Friday 22 July 2016

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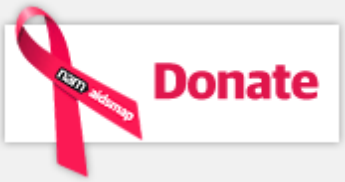

World's largest study of HIV self-testing

Community test distributor, Harrison Gwaze, explaining the benefits of taking an HIV self-test in Zimbabwe. Photo © Eric Gauss / UNITAID

There's strong demand for HIV self-testing, according to early data from the STAR study, which is being conducted in southern Africa.

STAR is the largest-ever HIV self-testing study. It will last four years and is intended to determine the feasibility of self-testing, its acceptability, costs and cost-effectiveness.

In the first phase of the study, 730,000 self-testing kits will be distributed across Malawi, Zambia and Zimbabwe, with the programme extended to South Africa in phase two.

A key research priority is where best to provide access to self-testing:

- Open access, via pharmacies
- Semi-restricted, via community health workers or peer support
- Restricted, via healthcare professions and providers.

Demand outstripped supply in a pilot project in rural Zimbabwe, with over 8000 testing kits distributed in one month. Volunteers were successful at reaching both men and women. Results showed that individuals preferred to self-test in private, rather than in the presence of a programme worker or volunteer. Focus groups showed that most people appreciated the offer of a self-test and found the volunteers knowledgeable and helpful.

Other initiatives have looked at self-testing as a way of improving testing rates among men, especially as men are less likely to have previously tested for HIV than women.

Coercion is a potential concern about self-testing, especially as many countries where self-testing is being considered have high rates of gender-based violence. Researchers in Malawi reported on their experience of coercion. Women bringing self-testing kits into their households found this empowering – however men sometimes said they felt pressured to test. People in stable relationships were more likely to report coercion.

Using a self-test kit in Zimbabwe. Photo © Eric Gauss / UNITAID

Manufacturers' concerns about demand and prices could mean that many self-testing kits currently in development never reach the market.

Four self-testing kits are currently available, having been approved by regulatory authorities, but a further nine are being developed.

In-depth interviews with companies developing self-testing products identified potential concerns that are making them reluctant to bring their products to market. These include concerns about demand, donor and governmental investment, cost, regulatory requirements and a requirement that manufacturers of self-tests facilitate linkage with healthcare providers in the event of a positive result.

The World Health Organization will issue further guidance on self-testing in December.

Related links

Read 'World's largest study of HIV self-testing gets off the ground' on aidsmap.com

Read 'Market constraints and uncertainties may limit the scale-up of HIV self-testing' on aidsmap.com

Visit our AIDS 2016 conference webpages

Viral load testing

Image from presentation by Munyaradzi Dhodho, Médecins Sans Frontières

HIV treatment programmes in southern Africa need to invest in better record-keeping, clinic procedures and personnel in order to make routine viral load testing work, according to results of a pilot study.

Viral load testing is beginning to become more widely available in resource-limited settings due to price reductions and donor investment. Viral load testing offers improved opportunities to prevent treatment failure, drug resistance and onward transmission.

Médecins Sans Frontières (MSF) presented data on how field programmes performed after the introduction of an algorithm in 2015. It showed steps to be taken after viral load testing detected viral rebound – viral load above 1000 copies/ml – in people taking antiretroviral therapy (ART).

The algorithm recommended three key actions:

- Enhanced adherence counselling
- Repeat viral load testing within 2-9 months of detectable result
- Switching to second-line therapy if viral load still detectable after second test.

Rates of viral load testing varied between field sites, from 91% in Zimbabwe to just 32% in Malawi. There was also considerable variation in the proportion of people experiencing viral rebound, ranging from 9 to 40%.

At one field site, over 40% of people who experienced viral rebound did not receive enhanced adherence counselling and at one site, only 15% of people who still had a detectable viral load after a second test were switched to an alternative ART regimen.

Factors that facilitated switching to second-line therapy included same-day viral load results; having a clinician on site at least once a week who was authorised to prescribe an alternative regimen; and having second-line drugs available on site.

The research highlighted several lessons learnt from the implementation programme:

- Value of training and targets for clinic staff
- Importance of good record keeping
- Reminder system on patient records
- Automatic viral load testing when CD4 cell count requested, especially if viral load testing rates are poor
- Prioritising patient education on viral load testing
- Acknowledge that undetectable viral load results are motivating for patients and can act as an opportunity to channel patients to different care models that can reduce waiting times and need for clinic visits.

MSF's reports on its experience of making viral load testing routine can be downloaded here.

MSF South Africa has produced an implementer's guide to introducing viral load testing, available here.

Related links

Read this news report in full on aidsmap.com

Download 'Making Viral Load Routine' from the MSF website

Download the viral load toolkit from the MSF website

Rolling out PrEP

Image from presentation by Iryna Zablotska, The Kirby Institute

Australia aims to "virtually eliminate" HIV transmissions among gay men by 2020 with an ambitious pre-exposure prophylaxis (PrEP) roll-out scheme.

Generic tenofovir/emtricitabine PrEP will be provided to an estimated 14,000 gay men at high risk of acquiring HIV.

Three-quarters of new HIV infections in Australia involve gay men. The country has good rates of HIV testing but is some way from meeting the UNAIDS 90-90-90 target: currently 88% of people

with HIV are diagnosed; 73% of those aware of their status are on ART; and 92% of people taking ART have an undetectable viral load. Overall, 59% of all people with HIV in Australia have an undetectable viral load, well short of the UNAIDS target of 72%.

PrEP roll-out to gay men at high risk of acquiring HIV is intended to bridge this gap.

Because of anticipated costs, the scheme will be using generic versions of the drugs, instead of the branded *Truvada*.

Investigators have identified four factors that are essential to the implementation of the programme:

- Commitment by the health ministry
- Consensus among medical professionals about the value of PrEP
- Supportive network of clinics and GPs
- Proactive LGBT community that has raised awareness of the therapy.

Before full roll-out, there will be implementation studies in each state.

But funding pressures mean that PrEP will have to be more gradually introduced in resource-limited settings with severe HIV epidemics.

For instance, Kenya has an HIV prevalence of 3% and there are 71,000 new infections in the country every year. A number of studies have shown the efficacy of PrEP in Kenya, and these will provide the basis for its formal approval by medicines regulators. Funding for PrEP schemes in the country is being provided by international donor organisations, such as PEPFAR (The US President's Emergency Plan for AIDS Relief). Training also needs to be provided to healthcare professionals to increase their knowledge of PrEP and willingness to prescribe the therapy.

Some key questions for a PrEP programme in the country still need to be answered, such as what constitutes "substantial" risk of HIV; development of risk assessments that don't reinforce stigma; and how to monitor adherence.

South Africa has the most severe HIV epidemic of any country in the world, and PrEP was licensed there in December 2015. The country has decided to phase in access to PrEP for groups at high risk of acquiring HIV. Cost isn't the only reason for this decision – sexual health services have still to determine referral pathways and eligibility criteria, and training for healthcare staff is a pressing priority.

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Injectable HIV therapies

David Margolis presenting at AIDS 2016. Photo by Liz Highleyman, hivandhepatitis.com

A regimen of two long-acting injectable antiretrovirals – administered every four to eight weeks – have maintained viral suppression in people who switched from oral HIV treatment.

Investigators presented results of a phase 2b study examining a combination of two injectable antiretrovirals – the experimental integrase inhibitor cabotegravir and the approved drug rilpivirine, from the non-nucleoside reverse transcriptase inhibitor (NNRTI) class.

The study recruited 309 people who had not previously taken ART. After an induction phase on oral therapy to suppress viral load, participants were randomised into three study arms. The first group remained on the oral regimen, the second received injectable therapy every eight weeks, and the third received injectable therapies every four weeks.

After 48 weeks, 92% of participants in the 8-week arm and 91% of those in the 4-week arm had an undetectable viral load, as did 89% of people taking oral therapy.

No participant having injectable therapy had serious side-effects, although almost all had injection-site reactions (for example pain or swelling).

Interviews showed that many participants found injectable therapy simpler, easier and more discreet than taking daily oral therapy. There were mixed feelings about attending clinics for injections – some thought that monthly attendance would be burdensome.

Clinicians reported that they would consider suitability for injectable therapy on a case-by-case basis. There was some concern about resistance, clinical management and not being able to remove therapy in the event of an adverse event.

Both these injectable drugs are also being considered for use as PrEP.

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HIV and hepatitis C virus (HCV)

Norbert Bräu presenting at AIDS 2016. Photo by Liz Highleyman, hivandhepatitis.com

Oral therapy for hepatitis C virus (HCV) consisting of once-daily sofosbuvir and velpatasvir is safe and effective across all HCV genotypes in people with HIV co-infection.

The ASTRAL-5 study enrolled 106 people with HIV and chronic HCV infection. Approximately a fifth had liver cirrhosis at the start of the study.

Overall, 95% had a sustained virological response 12 weeks after the completion of therapy (SVR12) – considered a cure for hepatitis C. Response rates were broadly comparable across HCV genotypes and cirrhosis did not affect treatment outcomes.

Approximately a fifth of participants experienced a grade3/4 laboratory adverse event (side-effect) – mainly elevations in bilirubin in people taking atazanavir. The most common side-effects were fatigue and headache. All the participants maintained an undetectable HIV viral load.

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Managing expanded treatment coverage in South Africa

Health checks at community adherence club for people with HIV in rural South Africa. Photo by Greg Lomas / Scholars and Gentlemen / Médecins sans Frontières

Health services in rural South Africa appear able to cope with people starting ART earlier than previously recommended. However, there are concerns that simply changing the eligibility criteria for therapy alone will not increase the number of people accessing treatment, and that investment in testing and linkage to care will be needed to reach treatment coverage targets.

In September 2016, South Africa – which has the world's largest HIV treatment programme – will start to implement the World Health Organization's "Treat All" guidelines. These call for ART for everyone with HIV, as soon as possible after diagnosis.

But will health services be able to cope with this expansion in the number of people eligible for therapy, and might people who are sick, and in need of urgent treatment, be crowded out by new patients in good health?

MSF therefore analysed the impact of switching from a treatment initiation at a CD4 threshold of 350 to a threshold of 500 at primary health clinics in KwaZulu-Natal. MSF conclude that expanding eligibility criteria didn't lead to services being swamped or the crowding out of sicker patients.

A separate modelling study showed without increased testing, linkage to care and faster treatment initiation, the number of people starting ART in South Africa would increase by just 5% a year. The country would therefore be unable to meet its 90-90-90 targets.

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As well as articles by our own editors, the apps include a daily hand-picked selection of HIV-related stories from other websites around the world.

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London AIDS 2016 event

NAM will be hosting a feedback session in London on Wednesday 27 July from 7-9pm to report on some of the key topics presented at the 21st International AIDS Conference (AIDS 2016).

Find out more on the NAM blog.

Related links

Find out more about the London event

Equal access, free choice

Eight global HIV advocacy groups have released a consensus statement setting out basic principles for provision of HIV treatment and pre-exposure prophylaxis (PrEP).

More than **800 people** have already signed to add their support.

Please read it, sign it and share it.

Related links

Visit the community consensus statement website

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