International HIV/AIDS Alliance
Together to end AIDS

STOP AIDS NOW!

GNP+ GLOBAL NETWORK OF PEOPLE LIVING WITH HIV

BRIEFING PAPER

Summary of the new 2013 Guidelines recommendations and key issues **from a community and civil society perspective**

The success of the WHO 2013 Consolidated ARV Guidelines – whether they lead to better outcomes for people living with and affected by HIV – may largely *depend on you and me!*

In the *2013 Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection* (*2013 Guidelines*), the World Health Organization (WHO) takes a welcomed step in recommending that people living with HIV everywhere be offered a standard of antiretroviral treatment and care that is closer to what is available in resource-rich countries.

The *2013 Guidelines* say much more than just 'start' earlier (i.e. at CD4 cell counts of or below 500 cells/mm^3). They emphasise that the guidelines should be implemented based on core human rights, health equity and ethical principles. Priority should be given to ensuring antiretroviral therapy (ART) for the people who are most ill and those already receiving treatment, while also working towards implementing expanded eligibility criteria and offering a higher standard of care than most people living in resource-limited settings are currently receiving.

However, the *2013 Guidelines* success depends upon the **community and civil society as advocates** involved in critical policy decisions, as these recommendations are adapted to the local setting, to make sure that they are implemented from a human rights perspective, making certain that the highest quality treatment is made available, with services tailored appropriately to different communities with different needs. They also depend on communities and civil society to serve as **mobilisers, educators, service providers and researchers** of their needs and perceptions.

But first, we must understand what the guidelines do – and do not – say, why the recommendations are being made, and how we, as people and communities affected, and as civil society, can engage to make sure the results we want get delivered. Thus, the Global Network of People Living with HIV (GNP+), the International HIV/AIDS Alliance and STOP AIDS NOW! have formed a partnership to develop the *Community Guide on ART for Treatment and Prevention* that offers some answers, guidance, checklists and raises questions not addressed by the *2013 Guidelines*. An Advisory Group has been formed consisting of a wide range of community and civil society partners to support the process.

This briefing paper is part of this process. It summarises some of the new *2013 Guidelines'* recommendations and highlights related key issues from a community and civil society perspective.

The new guidelines could have significant impact …

- WHO estimates that as many as 3 million AIDS-related deaths and 3.5 million new HIV infections could be averted between 2013 and 2025 on top of those averted by implementing the *2010 WHO ART Guidelines.*
- An estimated 26 million people living with HIV in low- and middle-income countries will be eligible for antiretrovirals (ARVs) – an increase of 9 million compared with the previous close to 17 million people (2010 estimate).
- Rapid scale up of ART is possible even in times of dwindling resources, as demonstrated by the 1.6 million more people who were receiving ART in low- and middle-income countries in 2012 compared with 2011.[1]

To ensure the best possible outcomes for people living with HIV, their sexual partners, families and communities, even greater efforts of engagement are needed now.

Look out for the full **Community Guide on ART for Treatment and Prevention.**
To be launched at this year's ICAAP **www.icaap11.org** and ICASA **www.icasa2013southafrica.org**

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[1] WHO, UNICEF, UNAIDS (2013). Global update on HIV treatment 2013: Results, impact and opportunities. Available at: http://www.who.int/hiv/pub/progressreports/update2013/en/

Key components[2] and recommendations of the *2013 Guidelines* and some issues from a community and civil society perspective

COMPONENT 1: CLINICAL GUIDANCE

Recommendations from the 2013 Guidelines	Key issues from a community perspective
▸ All adults and adolescents (aged 10–19) who are living with HIV should be offered treatment earlier (using safer first-line ART regimens with viral load based monitoring for treatment failure), after CD4 cell counts fall to 500 cells/mm^3 or below.	▸ While earlier treatment is being recommended, the **guidelines do not recommend** earlier treatment with the old, and now substandard, first-line ART regimens being phased out in many resource-limited settings. ▸ ART programmes should continue to prioritise or fast track providing treatment to those who have advanced symptomatic illness or with a CD4 cell count of 350 cells/mm^3 or below. ▸ The offer of treatment to healthier individuals should not jeopardise the existing programme and the continued decentralisation and scale-up of ART to sites that are convenient for people. It should also not hinder the continued improvement of drug regimens (safer drugs) and how drugs are being administered (easier to use). ⚠ Are we, as communities and civil society, ready to address the specific needs of key populations living with HIV, especially adolescents of key populations? The guidelines do not explore this question. They do stress, however, the limited capacity of healthcare systems in this area; the issues around child protection and parental consent; and the specific challenges when meeting the needs of adolescents from key populations.
▸ Programmes should offer safer first-line ART regimens to adults and adolescents living with HIV regardless of CD4 cell count in each of the following situations: – When there is a TB co-infection or a chronic hepatitis B co-infection. – When they are pregnant or breastfeeding – either limited to the period of transmission risk during pregnancy and breastfeeding or perhaps for life. – When the HIV-positive partner is in a serodiscordant relationship (where one partner is living with HIV and one partner is not). – When children under 5 years of age test positive for HIV (previously the recommendation was limited to children under the age of two).	▸ The recommendation for life-long ART for all pregnant and breastfeeding women is **conditional**, as it partly depends upon factors specific to the setting. When there are high fertility rates, or very prolonged breastfeeding and programmatic issues such as limited access to CD4 cell testing, an offer of immediate lifelong treatment could get more women onto ART for their own health and prevent HIV transmission to their children. Nevertheless, **there are some important gaps in the evidence base** about how best to implement this approach and whether this would be the best approach in other contexts. ▸ 'Serodiscordant couples' are defined by WHO as "married and cohabiting couples, premarital couples, polygamous unions and any other partnership". This definition restricts ART access to those who meet this definition and thus raises the question of equity. At IAS 2013, one person living with HIV questioned the definition of 'serodiscordant couples', saying, "I am in a serodiscordant relationship, anytime I am in bed with an HIV-negative person". ▸ Offering treatment to children remains a particular challenge. At IAS2013[3] women living with HIV raised the concern that there is a lack of a reliable supply of child-friendly formulations of ARVs in many resource-constrained settings, for instance, and the need for more consultation with affected women.

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[2] This briefing paper focuses only on the new recommendations, not the existing ones that were incorporated into the 2013 Guidelines.

[3] IAS2013 refers to the 7th IAS Conference on HIV Pathogenesis, Treatment, and Prevention, held in Kuala Lumpur, Malaysia on 30 June–3 July 2013. www.ias2013.org

COMPONENT 1: CLINICAL GUIDANCE

Recommendations from the 2013 Guidelines

- The *2013 Guidelines* explicitly state that, at this time, the evidence base is too weak to recommend immediate ART regardless of CD4 cell count to people with HIV-2 or hepatitis C.
- Similarly, they do not yet recommend offering it to people who come from communities most affected by HIV or so-called key populations (e.g. sex workers, men who have sex with men, transgender people or people who inject drugs) and people over 50 years of age – unless they also fulfil one or more of the other immediate treatment criteria (such as being pregnant or having TB).

Key issues from a community perspective

- While the evidence may indeed be too weak to recommend immediate ART for people with hepatitis C (HCV), the lack of guidance on HIV/HCV co-infections is of concern. ITPC, APN+ and ARASA[4] urged for treatment of HIV/HCV co-infections be recommended as part of all comprehensive treatment packages and governments be encouraged to provide and prioritise HCV testing and treatment, in particular among people who inject drugs (currently or formerly), to curb the HIV/HCV co-infection epidemic within this community.

The expert group reviewing the evidence concluded that there are less data on the prevention benefits of ART in key populations (e.g. whether ART is as protective against transmission in men who have sex with men). However, other groups disagree: singling out data in people with hepatitis C and people who inject drugs in particular. Conversely, activists representing sex workers have voiced concern that if ART were recommended regardless of CD4 cell count for sex workers, many might be forcibly tested and placed on treatment.

- Treatment should be standardised for all people living with HIV using the new preferred first-line antiretroviral regimens:
  - For adults, adolescents, and children over 3-years of age:
    - Efavirenz/Tenofovir and either lamivudine (3TC or FTC) – an easier to administer and tolerate regimen that is a large part of what makes earlier treatment safe and feasible.
  - For infants:
    - Ritonavir-boosted lopinavir-containing regimen.
    - If unavailable, a nevirapine-containing regimen may be used (although quite a few infants may have HIV-infections resistant to the drug, there is some limited evidence that nevirapine-containing regimens may still have some benefit).
    - If infant has or develops TB, give an abacavir-based triple nucleoside analog regimen.
  - Phase out d4T-containing regimens (strong recommendation) – it has too many serious side effects to be used in first-line regimens for early treatment.
  - Nevirapine-containing ARVs should only be used if efavirenz is unavailable or cannot be used.

- An estimated 1.1 million people are still on d4T (WHO 2013). Phasing out d4T is critical and received a lot of (73%) support from community members responding to a 2012 Community Consultation to inform the *2013 Guidelines*, in particular from people living with HIV (report available at: http://www.aidsalliance.org/Pagedetails.aspx?id=527). While some were concerned about retaining it for those using and tolerating it well and keeping a stock for salvage therapy, the existing stocks and lower costs were not considered reasons to continue using it. A question remains concerning the switch from d4T to tenofovir among infants/young children who are currently on d4T.

The treatment options for infants are, in general, far too limited – and child-friendly formulations are particularly difficult to provide in resource-limited settings.

- Whether it is safe to start treatment early with a nevirapine-containing regimen in adults is unknown.[5] There are limited data on nevirapine's safety in women with CD4 ≥350 cells/mm^3 and reports of life-threatening hepatic toxicity in uninfected people who used the drug as post-exposure prophylaxis. Individuals starting 'early' on a nevirapine-containing regimen should be advised about the risks and benefits and encouraged to be extra vigilant and to report side effects, seek remedy for them, etc.

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[4] Treatment 2.0: The Next Phase of HIV Treatment and Prevention Scale-Up: A Community-Based Response. Available at: http://www.apnplus.org/main/Index.php?module=news&news=80

[5] Systematic reviews have found that individuals were twice as likely to discontinue treatment due to the side effects if started on nevirapine rather than efavirenz.

COMPONENT 1: CLINICAL GUIDANCE

Recommendations from the 2013 Guidelines	Key issues from a community perspective
▶ When first-line regimens stop working, the *2013 Guidelines* recommend switching to a ritonavir-boosted (r) protease inhibitor anchored regimen, either r/lopinavir or r/atazanavir.	▶ Access to a second-line regimen may be a critical factor in deciding whether it is safe for a person to consider starting treatment at CD4 cell count of 500 cells/mm^3 or below – especially if there could be personal problems, family issues, civil unrest or stock-outs that could disrupt reliable access to treatment or adherence. Treatment literacy programmes need to take this into account. ▶ Sometimes, the switch to second-line regimens occurs prematurely. Individuals and healthcare providers need better insights into treatment failure (i.e. whether it occurred, whether adherence support or other interventions can prevent it from occurring). Thus, access to viral load monitoring needs to be accelerated.
▶ The *2013 Guidelines* **conditionally** recommend that countries start making plans for third-line regimens that take into account funding, sustainability and equity of access. These should include new drugs likely to be effective against virus resistant to earlier regimens (e.g. integrase inhibitors new non-nucleoside reverse transcriptase inhibitors and other boosted protease inhibitors). ▶ However, the *2013 Guidelines* note that there are little data on the use of these agents in resource-limited settings for individuals on failing treatment. If there are no third-line options, WHO recommends keeping individuals on previously used but well tolerated regimen.	▶ Keeping individuals on previously used but well tolerated regimens if there are no third-line options, is not an acceptable alternative. Data show that mortality among individuals with no further treatment options is very high. From a community perspective, it is important to be frank – the cost of these regimens is the real barrier, and must be brought down.
▶ Viral load monitoring is now the preferred method of monitoring the success and failure of treatment (in addition to CD4 and clinical monitoring).	▶ When treatment is started earlier, and we expect some people will need second and third line regimens, detecting when treatment failure begins, and to switch them before they begin falling ill or losing their CD4 cells, could save lives and improve their chances of responding to second-line treatment. Many people living with HIV view being able to find out whether one is undetectable (and therefore both responding to treatment and posing less of a risk of transmission to one's loved ones and other sexual partners) as a human right. The challenge here will be making viral load testing accessible, affordable and timely where people receive their treatment.
▶ WHO makes a strong push for the scale-up of community-based HIV-testing and counselling (door to door and outreach testing and counselling) with special recommendations for testing and counselling of adolescents and key populations. The 2013 Guidelines also emphasise the need to strengthen linkages between testing and counselling services and HIV treatment services in other programmes (e.g. TB clinics) to maintain a continuum of care (where people are effectively referred to the site where they will continue to receive treatment).	▶ Treatment cannot start without HIV counselling and testing. This recommendation is critical in terms of the role of communities in mobilising their peers to access testing, ensuring the acceptability of proposed service delivery models and that all HIV counselling and testing services are based on key ethical principles, as outlined in the *2013 Guidelines* (i.e. informed consent, confidentiality, etc.). ⚠ While the *2013 Guidelines* acknowledge that communities have a critical role, they do not emphasise sufficiently the roles that communities successfully play in treatment and rights literacy, in creating demand for and linking communities to health and interrelated services, in reaching those hardest to reach to increase impact, and the advantages of multi-sector service delivery models, such as the provision of complementary behavioural interventions at healthcare facilities (e.g. through peer education and counselling).

Recommendations from the 2013 Guidelines

- WHO recommends community-based testing and counselling with linkage to prevention, treatment and care in addition to provider-initiated testing and counselling, with particular focus on key populations and adolescents in concentrated epidemics and for everyone at risk of HIV in generalised epidemics.
- WHO recommends optimising adherence to ART through the use of mobile phone text messages; better service integration, especially through initiation of ART at maternal and child healthcare settings and TB or opioid substitution clinics depending on the epidemiology or prevalence; and strengthened decentralisation of HIV services, so that ART can eventually be initiated at peripheral health facilities with maintenance at the community level.

Key issues from a community perspective

- The interventions recommended by WHO are not fully aligned with the *Positive Health, Dignity and Prevention Policy Framework*. The framework coupled with the *Positive Health, Dignity and Prevention Operational Guidelines* can be useful tools for communities to engage in policy and programming processes.
- The critical role of communities in monitoring and evaluating the decision-making process and the implementation of recommendations and subsequent programming at country-level is not considered in the *2013 Guidelines*. Communities' role is mainly seen in the planning and design phase.
- Similarly, the value that communities add to and the many different roles that individuals and community groups and civil society organisations are playing in reducing the loss to follow up, in retaining people in care and plugging the leaks in the treatment cascade, and in building capacity in these areas of community stakeholders, has not been sufficiently described in the *2013 Guidelines*, nor has the evidence supporting this been provided.
- The 2012 Community Consultation shows that communities fully support the integration of ART services into TB, hepatitis B or C, sexual and reproductive health, maternal and child health, and harm reduction services, and vice versa (Report available at: http://www.aidsalliance.org/Pagedetails.aspx?id=527). Community respondents also support decentralisation and task shifting, but stressed that it must be implemented in a sensitive manner so that services remain available and acceptable to communities, particularly key populations, without exacerbating stigma and discrimination.
- The *2013 Guidelines* stress the importance of a combination prevention approach, including ARVs for treatment and prevention. They do not address effective structural and behavioural interventions and the fact that communities are the main providers of these intervention packages, in particular in relation to key populations. However, failing to invest in community mobilisation, structures, capacity and services, risks the failure of the entire HIV response.

⚠ Addressing the capacity-building needs of communities to deliver on the *2013 Guidelines*, coupled with the need to strengthen community structures and the respective investments required in these areas by governments and donors alike, is one of the biggest gaps of these guidelines.

COMPONENT 3: PROGRAMMATIC GUIDANCE

Recommendations from the 2013 Guidelines

- For deciding on the implementation of the clinical and operational recommendations, WHO recommends:
  - Transparent, open and informed process with broad stakeholder engagement, including meaningful participation from the affected communities.
  - Take into account data on the national and local HIV epidemiology, current ART programme performance and the socio-economic, policy and legal context, including the budgetary, human resource requirements and other health system implications.
  - Take into account the ethics, equity and human rights, the impact and cost-effectiveness and the opportunity and risk dimensions of alternative implementation options.

Key issues from a community perspective

- The *2013 Guidelines* do not say that every programme can implement all of the recommendations overnight. They recommend a progressive approach to implementation.
- The language on human rights in the *2013 Guidelines*, as rightly stressed by ITPC, APN+ and ARASA in their IAS2013 press release, is not decisive enough. Ethics, equity and human rights should not just be taken into account in decision-making, but should form the basis for decision-making, reflecting governments' obligations to promote, protect and fulfil the right to health, among other human rights.

⚠ Access to ART services should be recognised as fundamental to realising the universal right to health.

Governments need to create environments that enable people to exercise their rights and make informed decisions.

Stakeholder engagement and meaningful participation of people living with HIV is critical in planning and implementation and must be supported.

COMPONENT 4: FURTHER RESEARCH

Recommendations from the 2013 Guidelines

- The *2013 Guidelines* acknowledge and highlight gaps in the ART-related evidence base (e.g. in relation to whether starting ART above CD4 count of 500 cells/mm^3; retention on ART among people on opioid substitution therapy; and impact of ART among people with hepatitis C).

Key issues from a community perspective

- Social science and participatory research will play a critical role in answering open questions concerning earlier ART for treatment and prevention (e.g. what the effects will be on marginalised communities in terms of stigma and discrimination, rights and choices, community norms and perspectives, interpersonal and sexual relationships, etc.), feasibility, acceptability and scalability.

⚠ Communities need to be involved in research planning, design, implementation and monitoring.

KEY DOCUMENTS

WHO (2013). *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection.*

Available at: http://www.who.int/hiv/pub/guidelines/arv2013/en/

WHO (2010). *2010 ART guidelines for adults and adolescents – evidence map.*

Available at: http://www.who.int/hiv/topics/treatment/evidence/en/

GNP+ (2011). *Positive Health, Dignity and Prevention: A Policy Framework.*

Available at: http://www.gnpplus.net/en/resources/positive-health-digity-and-prevention/item/109-positive-health-dignity-and-prevention-a-policy-framework

GNP+, UNAIDS (2013). *Positive Health, Dignity and Prevention Operational Guidelines.*

Available at: http://www.gnpplus.net/images/stories/PHDP/positive%20health%20dignity%20and%20prevention%20operational%20guidelines%20-%20unaids%20gnp%202013.pdf

The forthcoming *Community Guide on ART for Treatment and Prevention* will look more closely at what the guidelines recommend, and the issues they raise from communities' perspectives.

The guide will look at how people living with and affected by HIV and civil society supporting community action can redouble their advocacy efforts with programme managers, funders and other policymakers, as well as how to revise community education to protect and empower people living with HIV and develop community-based services for better adherence support, linkages and retention in care.

The guide will be launched at ICAAP (www.icaap11.org) and ICASA (www.icasa2013southafrica.org) this year, so watch this space!

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