Title:

Enhancing national prevention and treatment services for sex workers in Zimbabwe: A process evaluation of the SAPPH-IRe Trial

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Abstract

Background: Targeted HIV interventions for female sex workers (FSW) combine biomedical technologies, behavioural interventions, and community mobilization of sex workers with the aim of empowering FSW and improving prevention and treatment outcomes. Understanding how to deliver such interventions most effectively in sub-Saharan Africa is critical to the HIV response.

Methods: The SAPPH-IRe randomized controlled trial in Zimbabwe tested an intervention to improve FSW engagement with HIV prevention and care services. SAPPH-IRe was nested within a comprehensive national FSW programme. After two years, results of the trial showed no significant difference between arms in proportion of all FSW with HIV viral load ≥1000 copies/ml. Both arms showed a steep decline in % FSW with HIV viral load ≥1000 copies/ml. Our process evaluation tracked the intervention's implementation using data from routine programme statistics, qualitative interviews with participants, and respondent driven surveys.

Results: The intervention proved feasible to deliver and was highly acceptable to FSW and providers. Intervention clinics saw more FSW for the first time (4082 vs 2754), performed more than twice as many HIV tests (2606 vs 1151) than control site clinics and nearly double the number of women were diagnosed with HIV (1042 vs 546). Community mobilization meetings in intervention sites also attracted higher numbers. We identified some gaps in fidelity of delivery: PrEP implementation took time to engage FSW, routine viral load monitoring was not performed, and the ratio of peer educators to sex workers was lower than intended. During the trial, reaching FSW with HIV testing and treatment became a national priority, leading to numbers increasing at both intervention and control clinics. Throughout Zimbabwe, ART coverage improved and HIV- stigma declined. FSW responded favourably to non-judgmental services and peer-led activities, which were available in all sites.

Conclusions: Zimbabwe's changing HIV policy context, including widespread intensification of targeted services, appeared to contribute to positive improvements across the HIV care continuum for all female sex workers over the course of the SAPPH-IRe trial. More intense community-based interventions for FSW may be needed to make further gains toward HIV epidemic control.

Trial Registration: Pan African Clinical Trials Registry (PACTR201312000722390)

Keywords: Zimbabwe, process evaluation, female sex workers, HIV/AIDS, Prevention, Treatment, Community mobilization

Background

Female sex workers (FSW) have among the highest rates of HIV and are prioritized in the global response [1, 2]. Barriers to their engagement with care are well documented, including how structural factors constrain both prevention and treatment of HIV among FSW [3-7]. Laws and local policing, service availability, stigma and peer norms are important determinants of sex workers' access to health services [8-11].

A growing evidence base points to effective programming approaches for FSW, many of which have been successfully replicated in different contexts [12]. Targeted interventions that empower sex workers and address structural determinants appear to reduce risks and increase service use among FSW [13, 14]. These combine individual behaviour change, biomedical technologies, and community mobilization of sex workers to strengthen peer support and reduce social stigma [15-17]. Successful responses in Thailand and Cambodia focused on the sex industry through brothel-based condom promotion, treatment of sexually transmitted infections, and peer education [18-21]. The Sonagachi and Avahan programmes in India demonstrate how bringing sex workers together into supportive networks and building collective efficacy empowers FSW to increase condom use, improve work conditions, and avoid violence from clients, police, and intimate partners [22-25].

A similarly targeted approach may be applicable to sub-Saharan Africa [26, 27], where 18-66% of new infections are attributed to sex work [28, 29]. In high prevalence settings, ensuring FSW benefit from growing availability of antiretroviral therapy (ART) is prioritised [30]. However, discrimination by providers, fear of side effects, and concerns that taking ART will disclose their status to peers or clients are among the barriers confronted by FSW living with HIV [31-33, 6]. Nonetheless, in some settings, programmes have achieved rates of treatment success comparable to women in the general population [34]. FSW engagement with services is becoming increasingly salient given universal test and treat strategies [35] and calls for making pre-exposure prophylaxis (PrEP) available to FSW [36-38].

The *Sisters' Antiretroviral Programme for Prevention of HIV: an Integrated Response* (SAPPH-IRe) randomized controlled trial tested an intervention designed to create a more enabling environment for FSW HIV care in Zimbabwe [39]. SAPPH-IRe was implemented 2014-2016 by the Centre for Sexual Health, HIV and AIDS Research (CeSHHAR), which delivers Zimbabwe's national sex work HIV programme 'Sisters with a Voice' on behalf of the National AIDS Council. The 'Sisters' programme provides HIV testing and sexual and reproductive health services to FSW. Those diagnosed HIV positive are referred to government services for antiretroviral treatment. As previously described [40], out of 14 paired study sites, one from each pair was randomly allocated to have the 'Sisters' programme enhanced to receive a combined package of intensified peer support, increased community organising activities, and provision of both on-site PrEP and ART at co-located sex worker clinics. The other paired site was allocated to usual 'Sisters' care. After two years, we did not find a significant difference between arms in the trial's primary outcome, which was proportion of all FSW living at intervention sites with HIV viral load ≥1000 copies/ml, measured among representative populations of sex workers recruited using respondent driven sampling. No significant differences were found for secondary outcomes, including % FSW who know their HIV status or % on ART. However, in both arms there was evidence of a steep decline over time of the proportion of FSW with HIV viral load ≥1000 copies/ml (by 35.1% in the usual care arm and 45.6% in the enhanced

intervention arm weighted percentage risk difference -2.8% (-8.1%, 2.5%), *p*=0.23). Results of the trial are reported elsewhere [39].

We conducted a process evaluation to track implementation of the SAPPH-IRe intervention, assess whether it was delivered as intended, and identify effects along the hypothesised causal pathway between activities and outcomes. We aimed to capture the realities of programme delivery, using mixed methods to triangulate information drawn from providers, participants, and the broader context into which the intervention was introduced [41, 42]. We explored feasibility and acceptability of the intervention components according to implementers and participants, aiming to help interpret observed outcomes and answer *how* and *why* the intervention did not produce its hypothesised effects [43]. Data from a process evaluation can be particularly useful in helping explain why a trial found no significant effect, helping to differentiate between poor implementation, contextual barriers, and conceptual failure [44-46]. We also sought to understand the role played by external events and broader trends occurring in Zimbabwe over the course of the trial.

Methods

Intervention

The SAPPH-IRe trial's intervention built on an existing sexual and reproductive health programme for FSW in Zimbabwe, *Sisters with a Voice* (Sisters). It was designed to lead to the primary study outcomes by improving the supply of HIV services for FSW, increasing demand for these services, and supporting adherence to them. On the supply side, SAPPH-IRe added on-site initiation and ongoing provision of ART to the targeted programme (instead of referral to government clinics) and made PrEP available to women who tested HIV negative. To increase demand, SAPPH-IRe recruited, trained and deployed additional peer educators to conduct outreach, increased frequency of participatory community mobilization sessions from monthly to weekly, and added topics specific to PrEP, ART and adherence, which were delivered by a specially trained nurse who circulated between sites. Women were offered adherence support through SMS appointment reminders, phone calls to those who missed appointments, and the opportunity to enrol in "Adherence Sisters," a "buddy system" in which paired FSW on ART or PrEP received adherence training together. Women who tested HIV negative in intervention sites and who declined to start PrEP were offered participation in a six-monthly repeat testing programme, also using SMS reminders. These services were run at 'Sisters' outreach sites, which were open for one weekday each week (increased from one weekday per fortnight).

The SAPPH-IRe package emphasised peer support and a cohesive social environment to increase sex workers' rates of HIV testing, initiating, and adhering to treatment [47, 48]. Evidence that peer-led adherence support can reduce loss-to-follow-up informed development of the "Adherence Sisters programme" for women on ART or PrEP [49]. The importance of "sex worker friendly" clinics and non-judgmental attitudes among providers in bolstering FSW service use underpinned on-site provision of ART and PrEP so that FSW could complete the entire care cascade in a "one-stop shop" [6, 5, 50, 10]. The efficacy of PrEP and treatment are well established in clinical trials [51, 36]. We therefore hypothesised that these efforts would (1) increase FSWs' perceptions of HIV service quality and acceptability, leading to higher rates of HIV testing; (2) facilitate their access to and uptake of ART and PrEP, and (3) create normative support for adherence within the FSW community.

In combination, these factors would increase the proportion of HIV positive FSW on treatment. We also hypothesised a small effect on the number of new infections. In planning the sample size for the trial, we considered plausible effects along the continuum of care [40]. We hypothesised a plausible reduction in the proportion of FSW with transmissible levels of HIV of 13 percentage points, from 41% in the control arm to 28% in the intervention arm, with 80% power given our trial design [40]. In fact, a greater reduction than this was seen in both trial arms.

Process Evaluation

Figure 1 presents the SAPPH-IRe evaluation framework, including outcome measures. Process evaluation tools comprised programme checklists and monitoring forms, client records, qualitative interviews with 36 participants, and data extracted from respondent driven sampling (RDS) surveys. Checklists recorded whether implementation activities were conducted on time in each intervention site, including hiring and training peer education workers. Monitoring forms documented numbers of FSW participating and topics addressed for each activity (e.g. Adherence Sisters or Community Mobilization sessions) and included a "project diary" into which unexpected or external events that might affect the intervention were entered. Client records were analysed to assess patient characteristics, and number and frequency of clinic visits, including uptake of testing, enrolment in PrEP or ART, and follow-up. FSW in both intervention and comparison sites were selected for semi-structured interview to reflect diversity in eligibility and use of different services. Finally, data extracted from RDS surveys assessed population-level coverage of activities and services and measured constructs from the Theory of Change such as FSW social networks and peer support for prevention and treatment, using an adapted cluster-summary approach to estimate risk differences in these mediating factors between trial arms, comparing adjusted and unadjusted means of RDS-II weighted site-specific proportions of the binary outcomes in each arm [40].

Figure 1 here

Ethical approval was obtained from the Medical Research Council of Zimbabwe, University College London, London School of Hygiene and Tropical Medicine and RTI International. Interview and survey respondents provided informed consent prior to data collection. A separate consent form was signed by women initiating PrEP.

Results

In keeping with guidance on process evaluations for complex interventions [52], we describe implementation of the SAPPH-IRe intervention compared to its intended design to present feasibility of delivery and overall fidelity, followed by evidence of its acceptability to FSW. We then consider changes occurring in Zimbabwe's health policy and social context over the trial period, and how all these factors may have interacted with SAPPH-IRe to produce a null result.

Implementation Feasibility and Fidelity

Programme activities started on schedule in April 2014, with government approval for provision of ART and PrEP finalized by July 2014 in 6 out of the 7 intervention sites. Forty peer educators were recruited, trained, and deployed from April 2014 to inform sex workers about services, promote HIV testing and uptake of both ART and PrEP, and lead weekly participatory group sessions. This was fewer than the number initially planned due to funders' concerns that hiring a larger number of peer

educators could prove unsustainable in the long term. Intervention clinic nurses received training in PrEP and a specialist HIV care nurse visited each clinic every other week to conduct the "Adherence Sisters" programme, in which paired sex workers on either ART or PrEP supported each other's adherence and retention.

Over the two years of the trial there were occasional interruptions to the 'Sisters' programme, illustrated in Figure 2 for two of the project sites. In Site 1 activities were implemented as planned and uptake of all intervention components higher throughout the trial, with the exception of during the Christmas period, in January 2015 when there were stock-outs of common STI drugs so they could not be provided without prescription charge, in April 2015 when call reminders reduced, or near the end of the trial when FSW were concerned about ART supply and more likely to initiate treatment elsewhere. The service uptake pattern seen in Site 1 was reflected to some degree across all 7 sites. Local authorities in Site 2were reluctant to authorise on-site ART and PrEP, resulting in a 4-month delay in initiating activities except community mobilization. Also in this site, complaints about two nurses "being rough" temporarily reduced one clinic's attendance in early 2015, but this was resolved in March by a public meeting between 'Sisters' staff and local sex workers, including a formal apology from the nurses involved. Figure 2 clearly demonstrates a concomitant increase following resolution of conflict.

Figure 2 here

In two other sites (not depicted), location of the 'Sisters' clinic, which was determined in consultation with stakeholders including local sex workers and constrained by the location of public health services, discouraged attendance at first, in one case because it was considered far out of town, and in the other within view of a public bus station so sex workers feared being identified by community members. 'Sisters' clinics are co-located with existing public health facilities, and as these two sites were the only locally available options, the programme worked to increase their acceptability over time rather than move them. Other temporary disruptions included police raids on sex work establishments in two sites in 2014, during which sex workers stopped attending services and could not be easily located by peer educators.

Acceptability of the intervention

Higher levels of contact with local sex workers in SAPPH-IRe intervention sites compared to control sites suggests the enhanced package was acceptable to its intended audience. In intervention sites, there were 17,013 contacts between sex workers and peer educators compared to 13,151 in control sites. Similarly, intervention clinics saw 4619 sex workers in 13,254 visits during the trial compared to 3612 sex workers in 10,026 visits. New clients accounted for a higher proportion of visits in intervention sites (88.4% vs. 76.2%). Intervention clinics performed more than twice as many HIV tests than control site clinics (2606 vs. 1151) and nearly double the number of women were diagnosed with HIV (1,052 vs 546). Community mobilization meetings in intervention sites also attracted higher numbers (16,884 attendances vs. 2344), partly due to the increase in frequency of sessions from monthly to weekly and introduction of new topics. A total of 537 community meetings were held in intervention sites and 145 in control areas. Notably, the average number of participants per session was 35 sex workers in intervention sites compared to 19 in control sites.

In both intervention and control sites FSW valued having "their own" targeted clinic, with non-judgmental and understanding staff, and free services.

> *When I came, I realized that they [services] were free. When you come, you tell them how you are feeling and she [nurse] will respond to you in a soft voice and not be harsh, and she will ask you if there is anywhere else that hurts. … You will find no reason why you should hide things from her. That is why we are comfortable coming here. (FSW #8, intervention site)*

> *I come and am treated for free. Here I am free to say everything that is painful to aunty [clinic nurse] because she is also free spirited … they encourage us and they love us …. (FSW #14, control site)*

This was borne out at community level measures of programme coverage. The endline RDS survey found that 'Sisters' services reached an extremely high proportion of local sex workers in all locations, with 82.4% reporting contact with the enhanced programme and 80.7% with usual care services.

Offering on-site ART and PrEP resulted in 768 and 500 initiations respectively, and 487 support pairs enrolled in the "Adherence Sisters" programme in intervention sites. ART was provided on-site by Population Services International (PSI) Zimbabwe, and FSW already on ART through government services could transfer their treatment to the 'Sisters' clinic, if they wished. This option was rarely taken up because the duration of the trial was perceived short and women knew they would need to transfer their care back to the public sector after the trial. All 1052 diagnosed with HIV by 'Sisters', plus some FSW already diagnosed but not yet on ART, were referred for ART initation through PSI (n=1100) with 768 (70%) initiating treatment on-site. Overall retention in treatment at April 2016 was 82% (with 150 lost to follow up, 4 deaths and 48 transferring to other treatment facilities). We had hoped to be able to support ART with regular viral load monitoring, but this was not introduced due to the logistical and financial difficulties of transporting appropriately processed blood samples over long distances. We were therefore unable to assess adherence to ART and tailor our support and counselling to FSW in greatest need.

On-site provision of ART was attractive to FSW, as it relieved them from spending additional time and potentially confronting stigmatizing attitudes at other clinics:

> *…when you go to the general clinic, you do not get all the medication that you want, but when we come here we can get all the medication plus they will treat you for any ailment, no matter what you are feeling they will treat you. But if you go to the general clinic with your dollar the service you get there will not satisfy you (FSW #12, intervention site)*

This contrasted with concerns expressed by sex workers in control sites, where women testing HIV-positive were referred from the 'Sisters' clinic to other health services for ART. Women worried this would disclose their HIV status to others:

> *… we were asking to be given the pills here ['Sisters' clinic] rather than go and queue again there. … That's how we should be given ARVs so that people don't see us when we are in the queue. … That if a person is tested and comes out positive, everything that is supposed to be done should be done here and not go public (FSW #15, control site)*

On the other hand, there was some evidence that the context of a randomized controlled trial itself affected service uptake. Several sex workers described anxiety over possible interruption in their ART care at the end of the trial, when they would need to re-register elsewhere.

> *I was taking the [ART] tablets from the hospital and then I changed to the Sister's clinic. It will change, what is going to happen after that? Where will we go when you have left this place and we have transferred? Are they going to agree that we transfer back to the hospital? (FSW #5, intervention site)*

Uptake of PrEP was initially slower than expected, apparently due to the waiting time between HIV testing and receiving PrEP as well as fears of severe side effects listed on the lengthy information sheet read out during counselling and then given to FSW to read again before the next enrolment visit. The information sheet was simplified in April 2015 to bring it in line with those used in other demonstration projects [53, 54] following increasing evidence on the safety and efficacy of PrEP in women [55]. WHO guidelines for PrEP were amended in July 2015 as a result of this accumulated evidence on safety and effectiveness in all populations [56].

Out of 1302 sex workers eligible for PrEP, 500 registered to take it and 405 returned for at least one follow-up appointment. On average, FSW attended 2-3 eligibility screening appointments over two weeks from PrEP registration to initiation, which several women complained about in qualitative interviews:

> *I thought that when I came, they would just give me the tablets. … They started by testing us and a lot of other things, and they said that I would get the tablets the coming week … The next week, last week I did not manage to come, so that is why I thought that I should come this week per chance I can get the tablets. … Ah it's a boring feeling because I had thought that they will give me the tablets when I come (FSW#20, intervention site)*

Fear of severe side effects and circulating rumours that PrEP was being introduced to kill off sex workers were further as barriers to uptake:

> *There is a paper about Truvada that they gave us to read, and it says that there are things that can happen to me, so I asked if it will happen as soon as I start taking it? … Yes, there are things that I was scared of … having diarrhea, vomiting and feeling weak. … When I saw it written, I was scared at first and thought that I could not accept that. (FSW#33, intervention site)*

> *We thought that this is the tablet that has come to kill us, because they are saying that there are too many sex workers now. Yes, it is an issue that we were discussing in the bar and we were asking each other, 'what kind of tablet is this that they want to give us? … Maybe they want us to die'. (SW#18, intervention site)*

We adapted PrEP activities to address these concerns, adding refresher training for all clinic staff, revising the PrEP information sheet to emphasise the extreme rarity of adverse effects, and engaged early adopters as PrEP advocates. Advocates were sex workers who were successfully taking PrEP and were willing to share their experiences and offer encouragement to others, usually travelling to other sites to maintain privacy in their home communities.

Sending automated SMS reminders to sex workers in advance of scheduled appointments or as part of the 6-monthly repeat testing programme proved difficult to monitor. A total of 16,759 SMS messages were sent but we were unable to establish whether women received messages intended for them, and thus could not determine whether this activity had any effect on retention in care. Furthermore, attempts to make follow-up calls to women who missed appointments demonstrated that sex workers did not always provide accurate contact details, and many routinely changed mobile phone numbers. At least once, funding for the reminder calls ran short (see Figure 2).

The evolving Zimbabwean context

The SAPPH-IRe intervention was introduced at a time of rapid HIV testing and ART scale-up across Zimbabwe. For example, the percentage of all adults aged 15-49 who tested for HIV in the past 12 months increased across consecutive DHS surveys from 7% in 2005/6 to 34% in 2010/11 and 49% in 2015/6 [57]. The Zimbabwe Population Based HIV Impact Assessment (ZIMPHIA) study found that a large majority (74.2%) of adults living with HIV knew their status in 2015/6 and 86.8% of these self-reported being on treatment [58]. This was reflected also in RDS surveys conducted for this evaluation. Despite on site initiation of ART being offered only in SAPPH-IRe sites, at endline, among sex workers reporting they were HIV-positive, 86.7% were taking ART in intervention and 83.1% in control sites.

Over the course of the trial, HIV-related stigma and discrimination were decreasing in Zimbabwe. Sex workers living with HIV feel stigmatized more for being sex workers than for being HIV-positive [59]. At baseline, 2.3% sex workers living with HIV reported perceiving discrimination by health providers due to their HIV status and 0.6% at endline, while 5.0 % and 3.5% of all surveyed FSW reported experiencing health service discrimination because they were sex workers at the same time points. The 2014 Zimbabwe Stigma Index [60] found similarly low levels of stigma; of 1905 people living with HIV surveyed across the country, 6.3% reported having been denied health services due to their HIV status in the past 12 months.

We also observed changes in policing practice toward sex workers in Zimbabwe [61]. A 2016 court order led to reductions in sex workers' reported experience of arrest and police harassment, which appeared to bolster their willingness to engage with public services. Sex workers in both arms felt they could rely on each other in cases of trouble at work and felt comfortable talking to each other about health and other issues. For example, over 90% of FSW agreed with the following statements: "My colleagues will help me if they see a client becoming aggressive or violent", "I feel comfortable talking to other sex workers about work issues," and "I feel comfortable talking to other sex workers about health-related issues." A similarly high proportion (88%) agreed that "sex workers can improve their working conditions by working together" regardless of exposure to the intervention.

Discussion

During the SAPPH-IRe trial, most components of the enhanced intervention proved feasible to deliver as planned and were implemented with good fidelity. Some aspects took time to engage clients (PrEP implementation), remained undelivered (routine viral load monitoring), or were delivered with lower intensity than intended (ratio of peer educators to sex workers). We saw greater uptake of services in intervention sites as hypothesised, including a higher proportion of new clients, double the number of new HIV infections diagnosed, and larger numbers of participants

attending community mobilization sessions. These data suggest acceptability of the enhanced sex worker programme, as do testimonies of FSW interviewed about their perceptions of the clinics and its activities.

We found high levels of engagement with services and large improvements in access to HIV testing and levels of HIV viral suppression among women in both arms over the course of the trial. Despite increased supply of sex-worker friendly services and improved demand for these, we did not find that the intervention significantly reduced the proportion of all sex workers with an unsuppressed HIV viral load when compared with the standard of care arm. There are several possible explanations for this, suggesting both potential weaknesses in our conceptual framework and unanticipated effects of broader contextual changes.

We hypothesised that increasing the supply of targeted HIV care services for FSW through on-site provision of ART and PrEP, combined with intensified demand-stimulation activities consisting of more frequent community mobilization sessions, peer outreach, and phone-based reminders, would lead to greater uptake of HIV services and increased community support for retention in care. In turn, this would result in significantly larger proportions of FSW who knew their status, took ART or PrEP, and had a viral load ≥1000 copies/ml in intervention sites. In fact, the proportion of FSW with HIV viral load ≥1000 copies/ml improved in both arms of the trial, and above that found in the general population of HIV positive adult women found in ZIMPHIA (63.7%).

One explanation for this is that on-site provision of both PrEP and ART did not add significantly to the appeal of the 'Sisters' clinics over their already well-respected "friendliness" and non-judgmental approach to treating FSW. *Sisters with a Voice* has provided clinical and social services to FSW in public health facilities across Zimbabwe since 2009. In the trial, both enhanced and usual care arms provided outreach, peer educators, and a welcoming and non-judgmental atmosphere. In 2014, outreach services to FSW were intensified across the programme and programme targets for numbers seen, engaged, tested and referred (including in control sites) were increased concomitantly. The number of clinic visits in the 'Sisters' programme as a whole (all 36 sites) increased from 10,960 in 2013 to 35,746 in 2016. FSW across sites described their appreciation for the 'Sisters' approach, believing it increased their confidence and motivation to improve health-seeking behaviour. It is possible that community mobilization activities in all clinics strengthened FSW self-efficacy to attend HIV services, as has been found in other targeted services with a community mobilization component [62, 27]. While intervention sites did enhance peer outreach and participatory sessions, it may be that the very introduction of targeted FSW services and peer engagement was enough to stimulate uptake of HIV testing and treatment.

It is also the case, however, that services for sex workers increased significantly across the country more broadly, as testing FSW and referring them to treatment became a national HIV policy priority. While in control sites FSW received ART through Ministry of Health staff, rather than specially trained 'Sisters' nurses, there was anecdotal evidence that nurses working alongside sex worker friendly services became less judgmental over time. In addition to increasing FSW-specific services, Zimbabwe was scaling up general HIV testing and treatment during this time, e.g. introducing Option B+ for pregnant women, which improved ART acceptability and coverage across the country, including among sex workers. Furthermore, a measurable reduction in both HIV stigma and police targeting of FSW also point to an increasingly enabling environment for FSW engagement with HIV

care. This is commensurate with the literature on pervasive stigma and criminalization of sex work as barriers to FSWs' health and well-being [63, 8, 64, 65].

We also note that some aspects of the intervention were not fully delivered, or experienced slower uptake than initially hoped. Viral load monitoring would have been an important improvement, although it is striking that levels of viral suppression improved steeply in both arms beyond that hypothesized in our sample size calculations [40]. Although beyond the remit of this paper, it is worth also noting that selection bias in the recruitment of samples of women in the two arms was also a potential explanation we have considered for our findings. Although respondent driven sampling is a complex process with the potential to recruit biased and hard to characterize samples of women, our pre-specified investigations into these biases, and especially into differences between the arms, revealed little evidence of this.

Conclusion

Our process evaluation complements the outcome results of the SAPPH-IRe trial. Interventions to improve service access, and especially to reduce the rate of new infections, among sex workers are still desperately needed in Zimbabwe and sub-Saharan Africa. 'Sisters' is a rare example in the region of a programme with national reach delivering high quality outreach services for sex workers. Recent years have seen both a strengthening of national HIV testing and treatment efforts, as well as strengthening and intensification of this dedicated programme for sex workers. It seems most likely that in this context, our efforts to improve treatment access and adherence in the SAPPH-IRe intervention arm did not sufficiently generate differences between the arms of the trial to have an additional effect beyond the underlying changes going on in the country over the same period. Sustained efforts to maintain progress in HIV testing and treatment, and more focused efforts including with PrEP to prevent new infections remain critical.

Figure titles

Figure 1: SAPPHIRE Process Evaluation Framework

Figure 2: Implementation timeline in 2 intervention sites of the SAPPH-IRe trial

List of Abbreviations

ART: Antiretroviral therapy

FSW: Female sex worker

PrEP: Pre-exposure prophylaxis

SAPPH-Ire: Sisters' Antiretroviral therapy Programme for Prevention of HIV: an Integrated Response (trial)

Declarations

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Implementation of Intervention		**Coverage & Quality**	**Behaviour Change**

Inputs/ Preparation	**Activities**	**Programme Delivery**	**1. Enabling Environment**

Inputs/ Preparation

1. Partnership with relevant partner agencies established (UNFPA, MoH, PSI, Gilead)

2. New staff/ peer educators recruited, trained and deployed

3. Clinic sites upgraded for enhanced intervention

4. Referral mechanisms put into place

5. CM activity protocols and tools introduced

6. Outreach activities to inform & recruit sex workers

Activities

DEMAND CREATION

1. Enhanced Community Mobilisation

2. Promotion of Repeat HIV Testing

STRENGTHENING SUPPLY

3. On-site delivery of ARV at international guidelines

4. Offer of PrEP

5. Enhanced support for treatment & PrEP

Programme Delivery
- Number of CM/adherence meetings
- Numbers of SMS messages sent
- Numbers of SW attending meetings
- Numbers of SW trained in adherence support

Quality of Activities
- Frequency of attendance by SW
- SW contact with peer educators
- Drugs & info available w/out stock out
- Knowledge & awareness of testing, PrEP & ART increased

Acceptability of Intervention
Staff Perceptions
- Positive & negative experiences
- Programme strengths & weaknesses
SW Perceptions
- Positive & negative experiences
- Likes & dislikes in content & delivery
- Views of CM and peer support

1. Enabling Environment
- Strengthened supportive social networks between SW
- Increased leadership capacity w/in SW community
- Peer norms encouraging repeat testing, treatment/PrEP initiation & adherence

2. Sustained health behaviour
- SW know their HIV status
- Adherence to PrEP & ARV
- Regular attendance at follow-up clinical appointments
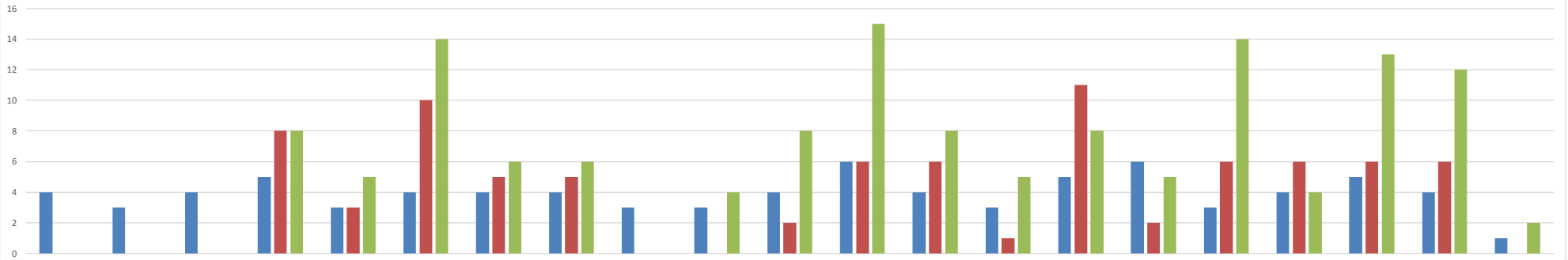- Increased condom use

Data Collection Tools

1. *Checklist of planned activities, with dates*
2. *Staff records*: **%** of staff hired in 2013 still in place each year;
3. *Trainings.* **#** conducted and **%** staff attending
4. *Programme records:* **#** CM activities designed; **#** sensitisation meetings to inform SW

1. *Programme records*: frequency of clinic openings; average waiting time from eligibility to treatment initiation
2. *Peer educator forms*: **#** active peer educators; **#** SW reached through peer educators
3. *CM and Adherence Sister meeting reports*: **#** participants, topics.
4. *SW "adherence sisters" records*: **#** pairs identified and participate in workshops; **%** remain active in programme over time

1. *RDS surveys*: knowledge & awareness; **%** SW covered by activities; frequency
2. *Programme records*: analysis of clinic records, stock-outs; SMS messages
3. *Semi-structured interviews with staff*
4. *In-depth interviews with FSW.*
5. *Interviews w/ other stakeholders* i.e. referral organisations & PSI staff at end of intervention

1. *RDS surveys:* levels of social support & peer norms; **%** SW community knowing status; condom use rates; service uptake
2. *In-depth interviews with SW in both intervention & control sites:* Community cohesion, social networks, perception of norms, support & leadership
3. *Programme records:* Clinic records on attendance and prescription re-fills

Diminishing control over the process by the intervention – *Project Diary to record external events affecting implementation*

Site 1

Site 2

Apr-14 May-14 Jun-14 Jul-14 Aug-14 Sep-14 Oct-14 Nov-14 Dec-14 Jan-15 Feb-15 Mar-15 Apr-15 May-15 Jun-15 Jul-15 Aug-15 Sep-15 Oct-15 Nov-15 Dec-15

■ # of CMM   ■ ART Init   ■ PREP Init

ART on site services started at 6 of 7 sites

ART and PrEP on site services began in site 1

Delay in annual donor funding disbursement. No STI drugs at Sisters Clinics.

In Site 1, following reports of 2 nurses being "rough", a meeting was held to resolve conflict with the community

Had overspent funding for phone follow up adherence support. Calls stopped for clinets who had defaulted a visit.

Police have stopped arresting sex workers for soliciting for sex and loitering as a result of the court rulling passed in May