Concise guidance for HIV healthcare providers on the use of antiretrovirals for prevention
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**INTRODUCTION**

**Who is this guidance for?**
This guidance is for anyone who provides HIV testing, treatment, prevention and care services delivered either in healthcare settings or in the community. It provides a concise signposting to other existing guidelines, frameworks and best practice guidance in order to assist healthcare providers counsel individual patients on HIV testing, treatment and prevention in a way that is supportive, respectful, equitable and non-discriminatory, and mindful of ethical, legal and operational issues.

**Why is this guidance needed?**
The 2013 consolidated HIV treatment and prevention guidelines from the World Health Organization (WHO) recognize for the first time the additional HIV prevention effect of antiretroviral therapy (ART). However, these guidelines are based on a public health approach to the further scaling up of antiretroviral drugs (ARVs) for treatment and prevention that considers feasibility and effectiveness across a variety of resource-limited settings. They are not aimed at HIV healthcare providers who may require support and information regarding counseling of individuals. This concise guidance should be seen as a companion to the WHO guidelines, not as a replacement for them.

**How was this guidance produced?**
It was conceived and drafted by members of the International AIDS Society’s (IAS) Implementation Advisory Group for Treatment as Prevention (TasP) and reviewed by a panel of experts, including people living with HIV and other key stakeholders.

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1 We seek to emphasize the fact that people living with HIV are not simply ‘patients’ – passive recipients of their own health care – but people whose rights as individuals are to be respected.
**Core Principles**

1. Everyone has the right to enjoy the highest possible standard of physical and mental health and the right to make voluntary decisions about their own healthcare. Consequently, healthcare providers must treat their patients as individuals, and respect their autonomy and dignity.

   This includes:
   - Being respectful, non-judgmental and doing no harm.
   - Listening to, and responding to, your client's concerns and preferences.
   - Providing clear information in a way they can understand.
   - Never abusing, coercing, discriminating, judging, pathologising or punishing.
   - Working in partnership with them and respecting their right to make their own decisions about HIV testing, treatment and/or care.

2. ART benefits both the health of the person living with HIV, by preventing morbidity and mortality, and the health of their HIV-negative intimate partner(s), by greatly reducing their risk of acquiring HIV. However, where access to ART is limited or rationed, individuals who require treatment based on a clinical need to prevent morbidity and mortality must always be prioritized.

3. The HIV prevention benefit of ART must never focus exclusively on “preventing onward transmission.” This is a potentially stigmatizing phrase that can create the perception of a one-sided responsibility for HIV prevention. It is important to emphasize that HIV is both transmitted and acquired. Undiagnosed and diagnosed people living with HIV, along with their partners and communities, should be included in HIV prevention programmes that highlight shared responsibility for HIV prevention regardless of known or perceived HIV status.

4. ART should never be used coercively as a public health measure in an effort to prevent new infections. No-one should ever be – or feel – coerced into HIV testing or treatment, which must always be voluntary. This is of particular concern for people belonging to stigmatized or criminalized populations who may be, or fear being, exposed or endangered by such programmes. Healthcare providers must always ensure that there are safeguards in place against real or perceived pressure, coercion or legal threats to people who do not wish to be tested or treated, in the name of public health. Healthcare providers should also be alert to the possibility of coercion by partners or others. They should establish whether the person living with HIV wishes to take ART of her/his own free will. This may be particularly significant in situations of gender-based violence or financial dependence.

**HIV Testing and Counselling**

The 2013 WHO guidelines recommend the following:

- All forms of HIV testing and counseling should be voluntary and adhere to the five C’s: ‘Consent’, ‘Confidentiality’, ‘Counseling’, ‘Correct test results’ and ‘Connections to care, treatment and prevention services’. Mandatory or coerced testing is never appropriate, whether that coercion comes from a healthcare provider or from a partner or family member.

- People receiving HIV testing and counseling must give informed consent (verbal consent is sufficient). They should be informed of the process of HIV testing and counseling and of their right to decline testing.

- HIV testing and counseling services must be confidential. The content of any discussion occurring during the process of testing and/or counseling, as well as the results themselves, cannot be disclosed to anyone without the expressed consent of the person being tested. (See also Ethical and Legal Issues)
• Although confidentiality should be respected, it should not be used to reinforce secrecy, stigma or shame. Healthcare providers should encourage disclosure and provide assistance and advice on the best ways to do so. Shared confidentiality with a partner, family members, trusted acquaintances and with healthcare providers is often highly beneficial. (See also Ethical and Legal Issues)

• Couples and partners should be offered voluntary HIV testing and counseling with support for mutual disclosure.³

• HIV counseling services must include both appropriate and high-quality pre-test information (which can be provided as group pre-test information in some settings) and post-test counseling. Supportive supervision and mentoring systems should be in place to ensure the provision of high-quality counseling.

• HIV testing and counseling providers should strive to provide high-quality testing services. Quality assurance mechanisms should be in place to ensure the provision of correct test results. These may include both internal and external measures and should include support from the national reference laboratory as needed.

• Connections to prevention, care and treatment services should include the provision of effective referral to appropriate follow-up services, including long-term prevention and treatment support (inclusive of sexual and reproductive health¹ and harm reduction⁵ services).

Understanding and Explaining ART Eligibility

The 2013 WHO guidelines recommend ART, regardless of CD4 count, for the following individuals:

• People living with HIV and active tuberculosis (TB) disease;
• People living with HIV and hepatitis B virus (HBV) infection with severe chronic liver disease;
• People living with HIV in a sero-discordant relationship;
• Women living with HIV who are pregnant and breastfeeding mothers;
• Children living with HIV who are younger than five years of age.

For all others, ART is recommended only when their CD4 count falls below 500 cells/mm³. Priority should be given to individuals with severe progression of HIV and/or to those with a CD4 count of 350 cells/mm³ or less.

Individuals who are not yet eligible for ART but who request to start it will require additional support in order to understand why they are not yet able to access ARVs. In order to avoid loss to follow-up, a full range of health and prevention services should be offered (see The Continuum of care) providing an opportunity for close clinical and laboratory monitoring and early assessment of eligibility for ART and timely initiation.

The Continuum of Care

As well as basic HIV prevention, health promotion and screening, prophylaxis and management of HIV-related co-infections, WHO recommends a package of thirteen prevention interventions for all people living with HIV, in order to reduce HIV transmission, prevent illness and improve quality of life. These include:

• Psychosocial counseling and support;
• Disclosure and partner notification support;
• Co-trimoxazole prophylaxis;
• Tuberculosis (TB) counseling, screening and preventive therapy;
• Prevention of common fungal infections;
• Prevention of sexually transmitted infections and support of reproductive health needs, including prevention of and screening for cervical cancer;
• Prevention and early treatment of malaria (especially among pregnant women);
• Vaccination against preventable diseases;
• Proper nutrition;
• Availability and use of family planning services;
• Prevention of mother to child transmission (PMTCT)
In addition, other influential guidelines recommend that people with HIV should be linked to community-based peer support services, and further stress the need for social and economic support.

**A rights-based approach to “positive prevention”**

Positive Health, Dignity and Prevention, developed by UNAIDS and the Global Network of People Living with HIV (GNP+), calls for a comprehensive set of actions – at both policy and service delivery levels – that take into consideration the individual’s lived environment, recognizing the importance of meeting not only the person’s clinical needs but also their health needs and to protect their human rights. Instead of being regarded by ‘positive prevention’ programmes as mere recipients of care and vessels of a virus that needs to be contained, in this new paradigm people with HIV are actively involved as part of the solution to the epidemic and not seen as part of the problem. Positive Health Dignity and Prevention emphasizes that responsibility for HIV prevention should be shared — and that preventing new HIV infections should be everyone’s goal regardless of their assumed or known status. Although supportive of many behavioural interventions, the framework calls for more sensitivity when approaching people with HIV who refuse to use condoms and/or have multiple concurrent partners noting that, “behaviour that may lead to HIV transmission is often the product of underlying economic, social and/or psychological issues, such as poverty, gender-based violence and/or homophobia.” More information is available here: http://www.gnpplus.net/en/programmes/positive-health-dignity-and-prevention/positive-health-dignity-and-prevention.

**Understanding and Explaining ART for Preventing Illness and Death**

**When to start - explaining benefits and risks**

Healthcare providers should explain the potential for progression of HIV, as well as the impact on infectiousness and risk of super-infection (see Understanding and Explaining ART for HIV Prevention) in the event the patient decides not to commence or continue treatment.

The 2013 WHO guidelines recommend the following:

*Before people start ART, it is important to have a detailed discussion with them about their willingness and readiness to initiate ART, the ARV regimen, dosage and scheduling, the likely benefits and possible adverse effects and the required follow-up and monitoring visits. For children with HIV, this conversation should directly involve the carer and include discussion about disclosing their HIV status. Retesting all people living with HIV before initiating ART is good practice to ensure correct diagnosis of HIV infection. Initiation of ART should always consider nutritional status, any comorbidities and potentially interacting medications for possible contraindications or dose adjustment. The choice to accept or decline ART ultimately lies with the individual person or his or her caretaker, and if they choose to defer initiation, ART can be offered again at subsequent visits. If there are mental health, substance use or other problems that are major barriers to adherence, appropriate support should be provided, and readiness to initiate ART should be reassessed at regular intervals. A wide range of patient information materials as well as community and peer support can help the person’s readiness and decision to start therapy.*

**What to expect in the first few months of ART**

The 2013 WHO guidelines recommend the following:

*People starting treatment and carers should understand that the first ART regimen offers the best opportunity for effective virological suppression and immune recovery, and that successful ART requires them to take the medications exactly as prescribed. They should be advised that many adverse effects are temporary or may be treated, or that substitutions can often be made for problematic ARV drugs. People receiving ART and carers should also be asked regularly about any other medications that are taken, including herbal remedies and nutritional supplements.*

Healthcare providers should explain that there is a potential for known and unknown side effects to ARVs. These should be balanced with the risks linked to the progression of HIV if left untreated.
Adherence support
Healthcare providers should discuss a patient's individual situation in order to identify and address any concerns before beginning ART. The patient should be given time to prepare for life-long treatment and, if possible, be given written information to take away and read. Readiness and willingness to commence ART are directly correlated with better adherence.

The 2013 WHO guidelines recommend the following:
Adherence interventions, such as text messaging, should clearly be provided as part of a total package of several interventions. Many individual level adherence interventions are indicated for reasons in addition to improving adherence to ART. For example, nutritional support, peer support, management of depression and substance use disorders and patient education are vital components of routine health and HIV care.
Efforts to support and maximize adherence should begin before ART is initiated. Developing an adherence plan and education are important first steps. Initial patient education should cover basic information about HIV, the ARV drugs themselves, expected adverse effects, preparing for treatment and adherence to ART. Adherence preparation should not delay treatment initiation, when prompt action is necessary.
Patient education and counseling are essential both when ART is initiated and throughout the course of treatment. Informing and encouraging people receiving ART and their families and peers are essential components of chronic HIV care. Studies show that counseling improves adherence to ART, and in some settings there is an association between peer support and high rates of adherence and retention.

Understanding and Explaining ART for HIV Prevention

The additional prevention effect of ART
Counseling relating to the benefit of ART on the prevention of new HIV infections should first focus on the well-being of the patient, rather than focusing solely on HIV prevention. No-one should feel pressured by a healthcare provider, community, family or partner to commence ART for the primary purpose of HIV prevention. The concept of risk reduction, as opposed to risk elimination, should be fully explained.

The 2013 WHO guidelines recommend the following:
People receiving ART should understand that while the ARV drugs reduce the risk of HIV transmission, they cannot be relied on to prevent other people from acquiring infection.

There is conclusive evidence that effective ART considerably reduces an individual's risk of transmitting HIV through vaginal sex, and convincing epidemiological and limited direct evidence states that this may also apply to anal sex. If patients are made aware of this evidence, they may be further motivated to start and continue with ART, be relieved of an undue burden of fear and anxiety of infecting others, and feel a sense of empowerment and control over the virus.

ART as part of a combination prevention package
The prevention benefit of ART should be included as part of a combination prevention package, along with up-to-date, accurate and non-judgmental information about how HIV is acquired and transmitted and high quality counseling. This information will help to ensure good sexual health and will increase awareness about HIV risk reduction strategies and technologies, including:
- Male and female condoms and lubricant;
- Harm reduction services for people who use drugs, including sterile injecting equipment and voluntary opiate substitution therapy;
- Prevention of PMTCT services;
- Voluntary male circumcision; and
- Any other new prevention technologies as they become available.

European AIDS Clinical Society (EACS) Guidelines include an algorithm for assessing HIV-positive persons' readiness to start and maintain ART, covering five stages: Precontemplation; Contemplation; Preparation; Action; and Maintenance. See (page 6): http://eacsociety.org/Portals/0/Guidelines_Online_131014.pdf
People living with HIV should be made to understand that they have choices, and should be allowed to make their choices according to their individual circumstances.

**ETHICAL AND LEGAL ISSUES**

It is crucially important that healthcare providers and their patients be aware of the laws relating to potential criminal or civil liabilities relating to breached confidentiality, non-disclosure of HIV-positive status and/or potential exposure to others to HIV.

HIV healthcare providers should recognize and respect their duty to protect the confidentiality of their patients and should only disclose highly personal information, such as HIV status, with the informed consent of the patient. Failure to maintain confidentiality may cause harm and is therefore in direct confrontation with the Hippocratic Oath provision to do no harm.

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Help when making difficult decisions

‘Difficult Decisions: A Toolkit for Care Workers’ has been created to help health care workers who are facing an ethical dilemma – a situation where different values, responsibilities, or concerns pull you in different directions. For example, if you want to protect one person, but are worried that by doing so, you might harm someone else. Or, you might be unsure of how to help someone, while still respecting the law. The toolkit will be available in 2014. More information is available here: http://www.ccaba.org/our-projects/policy/care-worker-guidance/.

When there is a clear indication that a third party may be harmed by the actions of the patient, the ethical principle of confidentiality may conflict with the ethical principle to ‘do no harm’. The healthcare provider must weigh the potential harms and benefits to the parties involved in order to decide how to proceed. Important relevant factors to consider include: patient confidentiality, public health concerns, the healthcare provider-patient relationship, and the need for a trusted protective environment in which issues of voluntary and beneficial disclosure can be raised and explored. It is important to remember that disclosure is a process rather than an event and that maintaining trust and a therapeutic relationship with patients in order to allow them safe spaces to examine disclosure issues will ultimately lead to far more beneficial outcomes than the threat of prosecution.

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To find laws relating to these issues in your country or jurisdiction, visit the GNP+ Global Criminalisation Scan: http://www.gnpplus.net/criminalisation.

Examples of beneficial disclosure involve instances where a person with HIV informs a sexual partner of their status for prevention purposes, or informs family, community members or healthcare providers in order to obtain support. Examples of harmful disclosure involve cases where disclosure is made without the consent of the person who is HIV-positive and has adverse consequences for that person, such as stigma, abandonment, physical violence, imprisonment, loss of job or housing, or other forms of discrimination. Harmful disclosure may also impair prevention and care activities because fear of lack of confidentiality and forced disclosure drives people away from HIV services, reducing opportunities to encourage and empower people to change their behaviour in order either to avoid getting infected or to avoid passing on their infection. It may also drive people away from other health care services, such as antenatal care or blood donation. See: UNAIDS. **Opening up the HIV/AIDS epidemic: Guidance on encouraging beneficial disclosure, ethical partner counselling & appropriate use of HIV case-reporting.**
**ADDITIONAL CONSIDERATIONS FOR SPECIFIC CLIENTS**

The 2013 WHO guidelines cover HIV prevention and treatment issues relating to specific groups. In addition, the particular needs of specific patients living with HIV must be effectively addressed and prevention, treatment and care should be tailored to their specific needs.

**Pregnant and breastfeeding women**
The 2013 WHO guidelines recommend the following:

- All pregnant and breastfeeding women with HIV should initiate triple ARVs (ART), which should be maintained at least for the duration of mother-to-child transmission risk. Women meeting treatment eligibility criteria should continue lifelong ART.
- For programmatic and operational reasons, particularly in generalized epidemics, all pregnant and breastfeeding women with HIV should initiate ART as lifelong treatment.
- In some countries, for women who are not eligible for ART for their own health, consideration can be given to stopping the ARV regimen after the period of mother-to-child transmission risk has ceased.
- Mothers known to be infected with HIV (and whose infants are HIV uninfected or of unknown HIV status) should exclusively breastfeed their infants for the first 6 months of life, introducing appropriate complementary foods thereafter, and continue breastfeeding for the first 12 months of life. Breastfeeding should then only stop once a nutritionally adequate and safe diet without breast-milk can be provided.

All pregnant women living with HIV must have access to PMTCT measures. Women have the right to access such services without fear of being coerced into terminating their pregnancy. PMTCT must recognize both the mother’s independent human right to health and the fact that the mother’s health also affects the health of her infant. It must be embedded within life-long access to treatment, care and support that does not cease once the baby is delivered.

**Women who are not pregnant or breastfeeding**
Although many women first learn of their HIV-positive status during services aimed at preventing mother-to-child transmission, it is important to remember that women are not only mothers, and their health and well-being is as important as their baby’s.

Women have the right to both a healthy sex life and the right to choose whether or not they wish to have children. In a broader context of gender inequality, women living with HIV require gender-responsive treatment services, antiretrovirals for themselves as well as for their babies, and care and support services that do not heighten their vulnerability.

**Children**
The 2013 WHO guidelines recommend the following:

- ART should be initiated in all children infected with HIV below five years of age, regardless of WHO clinical stage or CD4 cell count.
- ART should be initiated in all HIV-infected children five years of age and older with CD4 cell count ≤ 500 cells/mm³, regardless of WHO clinical stage.
- ART should be initiated in all children infected with HIV with severe or advanced symptomatic disease.
- ART should be initiated in any child younger than 18 months of age who has been given a presumptive clinical diagnosis of HIV infection.

Children living with HIV require access to health services that address both HIV-related issues as well as other developmental and health-related issues.

**Young people**
Young people living with HIV who access treatment, care and support often have needs that differ from adults, particularly due to age-of-consent restrictions on health services. Moreover, adolescents living with HIV have specific medical, sexual and reproductive and psychosocial needs as they transition into adulthood. These include support regarding disclosure of their HIV status when they first become sexually active.

**Older people**
The 2013 WHO guidelines do not recommend initiating ART above 500 cells/mm³ in people over the age of 50, even if they are in a relationship with an HIV-negative partner or living with TB or advanced hepatitis B co-infection. It would therefore be advisable to counsel such individuals on the lack of data regarding the safety and effectiveness of ART in people of their age. Based on this information, they should be allowed to make an informed decision regarding their commencement, or not, of ART.
Key Affected Populations

The 2013 WHO guidelines and new, consolidated guidance on HIV among key populations released by WHO in mid-2014, offer the potential for increased access to HIV testing, counseling and ART by key affected populations.

Although the 2013 guidelines recommend that ART initiation among key populations should follow the same overarching principles as for the general adult population (i.e. at a CD4 count below 500 cells/mm³), certain specific recommendations may be of particular relevance to key affected populations. Specifically that ART should be initiated regardless of CD4 count among certain vulnerable population groups, namely those with HIV and active TB, people with an HIV-Hepatitis co-infection accompanied by chronic liver disease, HIV-positive pregnant women, and HIV-positive people in sero-discordant sexual relationships.

The guidelines reaffirmed earlier WHO guidance that HIV testing and counseling should be routinely recommended for key affected populations in all health facilities where there are generalized epidemics. In areas with low or concentrated epidemics, voluntary testing and counseling should be included at all health facilities offering services for sexually transmitted infection, hepatitis, TB and antenatal care. Health services specifically targeting key population groups should be provided, to the extent possible.

New 2014 WHO key population guidance recommends that pre-exposure prophylaxis (PreP) be available as an option for sero-discordant couples and men/transgender women who have sex with men. PreP is not specifically recommended for other key populations.

Post-exposure prophylaxis has also been used in some countries among certain key affected populations. While it is an important prevention tool, it cannot be substituted for use of other proven prevention methods, including PreP, consistent condom use or the use of sterile injecting equipment.

If you are faced with an issue of dual-loyalty (if the law in your jurisdiction is in conflict with your ethical obligation to serve all patients fairly), it is important for all healthcare providers to prioritize their core obligation and their Hippocratic Oath. Healthcare providers must not participate in any form of abuse, coercion, discrimination, judgment, or punishment in their line of work. If you are likely to show your discomfort in serving any particular patient, you should refer your patient to a more friendly provider who can provide better quality care.

Men who sex with men (MSM)

Testing, treatment and care for MSM in settings where laws criminalize same-sex relationships and/or where there are high levels of social stigma towards MSM must be delivered in a way that prioritizes confidentiality and safety of the patient and that does not place them at risk of prosecution or further social marginalization.

People who inject drugs (PWID)

For people living with HIV who also inject drugs, services for ART and/or opiate substitution therapy (OST) should be tailored to each individual’s specific needs, taking into consideration the impact of both OST and ART on their health. Where laws criminalize people who use drugs and/or where there are high levels of social stigma towards people who use drugs, testing treatment and care must be delivered in a way that prioritizes confidentiality and safety of the patient and that does not place them at risk of prosecution or further social marginalization.

Sex workers

Testing, treatment and care services for sex workers must be delivered in a way that prioritizes confidentiality and safety of the patient and that does not place them at risk of prosecution or further social marginalization.

Transgender people

Transgender people living with HIV require treatment and care that takes into consideration hormonal therapies and gender-related social drivers. Where laws criminalize transgender people and/or where there are high levels of social stigma towards transgender people, testing treatment and care must be delivered in a way that prioritizes confidentiality and safety of the patient and that does not place them at risk of prosecution or further social marginalization.

*Referring collectively to People who Inject Drugs (PWID), Men who have sex with men (MSM), Sex Workers (SW) and Transgendered people (TG).
KEY REFERENCES


The Teresa Group. Difficult Decisions: A Toolkit for Care Workers Managing Ethical Dilemmas When Caring for Children and Families of Key Populations – People Living with HIV, People who use Drugs, Sex Workers, Transgender People, Gay Men, and other Men who have Sex with Men. (2014). Available at: http://www.teresagroup.ca/


MSMGF. Engaging with Men Who Have Sex with Men: A Primer for Physicians, Nurses, and Other Health Care Providers. (2011). Available at: http://www.msmgf.org/index.cfm/id/310/Publications/


FURTHER READING

British HIV Association/British Association of Sexual Health and HIV. HIV Transmission, the Law and the Work of the Clinical Team. (2013).


Department of Health (UK). BHA and EAGA position statement on the use of antiretroviral therapy to reduce HIV transmission. (2013).


Fakoya A et al. UK guidelines for the management of sexual and reproductive health (SRH) of people living with HIV infection. (2007).


IATT. Toolkit, Expanding and Simplifying Treatment for Pregnant Women Living with HIV: Managing the Transition to Option B/B+. (2013).


WHO. Guidance on HIV testing and counselling for adolescents and care for adolescents living with HIV. (2013).

WHO. Couples HIV testing and counselling including antiretroviral therapy for treatment and prevention in serodiscordant couples. (2012).


WHO. Guideline on HIV disclosure counselling for children up to 12 years of age. (2011).


PATIENT INFORMATION

NAM. The basics series: http://www.aidsmap.com/thebasics

- Basics
- Better off knowing
- When should I start treatment?
- How treatment works
- Taking drugs on time
- Transmission facts
- Transmission and viral load

NAM. Patient Information booklets: http://www.aidsmap.com/booklets

- Booklets
- Taking your HIV treatment

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2 Ibid. ‘Box 5.1 HIV testing and counselling: guiding principles’ (p69).
3 Further guidance is provided in WHO. Couples HIV testing and counselling including antiretroviral therapy for treatment and prevention in serodiscordant couples. (2012).
9 This section is adapted from Maximizing the benefits of antiretroviral therapy for key populations: A White Paper by the Key Affected Populations and Treatment as Prevention Working Groups of the International AIDS Society, July 2014.

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