Community consensus statement on the use of ARV treatment as prevention

1. This is a community consensus statement on the use and prescription of antiretroviral therapy (ART) to people living with HIV to reduce their risk of transmitting HIV.

2. ART has of course drastically reduced the toll of death and sickness due to HIV infection. There is now, in addition, conclusive evidence from a clinical trial,\(^1\) HPTN 052, that effective ART very considerably reduces an HIV positive person’s risk of transmitting HIV through vaginal sex. In this trial, treatment reduced the risk of HIV infection by 96%. There is widespread expert consensus that this reduction in infectiousness applies to anal sex and needle sharing too.\(^2\)

3. The HPTN 052 result and other declarations of the effectiveness of ART as prevention, such as the so-called ‘Swiss Statement’\(^3\) in 2008, have presented both enormous opportunities to people with HIV and people working in HIV prevention, but also considerable challenges:
   a. Aside from its public health benefit, ART as prevention has the potential to relieve the burden of guilt, anxiety and fear of criminal liability many people with HIV feel at the prospect of transmitting HIV.
   b. Equally, concerns have been raised by some community activists that using universal ART as prevention as a public health measure could lead to people with HIV being pressured into taking ART, regardless of clinical need.
   c. In addition, access to ART for treatment is still restricted globally and in parts of Europe. In a number of countries the vulnerable communities that need it most have the worst access to HIV treatment and to prevention and testing services,\(^4\) in part due to criminalisation\(^5\) and stigma,\(^6\) and many people still get ill and die from HIV because of lack of access to ART.
   d. In addition to its direct prevention and possible clinical benefits to the patient, the prescription of ART is also associated with much higher rates of retention in care.\(^7\) And yet even in some high-income countries, there is as yet no mechanism for funding the prescription of ART to people who do not meet guideline criteria for treatment. Cost pressures may perpetuate this.

4. For people with HIV, then, advocacy for the provision of ART as prevention has to include and to balance:
   a. Advocacy for the provision of ART to patients who wish or need to take it to reduce their risk of transmitting HIV, even if they fall outside criteria for its provision as treatment;
   b. Advocacy to safeguard the rights of patients who do not need or are not yet ready to take ART for clinical reasons and do not wish to take it for prevention reasons;
   c. Continued advocacy for the right of access to HIV prevention and testing for all affected communities and treatment for people with HIV;
   d. Advocacy and the provision of information on the positive impact and cost-effectiveness to individual and public health of ART as prevention, in order educate funders and health providers of its benefits.

5. The crucial issue that links these four advocacy aims is the safeguarding of patient choice.

6. It is important to ensure that providing ART for prevention will not in any way affect efforts to make ART available as treatment to anyone who needs it for clinical benefit. ART for
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7. In the case of people who do not want ART as prevention, however, there need to be safeguards against health providers using coercion, pressure, future denial of ART if the patient refuses it now, or legal threat to persuade them to take ART. These safeguards are particularly important if, as is the case in the US, a recommendation that all people with HIV should be prescribed ART on diagnosis is adopted.9

8. Even in the case of clinical need, patient readiness to take ART is crucial in order to support the high levels of adherence necessary to suppress HIV, and we welcome and recommend the adoption of the patient readiness paradigm, as outlined in the EACS treatment guidelines,10 as a model to follow.

9. We recommend that in the case of patients with high CD4 counts, readiness to take ART is explored well in advance of patients reaching CD4 criteria for treatment. If patients express readiness, ART should not be deferred until CD4 criteria are reached.

10. Many people with HIV remain unaware of the prevention benefits of ART or are uncertain of the evidence for it, and we also welcome and recommend the adoption by other guidelines of the BHIVA and EAGA statement in the UK11 that healthcare providers must inform all patients of the potential prevention benefits of ART, and must prescribe it if, on the basis of that information, the patient asks for it.

11. The prevention benefits of ART are also not widely known among people vulnerable to HIV12 and need publicising in order to encourage testing and enable people to take steps that may reduce their risk of HIV infection.

12. Most models predict that ART by itself will not end the HIV epidemic but will have to be used in combination with other methods.13 Expanding access to ARTs as prevention should not be a reason to restrict access to other methods of proven efficacy.

13. There remain many areas of uncertainty and lack of evidence that make the choice of whether to take ART as prevention and/or rely on it as a prevention measure difficult. These include:

   a. Most of the evidence we have about the efficacy of ART as prevention concerns transmission between heterosexuals or via vaginal sex alone, or from mother to baby.14 There is an urgent need for more research into the use of ART to reduce transmission via:

      i. Anal sex: in this case there is a small amount of evidence15 suggesting a considerable reduction in risk with the use of ART, but large observational studies in gay men and heterosexuals who have anal sex is urgently needed. We welcome studies such as the PARTNER Study16 and Opposites Attract study17 designed to answer this question.

      ii. Needle and drug equipment sharing: in this case there is population-level evidence from British Columbia that ART provision may have reduced incidence in injecting drug users (IDUs),18 but we again need an observational study of IDUs to assess the reduction in risk offered by ART.

   b. STIs: While there is clear evidence19 that most STIs significantly increase the risk of both transmission of and infection with HIV on people not taking ART or their partners, there is relatively poor evidence on whether the same increase in risk applies to people taking fully-suppressive ART.20
c. Clinical risk/benefit of ART in people with high CD4 counts: **There is poor, and disputed, evidence** as to whether ART offers any clinical benefit, over the risk of side effects, to people with CD4 counts over 500 cells/mm\(^3\) or even 350 cells/mm\(^3\).\(^\text{21}\) In this respect we welcome the [Start Study]\(^22\), which is designed to answer this question for CD4 counts over 350 cells/mm\(^3\), but we may need further studies to establish the risk/benefit ratio at higher CD4 counts.

d. Risk compensation. As the BHIVA/EAGA statement in the UK notes, ART is at least as efficacious as 100% attempted condom use in reducing HIV transmission.\(^23\)\(^24\) Concern remains however about the epidemiological consequences if people on ART and their partners were to reduce their use of condoms or increase partner numbers or risk behaviours because they feel safer from infection.\(^25\)\(^26\) We therefore need:

i. Implementation research in different populations to monitor possible changes in behaviour and risk attendant on the more widespread use of ART as prevention or as PrEP;

ii. More research to assess the efficacy of comprehensive ‘combination-prevention’ not based solely on condoms or ART alone; an example is the PopART study\(^27\) currently taking place in Zambia and South Africa,\(^28\) though different contexts would require different study designs.

e. We also strongly support the continued supply and promotion of condoms as a method of proven efficacy in preventing HIV. We emphasise that, unlike ART, they also prevent most of the other STIs that in themselves cause considerable morbidity and some mortality.

14. The lack of available evidence as to the efficacy of treatment as prevention to the groups and in the circumstances mentioned above should not be used as a reason to exclude people from access to treatment as prevention. Instead it should be seen as a call for more action in research in these areas.

15. The advent of ART as prevention faces both providers and recipients of HIV prevention methods and support with a considerable paradigm shift in what HIV prevention actually involves, who should provide it and what methods should receive priority. An ongoing programme of training and information is needed to help HIV prevention workers, advocates and recipients respond optimally to what is likely to be a new era in the prevention of HIV.

References

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11 See reference 2 above
16 See http://www.partnerstudy.eu/
17 See http://www.oppositesattract.net.au/
20 Fisher et al (ref 15 above) found a 2.8-fold increased risk of HIV transmission to or from gay men who had STIs, independent of ART status, but this was a small study and more are needed.
25 See Phillips AN et al. Ref 13 above.
27 See http://www1.imperial.ac.uk/medicine/research/researchthemes/infection/infectious_diseases/hiv_trails/hiv_prevention_t_echnologies/popart/.
28 See Phillips AN et al. Ref 13 above.