

Welcome

Welcome to the second STAR Research newsletter from the UNITAID/PSI HIV Self-Testing Africa (STAR) Project - a four-year initiative to catalyse the market for HIV self-testing.

The last quarter of 2016 has seen much progress from across STAR countries- Malawi, Zambia and Zimbabwe- and beyond.

Collection of baseline data has been completed in Malawi and Zambia, and descriptive analysis of baseline data from the Malawi and Zambia cluster randomised controlled trials (cRCTs) was begun. Also in Malawi, key population formative research and cognitive interviews were completed by the end of the year. In Zambia, Clinical Performance Study recruitment continued, recruitment and training of survey enumerators for the cRCT continued, and data collection for the discrete choice experiments and baseline efficiency analysis was completed. In Zimbabwe, qualitative data collection, transcription and translations are ongoing, as is the collection of costing data for all models.

Members of the STAR team supported various events at the African Society for Laboratory Medicine, on the regulation of HIV self-testing. The STAR consortium was active in the run up to World AIDS Day, with research partners both providing and amplifying tweets. Also in advance of World AIDS Day, WHO released new guidelines on HIV self-testing and an explanatory [video](#).

Read on for more information on selected STAR activities, and also visit the [STAR Research website](#) and follow us on Twitter @HIVSTAR_LSHTM.

Liz Corbett and Cath Beaumont



STAR's Quantitative Research Network implementers and researchers

Inside...

- ◆ Progress from year one of STAR
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2016

WORLD AIDS DAY

This World AIDS Day, we celebrate the launch of the World Health Organization's guidelines on HIV self-testing (HIVST). This is a critical step toward expanding HIV testing and achieving the United Nation's bold 90-90-90 targets for ending the HIV epidemic. As the world's largest evaluation of HIV self-testing, the UNITAID/PSI HIV Self-Testing Africa (STAR) Project is proud to have contributed important evidence to these guidelines and to have raised the profile of HIVST in Africa.

A year ago today, we launched the STAR Project. Today, we look back at our progress toward making HIV self-testing a reality for millions of people in Africa.



3 STAR COUNTRIES

distributing HIV self-tests through community and facility based distribution models.

31% OF SELF-TESTERS

in Malawi have never before been tested for HIV.



125,483 TESTS KITS

distributed as of November 2016.

2.4 TO 3.2 MILLION

estimated number of self-tests needed in STAR countries in 2020.

602 COMMUNITY-BASED DISTRIBUTORS

trained to distribute HIV self-test kits in STAR countries as of October 2016.



50%

of the people taking up HIV self-testing are men.



15-24

year olds have the highest uptake of HIVST in STAR countries.

2 HIVST KIT MANUFACTURERS with an active application for WHO pre-qualification.



3/3

STAR countries now have supportive national health policies on HIVST.

9 of 23

countries with national policies supportive of HIVST are in Africa.

The STAR Project looks forward to continuing to advance the adoption of HIV self-testing and to ensuring that the launch of the WHO guidelines is just the start of a movement to make HIVST a global reality.

Infographic produced by PSI



WHO issues new guidance on HIV self-testing ahead of World AIDS Day



Extracts from news release

29 November 2016 / GENEVA - In advance of World AIDS Day, WHO has released new guidelines on HIV self-testing to improve access to and uptake of HIV diagnosis.

According to a new WHO progress report lack of an HIV diagnosis is a major obstacle to implementing the Organization's recommendation that everyone with HIV should be offered antiretroviral therapy (ART).

The report reveals that more than 18 million people with HIV are currently taking ART, and a similar number is still unable to access treatment, the majority of which are unaware of their HIV positive status. Today, 40% of all people with HIV (over 14 million) remain unaware of their status. Many of these are people at higher risk of HIV infection who often find it difficult to access existing testing services.

HIV self-testing means people can use oral fluid or blood- finger-pricks to discover their status in a private and convenient setting. Results are ready within 20 minutes or less. Those with positive results are advised to seek confirmatory tests at health clinics. WHO recommends they receive information and links to counselling as well as rapid referral to prevention, treatment and care services.

HIV self-testing is a way to reach more people with undiagnosed HIV and represents a step forward to empower individuals, diagnose people earlier before they become sick, bring services closer to where people live, and create demand for HIV testing. This is particularly important for those people facing barriers to accessing existing services.

Who misses out on HIV testing?

HIV testing coverage remains low among various population groups. For example, global coverage rates for all HIV testing, prevention, and treatment are lower among men than women, and men account for only 30% of people who have tested

But some women miss out too. Adolescent girls and young women in East and Southern Africa experience infection rates up to eight times higher than among their male peers. Fewer than one in every five girls (15–19 years of age) are aware of their HIV status.

Testing also remains low among "key populations" and their partners - particularly men who have sex with men, sex workers, transgender people, people who inject drugs, and people in prisons - who comprise approximately 44% of the 1.9 million new adult HIV infections that occur each year.

Up to 70 % of partners of people with HIV are also HIV positive. Many of those partners are not currently getting tested. The new WHO guidelines recommend ways to help HIV positive people notify their partners about their status, and also encourage them to get tested.

Self-testing has been shown to nearly double the frequency of HIV testing among men who have sex with men, and recent studies in Kenya found that male partners of pregnant women had twice the uptake of HIV testing when offered self-testing compared with standard testing.

Twenty three countries currently have national policies that support HIV self-testing. Many other countries are developing policies, but wide-scale implementation of HIV self-testing remains limited. WHO supports free distribution of HIV self-test kits and other approaches that allow self-test kits to be bought at affordable prices. WHO is also working to reduce costs further to increase access. The new guidance aims to help countries scale up implementation.

WHO is supporting three countries in southern Africa which have started large scale implementation of self-testing through the UNITAID-funded STAR project and many more countries are considering this innovative approach to reaching those who are being left behind.

For more information contact:

Tunga Namjilsuren
WHO Department of HIV,
Global Hepatitis Programme
Email: namjilsurent@who.int

Overview of STAR project activities at the African Society for Laboratory Medicine (ASLM) Conference in Cape Town, 3rd to 9th December 2016

By Professor Rosanna Peeling, LSHTM, and Russell Dacombe, LSTM

This conference represented a unique opportunity to share the preliminary findings from the STAR regulatory research with a wider audience and work with key partners to promote the importance of the regulation of HIV self-tests.

STAR supported a number of events at the conference.

A forum of the Pan African Harmonisation Working Party (PAHWP) was held to discuss strategies for moving the group forward. PAHWP was launched in 2012 with a vision that valuable, quality assured, safe medical devices and diagnostics are made available where needed in Africa. Since its inception, PAHWP has convened a series of regulatory forums to provide a neutral platform whereby representatives from the ASLM, industry and public health programmes could explore collaborative mechanisms to accelerate test evaluation, regulatory review and approval, and post-market surveillance and harmonize medical devices and diagnostics regulation in Africa.

The objectives of the 2016 forum were to provide an update on activities of PAHWP and of diagnostic alliances from other regions, and to explore mechanisms for collaboration to accelerate test evaluation, regulatory review and approval among interested stakeholders. The forum was co-chaired by Agnes Kijo from the Tanzania FDA and Chair of PAHWP, and Patience Dabula from NHLS, South Africa, Secretariat PAHWP. Speakers included members of the Global Diagnostic Alliance, Duncan Blair from Alere, USA, Carlos Gouvea, head of the Latin American Alliance for in vitro

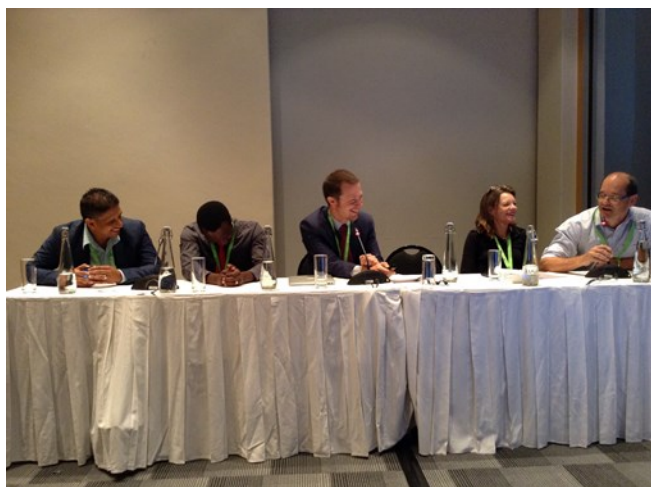


STAR regulatory workshop participants and facilitators

Diagnostics (ALADDIV) and Koshiha Michikatsu of Mitsubishi UFJ Research Consulting (MURC), Japan representing more than 40 members of the Access to Health Initiative around the world, Farouk Umaru from the U.S. Pharmacopeial Convention and Russell Dacombe from LSTM who spoke on behalf of the STAR project and its needs for regulatory capacity building.

A workshop to build capacity on regulatory science was held as part of the forum. The objective of the workshop was to understand how to assess risks and benefits in reviewing the performance and potential impact of diagnostic tests, using HIV self-tests as an example. Over 90 participants attended the event.

STAR co-hosted a symposium on the “Regulation of HIVST in Africa: Requirements, Readiness and Response,” with the University of Witwatersrand (WITS). This session was chaired by Francois Venter from WITS and included a presentation by Robyn Meurant from the World Health Organization’s Pre-Qualification of Diagnostics group on their assessment criteria for pre-qualification of HIVST. STAR’s Russell Dacombe gave a presentation on Developing Regulatory Pathways for HIVST. There were also country presentations on the readiness for HIVST regulation given by Washington Samukange from Zimbabwe and Mohammed Majam from South Africa.



Panel members at the “Regulation of HIVST in Africa: Requirements, Readiness and Response” symposium

Russell Dacombe presented a poster entitled, “Policy and regulatory environments for HIV self-testing in Malawi, Zimbabwe and Zambia,” as part of an oral poster presentation session.

STAR also funded the attendance of senior regulators, policymakers and laboratory staff from the three STAR countries. As well as enabling them to benefit from the numerous sessions on regulation at the conference, STAR also brought them together for a one day workshop, delivered by Russell Dacombe, Victoria Watson and Elliot Cowan, to help countries plan for the regulation of HIVST, to learn from their respective experiences to date, and to help foster positive working relationships between countries and between disciplines within countries.

Qualitative Research Network – The power of bringing STAR countries’ researchers and implementers together

Miriam Mutseta, STAR Programme Manager, PSI Zimbabwe

Collaborating on the curriculum for healthcare workers on HIV self-testing

For me, the Qualitative Research Network (QRN) is all about working across the groups in STAR – researchers, implementers and marketers. Last month we met in Lusaka for two days from 30th September to 1st October. People from research and implementation were there, including people attending a face to face QRN meeting for the first time. It was good and welcoming to all. At the meeting we were able to hear updates on the stages of our research and the research gaps, especially in implementation. We hope to meet more often to ensure the researchers and implementers continue talking.

It was great to get feedback on the curriculum. Compared to the last meeting I felt I got better feedback and it was useful to hear how the researchers had views based on their experiences interviewing the healthcare workers. We came up with a product that we were able to discuss with WHO so it felt good to be moving that along. It was also important to hear how the technical working groups (TWGs) for HIV self-testing are doing at national level. I am part of the Zimbabwe TWG. Some countries were lagging behind and in the gaps identified we didn’t realise in our context, in Zimbabwe, we did not have regulators in the true sense of regulators at the TWG meetings.

We also had a surprise visit from a Zimbabwean parliamentarian in the TB committee (Hon. Dr Ruth Labode who is the Chairperson, parliamentary portfolio committee on health and childcare). She popped in because she had been a student in Liverpool. She was so lively and maybe she can even help us.

Benefits of working together

The updates from research make it easier for me to understand our implementation and how research feeds into it. We get a lot of questions in implementation that we may not initially have answers to, and other situations that we are faced with during implementation where we end up theorising but don’t go into deeper. Having the research by our side means we can flag issues. It works the other way around too. The meeting between the two groups will actually help us to correct things as we go and also see what is working well that we can carry on doing.

For me as the Chairperson of the curriculum development sub group in STAR, it directs me to the gaps that we can address in training, e.g. healthcare workers lacking knowledge in HIV self-testing was raised by researchers, then in the field people were raising the same so we realised it is an area we as implementers need to address as a matter of urgency or the programme will not succeed. We can separate issues. Some can be flagged to marketing, who are also part of the QRN and who can come up with strategies. Researchers can take long to produce results and some papers I may miss in the busyness of things, so it is helpful to have this mechanism for giving continuous feedback.



STAR's Quantitative Research Network implementers and researchers

A message for my colleagues in research

One thing I would like the researchers to delve into more, which I raised in the meeting, is the issue of 'compassionate forced testing' and family dynamics in self-testing. This is a different space from where we were in Provider Delivered HIV Testing Services. We have had to redefine terminologies because we are now dealing with family issues, like involuntary disclosure of HIV status because testing is considered a family obligation. The head of the family takes the lead and expects everyone to follow suit, even in sharing results. At the end of the day, HIV has social and economic implications for the whole family but it brings dilemmas to people

like us who are used to a different setting, where people's rights were observed differently. As researchers are you classifying everything as social harm? Are these adverse events or benefits? Are these more our fears as providers than the fears of the family? Research could help us understand if HIV self-testing is strengthening to the good of the family or is actually causing harm. I am also worried about linkages. Are we ever going to be able to show that people are linking? We may not know how this will also work out once incentives are not there. Suppose it shows incentives work – what will we do with that information in the real world? It might just be a starting point of catalysing them and then things become normal and they link in the end.

Another striking thing was the similarities between the cultures of our three STAR countries – Malawi, Zambia and Zimbabwe. We have different economies and health systems, and different contexts but similar cultures and challenges that people face. We really have a lot in common. I am eagerly awaiting the next discussion session.

Coming Events: STAR

- ◆ STAR phase 2 planning meeting: 30th January to 1st February 2017, London.
- ◆ QERN meeting: 2nd to 3rd February 2017, London.
- ◆ QRN meeting: 6th to 10th February 2017, Liverpool.
- ◆ HIVST "Going to Scale" workshop: hosted by STAR: 29th to 31st March 2017, with a one and a half-day pre-meeting hosted by WHO to roll out the new WHO guidelines.

Coming Events: Other

- ◆ [Conference on Retroviruses and Opportunistic Infections](#): 13th to 16th February 2017, Seattle.
- ◆ [IAS Conference](#): 23rd to 26th July 2017, Paris.
- ◆ [International Health Economics Association Congress](#): 8th to 11th July 2017, Boston.

Blog Highlights from the [HIV STAR Research Website](#)

HIV STAR Research Studies in Zimbabwe

By Mary Tumushime, Research Coordinator at CeSHHAR



Kicking off the household survey on uptake of self-testing and post-test services in rural Zimbabwe

Population based survey

Equipped with lessons learned from the pilot study in Mazowe, HIV self-test kits are now being distributed more widely in selected rural communities in Zimbabwe. As before, a population-based household survey timed six weeks after programme implementation is ongoing and will move from district to district following the programme's cycle.

To date, the survey team has conducted data collection in Mberengwa, the first of the eight programme districts. Using Audio Computer Assisted Self Interview (ACASI) on computer tablets, data is being collected to determine the uptake of HIV self-testing and post-test

services, clients' experiences of self-testing and previous testing, as well as other key questions. Additionally, preference work on linkage to care after self-testing has also been done among nearly 500 survey participants, using pictorial discrete choice experiment (DCE) questionnaires. Having had to travel some difficult terrain and endure extreme heat, the team will have a change of pace as they head to Buhera district shortly, just ahead of the rainy season!

Qualitative research

What barriers or facilitators do clients face in linking to HIV treatment or prevention services? Now that three months have passed since distribution in Mberengwa, our Social Science team will explore these issues via in-depth interviews with clients who have self-tested, healthcare workers and community-based distributors (CBDs). Stay tuned for updates!

Sex work distribution programme

What methods of HIV testing do female sex workers in Zimbabwe prefer? Leading on from formative research on accuracy, uptake and acceptability of self-testing, we are expanding the offer of self-testing alongside provider-delivered testing from the Sisters Clinic in Harare to five other sex worker-friendly clinics in Zimbabwe.

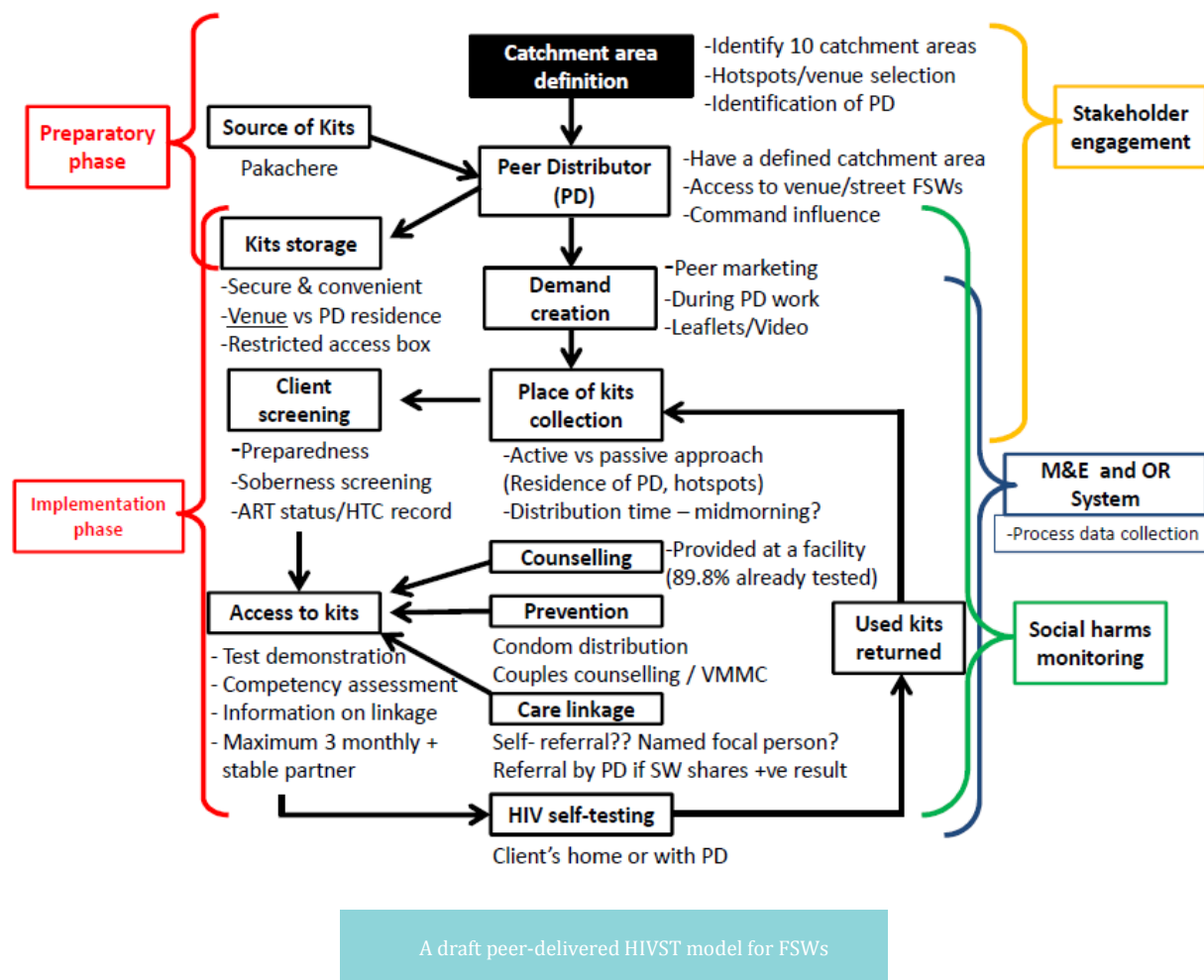
Clients opting for self-testing will have the chance to test on- or off-site. Telephone follow-ups of off-site testers are being done two weeks after kit collection, to determine whether and when they test themselves and link to care.



Self-testing is now being offered at this sex worker facility in Harare. Clinics in Bulawayo, Gweru, Karoi, Masvingo, Mutare to follow

Engaging key beneficiaries in intervention development - STAR-Malawi's participatory workshop with female sex workers

By Moses Kumwenda (Malawi-Liverpool Wellcome Trust)



As a key population, female sex workers (FSWs) require frequent repeat HIV testing. The nature of their work places them at increased risk of acquiring HIV and the stigma attached to this profession acts as a barrier to accessing healthcare services. Repeat HIV testing for FSWs through facility-based HIV testing and counselling (HTC) often fails to meet the specific testing needs of this underserved group, partly because of stigma and the lack of FSW-friendly HIV testing services within current government health services.

HIV self-testing as an innovative and revolutionary technology provides a unique opportunity to more effectively meet the testing needs of FSWs by acting as a screening tool for possible HIV infection. The Malawi-Liverpool Wellcome Trust's STAR team conducted a participatory workshop with FSWs and relevant stakeholders to refine a draft peer-delivered HIVST intervention that takes into account the needs of this specific target population.

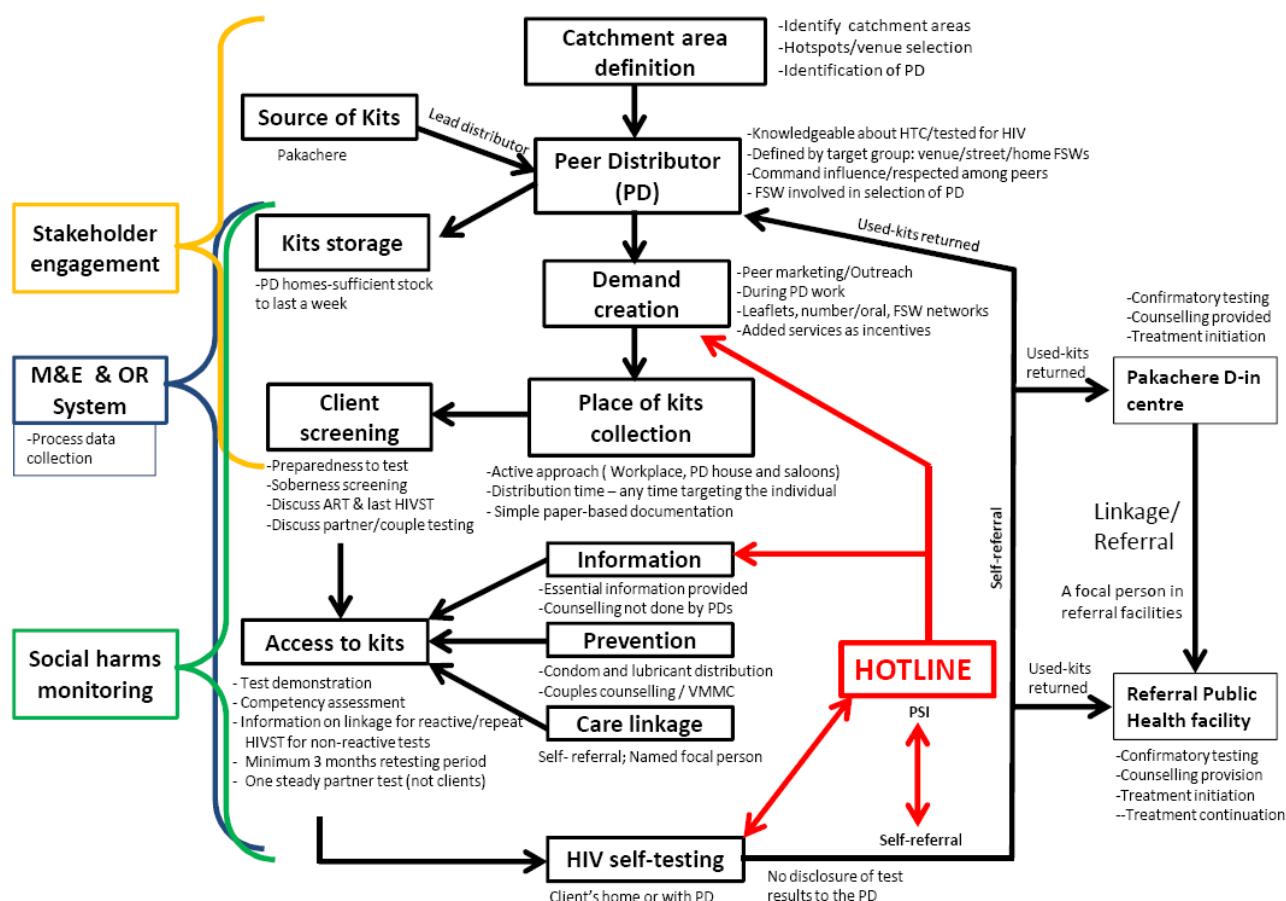
During the planning stage, a workshop manual was developed to guide each of the sessions, which included topics on delivery of HIVST kits, reporting of social harms and linkage to care. Fifteen FSWs and representatives from Pakachere (a sexual and reproductive health organisation that also focuses on key populations) and the Blantyre City Assembly (local government) attended the workshop. Mr Moses Kumwenda, Mr Kruger Kaswaswa, Mrs Basimenye Nhlema and Mr Mwiza Sambo facilitated the workshop while Mr Wakumanya Sibande and Miss Lusungu Kayira provided logistical support including note taking. In addition to the planned activities, Professor Liz Corbett and Cheryl Johnson led a session on social harms, where a series of case studies were ranked in order to generate a social harms grading system.

Workshop participants worked together in groups (see figure 3) to provide feedback on each aspect of the model. For example, participants preferred the use of participatory approaches to identify a peer-distributor who had a good reputation among peers. They also suggested that, given the often awkward dynamics between FSWs and bartenders, test kits should not be stored in hotspot bars but either at the peer-distributors' home, local pharmacies, nearby clinics/ health facilities or Pakachere drop-in centres.



Female sex workers in a group work activity

In terms of demand creation and distribution of the test kits, participants indicated that both peer-marketing and distribution of the kits should happen at the venues where sex work occur, a departure from what we had originally been envisioned in the draft model. In order to incentivise uptake, added interventions such as condoms and lubricants were said to be very important. This participatory workshop underlines the importance of involving key stakeholders in the development of HIVST models in order to tailor interventions to the specific needs of users



A refined peer-delivered HIVST model

Latest Publications from the HIV STAR Consortium

The following abstracts by STAR collaborators were accepted for the African Society for Laboratory Medicine, 3rd to 9th December 2016:

- Corbett EL, Indravudh P, Kumwenda M, Neuman M, Chisunkha B, Hatzold KC, Nkhoma C, Kalua T, Baggaley R, Taegtmeyer T. Introducing HIV self-testing to rural communities in Malawi: cognitive interviewing may alert implementers to the need for additional support beyond that provided by manufacturer's instructions-for-use (IFU)
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The following abstracts by STAR collaborators were accepted for CROI, 13th to 16th February 2017:

- Indravudh P, Kumwenda M, Neuman M, Chisunkha B, Hatzold H, Nkhoma C, Kalua T, Johnson C, Taegtmeyer M, Corbett L. [Providing user support for HIV self-testing beyond instructions-for-use in Malawi](#)
- Indravudh P, d'Elbee M, Kumwenda M, Choko A, Sakala D, Kalua T, Johnson C, Hatzold H, Corbett L, Terris-Prestholt F. [Informing HIV self-testing services in Malawi using Discrete Choice Experiments](#)
- Cambiano V, Johnson C, Figueroa C, Revill P, Baggaley R, Corbett EL, Apollo T, Hatzold K, Cowan F, Phillips A. [Cost-effectiveness of different delivery approaches for HIV self-testing](#)



Contact Us

London School of Hygiene & Tropical Medicine, Keppel Street, London, WC1E 7HT
Cath.Beaumont@lshtm.ac.uk +44 (0) 207 958 8235 www.hivstar@lshtm.ac.uk
Follow us on twitter @HIVSTAR_LSHTM

