Wednesday 29 July 2015

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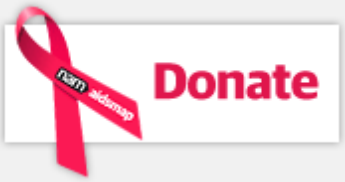

PrEP demonstration studies

Sybil Hosek at IAS 2015 photo ©Marcus Rose/IAS

As well as being remembered as the '90-90-90' conference, IAS 2015 will also be remembered as the conference where pre-exposure prophylaxis (PrEP) moved from clinical trials to real world use. As well as the results of studies of intermittent dosing (reported last week), IAS 2015 also heard results of demonstration studies designed to show how PrEP works in the 'real world', outside clinical trials.

These demonstration studies reported on the use of daily PrEP using tenofovir and emtricitabine (*Truvada*) in various settings in the United States. The studies found that people with the highest levels of risk were the most consistent users of PrEP.

The US Demo project reported on PrEP use in gay and bisexual men and transgender women in San Francisco, Miami and Washington DC. The study found that over the course of a year's follow up, participants adhered to 85% of doses. The highest levels of adherence were reported by those who also reported condomless sex with two or more partners in the previous three months. Adherence was notably lower among participants from Miami: it was 90% in San Francisco and 88% in Washington but only 65% in Miami. Participants in Miami tended to be younger, were more likely to be black and to have somewhat lower levels of HIV risk behaviour. There was a strong relationship between ethnicity and adherence: 97% of white participants had tenofovir levels in their blood samples indicating four or more doses a week, 77% of Latinos but only 57% of black people.

The ATN (Adolescent Trials Network) 110 study recruited 200 young gay and bisexual men in 12

cities in the United States. It also found evidence of an ethnic difference in PrEP adherence, with lower levels of adherence among young black men. Four participants acquired HIV during the study, at weeks 8, 32, 40 and 48, giving an annual incidence rate in participants of 3.29% a year. All these four had taken PrEP at some point but none had detectable levels of tenofovir in their blood at the study visit where HIV was diagnosed.

“ATN 110 successfully engaged young men who had sex with men who would be eligible for PrEP,” investigator Dr Sybil Hosek commented.

“The HIV incidence rate was high compared to PrEP arms in other open label trials but, given the high number of incident STIs [sexually transmitted infections], it would likely be even higher in the absence of PrEP.”

“This is a group of young men very few of whom have health insurance or go to healthcare regularly. We need to do more research on the health beliefs and levels of trust of our participants in order to understand what might support PrEP use.”

Related links

Read about the US Demo project on aidsmap.com

Read about the ATN110 study on aidsmap.com

Read or download a briefing paper on PrEP on aidsmap.com

Self-testing

Frog Designs /iTEACH self-test packaging, KwaZulu-Natal. Image from presentation by Sheri Lippman at IAS 2015.

Self-testing was another subject that attracted a lot of attention at IAS 2015. Some of the fullest sessions during the conference were the launch of World Health Organization (WHO) HIV testing guidelines and a symposium on new HIV testing modalities.

WHO guidelines stopped short of recommending self-testing because it is still unclear exactly how self-testing should be offered, and what safeguards need to be put in place to ensure linkage to care and to prevent coercion. At least 20 studies are underway to generate further evidence, but it is clear from studies already presented that there is huge demand for access to self-testing.

An important evidence gap relates to implementation in resource-limited settings with men who have sex with men, sex workers, people who inject drugs and other key populations. In places where pervasive social stigma and concerns about confidentiality make health services difficult to access, self-testing may have particular advantages for these groups in terms of privacy and autonomy.

But Peter MacPherson of the Liverpool School of Tropical Medicine said he was aware of 20 self-testing studies among the general population in African countries, but only of six among key populations. There are also few data on adolescents and older men, although HIV testing has low uptake in all these groups.

Funded by UNITAID, a partnership led by PSI is running the world’s largest evaluation of HIV self-testing to date. Different models of self-test distribution, both to the general population and to key

populations, will be piloted in Malawi, Zambia, and Zimbabwe, with around three quarters of a million self-test kits made available. PSI has experience of applying social marketing approaches to condoms, contraceptives, insecticide-treated bed nets and other health products. Robust communication and distribution efforts help ensure wide acceptance and proper use of the products.

The pilots will generate information about how to distribute self-test products effectively, ethically and efficiently, and will answer key questions about the feasibility, acceptability and impact of the intervention. WHO will use the results to develop guidance and to support the integration of self-testing in national policies. By removing regulatory barriers and getting a better sense of the likely size of the market for HIV self-testing, the project hopes to encourage manufacturers to enter the self-test market.

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HIV treatment and prevention for people who inject drugs

Evan Wood at IAS 2015 ©Marcus Rose/IAS

“We talk a lot about the success of treatment as prevention in Vancouver, but we always need to make sure people understand that this requires an integration of various approaches,” Dr Evan Wood of the University of British Columbia said in a plenary presentation to the IAS 2015 conference last week.

HIV diagnoses in people who inject drugs in British Columbia have fallen by more than 90% since the peak of the epidemic in 1996. This success has been achieved, Wood said, through a combination of community empowerment, harm reduction, treatment for addictions and universal access to HIV treatment and care. Nonetheless, the criminalisation and marginalisation of people who use drugs remained major obstacles.

“The success of treatment as prevention in injecting drug users in Vancouver has been phenomenal,” his colleague Professor Julio Montaner said in another session. “The reason why it’s working so well is because there is a synergy between the needle exchange, the supervised injection site, the methadone programme and the treatment as prevention.”

In 2006, 30% of those in care were taking HIV treatment and had an undetectable viral load. By 2012, the figure had risen to 71%.

Considerable efforts have been made to engage people who use drugs with HIV and harm reduction services, which are always free of charge for those who need them.

The conference also heard that a peer education project in Ukraine reduced new HIV infections in people who inject drugs by 41%. A cluster randomised trial recruited individuals who had an exceptionally high risk of HIV (each year, one in three acquired HIV). The intervention is thought to have worked by helping individuals make more use of needle exchange programmes.

For the study, people in recovery worked as outreach workers. They contacted and recruited 1205 HIV-negative people who inject drugs.

Half were randomised to receive the control intervention: a counselling and education

programme that was broadly similar to that typically proposed by the US National Institute on Drug Abuse.

The other half received the counselling and education, plus a peer-based intervention. This involved being trained to recruit and educate their peers on harm reduction practices. The training, led by the outreach workers, was scripted and involved role-play exercises. Each of the 'peer leaders' who had received the training was asked to bring two further people they knew who used drugs to the programme. The intervention was based on ideas of social learning, social identity, social norms and social diffusion.

Tetiana Deshko of the International HIV/AIDS Alliance in Ukraine told the conference that harm reduction interventions in some parts of Ukraine, with the support of international donors, had achieved reductions in HIV incidence among people who inject drugs. But now the political instability and Russian influence, especially in the Donetsk region, threatened the human rights and public health-based approaches that had been introduced.

Related links

Read about Dr Wood's presentation on aidsmap.com

Read about the project in Ukraine on aidsmap.com

New antiretrovirals

Tony Mills at IAS 2015. Photo by Liz Highleyman, hivandhepatitis.com

Newer antiretrovirals in development may offer advantages in the forms of improved tolerability and a reduction in long-term side effects, according to data presented at IAS 2015.

Tenofovir alafenamide (TAF) is a new formulation of tenofovir that reaches higher levels in HIV-infected cells. It achieves lower concentrations in the blood plasma and less drug exposure for the kidneys, bones and other organs and tissues. A phase 3 study, in treatment-experienced people with normal kidney function who switched from the old to the new tenofovir formulation, found that people who switched from *Atripla* or atazanavir/*Truvada* to TAF (10mg), emtricitabine (200mg), elvitegravir (150mg) and cobicistat (150mg) saw significantly better virological responses, while those who switched from *Stribild* did about the same. People who switched to TAF experienced improvements in kidney function markers, while those who stayed on regimens including the current formulation of tenofovir (TDF) worsened. Spine bone mineral density (BMD) rose by an average +1.79% in the TAF arm while falling by a mean of -0.28% among those who stayed on existing TDF regimens.

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Read the news story about TAF in full on aidsmap.com

Hepatitis C

Laurence Brunet at IAS 2015. Photo by Liz Highleyman, hivandhepatitis.com

Data presented at IAS 2015 confirmed that new interferon-free combinations of direct-acting antivirals are just as effective at curing hepatitis C in people with HIV as in people without HIV. Three different interferon-free regimens – sofosbuvir/ledipasvir, AbbVie's 3D regimen and grazoprevir/elbasvir – were well-tolerated and cured hepatitis C in more than 90% of participants with HIV and HCV co-infection in three clinical trials.

Separate research presented at the conference showed that people with HIV and HCV co-infection, with liver cirrhosis, who achieve sustained virological response (SVR) and experience an improvement in liver fibrosis are less likely to develop liver disease complications or die from liver-related causes. In some cases, fibrosis regression is beneficial even in the absence of a cure. A related study found that in the absence of hepatitis C treatment, a biomarker score that is moderately predictive of the progression of liver damage increased more rapidly in people receiving antiretroviral therapy containing abacavir and lamivudine, and/or a protease inhibitor.

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Read about research on liver fibrosis in full on aidsmap.com

Prevention of mother-to-child transmission

Fatima Kakkar at IAS 2015. Photo by Liz Highleyman, hivandhepatitis.com

Combination antiretroviral therapy containing the integrase inhibitor raltegravir (*Isentress*) appears safe and effective and may be an attractive option for treatment for women with HIV who are pregnant – and potentially their infants – to prevent perinatal HIV transmission, according to study findings presented last week at IAS 2015.

Current European and US guidelines generally recommend that pregnant women should receive the same type of combination antiretroviral therapy (ART) as other adults with HIV; however the US guidelines consider raltegravir an ‘alternative’ option because less is known about its use during pregnancy. However, due to its very rapid action in reducing viral load, it may be particularly beneficial for women with HIV who present for care late during pregnancy, without having received prenatal care, and who need to quickly bring down their viral load before delivery, or for women who experience treatment failure during pregnancy or have drug-resistant virus.

A study conducted in Thailand also presented at IAS 2015 showed that intensification of antiretroviral therapy – by the addition of nevirapine prophylaxis to standard triple ART for the mother and by addition of four weeks of antiretroviral prophylaxis instead of one week for the infant – prevented HIV transmission when mothers presented late or had less than eight weeks of antiretroviral therapy prior to delivery.

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Scientific analysis from Clinical Care Options

Clinical Care Options' (CCO) is the official online provider of scientific analysis for delegates and journalists.

Over the next few weeks, their coverage will include expert audio highlights, capsule summaries of important clinical data, downloadable slidesets, and more.

Related links

Visit the Clinical Care Options website

Stay in touch!

We hope you have found our news reporting from IAS 2015 useful. This is our final bulletin from the conference.

We publish HIV-related news all year round, on our website, on the aidsmap news app, and through our regular email bulletins. If you're not already a subscriber, do sign up to stay in touch.

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