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THE WHO CONSOLIDATED GUIDELINES ON THE USE OF ANTIRETROVIRAL DRUGS FOR TREATING AND PREVENTING HIV INFECTION; RECOMMENDATIONS FOR A PUBLIC HEALTH APPROACH — IMPLICATIONS FOR THE AFRICAN REGION

Report of the Secretariat

CONTENTS

BACKGROUND

1. The World Health Organization guidelines on the use of antiretroviral drugs (ARVs) for HIV infection were first published in 2002 and subsequently revised in 2003, 2006 and 2010. They have provided important guidance to countries for scaling up national ARV programmes during the past decade. [1] [2] [3] [4] More than 7.5 million people in the African Region were receiving HIV treatment by the end of 2012 compared with 50 000 people a decade earlier.[5] This has led to a decline of AIDS-related deaths especially in the East and Southern African subregion where an estimated 38% fewer deaths were reported in 2011 compared with 2005.[6] Life expectancy has also increased. For example between 2005 and 2011, it improved in South Africa from 54 to 60 years, a gain largely attributed to the roll out of ARV programmes.[7]

2. In addition, the rate at which people were infected with HIV fell by 50% or more in 12 countries[8] in the African Region mainly due to the scale-up of ARV use combined with classic prevention efforts.[9] This is in line with the MDG-6 target to "Have halted and begun to reverse the spread of HIV/AIDS by 2015". This progress was due to the intensification of national HIV/AIDS responses by governments as well as the financial and technical support from international partners including WHO; UNAIDS; the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM); the United States Presidential Emergency Plan for AIDS Relief (PEPFAR); the Canadian International Development Agency (CIDA); UNITAID; and the World Bank.

3. Since 2010 there has been increasing scientific evidence of the benefits to individuals and populations of early antiretroviral therapy (ART). Of particular importance has been the evidence of the benefits of starting ART earlier at a CD4 cell count of ≤500 cells/mm³ compared with ≤350 cells/mm³, with the potential for reducing HIV-related morbidity and mortality and onward transmission of HIV.[10] [11] [12] [13] Safer, simpler, more efficacious and more affordable new ARV regimens are now available as are newer testing and monitoring technologies and approaches for earlier diagnosis and patient follow-up. There is increasing awareness of the association between HIV infection and a broad range of other health conditions including various noncommunicable diseases and coinfections such as tuberculosis, malaria, viral hepatitis, requiring better integration of and linkage to programmes to leverage broader health outcomes.

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1 WHO, Scaling up antiretroviral therapy in resource-limited settings: guidelines for a public health approach. Geneva, World Health Organization; 2002.

2 WHO, A public health approach for scaling up antiretroviral treatment, Geneva, World Health Organization; 2003.

3 WHO, Antiretroviral therapy for HIV infection in adults and adolescents: recommendations for a public health approach. Geneva, World Health Organization; 2006.

4 WHO, Antiretroviral therapy for HIV infection in adults and adolescents: recommendations for a public health approach. Geneva, World Health Organization; 2010.

5 WHO, Global update on HIV treatment 2013: results, impact and opportunities. Geneva, World Health Organization; 2013.

6 UNAIDS, World AIDS Day Report 2012. Geneva, UNAIDS, 2012.

7 Bradshaw D, Dorrington R, Laubscher R. Rapid mortality surveillance report 2011. Cape Town, South African Medical Research Council, 2012.

8 Botswana, Burkina Faso, Central African Republic, Ethiopia, Gabon, Ghana, Malawi, Namibia, Rwanda, Togo, Zambia and Zimbabwe

9 UNAIDS, Global report: UNAIDS report on the global AIDS epidemic 2012. Geneva, UNAIDS 2012.

10 Lessells RJ et al. Reduction in early mortality on antiretroviral therapy for adults in rural South Africa since change in CD4+ cell count eligibility criteria. Journal of Acquired Immune Deficiency Syndromes, in press.

11 Moore RD et al. Rate of comorbidities not related to HIV infection or AIDS among HIV-infected patients, by CD4 cell count and HAART use status. Clinical Infectious Diseases, 2008, 47:1102–1104.

12 Baker JV et al. CD4R count and risk of non-AIDS diseases following initial treatment for HIV infection. AIDS, 2008, 22:841–848.

13 Cohen MS et al. Prevention of HIV-1 infection with early antiretroviral therapy. New England Journal of Medicine, 2011, 365:493–505.

4. In response to the above developments, in June 2013, WHO published new recommendations on the use of ARVs — *Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection; Recommendations for a Public Health Approach, June 2013*. The guidelines aim to consolidate existing and new guidance from different, fragmented sources, into one document that covers all aspects of the use of ARVs for HIV treatment and prevention in different populations, age groups and settings. The new recommendations promote earlier initiation of ART, further simplification of ART regimens, with a single preferred first line regimen, available as "a one pill a day fixed-dose combination", for adults, pregnant women, adolescents and older children, and improved monitoring of people on ART. They also promote immediate ART for all HIV-infected children below five years of age and HIV-infected pregnant and breastfeeding women. In addition, the guidelines provide advice on how to improve the efficiency and effectiveness of HIV services and how to plan HIV/AIDS programmes and use resources more efficiently.

5. It is estimated that implementing the 2013 WHO guidelines on the use of ARVs for HIV treatment and prevention could save an additional three million lives globally by 2025 compared with implementation based on the 2010 WHO guidelines. That corresponds to a further 39% reduction of AIDS-related deaths compared with outcomes based on the use of the 2010 guidelines. Furthermore, implementing the new guidelines could reduce new HIV infections by an additional 36% i.e. 3.5 million less of new HIV infections during the same period compared with the outcomes of treatment based on the 2010 guidelines.[14] This will contribute significantly to achieving universal access to HIV prevention, treatment, care and support in accordance with the goals and targets articulated in the 2011 Political Declaration on HIV/AIDS.[15]

6. This document discusses the key implications of the main recommendations of the 2013 WHO guidelines on the use of ARVs and proposes actions to be taken by Member States as they adapt and implement the guidelines.

ISSUES AND IMPLICATIONS

7. The WHO 2013 consolidated guidelines have the potential to reverse the HIV epidemic if implemented by Member States. However, there will be related implications. Based on the status of the epidemic as at the end of 2012, it is estimated that with the new guidelines the total number of individuals eligible for ART in the African Region would increase from 12.4 million to 19 million.[16] Thus an additional 6.6 million people will become eligible for ART, representing an increase of about 53%. Further investments in health systems will be required in order to provide access to ARVs and realize the full benefits of the application of the new guidelines.

8. More than half of the people living with HIV in the African Region do not know their HIV status[17] and, often, those who do know tested late. Weak linkage between HIV testing, counseling and care means that many people start treatment when they are already significantly immunocompromised, resulting in poor treatment outcomes and continuing HIV transmission. A meta-analysis from studies conducted in sub-Saharan Africa indicates that only about a quarter of the people who test positive for HIV actually initiate ART.[18] In addition, there are high rates of

[14] WHO, Global update on HIV treatment 2013: results, impact and opportunities. Geneva, World Health Organization; 2013.

[15] United Nations General Assembly. 2011 Political Declaration on HIV and AIDS: intensifying Our Efforts to Eliminate HIV and AIDS. New York, United Nations, 2011.

[16] WHO, Global update on HIV treatment 2013: results, impact and opportunities. Geneva, World Health Organization; 2013.

[17] WHO, HIV in the WHO African Region: 2011 update. Brazzaville, WHO Regional Office for Africa, 2011

[18] Mugglin C et al. Loss to programme between HIV diagnosis and initiation of antiretroviral therapy in sub-Saharan Africa: systematic review and meta-analysis. Tropical Medicine and International Health, 2012.

attrition along the treatment cascade from diagnosis of HIV to retention in HIV care and treatment.[19] In order to maximize the individual and public health benefits of earlier ART initiation, people need to be tested for HIV to enable those found to be infected to be linked to early care and treatment.

9. The human resource crisis facing several countries in the Region has impacted negatively on service delivery and the increase in the number of individuals eligible for the use of ARVs will exacerbate the situation. Laboratory capacity for HIV diagnosis among children and adults and for monitoring patients on treatment remains inadequate. The HIV medicines procurement and supply management systems including medicines and commodities for opportunistic infections remain weak and quite often lead to stock-outs. In addition, weak health information systems hamper effective monitoring of progress. Thus, implementing the WHO 2013 consolidated guidelines will have health systems implications as more medicines will be required, more efficient patient monitoring will be needed, laboratory capacity for viral load testing will have to be strengthened and innovative use of human resources including gender and human rights will have to be intensified to mitigate the existing shortages. This provides an opportunity for further addressing the health systems implications.

10. Current estimates show that the costs of medicines for treating a person requiring ART is between US$ 120 and US$ 200 per year while total costs, including service provision and a mix of first and second line ARVs, are about US$ 515 per patient per year.[20] Although the contributions of national governments have increased in recent years, dependence on external funding remains a matter of great concern. It is estimated that about 60% of these costs are covered from international sources, including donors and the Global Fund.[21] There will be need to mobilize a further US$ 1 billion in addition to the US$ 10-12 billion that is currently required to cover the comprehensive response to HIV in the African Region. This additional funding requirement is due to the increase in the number of people who will be eligible to use ARVs when the new guidelines are applied. The WHO provides guidance and support to countries for adaptation of technical guidelines; enforcement of norms and standards; development and review of strategic plans; capacity building of national human resources for health; and monitoring trends and progress of HIV response. However, the role of WHO in the Region has been constrained due to reduction in funding. Critical strategic and technical assistance has been constrained. Adequate funding for WHO would ensure sustained support to countries.

ACTIONS PROPOSED

11. ***Adapting national antiretroviral therapy (ART) guidelines:*** Countries should ensure that the national adaptation of the WHO consolidated guidelines enhances the legitimacy, acceptability, effectiveness and equity of HIV/AIDS programmes that address community needs. It is recommended that this should be guided by a review of the progress made so far and planning through a national dialogue involving government, civil society, donors, and partners to ensure national ownership, alignment with the planning and budgeting cycle of governments, and harmonization of all stakeholders. National HIV/AIDS programmes should set up a multidisciplinary working group to give advice on the choices and decisions necessary for updating and using a Stepwise approach adapted to countries' specificities. The role of the working group may include reviewing the current context of national HIV and TB infections,

[19] WHO, UNAIDS and UNICEF. Progress report 2011: global HIV/AIDS response. Epidemic uptake and health sector progress towards universal access. Geneva, World Health Organization, 2011.

[20] CHAI, Multi-Country Analysis of Treatment Costs For HIV/AIDS (MATCH): Unit Costing at 161 Representative Facilities in Ethiopia, Malawi, Rwanda, South Africa, and Zambia. International AIDS Conference 2012, Clinton Health Access Initiative, 2012.

[21] UNAIDS, Global report: UNAIDS report on the global AIDS epidemic 2012. Geneva, UNAIDS 2012.

assessing the performance of the current national HIV programme with a focus on coverage, equitable access, retention in care and ARV regimens in use. National HIV programmes should organize national ART guidelines adaptation workshops in order to update national ART guidelines. Plans for introducing and progressively rolling out the new national ARV guidelines should be prepared according to the specific context of each country.

12. ***Promoting uptake of HIV testing and counseling for HIV primary prevention:*** Countries should increase HIV testing and counseling rates among the general population to ensure that all HIV-infected individuals are identified and enrolled in care. This can be accomplished by scaling up an appropriate mix of approaches including voluntary testing, and provider-initiated HIV testing and counseling for all care seekers including pregnant or breastfeeding women. Additional approaches such as home-based testing, mobile outreach (including index partner testing, testing in workplaces, schools and universities, and accessible and safe venues for key populations), special testing events and campaigns are needed with effective referral systems and links to care and treatment. It should be noted that despite their contribution to prevention of HIV transmission, ARVs should be used in combination with an appropriate mix of other biomedical, behavioral and supportive structural HIV prevention interventions. In this regard it is important to emphasize the need to focus on HIV primary prevention. Interventions to scale up prevention should be strengthened including health promotion, behavior change counseling, quality-assured HIV testing and counseling, promotion of the use of male and female condoms, safe voluntary medical male circumcision and harm reduction for injection drug users. Community-based testing approaches will help reach more people with HIV to ensure early initiation of care and treatment. Combining approaches will result in synergies that have greater impact than any single intervention.

13. ***Integrating services related to HIV treatment and care***

13.1 To ensure comprehensive and consistent patient management over time, integrating and linking services will increase opportunities for initiating ART, enhance long-term adherence of patients and optimize patient retention in care. Programmes on HIV/AIDS, sexual and reproductive health, child health and TB should collaborate to ensure successful implementation of ART and related services at different levels of the health system. Areas of collaboration include information sharing and effective referral; mobilizing and allocating resources; training, mentoring and supervising health workers; procuring and managing drugs and other medical supplies; and monitoring and evaluation.

13.2 To improve access to ART in primary care settings, countries should decentralize ART services in order to promote equity. In addition, decentralizing HIV care and treatment will further strengthen community involvement, linking community-based interventions with health facilities. ART initiation and maintenance should be considered according to national context and the capacity at different levels of the health system. Costed operational plans are recommended to facilitate strengthening of the delivery capacity of health services at local level.

13.3 To ensure adherence and retention of people on ART, it is recommended that countries should: (a) improve social protection systems to minimize out-of-pocket payments at the point of care; (b) strengthen drug supply management systems to reliably forecast, procure, and deliver ARV drugs and diagnostics and prevent stock-outs; (c) promote patient education, counseling and peer support throughout the course of treatment and the use of innovative communication tools. Improved adherence and retention of patients will contribute to benefits such as suppression

of viral replication, improved clinical outcomes, prevention of ARV drug resistance, and reduction of the risk of transmitting HIV.

14. ***Improving procurement and supply of drugs and other commodities***

14.1 Countries should update their national essential medicines lists to include the newly recommended ARV regimens, drugs, diagnostics and commodities. In addition, the phasing in of new ARVs should be synchronized with the phasing out of old ARVs to minimize the waste of products. At the service delivery level, supplies management including monitoring of consumption, and proper quantification of all drugs, diagnostics and commodities should be strengthened. Appropriate formulations, particularly for infants and children, should be procured and adequate stocks should be maintained of old ARV regimens for those patients who cannot be transferred to the new preferred first and second line regimens.

14.2 Governments and partners should strengthen and harmonize national procurement and supply systems at all levels to ensure uninterrupted and sustained provision of high-quality ARVs, diagnostics and commodities. It is important that a publicly accessible database such as the Global Price Reporting Mechanism (GPRM)[22] be used to facilitate access to information on the prices of medicines.

14.3 Countries should strengthen their capacity for effective pharmaceutical regulation and set up fast track mechanisms for registration of ARVs, diagnostics and other commodities. They should promote local production of essential medicines including ARVs to ensure sustainable access and reduce dependency.

15. ***Strengthening laboratory capacity:*** countries should use viral load testing as the preferred approach to monitoring the success of ART and diagnosing treatment failure in addition to carrying out clinical and immunological (CD4) monitoring of people receiving ART and building the necessary capacity. Countries should improve access to diagnostics and viral load testing through the use of point-of-care technologies such as dried blood spots (DBS). Where viral load testing is limited, it should be phased in using a targeted approach. Access to ART should be the first priority and lack of laboratory testing for monitoring treatment response should not be a barrier to initiating ART.

16. ***Addressing the human resource implications:*** Given the rapidly evolving knowledge on HIV care and treatment, all health workers, including community health workers, should be regularly trained in teams to manage HIV. They should be mentored and supervised to ensure high-quality care and implementation of updated national recommendations. At the same time, decentralizing ART services will require task-sharing to enable trained medical doctors, clinical officers, midwives and nurses to initiate and maintain first-line ART. Likewise, in line with country-specific policies and legislation, supervised community health workers should contribute to dispensing first line ART. HIV care and treatment should be strengthened in existing pre-service courses so that more health workers will graduate and be certified. Strong linkages with community-based organizations, civil society groups and nongovernmental organizations should be established to enhance awareness, increase uptake of testing and counseling, improve treatment preparedness and literacy and scale up coverage of early treatment and care.

17. ***Improving strategic information systems:*** As countries adapt and implement these guidelines, national monitoring and evaluation systems should also be adapted to collect and analyze information for tracking the implementation and impact of the new recommendations. It

[22] WHO, Transaction Prices for Antiretroviral Medicines from 2009 to 2012: WHO AIDS Medicines and Diagnostics Services Global Price Reporting Mechanism. Geneva, World Health Organization 2013

will be essential to monitor the quality of service delivery and strengthen service linkages to improve retention throughout the cascade of care. As part of the national health information system, countries should establish a national database linking all data sources such as services for PMTCT, TB and ART and integrating HIV drug resistance monitoring.

18. ***Improving financial resources for ART scale-up:*** countries should continue to strive to achieve the Abuja Declaration target of allocating 15% of their national budgets to the health sector including HIV/AIDS prevention, treatment, care and support as a priority programme. The funding gap analysis should identify opportunities for additional domestic and external contributions and for enhanced efficiency and effectiveness in the implementation of the national HIV response. New and innovative financing options such as national HIV levies, earmarked taxes and private sector contributions should also be explored. Governments should build an investment case for HIV, counting on their own resources, and engage partners to seek additional funding from other sources such as the GFATM, PEPFAR, UNITAID and other multilateral and bilateral agencies. These efforts should help strengthen the national health services' capacity to ensure universal access to HIV prevention, treatment, care and support.

19. In accordance with its core functions, WHO will continue to work with financial partners in line with the global and regional HIV/AIDS strategies to provide harmonized support to countries and partners. In this regard, adequate funding will be required to support the role of WHO in the African Region.

20. The Regional Committee is requested to examine and adopt this document and the proposed resolution.