Tuesday 21 July 2015

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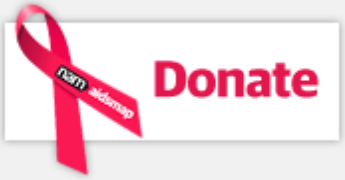

Non-daily PrEP may be an option

Tim Holtz and Sharon Mannheimer at IAS 2015. Photos by Liz Highleyman, hivandhepatitis.com

Pre-exposure prophylaxis (PrEP) is one of the major topics of discussion at IAS 2015: how to take it, who should be able to take it and when it will be available.

Three studies presented on Monday show that for some people in some settings, less frequent PrEP regimens with doses linked to sexual activity are feasible, with high numbers of sexual acts protected by PrEP. This may give people who want to use PrEP, and their doctors, additional options – allowing people to find a pattern of taking PrEP that best suits them.

Separate randomised trials with similar study designs were conducted with men who have sex with men in Bangkok; men who have sex with men in Harlem, New York; and women in Cape Town.

The researchers anticipated that the very different social, cultural and demographic characteristics of these populations would determine which PrEP regimen would work best – either once a day, twice a week (with an extra dose after sex) or before and after sex.

Both the daily and non-daily regimens worked well for the participants in Bangkok, who were mostly well-educated and employed. At the other two sites, where challenging social circumstances were more common, daily dosing proved easier to adhere to than non-daily regimens.

The results suggest some flexibility in the ways in which PrEP may be prescribed. But these small studies demonstrate feasibility rather than effectiveness. The best evidence for protection against infection comes from studies of daily PrEP.

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START trial provides definitive evidence of the benefits of early HIV treatment

Jens Lundgren at IAS 2015. Photo ©Steve Forrest/Workers' Photos/IAS.

People who start antiretroviral therapy (ART) immediately after HIV diagnosis, while their CD4 cell count is still high, rather than waiting until it falls below 350 cells/mm^3, have a significantly lower risk of illness and death, according to long-awaited findings from the START trial. The final study results were presented at the IAS 2015 conference and published simultaneously in the advance edition of the *New England Journal of Medicine*.

The study enrolled 4685 adults living with HIV in 35 countries worldwide, including just over half from low- and middle-income countries.

People taking part in the trial had a CD4 count above 500 when the trial started. They were randomly assigned to either start treatment immediately or to delay treatment until their CD4 count fell below 350 or they developed symptoms of AIDS.

Professor Jens Lundgren of the University of Copenhagen reported that 1.8% of study participants in the immediate treatment group experienced a combined endpoint of serious AIDS-related events, serious non-AIDS events and death, compared with 4.1% in the deferred therapy group – a 57% reduction. The most common events in both study arms were tuberculosis and cancer.

These findings suggest that HIV causes persistent immune system damage soon after infection, and "clearly indicate that ART should be provided for everyone regardless of CD4 count," Lundgren told aidsmap.com.

Early findings from the study were provided to the World Health Organization (WHO) panel working on updated global HIV treatment guidelines. WHO announced this week that its forthcoming guidelines will recommend treatment for all, regardless of CD4 count. US guidelines adopted universal HIV treatment in 2013 and the British HIV Association did so in its new draft guidelines, issued in June after the release of the preliminary START findings.

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No HIV infections from partners with fully suppressed viral load during long-term follow up of landmark treatment as prevention trial

Myron Cohen at IAS 2015. Photo ©Steve Forrest/Workers' Photos/IAS.

Final follow up of the HPTN 052 study of treatment as prevention shows no evidence of HIV transmission from people with fully suppressed viral load to their partners, four years after the first results from the study demonstrated that early HIV treatment reduced the risk of HIV transmission by 96%, Professor Myron Cohen told the conference on Monday.

After following participants from the unblinding of the study in 2011 until 2015, providing antiretroviral therapy to people in the deferred treatment arm and retaining two-thirds of couples in the study throughout the follow-up period, the investigators have concluded that early antiretroviral therapy reduced the risk of HIV transmission in serodiscordant couples by at least 93%.

All the infections that occurred in the follow-up phase, and which could be genetically linked to the partner on HIV treatment, occurred either before treatment was started, before viral load was fully suppressed in the weeks just after starting treatment, or else when treatment failed. No transmission occurred from people with fully suppressed viral load to their partners during the HPTN 052 study.

“Antiretroviral treatment is a durable means of preventing HIV transmission in heterosexual couples,” Professor Cohen told a press conference, and he told the conference “we see no reason why it should not be effective” for men who have sex with men. He advised delegates to watch out for longer-term follow-up from the PARTNER study, which reported no transmissions between men where the HIV-positive partner had fully suppressed viral load, in an interim analysis released in 2014.

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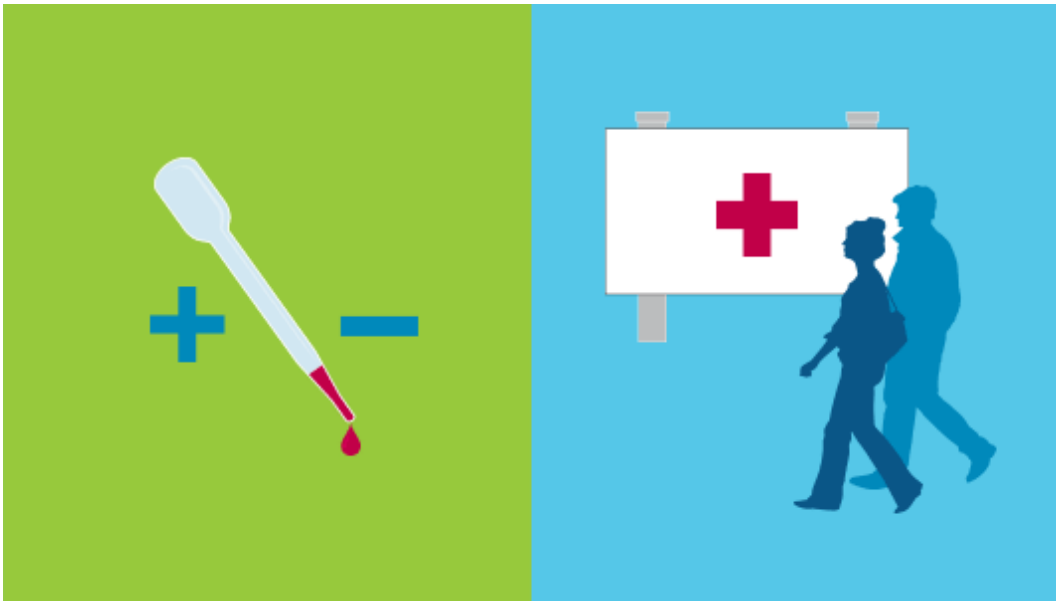
Linkage to HIV care and treatment



A systematic effort to promote HIV testing, linkage to care for people diagnosed with HIV and circumcision for those testing negative can result in high levels of diagnosis, linkage to care and viral suppression in rural communities, a randomised study of combination HIV prevention conducted in South Africa and Uganda has shown.

The Linkages study showed both lay counsellor follow-up and being accompanied to the HIV clinic by a lay counsellor were significantly more effective than standard clinic referral in ensuring linkage to care.

For men who tested HIV-negative, two innovative methods of promoting circumcision resulted in an increase in uptake of approximately 70% when compared to standard of care, with the greatest impact in the first three months after testing.

The Linkages study is one of the first studies to demonstrate that community-wide efforts to increase HIV diagnosis can be used as a platform to improve both linkage to care for people diagnosed with HIV, and linkage to prevention services for men who test HIV-negative.

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Twelve years off treatment – exploring HIV 'in remission'

Dr Asier Saez-Cirion speaking at the Towards an HIV Cure symposium. Photo ©Steve Forrest/Workers' Photos/IAS.

The conference heard on Monday about a young woman, who was infected with HIV at birth and received very early antiretroviral therapy (ART) as a child. She has stayed off ART for twelve years – since the age of six – with a viral load well below the detectability limit of standard tests. People in this unusual situation (so-called post-treatment controllers) are models for the 'functional cure' which is one of the goals of treatment research.

Dr Asier Sáez-Cirión of the Institut Pasteur in Paris, who also presented the results to the *Towards an HIV Cure* symposium the previous day, said that this was the first case of really prolonged remission seen in a person infected around the time of birth and who remains

undetectable off therapy. (In one previous case, the so-called Mississippi baby, the child developed a detectable viral load again after a period of two years and three months off therapy.)

Dr Sáez-Cirión said the current case added to the evidence that in certain cases very early treatment of HIV infection could lead to the person developing a kind of immune response that was able to control HIV in the absence of treatment.

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Towards an HIV cure symposium demonstrates breadth of cure research

Dr Daniel Kuritzkes of Harvard Medical School. Image by: Marcus Rose/IAS.

The *Towards an HIV Cure* two-day symposium has become a fixture in advance of the International AIDS Society conferences and this year's meeting featured a more varied range of experimental approaches than ever, in the search for ways of eliminating HIV from the body.

Dr Daniel Kuritzkes of Harvard Medical School, in his opening talk, told the delegates that to some extent the proliferation of different approaches was due to early disappointments in the cure field. There is still only have one person, Timothy Ray Brown, who has been cured of HIV and the six other cancer patients in whom the same stem-cell transplant therapy had been tried had all died – a reminder that a procedure as exacting as a bone-marrow transplant is never going to be an approach that can be used generally.

The main approach that cure researchers are still working on is the so-called 'shock and kill' strategy. This uses immune stimulants to induce the cells in which dormant HIV lies hidden – the so-called reservoir cells – to come out of hiding. The hope is then that their activation will in itself lead to their death through natural immune exhaustion; if not, the aim is to target them with directed cell-killing drugs. Without eliminating this reservoir, a small minority of cells capable of spitting out new HIV will remain in the body; experiments have shown that HIV can reappear even when undetectable with the most sensitive viral load tests, as in the case of the Mississippi baby.

Since the 'shock and kill' strategy has gained wide currency, there have been disappointments: the experimental agents used to reverse so-called 'latency' have certainly stimulated virus production by cells – but without resulting in any decrease in the size of the viral reservoir. This appears to be because the drugs chosen – HDAC inhibitors like panobinostat or romidepsin – have other, unforeseen immune effects, including suppressing activity in the very CD8 cells that might be central to the 'kill' part of the process.

Nonetheless, Kuritzkes said, for the time being, "latency reversal is a necessary, if not sufficient condition in reducing the reservoir of HIV-infected cells".

He told aidsmap.com: "Most of the interventions that are likely to eliminate infected cells require that the virus is visible to the immune system. The alternative idea – that of permanently suppressing viral production by reservoir cells (as in the study published last week of a tat inhibitor) – "at the moment would seem to involve taking a latency suppressor pill every day instead of antiretroviral therapy. That's not really a cure."

Visit aidsmap.com for a detailed report on emerging approaches in HIV cure research presented at the symposium.

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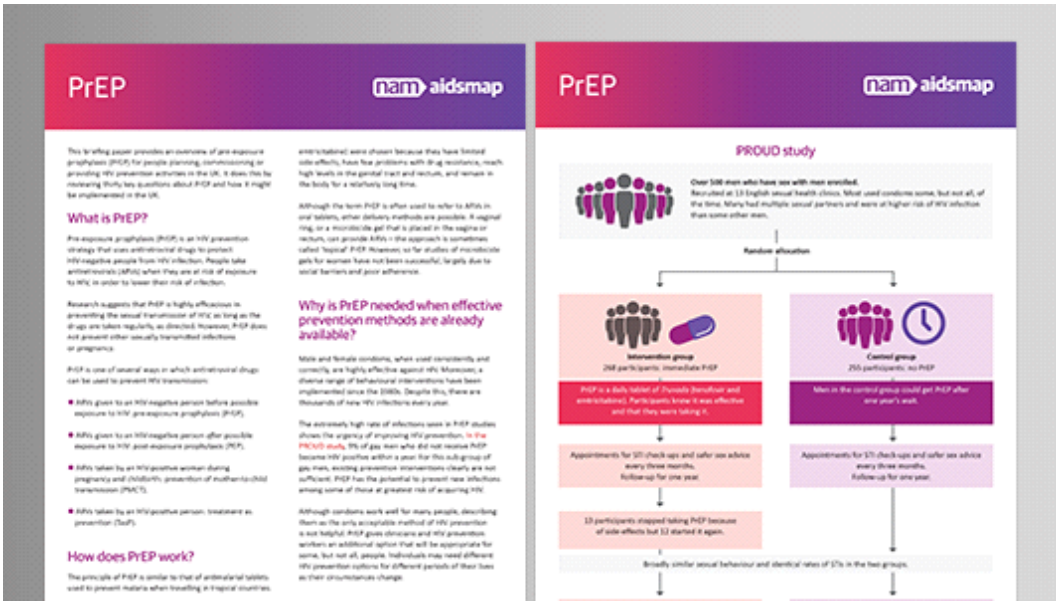
New briefing paper: PrEP



This new briefing paper provides an overview of pre-exposure prophylaxis (PrEP) for people planning, commissioning or providing HIV prevention activities in the UK.

The paper reviews thirty key questions about PrEP and how it might be implemented in the UK.

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Read or download the PrEP briefing paper

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