SECOND EUROPEAN HIV PREVENTION SUMMIT

Brussels, January 29—31, 2016

Meeting Report

Background

Following the popularity of the first expert meeting on prevention held in January 2015, a second European HIV Prevention Summit was held on 29-31 January 2016. Organised jointly by the European AIDS Treatment Group (EATG) and AVAC, the meeting brought pharmaceutical companies, public health experts, academics and leading scientists in the field of prevention research together with over 50 European community based advocates for three days of information exchange and debate in Brussels. The meeting agenda and slide presentations delivered at the meeting can be found at: http://eatgavacprevention.tumblr.com/

The meeting explored four hot topics in HIV prevention in depth:

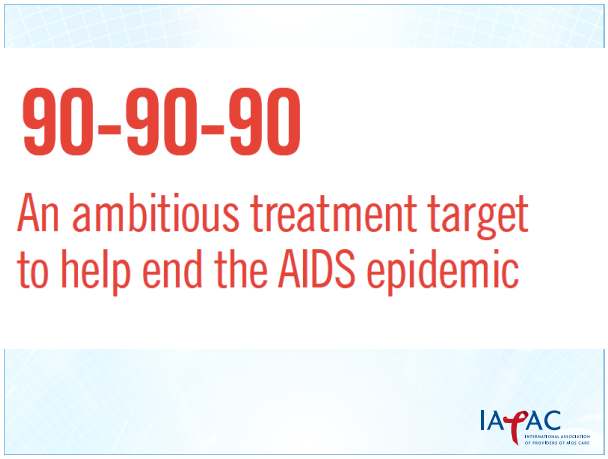
How do we get PreP to the people that need it in Europe?

This session reviewed the state of progress towards PrEP authorisation and access in the region to date. Updates were provided from four ongoing or concluded PrEP implementation studies in the UK, France, Belgium and the Netherlands, with powerful contributions from community-based PrEP activists in Germany, Greece and the UK. Noel Gill of Public Health England presented the results of a cost-effectiveness study designed to inform the upcoming decision of whether to make PrEP available on the NHS.

Considerable frustration was expressed that progress on PrEP remains so slow in Europe compared to the US. The strong demand for PrEP has been shown by the ease with which demonstration studies have been able to recruit – within 24 hours in the case of the Amsterdam study. Activists have begun to take matter into their own hands by providing information to gay men on how to import generic PrEP from abroad.

PrEP studies have given renewed impetus to HIV prevention efforts at the national level. Researchers and activists alike noted that PrEP should not be regarded as a purely biomedical intervention. It is acting as a catalyst towards better HIV behavioural interventions and relies on strong social packaging: "The advent of PrEP does not mean that we are dropping all the behavioural work we do in prevention. PrEP requires behaviour change and can act as a catalyst for change in someone's life and risk behaviour".

The discussion focused on a number of key questions that the community is grappling with, including how to ensure access to populations besides gay men, in Eastern Europe, and especially how to reach the "naïve risk takers". Concerns were also raised about people buying PrEP online without medical supervision. Participants also discussed whether the community should be demanding a lower price for Truvada as prevention. It was noted that the level of energy around PrEP is reminiscent of activism not seen in the HIV sector since the late 1990s. There is unjustified suspicion of PrEP but the community has legitimate questions that we must be able to answer.



What is the role of the Pharmaceutical industry in ending HIV and AIDS?

Three leading Pharmaceutical companies presented their prevention portfolios:

Gilead reported that 50,000 people are now taking Truvada as PrEP in the US. Most of this uptake is among gay men but the uptake is lowest among the gay men and MSM that need it most; among women there is no increase in numbers. The publication of CDC guidelines was the trigger for uptake among gay men. Gilead also noted that adherence in the second wave of PrEP studies [PROUD, Ipergay, Kaiser] improved because of community advocacy and awareness raising. The company continues to support PrEP trials all over the world by providing drug and technical assistance, and will file for regulatory approval on request. Gilead is looking into other drugs for PrEP and will commence a trial this year looking at the efficacy of F/TAF as PrEP, which will include European trial sites.

Janssen/J&J presented their preventative HIV vaccine development plan. The company is keen to find a global vaccine that works against all clades of HIV as part of its broader HIV portfolio. They are exploring viral vectors, mosaic and prime boost approaches and they are moving forward with a number of Phase 1/2a trials. In the second quarter of 2008, J&J will begin an efficacy trial with two studies. A proof of concept trial is meanwhile planned for 2017, for which European trial sites are needed.

ViiV provided an update on their HIV Prevention Programme, which is looking at a number of candidates as long-acting injectable (LAI) PrEP. Cabotegravir is an ideal injectable PrEP candidate for a number of reasons and the results of ÉCLAIR, a Phase IIa study among MSM in the US, are expected at CROI. HPTN077 is a Phase IIa safety, tolerability and acceptability study of an injectable HIV integrase inhibitor for PrEP in men and women. A Phase 3 study, HPTN 083, co-designed with Gilead to compare Cabotegravir with oral Truvada in men and trans women is planned. ViiV is also continuing to study oral Maraviroc for PrEP as an alternative to Truvada, and topical Maraviroc through the CHARM consortium. The results of the data in men from HPTN 069 will be presented at CROI, with data on women at a conference later in the year.

Generic manufacturer **Mylan** presented on the potential for generic ARVs in Europe. Mylan is keen to bring generic TDF/FTC to market within weeks of it coming off patent. Since there are different patent timelines in different countries and there can be multiple patents on the same drug, it will be complicated. A rolling introduction in Europe is likely. All their products are registered through the FDA or the WHO pre-qualification procedure.

The discussion period focused on pursuing greater clarity from Gilead as to their intent to file for regulatory approval for Truvada as PrEP from the EMA, the question of the difficulty in designing HIV prevention trials for new interventions in an era of PrEP, and how we can prepare for the introduction of generic options, including whether countries introduce TDF/3TC for PrEP. Advocates will need to continue good relationships with both the generic and branded sector as partners in ending AIDS.

Gateways to prevention: The contribution of testing and treatment to ending HIV

This session focused on key priority areas for Europe in terms of improving testing rates and access to treatment, with detailed updates from IAPAC, the European Centre for Disease Prevention and Control (ECDC) and ongoing EATG projects in this area.

Testing and treatment are more than ever inextricably linked to HIV prevention. The START study, by confirming that antiretroviral therapy (ART) is beneficial at all CD4 counts, removed any conflict

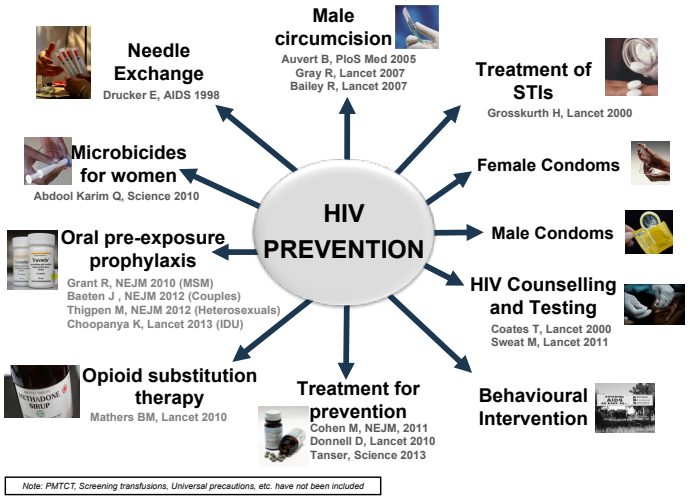
between providing ART for individual health and providing it for public health. This makes matters simpler: the aim then becomes to implement the right of each person with HIV to effective ART, and to identify and remove barriers to getting it.

The study of the HIV Care Continuum – the so-called "treatment cascade" – in different countries and regions is a useful surveillance and diagnostic tool in highlighting specific barriers and healthcare system weaknesses that prevent full access. Treatment cascades are evolving quickly as the new guidelines are taken up, but not quickly enough; one presentation highlighted the professional and institutional barriers, many of them grounded in outdated attitudes to HIV and ART, that leave too many people in many countries untested and undiagnosed.

It is important not to take individual HIV Care Continua at face value, as many are based on modelling or sketchy data, but look in depth at the detail in each context, including definition of terms as these differ by country. Nonetheless they can be useful in identifying which step in the cascade – testing, linkage to care, retention in care, ART provision, or adherence support and viral load monitoring – is weakest. Speakers highlighted numerous barriers, including the time-lag before new guidelines are implemented, lack of funding, persistent stigma, and legal and regulatory obstacles to increasing testing uptake. Asking the community for their specific and local experience of the barriers is crucial.

To highlight the scale of the challenge, representatives of organisations working in Russia and Ukraine shared their experiences of supporting women, children and people who use drugs to access services. The withdrawal of funding by the Global Fund is a major concern. The need for EATG and other actors to engage more in Russia and Ukraine was highlighted by participants, but the channels by which this is done will be important. Although there are tentative signs that the Russian government is finally realising the gravity of its HIV epidemic, it does not feel like that to individual workers providing care in the field, and it is important that western activists understand Russian political sensitivities. A strong plea was made for better horizontal communication between grassroots HIV activists and workers providing care in Western Europe and the numerous individual projects attempting to do the same in Russia, Ukraine and elsewhere in Eastern Europe.

The future is getting closer: Microbicides, vaccines and antibodies



In the fourth session, participants were update on key areas of ongoing HIV prevention research. Two new vaccine consortia funded by the European Commission's Horizon 2020 program were presented. The European AIDS Vaccine Initiative (EAVI) and the European HIV Vaccine Alliance (EHVA) will focus on generating preventive vaccine candidates to be taken forward by the European and Developing Countries Clinical Trial Partnership (EDCTP). The latter will also look at therapeutic approaches for people living with HIV - research closely linked to the search for a cure. The question of the ethics of treatment interruptions sparked hot debate; to guide such conversations EHVA is currently seeking community representatives to take up advisory roles. Together, these programs represent €45 million euros of funding, albeit a fraction of that invested by the US.

Another important research area is that of microbicides or topical PrEP, which includes rings, films and gels, and is the focus of the Microbicide Trial Network (MTN) in the US. Trials of oral PrEP in

young women have had mixed results and it is clear that biological differences mean higher concentrations in the rectum than the vagina. Adherence to gels and coitally dependent methods has been challenging. The efficacy results of the long-acting dapivirine vaginal ring, a product specifically designed to meet the needs of women having vaginal intercourse, are therefore eagerly awaited. Given the bias against women's products, the community will need to keep up the pressure if results are shown to be not that good.

Rectal microbicides meanwhile in the form of lubes, tablets, suppositories and enemas are being studied in terms of safety and acceptability. To address adherence challenges, there is considerable interest in long-acting PrEP injectables. These drugs remain in the body for many months, even years, which could be a major disadvantage.

What do we want to change?

The meeting concluded with a special session dedicated to addressing key areas for advocacy and action. Participants were divided into groups to produce recommendations. The following actions were proposed:

1.EATG should write to the EMA to urge rapid/ fast-track approval of Truvada as PrEP

2.All advocates need to coordinate their actions around PrEP – there is a need for a pan-European initiative that brings everything together

3. Map access to PrEP across the region, what is legal in terms of importing generics?
4. Ensure national guidelines are based on EACS and Paris models.
5. Community consultations on PrEP should be held with other key population networks such as IPPF, INPUD, NSWP
6. A meeting on trial designs needs to be held to answer key questions
7. Clarification is needed as to which PrEP combinations should be used e.g 3TC
8. EATG should seek clarification on Gilead's answer to the letter sent by EuroPrEP (European researchers)
9. Push for differential pricing for Truvada as prevention
10. Address the lack of funding for HIV prevention in general
11. Strengthen the EATG Prevention Portfolio – additional members of the Prevention Steering Committee are sought

On behalf of the organisers, Gus Cairns and Rebekah Webb closed the meeting with thanks to all the presenters, chairs, participants and those who worked behind the scenes to make the meeting a success. The meeting was closed with the issue of a joint press release.