UNAIDS PROGRAMME COORDINATING BOARD

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THIRTY-THIRD MEETING

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Venue: Executive Board Room, WHO, Geneva

Agenda item 4

Strategic use of antiretroviral medicines for treatment and prevention of HIV
Recalling the commitment of member states under the 2011 Political Declaration on HIV/AIDS to accelerate efforts to achieve the goal of universal access to antiretroviral therapy for those eligible based on World Health Organization (WHO) HIV treatment guidelines that indicate timely initiation of quality assured treatment for its maximum benefit, the Programme Coordinating Board (PCB) is invited to:

See decisions in paragraphs below:

132. Welcome this paper;

133. Call upon Member States to:

a. Ensure that acceleration of access to HIV treatment, including addressing the barriers to treatment access, are factored into all stages of HIV and health planning, implementation, monitoring and evaluation, and resource mobilization, particularly with regards to development of investment thinking approach, and support for the roll-out of the New Funding Model of the Global Fund to Fight AIDS, TB and Malaria (Global Fund);

b. implement the 2013 WHO consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection;

c. continue work towards further scale-up of access to HIV services including by strengthening community systems and the role of communities in creating demand and delivering services;

d. work to ensure the sustainability of national AIDS responses recognizing the principles of country ownership through strengthening of shared responsibility, innovative sustainable financing to meet increased demand, building of strategic partnerships, and based on multi-sectoral approaches;

e. ensure that programmes to expand access to HIV treatment offer quality HIV services, improve treatment literacy, are voluntary, non-coercive and respect the human rights of people living with HIV.

134. Request the Joint Programme to:

a. support on-going national and international processes led by countries and regional institutions to convene national and regional consultations for the definition of revised national targets for universal access to HIV treatment keeping in mind the lead for defining new milestones and targets for the AIDS response beyond 2015;

b. further support implementation of the 2013 WHO consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection;

c. support capacity development of communities to deliver local HIV services;

d. further support countries in the roll-out of the New Funding Model of the Global Fund, including through the development of a strategic investment approach;

e. continue to support the availability of the most favourable pricing for antiretroviral medicines and harmonizing medicines regulatory systems as well as the provision of technical support for countries to maximize utilization of the flexibilities under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Doha Declaration.
KEY TERMS AND DATA USE

Antiretroviral therapy: The use of a combination of three or more antiretroviral (ARV) medicines to suppress the HIV virus.

CD4 cells: These are cells that send signals to activate the body's immune response when they detect “intruders,” like viruses or bacteria. If HIV is untreated, CD4 cells become depleted and the body is left vulnerable to a wide range of infections that it would otherwise be able to fight. The normal count for CD4 cells in the human body is between 500 and 1500 cells/mm³. WHO in its consolidated guidelines on use of antiretroviral drugs for treating and preventing HIV infection, released in 2013, recommends that antiretroviral therapy should be initiated in all person living with HIV with CD4 count of ≤500 cells/mm³.

Early initiation of antiretroviral therapy: In 2013, WHO revised the 2010 ARV guidelines to recommend earlier initiation of HIV treatment. The threshold for starting ARVs was raised from a CD4 count of 350 cells/mm³ to 500 cells/mm³ because latest evidence showed that starting treatment earlier, when the immune system is stronger, prolongs life and results in fewer transmissions from an infected person to an uninfected person. In addition, they also recommend starting antiretroviral therapy for people who are coinfected with TB, co-infected with HBV, in serodiscordant relationships, and pregnant women living with HIV.

HIV treatment: This term is used interchangeably with antiretroviral therapy.

Eligible for antiretroviral therapy: People living with HIV for whom antiretroviral therapy is recommended according to definitions of clinical and immunological eligibility in WHO guidelines.

Universal access to antiretroviral therapy: When ≥ 80% of eligible people have access to HIV treatment, universal access has been achieved.

Viral suppression: The aim of antiretroviral therapy is to maintain the amount of HIV in a person’s body, called the viral load, below the level of detection of available assays, generally less than 50 copies per ml. The current WHO virologic criterion for treatment failure is 1 000 copies per ml or more.

UNAIDS

In this paper the term UNAIDS refers to the Joint United Nations Programme on HIV/AIDS, which consists of the 11 Cosponsors and the UNAIDS Secretariat. The World Health Organization (WHO) is the convening agency on treatment within UNAIDS.

Data usage

In this paper, unless otherwise stated, coverage data for access to treatment was calculated using the WHO 2010 ARV guidelines, which defined an individual’s eligibility for HIV treatment as a CD4 cell count of ≤350 cell/mm³.
INTRODUCTION

1. At its 31st meeting, the UNAIDS Programme Coordinating Board (PCB) requested that the theme of “Strategic use of antiretroviral medicines for treatment and prevention of HIV” be addressed in a regular meeting segment in 2013, following the emergence of critical new scientific learning in the area of HIV treatment science and implementation.1

2. This paper responds to the PCB’s request, and reviews the many strategic uses of antiretroviral for HIV treatment, prevention, care and support. It provides an update on the progress and achievements in scaling up HIV treatment, the emerging scientific evidence informing the use of antiretroviral medicines and the new guidelines for use of antiretroviral medicines by the World Health Organization.2 The paper also provides an overview of the persistent and emerging challenges that need to be overcome in order to achieve universal access to HIV treatment.

3. The primary purpose of antiretroviral therapy is to save the lives of people living with HIV by achieving viral suppression and strengthening the immune system. In addition antiretroviral medicines are a critical tool to prevent the transmission of HIV to children and for stopping sexual transmission of HIV.

4. Access to HIV treatment is an integral part of global efforts to the full realization of the right of everyone to enjoy the highest attainable standard of physical and mental health and contribute to Universal Health Coverage. Antiretroviral therapy is first and foremost about safeguarding the fundamental human rights to life and to health of people living with HIV and the effort to scale-up HIV treatment must be informed and guided by their lived experience. HIV treatment services, which include HIV testing and counselling, must always be voluntary, non-coercive and in the best interests of people living with HIV.

5. HIV treatment is not just about giving pills to people, but about transformation of communities and societies, by restoring health, dignity and respect of people affected by AIDS. Antiretroviral therapy improves the quality of life of people living with HIV and helps prevent households from becoming impoverished due to ill-health and mortality, averts the burden of care on women and girls, reduces the number of orphans, and accelerates progress towards global goals of reducing mortality among children and mothers and enables children, especially girls to access education.

6. The use of antiretroviral medicines is not however, a “magic bullet” or a single solution to the AIDS response. While its use for HIV prevention must be creative and maximized, it must also be in balance and in combination with other proven HIV prevention methods.

7. A way forward for countries is outlined in the paper, including the role of UNAIDS in supporting countries, to meet their commitments to provide antiretroviral therapy for people living with HIV and set targets for treatment access for 2020 to capitalize on the new evidence and standards. At the same time, the paper recognizes the need for comprehensive targets for the AIDS response post 2015, to take into account the unfinished MDG agenda and the High Level Meeting targets which are due in 2015.

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GLOBAL COMMITMENT TO UNIVERSAL ACCESS TO HIV TREATMENT—SEIZING NEW OPPORTUNITIES

8. As agreed in the 2011 United Nations Political Declaration on HIV/AIDS, member states “recognize that access to safe, effective, affordable, good quality medicines and commodities in the context of epidemics such as HIV is fundamental to the full realization of the right of everyone to enjoy the highest attainable standard of physical and mental health”.

9. Paragraph 66 of the 2011 United Nations Political Declaration on HIV/AIDS states that members states “Commit to accelerate efforts to achieve the goal of universal access to antiretroviral treatment for those eligible based on World Health Organization HIV treatment guidelines that indicate timely initiation of quality assured treatment for its maximum benefit, with the target of working towards having 15 million people living with HIV on antiretroviral treatment by 2015”.

10. These commitments and principles of access to HIV treatment—timely initiation, safe, effective, affordable, good quality medicines and commitment to achieve universal access based on eligibility as defined by WHO guidelines—must be applied in the context of the Consolidated Guidelines on the use for antiretroviral drugs for treating and preventing HIV infection (WHO 2013 ARV guidelines) issued by WHO in 2013, while setting numerical and quality targets for HIV treatment beyond 2015.

11. Within the context of the post-2015 development agenda, the World Bank recently set a target of reducing poverty to less than 9% by 2020 and eliminating poverty by 2030. The global AIDS response has a critical role in ensuring access to HIV treatment and prevention services plays its role in achieving these targets.

12. It is therefore necessary for countries to set new HIV treatment targets in line with new developments. This will mean that countries are able to meet the unmet need for HIV treatment for people living with HIV according to WHO 2013 ARV guidelines and accelerate efforts to reach the current global target of 15 million by 2015. Accordingly, countries have to a) prepare the health systems for managing and sustaining the increased demand; b) plan for and secure investments; c) review and accelerate innovation in HIV treatment; d) empower communities to demand, access and deliver HIV treatment services, including HIV testing and counselling); and e) ensure human rights of people living with HIV are protected.

13. UNAIDS estimates that 28.6 million people are eligible for HIV treatment in 2013 based on the WHO 2013 ARV guidelines. At the end of 2012, 9.7 million people were receiving antiretroviral therapy—an estimated 34% of people eligible based on WHO 2013 ARV guidelines. Achieving and maintaining 80% global coverage under the 2013 guidelines would prevent more than 3 million additional AIDS-related deaths and prevent an additional 3.5 million people from acquiring HIV through 2025 (see figure below).

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5 Global Update on HIV treatment: results, impact and opportunities and the new consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection, WHO, Geneva, 2013
STRATEGIC USE OF ANTIRETROVIRAL MEDICINES: THE EVIDENCE

The scientific evidence

14. People living with HIV can lead longer, healthier and more productive lives if they take antiretroviral medicines. If treatment is initiated early, and taken continually without interruption for life, life expectancy is thought to be the same as that of someone without HIV.

15. The strategic use of antiretroviral drugs brings clear health benefits at the personal level to individuals living with HIV. Before antiretroviral therapy was available, about 80% of the people living with HIV presenting at clinics with AIDS-defining illnesses died within two years. Now, even the most severely ill people have an 80% chance of survival after two years of antiretroviral therapy. In multiple studies and randomised control trials, early initiation of HIV treatment has been shown to consistently decrease the risk of progression to AIDS or death.

16. Cumulative evidence now indicates that earlier initiation of antiretroviral therapy is associated with improved quality of life and measurable health outcomes for people living with HIV. The pooled analysis of two randomized clinical trials and 21 observational studies has found an additional decreased risk of death and HIV disease progression where the CD4 threshold for initiating ART was 500 cells/mm³ compared with a threshold of 350 cells/mm³. Simply put, if you start HIV treatment earlier when you are healthier, your life expectancy will be longer than if you start antiretroviral therapy.

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therapy at a later stage when your immune system has begun to weaken.

17. Antiretroviral therapy also cuts the risk of a person living with HIV developing tuberculosis by 65%. Studies have also shown that early initiation of antiretroviral therapy reduces the risk of acquiring TB and reduces recurrent TB by about 50%. Modelling also suggests that initiation of antiretroviral therapy above 350 cells/mm³ could lead to a more substantial reduction in TB incidence in population level.

18. The other strategic use of antiretroviral medicines if for preventing HIV infection. These include their use as a prophylaxis to prevent new HIV infections among children; prevent HIV transmission among discordant couples; as post-exposure prophylaxis for health workers who are exposed to HIV and for women, men and children who are sexually assaulted or have unintended sexual or non-occupational exposures to HIV.

19. In randomized controlled trials, antiretroviral therapy has proven to be efficacious at preventing HIV transmission. Treatment for prevention is an integral part of combination HIV prevention strategies and people living with HIV must have the right to choose the HIV prevention tools best suited to their needs and life-circumstances. Treatment for prevention must always be voluntary and an informed choice of people living with HIV.


20. Post-exposure antiretroviral prophylaxis, first validated in the 1980s, is recommended for cases of occupational exposure and for non-occupational exposure such as for individuals who have experienced sexual assaults. Recent studies have also validated the efficacy of daily pre-exposure antiretroviral prophylaxis for heterosexual population.

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adults, men who have sex with men and people who inject drugs. However, not all studies showed efficacy and some were stopped. A series of pilot studies and demonstration projects are underway to clarify optimal regimens and methods for delivering pre-exposure prophylaxis with an emphasis on adherence and to understand concerns expressed by communities.

21. Recent studies have shown the effectiveness of antiretroviral medicines also as a pre-exposure prophylaxis (PrEP) for people at higher risk of HIV infection. The results from a study in South Africa showed that a gel containing an antiretroviral drug, tenofovir, used as a vaginal microbicide, before and after sex, was 39% effective in reducing a woman’s risk of becoming infected with HIV during unprotected sex. However there are other studies that have not found effectiveness of using oral antiretroviral medications to reduce HIV acquisition.

22. Providing pregnant women living with HIV access to antiretroviral medicines is one of the four pillars of the Global Plan towards elimination of new HIV infections among children by 2015 and keeping their mothers alive. Maximizing the strategic impact of antiretroviral medicines for prevention of mother-to-child transmission of HIV involves use of optimal regimens, providing access to antiretroviral medicines to women living with HIV for their own health as well as during pregnancy and the breastfeeding period. WHO 2013 ARV guidelines recommend the use of preferred first line treatment regimen for all pregnant and breastfeeding women.

23. A case study in Mississippi, United States found that a baby, whose mother had not received antiretroviral medicines during pregnancy, and was treated with antiretroviral drugs in the first 30 hours of life and continued on treatment for 18 months appeared to be functionally cured of HIV infection. In a cohort study in France, 20 adults that had taken HIV treatment for years and then stopped, were shown to remain healthy and may also have been functionally cured. These examples offer hope that early use of antiretroviral medicines may also play an important role in the development of a future cure for HIV.

Managing side effects of prolonged use of antiretroviral medicines

24. The ARV treatment landscape has rapidly evolved since the approval of the use of AZT (zidovudine) to treat people living with HIV. A large range of drugs and several classes of antiretroviral medicines are now available for use by people living with HIV and newer products are in the pipeline for release in the near future.

25. However since HIV is a chronic condition and HIV treatment has to be taken for life, the continuous use of antiretroviral drugs can bring health problems that need to be addressed jointly by researchers, health workers and patients. These health problems may include, depending on the regimens take, bleeding, bone marrow suppression, cardiovascular diseases, lipodystrophy, lactic acidosis and liver failure, neuropathies, neurologic disorders and renal complications among others. HIV treatment programmes

16 Pre-Exposure Prophylaxis for HIV in Women: Daily Oral Tenofovir, Oral Tenofovir/Emtricitabine, or Vaginal Tenofovir Gel in the VOICE Study (MTN 003). Marrazzo J et al. (2013). 20th Conference on Retroviruses and Opportunistic Infections, Atlanta (USA), 3-6 March 2013, Abstract No. 26LB.
must include measures to counteract these side effects and minimize them. It must be noted however that these drugs have saved millions of lives and the overall benefits of antiretroviral therapy far outweigh its risks by many times.

26. It is therefore important to include regimes with lower toxicity profiles, increase the health care options available to manage complications and scale up efforts to improve treatment literacy among health care providers and people living with HIV to ensure better health outcomes.

Programmatic evidence

27. Antiretroviral therapy has transformed medical management of HIV infection. At the end of 2012 there were 9.7 million people on antiretroviral therapy in low- and middle-income countries. Globally the number of people receiving HIV treatment has tripled over the last five years. The largest increase in the number of people newly starting HIV treatment was in 2012—1.6 million additional people were receiving antiretroviral therapy in 2012 compared to 2011.18

28. As a result, UNAIDS estimates that the number of AIDS-related deaths has fallen from a high of 2.3 million deaths in 2005, to 1.6 million deaths in 2012, a drop of more than 30%. Antiretroviral therapy has averted 6.6 million deaths worldwide since 1995, including 5.5 million deaths in low- and middle-income countries.19

29. South Africa and India have rapidly scaled up access to antiretroviral therapy. South Africa has the largest number of people on antiretroviral therapy, more than 2 million people; followed by India with more than 600 000 on HIV treatment.20

30. In KwaZulu-Natal, South Africa, HIV treatment scale-up was associated with an increase in life expectancy of 11.3 years between 2003 and 2011.21 In Rwanda, as HIV treatment was scaled up the annual number of AIDS-related deaths fell by more than two-thirds from 2001 to 2011.22 In 17 countries where HIV treatment access has expanded, TB deaths among people living with HIV have fallen by more than 50% since 2004.23

31. Specific experiences demonstrate the prevention benefits of treatment scale-up. In one district in rural South Africa, achievement of modest, yet meaningful, levels of HIV treatment coverage (30-40%) was associated with a 38% decline in HIV incidence in comparison to communities where treatment had yet to be scaled up.24 In the Canadian province of British Columbia, a 6.5-fold increase in the number of people receiving antiretroviral therapy from 1996 to 2012 was associated with a 42% reduction in HIV incidence.25 In San Francisco, USA, a 45% reduction in community viral load has been linked with a 40% decline in HIV incidence.26

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32. In 2012, the net increase in number of adults receiving antiretroviral therapy exceeded new HIV infections in adults in at least 13 countries with generalized epidemics – Botswana, Côte d’Ivoire, Ethiopia, Ghana, Haiti, Malawi, Namibia, Rwanda, South Africa, Swaziland, Tanzania, Zambia and Zimbabwe.27 This programmatic “tipping point”, indicates that national responses are outpacing the epidemic and represents an important milestone towards reaching the 2015 Global AIDS targets.

33. Due in large measure to the scale-up of access to antiretroviral medicines for pregnant women living with HIV, the annual number of new HIV infections among children declined by an estimated 52% from 2001 to 2012.28

34. In countries with adult HIV prevalence in excess of 10%, HIV treatment in combination with behaviour change programmes and voluntary medical male circumcision programmes may be key to achieving rapid declines in new HIV infections. Namibia, for example, is at the forefront of such an approach. The combined impact of treatment and prevention approaches has contributed to a 60% drop in new HIV infections by 2010 from 1999.29

35. Recent research has shown that the provision of antiretroviral therapy between 2005 and 2010 has reduced pregnancy related deaths in four southern African countries by more than 50%.30

**Investment evidence and the economic case**

36. Investing in treatment makes economic sense. By averting, or substantially delaying, acute-care costs associated with late-stage HIV disease, by preventing new infections and eventual health care costs, helping people to stay productive and employed, preventing children from becoming orphaned as a result of the epidemic and slowing the rate of new infections, immediate investments in HIV treatment services result in substantial savings over the long run. According to a recent economic review, in addition to the large health gains generated, the economic benefits of treatment will substantially offset, and likely exceed, programme costs within 10 years of investment. The expected economic returns can amount up to US$ 34 billion while costs associated with the programme are US$ 14.2 billion.31

37. A full investment in the AIDS response, of which treatment constitutes nearly one-third of the costs, will result in 29 million life years saved between 2011 and 2020 (it is not at least). At the cost of US$ 1 060 per life year gained, it is less than the per capita GDP of the world’s poorest region.32

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29 UNAIDS World AIDS day report 2011, Faster, Smarter, Better.
38. Access to and provision of antiretroviral therapy makes individuals able to work more hours and take fewer sick days, thereby increasing individual income. Higher worker productivity and lower absenteeism also means that companies are able to achieve higher revenues and profits than would have been seen in the absence of ART.

39. Meanwhile there are overarching savings in the health expenditures incurred by governments and households as a result of averted opportunistic infections, as well as a decrease in loss of gross domestic product to AIDS with the provision of the ARVs. Furthermore, treatment and support for those infected with HIV can reduce the number of AIDS orphans and thus decrease government spending in orphan care.

40. There is evidence that investing in HIV treatment yields positive economic returns to members of households that have been affected by AIDS. This is especially true for children in households with HIV. Children work fewer hours and accomplish higher levels of school attendance as compared with children whose parents don’t have access to antiretroviral therapy. Other studies suggest that income that accrues when people on antiretroviral therapy are able to work improves the nutritional status of the entire household.

41. Preliminary mathematical simulations indicate both cost and epidemiological benefits of initiating early antiretroviral therapy that could lead to substantial health benefits and be cost effective in both generalized and concentrated epidemic settings. The simulations also indicate that the increased cost of earlier antiretroviral therapy would be partly offset by subsequent reduced costs. They also show that the majority of the cost needs are in expanding access to treatment to people with CD4 cell count of ≤350 cells/mm³ and that the cost of further expansion to include CD4 count ≤500 count is relatively small, especially for countries already with high coverage. UNAIDS is convening a working group to further define the resource needs for scaling up antiretroviral therapy to all people eligible.

42. Evidence indicates that the use of simpler, less toxic and combined fixed-dose regimens minimizes the emergence of drug resistance, enhances treatment adherence and promotes efficient use of available resources.

**New global and national standards**

43. In 2013, WHO released consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection (see box below). Application of these guidelines increases the estimated number of people eligible for antiretroviral therapy in 2013 to 28.6 million.

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33 Rosen et al. Economic outcomes of patients receiving antiretroviral therapy for HIV/AIDS in South Africa are sustained through three years on treatment. PLoS ONE, 2010,5:E12731


36 Resch S et al. Economic returns to investment in AIDS treatment in low and middle income countries. PLoS ONE, 2011, 6:e25310


WHO 2013 consolidated guidelines on use of antiretroviral drugs recommendations:40

- Antiretroviral therapy (ART) should be initiated for all adult patients with a CD4 count equal or less than 500 cells per mm3. Symptomatic patients with WHO clinical stage 3 (advanced) and 4 (severe) disease, and asymptomatic individuals with a CD4 count equal or less than 350 cells/mm3, should be treated as a priority.

- ART should be initiated as soon as it is tolerated in all HIV positive adults with active TB irrespective of CD4 count. Patients should not wait until TB treatment is completed to initiate ART.

- ART should be given to HIV positive adult patients with active hepatitis B co-infection with evidence of severe liver disease, irrespective of CD4 cell count or WHO clinical stage. Liver disease is emerging as a leading cause of death in HIV-hepatitis B co-infected patients and some antiretroviral drugs used on HIV treatment also are active against hepatitis B virus (HBV), emphasizing the benefit of treatment of dual infection.

- ART should be initiated for all HIV-infected pregnant and breastfeeding women irrespective of CD4 cell count or WHO clinical stage. It brings benefits to mother’s health, prevents the exposed child from becoming infected, and may offer additional benefits for prevention of the sexual transmission of HIV.

- ART should be offered to all HIV-infected partners in a serodiscordant relationship irrespective of CD4 cell count. Results of HPTN052 trials and other observational studies strongly support the use of ART to prevent HIV transmission among serodiscordant couples.

44. Some countries are going one step further in setting bold national standards. Today, national leadership is often the driving force in re-thinking approaches to HIV treatment, with many now considering offering HIV treatment to people living with HIV regardless of their CD4 cell count. These countries include Brazil, France, Indonesia, Malawi, Thailand, United States of America, Viet Nam, and the Canadian province of British Columbia.

45. Several regional bodies and inter-governmental groupings have also begun to discuss new ways and targets to expand access to antiretroviral therapy. These include African Union Commission, New Partnership for Africa's Development (NEPAD) agency and regional economic communities including the Common Market for Eastern and Southern Africa (COMESA), the Southern African Development Community (SADC), the Economic Community of West African States (ECOWAS) and the Brazil, Russia, India, China and South Africa (BRICS) grouping. The Abuja+12 declaration called on African Union members states to champion the UNAIDS Treatment 2015 initiative.

New technologies and innovation

46. An increasing number of new diagnostic tests and point-of-care technologies are becoming available for use in HIV treatment programmes. These provide an opportunity to increase demand, treatment uptake and utilization, as well as more effectively monitor

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and evaluate treatment impact at the individual and community level.

47. Viral load testing is now recommended as a critical measure for monitoring the response to treatment and diagnosing and confirming treatment failure. To enable its widespread use with ease, it is vital to rapidly deploy new technologies for simplified viral load testing when available and make them affordable.

Community engagement evidence

48. Communities are vital partners in ensuring the success of the strategic use of antiretroviral medicines for HIV treatment and prevention. In many countries community organizations deliver a substantial share of HIV treatment and prevention programmes. Brazil, Kenya, Malawi, South Africa, Uganda, the United Republic of Tanzania and Zambia have integrated HIV testing in multi-disease community campaigns. In Zimbabwe, where sharp declines in new HIV infections and AIDS-related deaths have occurred, grassroots community organizations were pivotal to increasing uptake of HIV testing in the mid-2000s.

49. Clinical trials and extensive country-level experience have underscored the powerful value of community engagement and leadership in accelerating service uptake and improving outcomes, and a number of recommendations for community-based interventions are part of the 2013 WHO guidelines in relation to HIV testing and maintenance of ART.

CHALLENGES IN SCALING UP HIV TREATMENT

50. While there is clear evidence about the positive impact of increasing access to antiretroviral therapy to individuals and communities, there are several barriers—programmatic, technical, social and economic—that impede access and uptake of antiretroviral therapy. By addressing these barriers, it is possible to further expand the coverage, reduce inequities and increase impact.

Lack access to HIV testing and counselling services

51. UNAIDS estimates that only half of all people living with HIV know their HIV status. Without knowledge of HIV status, people are missing out on their opportunities to access HIV treatment and prevention services. The lack of knowledge of HIV status can be attributed to lack of understanding about HIV, stigma and discrimination and non-availability of HIV testing and counselling services. Recent advancements in home-based self-testing kits provide new opportunities for increasing the number of people who know their HIV status and promoting linkages to effective HIV services.

Loss to follow up

52. As a result of gaps at each stage of the HIV treatment cascade – from initial diagnosis, to linkage to care, receipt of antiretroviral therapy retention in care and maintain viral suppression, UNAIDS estimates that less than one in four people living with HIV in sub-Saharan Africa have achieved durable viral suppression. Scale-up of treatment access must also include reducing patient loss to follow-up across the continuum of care and this is where much stronger links between the formal health service and communities are

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needed.

53. Closing gaps in the continuum of HIV care will require far more pro-active and targeted approaches to HIV testing and counselling, systems to routinely monitor uptake of services, use monitoring data to inform policy and programme development, and encourage innovation to minimize patient loss (through such strategies as use of mobile technologies, peer support, expert patients, decentralization and community based delivery models).

Abbreviated HIV treatment cascade for sub-Saharan Africa, 2012

Source: UNAIDS Report on the global AIDS epidemic 2013

Human rights challenges

54. Persistent discrimination, including stigmatizing attitudes in health care settings, as well as legal barriers continue to inflict profound psychological and emotional distress on people living with HIV and in addition undermine programmatic efforts to maximize the strategic use of antiretroviral medicines.

55. Efforts and programmes are urgently needed to review, assess and revise problematic legal environments, to transform them from the punitive to the protective; increase the access of people living with HIV and key populations to legal services; and make concerted efforts to promote non-stigmatizing attitudes, particularly in light of the fact that HIV positive people on treatment are no longer infectious.

56. Legal frameworks in many countries fail to protect people living with HIV or key populations from discrimination and often reinforce negative attitudes towards these groups. In 2013, 61 countries have, in at least one jurisdiction, HIV-specific provisions that allow for the prosecution of HIV non-disclosure, exposure and/or transmission. According to non-governmental informants, 70% of countries in 2012 had laws, regulations or policies that present obstacles to effective HIV prevention, treatment, care and support for key populations and vulnerable groups.

Stigma and discrimination

57. Violations of human rights continue to impede efforts to deliver antiretroviral therapy to those who need it. Among 35 countries in which surveys through the People Living with HIV Stigma Index were undertaken in 2008-2013, at least 10% of people living with HIV reported having been denied health, including dental services, as a result of their HIV

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status. In eight of the 35 countries, at least one in five people living with HIV had experienced discriminatory denial of health services due to their HIV status.  

58. Marginalized individuals who reasonably fear experiencing discrimination, abuse, prosecution or even incarceration are less likely to seek HIV testing, prevention and treatment services.

**Multiple treatment regimens**

59. Despite WHO’s longstanding recommendation to simplify and harmonize treatment regimens, the median number of types of first-line regimens used by countries surveyed by WHO in 2012 was ten.  

Multiple treatment regimens create challenges for supply chain management, increase procurement and make it more difficult for health care providers and people living with HIV to manage effective care.

60. Because of its long-term, irreversible side-effects including lipodystrophy, peripheral neuropathy and lactic acidosis, WHO has recommended countries to phase out the use of Stavudine (d4T) in first-line therapy. However, despite progressive reduction in its use, is still widely used in some low- and middle-income countries due to its low cost and widespread availability. As of December 2011, 31% of all people on antiretroviral therapy were taking regimens that included Stavudine, even though since 2007 WHO has recommended countries to phase out the use of this drug. Reasons for the delay in implementing this recommendation vary by country and include national infrastructure challenges and insufficient resources.

**Quality assurance**

61. Assuring the quality, safety and effectiveness of antiretroviral medicines is an important component of treatment programmes and so manufacturers and products must be submitted to rigorous quality control mechanisms. National regulatory authorities therefore play a decisive role in ensuring that only assured-quality imported and/or locally produced medicines are available.

62. The WHO prequalification programme is an effective mechanism to promote access to quality medicines. This programme was created to support countries that are still improving their regulatory bodies to procure quality assured branded and generic products used to diagnose and treat HIV, tuberculosis and malaria. At the same time, national and regional regulatory agencies and systems need to be strengthened to facilitate local approval processes and accelerate access, mainly through collaboration and networking among other regulatory entities, regionally and worldwide.

**Gaps in HIV treatment coverage between regions, countries**

63. Profound coverage deficits persist in countries throughout the world. Based on the WHO 2013 ARV guidelines, only about one-third (34%) of treatment-eligible individuals were receiving antiretroviral therapy as of December 2012, underscoring critical challenges ahead. In South Sudan, only 9% of adults eligible for antiretroviral therapy under the earlier WHO 2010 ARV guidelines were receiving therapy as of December 2012.  

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64. While the number of people receiving antiretroviral therapy has increased sharply in a number of regions since 2005, no comparable increase in treatment coverage has occurred in Eastern Europe, Central Asia, the Middle East and North Africa where less than 40% of those eligible were receiving HIV treatment based on the WHO 2010 ARV guidelines.46

Unequal access for children and young people living with HIV

65. Only three out of ten children living with HIV in the 21 priority countries for preventing new HIV infections among children have access to HIV treatment. HIV treatment coverage of children is a little more than half that of adults.47

66. Of the 260 000 children eligible for antiretroviral therapy in Nigeria in 2012, only 12% received treatment.48 Among pregnant women who needed antiretroviral therapy for their own health in 2012, only 58% received HIV treatment—lower than the 68% treatment coverage for adults overall in Nigeria based on the older WHO 2010 ARV guidelines.49

67. As a result of a shortage of adolescent-friendly health services, and legal barriers that impede access, children and adolescents represent the only population among whom AIDS-related deaths are increasing—there has been a 50% increase in deaths among adolescents between 2005 and 2012 versus a 30% decline in deaths globally.

Key populations underserved

68. In both concentrated and generalized epidemics, certain populations are benefiting less from antiretroviral treatment than others. These populations include men who have sex with men, people who inject drugs, prisoners, sex workers and transgendered people. In many instances refugees, asylum seekers and migrants are also excluded from HIV services.

69. Key vulnerable and marginalized populations experience major challenges in accessing high-quality HIV services including treatment and prevention services. Although reliable data is difficult to obtain, UNODC estimates that only 4% of people who inject drugs are receiving HIV treatment. A lack of clear commitment to scale up coverage for many key populations has contributed to the neglect of their needs and a deficit in the establishment and expansion of HIV treatment and prevention services for them.

Health system constraints

70. The rapid pace of scale-up over the last decade conclusively demonstrates the feasibility of building sustainable capacity in countries as programmes are brought to scale. Increasing access to HIV treatment and ensuring quality of treatment will demand concerted efforts to strengthen national CD4 count and viral load testing laboratory capacity, introductions of point-of-care technologies and complementary efforts to increase the ability of clinicians to monitor viral load will be needed to improve treatment outcomes in the context of earlier initiation of antiretroviral therapy. Innovation in delivery models will need to include community strengthening to allow for community-based delivery of services with follow up for effective linkages to, and retention in care. These innovations will need to be combined with simplified staging and antiretroviral therapy

delivery in order to meet the increased demand.

71. To leverage existing capacity, and build additional capacity over time, programmes should intensify task-shifting and decentralization of HIV treatment, care and support programmes and support community-based delivery models. Experience has demonstrated that frontline health workers and community workers have been able to successfully deliver many of the clinical tasks associated with antiretroviral therapy delivery with appropriate supervision and referral support. As HIV treatment management for people living with HIV at an earlier stage of infection typically requires less complex clinical skills than for individuals in a later stage of infection, many clinical tasks can be shifted from physicians to nurses, midwives, clinical officers, physician assistants or other health workers. Community workers, networks of people living with HIV and key populations also have a potentially critical role to play in supporting linkage, retention, adherence and facilitate reduction of stigma and discrimination.

Community system constraints

72. Even though communities have played a pivotal role in scaling demand for and access to treatment and adherence, they often lack the capacity to play their optimal role in the planning, delivery, support and monitoring of HIV services. Community workers often go unpaid or underpaid, undermining the scalability of task-shifting strategies. Community groups sometimes have difficulty obtaining technical support or financing for basic operating costs. To maximize the role of communities in service scale-up, countries should incorporate robust community systems strengthening strategies as a core element of their national response and engage communities in all aspects of the AIDS response.

Financial constraints

73. In recent years about 55% of all HIV investments were spent on activities related to HIV care and treatment.\(^50\) Full implementation of the WHO 2013 ARV guidelines would more than double the number of people receiving antiretroviral therapy. Projected efficiency gains achieved through scale-up should partially offset the additional financial resources required. At the same time to maximize the impact of the benefits, front loading of resources will be required to rapidly scale-up access to treatment. Many countries are still overly dependent on international resources for funding their HIV treatment programmes and may lack the resources needed for expanding access to treatment from domestic sources alone.

Why targets?

1. **Targets inspire action.** The setting of specific targets for access to HIV treatment services has already helped countries to define their milestones for progress, generated demand for services, and channelled investment into strengthening health systems and innovative delivery mechanisms. Countries have used targets to drive progress. As just one example, Kenya’s time-bound indicators in the country’s AIDS response have provided the framework for periodic performance reviews, adaptation of approaches and regular progress reporting.\(^{51}\)

2. **Redefining success of antiretroviral therapy.** Suppressing HIV in the body is the ultimate goal of using antiretroviral medicines. The target setting process provides an opportunity to change how we measure the success of antiretroviral therapy: not just by quantifying the number of people on antiretroviral therapy, but also by measuring the level of viral suppression. Doing this will help to shift scale-up efforts towards early diagnosis and treatment initiation, improve quality of treatment and increase impact. In addition reducing HIV viral load among people living with HIV has added public health benefits by reducing the amount of virus circulating in a given community, thereby reducing HIV transmission.

3. **Accelerating transition time.** Whenever the guidelines for initiating HIV treatment have changed in light of scientific evidence, countries have taken up to two years to implement programmes that reflect the revised thresholds. Where the numerical targets for treatment access were not revised simultaneously with the new guidelines, programme roll out has been even slower. The early adoption of targets for the next five years, i.e. until 2020 will enable them to anticipate demand and prepare for their future.

4. **Targets generate demand.** In most countries waiting lines for HIV treatment have been virtually eliminated. This can lead to a false sense of complacency that everyone in need is being reached. Bold targets help to drive action and draw attention to marginalized and key populations who remain outside traditional systems of health care access. Increasing people’s knowledge of their HIV status early means they can be linked earlier to HIV care, improving outcomes.

5. **Loss-to-follow-up minimized.** Early knowledge of HIV status, linkage to care and timely initiation of HIV treatment ensures that fewer people living with HIV are lost to follow-up before starting treatment and the impact of antiretroviral medicines is maximized. People living with HIV are starting treatment much later than recommended and this has an adverse impact on AIDS-related mortality.

6. **Saving costs.** The early initiation of treatment for all people eligible is expected to contribute to reducing the overall costs of health care over time by averting the costs of HIV-related health problems when treatment is delayed.

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LEADERSHIP OPPORTUNITIES FOR EXPANDING ACCESS TO TREATMENT

Re-targeting

74. Defining revised national targets for universal access to HIV treatment for 2020, referred in this document as re-targeting, will help countries to accelerate and reinvigorate their HIV treatment programmes, bring innovation, community ownership and engagement, drive efficiencies and effectiveness, create and meet demand for services, secure investments, to ultimately save lives.

75. At the same time, it is important to begin shaping long-term targets for the overall AIDS response. The MDG as well as the High Level Meeting targets are due in 2015 and will most likely leave behind an unfinished agenda. It is crucial to articulate and envision revised national targets for all aspects of the AIDS response in line with the post-2015 development agenda of setting targets for 2030.

76. New treatment targets should be equitable and evidence informed. Specific targets must be in place for populations for whom treatment scale-up is lagging, including children, pregnant women, men, adolescents, men who have sex with men, people who inject drugs, sex workers, transgendered people and people in prison settings. Treatment access targets should also include people affected by humanitarian crises and migrants. In the context of the development of a post-2015 development agenda, it will be particularly critical for countries to provide consideration to this important aspect of treatment scale-up.

77. Special emphasis should also be given to treatment access for infants and children living with HIV. The failure, in many settings, to expand access to early infant diagnosis is an important reason why HIV treatment coverage remains much lower for children than for adults. In five priority countries, coverage of less than 5% was reported for early infant diagnostic services in 2012.\textsuperscript{52} In addition, efforts to develop new paediatric formulations must continue.

78. Efforts to provide HIV treatment for all pregnant women must be expanded. In 2012 fewer than half of pregnant women living with HIV and eligible for HIV treatment for their own health received antiretroviral therapy.\textsuperscript{53}

79. To achieve universal access to treatment countries have to a) prepare the health systems for managing and sustaining the increased demand of HIV and HIV-TB services; b) plan for and secure investments; c) review and accelerate innovation in HIV treatment; d) empower communities to demand, access and deliver HIV treatment services, including HIV testing and counselling; and e) ensure human rights of people living with HIV are protected.

\textbf{a. Prepare the health systems for managing and sustaining the increased demand of HIV and HIV-TB services}

80. The re-targeting process for HIV treatment must be an inclusive process that involves implementers, health care providers, civil society and affected communities. Their experiences in delivering HIV treatment, including HIV testing and counselling services will help countries to evaluate the gaps and obstacles in scaling up access to HIV

81. There is frequently a mismatch between the settings where services are most needed and where they are scaled up. In planning treatment service growth, focus should be on identifying local gaps in people’s knowledge of HIV status, service delivery and serving populations where unmet need for HIV treatment is greatest.

82. The delivery of a range of integrated services at appropriate points of entry into the health care system, where a chronic care model already exists, is a strategy that has been shown to increase treatment uptake and retention. In many locations, HIV services, have been effectively integrated with maternal and child health services, TB services, sexually transmitted infection clinics, drug dependence treatment and harm reduction services (such as opioid substitution therapy) and other general health services. The capacity of primary health care centres to offer HIV treatment including supportive supervision and mentorship to ensure quality of care, should be strengthened.

83. In addition HIV services must be integrated with sexual and reproductive health services, and link with services for chronic and non-communicable diseases. In addition effective linkages for delivery of HIV services and HPV vaccine for young women must be established.

84. Where relevant, countries should address the HIV and TB epidemics together, otherwise the targets of reducing TB-related mortality will not be achieved. The same rationale is applicable to the hepatitis C epidemic, which is an emerging health priority in some parts of the world.

b. Plan for and secure investments

85. Reaching 15 million people with HIV treatment by 2015 and advancing rapidly towards universal access to treatment according to new guidelines will require robust, sustained financing. Strategies to achieve this include making efforts to close the HIV resource gap by mobilizing resources through domestic and international sources, including innovative financing mechanisms and optimally using available resources for the greatest impact. It also involves the development of investment cases that demonstrate the return on investing in HIV treatment, increasing efficiency and effectiveness and giving priority to scaling up in key settings and populations with disproportionately high unmet need for HIV treatment. Investment in critical enablers and development synergies, including social protection and food security, to enhance the effectiveness of HIV testing and treatment programmes will be key.

86. The retargeting process will help countries to revaluate their resource needs for HIV treatment, examine their funding sources with a view to mobilize resources to meet the gap from international and domestic sources, as well as ensure resources are sustainable. The process will also provide an opportunity to review and optimize procurement and supply chain processes, reduce costs of delivery and minimize waste.

87. The roll out of the New Funding Model of the Global Fund to fight AIDS, TB and Malaria (Global Fund) provides new opportunities for countries to mobilise additional resources for HIV treatment.

88. Treatment unit costs are reducing. As treatment programmes are scaled up, important efficiencies are being realized. From 2005 to 2011, the per-patient cost of HIV treatment
for PEPFAR declined by more than half.⁵⁴ In recent years the cost of antiretroviral medicines has also fallen significantly. These gains have contributed to increasing the number of people accessing antiretroviral therapy.

89. All potential sources of HIV funding – including domestic contributions, international assistance and innovative financing mechanisms – will need to make robust contributions to treatment scale-up. The nearly 10 million people on antiretroviral therapy have access thanks to global solidarity and generosity and now increasingly shared responsibility among countries. Even as international assistance remains key for the AIDS response, domestic resources will need to be increased to reduce dependency and ensure sustainability.

90. To ensure the most favourable pricing for antiretroviral medicines, countries should maximize utilization of flexibilities under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Doha Declaration. Multinational purchasing should be expanded; both to help drive prices lower and ensure that all countries are obtaining the most favourable prices. Especially in sub-Saharan Africa, regional collaboration should focus on building regional pharmaceutical manufacturing capacity and harmonizing medicines regulatory systems and pooled procurement to increase access at lower costs while rigorously maintaining quality.

91. By taking AIDS out of isolation, promoting integration with health services and developing strong community linkages while accelerating HIV treatment programmes can contribute to achieving Universal Health Coverage. HIV treatment programmes can play a major role in strengthening health systems, bring innovation in healthcare delivery models and increase capacity of the health force. At the same time the AIDS response can be the Vanguard in improving effectiveness and efficiencies of health investments and promote sustainability—elements that are critical to ensuring Universal Health Coverage.

c. Review and accelerate innovation in HIV treatment

92. Countries can use the retargeting process to learn from the innovation in delivering HIV treatment, integrate this knowledge into current programmes and prepare for the future. Many of the best practices for HIV testing and access to treatment programmes have come from innovative solutions found by programme planners and implementers. Recently, Malawi, confronted by multiple barriers in scaling up antiretroviral services for pregnant women, devising the potentially transformative “Option B+”, which provides lifelong treatment for all pregnant and breastfeeding women living with HIV. This resulted in a 748% increase in the number of all HIV infected persons receiving antiretroviral therapy in a 15-month period in 2011-2012.⁵⁵

93. Improved technologies for early infant diagnosis and CD4 count and viral load monitoring at the point-of-care are entering the market. These tests can be performed at local facilities, overcoming the time and system constraints involved in transporting samples to central laboratories. Decreased waiting times reduces the risk that children and adults will be lost to follow-up. UNITAID, through their support to UNICEF and CHAI, is leading

the evaluation and scale-up of these new diagnostics. For maximum impact, countries must be prepared to rapidly roll out these innovations when they are confirmed ready.

d. **Empower communities to demand, access and deliver HIV treatment services, including HIV testing and counselling**

94. Although 28.6 million people are currently eligible for HIV treatment, actual demand for treatment services is far lower. In part, this is because many people who need treatment have yet to be diagnosed; in sub-Saharan Africa, UNAIDS estimates that half of all people living with HIV do not know their HIV status. In addition, many people living with HIV experience numerous impediments to their use of services, including a fear of discrimination and the inaccessibility of services. Innovation, including strategic use of point of care technologies, is needed to scale up HIV testing services, reach people and meet their need for treatment.

95. Decentralized HIV services brought closer to the people who need them is imperative to create demand. Communities have a pivotal role to play in building demand and addressing potential impediments to access such as fear of, and actual, stigma and discrimination inside and outside care settings. Initiatives such as the on-going ILO initiative on uptake of HIV testing “VCT@WORK” to reach 5 million workers (women and men) with voluntary HIV testing and counselling services are vital in normalising HIV testing.

96. Communities have done significant work since the beginning of the AIDS response including creating demand for testing and treatment, advocating for rights-based, quality services, keeping national and global responses to HIV accountable, and delivering services to those in need.

97. A substantial impediment to scale-up of antiretroviral therapy to date has been the failure to include communities as essential partners in the success of treatment programmes. Maximum scale-up will never be achieved unless and until communities are engaged at all steps of the treatment process, from strategic planning to service delivery to performance monitoring.

98. It is now well recognized that it will be impossible to deliver treatment to all unless community-led service demand and delivery is scaled-up. This will require a) reversing current diminishing resources for community systems; b) taking stock of good policy and practice to develop costed, adaptable and replicable models of community-led service demand and delivery; c) concerted efforts to improve the level and quality of community-led service delivery for key populations; d) support innovation in developing new models of work, such as community-led HIV testing; and e) creating better linkages with formal health systems and social care services, including through task shifting.

e. **Ensure human rights of people living with HIV are protected**

99. Programmes to expand access to treatment must respect the human rights of all people, especially people living with HIV. No one should be denied access to HIV treatment because of their HIV status, legal status, occupation or sexual orientation. No individual should be coerced or obliged to take an HIV test or forced to take HIV treatment without his or her informed consent. The retargeting process should review all legal and procedural barriers that impede access to effective HIV treatment.

100. Access to treatment must focus on reducing inequity and optimise its transformative potential for societies and communities. By ensuring human rights, access to treatment
can be increased, adherence promoted, and maximise return on investments. Most of all, human rights rejuvenates families and communities in contributing to social development.

101. Despite being disproportionately affected by HIV, many marginalized populations (including but not limited to sex workers, people who inject drugs, men who have sex with men, transgenders, people affected by humanitarian crises and people in prison settings) experience diminished access to high-quality, non-discriminatory health services. Experience has demonstrated that treatment scale-up is most rapid and sustainable when accompanied by a reduction in stigma and discrimination, a removal of punitive legal frameworks and concerted efforts to reach the unreached.

102. Setting of new targets for HIV treatment programmes must strike the right balance between access to antiretroviral medicines to save lives of people living with HIV and the use of antiretroviral medicines to prevent HIV transmission. While increased access to treatment will contribute to reducing new HIV infections significantly – a person with a suppressed viral load is significantly less infectious – this will not diminish the need for the continued implementation of evidence-informed combination HIV prevention programmes. There have been concerning recent reports of countries and implementing partners reducing their prevention budgets and/or procuring significantly less condoms than some years ago while scaling up treatment services. Re-allocations from one core proven programme area to another is not an effective strategy.

**ROLE OF UNAIDS IN EXPANDING ACCESS TO ANTIRETROVIRAL THERAPY**

**Policy and Leadership**

103. UNAIDS will support countries in facilitating a country-led, inclusive process to determine national targets for access to treatment that include numerical targets for treatment access but also impact targets for 2020 and 2030. These targets will be developed in consultation with all partners including people living with HIV, civil society, and implementers and will focus on maximising the strategic use of antiretroviral medicines for HIV treatment and prevention.

104. UNAIDS will continue to advocate for the achievement of universal access to HIV treatment, and TB treatment for people living with HIV, highlight policy and access gaps and provide technical support to countries in removing barriers to access to HIV treatment. WHO will lead efforts for implementation of the new consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection.

105. UNAIDS will engage and promote the leadership of political leaders, civil society, faith-based organizations, private sector and communities to ensure that countries have sound evidence-informed policies and mechanisms to increase access to treatment for people living with HIV. The Treatment 2015 initiative will serve as the platform for UNAIDS engagement on expanding timely and quality access to HIV treatment.
106. In July 2013, UNAIDS Secretariat joined with WHO, PEPFAR, the Global Fund and country partners to launch the Treatment 2015 initiative. Emphasizing speed, innovation and focus as critical priorities, Treatment 2015 outlines a framework to accelerate progress towards the 2015 target of 15 million and ultimately towards the aim of universal access.

107. Treatment 2015 proposes priority actions to ensure full and rapid implementation of the 2013 WHO guidelines, country preparedness, including stronger partnerships with communities and community systems strengthening, to make rapid gains in HIV treatment uptake, renewed commitments to achieve equity and non-discrimination in treatment and enhanced coordination of technical support, including through South-South collaboration. Under Treatment 2015, UNAIDS Secretariat is intensifying advocacy and with WHO as the technical lead, supporting adoption of new guidelines and acceleration plans in 30 countries that together account for 90% of the current global unmet need for HIV treatment.

108. UNAIDS under the leadership of WHO will provide policy guidance on scaling up HIV treatment programmes to countries based on new evidence, innovation and good practices.

Norms and standards

109. WHO continuously evaluates new evidence and development in the field of HIV treatment and prevention and takes the lead in providing normative guidance and standards for care. New guidelines will be issued as appropriate and technical support will be provided to countries to implement them swiftly.

110. As the focus of HIV treatment efforts shift towards measuring viral suppression, in addition to access to treatment, UNAIDS will provide support to countries to strengthen their monitoring and evaluation systems for HIV treatment programmes.

111. Technical support will be provided to strengthen the capacity of regulatory bodies to facilitate implementation of HIV treatment guidelines and use of antiretroviral medicines.

112. WHO and Stop TB partnership will work closely with the UNAIDS Secretariat, in supporting countries develop integrated strategies for TB-HIV in places with high burden of TB-HIV co-infection. Particular focus will be given to achieve the goal of reducing tuberculosis deaths in people living with HIV by 50%.

56 The 30 countries are: Angola, Brazil, Cameroon, Central African Republic, Chad, China, Colombia, Côte d’Ivoire, Democratic Republic of the Congo, Ethiopia, Ghana, India, Indonesia, Kenya, Lesotho, Malawi, Mozambique, Myanmar, Nigeria, Russian Federation, South Africa, South Sudan, Thailand, Togo, Uganda, Ukraine, United Republic of Tanzania, Viet Nam, Zambia and Zimbabwe.
Ensuring community engagement

113. UNAIDS will continue facilitating inclusive processes at country level with the meaningful participation of civil society and communities.

114. UNAIDS will support the empowerment of communities to demand, access and deliver HIV services by documenting and disseminating good policy and practice, and developing models based on lessons learned and innovation, especially in countries with HIV burden. It will provide guidance on how to cost, embed in national AIDS responses, and adapt to local contexts models of community-led service demand and delivery. In addition it will provide technical assistance for the implementation of innovative community-led services that are linked with national responses to HIV and formal health systems.

115. UNAIDS will support countries and communities in ensuring that HIV treatment programmes, including HIV testing, respect the human rights and dignity of all individuals and support the establishment of mechanisms for redress of human rights violations.

116. Without effective treatment education including treatment preparedness, the full potential of treatment is not likely to be realised. UNESCO will support countries in increasing treatment education among individuals and communities.

Securing investments

117. UNAIDS will continue to promote the concept of shared responsibility and global solidarity for the AIDS response. In promoting this concept, UNAIDS will support countries in planning for sustainability of their AIDS response and in particular help decrease dependency on international assistance for HIV treatment programmes.

118. UNAIDS will provide technical support to countries for the implementation of the Global Fund New Funding model, to host inclusive country consultations that lead to the development of investment cases that inform the country concept notes. UNAIDS will support countries to articulate the full funding envelope of resources available for treatment in their investment cases and use this information for coordinated program planning and decision making based on financial and programmatic realities to ensure that HIV treatment programmes receive adequate resources.

119. UNAIDS will advocate and explore for new opportunities for innovative financing for the AIDS response, including access to resources for HIV treatment. The use of a financial transaction tax, public-private partnerships, social health insurance and front-loading of investments for expanding access to treatment will be explored.

120. UNAIDS Secretariat together with partners will support countries in estimating the resource needs based on application of the 2013 WHO ARV guidelines. Both countries and technical support partners (including UNAIDS) will require additional capacity and resources to support countries in the roll out of the new guidelines. It has established an inclusive task force that will assess data on actual costs and cost saving innovations for achieving universal access to HIV treatment.
Pricing and commodity access

121. UNAIDS, under the leadership of WHO, will support countries in ensuring that systems are in place to ensure uninterrupted access to antiretroviral medicines and point-of-care technologies and minimize stock outs.

122. UNAIDS will work with partners to ensure that access to antiretroviral drugs, especially new formulations and second-line regimens, and new technologies remain affordable for national AIDS programmes. A large number of countries are either already, or transitioning into, middle-income countries and they face special challenges in securing life-saving medicines at affordable prices. UNAIDS will support middle-income countries in creating a platform for securing affordable pricing of antiretroviral medicines.

123. UNDP and UNAIDS Secretariat will provide technical support to countries to ensure that they maximize the use of the flexibilities allowed under the TRIPS agreement to ensure access to lifesaving medicines.

124. UNICEF and WHO together with partners are leading an effort to increase access to HIV treatment for children living with HIV and its related goal of reducing child mortality. This initiative will help to create demand for effective antiretroviral medicines for children, increase early infant diagnosis and reduce child mortality.

Implementation

125. UNAIDS, with WHO as the lead technical agency on HIV treatment, will support countries in developing revised implementation plans for the rapid scale-up of HIV treatment programmes in line with country investment cases.

126. UNAIDS will support countries in identifying implementation bottlenecks and help support the strengthening of supply chain systems, forecasting, procurement and distribution of lifesaving medicines and link them to national investment cases.

127. UNAIDS will help countries in strategies to increase demand for HIV treatment services, including a special emphasis in expanding access to HIV testing and counselling programmes. Newer approaches to HIV testing, including community-led approaches, will be supported by UNAIDS to close the wide knowledge gap of HIV status among people living with HIV, in line with national investment cases. ILO will take the lead in increasing uptake of HIV testing and counselling and linkage to treatment at the work place.

128. The World Food Programme will support countries in ensuring that the nutritional needs of people affected by AIDS are met. UNFPA, UNDP, UNODC and UNHCR will provide support to increase access of HIV treatment services for key populations such as men who have sex with men, sex workers, people who use drugs and transgender people. Special efforts will be taken to increase access of HIV treatment services for migrants and people affected by humanitarian crises.

129. UNAIDS will support countries in achieving a right balance in the use of antiretroviral medicines within the overall AIDS response. The use of antiretroviral medicines within the HIV prevention context must not be at the cost of promoting other evidence-informed HIV intervention tools and strategies including condom use, harm reduction programmes, behaviour change and male circumcision. Access to antiretroviral drugs
cannot be a substitute for preventing sexual exploitation of women and girls, reducing violence, and human rights violations. Access should be linked to and embedded within the investment case given cost implications.

CONCLUSION
130. The world has a unique opportunity at this time to strategically use antiretroviral medicines and make a lasting impact on controlling and reducing the consequences of the AIDS epidemic. Antiretroviral medicines save lives by stopping AIDS-related deaths, stopping TB disease and preventing new HIV infections among children and adults. Universal access to these lifesaving medicines has the opportunity to transform the lives of people, communities and face of the AIDS response in the near future and set a new standard for global action in the post-2015 agenda.

RECOMMENDATIONS
131. Recalling the commitment of member states under the 2011 Political Declaration on HIV/AIDS to accelerate efforts to achieve the goal of universal access to antiretroviral treatment for those eligible based on World Health Organization HIV treatment guidelines that recommend earlier and optimization of HIV treatment to maximize the clinical and preventive benefits with the target of working towards having 15 million people living with HIV on antiretroviral treatment by 2015. The Programme Coordinating Board is invited to:

132. Welcome this paper and

133. Call upon Member States to:
   a. Ensure that acceleration of access to HIV treatment, including addressing the barriers to treatment access, are factored into all stages of HIV and health planning, implementation, monitoring and evaluation, and resource mobilization, particularly with regards to development of investment thinking approach, and support for the roll-out of the New Funding Model of the Global Fund to Fight AIDS, TB and Malaria (Global Fund);
   b. Implement the 2013 WHO consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection;
   c. Continue work towards further scale-up of access to HIV services including by strengthening community systems and the role of communities in creating demand and delivering services;
   d. Work to ensure the sustainability of national AIDS responses recognizing the principles of country ownership through strengthening of shared responsibility, innovative sustainable financing to meet increased demand, building of strategic partnerships, and based on multi-sectoral approaches;
   e. Ensure that programmes to expand access to HIV treatment offer quality HIV services, improve treatment literacy, are voluntary, non-coercive and respect the human rights of people living with HIV.

134. Request the Joint Programme to:
   a. support on-going national and international processes led by countries and regional institutions to convene national and regional consultations for the definition of revised national targets for universal access to HIV treatment keeping in mind the lead for defining new milestones and targets for the AIDS response beyond 2015;
b. further support implementation of the 2013 WHO consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection;

c. Support capacity development of communities to deliver local HIV services;

d. further support countries in the roll-out of the New Funding Model of the Global Fund, including through the development of a strategic investment approach;

e. Continue to support the availability of the most favourable pricing for antiretroviral medicines and harmonizing medicines regulatory systems as well as the provision of technical support for countries to maximize utilization of the flexibilities under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Doha Declaration.