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### Permalink

<https://escholarship.org/uc/item/8ht1s1wq>

### Journal

AIDS and Behavior, 22(9)

### ISSN

1090-7165

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### Publication Date

2018-09-01

### DOI

10.1007/s10461-018-2140-3

Peer reviewed



# HHS Public Access

Author manuscript

*AIDS Behav.* Author manuscript; available in PMC 2019 September 01.

Published in final edited form as:

*AIDS Behav.* 2018 September ; 22(9): 2956–2965. doi:10.1007/s10461-018-2140-3.

## Impact of a Rapid Results Initiative Approach on Improving Male Partner Involvement in Prevention of Mother to Child Transmission of HIV in Western Kenya

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### Abstract

A rapid results initiative (RRI) aimed at increasing male involvement in prevention of mother-to-child transmission (PMTCT) and service uptake among pregnant women at 116 antenatal clinics in Western Kenya was compared at baseline, during the RRI, and 3-months post-RRI. Male involvement increased from 7.4 to 54.2% during RRI (risk difference [RD] 0.47, CI 0.45–0.48) then 43.4% post-RRI (RD 0.36, CI 0.35–0.37). Among HIV-infected women, facility delivery increased from 40.0 to 49.9% (RD 0.10, 95% CI 0.06–0.13) and 65.0% post-RRI (RD 0.25, 95% CI 0.22–0.28). HIV-infected pregnant women linkage to HIV care increased from 58.6 to 85.9% (RD 0.27, CI 0.24–0.30) and 97.3% post-RRI (RD 0.39, CI 0.36–0.41). Time to ART initiation reduced from 29 days (interquartile range [IQR] 6–56) to 14 days (IQR 0–28) to 7 days (IQR 0–20). A male-centered RRI can significantly increase men's engagement in antenatal care leading to improved partner utilization of PMTCT and antenatal services.

### Keywords

Rapid results initiative; Male involvement; PMTCT; HIV-1; Kenya

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**Conflicts of interest** The authors have no conflicts of interest to declare.

**Ethical Approval** For this analysis, the program evaluation protocol that allows Family Aids Care and Education Services (FACES) to utilize routinely gathered medical information for program evaluation and dissemination was reviewed and approved by the KEMRI ethical review committee, CDC, and the UCSF Committee on Human Research. In addition, informed consent was not obtained from participants because these were routine services accessible to all patients at the health facility. To protect patient privacy, all data were de-identified, and access to patient records restricted to authorized health workers.

## Introduction

Pediatric HIV infection remains a major public health challenge in sub-Saharan Africa. At the end of 2014, the World Health Organization (WHO) estimated that about 2.6 million children globally were living with HIV, with the majority being from sub-Saharan Africa [1, 2]. Most of these children acquire HIV from their mothers during pregnancy, birth or breastfeeding [3]. It is estimated that without any interventions, mother to child transmission of HIV ranges between 15 and 40% [3, 4].

Since the year 2000, the prevention of mother to child transmission (PMTCT) program has been rolled out in many resource-poor countries. For example, the Kenya National PMTCT Program was launched in 2002 and now provides PMTCT services at over 60% of health facilities countrywide [4]. The success of PMTCT programs in Kenya is demonstrated by the rapid decline in the number of new pediatric infections. Between 2009 and 2015 new pediatric infections decreased by 55% (23,200–10,440) [5]. However, the rate of mother to child transmission has stagnated over the last several years. In 2010, the mother to child transmission rate in Kenya was 12%, this reduced to 9% between 2011 and 2012. This leveled off at 8% between 2013 and 2015 [6], despite the 2012 launch of the Kenya National Elimination of Mother to Child Transmission of HIV Framework which aimed to reduce vertical transmission of HIV to less than 5% [7, 8]. Kenya adapted this framework from the Global Plan for Elimination of New HIV Infections among children, which also focuses on keeping mothers alive and maintaining their health [9]. The impact of keeping children alive and HIV free is compromised if their mothers are not alive and well in HIV care. Pregnant and postpartum women have poorer retention in HIV care than men and non-pregnant women, putting them at higher morbidity and mortality risk [10]. This highlights the urgent need for programmatic interventions aimed at keeping women enrolled in HIV care, healthy and alive [11].

Efficacious PMTCT interventions have benefitted the entire PMTCT cascade: HIV identification via antenatal testing, linkage to HIV treatment, skilled delivery, antiretroviral prophylaxis for babies, safe breastfeeding, early infant HIV diagnosis and enrollment in care. Attrition along the PMTCT continuum of care reduces PMTCT effectiveness, this is in part due to lack of partner awareness and support, accusations, fear of HIV status disclosure, violence, abandonment, and stigma [12, 13].

Studies have shown that male involvement in antenatal care and PMTCT services can increase uptake and adherence to PMTCT interventions [14, 15]. Women whose male partners take part in PMTCT have higher uptake of HIV testing, higher rates of delivery assisted by skilled birth attendants [16], greater adherence to ART [12], better retention in HIV care [17], adherence to infant feeding strategies, and lower incidence of infant HIV infection [18]. A cross-sectional study in Uganda showed that women who thought their husbands would allow them to be tested were six times more likely to accept testing as compared to those who thought their husbands would not allow them to be tested [3]. In Kenya, women who anticipated male partner stigma were more than twice as likely to refuse HIV testing [19].

Despite the WHO's current PMTCT strategic vision promoting increasing male involvement in PMTCT services in sub-Saharan Africa, male partner participation in antenatal care remains low, ranging between 12 and 16% [20, 21]. A systematic review of studies on male involvement in PMTCT revealed several barriers to male involvement in PMTCT services [22]. These include: (1) societal and cultural barriers that perceive the antenatal clinic as a woman's place [12]; (2) individual factors, for example lack of time and finances [12]; (3) information and knowledge barriers, for example male partners not understanding sero-discordancy, assuming they are HIV negative because their female partners tested HIV negative and limited knowledge of PMTCT [12].

In addition, there is currently no single widely-used indicator that measures male involvement [23, 24]. Some studies have defined male involvement as participation in HIV testing during antenatal care visits [25], participation in couple's HIV counseling and testing [26], or as men's roles as clients of health care services, as partners, or as agents of positive change [23].

Innovative approaches to improve male involvement in PMTCT have included extending clinic hours, reducing waiting time at the clinics, sending letters of invitation to male partners to attend the clinic and participate in PMTCT, and training midwives and nurses on male friendly PMTCT services [27, 28]. Other strategies include health education campaigns [29], improvement of health systems [14], community sensitization of men aimed at addressing cultural beliefs that impede male involvement, for example the perception that men who accompany their wives are weak [30], or the antenatal clinic is a place for women [31, 32]. Unfortunately, there have been few scientific evaluations of the impact of these strategies on male involvement in real-life settings [33]. With one of the UNAIDS Global Strategy targets being zero new infections among children and keeping mothers alive and well [9, 34], multi-faceted and novel approaches that address long-entrenched barriers to boost male involvement are critically needed to improve service uptake by pregnant women.

We implemented a rapid results initiative (RRI) with a package of novel strategies designed to address barriers to male involvement and their impact on PMTCT service uptake in a large HIV care program in Western Kenya. The RRI is a management concept that combines best practices from organizational psychology, change management, and capacity building [35]. This concept was formulated by Robert H. Schaffer & Associates and is geared towards producing immediate measurable results within short time periods of one hundred days or less [36]. The RRI methodology entails rapid cycles of (1) needs assessment and objective formulation, (2) implementation of interventions and (3) performance monitoring and improvement. Recently, RRIs have demonstrated success in improving performance in many aspects of health service delivery [37] and can involve a single area of focus or target several thematic areas. The short-term goals of any RRI are typically used as building blocks towards the achievement of long-term organizational goals [38].

This study sought to evaluate the impact of a male-centered RRI on the PMTCT cascade with a focus on: HIV testing and linkage to care for those HIV positive; keeping mothers alive through ART initiation and skilled deliveries; and uptake of early infant diagnosis.

## Methods

### Study Design

We employed a pre- and post-intervention study design to evaluate the impact of a male-centred RRI approach on partner testing, male involvement in antenatal clinic (defined as the male partner accompanying his female partner to the antenatal clinic at least once and receiving antenatal counselling messages), linkage of pregnant women to HIV care and treatment, uptake of skilled facility deliveries, and early infant HIV diagnosis at 116 antenatal clinics in Western Kenya.

### Study Setting

This study was implemented in Migori, Kisumu, and Homa Bay counties in Western Kenya. The HIV prevalence rates in these counties range between 13.2 and 17.0% with an estimated 4000–6000 woman in need of PMTCT services annually per county [39]. The health facilities involved in the study were Ministry of Health clinics supported by Family AIDS Care and Education Services (FACES), a program funded by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR)/U.S. Centers for Disease Control and Prevention (CDC). The Family Aids Care and Education Services (FACES) program is a collaboration between the University of California San Francisco (UCSF) and the Kenya Medical Research Institute (KEMRI), which supports comprehensive HIV prevention, care and treatment services including PMTCT.

### Study Procedures

**Standard of Care Practices to Promote Male Involvement Before the RRI**—At baseline, pregnant women, regardless of HIV status, attending antenatal clinics without their partners were given standard, non-personalized, unsigned letters inviting their male partners to the clinic. Pregnant women accompanied by their partners were given first priority, thus reducing their clinic waiting times. Mentor mothers and peer educators offered health education at the antenatal clinic waiting areas with information about male partner involvement in antenatal care and PMTCT.

The health education message content included: need for health care for men as individuals, need for support for women during pregnancy, childbirth and infant feeding, causes of maternal and neonatal mortality, support structures needed to reduce maternal and neonatal deaths, the role of men in maternal-neonatal child health, and benefits of involving men. In addition, the program implementers involved the chiefs, sub-chiefs, and village elders to promote male involvement in the antenatal clinic during community meetings such as: Community Unit action days, and the routine village chiefs' meetings also known as Chief "Barazas". Men attending these meetings received promotional health messages with male involvement themes consistent with those given during the antenatal clinic visits.

**Intervention Description**—We employed an RRI approach to introduce and sustain a package of high-impact interventions between April 2013 and June 2013. A participatory quality improvement process was utilized to roll out the RRI. Initial start-up activities included: (1) formation of multi-disciplinary Technical Working Groups (TWGs) with

community representation by Community Health Workers; (2) development of implementation standards of the RRI by TWGs; and (3) conducting site assessments to sensitize and train facility staff on the RRI activities.

We conducted the following throughout the RRI and post-RRI periods: (1) strengthening systems for collection of monthly PMTCT data, for example collecting routine data using standardized tools, training health workers on proper documentation, and conducting continuous quality improvement to assess and strengthen reporting; (2) strengthening facility community linkages through community meetings and engagement; (3) providing technical support via TWG site visits; (4) forming and regular meetings of district TWGs with representation in the provincial TWGs. The provincial and district TWGs conducted joint site visits which focused on: (1) demand creation (2) technology, and (3) service delivery (Fig. 1).

**New Strategies Introduced During the RRI Period**—To strengthen the conventional standard of care approaches for increasing male involvement, a carefully designed package of interventions was developed along three main domains: (1) demand creation (e.g. mobilization), (2) technology (e.g. text reminders), and (3) service delivery strategies (e.g. male checkup). These domains empowered men and, by extension, their pregnant partners to be aware of, and access PMTCT services during pregnancy, childbirth and early postnatal period. These interventions were applied at the community, health facility and individual level.

**Community**—At the community level, existing Community Units were leveraged to mobilize entire communities. PMTCT messages were provided in places where communities gather such as chief's meetings, women's groups, churches, and beaches. Messages targeted both men and women and allowed for peer discussions.

**Facility**—We introduced male-friendly services at the facility level; these included an abbreviated male medical checkup including blood pressure check, chest examination and counseling on prostate cancer. Men who accompanied their female partners were identified through active triage conducted by mentor mothers and given first priority to see the healthcare worker.

**Individual**—On an individual level, pregnant women, regardless of HIV status, were given a male invitation letter that was personalized with their partner's name and signed by the nurse at the health facility. Additionally, while still at the clinic, mentor mothers and peer educators called the male partner of every consenting woman and invited him to a free medical checkup together with his female partner as she attended her next clinic visit. The call also emphasized the benefits that men would receive upon coming to the clinic and reassured them that they would be fast-tracked at the clinic. Peer educators and mentor mothers also sent a text message one week before the next clinic visit to reinforce their benefits of clinic attendance and to remind couples of the clinic return date.

## Data Collection and Evaluation Methods

We collected data using routine program and Ministry of Health registers and monthly reporting templates; variables were extracted manually from site-level registers, aggregated into monthly reports, and entered into a database in MS Excel. We then merged data centrally for analysis. All pregnant women attending their first antenatal visit at the clinic, their male partners and HIV-exposed infants were included. Aggregated cohort data were collected over three 12-week periods: at baseline (January to March 2013), during the RRI (April–June 2013), and post-RRI (July–September 2013). These three time periods enabled us to measure the effectiveness of the RRI and to evaluate the carryover effect as well as the sustainability of the intervention post-RRI. During this period, we relied on the routine Ministry of Health data collection; no additional support for data collection was provided. Table 1 gives a detailed summary of indicators and data sources.

## Outcome Measure

The main outcome variables for this study included: (1) male involvement in antenatal care, defined as the male partner accompanying his female partner to the antenatal clinic at least for one visit, and receiving antenatal counselling messages, ascertained from the antenatal register with details of the pregnant women and her male partner; (2) partner testing within antenatal services; (3) uptake of skilled deliveries amongst all women; (4) uptake of skilled deliveries amongst HIV positive women; (5) linkage and time to HIV care enrollment and time to ART initiation for women diagnosed with HIV; and (6) HIV exposed infant testing within 0–8 months of age.

## Statistical Methods

Frequencies and proportions were calculated to examine indicator performance. We used median and interquartile range (IQR) to describe the duration of time to linkage and time to ART in days, as well as rank sum test to determine statistically significant differences between baseline time RRI and post-RRI periods. Cox Proportional Hazards Regression was used to explore the association between the three periods and time taken from testing to linkage and time from testing to ART initiation reporting the Hazard Ratio (HR) (95% CI). We used a Kaplan–Meier plot to display time to linkage and time to ART Initiation. Chi square test of proportions was used to compare the indicator performance differences between baseline, during the RRI, and post-RRI periods. Data analysis was performed using STATA Version 12 (STATA Corp, College Station, Texas USA).

## Results

### Partner Testing and Male Involvement

The percent of male partners tested for HIV increased from 5.4% during the baseline period to 50.1% (RD 0.45, 95% CI 0.43–0.46) during the RRI and 38.6% (RD 0.33, 95% CI 0.32–0.34) during the post-RRI period. Male involvement in antenatal care increased from 7.4% at baseline to 54.2% (RD 0.47, 95% CI 0.45–0.48) during the RRI and 43.4% (RD 0.36, 95% CI 0.35–0.37) during the post-RRI period (Tables 1 and 2).

## Linkage to Care

The proportion of HIV positive pregnant women successfully linked to care was 58.6% at baseline and 85.9% (RD 0.27, 95% CI 0.24–0.30) during the RRI period. Linkage further increased to 97.3% (RD 0.39, 95% CI 0.36–0.41) during the post-RRI period. Median time to linkage was one day (IQR 0.5, 35) at baseline and 0.5 days (IQR 0.5, 25) during the RRI and 0.5 (IQR 0.5, 4) during the post-RRI period. There was a significant difference in the time period within which the HIV positive women were linked to care between baseline and post-RRI period ( $p < 0.001$ ). At baseline 177 (63%) women were linked to care within a week, 179 (66.5%) were linked during RRI in the same duration while 182 (82%) were linked during post-RRI. (Tables 1, 2). HIV positive women took fewer days to be linked to care during the RRI (HR 1.32, 95% CI 1.11–1.57) and post-RRI (HR 1.76, CI 1.46–2.12) periods, compared to baseline (HR 1, CI 0.5–35) (Table 2, Figs. 2 and 3).

## ART Initiation

Among pregnant HIV-infected women eligible for ART ( $CD4 < 350$ ), median time to ART initiation reduced to 14 days (IQR 0–28) during the RRI ( $p < 0.001$ ) and to 7 days (IQR 0–20) during the post-RRI period ( $p < 0.001$ ) compared to 29 days (IQR 6–56) at baseline. (Table 2 and Figs. 4 and 5).

## Early Infant Diagnosis

Early infant diagnosis (EID) uptake (0–8 months) dropped from 54.3% at baseline to 41.2% (RD – 0.1, 95% CI: – 0.17 to 0.10) during the RRI, but increased significantly to 74.9% (RD 0.21, 95% CI: 0.17–0.24) during the post-RRI period (Table 2).

## Facility Delivery

Facility delivery among all women increased from 48.1 to 62.5% (RD 0.14, 95% CI 0.13–0.16) during the RRI and to 74.5% (RD 0.26, 95% CI 0.25–0.28) during the post-RRI period. The uptake of facility delivery among HIV-infected women increased from 40.0% at baseline, to 49.9% (RD 0.10, 95% CI 0.06–0.13) during the RRI and to 65.0% (RD 0.25, 95% CI 0.22–0.28) following the RRI (Table 2).

Performance indicators (proportions of HIV positive linked to care, partner tested, male involvement, early infant diagnosis uptake infants (0–8 months) and skilled delivery for both HIV-infected and all women) were significantly higher during the RRI period ( $p < 0.001$ ) and post-RRI period ( $p < 0.001$ ) compared to baseline (Table 2).

## Discussion

This study demonstrates how a male-centered RRI approach significantly contributed to increased uptake of HIV testing among male partners, earlier linkage to ART initiation among pregnant HIV-infected women, increased proportion of women delivering in a health facility and infants undergoing early infant diagnosis. Although other studies evaluating interventions have demonstrated gains across various steps within the PMTCT cascade [40], we found that a male-centered RRI improved intervention uptake across the PMTCT cascade during the RRI and continued to have elevated performance post-RRI. This is



corroborated by prior work using RRI approach for PMTCT [37] which showed benefits to using an intensive, short-term approach for systems delivery that can be sustained over time. There are many competing tasks at the healthcare provider and facility level and these findings illustrate that it can be helpful to focus on one area with intensity over a short block of time to build and sustain momentum.

Expectant fathers need to be empowered with information and services to enable them to invest in and protect their own and their families' health. Most PMTCT programs seek to address the needs of the pregnant women and their babies by engaging and educating pregnant women and mothers in appropriate care seeking and caregiving practices for themselves [21]. This has often led to men perceiving that PMTCT is "women's business" [21]. As such men are often uninformed or misinformed and ultimately disempowered to share in the responsibility of preventing mother to child transmission [29]. The outcomes of the RRI illustrate that male involvement activities are feasible even in resource-poor settings and can be implemented on a large scale.

By virtue of being key decision makers within families and communities, men play a vital role in decisions that affect uptake of PMTCT interventions along the entire PMTCT cascade [12]. To be able to make informed decisions, men need to understand the importance of pre- and postnatal care as well as the benefits of skilled birth attendance. Utilizing a multi-faceted approach that leverages technology to text message male partners, provides services for men, prioritizes men at the clinic and utilizes influential community members may have collectively increased male involvement in PMTCT.

Despite the growing awareness of the role that men can play in PMTCT, many countries face challenges at the implementation level [29]. When properly designed, RRIs can provide a natural context for stimulating attitude change, building confidence and improving teamwork [41]. For this project, we used a participatory approach by forming regional Technical Working Groups (TWGs) between Family AIDS Care and Education Service (FACES), the Ministry of Health and community members to design and oversee the implementation. This approach builds ownership and commitment among the key targeted change agents that are important post the RRI period [42].

The main limitation of this study was that we did not collect patient-level data but instead used aggregated program clinic data. While this may be different from traditional study designs, increasingly more studies are evaluating the impact of interventions at clinic or community levels rather than individual level, since the clinic/community rather than the individual is the target [43]. The delivery channel for this package of intervention is the health care provider at the clinic and the beneficiary population is the "expectant families". The clinic rather than individuals thus form the unit of evaluation. Admittedly, this design does not allow us to look at intra-individual and inter-individual changes over time.

However, since the intervention was applied at the clinic level, a serial rather than a longitudinal approach was important and sufficient to capture information at the level of the clinic and the program and to estimate differences in the pre- and post-intervention periods. In addition, we were not able to evaluate the individual components of the intervention

package to determine which individual strategy was the most effective. However, given the multiple systematic, knowledge and attitudinal barriers that limit the uptake and utilization of PMTCT, it is likely that a multi-preventive integrated-approach like the one described is more likely to result in significant and sustainable PMTCT gains.

## Conclusion

A male-centered, scalable RRI can significantly increase men's attendance at antenatal clinics, consent to HIV testing, and improve their female partner's utilization of PMTCT services and health facility skilled delivery. Strategies that deliberately address men's own health needs appear promising at engaging men in PMTCT. The RRI approach is a simple, innovative and efficient way of introducing and scaling up male engagement interventions. This approach has the potential to reduce both maternal and perinatal morbidity, and mortality in HIV-affected regions.

## Acknowledgements

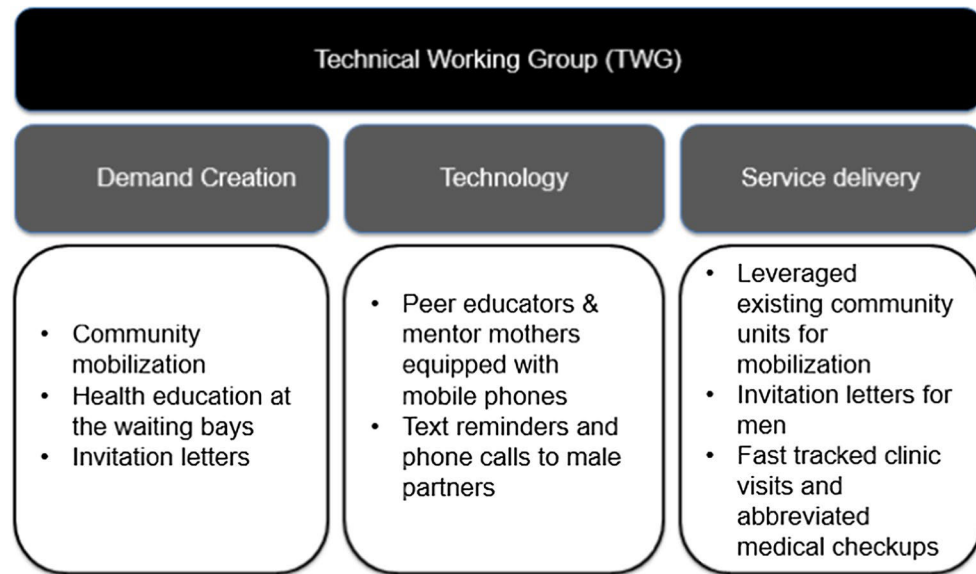
We thank the Kenyan women and men who participated in the study. We acknowledge the important logistical support of the KEMRI-UCSF Collaborative Group and especially Family Aids Care and Education Services (FACES). We gratefully acknowledge the Director of KEMRI, the Director of KEMRI's Centre for Microbiology, and the Nyanza Provincial Ministries of Health and the provincial and district reproductive health coordinators for their support in conducting this research. We also thank George Owino, Christine Osula, Benta Aloo, Jannes Kodero, and Charles Odoyo for their important contributions to this research. This publication was made possible by financial support from the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) through cooperative Agreement, #PS001913 through the U.S. Centres for Disease Control and Prevention (CDC), Division of Global HIV and TB (DGHT). The findings and conclusions in this publication are those of the author(s) and do not necessarily represent the official position of the CDC/Government of Kenya.

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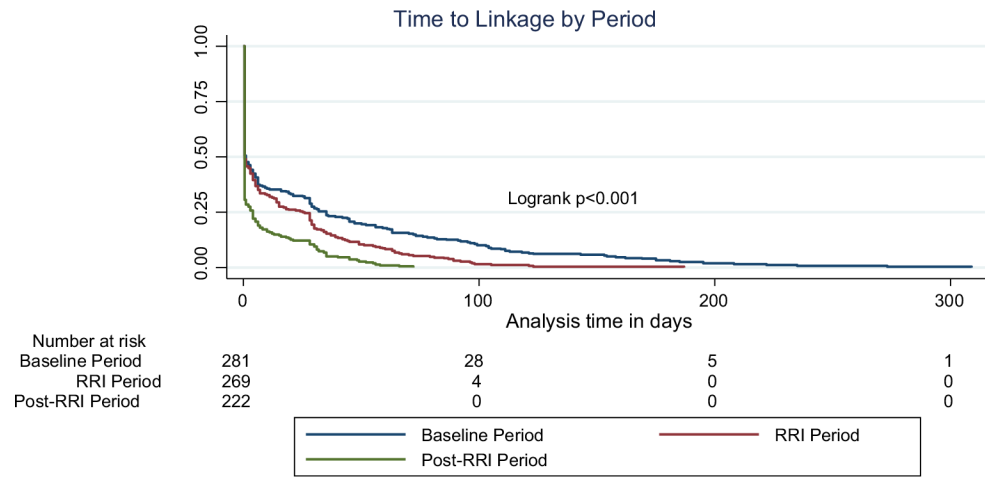
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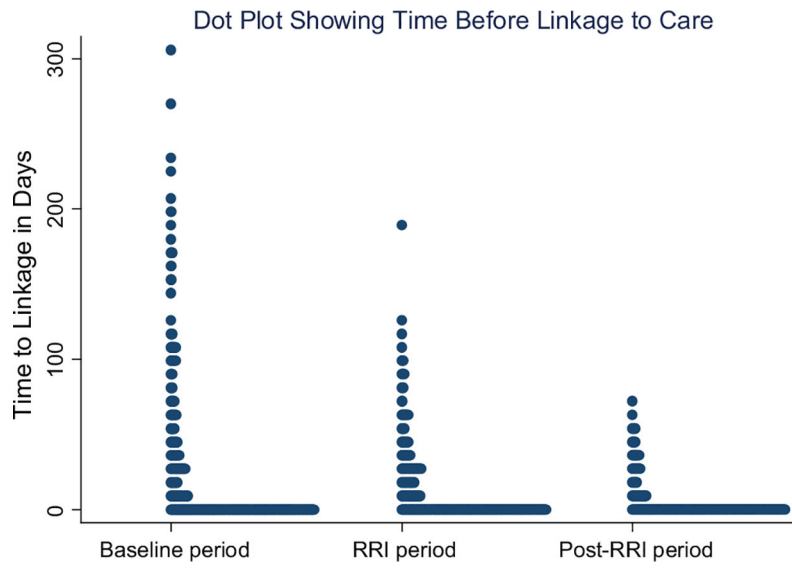
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**Fig. 1.**  
Rapid results initiative approach



**Fig. 2.**  
Kaplan Meier curves showing time to linkage to care by period



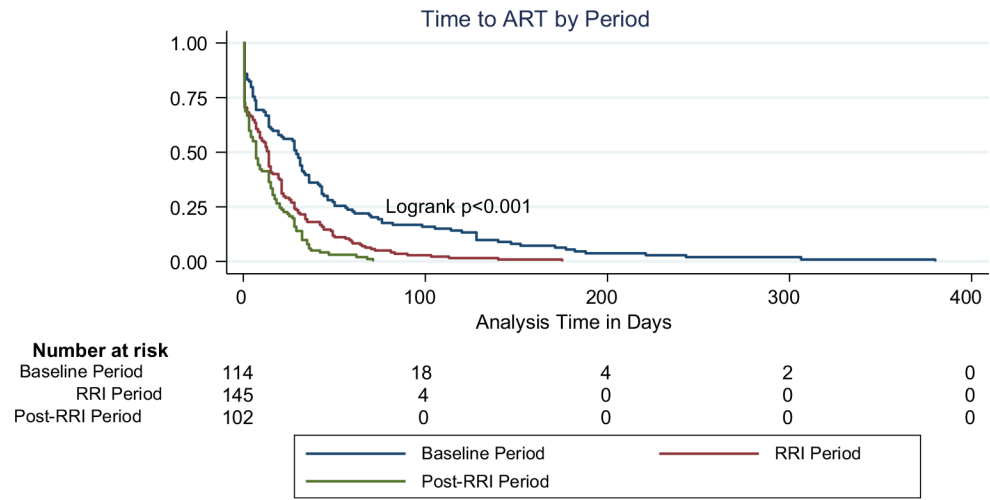
**Fig. 3.** A dot plot showing time to linkage between the three periods

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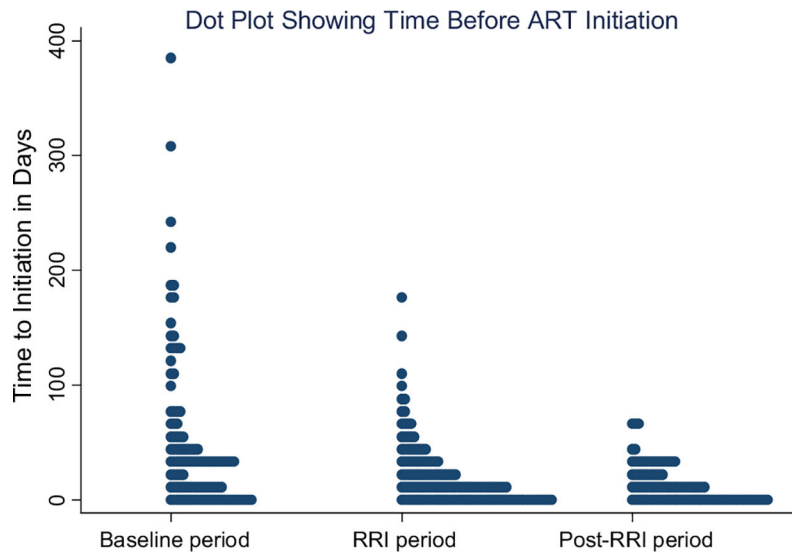
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**Fig. 4.** Kaplan Meier curves showing time to ART initiation by period





**Fig. 5.**  
A dot plot showing time from ART eligibility to initiation

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Table 1

## Indicator definition and data source

Indicator	Indicator definition	Data source
Proportion of male partners accompanying their female partners to antenatal care	Number of male partners accompanying their female partners to at least one ANC visit and receiving the comprehensive counseling services Denominator: all women attending their first ANC visit	Antenatal care register (ANC), Ministry of Health (MOH) 406
HIV prevalence for pregnant women at ANC	Numerator: Number of women attending ANC clinic who either tested HIV positive or had known positive HIV status. Denominator: all women attending their first ANC visit	ANC- MOH 406
Proportion of women receiving skilled delivery services	Numerator: number of women who delivered in a hospital. Proxy Denominator (proxy): all women who attended first ANC visit	Maternity register
Proportion of HIV-positive women receiving skilled delivery services	Numerator: number of HIV-positive pregnant women delivering in the hospital. Denominator (proxy): all the HIV positive pregnant women	Maternity register
Proportion of HIV-positive women successfully linked to care	Numerator: number of HIV-positive pregnant women successfully linked to care, evidenced by enrollment into the Pre ART register. Denominator: all HIV- Infected pregnant women	Pre ART register MOH 361A
Time to linkage to care	Median time to linkage to care at baseline, during and post the RRI measured in days	Pre ART register MOH 361 B
Proportion of HIV-exposed infants (HEI) getting HIV testing	Numerator: number of HEI tested with PCR between 0 to 8 months of age. Denominator: all HEI born during the same period.	HEI register
Proportion of partners receiving HIV testing	Numerator: Number of partners tested for HIV. Denominator (proxy): number of women tested at first visit less the number of women whose partners were known positives.	(ANC), MOH) 406

**Table 2**

PMTCT indicator performance by period

Indicator	Baseline Period		RRI period		Post-RRI period		Chi square/ rank sum test	Risk difference/ hazard ratio (95%CI)	Chi square/ rank sum test
	N (%) <sup>a</sup>	N (%) <sup>a</sup>	N (%) <sup>a</sup>	N (%) <sup>a</sup>	N (%) <sup>a</sup>	N (%) <sup>a</sup>			
HIV+ linked to care	899/1535 (58.6%)	1461/1701 (85.9%)	0.27 (0.24–0.30)	p < 0.001	1436/1476 (97.3%)	0.39 (0.36–0.41)	p < 0.001		p < 0.001
Median time (days) to ART initiation (IQR)	29 (6–56)	14 (0.5–28)	1.82 (1.41–2.35)	p < 0.001	7 (0.5–20)	2.51 (1.88–3.34)	p < 0.001		p < 0.001
Median time (days) to linkage (IQR)	1 (0.5, 35)	0.5 (0.5, 25)	1.32 (1.11–1.57)	p = 0.150	0.5 (0.5, 4)	1.76 (1.46–2.12)	p < 0.001		p < 0.001
Partner tested	385/7086 (5.4%)	3414/6818 (50.1%)	0.45 (0.43–0.46)	p < 0.001	2535/6569 (38.6%)	0.33 (0.32–0.34)	p < 0.001		p < 0.001
Male involvement	535/7236 (7.4%)	4022/7426 (54.2%)	0.47 (0.45–0.48)	p < 0.001	3089/7123 (43.4%)	0.36 (0.35–0.37)	p < 0.001		p < 0.001
EID uptake infants (0–8 months)	834/1535 (54.3%)	700/1701 (41.2%)	– 0.13 (– 0.17 to 0.10)	p < 0.001	1106/1476 (74.9%)	0.21 (0.17–0.24)	p < 0.001		p < 0.001
Skilled delivery (all)	4172/8668 (48.1%)	5806/9283 (62.5%)	0.14 (0.13–0.16)	p < 0.001	6129/8229 (74.5%)	0.26 (0.25–0.28)	p < 0.001		p < 0.001
Skilled delivery (HIV+)	614/1535 (40.0%)	848/1701 (49.9%)	0.10 (0.06–0.13)	p < 0.001	959/1476 (65.0%)	0.25 (0.22–0.28)	p < 0.001		p < 0.001

HR 1, CI 0.5–35)

<sup>a</sup>Except where noted