News from the 2017 IAS HIV Cure and Cancer Forum

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The 2017 IAS HIV Cure and Cancer Forum, preceding the 9th International AIDS Society Conference on HIV Science (IAS 2017), brought together researchers in the fields of HIV cure research and oncology to discuss the emerging overlaps between the cutting edges of HIV and cancer research.

The Forum heard about the experimental use of new cancer drugs, called immune checkpoint inhibitors, which might improve the ability of the immune system to clear HIV-infected cells by blocking the cellular receptors which switch off some immune responses. Studies so far have been confined to people with HIV who also have cancers, and show modest effects. Professor Sharon Lewin said that more studies will be needed, in people with HIV who do not have cancer, to establish whether these drugs can play a role in reducing the HIV reservoir.

One thing that would help efforts to cure HIV and to use new types of drugs to eradicate HIV-infected cells would be if reservoir cells could be identified more easily. The Forum heard that researchers at the University of Oxford have found that in people with HIV, reservoir cells had from 100 to 1000 times as much of the cellular receptor molecule CD32a on their surface. Detection of CD32a has the potential to be an important tool in cure research.

Controlling HIV off treatment was also a focus of the Forum. One of the most widely reported stories of the conference was the discovery of a South African child who had started treatment early but who had now been off antiretroviral therapy for 8.5 years without a viral load rebound. Research is still ongoing to understand why viral rebound has not occurred in this case, but other new findings from human and animal studies presented at the Forum suggest that a very low level of the anti-HIV antibodies of the type called IgG or very high levels of natural killer cells may characterise the best 'controller' responses. These findings may offer clues for the development of therapeutic vaccines that can help to control HIV off treatment.

Curing HIV infection completely, by eradicating the virus from the body, appears to have happened only in one case, after a bone marrow transplant replaced Timothy Ray Brown’s stem cells. Researchers think that the critical element in his case that led to eradication was the development of graft versus host disease – a condition in which the grafted bone marrow cells ‘reject’ the body’s own cells as foreign. Spanish researchers reported on a small international cohort of people living with HIV who have undergone bone marrow transplants and who have no trace of HIV – like Timothy Ray Brown. At the moment, all are taking antiretroviral therapy; experimental treatment interruptions are planned next year to see whether viral rebound occurs.

Experimental treatment interruptions will be a critical component of future cure studies, but the Forum heard from Michael Louella of the University of Washington AIDS Clinical Trials Unit that the single biggest barrier to recruitment to future cure studies may be a fear of becoming infectious again after stopping antiretroviral treatment.
“People are loath to lose their hard-won viral undetectability,” Louella commented.

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**US HIV funding decisions on PEPFAR in 2017 will have critical effect on ability to reach 90-90-90 goals**

A withdrawal of United States funding for HIV treatment and prevention in sub-Saharan Africa could lead to 7.9 million additional HIV infections and almost 300,000 AIDS deaths between now and 2030, according to modelling of the impact of US funding carried out by Imperial College, London, and presented last week at IAS 2017 in Paris.

As the largest global donor to the Global Fund to Fight AIDS, Tuberculosis and Malaria, and as the largest bilateral funder through its President’s Emergency Plan for AIDS Relief (PEPFAR), the funding provided by the United States government underpins the global AIDS response.

To date, the United States has given $70 billion through bilateral and multilateral programmes to fight HIV. But, in budget proposals put forward earlier this year, the new Trump administration proposed to cut the US foreign aid budget by one-third, and PEPFAR funding from over $6 billion to $5 billion in the 2018 budget.

To investigate the potential impact of budget changes, and to show how US funding has affected the trajectory of the HIV epidemic in 18 countries in sub-Saharan Africa accounting for 80% of the HIV burden, researchers from Imperial College, London, developed a model of the relationship between programme funding of treatment and prevention, and new HIV infections and deaths.
Starting in 2000, the model showed that the absence of US funding – and the absence of the Global Fund, which the researchers assumed would not have come into being without US support – would have led to approximately 4 million more HIV infections by 2016 and 5 million additional AIDS deaths.

In a worst-case scenario, where US funding is withdrawn from the Global Fund and PEPFAR programmes, up to 7.9 million additional HIV infections and around 300,000 AIDS deaths could occur by 2030.

The modelling also showed that maintaining funding only at existing levels will lead to a flatlining of the proportion of people living with HIV who are on treatment and virally suppressed. On the other hand, if expansion of US funding is accompanied by increases in domestic funding and more efficient allocation of funding within each country, there could be rapid progress towards the 90-90-90 target by 2022.

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Major PrEP demonstration study launched in France

France is launching a new study which will enrol 3000 new pre-exposure prophylaxis (PrEP) users over the next three years, Jean-Michel Molina told IAS 2017 last week. Whereas previous studies, including Molina’s own IPERGAY study, proved the benefit of PrEP to the individual taking it, the new study has set an ambitious target in relation to the public health benefit of PrEP. The aim is to show that having an extra 3000 people take PrEP will result in a marked fall in HIV diagnoses among men who have sex with men in the Paris region.

The demonstration study will also gather data on the best ways to deliver PrEP and on how to engage migrants and other social groups who currently have relatively low awareness of PrEP.
France was the first European country to approve PrEP, in January 2016. It is available through hospitals, HIV testing centres and general practitioners and its cost is fully reimbursed by the country's health system.

The new study, called ‘Prévenir’ (prevent) focuses on Île-de-France, which is the region of Paris and its suburbs. HIV is concentrated in the capital region – of around 6000 new HIV diagnoses made in France in 2015, 2500 occurred in Île-de-France. Gay men are particularly affected.

The researchers are hoping to demonstrate that the scale-up of PrEP, with 3000 additional people taking PrEP, will reduce the rate of new infections in men who have sex with men in Île-de-France by 15%.

Helping participants work out which dosing schedule works best for them and how they can put it into practice will be peer counsellors from AIDES.

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Daily or on-demand PrEP?

A study in the Netherlands has looked at why gay men prefer daily or on-demand pre-exposure prophylaxis (PrEP), and why they switch from one to the other.

At the beginning of the AmPREP demonstration study, almost three-quarters (72%) of men chose daily PrEP and almost half (43%) of those who chose on-demand PrEP subsequently switched to daily PrEP. Only 14% of those who chose daily PrEP subsequently switched to on-demand PrEP.

In all, 83 out of 376 men enrolled in the study have switched from one mode to the other.

Daily PrEP users chose it because they wanted daily structure, or because they anticipated adherence problems with on-demand dosing, or because they expected to have frequent or
unplanned sex.

On-demand PrEP users chose it because they usually planned when to have sex, or had risky sex rarely, or had concerns about the toxicity of daily PrEP or their ability to adhere to it.

Men who switched from on-demand PrEP to daily PrEP did so because they were having risky sex more frequently or found it difficult to plan sex. A small proportion said that side-effects had made them switch from on-demand to daily PrEP.

Men switched from daily to on-demand PrEP because they were having less sex than expected, or didn’t like taking it every day, or had experienced side-effects. Adherence was rarely cited as a reason for switching by anyone in the study.

Although it was rare for men to stop PrEP, those who stopped did so mainly due to side-effects (8 out of 376 men who started PrEP), due to reduced sexual risk or lack of sexual opportunity.

The researchers say that their findings underline the importance of offering a choice of ways to take PrEP; programmes will need to recognise that needs are likely to change over time and that stopping, re-starting and changing PrEP dosing patterns will be common.

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First single-tablet protease inhibitor-based combination

Jean-Michel Molina at IAS 2017. Photo by Liz Highleyman, hivandhepatitis.com

Recommended antiretroviral therapy for first-line HIV treatment often involves single-tablet regimens that are taken as one pill, once daily. Taking fewer pills can improve adherence, but there are fewer single-pill options for second-line therapy. Many treatment-experienced people who have developed drug resistance may require a protease inhibitor, a drug class with potent and durable antiviral activity and a high barrier to resistance.
The first once-daily single-tablet regimen containing a protease inhibitor maintained viral suppression in almost everyone who switched after achieving undetectable HIV RNA on a multi-pill regimen, according to a report at the conference.

The EMERALD study evaluated the efficacy of switching to a single-tablet regimen – dubbed D/C/F/TAF – containing the protease inhibitor darunavir (Prezista), cobicistat as a booster, and emtricitabine and tenofovir alafenamide (TAF) as a nucleoside reverse transcriptase inhibitor (NRTI) backbone. This regimen was compared to maintenance treatment with a boosted protease inhibitor, emtricitabine and the older formulation of tenofovir, TDF (tenofovir disoproxil fumarate).

The study showed that 96% of people who switched treatment maintained an undetectable viral load 24 weeks later, and there was no difference in viral rebound between those who switched and those who remained on a multi-pill regimen.

The single-tablet regimen has been recommended for approval by the scientific committee of the European Medicines Agency and will be marketed as Symtuza in the European Union after formal marketing approval by the European Commission later this year.

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MK-8591, an experimental long-lasting antiretroviral drug

A new antiretroviral drug has the potential for once-weekly dosing, according to results of a study presented at IAS 2017.

MK-8591, also known as EFdA, is a long-acting nucleoside reverse transcriptase translocation inhibitor (NRTTI) that is being developed by Merck.
A study in 30 previously untreated people with HIV found that a single oral dose of the drug suppressed HIV replication by more than 90% for at least 7 days.

A study in rats showed that an injected formulation of MK-8591 might maintain adequate drug levels for six months or more.

MK-8591 was one of several long-acting antiretrovirals that attracted attention at IAS 2017. The conference also heard about the use of injectable cabotegravir for PrEP and four-weekly or eight-weekly injections with cabotegravir and rilpivirine for treatment of HIV.

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Antibody delays but does not prevent viral rebound after interruption of treatment

Trevor Crowell at IAS 2017. Photo by Liz Highleyman, hivandhepatitis.com

The first test of a broadly neutralising antibody to control HIV in people who stopped treatment showed only a modest effect, but researchers say they still hope that monoclonal antibodies, selected for their ability to neutralise many different variants of HIV, will have some role in the future treatment of HIV.

Researchers have explored a wide range of approaches for curing HIV, or more accurately, bringing about periods of long-term remission while off antiretroviral drugs. Most of these avenues have been disappointing so far, but researchers hold out some hope for broadly neutralising monoclonal antibodies, or bNAbs, that can disable multiple strains of HIV.

Trevor Crowell of the US Military HIV Research Program presented results of a small study of the antibody VRC01 in 19 people who had started HIV treatment very soon after infection. Study participants had undetectable viral load for two years before joining the study. Participants stopped treatment and received infusions of VRC01, or a placebo, every three weeks for 24 weeks.

The researchers monitored viral rebound. In the placebo arm, all but one participant had a
rebound within three weeks. In the VRC01 arm, rebound was slightly delayed. In two participants rebound was delayed by 7 and 9 weeks, and in another by 42 weeks. Study investigators are now looking for factors associated with delayed rebound before developing further studies of broadly neutralising antibodies.

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Stillbirth more common in women with HIV, UK and Ireland study finds

Graziella Favarato at IAS 2017. Image credit: Dr Heather Bailey (@DrHeatherBailey)

Women living with HIV are significantly more likely to experience pre-term delivery, to deliver babies with low birth weight and to have a stillborn baby. Much of the data on the risk of adverse birth outcomes come from sub-Saharan Africa and less is known about adverse birth outcomes in higher-income settings.

The stillbirth rate among women living with HIV in the UK and Ireland from 2007 to 2015 was more than twice that of the general population, Graziella Favarato, presenting on behalf of the National Study of HIV in Pregnancy and Childhood (NSHPC), told participants at the conference last week.
Adolescents with HIV do better in more prosperous African countries

While global access to antiretrovirals is expanding, the emerging population of adolescents with perinatally acquired HIV (passed on from mother to child during pregnancy, birth or breastfeeding) continues to grow. Eighty per cent of adolescents living with HIV live in sub-Saharan Africa.

Research presented at IAS 2017 showed that adolescents who acquired HIV perinatally were less likely to die, grew faster and had better immune restoration on treatment if they lived in upper-middle income countries in sub-Saharan Africa (Botswana, South Africa) when compared to the countries with the lowest income in Africa (e.g. Ethiopia, Malawi, Mozambique, Rwanda, Tanzania, Uganda, Zimbabwe).

The study looked at outcomes of 30,296 adolescents living with HIV in sub-Saharan Africa who entered care before the age of 10 years. In lower-income countries, 85% received antiretroviral therapy (ART) at some point, compared to 87% in lower-middle income and 95% in upper-middle income countries.

Of adolescents who had ever received ART, those in low- and lower-middle income countries had a two and a half- to three-fold greater risk of death than adolescents in upper-middle income countries.

Adolescents in upper-middle income countries also had the greatest improvement in height.

The results suggest that factors beyond the ART programme still play an important role in the health and wellbeing of adolescents with perinatally acquired HIV, said Dr Amy Slogrove,
presenting on behalf of the Collaborative Initiative for Paediatric HIV Education and Research (CIPHER) Global Cohort Collaboration Adolescent Project Team.

Nutrition, quality of health care and the burden of other infectious diseases are each affected by the income level of a country and each will have an impact on the survival, growth and immune status of adolescents.

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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 capsule summaries of important clinical data, downloadable slidesets and expert webinars.

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