



HIV STAR RESEARCH NEWS

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April to June 2016

Welcome

Welcome to the first 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 STAR project is currently in Phase One, in which we are conducting the world's largest evaluation of HIV self-testing to date, involving the distribution of nearly 750,000 self-test kits in Zambia, Zimbabwe and Malawi, and piloting HIV self-testing models among various populations.

This will generate vital information about how to distribute self-test products effectively, ethically and efficiently, with adequate post-test support services, and will answer key questions about the feasibility, acceptability and impact of this intervention. These results, and other emerging evidence, will inform WHO normative guidance, support the establishment of appropriate policy and encourage new manufacturers to enter the self-test market.

The STAR project is funded by [UNITAID](#) and is implemented by a consortium headed by [Population Services International](#) (PSI), in close collaboration with the World Health Organization. Research activities are designed and led by the [London School of Hygiene & Tropical Medicine, Liverpool School of Tropical Medicine](#), and [University College London](#). PSI leads the implementation of HIV self-test distribution in each country, including all marketing and demand creation activities, and in-country HIV self-testing research activities are led by local research institutions: [Malawi-Liverpool-Wellcome Trust Clinical Research Programme](#), [Zambart](#), and the [Centre for Sexual Health and HIV/AIDS Research Zimbabwe](#).

On behalf of the London School of Hygiene & Tropical Medicine and all of our partners, we would like to welcome you to our first newsletter, which brings you recent STAR research highlights and more.

Liz Corbett and Cath Beaumont



Professor Liz Corbett:
STAR Principle



Cath Beaumont: STAR
Project Manager, LSHTM



The STAR team at the April 2016 consortium partners' meeting in Johannesburg

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The Qualitative Research Network: An Introduction

HIV self-testing (HIVST) is a process by which a person who wants to know their HIV status performs a HIV test themselves and interprets the results away from a clinical setting. While non-reactive tests are considered negative, all reactive self-test results need to be confirmed according to national practice in order for patients to access care.

At the Liverpool School of Tropical Medicine (LSTM), [Dr Miriam Taegtmeier](#) is coordinating the STAR Qualitative Research Network and leading the HIVST regulatory pathways work stream. In March 2016 LSTM played host to a three day workshop with partners to agree terms of reference for the network, discuss roles and responsibilities, map research activities, review emerging themes and design the inter-country analysis. Dr Taegtmeier said: "I was delighted to welcome STAR country representatives and our colleagues from LSHTM to Liverpool, for what was a very informative three day meeting. It gave us the opportunity to not only bring together all those across the consortium who are carrying out qualitative research, but also those working across other disciplines such as marketing, epidemiology and health economics- vitally important if we are to answer key research questions about users' preferences, potential social harms of HIVST, how to generate HIVST demand and scale up in three different countries."

The work carried by the network will also inform work around the regulatory pathways and quality assurance systems required for scale up. LSTM's [Dr Russell Dacombe](#) is working with Dr Taegtmeier on the regulatory work stream. He said: "As well as carrying out policy reviews we will talk to key decision makers in country about their ideas and experiences. This will enable us to look at the current and future regulatory direction of the countries and enable us to develop pathways which can guide that country to a more favourable regulatory framework for HIV self-testing."

At the April consortium partners' meeting in South Africa Dr Taegtmeier updated consortium members on the progress made to date. She continued: "The ultimate goal of our work, and that of STAR generally, is to identify and break down the barriers to HIV testing services. HIV self-testing could play an important role in increasing the number of people who know their HIV status, link to treatment and go on to achieve durable viral suppression."



Coming Events: STAR

- ◆ STAR Economics workshop: 4th to 6th July 2016, London.
- ◆ STAR Research meeting: 7th to 8th July 2016, London.
- ◆ STAR consortium partners meeting: 3rd to 7th October 2016, Lusaka.
- ◆ HIVST symposium, hosted by STAR: 1st to 3rd March 2017, with a half-day pre-symposium meeting hosted by WHO on 28th February to roll out the new WHO guidelines. Dates to be confirmed.

Coming Events: Other

- ◆ [International AIDS Conference](#): 18th to 22nd July, Durban, including an HIVST satellite held by PSI, and a WHO HIVST satellite including the STAR Zambia CPS.
- ◆ [HIV Research for Prevention Conference](#): 17th to 21st October 2016, Chicago.
- ◆ [African Society for Laboratory Medicine](#): 3rd to 8th December, Cape Town.
- ◆ [Conference on Retroviruses and Opportunistic Infections](#): 13th to 16th February 2017, Seattle.

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

HIV STAR clinical performance study: Can HIV self-tests be used effectively in rural Zambia?

By Dr. Melissa Neuman, LSHTM, April 2016



The STAR Zambia team and community leaders from Kanakantapa after a meeting to discuss the STAR clinical performance study

Can oral fluid tests for HIV be used effectively and read correctly across diverse populations in sub-Saharan Africa? The HIV STAR project will compare the results of oral fluid tests with a laboratory-based blood test to determine the accuracy of the test when used by urban and rural Zambians. In April 2016, I travelled with Kezia Kapaku, study coordinator for the HIV STAR clinical performance study, and many Zambian colleagues to one of the locations where we will be assessing the accuracy of HIV self-tests: rural Kanakantapa, in Chongwe district, Zambia.

There, we met with community leaders and health care providers at the Rural Health Centre. Kezia described the HIV STAR project and the clinical performance study, and took questions about adolescent testing in the project and how the study team would address unintended consequences, including forced testing or difficulties accepting a positive HIV test.

Next, Kezia and the team will travel to M'tendere, near Lusaka, which is the other location for the HIV STAR clinical performance study. Fieldwork for this part of the HIV STAR project is expected to begin in May 2016, with final results published in mid-2017.

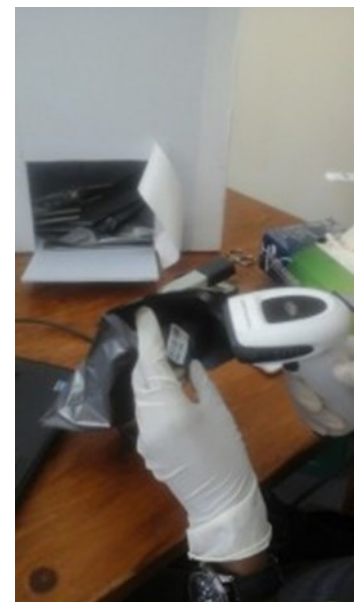
HIV STAR research studies in Zimbabwe

By Ms Mary Tumushime, CeSHHAR, May 2016

Building on momentum and knowledge from past research in Zimbabwe, comes the HIV STAR project; a grand undertaking which seeks to explore ways of distributing oral fluid HIV self-test kits. One such way is in rural communities using trained lay health workers. While the approach is still being piloted in parts of Mazowe district, a trial is on the horizon. Eighty communities will be randomised to one, both or neither of two interventions to improve linkage to care – incentivising lay health workers to link self-testers to care and incentivising clients to link to HIV treatment, care and prevention services.

Within this trial are several studies scheduled to take place after community-based distribution: a population-based survey on receipt and use of self-tests; interviews with clients, healthcare workers and key informants on barriers and facilitators to accessing post-test services; costing of resources and cost-effectiveness analyses. Throughout the study, data will be collected to capture progress and will also provide feedback on whether the interventions were successful and if so, how and why.

Findings from focus group discussions in the pilot are encouraging; people welcomed the idea of self-testing. Having lay health workers, who are knowledgeable and familiar in the communities, was effective all round and particularly at reaching those who were unlikely to visit health facilities. In preparation for the main study, stakeholder sensitisation and public randomisation meetings are scheduled for late-May with the trial kick-off planned for July. Lessons learned from the pilot distribution program will feed into the main study.



Quality assurance check via late reading of returned HIV self-test kits distributed in the pilot study

STAR-Malawi rolls out social harms reporting systems in readiness for HIVST

By Mr Mwiza Sambo and Mr Wakumanya Sibande, MLWT

How do we know that introducing HIV Self-Testing (HIVST) will not increase occurrence of social harms and serious adverse events such as physical violence, sexual violence, verbal violence, psychological violence and even death and attempted suicide in villages where HIVST will be introduced? To answer this question, a community engagement system will be developed in the participating villages surrounding health centres that were randomly selected for HIVST kits distribution in the four southern districts of Blantyre, Neno, Mwanza and Machinga. The STAR general population Community Engagement (CE) team in Malawi has rolled out the process of developing the engagement system to capture the social harms across the four districts.

The CE team comprised of two Research Assistants: Wakumanya Sibande and Mwiza Sambo from [Malawi-Liverpool-Wellcome Trust](#) (MLWT), a clinical research institution based in Blantyre which is responsible for the research component of Self-Testing Africa Malawi (STAR-M). The first districts to roll out the activity were Neno and Machinga. The activity mainly aimed at conducting a situation analysis/stakeholder mapping in the participating villages, which included exploring existing community reporting structures in the villages, identifying different key stakeholders working in the villages and their interests. The activity also aimed at developing prototype social harms reporting systems for the villages through a participatory process with the village members and village heads in group discussions and informal interviews respectively. The prototype systems developed by the village members were later validated by the key stakeholders through a one day community stakeholders' workshop.



A community stakeholder making a presentation during a workshop in Machinga district



A community member draws a village map during a stakeholder mapping in Machinga district

Through participatory methods, village members were given the space to identify existing institutions, organisations, groups and individuals that operate in their villages mainly on HIV/AIDS, general health and Gender Based Violence (GBV) issues. After identifying these stakeholders, community members were asked to point out those that have effective and active reporting structures through which community members themselves report health and GBV cases. Reporting structures such as village heads, village health workers, mothers groups, Community Based Organisations (CBOs) and religious leaders were identified during the exercise. At the community stakeholders' workshop, mapped key

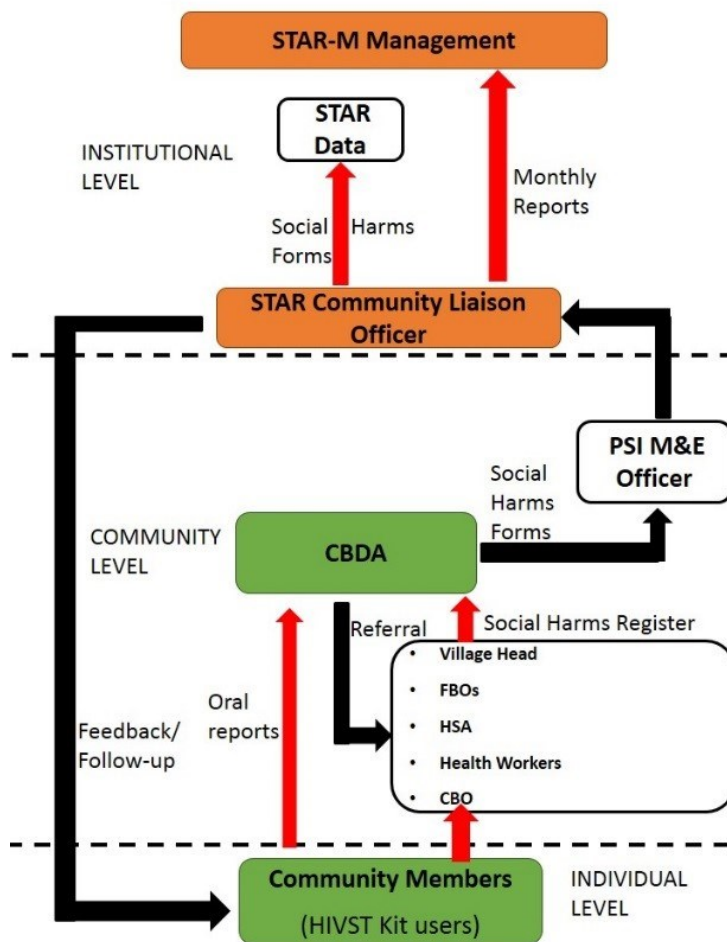
stakeholders in the villages were invited to be part of the development of the community reporting systems through validation of the prototypes that were solicited from the community members, and to be informed about their roles in reporting social harms and who they will work with. Among other invited key stakeholders were village heads, CBOs, Faith Based Organisations (FBO), health workers, Health Surveillance assistants (HSAs), and community police, just to mention a few.

During the workshop, participants were briefed by the Research Assistants about the STAR-M project, potential social impacts of introducing HIVST, and the development of community reporting systems to be used in reporting social harms.

The one-day workshops concluded with a training on how the CBDAs will be recording cases using the social harms reporting form and operation of the reporting systems. The exercise will proceed to the other two remaining districts of Blantyre and Mwanza where STAR-M is going to be implemented.

The social harms reporting systems in the participating villages will comprise of a number of components to ensure effective reporting of social harms cases. At the center of the systems at community level are Community Based Distribution Agents (CBDAs) under Population Services International (PSI), who will be responsible for the distribution of HIVST kits in the communities, and identified community key stakeholders working on HIV/AIDS and GBV. Social harms victims will be able to report their cases direct to the CBDA or through the community based institutions/ reporting structures. This is to allow flexibility in reporting, since different people in the communities may have different preferences and willingness, and when it comes to reporting their concerns have to be addressed.

Social harms reporting systems will be established across the selected evaluation villages in the four districts and will include both intervention and control villages. The system in the control villages will be capturing social harms resulting from facility based



Social harms reporting flowchart



Research Assistants with stakeholders after a workshop in Neno district

testing, since HIVST will not be implemented there, and the one in the intervention villages will capture social harms resulting from HIVST and HIV testing and counselling. This will be used to make a comparison between facility based testing and HIVST on occurrence of social harms and serious adverse events.

The one-day workshops concluded with a training on how the CBDAs will be recording cases using the social harms reporting form and operation of the reporting systems. The exercise will proceed to the other two remaining districts of Blantyre and Mwanza where STAR-M is going to be implemented.

Contact Us

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Latest Publications from the HIV STAR Consortium

Choko AT, Taegtmeier M, MacPherson P, Cocker D, Khundi M, Thindwa D, Sambakunsi R, Kumwenda M, Chiumya K, Malema O, Makombe S, Webb E, Corbett EL. Initial Accuracy of HIV Rapid Test Kits Stored in Suboptimal Conditions and Validity of Delayed Reading of Oral Fluid Tests. Plos One. June 23, 2016. <http://dx.doi.org/10.1371/journal.pone.0158107>

STAR team members Professor Elizabeth Corbett (London School of Hygiene & Tropical Medicine) and Cheryl Johnson (World Health Organization) wrote a [Lancet commentary](#), published in April 2016, on HIV self-testing to scale up couples and partner testing, with reference to [Harsha Thirumurthy's article](#): "Promoting male partner HIV testing and safer sexual decision making through secondary distribution of self-tests by HIV-negative female sex workers and women receiving antenatal and post-partum care in Kenya: a cohort study".

The following abstracts by STAR collaborators were accepted for the 2016 International AIDS Conference in Durban:

Kumwenda M, Munthali A, Choko A, Chikovore J, Mliwasa M, Sambakunsi R, Chipungu G, Mwapasa M, Kaswaswa K, Gutteberg T, Corbett EL, Desmond N. The influence of masculinity on HIV ST community intervention: a qualitative evaluation of empirical evidence from Blantyre, Malawi.

Choko A. Acceptability of woman-delivered HIV self-testing to the male partner: a qualitative study of antenatal clinic-linked participants in Blantyre, Malawi.

Figuroa C, Johnson C, Verster A, Dalal S, Baggaley R. Systematic review on HIV self-testing (HIVST) performance and accuracy of results.

Madanhire C, Sibanda E, Ruhode N, Hatzold K, Cowan FM, Mavedzenge SN. "Not without us..." – Views on the introduction of HIV self-testing among Health Care workers providing integrated HIV and sexual & reproductive health services.

Napierala Mavedzenge S, Sibanda E, Mavengere Y, Dirawo J, Hatzold K, Mugurungi O, Padian N, Cowan F. Acceptability, feasibility, and preference for HIV self-testing in Zimbabwe.

Mavengere Y, Sibanda E, Hatzold K, Mugurungi O, Cowan FM, Mavedzenge SN. Can 'late-read' of self-test devices be used as a quality assurance measure? Results of a pilot HIV self-test project in Zimbabwe.

Lora W, Chipeta E, Desmond N. Understanding coercion in the context of semi-supervised HIV self-testing in urban Blantyre, Malawi.

Sibanda E, Mutseta M, Hatzold K, Gudukeya S, Dhilwayo A, Lopez C, Tumushime M, Watadzaushe C, Maringwa G, Mapingure M, Mugurungi O, Ncube G, Weiss H, Taegtmeier M, Neuman N, Corbett E, Cowan FM. Community-based distribution of HIV self-test kits: results from a pilot of door-to-door distribution of HIV self-test kits in one rural Zimbabwean community.

Mangenah C, Sibanda E, Hatzold K, Mugurungi O, Cowan FM, Thirumurthy H. Evaluating the relative economic costs of integrating sexual and reproductive health, and HIV services in four operational service delivery modalities in Zimbabwe

Mangenah C, Sibanda E, Hatzold K, Maringwa G, Mugurungi O, Cowan FM, Thirumurthy H. Estimating the economic costs of clients accessing integrated sexual and reproductive health and HIV services in Zimbabwe.

