

EATG position paper on HIV Prevention

European AIDS Treatment Group
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The European AIDS Treatment Group (EATG) was founded in 1991. It is a voluntary organization made up of 90 members from 34 different European countries. Our members are representatives of different communities affected by HIV/AIDS in Europe. Since its founding, EATG has been at the forefront of developing the civil society response to the HIV epidemic in Europe.

EATG's mission is to achieve the fastest possible access to state-of-the-art medical products, devices and diagnostic tests that prevent or treat HIV infection or improve the quality of life of people living with or at risk for HIV.

In responding to HIV, EATG also addresses major HIV co-infections, as well as other health issues that increase the risk of HIV infection. EATG's primary geographic focus is the 53 member states of the WHO European Region. For more information, visit www.eatg.org.

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Abbreviations

AIDS – Acquired Immunodeficiency syndrome
CDC - Centres for Disease Control and Prevention
EACS – European AIDS Clinical Society
EATG – European AIDS Treatment Group
ECAB – European Community Advisory Board
ECDC – European Centre for Disease Prevention and Control
EMA – European Medicines Agency
EU – European Union
HAART – Highly active antiretroviral treatment
HIV – Human Immunodeficiency virus
HSV-2 – Herpes simplex virus 2
ICSI – Intra-cytoplasmic sperm injection
IDUs – Intravenous drug users
GHVE – Global HIV Vaccine Enterprise
NONOPEP – non-occupational post-exposure prophylaxis
NPEP – non-occupational post-exposure prophylaxis
NPTs – New preventive technologies
PEP – Post-exposure prophylaxis
PrEP – Pre-exposure prophylaxis
STIs – Sexually transmitted infections
UK – United Kingdom of Great Britain and Northern Ireland
USA – United States of America
WHO – World Health Organisation

Executive Summary

1. HIV prevention as well as treatment is necessary if we are to control the HIV epidemic globally and in Europe. No one prevention intervention is ever likely to stop the epidemic by itself and EATG therefore demands a comprehensive response involving social, behavioural and biomedical interventions.
2. Europe has a heterogeneous epidemic involving all three main at-risk groups. There is equal heterogeneity in levels of support for prevention measures and in the legal constraints under which they operate. Not only the EU, but also the whole World Health Organisation (WHO) Europe area needs to work towards an effective and comprehensive approach to HIV prevention.
3. There is no such thing as a 'high risk person' or community. Individuals move in and out of high risk for HIV as their lives change. People therefore need a varied package of prevention interventions which should include access to condoms (male and female) and access to clean needles in all settings including prisons, opiate therapy where needed, information on HIV, behavioural support and interventions, and social support.
4. Much prevention provision in Europe is not evidence-based or is based on non-European evidence. EATG urges more scientific research, and additional funding for it, into behaviour change and support programmes to populations living in Europe, especially marginalised and invisible groups.
5. EATG considers that the HIV prevention needs of people already living with the virus have been neglected and that targeting HIV-positive people for prevention help and support would be an equitable and cost-effective way of preventing HIV. There needs to be more research into behaviour-change and support programmes for people with HIV and more support in general to help people with HIV negotiate safer sex and disclose to partners. It is also important to

combat social and cultural barriers against testing and disclosure, in particular the criminal prosecution of HIV transmission and exposure.

6. EATG supports moves to increase the proportion of people with HIV who are aware of their status, to extend HIV testing to more people and offer it in more settings, including community settings and in primary healthcare, and to investigate the potential positive and negative effects of legalising home testing. EATG opposes the use of 'provider-initiated' testing but does support the use of 'opt-out' testing in certain settings such as sexually-transmitted infections (STIs) treatment, antenatal care, and outreach programmes, as long as it occurs in an environment where all due process with regard to human rights and informed consent is followed.
7. EATG supports methods and technologies, which help to prevent HIV transmission between sero-discordant partners who have a desire for childbirth. Therefore, more countries should set up assisted reproduction centres for people with HIV and provide easier access to these technologies, including funding them.
8. EATG encourages counselling and offering voluntary HIV testing to every pregnant woman. EATG considers it extremely important for pregnant women, who are often treated as if their own health choices do not matter, not to be coerced into deciding whether to give birth, whether to test for HIV, and whether to take antiretrovirals. EATG opposes any stigmatising and discriminatory practices that exclude pregnant women from HIV healthcare, and urges that effective antiretroviral treatment be provided both to prevent transmission of HIV to the child *and* to secure the continued health of the mother.
9. EATG supports the adoption of a standard set of European guidelines on post-exposure prophylaxis (PEP), and continued awareness campaigns to alert communities to this important prevention measure.
- 10a. EATG supports continued research into new biomedical methods of prevention such as microbicides, pre-exposure prophylaxis (PrEP), prophylaxis

against other STIs, and vaccines. It urges better co-ordination of research efforts to avoid waste, duplication and failures in this field.

10b. These 'new prevention technologies' (NPTs) will suit different populations differently. For instance, the one intervention that has been shown to have efficacy, circumcision in men, is likely only to have impact in countries with generalised heterosexually spread epidemics. NPTs, if they do work, may work better in combination, and research should therefore not be preferentially directed towards one method. Research should, where feasible, investigate whether the intervention reduces HIV positive people's chance of transmitting HIV as well as HIV negative people's chance of acquiring it.

10c. Advocates need to strike a careful balance between mobilising support and funds for NPTs and creating unrealistic expectations that will be disappointed. They also need to advocate for researchers to strike an equally careful balance between making trials possible and ensuring that they are targeted at the right populations and that the risk of negative impact on those populations is minimised.

10d. If an NPT does prove to be effective, implementation programmes must be resourced fully, designed ethically, and targeted as the right populations.

Position paper

1. The general need for effective prevention

Without effective prevention programmes, mathematical models indicate that the number of people infected with HIV, globally and in Europe, is likely to continue to rise. The more widespread provision of HIV treatment may exacerbate this, because people with HIV will be living longer and more sexually active lives.

HIV prevention programmes can work. Examples include the provision of needle exchange and substitution therapy to injecting drug users, as in a number of European countries; national programmes providing and encouraging condom use, as seen in countries like Thailand; and – possibly – programmes encouraging partner reduction, seen in some African countries.

HIV prevention is intrinsically a complex endeavour. It involves dealing not just with the physical health of the individual, but with their psychological and emotional needs, their ability to make choices about their life and behaviour, and their socioeconomic position.

No single HIV prevention method that is currently available or likely to be available soon can be a ‘magic bullet’ that will stop HIV in its course; HIV prevention therefore needs a comprehensive response involving approaches on the biomedical, behavioural and social levels.

In addition marginalisation, stigma and discrimination affect HIV prevention programmes negatively. They impact on people’s ability to seek advice and care and to choose behaviours that do not risk HIV acquisition. Prevention programmes cannot work without social support and anti-discriminatory action.

2. The current situation in Europe

Europe faces a heterogeneous HIV epidemic or series of epidemics, including all three main modes of adult transmission (needle-sharing, male-female sex and male-male

sex). These epidemics range from long established and continuing to relatively new and expanding types, and include (in different proportions in different countries) two of the most stigmatised and marginal groups in society, injecting drug users and undocumented immigrants.

The picture in terms of the provision of HIV treatment and the constraints under which prevention programmes operate (such as the unavailability of needle exchange in some countries and of condom provision in prisons in most) is similarly varied. Not only the EU, but also the whole WHO Europe area needs to work towards an effective and comprehensive approach to HIV prevention.

3. The prevention needs of people at risk of HIV through sex

There is no such thing as a ‘high risk person’ or ‘high risk group’. Behaviours, not people, confer high risks of acquiring or transmitting HIV, and people may move in and out of HIV risk situations as their lives change. HIV prevention therefore needs to provide access to the right **combination** of information and of biomedical, behavioural and social interventions to the right **people** at the right **time** in the right **context**.

In terms of **resources** and prevention technologies, condoms are still the most effective method for preventing HIV transmission. EATG recommends the continuation and strengthening of funding for well-targeted condom distribution programmes. Behaviour-change programmes should never be funded in preference to condom-distribution programmes, and condoms should be provided as part of behaviour-change programmes.

In terms of **information**, most prevention programmes provide targeted and mass-media information and education resources. However there is evidence to suggest that information works best when it is coupled with the teaching of skills or with a degree of interactivity. As information cannot always be coupled to in-person interventions, more use should be made of innovative media such as the Internet and text messaging to provide a degree of skill building, interactivity and discussion.

In terms of **behaviour change programmes**, which offer counselling or skills-building to decrease risk behaviour and improve safer-sex skills, Europe as a whole and individual countries lack an evidence base which makes it possible to determine which programmes are likely to be effective, and which are not. One of the most glaring gaps in HIV prevention in Europe is the lack of co-ordinated scientific research into behaviour change programmes. This makes it impossible to compile a list of recommended interventions, in contrast to the USA, where one exists. EATG recommends the funding of a co-ordinated programme of research into which behaviour-change programmes are effective in European contexts.

4. The additional prevention needs of people at risk through injecting drug use

Eastern Europe continues to experience an epidemic of HIV spread through injecting drug use; whereas in many countries in Western Europe the spread of HIV has been contained, at an early or later stage, by the use of effective prevention measures. Indeed the provision of sterile needles and injecting equipment and opiate substitution therapy are probably the demonstrably most effective prevention interventions in the history of HIV. It is therefore purely political and cultural resistance that prevents the universal adoption of these measures. Economic, political and criminal interests also conspire to upkeep the current systems of criminalisation and pressure.

EATG will therefore continue to campaign vocally for the adoption of these measures in *all* countries of the WHO European region.

The stigmatisation and marginalisation of injecting drug users is also the reason for their disproportionate lack of access to HIV treatment and care in many countries in the region. Since antiretroviral treatment reduces the average infectivity of a group, and since integration into health care is a proven method of reducing social marginalisation, the provision of equitable HIV treatment, including antiretrovirals, is a prevention measure as well as a treatment measure, and EATG will continue to demand it.

5. The additional HIV prevention needs of people with HIV

Targeting HIV prevention at people who already have the virus and know about their status makes sense on an economic, social, legal and public health level: People who know they have HIV usually reduce their risk behaviour and have potentially greater power to ensure transmission does not happen. They have demonstrably greater sexual health and mental health needs. In some countries, they are at risk of prosecution for transmission, and everywhere they run the risk of being blamed and stigmatised for transmitting it.

Surprisingly few randomised controlled studies have been done into behaviour change interventions for people with HIV^{1,2} and almost none in Europe. EATG recommends that more should be done, and that a programme of research into behaviour change interventions for people with HIV be set up, possibly by European Centre for Disease Prevention and Control (ECDC).

Research shows that people with HIV adopt a variety of methods to attempt to reduce the risk of HIV transmission. Some of these are controversial. An example includes 'serosorting', or the attempt to restrict unprotected sex to other people living with HIV. This method is controversial because while it would be effective as an anti-HIV measure it exposes people with HIV to other infections (and possibly other strains of HIV), and is also fallible in that it relies on openly disclosed rather than assumed HIV status. A similar example is 'seropositioning': the attempt to limit transmission by choosing a receptive role as the HIV-positive partner in sexual encounters.

However insisting that 100% condom use (in people with HIV must be the sole aim of HIV prevention programmes is probably doomed to failure. It ignores situations in which people with HIV cannot use condoms and fails to respect the right of individuals within relationships to negotiate the dress of safety they want and which is compatible with other needs such as exploring their own sexuality, conceiving children, emotional closeness and trust.

¹ Johnson BT et al. Sexual risk reduction for persons living with HIV: Research synthesis of randomised controlled trials, 1993 to 2004. *JAIDS* 41(5): 642-650. 2006.

² Crepaz N et al. Do Prevention Interventions Reduce HIV Risk Behaviors Among People Living With HIV? A Meta-Analytic Review of Controlled Trials *AIDS*. 2006;20(2):143-157.

EATG's position on condom use and choice therefore is:

- “If you are going to have unprotected sex, always disclose your own status”
- “If you are unable or unwilling to disclose, always use a condom or do not have penetrative sex”
- “Where your partner's HIV status is different from your own or unknown to you, always use a condom or do not have penetrative sex”
- “Do not make assumptions about HIV status”

Sexual harm reduction relies on disclosure of HIV status as a strategy. However, many people with HIV are extremely limited in whom they can disclose their status to. In general disclosure can represent an intrinsically empowering act because to be *able* to speak the truth about one's status implies that one has already undergone a process of combating internal stigma and shame.

However disclosure should never be required as a legal or moral *obligation* on the part of people with HIV, People with HIV who wish to disclose their status should be supported to do so, programmes should be devised to facilitate disclosure skills, and research needs to be done into the efficacy of these programmes.

People with HIV also face social and cultural barriers against disclosure. The pervasive stigma against HIV makes people with HIV afraid to disclose and seek help and people at risk afraid to seek testing. In many countries the criminal prosecution of people with HIV for non-intentionally transmitting the virus or exposing others to it has had adverse effects on the doctor-patient relationship, upon research into risk behaviour, and on the willingness of people to be tested. EATG will campaign vocally against the stigmatisation of people with HIV and against the criminal prosecution of people with HIV for reckless transmission or exposure, except for intentional transmission.

6. Voluntary counselling and testing

The other thing people with HIV need in order to reduce the chance of transmitting the virus is to know their HIV status in the first place. Studies have shown that the majority

of people with HIV, once diagnosed, reduce their risk behaviour by anything from 25% to 85%. In addition, a quarter to a third of AIDS-related deaths in developed countries are now due to late diagnosis.

In the USA the Centres for Disease Control and Prevention (CDC) has proposed to make HIV testing a routine part of medical care on an 'opt-out' basis. In other words, to quote the CDC,³ "an HIV test is performed unless the patient specifically declines." Opt-out testing can only too easily become obligatory, non-consensual testing in situations where there are large power differentials between tester and testee. Healthcare providers may also be ignorant of the social context in which people vulnerable to HIV survive and may minimise the effect of anti-HIV stigma, both real and internalised. For this reason EATG opposes such blanket use of opt -out testing, a stance backed by the European AIDS Clinical Society (EACS). At the 2007 EACS conference the organisation's Jens Lundgren characterised universal opt-out testing as "not compatible with European philosophy."⁴

However, EATG does support measures to increase the number of settings in which HIV tests are offered and recognises that to fail to offer an HIV test in situations where it is clearly indicated amounts to neglecting the right of the patient to receive diagnosis and care. EATG therefore supports the use of opt-out testing in situations where it is reasonable to presume consent, as in patients seeking a check-up for sexually transmitted infections and (with all due regard to genuinely informed consent) antenatal care.

EATG believes that if HIV testing is made more available in more settings, patient choice and informed consent must be the principles on which it is founded, and that confidentiality and anonymity should be guaranteed. While it should not be assumed that all people coming seeking or who are offered an HIV test need counselling, they certainly need information, and counselling *must* be available, especially for those who test positive.

³ See <http://chppm-www.apgea.army.mil/dhpw/documents/HIVTestingRecommendations.doc>

⁴ Lundgren J, Gazzard B, Clumeck N. Optimal HIV testing and earlier care in Europe. Eleventh European AIDS Conference, Madrid, special session 3, 2007.

There should be more use of rapid testing and of community-based schemes and consideration should be given, like in the USA, for the legalisation of home testing kits as long as there are support structures in place for those who test positive. Advantage should be taken of the waiting time for results in rapid-testing schemes to offer brief safer-sex counselling to all having taken the test.

Valid HIV prevalence and incidence surveillance should be based on a coded or anonymised system, not on a name-based system.

In short, EATG supports increased use of opt-out testing as long as it is anonymised, and more widespread access to HIV testing in general in a variety of settings such as STI treatment, antenatal care, outreach programmes, community settings and primary healthcare, as long as it occurs in an environment where all due process with regard to human rights and informed consent is followed.

7. Reproductive technologies

Although recent papers have suggested that the risk of HIV infection in carefully-timed unprotected sex between HIV serodiscordant partners where the positive partner is on highly-active antiretroviral treatment (HAART) and has an undetectable viral load is so low as to be worth risking, many couples will still be unwilling to take this risk.

EATG therefore urges that more countries set up assisted reproduction centres for people with HIV and provides easier access to technologies like sperm washing and intra-cytoplasmic sperm injection (ICSI). Access to existing centres is expensive and inequitable and EATG urges that consideration be made towards some public funding for women with HIV positive partners who wish to conceive.

8. Mother-to-child transmission

We have the means to reduce mother-to-baby transmission of HIV to virtually zero. It is therefore shocking that in one year, 2004, 9200 babies were born with HIV in one country – Russia – and that 25 to 40% of all HIV-positive women who were delivering a baby did not seek prenatal care there, due to anticipated stigmatising attitudes,

refusal of service, and pressure to have a termination of pregnancy.⁵ What is if anything more shocking is that children are still being needlessly born positive to mothers who seek care late in Western Europe. One 2006 study found that 47% of HIV positive mothers attending one hospital in London gave birth with a viral load over 50 and 14% with a viral load over 1000.⁶ This was not due to ARV treatment failure but largely due to the failure of mothers to seek care until very late in pregnancy. The study authors directly ascribed this to fear of being charged for care among the patient group, many of whom are undocumented immigrants who are expressly excluded from free HIV treatment by UK government guidelines.

While it is extremely important for pregnant women, who are often treated as if their own health choices do not matter, not to be coerced into deciding whether to give birth, whether to test for HIV, and whether to take antiretrovirals and in what regimen, EATG is confident that the vast majority of women diagnosed with HIV would take steps to protect their baby from transmission if fully informed of the options.

We therefore oppose any stigmatising and discriminatory practices that exclude pregnant women from HIV healthcare, and urge that effective antiretroviral treatment be provided both to secure the continued health of the mother *and* to prevent transmission of HIV to the child.

9. Post-Exposure Prophylaxis (PEP)

PEP is the provision of a course of antiretroviral drugs to someone who has been involved in an HIV exposure risk. Where this risk is non-occupational, e.g. through sex or needle sharing, it is sometimes called NPEP or NONOPEP.

PEP is unlikely to make a large contribution to HIV prevention on a population level, largely because even people who are aware of it do not use it consistently or are poor at estimating which incidents have posed an HIV risk. However, while PEP may not

⁵ Ministry of Health of the Russian Federation, *Pregnancy and Births Among Women Living with HIV/AIDS in the Russian Federation, 2000–2001*, 27 June 2002, Moscow, Russian Federation.,

⁶ Forbes KM et al. *Use of antiretroviral therapy in pregnancy – how have BHIVA guidelines changed our practice?* Eighth International Congress on Drug Therapy in HIV Infection, Glasgow. Abstract P382. 2006.

make a difference to HIV prevention on a public health level, it may make a huge difference to the individuals involved, and to deny PEP is to deny people a chance of remaining HIV negative. Another reason people do not use PEP is because they are not aware of it. And when people are aware, barriers to seek PEP might exist.

While it is valid to have guidelines to ensure that PEP is not prescribed inappropriately, the application to the individual case should be based on the present risk to the individual rather than moralistic concerns or on their previous behaviour.

PEP use is well monitored in some countries and inadequately in others. EATG therefore recommends:

- That all HIV clinics in the European Medicines Agency (EMA) area should join the NONOPEP registry⁷
- That a consistent set of European guidelines should be established. These:
 - Should recommend up-to-date and tolerable regimens
 - Should set the time limit to PEP as 72 hours^{8, 9}
 - Should recommend PEP according to the riskiness of the incident, not according to who is asking for PEP or how many times they have sought it before
 - Should be reviewed periodically
- That continued awareness campaigns, particularly targeted at high-risk populations, are carried out in order to maintain public awareness of PEP.

⁷ Almeda J. *Putting Non-Occupational PEP Into Practice: What Are the Implications?* IAPAC European Sessions 2006, Budapest.

⁸ World Health Organisation. *Post-Exposure Prophylaxis To Prevent HIV Infection: Joint WHO/ILO Guidelines on post-exposure prophylaxis (PEP) to prevent HIV infection* p. 2007, p. 9.

⁹ Kindrick A et al. *HIV post-exposure prophylaxis following sexual exposure is started too late for optimal benefit*. Thirteenth Conference on Retroviruses and Opportunistic Infections, Denver, 2006. Abstract #906.

10. New Prevention Technologies

The New Prevention technologies (NPTs) form a group of biomedical interventions that are only now being evaluated for efficacy. None of the methods currently under study is a ‘magic bullet’, which will finally solve the problem of HIV transmission and render current approaches unnecessary. The NPTs are better viewed as additions to current HIV preventions, which may offer people at risk of acquiring or transmitting HIV new choices and/or additional degrees of safety.

Advocates for the NPTs therefore need to strike a balance between urging for trials of approaches that, were they to prove effective, might reduce HIV incidence, and in counselling caution both in study design and in conclusions that may be derived from studies.

Advocates also need to strike a balance, or call upon researchers to strike the right balance between making trials possible and making sure they are targeted at the right populations, thus ensure that the trial impacts negatively on participants. It is in the very nature of scientific trials that negative results – e.g. more HIV infections in the intervention arm – may happen, but trials must be designed such that avoidable risks are minimised and participants have access to established protection methods.

The fear has often been expressed that NPTs would simply cause people to abandon condoms and other current methods so that even if they would be effective the net effect on HIV transmission would be neutral or even negative (‘behavioural disinhibition’). In previous trials so far there has been little evidence of this but the way NPTs are introduced and information about them is disseminated will be crucial to ensure that behavioural disinhibition is minimised. One job of community advocates like EATG will be to ensure that accurate and comprehensible information and messages about their efficacy is disseminated to the community.

We do have one biomedical intervention where efficacy in preventing 50% or more of infections has recently been proved – male circumcision. The fact that mass circumcision programmes were not immediately put into action in countries with high-prevalence heterosexual epidemics, and that there is currently considerable debate not only over how to do this but about the ethics and social impact of doing it at all, shows

that proving efficacy will only be the start of the story with these interventions. This example also highlights two other dilemmas: how do we know what is an acceptable level of efficacy for a prevention method to be met before it can be recommended? And what do we do about efficacy methods that only directly protect some groups?

At this point of the discussion regarding the implementation of effective NPTs and current state of research, the biggest difference community advocacy may make is in urging that programmes are resourced fully, designed ethically, and targeted at the right populations.

An example would be pre-exposure prophylaxis: If this is shown to work, who will get it, in what parts of the world, and what changes need to be made to drug pricing policies and healthcare infrastructure to make its widespread use possible?

Research into some NPTs – microbicides, vaccines, even PrEP – is an evolving area of science and, as has already been found with HIV vaccines, the first few types of approach may not work, for one reason or another. One of the jobs of NPT advocates is to manage disappointment, to make it clear that the development of new methods of HIV prevention is a very long-term process and to advocate for sustained funding mechanisms that are not dependent on the success of specific trials or upon the policy of specific governments.

EATG also urges that all research into the new prevention technologies and biomedical interventions need to be *bi-directional*. This means that all research should include trials to establish whether the method can reduce the likelihood of a person with HIV transmitting the virus as well as of a person without the virus acquiring it.

i) Microbicides

The field of **microbicides** is already well served by organisations such as the International Partnership for Microbicides, the Global Campaign for Microbicides, and the International Rectal Microbicides Alliance. EATG supports the work of these organisations. EATG also supports microbicide development through its involvement in the EUROPRISE Network of Excellence.

There is already evidence that the first generation of microbicides taken into efficacy trials may not prove to have sufficient efficacy to be licensed. EATG urges that all funders of research programmes take careful consideration of the efficacy and biological plausibility of prevention methods before supporting large-scale efficacy trials.

Second-generation microbicides will involve antiretroviral drugs as active ingredients and EATG, primarily via the European Community Advisory Board (ECAB), will urge drug companies to become actively involved in microbicide development, not just in screening and off-licensing possible candidate compounds, but in actively developing microbicides themselves.

What little microbicide research has been done with the intensely at-risk populations of Eastern Europe has sponsored by US organisations like Family Health International and the National Institutes of Health. EATG urges that European researchers get more involved in microbicide development in Russia and the Newly Independent States.

ii) Pre-exposure Prophylaxis (PrEP)

PrEP is an approach that may work as prevention in populations where microbicides will not (ie in injecting drug users), and it has other advantages - such as easy concealment. Despite the controversies that have arisen about this prevention method, EATG therefore urges that ongoing and planned studies are completed to find out if this approach can work.

In practice PrEP is likely to be taken intermittently rather than regularly and EATG supports the concept of a trial of intermittent PrEP amongst MSM in several countries, including European countries.

EATG urges for pan-European PrEP trial amongst MSM, and would like to see similar studies funded amongst injecting drug users in high-prevalence countries for intravenous drug users (IDUs) and amongst serodiscordant couples.

EATG stresses that condoms and proper safer-sex counselling be provided to all participants (not just an orientation session at the start of the trial), and that the option of PEP also be provided for use in situations of unintentional or regretted exposure.

EATG would also like the problem of the relative isolation of PrEP within the NPTs field to be addressed: it is not structured into initiatives like EUROPRISE. Once some kind of efficacy is established, it may be important to do trials of PrEP in combination with other approaches.

iii) Vaccines

The recent failure of the STEP study (a Multicenter, Double-Blind, Randomized, Placebo-Controlled Phase II Proof-of-Concept Study to Evaluate the Safety and Efficacy of a 3-Dose Regimen of the V520 Vaccine in Adults at High Risk of HIV-1 Infection) has been a setback for vaccine development and EATG urges that both researchers and vaccine advocates take stock of the results and investigate them fully before proceeding further in HIV vaccine development, particularly when researching CD8-response vaccines using vectors such as the V520 vaccine in the STEP study.

HIV vaccine development has suffered from competitiveness, duplication and lack of co-ordination and information flow between researchers is vital or teams of scientists may pursue what they consider a 'promising direction' in ignorance of results that already invalidate it or mean it requires modification.

EATG therefore welcomes the establishment of co-ordinating bodies such as the Global HIV Vaccine Enterprise (GHVE), and it urges that GHVE be given real power and influence in the decisions taken about which directions to pursue.

EATG urges that HIV vaccine studies, especially of CD8 vaccines that stimulate the cellular immune response, should include arms that study their effect on people with HIV infection. From a prevention point of view these studies would include addressing the question whether they bring about long-term reductions in viral load. This is not just because therapeutic vaccination is neglected as a concept, but because we are still far from an exact understanding of how HIV damages the immune system and for this reason it is important to include both acutely and chronically infected people in trials of immune interventions.

iv) Circumcision

Male circumcision is the first biomedical intervention other than condoms that has so far been shown to be at least 50% effective in reducing HIV infections as part of a

randomised clinical trial. Despite this, it is extremely important that any promotion of this method of prevention:

- Takes account of circumcision's special position as a cultural and religious signifier;
- Respects the rights of any and every man both to seek circumcision as an HIV/STIs prevention measure, and to refuse it;
- Ensures that the operation is carried out in a safe and sterile environment;
- Ensures that recipients of circumcision are warned that it only reduces, not eliminates, the probability of HIV infection, and does not directly protect women or anally receptive men.

Circumcision as an answer to HIV has almost entirely centred on Africa and therefore of its efficacy amongst a generalised, heterosexually-driven epidemic. EATG urges that researchers continue and initiate studies of circumcision amongst female partners (this is being done in Rakai in Uganda) and amongst gay men in order to find out if these communities will be offered any protection by the measure.

Europe, which has lower rates of circumcision than the USA, is in many respects a good place in which to conduct a circumcision trial amongst at-risk heterosexuals, in particular, and possibly amongst gay men. Even before funding is sought, however, there needs to be community assessment to find out whether this would be an option acceptable to enough people to make a trial feasible in terms of numbers of trial participants.

v) STIs prophylaxis

Some studies have shown that using drugs to suppress herpes (HSV-2) in people with and without HIV can reduce levels of acquisition and transmission of HIV, though other studies indicate the effects might be modest. These studies have been mainly done in women.^{10, 11, 12}

¹⁰ Nagot N et al. *Impact of valaciclovir on genital and plasma HIV-1 RNA: a randomised controlled trial among women taking HAART (ARNS 1285b)*. Sixteenth International AIDS Conference, Toronto, abstract TUPE0402, 2006.

Gay men have very high levels of HSV-2, and EATG suggests that a community study of acyclovir or valaciclovir prophylaxis amongst HIV negative and HIV positive gay men in order to find out whether the suppression of HSV-2 replication and shedding in this population reduces the risk of HIV acquisition and transmission.

vi) Early HIV treatment as a prevention intervention

HAART drastically reduces viral load and with it the average infectiousness of the person taking it. A large international trial of early provision of HAART as a prevention measure amongst serodiscordant heterosexual couples is underway.¹³

However, studies indicate that casual sex, particularly with people with STIs or on early infection, is more likely to lead to transmission of on HIV. Despite this, there are studies showing that people with HIV and their partners, especially within the gay community, are already using viral load as criterion to decide whether or not to have unprotected sex.

This question was given additional urgency last year when the Swiss Federal Commission on HIV/AIDS announced that in its opinion “An HIV-infected person on antiretroviral therapy with completely suppressed viraemia (“effective ART”) is not sexually infectious, i.e. cannot transmit HIV through sexual contact.”¹⁴

EATG therefore believes that there is a need for epidemiological and clinical research, amongst gay men in particular, to establish whether people with undetectable plasma viral loads are able to transmit HIV and if so how often. This would be a difficult study to conduct in a randomised way as it would essentially mean contact-tracing the partners of recently infected people. However, it may be possible to do a study of HIV infection amongst newly (less than six months old) serodiscordant relationships,

¹¹ Dunne E et al. *The effect of suppressive aciclovir therapy on HIV cervicovaginal shedding in HIV- and HSV-2-infected women, Chiang Rai, Thailand.* Fourteenth Conference on Retroviruses and Opportunistic Infections, Los Angeles, abstract 30, 2007

¹² Delany S et al. *Impact of HSV-2 suppressive therapy on genital and plasma HIV-1 RNA in HIV-1 and HSV-2 seropositive women not taking ART: a randomised, placebo-controlled trial in Johannesburg, South Africa.* Fourteenth Conference on Retroviruses and Opportunistic Infections, Los Angeles, abstract 154LB, 2007.

¹³ See http://www.hptn.org/research_studies/HPTN052.asp

¹⁴ Vernazza P et al. *Les personnes séropositives ne souffrant d'aucune autre MST et suivant un traitement antirétroviral efficace ne transmettent pas le VIH par voie sexuelle.* Bulletin des médecins suisses 89 (5), 2008.

relating the incidence of infection to the HIV positive partner's viral load, though this would take a large cohort.

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