, cleaner, accountant/bookkeeper, etc.). The costs are then calculated for each cadre by multiplying the reported time spent by the average salary of each support staff cadre based at that facility and the estimated proportion of time spent supporting each type of service reported by the same facility. Where the support staff were unable to provide an estimate of the time spent supporting each type of service, costs were estimated by multiplying the staff salary by the proportion of patients or patient visits by service area. The patient proportion by service area is calculated by dividing the number of patients or patient visits for each service area by the total number of patients or patient visits for each facility, respectively, depending on which of these two sets of data is available.

4. **Integrated multidisciplinary management team costs:** This is defined as the average amount of time each facility's multidisciplinary team member spends in meetings to improve coordination of care and follow-up for patients lost to follow-up. This cost is calculated by the amount of reported time spent in meetings per month multiplied by the average salary of each team member and the number of meetings a year (12). These costs are apportioned to each of the five service areas for each facility using the number of patients or patient visits divided by the total number of patients or patient visits for each facility, respectively, depending on which of these two sets of data is available.

5. **District health management team:** This is the cost of the average reported time spent by the Maseru district health management staff supervising and supporting each facility program and the average time spent visiting/supervising each facility per month multiplied by the number of months in a year (12) and the average annual salary of each cadre of the district health management team. These district support teams also include MOH as well as implementing partner staff.

6. **Drugs and commodities costs:** This is calculated as the average quantity of each drug, medical commodity, and supply item used during a patient visit for each type of service reported by facility-based clinical providers multiplied by the cost per item of that drug, medical commodity, or supply. The cost of two key drugs and commodities—ARVs and contraceptive commodities[1]— were calculated using an average weighted cost based on the number of patients on each of

[1]National Drug Service Organization-Central Store Price List and UNFPA/Lesotho price list.

the four major ARV regimens used by patients across the 12 sites[2] and the five contraceptive methods reported in Lesotho's most recent DHS survey, (MOH and ICF International 2016) respectively.

7. **Operating costs:** This is defined as the cost of utilities (water, telephone, electricity, etc.), transportation (per diem, mobile and emergency vehicle maintenance, etc.), and maintenance costs (building and equipment maintenance). These costs are apportioned to each of the service areas for each facility using the number of patients or patient visits divided by the total number of patients or patient visits for each facility, respectively, depending on which of these two sets of data is available.

8. **Equipment costs:** These are the cost of medical equipment and furniture estimated by amortizing the cost of each piece of equipment used the year it was purchased, its lifespan/replacement period and whether or not it was used for each of the types of services. Like operating costs, these costs are apportioned to each of the service areas for each facility using the number of patients or patient visits divided by the total number of patients or patient visits for each facility, respectively, depending on which of the two sets of data is available.

Data collection process

All financial and cost data were collected in local currency (Maloti) and then converted to U.S. dollars (USD) using the average exchange rate over the study period (November 2017 to October 2019).[3] All 12 facilities offered ANC, HCT, PMTCT, PNC, and pediatric ART services. Only five of the 12 facilities offered FP services—two in the control arm and three in the intervention arm (including one hospital). Some of the costs pertaining to the intervention could not be separated from general program costs, specifically pre-implementation costs for the development of job aids, training at the site level for use of these aids, and start-up costs of the multidisciplinary team meetings, and thus were not available for analysis. The incremental cost of the additional home visit was also not available, as it was performed for all patients (including non-study participants) and across all facilities (including non-study facilities); as such it could not be allocated to either the control or intervention arm.

Data analysis

To compare between control and intervention facility costs, data were averaged across the six facilities in each of the two arms. Since FP services were only offered in two control and three intervention facilities, FP service costs were averaged for these two groups of facilities for comparison. Lastly, the percentage cost difference of each service area was calculated by subtracting the total average unit cost of each service in the control arm from the total average unit cost of the corresponding service in the intervention arm, the result of which was then divided by the total average unit cost of that service in the control arm and multiplied by 100 to convert to percent.

---

[2]Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), Lesotho country program data.

[3]International Monetary Fund, Representative Exchange rates accessed via https://www.imf.org/external/np/fin/ert/GUI/Pages/Report.aspx?CT=%27ZAF%27&EX=REP&P=DateRange&Fr=636051744000000000&To=637079904000000000&CF=Compressed&CUF=Period&DS=Ascending&DT=Blank

ETHICAL REVIEW

This study was reviewed by the Lesotho National Health Research and Ethics Committee, the Population Council IRB, and the George Washington University Committee on Human Research IRB. In addition, for the qualitative component, the National University of Lesotho Ethics committee also provided review.

KEY FINDINGS/RESULTS

FACILITY-LEVEL CHANGES IMPLEMENTED BY MULTIDISCIPLINARY TEAMS

Six multidisciplinary teams (MDTs)—one for each intervention facility—were formed from existing facility MCH staff and lay health workers (both facility- and community-based), who were trained as a team and met regularly to coordinate patient-focused PMTCT/MCH services. Teams mapped their facility's points of care and support (from facility to community settings), identified potential barriers, and brainstormed how to improve women's experiences. Examples of changes made by the MDTs include:

Enhancing the patient experience

- One facility MDT noted that pregnant women had to wait for long periods between service delivery points, including taking their own specimens to the lab and waiting to collect the results. The MDT decided to have MCH nurses take blood specimens to the lab and collect the results. MCH nurses also began conducting urine tests for pregnancy in the MCH clinic as a point-of-care lab service rather than requiring women to make an additional trip to the lab.

- One facility required patients to pay M1.00 to access the toilets, including pregnant women who had to provide a urine specimen. Working with facility administration, MDTs developed a card system to ensure the toilet fee was lifted for pregnant women.

Improved implementation of MOH policies and tools

- Prior to the study, none of the six intervention facilities was scheduling HIV-negative women for HIV retesting, and minimal collaboration and communication existed between facility- and community-based tracking staff that provided mother-baby pair PMTCT/MCH services. The MDTs set up monitoring systems to ensure repeat testing was scheduled per MOH guidelines. In addition, MDTs required all partners to implement the MOH patient tracking tool for home visit services.

Development of innovative tools

- The catchment of one facility, located in mountainous terrain, included villages that were not accessible by car, had limited mobile network access, and had no lay health workers. To assist with patient tracking, the MDT developed their own referral slip to be used with the MOH's standard tracking tool. The new referral sheet was given to every pregnant woman at their first ANC visit so that they could initiate one-on-one contact with a lay health worker in their area. The lay health worker used the referral to build rapport with the women, and the referral slips were saved for documentation. The lay health workers were then able to present process reports on their tracking efforts during the monthly MDT meetings.

There were several overall lessons learned across the six MDTs. First, improved communication and coordination between facility and community teams built trust, improved working relationships, and reduced duplication of activities. Working as a team, the MDTs were able to provide more active monitoring of new policies and guidelines, which are important to ensure effective implementation at the facility. Finally, the MDTs highlighted that the lack of clear systems for cross-district (even cross-catchment area) linkages for follow-up jeopardized retention in care and the accuracy of reporting.

SCREENING AND ENROLLMENT

Figure 3 presents the flow of study screening and enrollment. By the end of the study, there were 12 maternal deaths: 3 HIV-positive women during pregnancy, 7 HIV-positive women after delivery, and 2 HIV-negative women after delivery.

Figure 3 Participant screening, enrollment, and follow-up to the end of the study

Screened = 1382

Eligible = 1226

Enrolled = 1004

HIV-positive = 614 | HIV-negative = 390

HIV-positive — Intervention

Enrollment: 310
- Not eligible= 1*
- Died = 1
- Withdrew = 6
- LTFU/Rel. = 9

Delivery: 293
- Died = 2
- Withdrew = 11
- LTFU/Rel. = 14

6 Months: 266
- Died = 1
- Withdrew = 3
- LTFU/Rel. = 8

12 Months: 254
- Died = 2
- Withdrew = 1
- LTFU/Rel. = 12
- EOS = 5

18 Months: 234
- Died = 1
- Withdrew = 1
- LTFU/Rel. = 6
- EOS = 67

24 Months: 159

HIV-positive — Control

Enrollment: 304
- Died = 2
- Withdrew = 7
- LTFU/Rel. = 19

Delivery: 276
- Died = 1
- Withdrew = 18
- LTFU/Rel. = 12

6 Months: 245
- Withdrew = 1
- LTFU/Rel. = 11

12 Months: 233
- Withdrew = 4
- LTFU/Rel. = 7
- EOS = 9

18 Months: 213
- Withdrew = 1
- LTFU/Rel. = 9
- EOS = 81

24 Months: 122

HIV-negative — Intervention

Enrollment: 197
- Withdrew = 4
- LTFU/Rel. = 14

Delivery: 179
- Died = 2
- Withdrew = 6
- LTFU/Rel. = 8

6 Months: 163
- Withdrew = 2
- LTFU/Rel. = 11

12 Months: 150
- Withdrew = 1
- LTFU/Rel. = 7
- EOS = 18

18 Months: 124
- Withdrew = 1
- LTFU/Rel. = 2
- EOS = 64

24 Months: 57

HIV-negative — Control

Enrollment: 193
- Withdrew = 4
- LTFU/Rel. = 15

Delivery: 174
- Withdrew = 2
- LTFU/Rel. = 27

6 Months: 145
- Withdrew = 0
- LTFU/Rel. = 16

12 Months: 129
- Withdrew = 0
- LTFU/Rel. = 10
- EOS: 17

18 Months: 102
- Withdrew = 0
- LTFU/Rel. = 3
- EOS: 49

24 Months: 50

Withdrew = Withdrawal of consent, LTFU/Rel. = Lost to follow-up or relocated (transfers outside of the study district), EOS = End of study (not eligible for further follow-up due to end of study follow-up period)

* One HIV-positive woman at an intervention site completed her enrollment visit before it was determined that she was not actually pregnant. She was terminated and her data have been excluded from analysis.

Note: Reasons for refusing enrollment: 1. Plans to attend postnatal care in another district (n=70), 2. No interest in participation (n=60), 3. Feeling that the study would be too time-consuming (n=23), 4. Too emotional to consent (n=14).

CHARACTERISTICS OF THE PARTICIPANTS AT ENROLLMENT

HIV-positive study participants were similar at enrollment in both the intervention and control arms (Table 1). For HIV-negative pregnant women, participants in the intervention arm were significantly older, were more likely to be married or living with partner, and had more previous pregnancies ($p < 0.05$).

Table 1 Baseline characteristics of study participants at enrollment

Characteristics	HIV-positive (n=613)				HIV-negative (n=390)			
	Intervention n=309 n (%)	Control n=304 n (%)	Total n	p-value	Intervention n=197 n (%)	Control n=193 n (%)	Total n	p-value
Maternal age (years)								
N	308	304	612	0.515	197	193	390	0.062
Mean (SD)	28.6 (5.9)	28.0 (6.0)			24.5 (5.0)	23.1 (5.2)		
Maternal age (years)								
<19	9 (2.9)	15 (4.9)	24	0.451	15 (7.6)	33 (17.1)	48	<0.001
19–24	73 (23.7)	80 (26.3)	153		96 (48.7)	102 (52.9)	198	
25+	226 (73.4)	209 (68.8)	435		86 (43.7)	58 (30.1)	144	
Missing	1	0			0	0		
Marital status								
Married or living with a partner	247 (80.2)	233 (76.6)	480	0.160	158 (80.2)	134 (69.4)	292	<0.001
Never married (not living with partner)	39 (12.7)	53 (17.4)	92		37 (18.8)	58 (30.1)	95	
Divorced/separated	10 (3.2)	12 (4.0)	22		2 (1.0)	0	2	
Widowed	12 (3.9)	6 (2.0)	18		0	1 (0.5)	1	
Missing	1	0			0	0		
Highest level of education								
No more than primary school	109 (35.4)	112 (37.0)	221	0.593	51 (25.9)	38 (19.7)	89	0.057
No more than high school	173 (56.2)	174 (57.4)	347		120 (60.9)	142 (73.6)	262	
Beyond high school	26 (8.4)	17 (5.6)	44		26 (13.2)	13 (6.7)	39	
Missing	1	1						
Number of pregnancies								
1 (just this pregnancy)	56 (18.4)	73 (24.3)	129	0.264	75 (38.9)	107 (55.7)	182	<0.001
2	121 (39.8)	108 (36.0)	229		68 (35.2)	58 (30.2)	126	
3	71 (23.4)	64 (21.3)	135		34 (17.6)	19 (9.9)	53	
4 or more	56 (18.4)	55 (18.3)	111		16 (8.3)	8 (4.2)	24	
Missing	5	4			6	1		
Partner/husband testing history								
Unknown (including Not Tested),	71 (23.1)	82 (27.1)	153	0.551	97 (49.2)	106 (55.2)	203	0.637
HIV-positive	104 (33.8)	104 (34.3)	208		6 (3.1)	6 (3.1)	12	
HIV-negative	133 (43.2)	117 (38.6)	250		94 (47.7)	80 (41.7)	174	
Missing	1	1			1	1		
Estimated gestation (weeks) at enrollment								
N	299	293	592	0.569	193	191	384	0.629
Mean (SD)	19.8 (7.7)	20.4 (7.5)			21.0 (6.4)	21.4 (6.8)		
Newly diagnosed with HIV at first ANC visit								
Yes					N/A	N/A	N/A	
No	85 (27.6)	86 (28.4)	171	0.841				
Missing	223 (72.4)	217 (71.6)	440					

PREGNANCY AND DELIVERY OUTCOMES

ANC and maternity service uptake differed for HIV-positive women in the intervention arm compared with the control arm, but no differences were seen with HIV-negative women (Table 2). HIV-positive women in the intervention arm had significantly more ANC visits and were more likely to deliver in a health facility compared to women in the control arm. Multivariable analysis comparing the number of ANC visits for all women (HIV-positive and HIV-negative) in intervention vs. control arms yielded an adjusted odds ratio (AOR) of 1.55 (95% Confidence Interval [CI]: 0.86–2.77). Similarly, for combined analysis of facility deliveries, the AOR was 1.43 (95% CI: 0.70–2.92).

Pregnancy/delivery outcomes were collected from 571 HIV-positive women and 352 HIV-negative women in both arms of the study combined (Table 3). HIV-positive women in the intervention arm were less likely to have their pregnancy end in a stillbirth compared to HIV-positive women in the control arm. There were no differences in pregnancy outcomes among HIV-negative women. When we compared outcomes of all HIV-positive mothers to those of all HIV-negative mothers, we found that HIV-positive women were significantly more likely to experience miscarriage or stillbirth, have a low birth weight infant, or experience any adverse pregnancy/delivery outcomes, even after adjusting for maternal age, education, and estimated gestation at the mother's first antenatal care visit (data not shown).

Table 2 ANC and maternity service uptake by HIV status and by study arms (excludes miscarriages)

	HIV-positive				HIV-negative			
	Intervention n=284 n (%)	Control n=266 n (%)	Total n=550 n	p-value*	Intervention n=177 n (%)	Control n=173 n (%)	Total n=350 n	p-value*
Facility delivery								
Yes	260 (92.2)	226 (85.0)	486	0.025	158 (89.3)	162 (93.6)	320	0.247
No	22 (7.8)	40 (15.0)	62		19 (10.7)	11 (6.4)	30	
Missing	2		3			2	3	
Number of ANC visits								
1	20 (7.1)	34 (12.9)	54	0.026	14 (8.0)	12 (7.0)	26	0.427
2	38 (13.4)	41 (15.5)	79		20 (11.4)	28 (16.4)	48	
3	57 (20.1)	70 (26.5)	127		33 (18.8)	41 (24.0)	74	
4 or more	168 (59.4)	119 (45.1)	287		109 (61.6)	90 (52.6)	199	
Missing	1	2	3		1	2	3	

*p-values=Rao-Scott chi-square test accounting for clustering by study site

Table 3 Pregnancy outcomes by HIV status and by study arms

	HIV-positive				HIV-negative			
	Intervention n (%)	Control n (%)	Total n	p-value	Intervention n (%)	Control n (%)	Total n	p-value
Denominator: All women with a pregnancy outcome	n=292	n=279	n=571		n=178	n=174	n=352	
Miscarriage								
Yes	8 (2.7)	13 (4.7)	21	0.473	1 (0.6)	1 (0.6)	2	0.987
No	284 (97.3)	266 (95.3)	550		177 (99.4)	173 (99.4)	350	
Denominator: Excludes miscarriages, twin deliveries	n=281	n=261	n=542		n=172	n=170	n=342	
Stillbirth								
Yes	7 (2.5)	13 (5.0)	20	0.015	4 (2.3)	2 (1.2)	6	0.292
No	273 (97.5)	248 (95.0)	521		168 (97.7)	168 (98.8)	336	
Missing	1		1					
Any congenital abnormality								
Yes	4 (1.4)	3 (1.2)	7	0.781	2 (1.2)	2 (1.2)	4	0.989
No	276 (98.6)	257 (98.9)	533		170 (98.8)	168 (98.8)	338	
Missing	1	1						
Low birth weight (<2.5 kg)								
Yes	32 (12.2)	32 (14.3)	64	0.421	12 (7.6)	13 (8.1)	25	0.863
No	230 (87.8)	192 (85.7)	422		145 (92.4)	147 (91.9)	292	
Missing	19	37	56		151	10	25	

CLINICAL OUTCOMES OF INTERVENTION GROUPS COMPARED TO CONTROL GROUPS
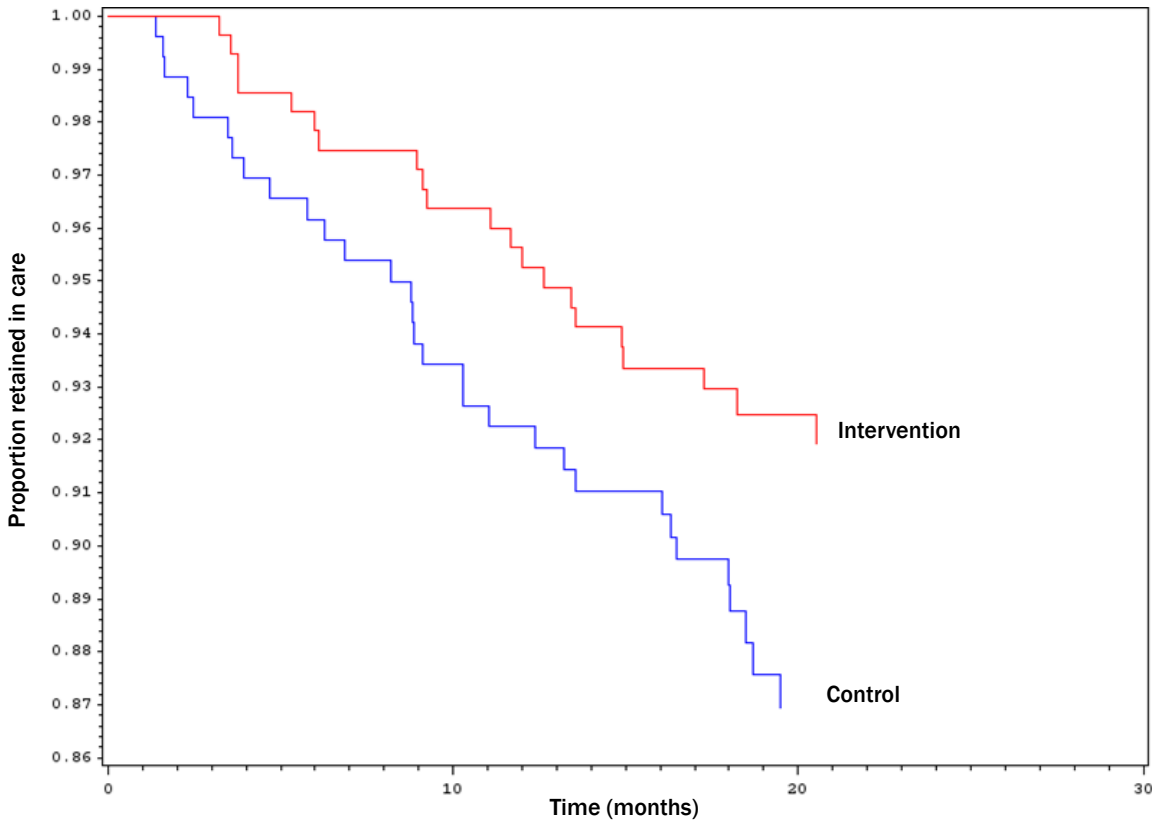
Retention in care

We measured the average number of months the study women were retained in care (whether at the original facility where she was enrolled or at another facility). Retention over time is shown in the Kaplan-Meier curves in Figures 4 and 5. HIV-negative women in the intervention arm remained in care significantly longer, for an average of 17.3 months compared to 16.8 months for women in the control arm (p<0.001). Using a proportional hazards model, we found that women in the control arm were three times more likely to be LTFU before the end of the study compared to women in the intervention arm (HR 3.1, 95% CI: 1.8-5.3).

Figure 4 Kaplan-Meier curve of retention care of HIV-negative women comparing intervention arm in red to control arm in blue
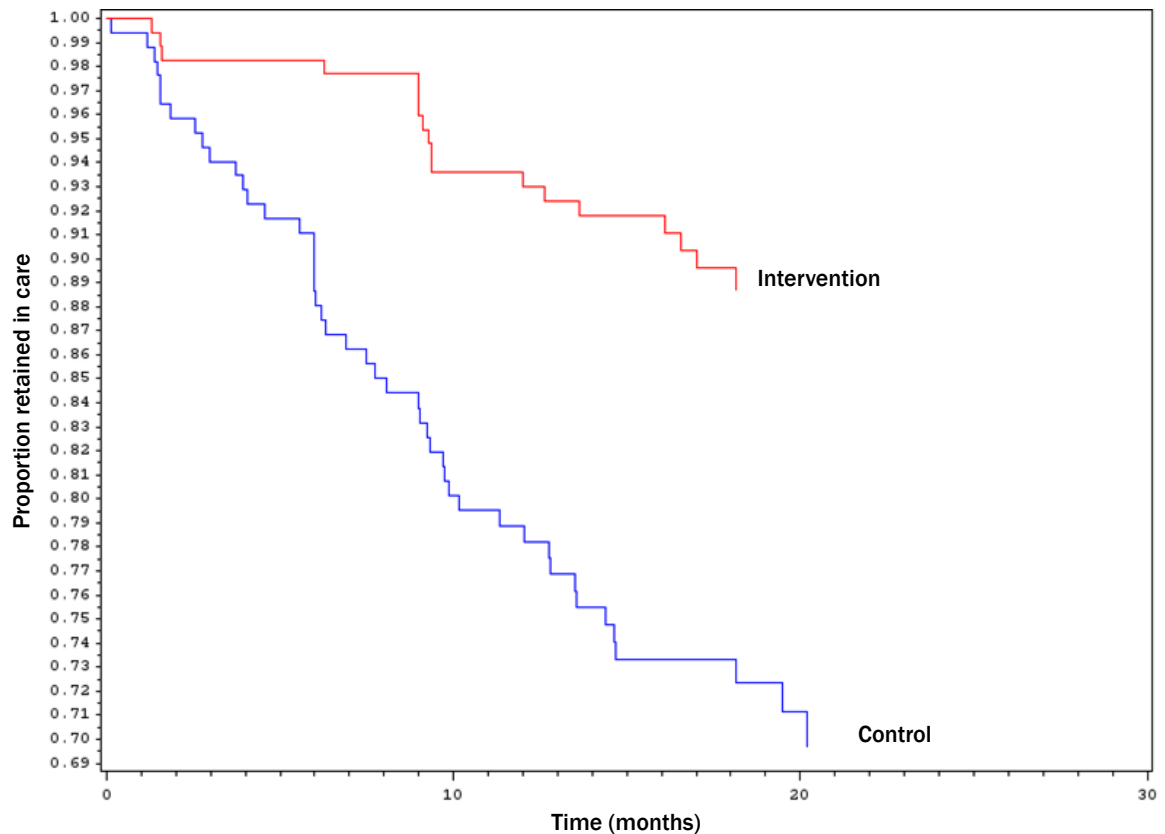
Overall, HIV-positive women had higher rates of retention in care than HIV-negative women. HIV-positive women in the intervention arm remained in care for an average of 19.8 months, compared to 18.3 months for HIV-positive women in the control arm, though this difference was not statistically significant (p=0.072). HIV-positive women in the control arm were 1.6 times more likely to be LTFU (HR 95% CI: 0.9–2.9].

ART adherence in HIV-positive women

Adherence was measured based on national guidelines with adherence to ART assessed as "good," "fair," or "poor" based upon health care worker pill counts documented in the patient clinical records. A response of "good" corresponds to over 95 percent adherence.

All available data on adherence for each woman were reviewed and summarized as either "adherent at all visits" (adherence classified as "good" for each visit where such data was available), "mixed adherence" (for participants with at least one visit with a designation of "good" and at least one other visit classified as "fair" or "poor"), or "non-adherent at all visits."

Overall, most women were consistently adherent to ART, although adherence rates were lower than required for optimal viral suppression and maternal health. Of the 582 HIV-positive women who had documented adherence (Table 4), women in the intervention arm were significantly more adherent compared to women in the control (767% vs. 66%, p=0.003). Recognizing that women in the study varied in the number of study visits completed, we also ran a model of the relationship between intervention arm and consistent adherence (compared to mixed or non-adherence) that adjusted for the number of study visits. In this model, the association between intervention arm and adherence remained, with women in the intervention arm being 1.81 times more likely to have consistent adherence documented (95% CI: 1.03–3.18).

Table 4 Adherence of HIV-positive women to ART comparing intervention arm to control (n=582)

	Intervention n (%)	Control n (%)	Total	p-value	Adjusted model n	Adjusted OR (95% CI)
Adherent at all visits	226 (776.6)	188 (65.5)	414			
Mixed adherence	67 (22.7)	91 (31.7)	158	0.003	581	1.81 (1.03–3.18)
Non-adherent all visits	2 (0.7)	8 (2.8)	10			
Total	295	287	582			

Viral suppression in HIV-positive women

Viral load (VL) measurements were analyzed in two ways for both arms of the study: (1) comparing those with undetectable to detectable VL at 12 and 24 months, and (2) comparing those with suppressed (<1,000 copies/mL) vs. unsuppressed VL (≥1,000 copies/mL) (Table 5).

At 12 months, we had VL results on 350 participants. Over 90 percent of women living with HIV had a suppressed VL at 12 months postpartum with no difference between arms, but a significantly higher proportion of women in the intervention arm had an undetectable VL (p=0.037). In the multivariable model, women in the intervention group were 1.88 times more likely to have an undetectable viral load (95% CI: 0.86–4.14)

At 24 months postpartum, of the 249 participants who had VL results, suppression remained very high (over 90% of women). There was no difference between both arms in terms of undetectable rate (p=0.179). It is also notable that while the numbers of women in each study arm contributing data at 12 months were identical, at 24 months data were available for a larger number of women in the intervention arm.

Table 5 12-month VL monitoring (n=350) and 24-month VL monitoring (n=249) among study participants

	Intervention n (%)	Control n (%)	Total n (%)	p-value	Adjusted model n	Adjusted OR (95% CI)
12-month VL monitoring	n=175	n=175	n=350			
Undetectable	146 (83.4)	126 (72.0)	272 (77.5)	0.037	349	1.88 (0.86–4.14)
Detectable	29 (16.6)	49 (28.0)	78 (22.5)			
<1,000 copies/mL	166 (94.9)	158 (90.3)	324 (92.6)	0.081	349	1.87 (0.90–3.91)
≥1,000 copies/mL	9 (5.1)	17 (9.7)	26 (7.4)			
24-month VL monitoring	n=140	n=109	n=249			
Undetectable	107 (76.4)	89 (81.7)	194 (78.5)	0.179	249	0.68 (0.45–1.06)
Detectable	33 (23.67)	20 (18.4)	53 (21.5)			
<1,000 copies/mL	129 (92.1)	100 (91.7)	229 (91.1)	0.841	249	0.77 (0.42–1.43)
≥1,000 copies/mL	11 (7.9)	9 (8.3)	20 (8.1)			

REPEAT HIV TESTING AMONG HIV-NEGATIVE WOMEN

Repeat testing among HIV-negative women is critical to identifying incident infections. In Lesotho, HIV-positive pregnant women are eligible for retesting after 36 weeks gestational age if it has been more than 6 weeks from their last HIV test. During the study, 318 pregnant women who had a record of initial HIV-negative results were retested for HIV (Table 6). Participants in the intervention arm were more likely to be retested during this period compared to control arm (77% vs 64%, p≤ 0.001). This remained significant in the multivariable model with an AOR =1.95 (95% CI: 1.23–3.08). Overall, 80 percent of HIV-negative women had a record of at least one repeat HIV test between delivery and 12 months postpartum. There was no significant difference in retesting by 12 months between study arms. Overall, four HIV-negative participants seroconverted, one in the intervention arm and three in the control arm. One woman tested HIV-positive at 14 weeks, two women tested HIV-positive at 12 months, and one woman tested HIV-positive at 18 months.

Table 6 HIV retesting between 36 weeks and delivery among pregnant women who reported an initial HIV-negative result (n=318)

Repeat test timing	Intervention n (%)	Control n (%)	Total n	p-value	Adjust model n	Adjusted OR (95% CI)
Had repeat test prior to delivery	129 (77.3)	96 (63.6)	225			
No repeat test prior to delivery	38 (22.8)	55 (36.4)	93	<0.001	318	1.95 (1.23–3.08)
Total	167	151	318			

ADDITIONAL PREGNANCIES AND USE OF CONTRACEPTION

Additional pregnancies during follow-up were reported by 4 percent of HIV-negative women and 7 percent of HIV-positive women, with no difference by study arm. As with adherence, contraception use was classified as either consistent use of modern methods, mixed use (reports of both use and non-use of modern methods), or consistent non-use across all postpartum visits with data available on contraceptive use. By HIV infection status, there were no significant differences in intervention vs. control arms (Table 7). However, in multivariable analysis with all women (HIV-positive and HIV-negative) combined, women in the intervention group were 1.62 times (95% CI: 1.05-2.5) more likely to report consistent use of a modern method of contraception than women in the control arm.

	HIV-positive				HIV- negative			
	Intervention n (%)	Control n (%)	Total n	p-value	Intervention n (%)	Control n (%)	Total n	p-value
Consistent use of modern method of contraception	117 (41.9)	78 (29.9)	191		82 (48.0)	55 (34.0)	137	
Mixed use	143 (51.3)	154 (59.0)	286	0.096	73 (42.7)	80 (49.4)	153	0.157
Consistent non-use of modern method	19 (6.8)	29 (11.1)	59		16 (9.4)	27 (16.7)	43	
Total	279	261	554		171	162	333	

IMMUNIZATION

The key vaccines considered for this analysis were those to protect against tuberculosis (BCG vaccine), poliovirus (a series of four doses by age 14 weeks), and measles (a series of two doses, only one of which is administered by 12 months of age), as well as the pentavalent vaccine which provides immunity against diphtheria, tetanus, whooping cough, hepatitis b, and haemophilus influenza type b (three doses by age 14 weeks). We considered a child fully immunized for each type of vaccine if s/he had record of receiving BCG, Polio 3, Penta 3, or Measles 1 (Table 8). Measles 2 was not included, as not all children in the study reached the age for Measles 2 receipt. Immunization coverage in HIV-exposed infants (HEI) in the intervention arm was not statistically different from HEI in the control arm. For HIV-unexposed infants (HUI), infants in the control arm were more likely to receive BCG compared to the intervention arm (86% vs.75%, p=0.03)

Table 8 Uptake of full immunization among enrolled children

Fully immunized	HIV-exposed				HIV-unexposed			
	Intervention n (%)	Control n (%)	Total	p-value	Intervention n (%)	Control n (%)	Total	P-value
BCG	216 (78.0)	211 (82.8)	427	0.33	131 (75.3)	146 (85.9)	277	0.03
Polio 3	173 (68.4)	165 (69.6)	338	0.93	102 (63.4)	91 (61.1)	193	0.85
Penta 3	180 (71.2)	168 (70.9)	348	0.98	106 (65.8)	93 (62.4)	199	0.78
Measles 1	211 (91.7)	196 (91.6)	407	0.95	122 (83.6)	111 (90.2)	233	0.10

CHILD OUTCOMES

Excluding miscarriages and stillbirths, there were 38 child deaths among HIV-exposed infants (17 control, 21 intervention) and 12 deaths among HIV-unexposed infants (4 control, 8 intervention). Among HIV-exposed infants with data available, 98 percent (520/531) received antiretroviral (ARV) prophylaxis, with 475 (91%) starting prophylaxis immediately after birth.

At 6 weeks post-delivery, 6 HIV-exposed infants (1.2%) had been identified as HIV-positive out of 495 infants with HIV testing data available. Another two infants were identified as HIV-positive around the time of the 14 week visit (including one infant of a women who had tested HIV-negative during pregnancy but tested positive at the 14 week visit). One infant tested positive at 12 months and a final infant tested positive at 18 months postpartum. A total of 10 infants were infected, for an MTCT rate at 18 months of 2.8 percent. Information about each HIV-positive child and their mothers is presented in Table 9.

Table 9 Maternal and child information for the 10 HIV-positive children

	Arm	Visit at first diagnosis	Mother age	Marital status	GA + first ANC	ART mother (TDF/3TC/EFV)	Adherence and VL during pregnancy	Infant rec'd NVP prophylaxis
1	Intervention	6 weeks	26	Married	20	Started first ANC visit	Good adherence VL 1447 at delivery	Yes
2#	Intervention	6 weeks	31	Married	20	Started first ANC visit	Good adherence	No; NVP not given to the mother
3	Intervention	6 weeks	23	Married	28	Started first ANC visit	Good adherence	Yes
4	Intervention	6 weeks	37	Widowed	30	Started first ANC visit	Not available (NA)	Yes
5	Control	6 weeks	22	Never married	NA	Started first ANC visit	Sub-optimal adherence	Yes
6	Control	6 weeks	18	Never married	16	Started before pregnancy	Sub-optimal adherence	Yes, but missed doses
7	Control	14 weeks	20	Never married	24	Started first ANC visit	Sub-optimal adherence VL 26694 during pregnancy	No
8*	Control	14 weeks	20	Married		NA—mother and infant tested positive at same visit	NA	NA
9	Control	12 months	27	Married	31	Started first ANC visit	Sub-optimal adherence	Yes
10	Control	18 months	36	Married	22	Started shortly after first ANC visit	Good adherence	Yes

+Gestational age; #Twin; *Mother HIV-seroconverted by 14 weeks postpartum

DEPRESSION, STIGMA, AND SELF-EFFICACY AMONG STUDY PARTICIPANTS

Depression

Relatively few women in the study reported symptoms of moderate to severe depression as measured by the Patient Health Questionnaire (PHQ-9); this did not differ significantly by study arm (Table 10). We created a summary score from all nine elements of the questionnaire and categorized women as having mild or no depressive symptoms or as having symptoms of moderate to severe depression. Women in the study first responded to the questionnaire during their second ANC visit, where we found that overall HIV-negative women were significantly more likely than HIV-positive women to report symptoms of moderate to severe depression (14% of HIV-negative women compared to 8% of HIV-positive women, p=0.036). For all postpartum visits, fewer than 10 percent of all women reported signs of moderate to severe depression, with no difference by study arm.

Table 10 Summary of depression among study participants during ANC

Depression score	HIV-positive women				HIV-negative women			
	Intervention n (%)	Control n (%)	Total n	p-value	Intervention n (%)	Control n (%)	Total n	p-value
"None–mild" (0–9)	226 (93.8)	179 (88.6)	405		126 (86.9)	117 (86.0)	243	
"Moderate–severe" (10–27)	15 (6.2)	23 (11.4)	38	0.19	19 (13.1)	19 (14.0)	38	0.88
Total	241	202	443		145	136	281	

Stigma

For stigma, we administered both the HASI-P and another 9-item stigma scale developed in Botswana (Weiser et al. 2006). Few women reported experiencing or fearing most items on the HASI-P, but according to the 9-item "projected HIV stigma" scale, HIV-positive women in the control arm were consistently more likely through the 18-month study visit to report fearing that they would be treated badly at work or school, experience a break-up of their relationship, become a social outcast, or lose their friends. At the 24-month visit, however, there were no longer any significant differences by study arm, though there was a much smaller sample size at that time point.
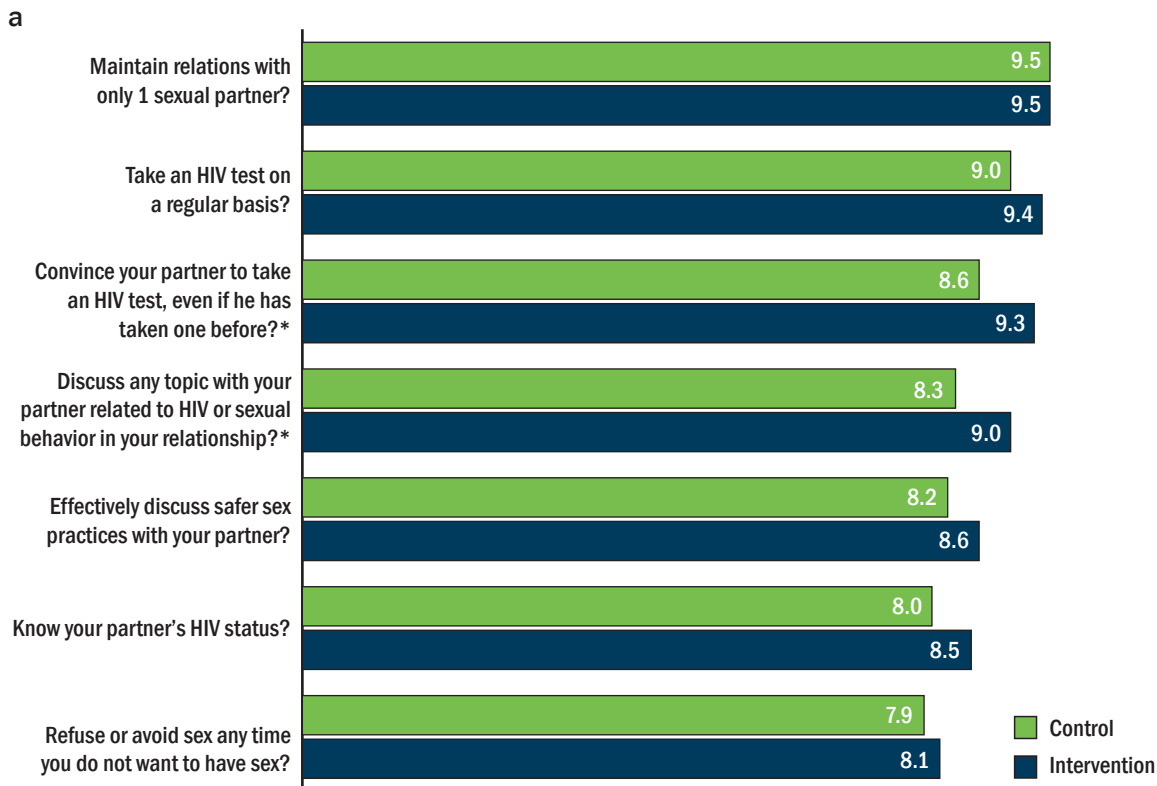
Among HIV-negative women, there were no differences by study arm in this projected HIV stigma scale before delivery, but at 6 weeks and 6 months postpartum, women in the control arm were significantly more likely to report fearing that they would experience outcomes such as loss of job/livelihood, poor treatment at work or school, or becoming a social outcast if they were to test positive for HIV and others found out. By 12 months postpartum, there were no longer any significant differences by study arm.
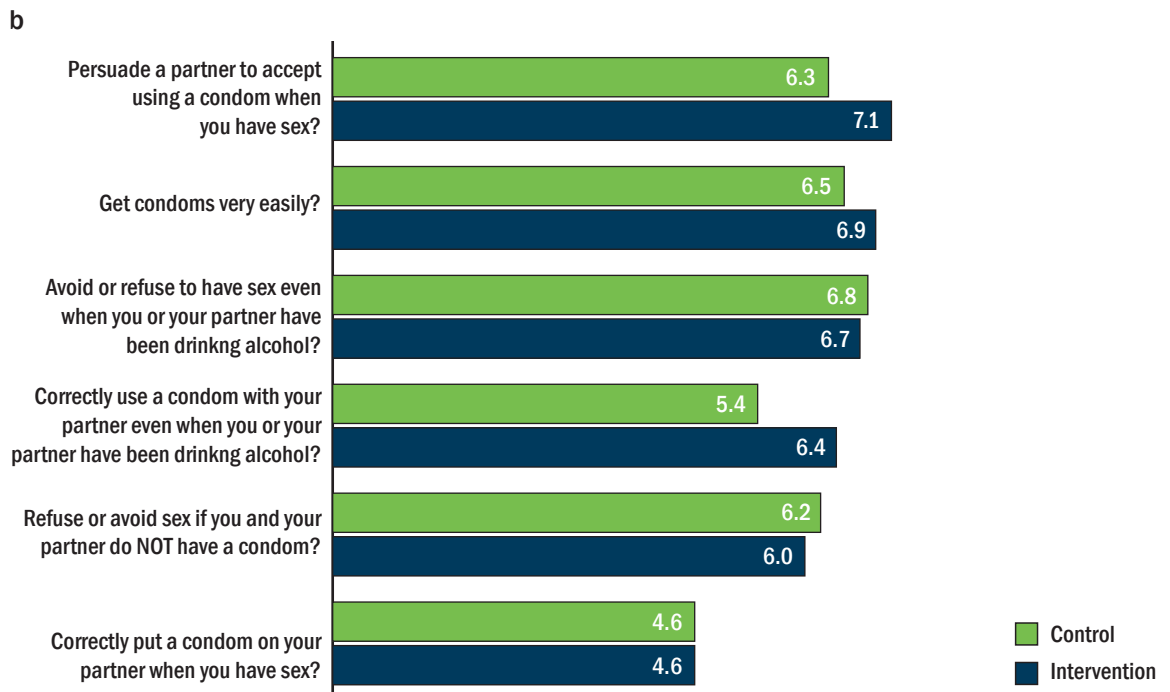
Self-efficacy

HIV-positive women were asked about their confidence in their abilities to adhere to ART. Across all visits, the majority of HIV-positive women reported very high (10 on a scale of 0-10) self-efficacy for all measures, though a subset of women reported having challenges. HIV-negative women were much less confident in their abilities to negotiate and implement prevention measures, particularly around correct and consistent use of condoms (Figures 6a and b). Women in the intervention group were significantly more confident than women in the control group in their ability to convince their partner to take an HIV test, even if he had taken one before, and to discuss any topic with their partner related to HIV or sexual behavior in their relationship.

Figure 6 HIV-negative women HIV prevention self-efficacy

On a scale of 1 (not at all) to 10 (completely), in the past month, how confident have you been that you can...

a

	Control	Intervention
Maintain relations with only 1 sexual partner?	9.5	9.5
Take an HIV test on a regular basis?	9.0	9.4
Convince your partner to take an HIV test, even if he has taken one before?*	8.6	9.3
Discuss any topic with your partner related to HIV or sexual behavior in your relationship?*	8.3	9.0
Effectively discuss safer sex practices with your partner?	8.2	8.6
Know your partner's HIV status?	8.0	8.5
Refuse or avoid sex any time you do not want to have sex?	7.9	8.1

b

	Control	Intervention
Persuade a partner to accept using a condom when you have sex?	6.3	7.1
Get condoms very easily?	6.5	6.9
Avoid or refuse to have sex even when you or your partner have been drinkng alcohol?	6.8	6.7
Correctly use a condom with your partner even when you or your partner have been drinkng alcohol?	5.4	6.4
Refuse or avoid sex if you and your partner do NOT have a condom?	6.2	6.0
Correctly put a condom on your partner when you have sex?	4.6	4.6

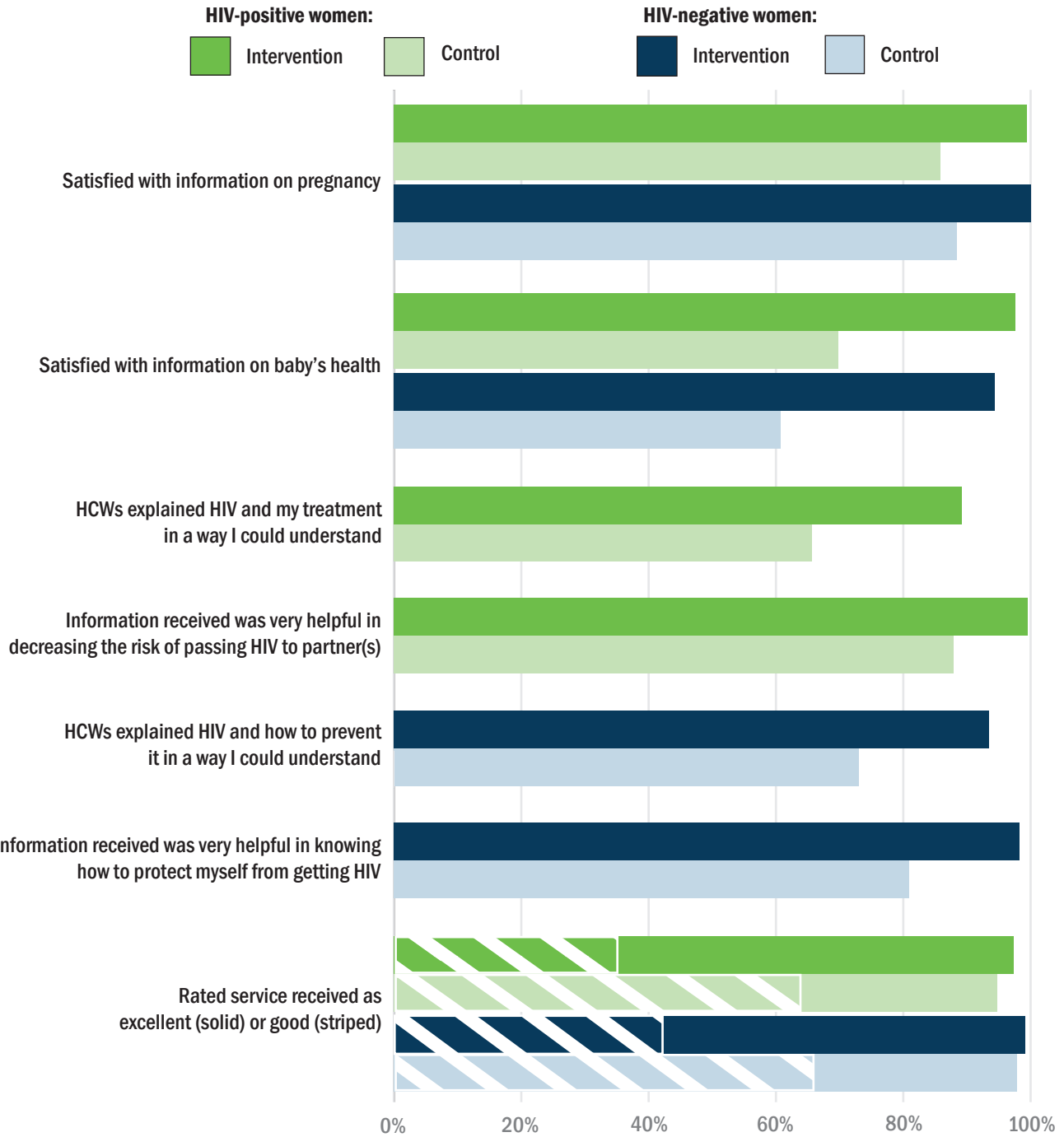## Participant satisfaction with counseling and services received

Study women were asked about their satisfaction with the counseling and services received by facility staff during each of their clinic visits to assess the effect of the PHDP and client-focused training received by staff in the intervention facilities. For almost all of the questions asked for both HIV-positive and HIV-negative women, the ratings were significantly higher among women in intervention facilities than those in control facilities across the visits. Selected results from the 12-month visit are presented in Figure 7, with the exception of the pregnancy question which was taken from the enrollment visit. Results for the other questions at enrollment were similar to the 12 months results presented in the figure.

ATTITUDES OF HCWS, LAY SUPPORTERS, VHWS, AND STUDY PARTICIPANTS TOWARD MCH/PMTCT SERVICES AND FEASIBILITY/ACCEPTABILITY OF THE IMPROVE INTERVENTION

In-depth interviews with study women

The study women interviewed from the control arms reported long waiting times and fragmented services compared to women in the intervention arms, who reported that services were well-coordinated with few delays. Women in the intervention arm were thoroughly satisfied with the services they received, while women in the control arm reported that there were areas for improvement but they were mostly satisfied. In both arms, some women reported never being visited at home by a VHW or CHW. Most women in both arms reported that they received no maternal care during PNC, the focus of which was on the baby only.

Figure 7 Participant satisfaction at 12 months postpartum by HIV status and study arm

HIV-positive women:
■ Intervention   ■ Control

HIV-negative women:
■ Intervention   ■ Control

Satisfied with information on pregnancy

Satisfied with information on baby's health

HCWs explained HIV and my treatment
in a way I could understand

Information received was very helpful in
decreasing the risk of passing HIV to partner(s)

HCWs explained HIV and how to prevent
it in a way I could understand

Information received was very helpful in knowing
how to protect myself from getting HIV

Rated service received as
excellent (solid) or good (striped)

0%   20%   40%   60%   80%   100%

FGDs with HCWs and lay facility and community workers/supporters

All groups reported that the various cadres collaborated well overall, but challenges sometimes existed with village health workers (i.e., problems with stipends and confidentiality concerns). HCWs in the intervention arms felt they provided better care to patients after implementing IMPROVE interventions (training, job aids, MDTs), due to improvement in their knowledge, interdisciplinary care, attitudes, and communication with women.

HCWs expressed that the IMPROVE intervention should continue and that they thought the MOH should support it. A HCW at one IMPROVE intervention site said:

> *Maybe there could be some of the things that they [the MOH] could copy from IMPROVE and include them in the policies....IMPROVE has caused improvement within departments and within the facility....*

However, HCWs also expressed staffing concerns affecting quality services, noting that the staff number had not increased, yet the programs and services provided had increased considerably. Participants from intervention arms recommended that the IMPROVE interventions be incorporated in national service delivery.

COSTING RESULTS

The average cost per person per year for each of the five service areas and the percentage difference (intervention cost relative to control cost) by study arm are shown in Table 11 below.

Table 11 Cost per woman per year by service area and study arm (USD)

	Control USD	Intervention USD	Cost difference (intervention cost– control cost) USD	Percentage difference of intervention cost relative to control cost %
Antenatal care	205	277	72	35
Family planning	81	87	6	8
PMTCT	296	311	15	5
Postnatal care	84	97	13	15
Pediatric ART	321	347	26	8

As anticipated, the estimated total average unit cost was highest for PMTCT and pediatric ART patients, in both arms. The total average unit cost for PMTCT patients was $296 in the control arm versus $311 in the intervention arm, while the total average unit cost for pediatric patients was $321 and $347 for the control and intervention arms, respectively. The total average unit cost for ANC services was $205 and $277 in the control and intervention arms, respectively. However, it is important to note that when the cost of counseling and testing (including the cost of HIV test kits) was excluded from ANC services, the cost fell to $190 and $263 in the control and intervention arms, respectively. The total average unit cost for PNC services was approximately $84 in the control arm and $97 in the intervention arm. The total average cost per woman per year for FP services in the control arm was $81 and $87 in the intervention arm.

The total average unit cost for each of the services provided in the intervention arm was relatively higher than the total average unit cost in the control arm. The results show that the percentage cost difference for FP, PMTCT, and pediatric ART were 8 percent, 5 percent, and 8 percent, respectively. The intervention cost of PNC was 15 percent higher than the control cost, while ANC had the highest percentage cost difference at 35 percent.

The cost per person by service area is further disaggregated into eight cost categories, which are displayed in Table 12.

Table 12 Unit cost by service and by cost proportions—control and intervention arms

Service area/cost component	Control		Intervention	
	Cost (USD)	Cost (%)	Cost (USD)	Cost (%)
Antenatal care				
Clinical staff costs	46.01	22	49.19	18
Laboratory costs	108.19	53	112.39	41
Support staff costs	0.03	0	0.02	0
Multidisciplinary team costs	NA	0	54.78	20
District health staff costs	0.02	0	0.02	0
Drugs and commodities	8.07	4	14.63	5
Operating costs	13.39	7	25.67	9
Equipment costs	29.32	14	20.51	7
Family planning				
Clinical staff costs	46.37	58	37.28	43
Laboratory costs	—	0	—	0
Support staff costs	0.03	0	0.01	0
Multidisciplinary team costs	NA	0	22.58	26
District health staff costs	—	0	0.02	0
Drugs and commodities	33.82	42	26.82	31
Operating costs	0.14	0	0.19	0
Equipment costs	0.26	0	0.28	0
PMTCT				
Clinical staff costs	89.26	30	95.66	30.8
Laboratory costs	75.79	26	80.54	25.9
Support staff costs	0.03	0	0.01	0.0
Multidisciplinary team costs	NA	0	5.28	2
District health staff costs	0.04	0	0.03	0
Drugs and commodities	117.07	39	115.84	37
Operating costs	5.33	2	8.24	2.7
Equipment costs	8.96	3	4.97	1.6
Postnatal care				
Clinical staff costs	46.01	55	49.19	51
Laboratory costs	—	0	—	0
Support staff costs	0.02	0	0.01	0
Multidisciplinary team costs	NA	0	10.43	11
District health staff costs	0.02	0	0.01	0
Drugs and commodities	7.64	9	10.58	11
Operating costs	13.65	16	12.22	13
Equipment costs	16.69	20	14.54	15
Pediatric ART				
Clinical staff costs	124.04	39	148.72	43
Laboratory costs	76.14	24	77.09	22
Support staff costs	0.02	0	0.01	0
Multidisciplinary team costs	NA	0	0.41	0
District health staff costs	0.02	0	0.01	0
Drugs and commodities	119.28	37	119.28	34
Operating costs	0.38	0	0.56	0
Equipment costs	0.77	0	0.51	0

Although the average total cost of each of the service areas was higher in the intervention arm relative to the control arm, when disaggregated into their respective cost components, those differences showed wider variation within each study arm that did not match the same pattern as the total average cost. Additional analysis of the disaggregated cost components showed that these variations were primarily as a result of three key input factors:

1. Variation in provider responses on average time spent per patient per service area, the average number of visits per patient per year by service area and the average time spent per patient per visit, and the quantity of drugs and commodities used for each patient per visit. The data collection strategy relied heavily on staff responses and even though all facilities noted following standard treatment protocols for all five service areas, these treatment protocols do not stipulate standard time spent per patient per visit. Equally important, the quantity of certain drugs and commodities vary by patient need, while the number of visits per patient per year are dependent on patient-specific factors (availability, accessibility, and affordability).

2. The allocation key used in apportioning shared costs. The proportion of patient or patient visits by service area assumes that all patients utilize facility resources equally regardless of the type of service provided. In other words, a patient who comes for ANC services receives similar services as a patient who comes for FP, PMTCT, PNC, and pediatric ART. While not the most precise method for apportioning shared costs, this method was the most efficient given the study limitations. Additionally, the method weights MCH patients more, particularly ANC patients, who represent the majority of patients—9 percent of patients in the control arm and 10 percent of patients in the intervention arm.

3. Financial records on operating and equipment costs showed variation within each arm. Hospitals reported higher operating costs, and these costs were higher on average for facilities in the intervention arm relative to the control arm. Similarly, available records showed medical equipment used in the control arm were slightly newer (average purchase date May 2016) than the intervention arm (average purchase date February 2015). This means that on average the estimated value of equipment used for patients in the control arm was slightly higher than the estimated value of equipment used for patients in the intervention arm.

With these key variations in mind, the cost drivers are discussed by service area below.

Antenatal care

Cost drivers for ANC services vary between the control and intervention arms. The largest contributor to costs in the control arm were laboratory services, accounting for 53 percent of the total average ANC cost, a major portion of which was the result of the high cost of HIV, STI, and blood grouping tests. The second largest share of ANC service costs provided under the current guidelines were clinical staff costs (22%), followed by equipment costs (14%), operating costs (7%), and drugs and commodities (4%). Similar to control facilities, lab costs account for the largest share (41%) of ANC services provided by IMPROVE intervention facilities. However, this is followed by the cost of oversight and support provided by the multidisciplinary team (20%), then clinical staff cost (18%), operating costs (9%), equipment costs (7%) and, lastly, the cost of drugs and commodities (5%). The key contributing factor to the difference between the study arms is the inclusion of costs associated with the oversight and support provided by the multidisciplinary

team at each intervention facility. Of the $72 (35%) cost difference between intervention and control facilities, an estimated $55 can be attributed to the cost of the multidisciplinary team, representing a substantial two-thirds of the cost difference between intervention and control ANC services.

Family planning

When disaggregated into the eight cost components, cost drivers for control and intervention facilities mostly followed similar distribution patterns. For FP services in the control arm, costs were split across clinical staff costs and the costs of drugs and commodities, with clinical staff costs accounting for the largest share (58%), while drugs and commodities account for the remainder (42%). In the intervention arm, FP services are split across three cost components—clinical staff (43%), drugs and commodities (31%), and the multidisciplinary team (26%). In both arms, the allocated costs (support staff, operating costs, equipment costs) account for a minimal share of total costs, less than 1 percent.

PMTCT

The largest share of the unit cost of PMTCT services was the cost of drugs and commodities, estimated to be 39 percent of the average cost of services at control facilities and 37 percent of the total average cost per woman per year at intervention facilities. As expected, ARVs accounted for the largest share of PMTCT costs at 36 percent and 34 percent of the total average unit cost in control and intervention facilities, respectively. After drugs and commodities, the cost of clinical staff time accounted for approximately 30 percent and 31 percent of total average PMTCT costs in control and intervention facilities, respectively. Laboratory costs accounted for the third largest share of costs (26%) of PMTCT services in both the control and intervention facilities. At this point, the cost distribution for both control and interventions diverged. In the control arm, the remainder of the share of cost of PMTCT services was divided into equipment (3%) and operating costs (2%). In the intervention arm, the remainder of the share of PMTCT service costs was split by operating (3%), multidisciplinary team (2%) and equipment (2%) costs.

Postnatal care

In control facilities, clinical staff costs accounted for a little more than half (55%) of the estimated average unit cost of PNC, followed by equipment costs (20%), operating costs (16%), and the cost of drugs and commodities (9%). In intervention facilities, clinical staff costs also accounted for a little more than half (51%) of the share of the cost of PNC services, followed by equipment (15%) and operating costs (13%), with the remainder split evenly between the cost of drugs and commodities (11%) and the multidisciplinary team (11%). As with ANC cost, the $11 cost of the multidisciplinary team represents more than two-thirds of the $13 cost difference between PNC services in intervention facilities relative to control facilities.

Pediatric ART

The cost distribution of pediatric ART services follows the same pattern for both control and intervention facilities. Clinical staff costs represent the largest share of pediatric ART service costs, accounting for 39 percent of total average cost per child per year in control facilities and

43 percent of total average costs per child per year in intervention facilities. In both study arms, the cost of drugs and commodities account for the second largest share of costs accounting for 37 percent in control facilities and 35 percent in intervention facilities. Laboratory costs account for the remainder of the share of total average pediatric ART services at 24 percent in control facilities and 22 percent in intervention facilities.

The percentage cost differences between the arms were significantly higher for ANC services (35%), but only slightly higher for the other services—FP (8%), PMTCT (5%), PNC (15%), and pediatric ART (8%). Scaling up the intervention, however, would not require a significant amount of financial support or significant human resources.

RESEARCH UTILIZATION

A key component of the IMPROVE study was the roadmap for result utilization through early (protocol development) and regular engagement of stakeholders and policymakers to ensure that the interventions were aligned with the priorities of the national program. Frequent presentations on study progress and results were shared with the Lesotho AIDS Development Partner (ADP) forum and with the National Technical Working Group for PMTCT and pediatric HIV care and treatment. In addition, there was regular communication and feedback about information learned about the implementation of the routine PMTCT program between the IMPROVE researchers and the EGPAF program implementation and MOH staff to ensure that challenges or gaps identified during the study were addressed by the program. For example, the study team found that one study facility was not providing ANC services with the frequency required by the MOH; this was discussed with MOH investigators and personnel and the facility administration and the services were changed to meet the MOH standard. Regular investigator meetings that included MOH investigators allowed critical information learned to be shared and acted upon more broadly than just for the study benefit. This regular communication with stakeholders ensured that the program benefitted from the conduct of the study throughout the study period, not just at the end when final results were available.

DISCUSSION

The IMPROVE study found that implementation of a simple package of service delivery interventions improved PMTCT/MCH program efficiency, coordination among HCWs and lay cadres of providers, and provider-patient communication. This resulted in improvement in several key health outcomes among women in the intervention arm compared to women receiving standard care in the control arm, such as antenatal visits, facility delivery, retention in care, ART adherence, contraception use, and undetectable viral loads. However, results often varied between HIV- positive and HIV-negative women and often differences faded over time.

A key component of the IMPROVE interventions was the introduction of multidisciplinary teams that consisted of MCH and PMTCT service providers, including both health care workers and lay workers from facilities and the community. An innovative approach to support the work of the MDTs was the joint patient centered, PHDP-focused counseling and skills building training that was conducted with the HCWs, VHWs, lay counselors/peer supporters, and nursing supervisors together. This facilitated better understanding of each other's roles and responsibilities, a team approach to identification of service delivery gaps and problem solving, and consistent HIV and MCH messaging for pregnant and postpartum women. The IMPROVE intervention addresses most of the components for successful models of interdisciplinary HIV care identified by Ojikutu and colleagues (2014) that include (1) patient-centered, one-stop-shop approaches with integrated or co-located services; (2) diverse teams of clinical and nonclinical providers; (3) a site culture that promotes a stigma-reducing environment for clients; (4) the availability of a comprehensive array of medical, behavioral health, and psychosocial services; (5) effective cross team communication; and (6) a focus on quality (Ojikutu et al. 2014). Similar to IMPROVE study outcomes, strong multidisciplinary teams have been found to improve quality of care and patient outcomes as well as staff performance and job satisfaction across many health care disciplines (Epstein 2014).

As noted above, the IMPROVE intervention was associated with some improvements in clinical outcomes among both HIV-positive and HIV-negative women. Among HIV-positive women, women in the intervention arm had more antenatal clinic visits, and were more likely to deliver in a facility, consistently maintain ART adherence over 95 percent, and report consistent use of modern contraception. While women in the intervention arm were retained in care longer than women in the control arm, the difference did not reach statistical significance. While retention levels in the study were higher than those reported in the routine program, they did not achieve the goal of having over 90 percent retention in care. The mobility of this population limits the extent to which true retention in care can be measured, as indicated by the number of women who actively reported that they moved outside of the study region and those lost to follow-up that likely includes some who transferred their care elsewhere but for which there is little documentation of whether they remained in care. In addition, village health workers and lay community tracking cadres were unable to follow up with women who resided outside their catchment area, regardless of whether the women were receiving care in their facilities or not. The challenge of retaining HIV-positive women in care and the documentation thereof needs to be explored further, especially to determine the influence of the scale-up of multimonth ART

dispensing or the community-based distribution of ART. Health facilities need to continue to be sensitized to ensure all HIV-positive patients are actively followed and retained in care in accordance with national guidelines.

Overall, we found high HIV viral suppression rates with no statistical difference between intervention and control arms, which we would expect with increased ART adherence found in women in the intervention arm. This is mainly due to the high viral suppression rate in the control arm, limiting our ability to statistically detect a difference based on our sample size calculation estimates of suppression in the control group. As defined by the World Health Organization (WHO), treatment success for patients on lifelong ART is achieved when a patient's VL is less than 1,000 copies/mL. This finding indicates that once on treatment and retained in care, HIV-positive women in Lesotho generally achieve viral suppression. Suppression rates were consistently over 90 percent in both arms, which is higher that the estimated suppression rate of 88 percent among adult females reported in the LePHIA Study (Lesotho Ministry of Health 2018). This difference may be attributed to the different populations of pregnant and non-pregnant women or may reflect some effect due to participation in the study. The timing of viral suppression is important, with the optimal benefit for reduction of MTCT being achievement of undetectable viral load as early as possible and critically before the time of delivery. Unfortunately, we were not able to assess viral load results at this critical time period.

While viral suppression was similar across the two arms, we did find that women in the intervention arm were more likely to achieve an undetectable VL at 12 months postpartum. This may be particularly important for PMTCT. Mandelbrot et al. described the relationship between VL and MTCT and found an interaction between the timing of ART initiation, VL, and MTCT (Mandelbrot et al. 2015). Their study found differences in MTCT when maternal VL was <50, 50–400, and >400 copies/mL and showed some gradient of increased MTCT risk as VL became >50 copies/mL. This indicates that reaching an undetectable VL may provide further protection against MTCT than viral suppression alone.

Among HIV-negative women, women in the intervention arm were more likely to be retained in care, undergo repeat HIV testing prior to delivery, and report consistent use of modern contraception than women in the control arm. We found a significantly higher rate of repeat HIV testing between 36 weeks and delivery for women with initial HIV-negative status in the intervention arm than the control arm. Lesotho national guidelines recommend that any HIV-negative woman who had their status documented more than 6 weeks prior to the 36 weeks gestation to delivery time period should be retested for HIV to identify potential transmission risk to infants by the time of delivery. All HIV-negative women should also be retested yearly during the 24-month postpartum period. Incident HIV infection around the peripartum period is known to increase the risk of MTCT (Drake et al. 2014). A recent cohort study in Lesotho found a high rate of seroconversion among pregnant and breastfeeding women, with an estimated overall incidence rate of 1.58 per 100 person-years (Machekano et al. 2018). Incidence was nearly double during pregnancy compared to the postpartum period (2.62 vs. 1.36 per 100 person-years). Limited HIV retesting represents a significant missed opportunity in the PMTCT cascade, as we found in our Project SOAR-funded study in Kenya and Uganda (Gill et al. 2020). Among the mothers of newly diagnosed HIV-positive children who attended ANC and were tested for HIV, 65 percent tested negative at the time. Lack of later testing led to delayed diagnosis of HIV infection

in the mother and, as a consequence, delayed testing of the child. Another study in Kenya found that although 28 percent of study participants had at least four ANC visits, 58 percent of all women went to delivery without a retest (Rogers et al. 2017). Although 77 percent of HIV-negative participants in the intervention arm of our study were retested prior to delivery and 80 percent of women were retested in the first year after delivery, there is room for further improvement.

Improved retention among HIV-negative women is an important finding in this study. Similar to other sub-Saharan African countries, the maternal mortality rate in Lesotho is very high (WHO Regional Office for Africa 2014). There is a growing consensus that significant improvement in women's health will require broad-based health systems strengthening at all levels of care, rather than through vertical strategies (Kerber et al. 2007; Satti et al. 2012). In routine postpartum care, HIV-negative women are not expected to come back to health facilities except for specific health interventions such as family planning. However, in a country with high HIV incidence like Lesotho, the postpartum provision of primary health care-related sexual and reproductive health and HIV prevention services is needed. Women in both study arms reported receiving little to no care for themselves postpartum, and mainly received services for their babies. Retaining HIV-negative women in care is also critical to identifying incident infections and ensuring women who seroconvert during pregnancy and breastfeeding are initiated on ART and their infants are assessed for potential acquisition of HIV (Drake et al. 2014; Machekano et al. 2018). This is further evidenced by our results, in which three out of the four women who seroconverted were identified 12 or more months after delivery.

Consistent use of contraception remains a challenge in Lesotho. We found that the consistent use of contraception was significantly higher in the IMPROVE intervention arm compared to the control for both HIV-positive and HIV-negative women. This second prong of PMTCT continues to lag behind in several national programs (FP2020 2019; Haberlen et al. 2017). The unmet need for family planning in Lesotho remains high at 16 percent. In our study, 4–7 percent of study women became pregnant again during the 12–24 month post-delivery follow-up, with no difference between study arms. It is not known whether these pregnancies were planned or were related to non-use of modern contraception methods. For Lesotho, to boost implementation of comprehensive PMTCT, prevention of undesired pregnancy among women should be given the necessary attention (Mutabazi, Zarowsky, and Trottier 2017; Polis C 2016; The Inter-Agency Task Team for Prevention and Treatment of HIV Infection in Pregnant Women 2012; Tsui, McDonald-Mosley, and Burke 2010).

We found overall proportions of HIV-negative and HIV-positive antenatal women reporting moderate to severe depression to be 8-13 percent, with higher rates reported in HIV-negative women. There was a trend to lower depression in the HIV-positive women in the intervention arm (6%) compared with the control arm (11%) but this did not reach statistical significance. Twice as many HIV-negative women in both arms reported depression (13% intervention, 14% control) than HIV-positive women in the intervention arm. While some other studies of depression in pregnant and postpartum women used different depression scales, the proportion of women with depression in our study was consistent with some (Mokhele et al. 2019; Nydoo, Naicker, and Moodley 2017; Yotebieng, Fokong, and Yotebieng 2017) but not all other studies. Our finding of higher depression scores in HIV-negative women was not reported in the other studies (Turan et al. 2014). The higher depression in HIV-negative women may be associated with our finding of

strong treatment self-efficacy in HIV-positive women but low HIV prevention self-efficacy among HIV-negative women and the counseling and psychosocial support generally provided to HIV-positive women, but not to HIV-negative women.

The qualitative component of the study provides evidence that facilities implementing the IMPROVE intervention were able to overcome some of the health system barriers to PMTCT services outlined in the systematic review by Colvin and colleagues (Colvin et al. 2014). Some of the barriers in this review included poor communication/coordination among service providers, lack of training (particularly on updated policies and procedures) and supervision, suboptimal provider-patient relationships (confidentiality concerns, negative attitudes, stigma), and long wait times reported by patients (poor scheduling and management of patient flow). Women in the intervention arm were satisfied with their care and reported that services were well coordinated with few delays, while women in the control arm reported long waiting times and fragmented services. Similarly, health care workers felt that the intervention improved the quality of care they provided by building trust among health workers; improving their knowledge, attitudes, and patient relationships; reducing duplication of efforts; and promoting implementation of new policies, guidelines, and tools. The IMPROVE interventions also address health system failures and inadequate implementation of national policies, which have been noted as major factors obstructing national program success (Correa-de-Araujo 2016; Mathieson, Grande, and Luker 2019).

The cost of the IMPROVE intervention, especially the integrated approach for FP, PMTCT, and pediatric ART is not prohibitive and has the potential to improve coordination of care at relatively low increased cost compared to existing services. More specifically, this relatively low cost difference suggests that the IMPROVE intervention's integrated approach does not require substantial investments to provide integrated services for HIV-positive women and their HIV. With a relatively low cost, and potential for overall improvement in coordinated care, it is worth exploring the expansion of the IMPROVE intervention beyond PMTCT programming, and to adapt it to additional health areas and care models.

As an entry point for the intervention, the coordinating efforts of the multidisciplinary team add some costs to ANC services relative to the other service areas. However, this is likely because ANC is often where women needing additional support are identified and providers likely spend more time in the multidisciplinary groups discussing individualized care plans, supplementary support, and/or additional home visits. The multidisciplinary team's higher cost-share of ANC services relative to the lower cost-share of subsequent services (FP, PNC for HIV-negative women, PMTCT for HIV-positive women), suggests that the early investment in ANC services reduces the need for additional care coordination in PMTCT and other MCH services. In an already overburdened and resource strained healthcare system, reducing the need for this additional care management could free up valuable financial and human resources to be utilized elsewhere. The opportunity to repurpose these resources, coupled with the low cost of the intervention, suggest that the IMPROVE model can have multiple beneficial effects upon the overall healthcare system.

A key lesson from the IMPROVE intervention is that there is a need to explore the possibility that integration and coordination across other MCH-related programs (for example, malaria, nutrition, etc.) at a key service entry point like ANC may reduce the cost of additional support services in

the subsequent service areas outlined above (FP, PNC, PMTCT, and pediatric ART). Future studies will need a more comprehensive approach to track patient resource-use (while ensuring there are ethical safeguards in place) to better understand and document how investment at key service entry points relates to future service utilization and, possibly, long-term efficiencies in service delivery.

LIMITATIONS

Evaluation of the IMPROVE intervention is subject to a number of limitations. The major limitation for the IMPROVE study was the slow enrollment of HIV-positive women in the study, which led to the termination of the study before all participants reached the 24-month endpoint. Follow-up was complete to 12 months with the number of women who reached the end of the study before reaching the 18- or 24-month time points indicated on the flow diagram. In addition, we were not able to conduct viral load testing on specimens collected at the time of delivery due to problems with the proper transport and storage of DBS specimens. VL results would have provided important additional evidence about the effect of the intervention at this critical time point. The mobility of the study population with concomitant shifts in the facilities in which women received care made it difficult to accurately assess retention in care. Loss to care in the facility in which a woman initiated antenatal care does not equate to loss to care overall; thus, there may be more women still active in care who were reported as lost to follow-up. Similarly, women who were seen for their postnatal follow during outreach services are not easily documented using the current program tools, particularly for HIV-negative women. Lastly, the study was conducted only in Maseru district of Lesotho, which may limit the generalizability of the study findings. To minimize this, we included both rural and urban facilities and government and Christian Health Association of Lesotho facilities within the district. In addition, the interventions were designed to promote facility specific adaptations that should be relevant across Lesotho and beyond.

There were several additional limitations to the costing component. Several costs pertaining to the intervention were not available: pre-implementation costs for the development of job aids, training at the site level for use of these aids, and the start-up cost of the multidisciplinary team meetings. The incremental cost of the additional home visit was also not available, as it was performed for all patients (including non-study participants) and across all sites (including non-study facilities); as such, it could not be allocated to either the control or intervention arm. In most cases, clinical and support staff were only able to provide a best estimate of the amount of time spent with patients in each type of service rather than actual observed time. While it was the most efficient data collection methodology for the study, these estimates are likely subject to reporting bias. National averages had to be used as proxy for some cost data (e.g., government lab salaries, laboratory sample transportation). The number of PNC patients or patient visits could not be triangulated with DHIS2 or other sources to verify accuracy. This has implications for the methodology used to apportion costs by each service area's proportion of number of patients or patient clinic visits, and overall cost estimates. Data for one category of operating costs—external services—were only available for one of the control facilities and were estimated to be over $20,000 in one year. The inclusion of these data would have skewed the average operations cost in the control arm, and as such they were excluded from the results.

CONCLUSION AND RECOMMENDATIONS

CONCLUSIONS

The IMPROVE interventions were designed to be relatively easy to implement in routine care settings with existing staff and minimal additional resources. We found that it was acceptable, feasible, and adaptable across a range of facilities in Maseru District. Introducing multidisciplinary teams using a patient-focused approach to MCH/PMTCT service delivery led to improved services and provider-patient relationships that benefitted both patients and staff and led to some improvement in select health outcomes. These included antenatal attendance, facility delivery, retention, ART adherence, and 12-month viral load results. Overall there was high viral suppression in both groups of study women, achieving the 90 percent WHO target and approaching the 95 percent goal. The IMPROVE interventions also were associated with increases in HIV retesting of HIV-negative women during pregnancy and consistent modern contraceptive use in both HIV-negative and HIV-positive women—both of which are important in strengthening the much neglected first and second prongs of PMTCT. While moderate–severe depression was uncommon in all groups, interestingly it was higher among HIV-negative women than HIV-positive women. This, coupled with the HIV-negative women's reports of lack of self-efficacy in several key areas for protecting themselves from acquiring HIV, highlights the need for more attention to be focused on counseling and support for HIV-negative women. While there were improvements seen in the intervention group, several of the outcomes still did not reach MCH/PMTCT goals, highlighting areas where gaps remain and additional efforts are needed. Better systems for tracking patients who move between facilities within a district and between districts are needed to ensure follow-up of mother-baby pairs after delivery and document that they continue to access the necessary health services in their new location. Overall, implementation of the IMPROVE interventions was found to be an effective strategy to enhance MCH/PMTCT service delivery and improve provider-patient interaction and patient outcomes.

The IMPROVE intervention resulted in a better understanding of inefficiencies at the service delivery level in Lesotho and helped to spark conversations around the importance of patient-centered care and efficient, low-cost methods of improving both facility- and community-based care models. The intervention proved to have a minimal additional cost and is potentially scalable beyond the Maseru district in Lesotho, and beyond PMTCT/MCH services. The collection of cost data also identified areas in which there is limited visibility into cost and operational data, which can potentially help inform the design of future cost studies in similar settings. Cost data from IMPROVE will continue to be utilized beyond this final analysis, and will contribute to a growing database of cost data via the Global Health Costing Consortium, helping to inform future planning methods, models, and analysis focused on HIV testing, PMTCT, MCH, and FP.

RECOMMENDATIONS

There are several important recommendations based on the findings from the IMPROVE study that could improve program implementation and achieve better overall MCH and HIV outcomes for women and children in Lesotho. The recommendations are also consistent with both MOH and PEPFAR priorities that include improving the quality of HIV prevention and care services, the retention of HIV-positive patients in care, facility and community linkages, the integration of services, and efficiencies in program implementation.

Based on ongoing presentations and discussion of results with the MOH and other stakeholders through the ADP forum and TWGs, we recommend that the IMPROVE interventions be integrated into routine service delivery throughout Lesotho. This would involve establishing formal, structured, multidisciplinary teams that would replace the informal and often duplicative communication channels and responsibilities that may or may not exist currently with clear accountability for the MCH and PMTCT program outcomes and documentation. We recommend that existing staff trainings be modified to include a patient-focused, PHDP-principled approach coupled with joint, rather than vertical, trainings according to the cadre of staff. Based on our findings of low self-efficacy among HIV-negative women, we also recommend provision of additional support to HIV-negative women in negotiating protective behaviors. Considering that a number of women move out of their primary district during pregnancy and for a few months after delivery, we also recommend that the MOH implement a system to track patients' movement between districts.

There are several lessons learned from the implementation of the IMPROVE interventions across the study facilities that can inform the design of a nationwide program for scale up to achieve even better outcomes than found in the study. These include:

- Identifying the specific changes that individual intervention facilities made to improve their service delivery and incorporating these lessons learned into the new program guidelines.

- Taking advantage of the strong MDT leaders in the current IMPROVE intervention facilities to contribute to the program design and training of new MDT leaders across Lesotho.

- Updating and expanding the job aids to reflect current guidelines and additional priority messages.

- Including clear procedures for linking and documenting service uptake for women who move from one facility to another—through VHW to VHW contact across catchment areas, lay community and facility workers direct contact with their counterparts in other areas, and MDT follow-up of all women who do not return for care.

- Reviewing the service delivery and outcome gaps that remain and identifying potential interventions to address them.

- Adapting current documentation and reporting structures to more accurately reflect the receipt of MCH and HIV/PMTCT services through community services and differentiated service delivery models.

In addition, establishing clear processes for cross-facility sharing of lessons learned and ongoing monitoring of the fidelity to program implementation and national guidelines is critical. Evaluation

after the scale-up of these interventions across Lesotho will be important to determine the effectiveness of this program on improving MCH and HIV/PMTCT outcomes, including population-based community evaluation of health seeking behaviors, family uptake of HIV testing and HIV care services, and HIV-free survival in children after all HIV exposure.

While the IMPROVE study was conducted within MCH and PMTCT service delivery programs, the interventions that were effective in this setting may also translate to general adult and pediatric HIV prevention, care, and treatment settings.

REFERENCES

Basta, Y. L., S. Bolle, P. Fockens, and K.Tytgat. 2017. "The value of multidisciplinary team meetings for patients with gastrointestinal malignancies: A systematic review," *Annals of Surgical Oncology* 24(9): 2669–2678. doi: 10.1245/s10434-017-5833-3.

Buregyeya, E. et al. 2017. "Facilitators and barriers to uptake and adherence to lifelong antiretroviral therapy among HIV infected pregnant women in Uganda: A qualitative study," *BMC Pregnancy Childbirth* 17(1): 94. doi: 10.1186/s12884-017-1276-x.

Cichowitz, C. et al. 2019. "Vulnerable at each step in the PMTCT care cascade: High loss to follow up during pregnancy and the postpartum period in Tanzania," *AIDS Behavior* 23(7):1824–1832. doi: 10.1007/s10461-018-2298-8.

Clouse, K. et al. 2013. "Loss to follow-up before and after delivery among women testing HIV positive during pregnancy in Johannesburg, South Africa," *Tropical Medicine and International Health* 18(4): 451–60. doi: 10.1111/tmi.12072.

Colvin, C. J. et al. 2014. "A systematic review of health system barriers and enablers for antiretroviral therapy (ART) for HIV-infected pregnant and postpartum women," *PLoS One* 9(10): e108150. doi: 10.1371/journal. pone.0108150.

Correa-de-Araujo, R. 2016. "Evidence-based practice in the United States: Challenges, progress, and future directions," *Health Care for Women International* 37(1): 2–22. doi: 10.1080/07399332.2015.1102269.

Drake, A. L., A. Wagner, B. Richardson and G. John-Stewart. 2014. "Incident HIV during pregnancy and postpartum and risk of mother-to-child HIV transmission: A systematic review and meta-analysis," *PLoS Medicine* 11(2): e1001608. doi: 10.1371/journal.pmed.1001608.

Epstein, N. E. 2014. "Multidisciplinary in-hospital teams improve patient outcomes: A review," *Surgical Neurology International* 5(Suppl 7): S295-303. doi: 10.4103/2152-7806.139612.

Family Planning 2020. 2019. "Lesotho, FP2020 core indicator summary sheet: 2018–2019 Annual Progress Report." Family Planning 2020.

Futterman, D. et al. 2010. "Mamekhaya: A pilot study combining a cognitive-behavioral intervention and mentor mothers with PMTCT services in South Africa," *AIDS Care* 22(9): 1093–100. doi: 10.1080/09540121003600352.

Gill, M.M. et al. 2020. "Active pediatric HIV case finding in Kenya and Uganda: A look at missed opportunities along the prevention of mother-to-child transmission (PMTCT) cascade," *PLoS ONE* 15(6):e0233590. doi: 10.1371/journal.pone.0233590.

Goga, A. E. et al. 2015. "First population-level effectiveness evaluation of a national programme to prevent HIV transmission from mother to child, South Africa," *Journal of Epidemiology and Community Health* 69(3): 240–248. doi: 10.1136/jech-2014-204535.

Gourlay, A. et al. 2013. "Barriers and facilitating factors to the uptake of antiretroviral drugs for prevention of mother-to-child transmission of HIV in sub-Saharan Africa: A systematic review," *Journal of the International AIDS Society* 16: 18588. doi: 10.7448/IAS.16.1.18588.

Government of Lesotho, Ministry of Health. 2017. "Final report for a joint review of HIV/tuberculosis and hepatitis programmes." Maseru, Lesotho: Government of Lesotho.

Haberlen, S. A., M. Narasimhan, L. K. Beres and C. E. Kennedy. 2017. "Integration of family planning services into HIV care and treatment services: A systematic review," *Studies in Family Planning* 48(2): 153–177. doi: 10.1111/sifp.12018.

Hamilton, E. et al. 2017. "Using the PMTCT cascade to accelerate achievement of the Global Plan Goals," *Journal of Acquired Immune Deficiency Syndrome* 75(Suppl 1): s27–s35. doi: 10.1097/qai.0000000000001325.

Hodgson, I. et al. 2014. "A systematic review of individual and contextual factors affecting ART initiation, adherence, and retention for HIV-infected pregnant and postpartum women," *PLoS One* 9(11): e111421. doi: 10.1371/journal.pone.0111421.

Holtzman, C. W., K. A. Brady and B. R. Yehia. 2015. "Retention in care and medication adherence: Current challenges to antiretroviral therapy success," *Drugs* 75(5): 445–454. doi: 10.1007/s40265-015-0373-2.

Holzemer, W. L. et al. 2007. "Validation of the HIV/AIDS stigma instrument—Plwa (Hasi-P)," *AIDS Care* 19(8): 1002–1012. doi: 10.1080/09540120701245999.

Johnson, M. O. et al. 2007. "The role of self-efficacy in HIV treatment adherence: Validation of the HIV Treatment Adherence Self-Efficacy Scale (HIV-Ases)," *Journal of Behavioral Medicine* 30(5): 359–370. doi: 10.1007/s10865-007-9118-3.

Kanyangarara, M., K. Sakyi and A. Laar. 2019. "Availability of integrated family planning services in HIV care and support sites in sub-Saharan Africa: A secondary analysis of national health facility surveys," *Reproductive Health* 16(Suppl 1):60. doi: 10.1186/s12978-019-0713-x.

Kerber, K. J. et al. 2007. "Continuum of care for maternal, newborn, and child health: From slogan to service delivery," *Lancet* 370(9595): 1358–1369. doi: 10.1016/s0140-6736(07)61578-5.

Kim, M. H. et al. 2012. "The Tingathe Programme: A pilot intervention using community health workers to create a continuum of care in the prevention of mother to child transmission of HIV (PMTCT) cascade of services in Malawi," *Journal of the International AIDS Society* 15(Suppl 2): 17389. doi: 10.7448/ias.15.4.17389.

Knettel, B. A. et al. 2018. "Retention in HIV care during pregnancy and the postpartum period in the Option B+ era: Systematic review and meta-analysis of studies in Africa," *Journal of Acquired Immune Deficiency Syndrome* 77(5): 427–438. doi: 10.1097/QAI.0000000000001616.

Kroenke, K., R. L. Spitzer, and J. B. Williams. 2001. "The PHQ-9: Validity of a Brief Depression Severity Measure," *Journal General Internal Medicine* 16(9): 606–13. doi: 10.1046/j.1525-1497.2001.016009606.x.

Lesotho Ministry of Health, ICAP. 2018. "Lesotho Population-Based HIV Impact Assessment 2016–2017: Summary sheet, preliminary results." Maseru, Lesotho: Lesotho Ministry of Health and ICAP.

Lewycka, S. et al. 2013. "Effect of women's groups and volunteer peer counselling on rates of mortality, morbidity, and health behaviours in mothers and children in rural Malawi (Maimwana): A factorial, cluster-randomised controlled trial," *Lancet* 381(9879): 1721–1735. doi: 10.1016/s0140-6736(12)61959-x.

Machekano, R. et al. 2018. "HIV incidence among pregnant and postpartum women in a high prevalence setting," *PLoS One* 13(12): e0209782. doi: 10.1371/journal.pone.0209782.

Mandelbrot, L. et al. 2015. "No perinatal HIV-1 transmission from women with effective antiretroviral therapy starting before conception," *Clinical Infectious Diseases* 61(11): 1715–1725. doi: 10.1093/cid/civ578.

Mathieson, A., G. Grande and K. Luker. 2019. "Strategies, facilitators and barriers to implementation of evidence-based practice in community nursing: A systematic mixed-studies review and qualitative synthesis," *Primary Health Care Research and Development* 20: e6. doi: 10.1017/s1463423618000488.

Ministry of Health [Lesotho] and ICF International. 2016. Lesotho Demographic and Health Survey 2014. Maseru, Lesotho: Ministry of Health and ICF International. https://dhsprogram.com/pubs/pdf/FR309/FR309.pdf

Mitchell, G. K., J. J. Tieman, and T. M. Shelby-James. 2008. "Multidisciplinary care planning and teamwork in primary care," *Medical Journal of Australia* 188(S8): s61–64.

Mokhele, I. et al. 2019. "Prevalence and predictors of postpartum depression by HIV status and timing of HIV diagnosis in Gauteng, South Africa," *PLoS One* 14(4): e0214849. doi: 10.1371/journal.pone.0214849.

Mutabazi, J. C., C. Zarowsky, and H. Trottier. 2017. "The impact of programs for prevention of mother-to-child transmission of HIV on health care services and systems in sub-Saharan Africa—a review," *Public Health Reviews* 38: 28. doi: 10.1186/s40985-017-0072-5.

Mutevedzi, P. C., R. J. Lessells, and M. L. Newell. 2013. "Disengagement from care in a decentralised primary health care antiretroviral treatment programme: Cohort study in rural South Africa," *Tropical Medicine & International Health* 18(8): 934–41. doi: 10.1111/tmi.12135.

Nachega, J. B. et al. 2012. "Adherence to antiretroviral therapy during and after pregnancy in low-income, middle-income, and high-income countries: A systematic review and meta-analysis," *AIDS* 26(16): 2039–2052. doi: 10.1097/QAD.0b013e328359590f.

Ngarina, M. et al. 2013. "Reasons for poor adherence to antiretroviral therapy postnatally in HIV-1 infected women treated for their own health: Experiences from the Mitra Plus Study in Tanzania," *BMC Public Health* 13: 450. doi: 10.1186/1471-2458-13-450.

Nungu, Saumu Iddy et al. 2019. "Uptake and determinants for HIV postpartum re-testing among mothers with prenatal negative status in Njombe Region, Tanzania," *BMC Infectious Diseases* 19(1): 398–398. doi: 10.1186/s12879-019-4062-8.

Nydoo, P., T. Naicker, and J. Moodley. 2017. "Depressive scores in newly diagnosed HIV-infected and HIV-uninfected pregnant women," *South African Journal of Psychiatry* 23: 1085. doi: 10.4102/sajpsychiatry.v23i0.1085.

Ojikutu, B. et al. 2014. "Interdisciplinary HIV care in a changing healthcare environment in the USA," *AIDS Care* 26(6): 731–735. doi: 10.1080/09540121.2013.855299.

Polis, C. et al. 2016. "Contraceptive failure rates in the developing world: An analysis of demographic and health survey data in 43 countries." New York: Guttmacher Institute.

Prades, J., E. Remue, E. van Hoof, and J. M. Borras. 2015. "Is it worth reorganising cancer services on the basis of multidisciplinary teams (MDTS)? A systematic review of the objectives and organisation of MDTS and their impact on patient outcomes," *Health Policy* 119(4): 464–474. doi: 10.1016/j.healthpol.2014.09.006.

Psaros, C. et al. 2015. "Adherence to HIV care after pregnancy among women in sub-Saharan Africa: Falling off the cliff of the treatment cascade," *Current HIV/AIDS Reports* 12(1): 1–5. doi: 10.1007/s11904-014-0252-6.

Rogers, A. J. et al. 2017. "Implementation of repeat HIV testing during pregnancy in southwestern Kenya: progress and missed opportunities," *Journal of the International AIDS Society* 20(4): e25036. doi: 10.1002/jia2.25036.

Rogers, Anna Joy et al. 2016. "Implementation of repeat HIV testing during pregnancy in Kenya: A qualitative study," *BMC Pregnancy and Childbirth* 16(1): 151. doi: 10.1186/s12884-016-0936-6.

Rotheram-Borus, M. J. et al. 2014. "A cluster randomised controlled effectiveness trial evaluating perinatal home visiting among South African mothers/infants," *PLoS One* 9(10): e105934. doi: 10.1371/journal.pone.0105934.

Rucinski, Katherine B. et al. 2018. "Longitudinal patterns of unmet need for contraception among women living with HIV on antiretroviral therapy in South Africa," *PLoS One* 13(12): e0209114. doi: 10.1371/journal.pone.0209114.

Sariah, A. et al. 2019. "Why did I stop? And why did I restart? Perspectives of women lost to follow-up in Option B+ HIV care in Dar Es Salaam, Tanzania," *BMC Public Health* 19(1): 1172. doi: 10.1186/s12889-019-7518-2.

Satti, H. et al. 2012. "Comprehensive approach to improving maternal health and achieving MDG 5: Report from the mountains of Lesotho," *PLoS One* 7(8): e42700. doi: 10.1371/journal.pone.0042700.

Sherer, R. et al. 2002. "HIV multidisciplinary teams work: Support services improve access to and retention in HIV primary care," *AIDS Care* 14(sup1): 31–44. doi: 10.1080/09540120220149975.

The Inter-Agency Task Team for Prevention and Treatment of HIV Infection in Pregnant Women, Mothers, and Their Children. 2012. "Preventing HIV and unintended pregnancies: Strategic framework 2011–2015." The Inter-agency Task Team for Prevention and Treatment of HIV Infection in Pregnant Women, Mothers, and their Children.

Thompson, M. A. et al. 2012. "Guidelines for improving entry into and retention in care and antiretroviral adherence for persons with HIV: Evidence-based recommendations from an International Association of Physicians in AIDS Care panel," *Annals of Internal Medicine* 156(11): 817–833, w-284, w-85, w-86, w-87, w-88, w-89, w-90, w-91, w-92, w-93, w-94. doi: 10.7326/0003-4819-156-11-201206050-00419.

Tsui, A. O., R. McDonald-Mosley, and A. E. Burke. 2010. "Family planning and the burden of unintended pregnancies," *Epidemiologic Reviews* 32: 152–174. doi: 10.1093/epirev/mxq012.

Turan, B. et al. 2014. "Linkage to HIV care, postpartum depression, and HIV-related stigma in newly diagnosed pregnant women living with HIV in Kenya: A longitudinal observational study," *BMC Pregnancy Childbirth* 14:400. doi: 10.1186/s12884-014-0400-4.

Turan, J. M. and L. Nyblade. 2013. "HIV-related stigma as a barrier to achievement of global PMTCT and maternal health goals: A review of the evidence," *AIDS and Behavior* 17(7): 2528–2539. doi: 10.1007/s10461-013-0446-8.

U.S. Department of Health and Human Services, Health Resources and Services Administration, Bureau of Primary Health Care. 2017. Integrating HIV Care, Treatment & Prevention Services into Primary Care—a Toolkit for Health Centers. Rockville, Maryland.

UNAIDS. 2019. "UNAIDS data 2019." Geneva, Switzerland: UNAIDS.

Vrazo, A. C. et al. 2018. "Interventions to significantly improve service uptake and retention of HIV-positive pregnant women and HIV-exposed infants along the prevention of mother-to-child transmission continuum of care: Systematic review," *Tropical Medicine and International Health* 23(2): 136–148. doi: 10.1111/tmi.13014.

Ware, N. C. et al. 2013. "Toward an understanding of disengagement from HIV treatment and care in sub-Saharan Africa: A qualitative study," *PLoS Medicine* 10(1): e1001369; discussion e69. doi: 10.1371/journal.pmed.1001369.

Watt, M. H. et al. 2019. "Predictors of postpartum HIV care engagement for women enrolled in prevention of mother-to-child transmission (PMTCT) programs in Tanzania," *AIDS Care* 31(6): 687–698. doi: 10.1080/09540121.2018.1550248.

Weiser, Sheri D. et al. 2006. "Routine HIV testing in Botswana: A population-based study on attitudes, practices, and human rights concerns," *PLoS Medicine* 3(7): e261–e61. doi: 10.1371/journal.pmed.0030261.

WHO Regional Office for Africa. 2014. "WHO cooperation strategy 2014–2019, Lesotho." Brazzaville, Republic of Congo: WHO Regional Office for Africa.

Yotebieng, Kelly A., Kunuwo Fokong and Marcel Yotebieng. 2017. "Depression, retention in care, and uptake of PMTCT service in Kinshasa, the Democratic Republic of Congo: A prospective cohort," *AIDS Care* 29(3): 285–289. doi: 10.1080/09540121.2016.1255708.

APPENDIX

LIST OF STUDY FACILITIES

Intervention sites	Control sites
Loretto Health Center	St Joseph Hospital
St Leonard Health Center	St. Leo Health Center
Scott Hospital	Thamae Health Center
Matsieng Health Center	Ramabanta Health Center
Domiciliary Health Center	Thaba Bosiu Health Center
Paki Health Center	Nazareth Health Center

**POPULATION
COUNCIL**

Ideas. Evidence. Impact.