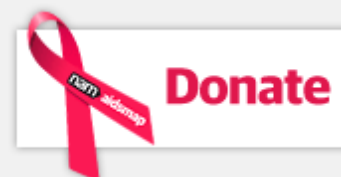




Thursday 8 March 2018

Contents

- | [Open-label studies of vaginal ring have higher adherence and effectiveness](#)
- | [Average time from HIV diagnosis to treatment in San Francisco: six days](#)
- | [Statin users have lower rates of many types of cancer](#)
- | [Efavirenz may undermine effectiveness of the vaginal ring contraceptive](#)
- | [Transgender women and transmission clusters](#)
- | [Ibalizumab is active against highly resistant HIV](#)
- | [New edition: *HIV & hepatitis*](#)
- | [Support our work](#)



Open-label studies of vaginal ring have higher adherence and effectiveness



Jared Baeten and Zeda Rosenberg at CROI 2018. Photo by Liz Highleyman.

Two parallel open-label studies of the dapivirine vaginal ring released interim results at the [25th Conference on Retroviruses and Opportunistic Infections \(CROI 2018\)](#) on Wednesday. They indicate that women used the ring more consistently than in the earlier randomised studies and as a result the ring was more effective in preventing HIV infections. The ring stopped more than half of the HIV infections that would otherwise have occurred.

The ring, which is similar to devices used for contraception, is designed to be worn inside the vagina for a month at a time; women can insert and remove it themselves.

The two studies, HOPE (MTN 025) and DREAM (IPM 032), are open-label extensions of the two randomised, placebo-controlled studies of the vaginal ring known as ASPIRE (MTN 020) and the Ring Study (IPM 027). These two studies previously reported effectiveness of 27% and 31% respectively.

These two open-label studies are very similar, recruiting women in countries in southern and eastern Africa who had taken part in the previous randomised studies. Participants know they are receiving an active product and that it has proven to be effective and safe.

The HOPE study enrolled 1407 participants with an average age of 31, while DREAM enrolled 900 participants with an average age of 29. A significant proportion had sexually transmitted infections when recruited to the studies: 16% and 18% respectively. Recruitment and retention

has generally been good.

Adherence appears to be higher than in the randomised studies. Adherence is estimated by measuring drug levels in the rings that are returned after use. This indicates that 89.5% and 96% of women in HOPE and DREAM had used the ring at least some of the time in the previous month. This compares to 77% and 83% in the randomised studies.

As the open-label studies do not have placebo arms (a comparison group that does not receive the intervention), effectiveness cannot be directly measured. Nonetheless, the researchers would expect HIV incidence in the two cohorts to be 4.1% and 3.9% respectively. In fact, it was 1.9% and 1.8% in the two studies, each indicating an effectiveness of 54%.

Jared Baeten of the Microbicide Trials Network made a comparison with oral pre-exposure prophylaxis (PrEP). In the original iPrEx study of PrEP, effectiveness had only been 44%, but it was 50% in its open-label extension and 100% in people who took four or more doses a week. Further studies and demonstration projects were needed to demonstrate PrEP's extremely high efficacy in circumstances where adherence was high.

The vaginal ring studies have essentially started the second stage of this process, Baeten said. The final results will be released next year and will stratify users by adherence, relating adherence to efficacy rates.

Related links

[Read this news story in full on aidsmap.com](#)

[Watch the webcast of the HOPE study presentation on the conference website](#)

[Watch the webcast of the DREAM study presentation on the conference website](#)

[Visit the CROI 2018 webpages on aidsmap.com](#)

Average time from HIV diagnosis to treatment in San Francisco: six days

The average time from HIV diagnosis to starting treatment in San Francisco shrank from 35 days to six days between 2013 and 2016, the conference heard. The time from HIV diagnosis to having viral load suppressed below 200 copies/ml halved during the same period, from 134 days to 61 days.

In 2015 the city implemented RAPID, a protocol to speed up treatment initiation, as part of a broader initiative to eliminate new HIV infections. RAPID aims to link everyone diagnosed with HIV to care within five days and, unless there are clinical indications that the patient is at risk of immune reconstitution inflammatory syndrome (IRIS), treatment should be initiated at the first care visit using the most potent regimen available. Antiretrovirals which would require baseline lab testing (such as abacavir or non-nucleoside reverse transcriptase inhibitors) are not used.

Newly diagnosed people are linked to care by navigators who identify the most appropriate clinic based on insurance coverage and psychosocial needs. The availability of the Medicaid health coverage programme for people on low incomes is an important foundation of the programme – 39% of people start antiretroviral therapy at 'safety net' public clinics and 60% at clinics that accept Medicaid and uninsured patients.

In 2016, there was no significant demographic difference between those who started treatment and those who did not. Time from diagnosis to viral load suppression decreased significantly for

all groups, but especially for homeless people, Asian and Pacific Islanders, and Latinos.

The results show that multi-sectoral collaboration can shorten the time from HIV diagnosis to virologic suppression, said Dr Oliver Bacon of the San Francisco Department of Public Health, but routine surveillance data and case reviews are essential for mapping the care pathway and identifying opportunities for improvement.

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Statin users have lower rates of many types of cancer



Roger Bedimo presenting at CROI 2018. Photo by Liz Highleyman.

Both HIV-positive and HIV-negative people who use statins to manage cardiovascular disease risk also have a lower risk of cancer, according to research presented yesterday at the conference.

Statins are used to lower blood lipid levels and reduce the risk of cardiovascular disease. But they also have other effects including reducing inflammation and influencing T-cell proliferation and activity in a way that may enhance immune responses against tumours. Findings on statin use and cancer in the general population have been inconsistent, but the beneficial effects might be greater for people with chronic infections like HIV that can cause ongoing immune activation and inflammation.

Dr Roger Bedimo of the Veterans Affairs North Texas Health Care Center in Dallas and colleagues analysed associations between statin exposure and cancer risk in the Veterans Aging Cohort Study. They identified 12,014 statin users and an equal number of non-users, around a fifth of whom had HIV.

Cancer was newly diagnosed in 9.0% of HIV-positive people and 7.1% of HIV-negative people during five years' follow-up. Overall, statin use was associated with a 39% lower risk of all cancers combined. The protective effect of statins was stronger among people with HIV compared with HIV-negative people (49% vs 35% overall reduction, respectively).

The protective effect appeared to be stronger for cancers which can be caused by viral infections. These include lymphomas (which can be caused by Epstein-Barr virus), liver cancer (hepatitis B and C), oral cancer (human *papillomavirus*, HPV) and anal cancer (also HPV). In contrast, statins had a limited impact on prostate cancer.

Looking at all-cause mortality, the risk of death was 45% lower among statin users compared with non-users.

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Efavirenz may undermine effectiveness of the vaginal ring contraceptive



The antiretroviral drug efavirenz significantly reduces the levels of both hormones in the vaginal ring contraceptive in women with HIV, researchers reported on Wednesday at CROI 2018. It was already known that efavirenz has an impact on some hormonal contraceptives, but its effect on the vaginal ring was unknown.

The *NuvaRing* vaginal ring releases etonogestrel (a progestin) and ethinyl estradiol (an oestrogen). It contains enough of the hormones to provide contraception for one month.

The researchers measured plasma concentrations of etonogestrel and ethinyl estradiol on the day women commenced using the vaginal ring and day 7, day 14 and day 21. Seventy-four women living with HIV took part, split into three groups: those not taking HIV treatment, taking an efavirenz-based regimen and taking an atazanavir/ritonavir based regimen.

Levels of etonogestrel were reduced by 76-79% in the efavirenz group, but increased by 71-79% in the atazanavir/ritonavir group. Levels of ethinyl estradiol were reduced by 53-57% in the efavirenz group and were reduced by 29-35% in the atazanavir/ritonavir group.

The researchers say that atazanavir/ritonavir based treatment is unlikely to impact the effectiveness of vaginal ring contraceptives.

But the results for efavirenz are of more concern. "If I was a woman receiving an efavirenz-based antiretroviral regimen I would be uncomfortable with the degree of contraceptive protection I would be getting from the vaginal ring," Dr Kimberly Scarsi of the University of Nebraska Medical Center told the conference.

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Transgender women and transmission clusters



Manon Ragonnet-Cronin at CROI 2018. Photo by Liz Highleyman.

[A phylogenetic study of HIV infections in Los Angeles has found that transgender women are more likely than any other risk group to be in a genetically connected cluster of cases](#), which is a marker of being in a network with a high incidence of HIV.

Cisgender heterosexual women were the group the least likely to be in a cluster. Compared to them, cisgender heterosexual men were 1.8 times more likely to be in a cluster, men who have sex with men (MSM) 2.1 times more likely and transgender women 2.3 times more likely.

But transgender women were much less likely to be diagnosed than MSM.

The analysis of clusters also sheds light on sexual behaviour by giving information about chains of infection. A cluster is a group of two or more people whose viruses are so similar that they must share a common origin.

The study found that transgender women were 45% more likely to be connected to cisgender heterosexual men than would be expected if they mixed randomly, and 450% more likely to be connected to other transgender women. They were 22% less likely to be connected to MSM than would be expected in random mixing.

Partners of transgender women also clustered together strongly. This implies that there is a distinct population of cisgender men – who may define as MSM or heterosexual – who either sometimes or primarily have transgender women as their partners.

Manon Ragonnet-Cronin of the University of California, San Diego suggested that phylogenetic analysis could be used to engage the partners of transgender women with partner services. It could help link transgender women with HIV testing, pre-exposure prophylaxis (PrEP) and linkage to care.

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Ibalizumab is active against highly resistant HIV

"Trogarzo is the first drug in a new class of antiretroviral medications that can provide significant benefit to patients who have run out of HIV treatment options."

Dr Jeff Murray, Food and Drug Administration

Ibalizumab, a long-acting monoclonal antibody that prevents HIV from entering cells, is active against virus strains that have developed resistance to multiple other antiretrovirals, according to a study presented at CROI 2018.

During the conference the US Food and Drug Administration (FDA) announced that it has approved ibalizumab-uiyk, to be marketed as *Trogarzo*, for people with HIV who have limited options due to extensive prior treatment experience and multidrug-resistant virus. The drug has been in development for more than 10 years under the sponsorship of multiple pharmaceutical companies.

Rather than attacking HIV directly, ibalizumab is an antibody that binds to the CD4 receptor on T-cells. It is administered by intravenous infusion every two weeks.

Ibalizumab is the first biologic agent to be approved for HIV, the first antiretroviral that does not require daily dosing, and the first anti-HIV therapy with a novel mechanism to be introduced in a decade. It will be priced at US\$118,000 annually – far exceeding the cost of existing HIV medications, but in line with biologic agents for cancer and other diseases.

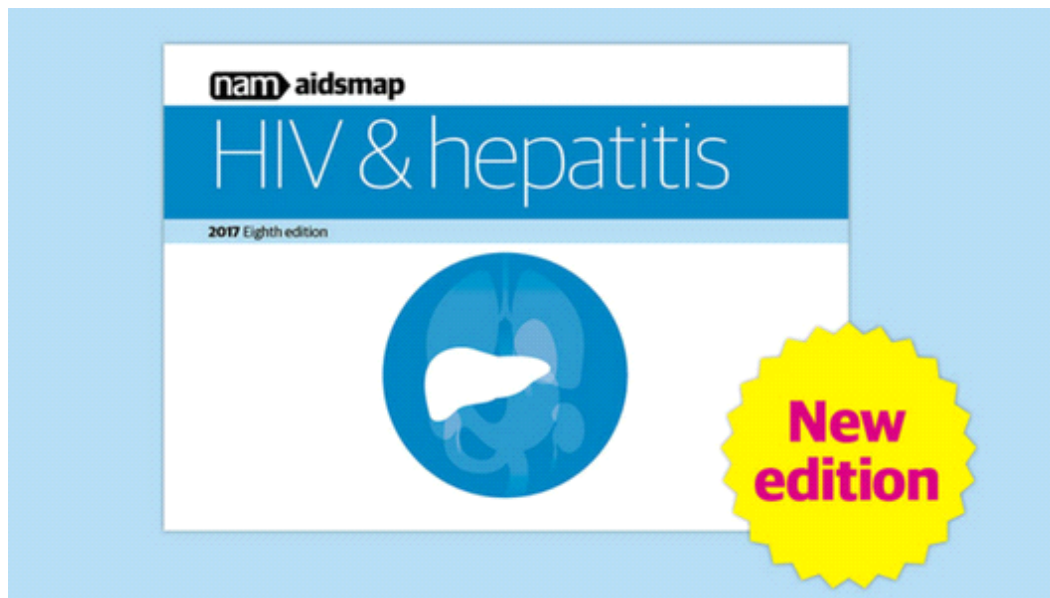
The study at CROI reported findings from an analysis of virus isolates in blood samples collected from participants in a phase 3 trial. This showed that ibalizumab was equally active against HIV that was sensitive to or resistant to other antiretrovirals from all drug classes. This confirms that ibalizumab is a potent tool for the treatment of multidrug-resistant HIV.

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New edition: *HIV & hepatitis*



A new edition of our booklet *HIV & hepatitis* is available online.

The booklet is for people living with HIV who want to know more about hepatitis A, B and C. The information in the booklet can help you to avoid getting these viruses or to treat and manage the viruses if you have them.

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