



European
AIDS Treatment
Group

POSITION ON HIV PREVENTION

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Preface

The first EATG position paper on HIV prevention was written in 2009. Since that time there have been major breakthroughs in this field, especially in our understanding of how antiretroviral therapy (ART) impacts on the transmissibility of HIV and the role that antiretroviral drugs (ARVs) can play in prevention.

This updated position paper on prevention is designed to reflect the consensus of the EATG membership on HIV prevention, particularly in relation to new advancements in the field. It incorporates language from several key policy documents recently endorsed or developed by EATG, including the 'HIV Prevention Manifesto' and the 'Community Consensus Statement on Treatment as Prevention'. It also draws on the conclusions from recent meetings organised jointly by EATG with other partners including the New Developments in HIV prevention meeting in January 2015 and the Fear No More consultation in June 2015.

Acknowledgements

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Acronyms

ART	Antiretroviral treatment
ARVs	Antiretroviral drugs
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
MSM	Men who have sex with men
OST	Opioid substitution therapy
PEP	Post-Exposure Prophylaxis
PMTCT	Prevention of Mother to Child Transmission of HIV
PREP	Pre-Exposure Prophylaxis
STI	Sexually transmitted infection
TB	Tuberculosis
VCT	Voluntary Counselling and Testing
VMMC	Voluntary Medical Male Circumcision
WHO	World Health Organisation

Summary of EATG recommendations

Prevention overall

- EATG calls for the improvement and expansion of access to HIV prevention tools and strategies in Europe, particularly for key affected populations.
- EATG supports the human rights, dignity and self-determination that enable people to make the choices that most benefit their health and wellbeing and that of their partners.
- EATG will campaign vocally against the stigmatisation of people living with HIV and against the criminal prosecution of people living with HIV for non-disclosure, potential or perceived exposure and/or allegations of non-malicious transmission.
- EATG recommends the funding of a co-ordinated programme of research, developed with the full involvement of affected communities; to further understand which prevention programmes are most effective and acceptable in European contexts.

Testing

- EATG is in favour of the facilitation of HIV testing for members of all populations, and especially of key affected populations. EATG opposes medical, legal, cultural and economic climates that make diagnosis a catastrophe or something to be feared.
- EATG nonetheless supports the right of people to not test or to delay it, but stresses that it is a matter of good medical and social practice to ensure that people are as fully informed as possible of the benefits of testing, and that they receive support to help them continue to make the best choices for their health and overall quality of life.
- EATG opposes blanket use of opt-out testing. 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 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 and as long as it occurs in an environment where all due process with regard to human rights and informed consent is followed.
- EATG 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.
- EATG opposes any proposals to introduce compulsory or coerced HIV testing.

The prevention benefits of treatment

- EATG calls for much better public information to be made available in Europe and globally about the prevention benefits of ART, and that HIV-positive people with undetectable viral loads are not infectious.
- EATG will continue to push for increased and sustainable access to treatment across the region and support advocates in countries where governments are not meeting their responsibilities. In

particular, EATG calls for good access to non-judgmental medical care for all people diagnosed with HIV and the removal of all barriers to access to, and retention in, care for key populations.

- EATG opposes any proposals to introduce coerced ART for people living with HIV.
- As with testing, EATG supports the right of people to not take HIV treatment or to delay it, but stresses that it is a matter of good medical and social practice to ensure that people are as fully informed as possible of the benefits of treatment, and that they receive support to help them continue to make the best choices for their health and overall quality of life.

PrEP

- EATG calls for much better public information about PrEP to be made available across Europe, especially among key populations, so people can make good judgement of their HIV risk and their need of PrEP, of its dosing, benefits and possible risks.
- EATG has called for greater transparency from the EMA and Gilead Sciences on the question of licensing Truvada® as PrEP in Europe.
- EATG recommends that for now only daily PrEP be recommended for heterosexuals as there is no evidence as yet that intermittent PrEP works as well as daily PrEP for women or for men whose exposure to HIV is penile/urethral alone.
- EATG supports continued PrEP implementation research among under-studied groups, including refugees and migrants, female sex workers, trans* women and men, drug users who are also at risk of HIV exposure through sex, prisoners, adolescents and other key affected populations.

Other prevention strategies

- EATG will continue to campaign vocally for the adoption of harm reduction for people who use drugs and decriminalisation of drug use in all countries of the WHO European region.
- EATG recommends that a consistent set of European PEP guidelines should be established and that continued awareness campaigns are carried out in order to maintain public awareness of PEP.
- EATG recommends the continuation and strengthening of funding for well-targeted condom distribution programmes.
- EATG calls for national information campaigns on the benefits of circumcision directed at heterosexual men in the African diaspora (or men with another reason to be at higher than usual risk of HIV).
- EATG opposes any stigmatising and discriminatory practices that exclude pregnant women from HIV healthcare or prevent/discourage women living with HIV from becoming pregnant.
- EATG supports the continued availability of reproductive technologies for couples who may wish to be 100% sure of safe conception.
- EATG calls for services urgently to be developed to meet the specific needs of people who are engaged in chemsex (the use of recreational drugs in a sexualised context).

Research

- EATG urges European donors to continue their role as key funders of HIV prevention research programs including vaccines and microbicides.
- EATG asks that research into biomedical prevention be conducted with as much attention to the prevention needs of people already living with HIV as to people who are HIV negative.

- EATG supports the continued use of surveys to establish people’s understanding of vaccine and cure research, what they want from it, and the risks they may be prepared and not prepared to take as test subjects.

1. The General Need for Effective Prevention

Without effective prevention programmes, mathematical models indicate that the number of people living with HIV, globally and in Europe, is likely to continue to rise¹. We therefore need to improve and expand access to the HIV prevention tools and strategies for key affected populations at increased risk of HIV acquisition. In Europe this includes men who have sex with men, trans* people, people in prison, people who inject drugs, sex workers, refugees and migrants².

The “Prevention Revolution”

HIV prevention programmes can work. Traditional 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.

The landscape of HIV prevention however has completely changed with the recent advancement in our knowledge of the crucial role that ARVs can play in reducing both the transmission and acquisition of HIV. It would be tempting to think therefore that traditional strategies or new prevention options are no longer needed. However there is plenty of reason to believe that treatment alone will not lower HIV incidence in all populations. The increase in diagnoses among gay men, in particular, suggests that in this group the vulnerability to HIV and incidence of acute infections is too high to be dealt with by HIV treatment alone. Many people living with HIV are unaware of their status and are most likely to pass on HIV infection before they are tested and commence treatment. It is therefore essential that HIV prevention efforts are continued and scaled up alongside treatment access.

Critical enablers and building prevention competent communities

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.

In each society, factors such as stigma³ and discrimination, gender inequality, violence, lack of community empowerment, violations of human rights, and laws and policies that criminalise HIV exposure and non-disclosure, diverse forms of gender identity and sexuality and drug use can play a major role in limiting HIV prevention efforts⁴.

Marginalisation, stigma and discrimination and human rights violations affect all HIV prevention programmes negatively. They impact on people’s ability to seek advice, testing and care and to choose behaviours that do not risk HIV acquisition. In many countries for example, the vulnerable populations

¹ Transformation of HIV from pandemic to low-endemic levels: a public health approach to combination prevention; Alexandra Jones et al. The Lancet - 19 July 2014 (Vol. 384, Issue 9939, Pages 272-279) DOI: 10.1016/S0140-6736(13)62230-8.

² Dublin Declaration reporting does not attempt to define migrants, as countries use the term migrants in different ways. In the context of HIV, countries refer to three main groups: migrants from countries with generalised HIV epidemics; migrants who are part of particular sub-populations at increased risk of HIV infection, such as men who have sex with men (MSM), sex workers and people who inject drugs (PWID); and labour migrants. <http://ecdc.europa.eu/en/publications/Publications/dublin-declaration-migrants-2014.pdf>

³ Throughout the paper, references to stigma include self-stigma or internalised stigma.

⁴ WHO. Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations, July 2014.

that need ART most have the worst access to HIV services in part due to criminalization, stigma and systematic violations of human rights. The health and prevention benefits of ART will be undermined if these are not simultaneously and urgently addressed. Prevention programmes cannot work without social support, community engagement and anti-discriminatory action and must always be linked to care. Biomedical, structural and behavioural interventions need to be delivered in the context of a community-centred mobilization for health and rights.

The recognition of the efficacy of effective biomedical prevention methods, and their integration into existing programmes, may be an opportunity to refresh, rethink or challenge community norms that are not sufficiently protective, are difficult or impossible to sustain for some people, or are counterproductive. Typically these norms have required 100% adherence to a strategy such as condom use or sexual abstinence before marriage, or define condomless sex as unsafe in all contexts. EATG supports the human rights, dignity and self-determination that enable people to make the choices that most benefit their health and wellbeing and that of their partners.

Part of HIV prevention is also ensuring that our language around HIV is positive and blame-free⁵. Rhetoric that talks prematurely of the 'elimination' or 'eradication' of HIV is stigmatising and unhelpful. A key aim of HIV prevention programming should be to promote changes that reduce vulnerability to HIV and support individuals in reducing risk and avoiding harm with evidence and human rights based approaches.

The decision to test, to take HIV treatment or to take other steps to reduce the risk of HIV infection or transmission are fundamental individual rights. EATG supports the right of people to not test or to delay it, but stresses that it is a matter of good medical and social practice to ensure that people are as fully informed as possible of the benefits of testing and that they receive support to help them continue to make the best choices for their health and overall quality of life.

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 needs a comprehensive response involving strategically combining approaches on the biomedical, behavioural and social levels. It is increasingly recognised that only 'combination prevention' strategies tailored to specific epidemics and populations will bring an end to the HIV pandemic.

2. The Current Situation in Europe⁶

Europe is home to over 2.2 million people living with HIV, and the numbers of infections continue to rise at a rate that is 'unacceptably high'⁷. The most significant challenges in the region include high numbers of undiagnosed infections, still limited access to treatment - particularly in Central and Eastern Europe - and high levels of co-infection with TB and viral hepatitis⁸. The region as a whole 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) some of the most highly stigmatised and marginalised groups in society - injecting drug users, sex workers and undocumented migrants and refugees. HIV infections are also increasing particularly

⁵ Welbourn A. HIV and AIDS: language and the blame-game, 27 July 2015. <https://www.opendemocracy.net/alice-welbourn/hiv-and-aids-language-and-blame-game>

⁶ Europe is defined throughout this paper as the WHO European Region, which includes the 28 countries of the EU and 25 other countries.

⁷ ECDC. Evidence Brief: HIV Prevention in Europe, 2015.

⁸ WHO, 2015. <http://www.euro.who.int/en/health-topics/communicable-diseases/hiv/aids/hiv/aids>

among men who have sex with men, trans* people, people in prison, and sex workers. The vertical transmission of HIV remains an issue in some contexts.

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 most, especially in prisons), is similarly varied. Not only the EU but the whole WHO Europe region 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’. There are certainly key affected populations, but behaviours, not people, confer high risks of acquiring or transmitting HIV, and individuals 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.

The prevention needs of people at risk of HIV through sex are distinct from those at risk of HIV through injecting drug use (although of course people who use or inject drugs can face both risks). In Europe, those at highest risk of HIV via sexual transmission include migrants and refugees, gay men (especially those under 24 years), young women, sex workers and prisoners⁹. Youth unemployment is high and growing in Central and Eastern Europe. The incidence of casual sex work and related drug use are increasing factors in transmission¹⁰. HIV prevention efforts need to be targeted at the needs of these specific populations.

Recently, there have been concerns that HIV risk is increasing due to ‘chemsex’, a specific form of recreational drug use, whereby gay men take one or more of drugs such as mephedrone, GHB/GBL and crystal methamphetamine to facilitate or enhance sex. Chemsex is a phenomenon across Europe, predominantly in large urban centres. A study of recreational drug use, polydrug use, and sexual behaviour in HIV-diagnosed men who have sex with men in the UK however found that the overall prevalence of higher-HIV-risk serodiscordant condomless sex was low (7%)¹¹.

It is important that this phenomenon is better understood, and further evidence needs to be gathered across the region in order to design best practice interventions. Since some drugs are injected, there is a need for closer collaboration between activists for MSM prevention and harm reduction activists for people who inject drugs to share best practice.

The HIV prevention needs of chemsex users and especially injectors may not be met by traditional drug-user services. A key aspect of this is that many chemsex injectors or “slammers” do not consider themselves as ‘people who inject drugs’. There are almost no services that do meet the specific needs of ‘slammers’ and EATG calls for these urgently to be developed.

Further training may be required for health care professionals working in sexual health services on harm reduction practices. EATG recognizes the need for closer collaboration and community perspective provision to health care professionals in order to effectively address these issues.

⁹ ECDC, 2015.

¹⁰ <http://www.aidsmap.com/Recession-and-income-inequality-have-fuelled-HIV-infections-in-European-drug-users/page/2892573/>

¹¹ Daskalopoulou M et al. Recreational drug use, polydrug use, and sexual behaviour in HIV-diagnosed men who have sex with men in the UK: results from the cross-sectional ASTRA study, in: *The Lancet HIV*, 2014; 1: e22–31.

4. The Prevention Needs of People at Risk through Injecting Drug Use

Europe, particularly in the East of the region, continues to experience an epidemic of HIV acquired through injecting drug use; whereas in many countries in Western and Central Europe the spread of HIV has been largely contained, at an early or later stage, by the use of effective prevention measures¹². Indeed the provision of sterile needles and injecting equipment and opiate substitution therapy are among 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 harm reduction for people who use drugs and decriminalisation of drug use in all countries of the WHO European region.

The stigmatisation, marginalisation and criminalisation 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 Prevention Needs of People Living with HIV

Offering HIV prevention support, and effective prevention methods, to people already living with HIV and know about their status can be beneficial on an economic, social and public health level: People who know they have HIV usually reduce their risk behaviour and have potentially greater knowledge to ensure transmission does not happen. People living with HIV have demonstrably greater sexual health and mental health needs. In some countries, they are at risk of prosecution for transmission, exposure or non-disclosure, and everywhere they run the risk of being blamed and stigmatised for new HIV infections.

People living with HIV now have the comfort of knowing that by taking HIV treatment, they are dramatically reducing their risk of passing on their infection. Even before this was known, research showed that people with HIV adopted a variety of methods to attempt to reduce the risk of HIV transmission, such as 'sero-sorting' and 'sero-positioning'. Some people (both living with, and at risk of, HIV) may now choose to select partners who are 'HIV positive and undetectable' as opposed to those who state they are HIV negative, on the basis that the former actually poses less HIV risk¹³.

Disclosure

Until recently, one strategy of sexual harm reduction was an (over) reliance on disclosure of HIV status. With widespread acknowledgment of the additional prevention benefit of treatment as well as the rollout of PrEP, this is changing. It remains the case however that many people with HIV are extremely limited in whom they can disclose their status to. Whilst disclosure can represent an empowering act

¹² However, outbreaks resulting in a significant number of new cases in people who inject drugs have been reported in some EU/EEA countries. ECDC, HIV Prevention in Europe, September 2015.

¹³ <http://www.positivelite.com/component/zoo/item/fuck-poz-guys>

because being able to speak the truth about one's status implies that one has already undergone a process of combating internal stigma and shame, it is not necessarily an effective HIV prevention method¹⁴.

Although disclosure should be encouraged, it should never be required as a legal or moral obligation on the part of people living with HIV. People living 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 living with HIV also face social, economic and cultural barriers against disclosure. The pervasive stigma against HIV makes people living with HIV afraid to disclose and seek help, and people at risk afraid to seek testing. In many countries the criminal prosecution of people living with HIV for non-intentionally transmitting the virus or potentially 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 living with HIV and against the criminal prosecution of people living with HIV for non-disclosure, potential or perceived exposure and/or allegations of non-malicious transmission¹⁵.

6. Proven Prevention Strategies

6.1. Voluntary Testing and Counselling

Knowing one's own HIV status is the first step in reducing the chance of acquiring or transmitting the virus. Studies have shown that once diagnosed, the vast majority of people reduce their risk behaviour by anything from 25% to 85%^{16 17}. In Europe, only half of all people living with HIV know their status¹⁸ and similarly almost half of reported HIV cases are diagnosed late. The proportion of late presenters is highest among heterosexual people coming from countries with generalised HIV epidemics (59%) and then among people who inject drugs (56%). More than one third of men who have sex with men are also diagnosed late¹⁹. The unnecessary personal and society harm done by late presentation cannot be overstated.

HIV testing is critical in terms of both treatment and prevention. Early diagnosis enables people living with HIV to start treatment at the most appropriate time for them, increasing their chances of living a long, healthy life. Testing decreases the proportion of those who may be passing on HIV unknowingly. HIV testing is also important because people who do not have HIV can then take steps to remain HIV negative²⁰.

EATG is in favour of the facilitation of HIV testing for members of all populations, and especially of key affected populations. The civil rights implications of an HIV diagnosis are far more serious, and harder to hide, for some sections of the population (e.g. female sex workers) than others and in some areas. EATG opposes medical, legal, cultural and economic climates that make diagnosis a catastrophe or something

¹⁴ <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4536943/> and <http://www.ncbi.nlm.nih.gov/pubmed/20024704>

¹⁵ EATG. Position Paper on HIV criminalisation and <http://www.hivjustice.net/moreharm/>

¹⁶ Marks G et al. *Meta-analysis of high-risk sexual behaviour in persons aware and unaware they are infected with HIV in the United States*. JAIDS, 39(4):446-53, 2005.

¹⁷ McClelland RS et al. *HIV-1 acquisition and disease progression are associated with decreased high-risk sexual behaviour among Kenyan female sex workers*. AIDS 20(15): 1969-1973, 2006.

¹⁸ WHO, 2015. <http://www.euro.who.int/en/health-topics/communicable-diseases/hiv/aids/hiv/aids>

¹⁹ ECDC, 2015. <http://ecdc.europa.eu/en/publications/Publications/dublin-rome-10-years-hiv-europe-central-asia.pdf>

²⁰ ECDC. HIV Testing in Europe, 2015.

to be feared. Testing must be offered in a way people can and will use, without fear of exposure and without compulsion.

Opt-out testing

'Opt-out' testing, whereby individuals are assumed to have given consent unless they state a preference not to receive an HIV test, 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 external and internalised. For this reason EATG opposes such blanket use of opt-out testing, a stance echoed by the European AIDS Clinical Society, which in 2007 characterised universal opt-out testing as "not compatible with European philosophy."

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. Counselling is an important opportunity to talk about risk reduction and to discuss the evidence for the benefits of knowing one's status.

There should be more use of rapid testing and of community-based schemes. Advantage could be taken of the waiting time for results in rapid-testing schemes to offer brief safer-sex counselling to all having taken the test. It should not however, be presumed that people coming forward for an HIV test need counselling; they may already be fully informed and simply wish to take a 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 as long as it occurs in an environment where all due process with regard to human rights and informed consent is followed. It also supports more widespread access to HIV testing in general in a variety of settings such as STI treatment, antenatal care, outreach programmes, community settings, primary and emergency healthcare. EATG opposes any proposals to use compulsory or coerced HIV testing as a public health measure.

Home testing/Self testing

Home testing kits for HIV became legal in much of Europe in 2014 and the UK and France have updated their legislation. In theory, this technology should make testing easier and safer for some people, though there is a lack of evidence yet on how exactly it is going to be used. Concerns remain around the support structures in place for those who test positive, especially when Europeans can purchase a test kit in a country other than their own and therefore without the local support and materials in their own language. Home testing kits should be cheaper and made more widely available.

Comprehensive sexuality education and prevention support

All young people should receive accurate information about how HIV is transmitted and ways in which they can reduce their risk. This should be a fundamental component of the comprehensive sexuality education (CSE) they receive in school, but should also continue into adulthood.

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.²¹ As information cannot always be coupled to in-person interventions, more use should be made of innovative media such as the internet and other digital media to provide a degree of skills-building, interactivity and discussion without sacrificing essential face to face dialogue.

A number of HIV prevention programs are looking at ways in which 'e-health' could be used to support people reduce their risk. E-health includes all healthcare and prevention practices supported by electronic processes and communication (such as applications and links on smartphones), which are not necessarily covered by the social media channels²².

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.²³ EATG recommends the funding of a co-ordinated programme of research, developed with full involvement of affected communities, to further understand which prevention programmes are most effective and acceptable in European contexts.

6.2. The Prevention Benefits of Treatment

ARVs can effectively prevent both vertical and horizontal HIV transmission. EATG calls for much better public information to be made available in Europe and globally about the prevention benefits of antiretroviral therapy (ART), and in particular the fact that HIV-positive people with undetectable viral loads are not infectious. Widespread ignorance of this fact helps perpetuate stigma against and criminalisation of people living with HIV and it should be the subject of a funded public awareness campaign, possibly to run in conjunction with a PrEP awareness campaign.

It has been known for years that ARVs can effectively prevent HIV transmission. ART reduces women's risk of transmitting HIV via breastfeeding; and there are a range of strategies that use ARVs (individual antiretroviral drugs and/or combinations) to reduce risk of HIV vertical transmission during pregnancy and labour²⁴. However there is now conclusive scientific evidence that HIV treatment can dramatically reduce the chance of horizontal transmission between adults.^{25 26}

The primary data come from a trial known as HPTN 052, which enrolled 1,763 serodiscordant couples (one HIV-positive and one HIV-negative partner) to look at ARV treatment as prevention in a number of countries. It asked whether initiating treatment in the HIV-positive partner could help reduce the risk of

²¹ Albarracín D et al. *A test of major assumptions about behaviour change: a comprehensive look at the effects of passive and active HIV-prevention interventions since the beginning of the epidemic*. Psychological Bulletin 131(6), 856-897, 2005

²² ECDC. Understanding the Impact of Smart Phone Applications on MSM Sexual Health and STI/HIV Prevention In Europe. Meeting Report, Stockholm February 2015.

²³ See <https://effectiveinterventions.cdc.gov/>

²⁴ <http://www.avac.org/treatment-as-prevention/basics>

²⁵ Cohen MS et al. *Prevention of HIV-1 Infection with Early Antiretroviral Therapy*. NEJM 365:493-505. 2011.

²⁶ Rodger A et al. *HIV transmission risk through condomless sex if HIV+ partner on suppressive ART: PARTNER study*. 21st Conference on Retroviruses and Opportunistic Infections, Boston, abstract 153LB, 2014.

sexual transmission of HIV to the HIV-negative partner and whether the effect was durable. HPTN 052 found that immediately initiating therapy reduced the risk of HIV transmission by 96 percent. Another trial, known as PARTNER, found similarly high levels of protection in the context of anal sex among heterosexual and gay serodiscordant couples. There have been a range of other trials and observational data studies, many of which also support the prevention benefit of expanding access to treatment.

Significantly, we now know that early treatment is also in the interests of the health of the person living with HIV. The START trial, a large international study conducted over three years, showed people who start ART immediately after HIV diagnosis, while their CD4 cell count is still high rather than waiting until it falls below 350 cells/mm³, have a significantly lower risk of illness and death.²⁷ This implies that extending ART to everyone diagnosed with HIV is no longer medically unethical. As the Vancouver Consensus statement argues, all people living with HIV must be offered access to ART *upon diagnosis*²⁸.

The decision to start treatment is one that people may need time to consider. Providers should establish that the person understands that the decision to start is their own and that they wish to take ART of their own free choice. Young people especially may have concerns about life-long treatment if they are otherwise healthy and this needs to be taken into account. Concerns about stock outs in some Eastern European or Central Asian contexts may also impact the decision on when to start.

As stated in the Community Consensus Statement on Treatment as Prevention,²⁹ EATG opposes any proposals to use coerced ART. HIV prevention should not be viewed as an aim of ART that is separate from the overall health and wellbeing of the person taking it. The provision of ART for prevention purposes should never violate individuals' rights to health, self-determination, consent or confidentiality. In addition, ART should not be adopted as the sole component of HIV prevention programmes and should not replace existing effective methods or prevent the introduction of new ones such as PrEP.

The scientific evidence suggests that we should now offer treatment to all people living with HIV treatment upon diagnosis. The implications of this are huge in a context where access to treatment is far from universal. Eastern Europe has the second lowest level of access to treatment of any region in the world. In many places, people who most need ART have the worst access to it. Stigma, persecution and criminalisation play a large part in unequal access, and the prevention benefits of ART cannot be successfully realised until these are addressed.

EATG will continue to push for increased, sustainable and timely access to treatment across the region and support advocates in countries where governments are not meeting their responsibilities. In particular, EATG calls for unfettered access to non-judgmental medical care for all diagnosed with HIV and the removal of all barriers to access to, and retention in, care for key populations. Programmes of universal ART access must provide equitable non-interrupted access to hard-to-reach and marginalised populations including people who are criminalised and/or undocumented.

As with testing, EATG nonetheless supports the right of people to not take HIV treatment or to delay it, but stresses that it is a matter of good medical and social practice to ensure that people are as fully informed as possible of the benefits of treatment, and that they receive support to help them continue to make the best choices for their health and overall quality of life.

EATG opposes any proposals to introduce coerced ART for people living with HIV.

²⁷ Lundgren JD et al. *Initiation of Antiretroviral Therapy in Early Asymptomatic HIV Infection*. New England Journal of Medicine. [July 20, 2015](#).

²⁸ <http://vancouverconsensus.org/>

²⁹ See www.hivt4p.org

Because HIV prevention responsibility is shared between both partners and especially now we know for sure that someone with fully-suppressed HIV on treatment (i.e. with an 'undetectable' viral load) is non-infectious, there should be no ethical obligation for people living with HIV who are undetectable to disclose HIV status before sex, or before condomless sex. People should be aware however that some countries/jurisdictions still mandate HIV disclosure or prosecute non-disclosure before sex, or before condomless sex even if there is no actual exposure or transmission.

6.3. Pre-Exposure Prophylaxis (PrEP)

Pre-Exposure Prophylaxis (PrEP) refers to the use of antiretroviral medication (daily or intermittently) by people who are known to be HIV-negative to prevent them from acquiring HIV³⁰. The US Food and Drug Administration (FDA) approved daily oral TDF/FTC for PrEP in 2012.

PrEP is not effective for everyone: there are populations for whom PrEP is very suitable, and populations for whom it is not suitable. In particular, PrEP is most suitable for people whose exposure may not be protected by other means, such as harm reduction or condoms.

PrEP and gay men/MSM

The scientific evidence for the effectiveness of PrEP in gay men and men who have sex with men (MSM) is now overwhelming. This is based on a number of high quality randomised clinical trials and real-world demonstration studies, including pivotal European studies. Their results show that PrEP dramatically reduces the risk of HIV transmission^{31 32 33}.

EATG welcomes the recommendation by WHO, made in July 2014 in the 'Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations', that PrEP should be offered as an additional HIV prevention choice within a comprehensive HIV prevention package for men who have sex with men.

Both the PROUD and Ipergay studies and other community-based research show that there is demand from people at high risk of HIV. PrEP is no doubt being used informally in Europe (purchased online) by individuals who may not know their HIV status and without medical supervision. Self-prescribed PrEP is clearly a second-best but if people are going to use it there should be information on how to use it safely.

Affordable PrEP (e.g. with drug price reductions) should be available consistently throughout Europe without criteria that are too restrictive for people who consider themselves to be vulnerable to HIV, or at 'imminent risk'. Ideally it should be the person's own judgement of risk that should be the guideline as to whether to offer PrEP, as evidence shows that people have a good estimate of risk. All key populations need to choose if they want to use PrEP and to be able to use it safely.

EATG calls for much better public information about PrEP to be available in Europe, especially key populations, so people can make good judgement of their HIV risk and their need of PrEP, of its dosing, benefits and possible risks.

³⁰ http://www.unaids.org/sites/default/files/media_asset/UNAIDS_JC2764_en.pdf

³¹ Grant RM et al. Results of the iPrEx open-label extension (iPrEx OLE) in men and transgender women who have sex with men: PrEP uptake, sexual practices, and HIV incidence. 20th International AIDS Conference, Melbourne, abstract TUAC0105LB, 2014.

³² PROUD study statement. PROUD study interim analysis finds pre-exposure prophylaxis (PrEP) is highly protective against HIV for gay men and other men who have sex with men in the UK. (16 October 2014). <http://www.proud.mrc.ac.uk/PDF/PROUD%20Statement%20161014.pdf> (PDF)

³³ Ipergay press statement. Un grand succes dans la lutte contre le VIH./SIDA. Un médicament pris au moment des rapports sexuels réduit efficacement le risque d'infection. (29 October 2014). <http://www.ipergay.fr> Press release (English version) Ipergay October 2014: <http://i-base.info/wp-content/uploads/2014/10/Press-release-IPERGAY-october-2014.doc> (Word.doc)

EATG has called for greater transparency from the EMA and Gilead Sciences on the question of licensing once daily Truvada® as PrEP in Europe in the HIV prevention manifesto. There is an urgent need to clarify the referral pathways for HIV negative people across Europe. Additional demonstration projects changes in health policy may be needed, for example in Germany and Switzerland, to clarify how PrEP could be rolled out within the local health system; but demonstration projects should not be used as a tactic to delay plans for national provision. Advocates need to push for national guidelines to be established with community insight, based on the UK model.

PrEP and heterosexual men and women

There is a strong body of evidence that PrEP has significant effectiveness in preventing HIV transmission between heterosexual partners via vaginal transmission. Although two studies of PrEP in heterosexuals achieved null results, this was due to low adherence and not lack of efficacy.^{34 35} Two other studies in Africa have showed significant effectiveness in serodiscordant couples and in both men and women^{36 37} and there were no infections seen in a continuation study in which PrEP was used in the HIV-negative partner until their HIV-positive partner became stably virally suppressed on antiretroviral therapy.³⁸

However evidence also suggests that efficacious drug levels are reached more slowly in vaginal than rectal tissue³⁹, and that intermittent PrEP on the Ipergay model may not be very effective in women; there is a lack of research on absorption in penile tissue and effectiveness in heterosexual men.⁴⁰ EATG therefore recommends that for now only daily PrEP be recommended for heterosexuals who consider themselves to be sufficiently vulnerable to HIV as there is no evidence as yet that intermittent PrEP works as well as daily PrEP for women or for men whose exposure to HIV is penile/urethral alone.

HIV incidence among heterosexuals, even among people from high-prevalence countries, is generally lower than it is in gay men, but this may conceal considerable differences in vulnerability in individuals. The need for PrEP should therefore be assessed on the basis of the individual's risk of and vulnerability to HIV and not what population she or he comes from.

PrEP and people who inject drugs

The one randomised study conducted in people who inject drugs, although reporting that PrEP was nearly 50% effective, could not distinguish between effectiveness against sexually acquired HIV and effectiveness against injection-acquired HIV.⁴¹

EATG supports continued PrEP implementation research among under-studied groups. Studies of how PrEP would meet the needs of trans* women, gay-identified trans* men, female sex workers, migrants and refugees, adolescents, prisoners and people who inject drugs who may also be at risk through sex and their partners, demonstration studies designed for these populations and plans devised for their inclusion in PrEP rollout would be welcome.

³⁴ Van Damme L et al. *Pre-exposure Prophylaxis for HIV Infection among African Women*. NEJM 367:411-22. 2012.

³⁵ Marrazzo JM et al. *Tenofovir-based pre-exposure prophylaxis for HIV infection among African women*. NEJM 372(6): 509-518. 2015.

³⁶ Baeten JM et al. *Antiretroviral Prophylaxis for HIV Prevention in Heterosexual Men and Women*. NEJM 367:399-410. 2012.

³⁷ Thigpen MC et al. *Antiretroviral pre-exposure prophylaxis for heterosexual HIV transmission in Botswana*. NEJM 367(5):423-34. 2012.

³⁸ Baeten J et al. *Near Elimination of HIV Transmission in a Demonstration Project of PrEP and ART*. 2015 Conference on Retroviruses and Opportunistic Infections (CROI), Seattle, USA, [abstract 24](#), 2015.

³⁹ Glidden D et al. *How to start and stop PrEP: a pharmacology perspective (HPTN 067 and more)*. Symposium presentation, eighth International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention. Presentation no MOSY0109. 2015.

⁴⁰ Bekker LG et al. *HPTN 067/ADAPT Cape Town: a comparison of daily and nondaily PrEP dosing in African women*. 2015 Conference on Retroviruses and Opportunistic Infections, Seattle, [abstract 978LB](#), 2015.

⁴¹ Choopanya K et al. *Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial*. Lancet [381\(9883\)](#):2083–2090. 2013.

6.4. Post-exposure Prophylaxis (PEP)

PEP is the provision of a course of antiretroviral drugs given to someone within 2-3 days of an HIV exposure risk⁴². PEP includes counselling, first aid care, HIV testing, and administration of a 28-day course of ARV drugs with follow-up care. Where the HIV risk is non-occupational, e.g. through sex or needle sharing, it is sometimes called 'NPEP' or 'NONOPEP'.

Updated WHO guidelines issued in December 2014 recommend PEP use for both occupational and non-occupational exposures and for adults and children. The new recommendations provide simpler regimens and are designed to improve prescribing, better adherence and increased completion rates.

Although studies show that PEP is very effective on an individual level, it is not suitable as a primary method of HIV prevention to those at high risk. Evidence from PrEP studies show that a number of gay men are relying on PEP and returning for repeat prescriptions. PrEP would be clearly preferable to repeated PEP use for these individuals.

In any case, PEP is unlikely to make a large contribution to HIV prevention on a population level. 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 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; 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. The latest EACS guidelines on PEP state that PEP should be started ideally within four hours after the exposure, and no later than 48 hours.

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

- A consistent set of European guidelines should be established. These
 - Should recommend up-to-date and tolerable regimens
 - Should never be prescribed more than 72 hours after exposure and preferably within 48 hours^{43 44}
 - 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
 - Should recommend that repeat PEP seekers are offered PrEP.
- Continued awareness campaigns, particularly targeted at high-risk populations, are carried out in order to maintain public awareness of PEP.

⁴² PEP is no longer recommended following occupational exposure to a source with an undetectable viral load.

⁴³ WHO. Post-Exposure Prophylaxis to Prevent HIV Infection: Joint WHO/LO Guidelines on PEP to prevent HIV infection, 2007, p.9.

⁴⁴ 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.

6.5. Harm Reduction

Harm reduction refers to the provision of a range of policies, programmes and practices that aim to reduce the harms associated with the use of psychoactive drugs in people unable or unwilling to stop. The defining features are the focus on the prevention of harm, rather than on the prevention of drug use itself, and the focus on people who continue to use drugs⁴⁵.

Harm reduction works: HIV prevalence is demonstrably much lower in people who inject drugs in areas where it is offered,⁴⁶ and the vast majority of studies have found that harm reduction is effective⁴⁷ and cost-effective.⁴⁸

The prevention of HIV in people who inject drugs is primarily based on needle and syringe exchange and opioid substitution therapy (OST) within a wider package of prevention measures including counselling, access to condoms and management of STIs, TB and viral hepatitis.

The ECDC recommends the following seven key intervention components and where possible, in combination:

- Injection equipment: Provision of, and legal access to, clean drug injection equipment, including sufficient supply of sterile needles and syringes free of charge, as part of a combined multi-component approach, implemented through harm-reduction, counselling and treatment programmes.
- Vaccination: Hepatitis A and B, tetanus, influenza vaccines, and, in particular for HIV-positive individuals, pneumococcal vaccine.
- Drug dependence treatment: Opioid substitution treatment and other effective forms of drug dependence treatment.
- Testing: Voluntary and confidential testing with informed consent for HIV, Hepatitis C (Hepatitis B for unvaccinated) and other infections including TB should be routinely offered and linked to referral to treatment.
- Infectious disease treatment: Antiviral treatment based on clinical indications for those who are living with HIV, Hepatitis B or Hepatitis C. Anti-tuberculosis treatment for active TB cases. TB prophylactic therapy should be considered for latent TB cases. Treatment for other infectious diseases should be offered as clinically indicated.
- Health promotion: Health promotion focused on safer injecting behaviour; sexual health, including condom use; and disease prevention, testing and treatment.
- Targeted delivery of services: Services should be combined and organised and delivered according to user needs and local conditions; this includes the provision of services through outreach and fixed site settings offering drug treatment, harm reduction, counselling and testing, and referrals to general primary health and specialist medical services.

Lately there has been a welcome increase in research in this field demonstrating unequivocally that harm reduction works. According to the ECDC however the number of syringes distributed is below

⁴⁵ Harm Reduction International, *The Global State of Harm Reduction*, 2015.

⁴⁶ Iversen J et al. *Extremely low and sustained HIV incidence among people who inject drugs in a setting of harm reduction*. AIDS, online edition: DOI: 10.1097/QAD.000000000000068, 2013.

⁴⁷ World Health Organization. *Effectiveness of sterile needle and syringe programming in reducing HIV/AIDS among injecting drug users*. 2010.

⁴⁸ Naning H et al. *Cost-effectiveness and return on investment of harm reduction programmes for people who inject drugs in Malaysia*. Seventh IAS Conference on HIV Pathogenesis, Treatment and Prevention, Kuala Lumpur, 2013, abstract WEAD0101.

acceptable standards in one third of the European Union and EEA area, and in most of the wider region; OST coverage is similarly abysmal⁴⁹.

6.6. Condoms (males and female)

Condoms (both male and female versions) remain one of the most effective methods for preventing the sexual transmission of HIV when used consistently and correctly, with about 80% effectiveness for consistent use in vaginal sex⁵⁰, and slightly lower in anal sex.⁵¹ Access to free and effective condoms and safe lubricants⁵² for MSM and female condoms for women, especially female sex workers, including trans* female sex workers is one of the most effective ways of reducing HIV incidence⁵³.

Traditionally, condom use has been one of the corner stones of HIV prevention. There are however people for whom male condom use is not an option (serodiscordant couples who wish to conceive, receptive partners in contexts of vulnerability, and those with erectile dysfunction) and there are several populations in which condom use is now in slow decline or has reached a ceiling even with full availability. Condom-based strategies alone are unlikely to drive down HIV infections to zero.

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

Since treatment as prevention and PrEP now mean it is possible to have safer sex without a condom, definitions of 'safer sex' and 'unprotected' need to be revised. Condomless sex need no longer be unsafe sex. Those that find condom use difficult or impossible should not be criticised and shamed. Likewise, people who are happy with condom use should be continued to be supported.

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

- Access to free and effective condoms and safe lubricant for MSM, and to condoms and female condoms for female sex workers, including trans* women, are still some of the most effective ways of reducing HIV incidence.
- Condoms (with safe lubricant) are still a very important way of reducing the risk of transmission of sexually transmitted infections (STIs), are inexpensive and widely available, and are still the most widely used form of HIV prevention.
- Not everyone finds condoms easy or pleasurable to use. However if you don't always use them, it is important not to base your condom-use decisions on assumptions or guesses about partners' HIV status, especially since the majority of HIV infections in countries with high treatment rates are now transmitted by people unaware that they have HIV.
- Discussion of HIV risks with partners before sex and especially before condomless sex are always a good idea, but fear of rejection, stigma, lack of awareness, haste, intoxication and mistaken beliefs about HIV may all make such discussions difficult.

⁴⁹ ECDC. Evidence Brief: HIV Prevention in Europe, 2015.

⁵⁰ Weller SC, Davis-Beatty K. *Condom effectiveness in reducing heterosexual HIV transmission (Review)*. The Cochrane Collaboration, 2007. See <http://apps.who.int/whit/rhl/reviews/CD003255.pdf>

⁵¹ Smith DK, Herbst JH, Zhang XJ, Rose CE. *Condom effectiveness for HIV prevention by consistency of use among men who have sex with men (MSM) in the US*. JAIDS 68(3):337-44. 2015.

⁵² <http://irma-rectalmicrobicides.blogspot.co.uk/p/lube-safety-info.html>

⁵³ Charania MR et al. *Efficacy of structural-level condom distribution interventions: a meta-analysis of U.S. and international studies, 1998-2007*. AIDS Behav. 15(7):1283-97. 2011.

- Because HIV prevention responsibility is shared between partners and especially because someone with fully-suppressed HIV on treatment (i.e. with an ‘undetectable’ viral load) is non-infectious, there should be no ethical obligation for people with HIV who are undetectable to disclose HIV status before sex, or before condomless sex. People should be aware however that some countries/jurisdictions still mandate HIV disclosure or prosecute non-disclosure before sex, or before condomless sex even if there is no actual exposure or transmission.
- If you are HIV-positive and not virally-suppressed, or believe yourself to be HIV-negative but have not had a recent negative HIV test result and no other risks since, then disclosure of these facts and/or condom use would be ethically and (in the case of a person living with HIV) legally advisable.
- If you are HIV-negative and would like to have condomless sex, you can either choose an HIV-positive partner who has a stable undetectable viral load and/or consider taking PrEP: while this is not yet widely available through health services in Europe, generic PrEP is available online at authenticated websites.

EATG recommends the continuation and strengthening of funding for well-targeted condom and safe lubricant distribution programmes (i.e. where condom use works well as a strategy and meets prevention needs). Behaviour-change programmes should never be funded in preference to condom-distribution programmes, and condoms should be provided as part of behaviour-change programmes. The provision of female condoms should be expanded to meet the needs of women who are unable to demand male condom use from their partners. Condom use should never be criminalised or used as evidence to prosecute sex workers.

6.7. Voluntary Male Medical Circumcision (VMMC)⁵⁴

Voluntary medical male circumcision (VMMC) is the surgical removal of the foreskin of the penis by a trained health professional. Medical male circumcision reduces the risk of female-to-male sexual transmission of HIV by approximately 60% and up to 75% over time⁵⁵. VMMC is a one-time intervention that provides heterosexual men life-long partial protection against HIV as well as some other sexually transmitted infections. However evidence suggests that it does not provide any protection for gay men⁵⁶. To improve the safety and cost-effectiveness of VMMC, a number of devices are being investigated that would remove the need for surgery⁵⁷.

Europe has lower rates of circumcision than the USA and other parts of the world. It is extremely important that any promotion of VMMC:

- 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/STI 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 research to date has almost entirely centred on Africa and therefore on its efficacy amongst a generalised, heterosexually-driven epidemic. The effectiveness of circumcision in

⁵⁴ In some cultures, traditional circumcision is practised as a religious ritual or cultural rite of passage. For this reason the term VMMC is used to indicate that only voluntary male medical circumcision is appropriate as an HIV prevention method.

⁵⁵ <http://www.avac.org/vmmc/basics>

⁵⁶ <http://www.aidsmap.com/Might-circumcision-benefit-gay-men/page/1746342/>

⁵⁷ <http://www.avac.org/sites/default/files/resource-files/NonsurgicalDevicesFAQ2013.pdf>

heterosexual men from high-prevalence countries within migrant communities in Europe has not been studied. Heterosexual men and their partners should be better informed than they are currently about the role that circumcision can play in reducing their risk.

EATG therefore calls for national information campaigns on the benefits of circumcision directed at heterosexual men in the African diaspora (or men with another reason to be at higher than usual risk of HIV), especially as they are the group most likely to be diagnosed late and who may face the biggest barriers to treatment access. A demonstration project in this population would be useful in order to demonstrate the feasibility of a VMMC program.

6.8. Prevention of Vertical Transmission

The vertical transmission of HIV refers to the transmission of HIV from an HIV-positive woman to her baby during pregnancy, labour, delivery or breastfeeding. Without intervention the risk of transmission is between 15-45%. This is sometimes referred to as 'mother-to-child transmission', however women's organisations have pointed out that this term is stigmatising to women as it ignores the role of the father.

Effective ARV interventions can reduce perinatal transmission to virtually zero. The number of HIV infections transmitted in this way in the European Union has decreased by 22%, from 246 infections in 2006 to 191 in 2012⁵⁸. However in the region as a whole, over 500 babies acquired HIV in 2013, most of them in the east⁵⁹. 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 1000⁶⁰. This was not due to ARV treatment failure but largely due to parents not seeking 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 who are undocumented migrants who are expressly excluded from free HIV treatment by UK government guidelines.

To avoid this, better access to voluntary HIV testing and treatment must be expanded for all pregnant women and their partners. It is also important that women are tested for HIV more than once during pregnancy, as this is a time of increased HIV risk. Good guidelines are needed for intravenous prophylaxis and so-called 'baby PrEP', when a woman is diagnosed HIV positive during labour.

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 and their partners would take steps to protect their baby from transmission if fully informed of the options.

EATG therefore opposes any stigmatising and discriminatory practices that exclude pregnant women from HIV healthcare or which prevent/discourage women living with HIV from becoming pregnant, 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.

⁵⁸ <http://ecdc.europa.eu/en/publications/Publications/sexually-transmitted-infections-HIV-AIDS-blood-borne-annual-epi-report-2014.pdf>

⁵⁹ ECDC. HIV/AIDS surveillance in Europe, 2013. See also <http://www.euro.who.int/en/health-topics/communicable-diseases/hiv-aids/news/news/2014/07/hiv-aids-epidemic-in-europe-mother-to-child-transmission>

⁶⁰ 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.

6.9. Reproductive Technologies

The proven effectiveness of treatment as prevention and PrEP mean that serodiscordant couples can now conceive children safely without the need for assisted conception or reproductive technologies, such as artificial insemination and sperm washing. Nonetheless, the reproductive rights of people who cannot access or do not wish to take ART or PrEP should be respected. Some couples may still choose to use them as a 'belt-and-braces' approach. EATG therefore supports the continued availability of such technologies for those couples who may wish to be 100% sure of safe conception.

7. Prevention Research

A range of novel HIV prevention interventions continue to be the subject of global research programmes. Some are based on well-established strategies, such as immunisation, while others are entirely new concepts. New methods would offer people at risk of acquiring HIV greater choice, and would be particularly suited to people for whom current options are untenable. None of the methods currently under study is a 'magic bullet' that would finally solve the problem of HIV transmission and render current approaches unnecessary.

Research into new prevention options 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 prevention 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 urges that research into biomedical prevention is conducted with as much attention to the prevention needs of people already with HIV as to people who are HIV negative. In particular, research is needed into methods such as microbicides that may be bi-directional, i.e. prevent both HIV transmission and HIV infection.

7.1. Vaccines

A preventive HIV vaccine would offer protection to HIV negative individuals via any route of transmission. It is estimated that even a partially effective vaccine could reduce new infections by 40% in its first decade and by almost half in 25 years, averting up to 42 million infections by 2070, depending on the success of other interventions⁶¹. The appeal of vaccines is based on several factors including their history in tackling infectious disease and their cost-effectiveness. Vaccines are long-acting, do not require behaviour change or adherence and can be given to an entire cohort of young people before they become sexually active.

Many vaccine candidates have been looked at since 1987 with little success. The first proof of concept that an HIV vaccine is possible came in 2009, when the RV144 study demonstrated a modest level of protection. Efforts are now underway to improve that regimen and move forward with another large scale trial in Thailand in the next few years (the P5 initiative).

Another important area of research is looking at therapeutic vaccines. These would be given to HIV-positive people to strengthen their immune systems. The hope is that vaccine-induced immune responses can contribute to control of the virus in the absence of antiretroviral treatment, and perhaps

⁶¹ International AIDS Vaccine Initiative, 2015.

also help eliminate latently infected cells. In this way there is considerable overlap with research into a cure for HIV, which would eliminate HIV from a person's body, or permanently control the virus and render it unable to cause disease or to be transmitted.

Europe has been and has the potential to be a major funder of vaccine and cure research via aid, research and innovation budgets. EATG supports continued investment into promising leads in vaccine research.

Vaccine and cure research may involve test subjects being willing to take risks of infection or disease progression. EATG supports the continued use of surveys, such as one done recently in the UK, to establish people's understanding of vaccine and cure research, what they want from it, and the risks they may be prepared and not prepared to take as test subjects.⁶²

7.2. Microbicides

Microbicides are the name given to a range of substances that could reduce HIV risk from sexual exposure when applied to the vagina or rectum. They could take the form of a gel, cream, film, suppository, lubricant or enema. Most microbicides in development are now based on ARVs and the most advanced candidates take the form of a lubricant administered with an applicator, or as a vaginal ring that slowly releases product over time. The advantage of a topical microbicide over a pill that is taken orally is that it delivers drug to where it needs to be at the right time and in a lower concentration. There has been very little pharmaceutical interest in microbicides, with almost all of the funding for research coming from governments and public sources driven by high profile campaigns and advocacy.

The first proof of concept that a microbicide could work was demonstrated by the Centre for the AIDS Programme of Research in South Africa (CAPRISA) in 2010. A gel containing 1% tenofovir was shown to reduce HIV risk by 39%⁶³. Subsequent trials, however, have been unable to repeat or improve upon this success. There were multiple causes for these disappointing outcomes, including distrust of researchers, other motives for joining the study such as free HIV testing, environmental difficulties such as lack of privacy, peer influence and false health beliefs⁶⁴. It is important to learn from these studies as they give important clues about how to better align prevention studies with the needs of the populations in which they are done.

There are two ongoing efficacy trials of a vaginal ring containing the antiretroviral drug dapivirine designed to be inserted for four weeks at a time. These are ASPIRE (MTN 020) and the Ring Study (IPM 027). The first expanded safety study (Phase II trial) of a rectal microbicide, a reformulated version of tenofovir gel, began in late-2013 (MTN 017). The results of all these studies are expected in 2016.

Advocacy is needed to ensure that research continues into dual compartment options, non-ARV based formulations (for people living with HIV) and the question of whether hormonal contraception increases HIV risk. As with vaccines, EATG urges European donors to continue their role as key funders of research programs. In particular, European funding for rectal microbicides research is notably lacking.

⁶² Simmons R et al. *A UK survey of HIV-positive people's attitudes towards cure research*. BHIVA conference, Brighton, April 2015, abstract P39. AND Kall M et al. *Altruism and medical advice are key factors in decision-making about participating in HIV cure research: results from a UK-wide survey of people living with HIV*. BHIVA conference, Brighton, April 2015, abstract P159.

⁶³ Abdool Karim Q et al. *Effectiveness and safety of tenofovir gel, an antiretroviral microbicide, for the prevention of HIV infection in women*. *Science* 329(5996):1168-74. 2010.

⁶⁴ Van der Straten A et al. *Women's Experiences with Oral and Vaginal Pre-Exposure Prophylaxis: The VOICE-C Qualitative Study in Johannesburg, South Africa*. *PLOS ONE* 9:e89118, 2014. AND Van der Straten A et al. *Perspectives on use of oral and vaginal antiretrovirals for HIV prevention: the VOICE-C qualitative study in Johannesburg, South Africa*. *Journal of the International AIDS Society* 17:19146, 2014.

7.3. Multi-purpose prevention technologies

Multi-purpose prevention technologies are now in development to simultaneously prevent unintended pregnancy and protect against HIV and other sexually transmitted infections. Like microbicides they could take the form of vaginal rings, diaphragms, films, gels or injectables. By addressing multiple health concerns in convenient, easy-to-use formulations, these technologies might also help ensure high levels of product adherence.

7.4. STI 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^{65 66 67}. It is now clear that the effect of STIs on the transmissibility of HIV and the health of people living with HIV when they are on treatment is lower than was first thought⁶⁸. However for those people living with HIV who are not on treatment, STI prevention and treatment remains important. More research in this field is warranted.

7.5. Injectable PrEP

Since adherence to a daily pill can be hard to maintain over time, there is now considerable pharmaceutical interest in injectable PrEP that could provide protection for several months. These may contain the same drugs that are being selected for long-term ARV injectables such as rilpivirine (also known as TMC278, brand-name Edurant) and GSK744, which is an analogue of the drug dolutegravir⁶⁹.

⁶⁵ Nagot N et al. Impact of valaciclovir on genital and plasma HIV-1 RNA: a randomised controlled trial among women taking HAART (ARNS 1285b). International AIDS Conference, Toronto, abstract TUPE0402, 2006.

⁶⁶ Dunne E et al. The effect of suppressive aciclovir therapy on HIV cervicovaginal shedding in HIV- and HSV-2-infected women, Chiang Rai, Thailand. CROI, Los Angeles, abstract 30, 2007.

⁶⁷ 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. CROI, Los Angeles, abstract 154LB, 2007.

⁶⁸ See Rodger A 2014, above.

⁶⁹ <http://www.avac.org/sites/default/files/infographics/Px%20Wire%20Infographic%20%20Vol%207%20No%202.pdf>