the success of Treatment 2.0. National and global advocacy and activism will increase the demand for financial resources, HIV testing and counselling services, ART and related health services. An expanded role for community-based services, including testing, treatment monitoring, and adherence and retention in care supportive services are critical for health systems to have the capacity to meet the treatment and care needs of people living with HIV, particularly for underserved key populations.

TREATMENT 2.0: QUESTIONS & ANSWERS

1. **Optimized Drugs: How will Treatment 2.0 facilitate regulatory approval of fixed-dose combinations?** **Fixed-dose combinations** (FDCs) offer convenience for patients and have been shown to improve adherence, however, uptake in many low and middle income countries has been slow. FDCs are recommended by WHO as the preferred drug delivery approach, but access to some of the less toxic and more patient-friendly FDC regimens, such as TDF/3TC/EFV is still limited. In addition, there are concerns about the safety of TDF in children, as well as the potential links between EFV and teratogenicity, which make it difficult to recommend this regimen for all patients. WHO, UNAIDS and its global partners are driving a research agenda to definitively address these concerns and to incentivize the production of these and other co-formulations by placing them on the WHO's medicines lists, and working with manufacturers to ensure they address criteria for efficacy, reduced toxicity, and simplified dosing.
2. **Simplified Diagnostics: How will Treatment 2.0 deal with a diagnostics market that is fragmented among many products, none of which meet optimal criteria for affordability, reliability, throughput, and availability at or near the point of care?** Simplified diagnostic platforms for CD4 estimation that will permit use at the POC or in basic laboratory settings will be commercially available shortly. Other diagnostic technologies in the pipeline include semi-quantitative dipsticks for virologic testing and simplified PCR-based multi-disease platforms for diagnosis of HIV, TB, STI and viral hepatitis. Such innovative approaches hold the promise of being able to manage HIV entirely at the POC. WHO, UNAIDS and diagnostic experts are developing an approach to incorporate these newer technologies into normative guidance in order to drive investment, reduce prices and improve access while at the same time ensuring quality, reliability and accuracy.
3. **Is the focus on reducing costs and improving efficiencies of existing resources an admission that no new financing for HIV will become available?** No, we must advocate for a fully-funded HIV response while at the same time demonstrating we can secure additional efficiencies and costs reductions through innovation in a number of major cost areas (drugs, diagnostics, procurement mechanisms, service delivery), and by ensuring that services are tailored to most affected populations. Retaining or improving the quality and efficacy of products and services is essential, as is employing other policy mechanisms, such as those included in the TRIPS Agreement, to reduce costs.
4. **How will Treatment 2.0 address resistance from governments or regulatory bodies that delineate which health professionals or health services can provide certain services?** Delegating some treatment delivery activities to lower cadres of HCWs is common in many countries and needs to be expanded to increase health system capacity. Demonstrating that a decentralized, integrated approach to service delivery will significantly expand treatment access and free up time for health care workers to see other patients is a powerful argument for both policymakers and the health workforce. Coordination and linkages between HIV and related health services, such as TB, maternal and child health or substance abuse programmes, are critical to ensuring retention in care. WHO and UNAIDS will continue to advocate for such approaches to service delivery.
5. **How will communities be further mobilized to increase the scope of their activities?** There are important opportunities to invest further in community system strengthening, and to train community service providers to link with the formal health care system to deliver expanded services, such as adherence counselling and to support retention in care. The specific services community organizations deliver will vary from setting to setting; UNAIDS and the community partners are undertaking regional consultations with communities to identify the roles, as well as the financing required, to strengthen community mobilization in Treatment 2.0.
6. **What is the role of WHO and UNAIDS in Treatment 2.0?** WHO and UNAIDS are co-leading the strategy, with roles and responsibilities allocated across the different workstreams according to their profile and institutional mandate. As the directing and coordinating authority on international health, WHO takes the lead within the UN system for the global health sector response to HIV. This mission is accomplished by providing leadership, setting norms and standards, engaging in partnerships, shaping the research agenda and monitoring the implementation of evidence policy options on matters critical to public health. UNAIDS has a more broad mission, as the main advocate for an accelerated, comprehensive and coordinated global action in response to the HIV epidemic with involvement of multiple sectors and partners from government and civil society. Aligned with these principles, WHO will contribute through its lead role on the normative and technical components of the strategy, particularly on the drug optimization, simplified diagnostics, adapting system delivery workstreams. UNAIDS is excercising its leading role on the reducing costs and community involvement cross-cutting workstreams.
7. **Why is Treatment 2.0 built on a multi-partnership framework?** Treatment 2.0 is a multi-partnership framework with complementary synergy and cooperation between implementing partners across the different work streams. Working with UN and external partners, WHO and UNAIDS will be more effective in their core functions and will help countries to better monitor their response to the HIV treatment and care agenda. This in turn will facilitate better use of strategic information and guide policy and programmatic actions. Consolidation and integration of ongoing collaborations such as the HIV drug resistance (HIVDR) and ART pharmacovigilance projects supported by Gates Foundation, and the establishment of new collaborations with other key partners as CHAI, Global Fund, MSF, PEPFAR, UNITAID and World Bank are essential for the success of the Treatment 2.0 strategy.

For more information, contact:

World Health Organization
Department of HIV/AIDS

20, avenue Appia
1211 Geneva 27
Switzerland

E-mail: hiv-aids@who.int
www.who.int/hiv

TREATMENT 2.0 AT-A-GLANCE

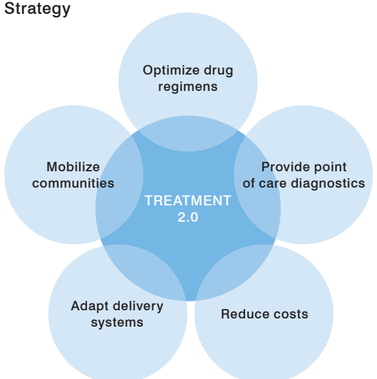
World Health Organization
UNAIDS

TREATMENT 2.0 AT-A-GLANCE

▶ What is Treatment 2.0?

- *Treatment 2.0* is a WHO/UNAIDS initiative that aims to catalyse the next phase of HIV treatment scale up through promoting innovation and efficiency gains. It will help countries to reach and sustain universal access to treatment, and capitalize on the preventive benefit of antiretroviral therapy (ART) through focused work in five priority areas (see Figure 1).
- WHO/UNAIDS are working with global partners, technical experts and other UN co-sponsors to implement the initiative, with short-, medium- and long -term targets and milestones – such as the release of updated normative guidance in key technical areas – outlined in *The Treatment 2.0 Framework for Action: Catalysing the Next Phase of Treatment, Care and Support (available at: http://www.who.int/hiv/pub/arv/treatment/en/index.html.*

Figure 1: Priority work areas of Treatment 2.0 Strategy



▶ Where are we in 2011?

✓ **The number of people accessing treatment has increased 22-fold since 2001**

- An estimated 6.6 million people living in low- and middle-income countries (LMICs) were on ART at the end of 2010.
- Between 8 and 9 million treatment-eligible people still do not have access to ART and many do not yet know their HIV status. If aggressive action is not taken to expand testing and ART access, many of these individuals will be at risk of death before finally initiating ART.

✓ **ART has enormous clinical, preventive and cost benefits**

- An additional 1.4 million people were started on ART in 2010 and fewer people died from AIDS-related causes than in prior years. Annual deaths have reduced by 20% when compared with 2005 and more than 14 million life years have being gained due to the provision of ART since 1996. In countries with high ARV coverage, the annual AIDS associated death rates have decreased by more than 50% in LMICs, with dramatic reductions in the incidence of TB and some other opportunistic infections.
- New infections are declining globally; the incidence of HIV infection declined approximately 20% in the last decade, and in 33 countries, including 22 in Sub Saharan Africa, this reduction exceeded 25%.
- A randomized control trial of serodiscordant couples (HPTN 052) found that the risk of transmission dropped by 96% among couples when the HIV-positive partner was on ART; the trial confirms findings from a number of earlier observational studies indicating that ART significantly reduces HIV transmission.
- Not only does provision of ART reduce illness and death rates, it is also cost-effective; in many settings it costs less than US$ 300/year to provide HIV care, including ART, with earlier treatment intiation, versus more than US$ 1,000/year when ART is initiated late and there are associated with significant hospital costs.

✓ **Simplification, standardization, decentralization, community mobilization and cost reduction**

- The above principles were the foundation for the previous WHO '3 by 5' initiative and the first phase of treatment scale-up; Treatment 2.0 is expanding on these principles, applying them across the five priority work areas to accelerate the development and delivery of drugs, diagnostics and services and put into place the community mobilization needed to achieve universal access in a way which maximizes value for money.

TREATMENT 2.0: FIVE PRIORITY AREAS

1. Optimize Drug Regimens

2020 Goal: Effective, affordable, one pill, once-daily potent ARV regimens, suitable for most populations with minimal toxicities or drug interactions and high barrier to resistance are available in low and middle income countries (LMICs)

WHO, UNAIDS, and its global partners and technical experts are working to incentivize the development and use of simplified, less toxic drug regimens, with high barriers to drug resistance, that require minimal clinical monitoring while maintaining therapeutic efficacy. Drug regimen optimization includes establishing optimal dosages of ARVs (including possible dose reductions), developing 'one pill a day' fixed dosed combinations (FDCs), to improve adherence, improving paediatric formulations, and expanding access to effective, safer, and affordable first-, second- and third-line drug regimens, including those that can be safely during pregnancy, by children, and with concomitant TB treatment.

2. Provide point-of-care (POC) and other simplified diagnostic and monitoring tools

2020 Goal: A package of simple, affordable, reliable, quality-assured POC and other simplified diagnostics are available and accessible in LMICs

A package of affordable and easily-performed diagnostics using point-of-care (POC) and other simplified technologies needs to be developed and validated to expand HIV diagnostic testing and virologic and immunologic tests used for staging and for management of ART. WHO and UNAIDS are working with technical experts to formulate recommendations for the use of POC and other simplified platforms and provide guidance on the short, medium and long term priorities for optimization of current and pipeline technologies.

3. Reduce costs

2020 Goal: High-quality HIV prevention, care and treatment programmes are available at the lowest possible cost with optimal efficiency to all in need in LMICs

While greater HIV investment is required, there are significant opportunities for cost reductions and efficiency gains in HIV programmes: commodity costs can be reduced by pooled procurement of drugs and diagnostics, simplified manufacturing processes, potential dose reductions and negotiations to reduce costs of pharmaceutical ingredients (APIs), drugs and diagnostics. Efficiency gains can be achieved in service delivery, particularly through task-shifting and an expanded role for communities, and LMICs can take better advantage of flexibilities under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement.

4. Adapt service delivery

2020 Goal: HIV care and treatment programmes are decentralized and appropriately integrated with other HIV and non-HIV health services, with increased community engagement in service delivery and improved retention in care

Decentralizing and integrating treatment with other areas of health care, such as drug dependency services, maternal and child health, TB services and general primary health services, will help leverage scarce resources for maximum effect. Increasing HIV testing and counselling (HTC) and improved linkages to care will result in significantly increased demand on prevention, care and treatment programmes. Ensuring these programmes are available where and when people need them can be achieved by promoting local, decentralized service delivery approaches, including expanded community services, to ensure access for all in need. WHO, UNAIDS and its partners are undertaking a comprehensive review of service delivery models to develop recommendations on optimal integrated, decentralized service delivery approaches that will meet expanded demands on treatment programmes and deliver decentralized services close to the community.

5. Mobilize communities

2020 Goal: People living with HIV and key populations are fully involved in the demand creation, planning, delivery and evaluation of quality-assured, rights-based HIV care and treatment programmes in all LMICs

The full engagement of people living with HIV and their affected families and communities is essential to