

GNP+ Position Paper

# **ART for Prevention**

18 July 2012

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## GNP+ positions

Based on what we know and do not know, and given the potential opportunities presented by ART for prevention, and the conditions that need to be in place for ART for prevention to work, GNP+ asserts the following:

1. The primary purpose of ART for someone who is HIV-positive is to benefit their own health. Preventive benefits are important, but secondary, considerations. Public health benefits are secondary to respect for individual-level benefits and patient autonomy in decision-making.
2. HIV testing must always be voluntary and confidential, as well as available anonymously, and must be accompanied by full, complete and accurate information regarding the medical and legal consequences of testing HIV-positive.
3. People living with HIV must be counselled on the health benefits they can expect from ART, the known short-term and long-term side effects of ART, the fact that not all side-effects can currently be known due to ART comprising relatively new drugs and that science is unclear whether treatment over CD4 350 delivers a net benefit or net harm. People living with HIV must be counselled on the potential progression of the disease in the event they are not treated. This information must be specific to the individual's clinical situation (including CD4 count, viral load, and symptoms).
4. People living with HIV, regardless of their individual medical need<sup>1</sup> for ART, must be counselled about what is currently known (and unknown) regarding the potential preventive effects of ART. This counselling should explain in what circumstances ART can potentially greatly reduce HIV sexual infectiousness and, therefore, provide greater confidence in one's ability to protect their sexual partner(s) and make informed choices about whether and how to conceive and enjoy a family.
5. Decisions about when, and if, to start treatment must be made by the person living with HIV. The person living with HIV must have access to all available information (including CD4 and viral load, treatment adherence, resistance to medications and potential side effects), in a format and language that the person can readily understand. Support systems, including peer support, must be put in place and funded to ensure that a person living with HIV can access non-biased, non-judgemental, accurate, and current information about treatment and prevention and can be supported in their decisions about ART initiation or deferral.
6. Every healthcare worker who prescribes ART must have access to all available information, in a format and language that the person can readily understand. This information must be unbiased, accurate, and current and must stress the possible

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<sup>1</sup> Medical need is a clinical term. Everyone who qualifies for medical need has the right to be fully informed and the option to take treatment or not.

benefits and risks of treatment to an individual's health as well as its impact on HIV prevention.

7. Where access to ART is limited, individuals who require treatment based on clinical need for their individual health in accordance with local guidelines must always be prioritised. The WHO ART Guidelines recommend starting treatment when CD4 cells fall below 350<sup>2</sup>.
8. ART for prevention must be considered part of a combination prevention package<sup>3</sup>, along with access to information about how HIV is acquired and transmitted, male and female condom use, harm reduction measures for people who use drugs, vertical transmission services, male circumcision, ensuring protection of human rights and the reduction of HIV-related stigma. People living with HIV must be supported to understand and be allowed to make choices from this package that suit their individual circumstances.
9. Laws and policies, aimed at people living with or at high risk of acquiring HIV, should create an enabling and non-discriminatory environment in which all people living with HIV—including members of key populations such as people who use drugs, sex workers, men who have sex with men, and transgender people—are able to equitably access non-discriminatory health and support services. Key populations are groups at higher risk of being infected or affected by HIV; and in many countries, they are marginalised, stigmatised and discriminated against and often left out of the HIV response. Promoting their involvement in the HIV response and creating a supportive environment will ensure the widest possible access of voluntary HIV testing and treatment, increase confidence in negotiating safer sex and making use of harm reduction services and ensure retention to HIV care and support, making the most of the potential prevention benefit of ART.
10. Further research is critical to understand what ART for prevention means for key populations, in particular the impact of treatment on the risk of HIV transmission for sex between men, in relation to anal sex, in the case of STI co-infection and in relation to contact with blood (for example, through needle sharing or with medical equipment).

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<sup>2</sup>World Health Organisation. (2010). Antiretroviral therapy for HIV infection in adults and adolescents: recommendations for a public health approach- 2010 rev. [http://whqlibdoc.who.int/publications/2010/9789241599764\\_eng.pdf](http://whqlibdoc.who.int/publications/2010/9789241599764_eng.pdf)[http://whqlibdoc.who.int/publications/2010/9789241599764\\_eng.pdf](http://whqlibdoc.who.int/publications/2010/9789241599764_eng.pdf)

<sup>3</sup>Press Release. UNAIDS promotes combination HIV prevention towards universal access goals. Geneva, 18 March 2009.

# Introduction

There is growing interest in the evidence that antiretroviral therapy (ART) can be used not only as treatment for people living with HIV, but to prevent or reduce transmission of HIV.

This paper focuses on the prevention of sexual transmission from persons living with HIV through the use of ART. The paper focuses on what this means for people living with HIV (at an individual level) and what it means for public health (at the population level).<sup>4</sup>

Informed by a consultation with GNP+'s Board and Secretariat, it articulates conditions needed for treatment as prevention to work effectively while protecting the rights of people living with HIV.

## The science: what we know and do not know

### ART can reduce the risk of HIV transmission

A number of studies has shown that where ART is widely available and reliably accessible, it has the potential to greatly reduce the sexual risk of HIV transmission between heterosexual couples of different HIV status<sup>5</sup> and has an impact on new infections at a population level.<sup>6,7</sup> These results have been found in both high- and low-income countries.

In May 2011, preliminary results from the HPTN 052 clinical trial<sup>8</sup> demonstrated that ART taken by people living with HIV, when clinically indicated, reduced the risk of HIV heterosexual transmission to the HIV-negative partner by 96%. It also suggested that earlier ART initiation may slightly decrease the risk of TB.

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<sup>4</sup> GNP+ NPT Advocacy Agenda

[http://www.gnpplus.net/images/stories/PHDP/NPT\\_Advocacy\\_Agenda\\_English\\_v4.pdf](http://www.gnpplus.net/images/stories/PHDP/NPT_Advocacy_Agenda_English_v4.pdf) December 2010

<sup>5</sup> 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.

[English translation. (including translator's affidavit) [HIV-positive individuals not suffering from any other STD and adhering to an effective antiretroviral treatment do not transmit HIV sexually.](#)]

<sup>6</sup> Das-Douglas, M., et al. [Decreases in Community Viral Load Are Associated with a Reduction in New HIV Diagnoses in San Francisco.](#) Seventeenth Conference on Retroviruses and Opportunistic Infections, San Francisco, abstract 33, Feb 2010.

<sup>7</sup> UNAIDS welcomes further evidence of the positive impact of antiretroviral therapy on preventing new HIV infections. Press Release, Geneva, 8 March 2012.

<sup>8</sup> HPTN052 was a multi-country randomised trial conducted in 13 sites across Africa, Asia and the Americas. The trial was designed to evaluate whether immediate versus delayed use of ARVs by individuals living with HIV would reduce sexual transmission to their HIV-negative partners and potentially benefit the individual living with HIV as well. As clinical trials take place in a controlled setting, there always remains the question about the applicability of their results to the 'real world'.

### **The link between infectiousness, viral load and risk of HIV transmission**

HIV transmission risk can be affected by a large number of factors such as:

- (a) the type of sexual activity
- (b) the roles during penetrative sex, i.e. who is the insertive partner and who is the receptive partner (receptive sex carries a higher risk of HIV acquisition than insertive sex)
- (c) the amount of HIV in the bodily fluid to which the at-risk person is exposed
- (d) whether or not a male or female condom has been used correctly and consistently
- (e) the presence or absence of other sexually transmitted infections (STIs) in either partner; and
- (f) whether or not the penis of the potentially exposed male partner has been circumcised.

The thinking behind ART for prevention is that a major factor governing the infectiousness of a person with HIV is the amount of virus in their body (this “viral load” is usually measured in the blood). The lower the viral load, the lower the risk of HIV transmission. However, as described above, other factors, in both the person with and person potentially exposed to HIV, also have an impact on whether HIV transmission actually occurs.

ART can lower a person’s viral load to extremely low levels in the blood, often undetectable by standard laboratory tests (although HIV can sometimes still be found using very sensitive tests). By reducing viral load, ART reduces a person’s infectiousness and the risk of HIV transmission.

It is important to note that some people have a very low viral load (temporarily or permanently) without ART. Conversely, some people on ART do not achieve a very low viral load.<sup>9</sup>

A person’s viral load does not always stay the same. A person’s viral load may change depending on a number of factors, including resistance (often a result of poor adherence) and the presence of infection, including sexually transmitted infections (STIs). The viral load in the blood may differ from the viral load in genital or rectal secretions, pointing to the need for further research into the preventive impact of ART for anal sex and sex between men who have sex with men.<sup>10</sup>

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<sup>9</sup>See data from the United States indicating the percentage of people living with HIV on ART who have and do not have an undetectable viral load

[http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6047a4.htm?s\\_cid=mm6047a4\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6047a4.htm?s_cid=mm6047a4_w)

<sup>10</sup>Zuckerman R A et al. *Higher concentrations of HIV RNA in rectal mucosa secretions than in blood and seminal plasma, among men who have sex with men, independent of antiretroviral therapy.* J Infect Dis 189: 156-161, 2004

## Unanswered questions

There are critical questions that remain unanswered. One is the optimal time to initiate ART to benefit the health of the person living with HIV.<sup>11</sup> Science is unclear whether treatment over CD4 350 delivers a net benefit or net harm. The individual risks and benefits of commencing treatment at CD4 counts above 350 cells/mm<sup>3</sup> for treatment or preventative purposes require considered discussion.

Given the uncertainty as to the long-term impact of treatment side effects on the individual, how are the interests of the individual and public health balanced? Starting treatment early may bring no individual benefit, and might conceivably harm both the individual (in terms of adverse side effects and reduced treatment options should resistance occur) and public health (in terms of the potential of transmitted resistance)?

In addition, we do not know whether ART offers any health or prevention advantage for people living with HIV who have naturally very low viral loads (temporarily or permanently).

These are critical questions for people living with HIV who are unsure whether ART may improve or harm their health, but are potentially interested in ART to reduce their chance of transmitting HIV to others.

Further research is required to understand what ART for prevention means for key populations. There are some small studies that have been conducted. For example, a UK study of men who have sex with men in Brighton found an association between a higher viral load and a greater risk of HIV transmission. The study found that recent infection or co-infection with an STI significantly increased the risk of transmission due to higher viral loads. Studies in Canada and the US have also shown that ART reduces community viral load amongst injecting drug users.<sup>12</sup> However, there is a need for further research to draw conclusions on the impact of treatment on the risk of HIV transmission for sex between men, in relation to anal sex, in the case of STI co-infection and in relation to contact with blood (for example, through needle sharing or with medical equipment).

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<sup>11</sup>The Strategic Timing of Antiretroviral Treatment (START) study, conducted by the International Network for Strategic Initiatives in Global HIV Trials (INSIGHT), currently enrolling at 90 sites in nearly 30 countries, seeks to answer this question. See: <http://clinicaltrials.gov/ct2/show/NCT00867048>

<sup>12</sup>Montaner J et al. Association of expanded HAART coverage with a decrease in new HIV diagnoses, particularly among injection drug users in British Columbia, Canada. 17th Conference on Retroviruses and Opportunistic Infections, San Francisco, abstract 88LB, 2010.

## Conditions for treatment to work for prevention

ART for prevention is currently being discussed by HIV advocates, Ministries of Health, UN agencies and others for both its individual and population-level impact. There sometimes is a tension between the individual and population level impact of ART for prevention. The two approaches are not necessarily mutually exclusive. However, certain conditions need to be in place for treatment to work as prevention at both levels.

### **At an individual level**

Individuals have a right to access testing services that are voluntary, confidential and, if desired, anonymous. It is unacceptable for testing or treatment to be coerced or confidentiality to be breached. This is key to providing a supportive environment for individuals to choose to learn their HIV status and to decide whether HIV prevention and treatment services are appropriate for them, without fear of experiencing stigma and discrimination.

Individuals have a right to access and be offered treatment, prevention, care and support services that meet their needs and respect their choices.

Individuals need to be informed of the benefits and risks of treatment before they make a decision to start treatment. This includes currently available information on when to start treatment, including the absence of high-quality evidence demonstrating a net benefit of ART treatment for individuals with high CD4 counts, known and potential side effects of treatment, what is currently known and not known about the potential preventive effect of ART on sexual transmission and the conditions necessary for this potential preventive effect to be realised.

Individuals should be provided with readily understandable information, be encouraged to weigh the benefits, risks and timing of starting treatment in their own time, and should never be coerced into taking a decision before they are ready. Examples of coercion have been documented in HIV testing<sup>13</sup>. This is unacceptable - decisions to test for HIV or to commence ART must always respect individual autonomy. By making personal informed decisions, individuals are more likely to continue accessing health services and, if or when they choose treatment, to adhere to their ART regimes.

Once individuals start ART, they must have uninterrupted access to all components that make up ART as prescribed, as well as regular, reliable and free/affordable monitoring for viral load and CD4. For those who are also co-infected with TB or Hepatitis B or C, treatment for these other conditions should also be provided. This is critical for maintaining the health of an individual living with HIV, for promoting adherence and for minimising the development of drug resistance. Regular monitoring is also important for the person living with HIV, since it is further motivation to remain in contact with their clinic in order to be able to access a range of other health and prevention services.

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<sup>13</sup>Kaiser Family Foundation. Harare Maternity Clinics Reportedly Conducting Compulsory HIV/AIDS Tests On Pregnant Women, January 19 2012. <http://globalhealth.kff.org/Daily-Reports/2012/January/19/GH-011912-Harare-HIV-Tests.aspx>



Individuals must be counselled on how, if they chose to do so, initiating treatment early could protect their sexual partner(s) and support them in conceiving and having children.

Individuals on ART must also have access to readily understandable information regarding ART adherence, side effects and the importance of regular monitoring. This information must also include the potential HIV prevention benefits of ART as well as access to a range of combination prevention methods, including male and female condoms, early diagnosis of STIs, and other harm reduction measures, to enable them to make fully informed choices about their sexual relationships and their health.

### **At a population level**

High rates of testing and treatment uptake cannot be achieved in an environment of stigma and marginalisation, nor where programmes are affected by potential human rights violations—such as forced or uninformed testing, coerced or uninformed initiation of ART or prioritising public health benefits over those to the individual. These violations are likely to lead to loss of follow-up, poor levels of adherence, and a possible increase in the prevalence and transmission of drug resistant strains of HIV—all of which will undermine both the therapeutic and preventive benefits of ART, as well as the rights of people living with HIV.

There must be greater efforts to ensure universal access to ART for all people living with HIV who need it for health reasons according to current WHO guidelines. It is unacceptable if people at risk of acquiring HIV, or those living with HIV who do not require ART for their own health, have access to ART for reducing their risk of HIV acquisition or transmission, but people living with HIV who currently need ART to stay alive and healthy do not.

The scale-up of testing, treatment and clinical monitoring requires a substantial and sustained scale-up of infrastructure and resources, including greater access to point-of-care testing and a better combination of treatment regimens, improved linkages within care, training of existing and additional health care workers, and strengthening community involvement. An investment in rapid and extensive scale-up of ART now will result in significant health improvement and a dramatic reduction of financial costs in the long-term.<sup>14</sup> Key to this investment is the political commitment of governments to understand and meet the health and rights needs of their communities.

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<sup>14</sup>UNAIDS (2011). A new investment framework for the global HIV response. Issues Brief. [http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2244\\_Investment\\_Framework\\_en.pdf](http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2244_Investment_Framework_en.pdf)

## What are the opportunities?

ART for prevention presents several opportunities for people living with HIV.

ART for prevention provides an opportunity to further advocate for scaling-up universal access to testing, treatment, and care. It is an opportunity to ensure access to testing for those who are unaware of their HIV-status (i.e. the vast majority of the world's population) and access to treatment for those who need it, as well as other essential services, such as viral load testing, resistance testing, and regular screening and treatment for STIs and TB.

While the on-going START<sup>15</sup> and TEMPRANO<sup>16</sup> studies will provide us with important new data about the optimal time to start treatment, evidence already suggests that once CD4 counts reach 350 cells/mm<sup>3</sup> regular, uninterrupted ART delays disease progression, increases CD4 cell count and supports other health outcomes, such as a reduction in tuberculosis (TB) incidence.<sup>17</sup> These on-going studies provide an opportunity for people living with HIV to advocate for reliable information about the potential benefits or harms to initiating ART compared to the potential benefits or harms of delaying ART.

The potential preventive effect of ART on an individual level also allows people living with HIV to have more choices in their sexual relationships. People living with HIV may choose to consider the preventive effects of being on ART in their decision-making process around disclosure and risk reduction, particularly in the context of HIV-discordant sexual relationships. This can provide an opportunity for greater intimacy and safety. Some people living with HIV may choose to combine consistent condom use with their knowledge of their reliance on undetectable viral load in order to remove any residual fears of any possible risk of transmission. Additionally, some *partners* of people living with HIV may also make informed decisions based on information and support. For example, they may choose not to use condoms and rely instead on their partner's undetectable viral load. Others could rely on an undetectable viral load occasionally, for example, when they are trying to conceive. These are individual and personal decisions that need to be made by people living with HIV and/or their partners who are fully informed about the benefits and risks of such decisions.

ART for prevention may also change the way in which people living with HIV think of themselves and how they are perceived by others. The stigma and fear associated with HIV transmission may be reduced through the preventive benefits of ART. It may change perceptions within relationships and within society about sexuality as positive and non-threatening.

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<sup>15</sup>Strategic Timing of Antiretroviral Treatment (START) )<http://clinicaltrials.gov/ct2/show/NCT00867048>

<sup>16</sup>Early Antiretroviral Treatment and/or Early Isoniazid Prophylaxis Against Tuberculosis in HIV-infected Adults (TEMPRANO)) <http://clinicaltrials.gov/show/NCT00495651>

<sup>17</sup>HIV Prevention Trials Network. Initiation of Antiretroviral Treatment Protects Uninfected Sexual Partners from HIV Infection (HPTN Study 052). 12 May 2011.  
[http://www.hptn.org/web%20documents/PressReleases/HPTN052PressReleaseFINAL5\\_12\\_118am.pdf](http://www.hptn.org/web%20documents/PressReleases/HPTN052PressReleaseFINAL5_12_118am.pdf)

The evidence around ART for prevention is also influencing discourse and policy on HIV criminalisation. In the Netherlands, Switzerland, Canada and Denmark, ART's preventative effects are influencing the reconsideration of criminal laws and, in some cases, allowing for a revisit of previous rulings based on outdated notions of the risk of HIV transmission<sup>18</sup>.

The ART for prevention agenda also provides an opportunity to work collaboratively between treatment and prevention advocates, along with networks of people living with HIV, to reach testing, treatment and prevention targets. It is an opportunity to mobilise increased and more synergistic funding and programmes around comprehensive treatment and prevention approaches.

It is also an opportunity to build on the momentum to push for a more robust research agenda that clarifies both the health and prevention benefits of ART, particularly as it relates to the issue of early treatment. The long-term effects of starting treatment early are presently unknown.

## **PLHIV leadership through Positive Health, Dignity and Prevention**

ART for prevention allows for a new vision regarding current prevention and treatment efforts.

This new vision must be led by people living with HIV within the context of Positive Health, Dignity and Prevention<sup>19</sup>. Positive Health, Dignity and Prevention is a PLHIV-led paradigm, which places the person living with HIV at the centre of managing their health and wellbeing.<sup>20</sup> ART for prevention relies on people's willingness to test, to be informed regarding whether and when to commence ART, and, subsequently to adhere to lifelong HIV treatment. This requires the visible leadership of people living with HIV and the support of communities. Investing in people living with HIV and in the communities they are part of is critical to achieving HIV prevention and treatment programmes that are effective and that are also appropriately tailored to communities.

The leadership of people living with HIV is a key principle of Positive Health, Dignity and Prevention – an approach that is based on a human rights framework and focuses on both legal protections from discrimination for people living with HIV and access to HIV treatment, care and support services. Positive Health, Dignity and Prevention places the person living with HIV at the centre of managing their health and social needs. By empowering a person living

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<sup>18</sup>Bernard EJ and Bennett-Carlson R. [Criminalisation of HIV Non-disclosure, Exposure and Transmission: Background and Current Landscape](#). UNAIDS, Geneva, February 2012.

<sup>19</sup>The term used in the Asia Pacific region is 'Positive Health', see GNP+, UNAIDS. 2011. Positive Health, Dignity and Prevention: A Policy Framework. Amsterdam, GNP+.p48

<sup>20</sup>GNP+, UNAIDS. 2011. Positive Health, Dignity and Prevention: A Policy Framework. Amsterdam, GNP+.

with HIV about their range of needs and choices, this promotes informed decision-making about their physical and sexual health as well.

The leadership of people living with HIV is critical in a number of ways:

### **Rights-based treatment literacy**

People living with HIV play a central role in developing and implementing treatment literacy for other people living with HIV. Within the context of ART for prevention, this means encouraging and supporting people living with HIV to be fully informed of scientific developments, including how treatment can reduce infectiousness and the complexity and ambiguity about when it is in their best health interest to start treatment. This will enable people living with HIV to make informed choices about taking an HIV test and choosing if and when to start HIV treatment. It would also provide people living with HIV with the skills to engage with healthcare professionals around their care, to question, to say 'no' to some decisions and to defend our rights as a client.

### **Delivering community-based programmes**

People living with HIV have a role to play in increasing demand for and delivering services within communities. In 2011 at the UN General Assembly High Level Meeting on HIV, member states committed to the goals of 15 million people on ART, a 50 per cent reduction in sexual transmission and an end to vertical transmission by 2015.<sup>21</sup> These ambitious targets will require a significant increase in service provision. People living with HIV can play a critical role in delivering health promotion and providing counselling, HIV testing, linkages to care, adherence support, legal support and support to other people living with HIV to remain in care to access a range of health services.

### **Building evidence**

People living with HIV play a key role in researching the environmental elements and social conditions that enhance voluntary access to testing, treatment and care. People living with HIV also have a role to play in monitoring the implementation of ART for prevention approaches. Meaningfully engaging and supporting people living with HIV to develop data collection tools, conduct evaluations, and review and analyse data can result in greater understanding as their lived experiences can inform these activities. This helps to ensure that programmes are continually informed by a strong and relevant evidence base that is grounded in the reality of those hoping to benefit from these programmes.

### **Development of rights-based guidance**

People living with HIV also have a role to play in the development of rights-based guidance at global, regional and national levels. Working with UN agencies, people living with HIV can ensure easily understood guidance is developed and published for individuals and couples on how to make informed decisions about the HIV treatment and prevention options that work

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<sup>21</sup> Political Declaration on HIV/AIDS: Intensifying our Efforts to Eliminate HIV/AIDS  
[http://www.unaids.org/en/media/unaids/contentassets/documents/document/2011/06/20110610\\_UN\\_A-RES-65-277\\_en.pdf](http://www.unaids.org/en/media/unaids/contentassets/documents/document/2011/06/20110610_UN_A-RES-65-277_en.pdf)

best for them, as well as guidance for those providing services to those in need of accessing ART. This guidance must include information about the benefits and risks involved in taking ART, and skills to discuss and negotiate the various options – all essential for good adherence to both prevention and treatment.

## Studies and programmes on ART for prevention

There are on-going studies on the use of ART in combination with existing prevention methods in order to reduce new HIV infections on a population level. These include:

- Increased treatment uptake, also known as 'seek and treat' (pilot study, Vancouver, Canada).
- Increased testing with linkage to care and treatment based on clinical need, also known as 'testing and linkage to care plus treatment' or TLC+ (pilot study, Bronx and Washington DC, United States, HPTN 065). A variation of this approach is to provide testing, with linkage to care including earlier treatment, though not immediate treatment. For instance MSF's study is evaluating the feasibility of providing testing, linkages to care, and offering treatment to people with CD4 cell counts below 500 or above 500 if their viral load is above 10,000 copies per ml. They are also evaluating their retention in care and evaluating the intervention's impact on HIV and TB incidence, HIV- and TB-related morbidity and mortality where the study is being performed in KwaZulu Natal, South Africa.
- A couple of trials are evaluating the best time to start ART. The START trial - Strategic Timing of Antiretroviral Treatment, is a randomized controlled study in 37 countries evaluating whether starting ART at CD4 cell counts above 500 compared to deferring ART until CD4 cells fall below 350 reduces the chances of developing AIDS and other illnesses. It is also looking at the risk of drug resistance, the impact on quality of life, health care utilisation and the cost of care. The Effect of Early Versus Deferred ART for HIV on Survival Trial (US and Canada) is looking at the relative risk of death when starting treatment at a CD4 count >350 cells/mm<sup>3</sup> or above >500 cells/mm<sup>3</sup> versus the current WHO guidelines (CD4 <350). TEMPRANO (Early Antiretroviral Treatment and/or Early Isoniazid Prophylaxis against TB in HIV-infected Adults) is an on-going randomised controlled study in the Côte D'Ivoire comparing the effects of immediate ART versus deferred ART (CD4 <350) on mortality (all-cause), AIDS-defining disease, non-AIDS-defining malignancy, and non-AIDS-defining invasive bacterial disease.
- The clinical trial HPTN052 explored early versus deferred treatment to understand the optimal CD4 count to initiate treatment and appropriately balance the health needs of the individual with the additive preventive benefit of ART. The study took place in eight low- and middle-income countries and Boston, US.
- The HIV-discordant couples' cohort team (DISCO) study is measuring the preventive effects of immediate ART regardless of CD4 cell count in Uganda but without clinical endpoints.
- There are a few studies underway exploring universal voluntary testing and treatment at any CD4 count. They are proposing to provide testing and treatment for entire communities and, in some of their intervention arms, begin ART for anyone who tests HIV-

positive. These include PopART (The Population Effects of ART trial), a combination prevention intervention, in South Africa and Zambia; the African Centre TasP (Treatment as Prevention) trial in South Africa; SEARCH (the Sustainable East Africa Research for Community Health) in Kenya, Uganda and Tanzania;; and TTEA (Test and Treat to End AIDS).

There are also several programmatic developments on ART for prevention:

Based on the HPTN 052 results, Rwanda has developed a policy to offer ART to all HIV-positive Rwandans in discordant sexual relationships as soon as they test HIV-positive as part of a plan to boost national HIV prevention and treatment efforts.<sup>22</sup>

In Swaziland, the Maximising ART for Better Health and Zero New HIV Infections (*MaxART*) programme is aiming to take testing and treatment to a greater scale, by increasing opportunities to test for HIV and supporting those who are living with HIV and in need of ART according to current treatment guidelines (i.e. those with CD4 count of 350 and under) to start treatment as soon as possible.

In Malawi, the government has decided to offer HIV testing and to encourage all pregnant women diagnosed HIV-positive to start taking ART to minimise the risk of HIV transmission to their children and to continue taking treatment for life.<sup>23</sup>

In addition, a population-based 'treatment as prevention' approach is currently being implemented in San Francisco, which focuses on recommending increased testing frequency (every six months) and recommending treatment for everyone who tests HIV-positive regardless of their CD4 count.<sup>24 25</sup>

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<sup>22</sup>Plus News <http://www.plusnews.org/report.aspx?reportid=93706>

<sup>23</sup>NAM <http://www.aidsmap.com/Malawi-plans-test-and-treat-approach-for-pregnant-women-to-cut-mother-to-child-HIV-transmission/page/1494940> July 2010.

<sup>24</sup>Hemmelgarn, S. *HIV prevention effort shifts to 'status awareness'*. Bay Area Reporter, March 25, 2010.

<sup>25</sup>Highleyman, L. *SF health officials advise early treatment for people with HIV*. Bay Area Reporter, April 15, 2010.