Accelerating HIV treatment

in the WHO Eastern Mediterranean and UNAIDS Middle East and North Africa regions







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Foreword

Antiretroviral therapy has transformed the global HIV response, but whether people living with HIV benefit from the life-saving and prevention benefits of treatment depends too often on where they live. Worldwide, HIV treatment coverage is lowest in the WHO Eastern Mediterranean Region and UNAIDS Middle East and North Africa Region (referred to in this report as the "Region"), and does not exceed 15% of the estimated people in need of treatment. The situation in the Region is critical and we are not keeping up with the global pace of treatment access – the rate of growth in treatment coverage is lower in the Region than it is globally and this disparity is increasing over time.

This needs to change. Not only do people living with HIV have the same rights to treatment as their peers in other parts of the world, but antiretroviral treatment prevents new infections. Even as the global community celebrates the decline in new infections worldwide, the Region is one of two in the world where new HIV infections are still on the rise.

Fortunately, we know how to reverse these trends. Experience around the world has shown that it is possible to bring HIV testing and treatment to scale, and leaders in the Region have made clear commitments to take action to bring these services to the people who need them. Business as usual is not working and this report provides a framework for action to accelerate HIV testing and treatment coverage.

The report outlines what needs to be done to close the gap and move towards universal access to treatment. We need to ensure that policies reflect recent advances in science emphasizing the importance of earlier testing and treatment, particularly for key populations.

Putting the Region on track to reach universal access will require intensified focus on the geographical settings and populations where both HIV prevalence and unmet needs for testing and treatment services are highest.

Experiences in diverse countries underscore the importance of rapid scale-up to enable national responses to outpace the epidemic itself. We cannot wait to act. To reach our treatment goals, we need to encourage the promotion and delivery of HIV testing and treatment services, working closely with affected communities to address stigma.

One set of stakeholders alone cannot bring HIV treatment to all those who need it. Only a partnership approach will work, with the engagement of public institutions, the private sector, civil society, religious leaders and people living with HIV.

WHO and UNAIDS are committed to joining forces to assist the Region in meeting its treatment goals. It is our hope that this framework will help renew commitment to the response, help overcome roadblocks, and accelerate progress towards our shared goal of laying the foundation to end the AIDS epidemic.



Michel Sidibé Executive Director UNAIDS



Ala AlwanRegional Director
WHO Regional Office for the Eastern
Mediterranean

Key actions recommended in the report

The aim

Unfolding a bold tailored initiative to increase access to HIV treatment in the Region, in line with the WHO 2013 consolidated antiretroviral guidelines and the Treatment 2015 initiative.

The rationale

The HIV treatment crisis in the Region is reversible. Implementing the recommended actions soonest will enable the Region to achieve universal coverage for HIV treatment.

Key recommended actions

Commit to urgent action

1. Set ambitious annual targets for HIV testing and treatment at national and local levels, monitor progress closely and take urgent remedial action if targets are not met.

Create demand

- 2. Implement bold action plans to overcome the stigmatization and discrimination in health services.
- 3. Adopt and implement rapid testing technologies that permit same-day test results.
- 4. Provide HIV testing services in community settings in order to reach key populations at higher risk of HIV exposure.
- 5. Normalize HIV testing in health-care settings by routinely offering it as a component of regular health care in appropriate services in antenatal care, tuberculosis, STI, drug prevention and treatment, and other relevant services.
- 6. Adopt, client-friendly, standardized, free-of-charge HIV treatment and care services to facilitate prompt linkage to care upon HIV diagnosis, earlier initiation of ART, treatment adherence and retention in care.

Mobilize sustained investments

- 7. Increase the share of domestic investment for HIV through sustainable and predictable financing mechanisms at country level.
- 8. Reduce costs associated with antiretroviral medicines, including expanded use of generic medicines, exploration of bulk purchasing and investments to build regional pharmaceutical manufacturing capacity.

- 9. Track and develop opportunities to increase the efficiency and effectiveness of testing, treatment and care activities, starting with an increased focus of resources on key populations specific for each country and locality.
- 10. Build community capacity to help design and support testing and treatment scale-up and to improve long-term treatment outcomes.
- 11. Develop health system capacity to deliver chronic care inclusive of HIV.

Deliver results in an equitable manner

- 12. Simplify treatment protocols and move towards fixed dose combinations with "one pill per day" regimens.
- 13. Offer ART, irrespective of immunological status, to the following groups of people living with HIV: those in discordant couples, pregnant and breastfeeding women, children aged five years and below, those with active tuberculosis and those with hepatitis B with severe chronic liver disease.
- 14. Avoid service interruptions as a result of stock-outs of medicines and laboratory supplies.
- 15. Strengthen and expand laboratory services for monitoring of the response to treatment, including CD4 and viral load monitoring.
- 16. Decentralize routine patient care and HIV treatment monitoring to selected primary care and community-based settings based on need assessment, with consideration to the involvement of both public and private providers.
- 17. Integrate HIV treatment and care in other health services such as mother, neonatal and child health services, tuberculosis clinics and drug use harm reduction services.

Introduction

The scaling up of antiretroviral therapy (ART) has transformed the global response to the HIV epidemic. In 2011, AIDS-related deaths worldwide were 24% lower than in 2005, with scaled-up ART adding 14 million life-years in low- and middle-income countries (1). The preventive impact of ART, too, is increasingly evident including in concentrated HIV epidemics (2,3,4). Due to the therapeutic and preventive benefits of ART, there is growing confidence in the world's ability to lay the foundation for an AIDS-free generation (5).

Globally, ART scale-up averted an estimated 4.2 million deaths in low- and middle-income countries in 2002-2012 (6). However, the health impact of ART has barely been felt in the WHO Eastern Mediterranean Region/ UNAIDS Middle East and North Africa Region (the "Region")¹, where HIV treatment coverage is the lowest in the world. A person living with HIV in sub-Saharan Africa in 2011 was more than four times more likely to receive ART than a person living with HIV in the Region (1). Whereas HIV-related deaths worldwide continue to decline, the number of people dying of HIV-related causes in the Region rose by 138% from 2001 to 2012. At the same time that regional ART coverage lags, the Region is one of only two worldwide where new infections are on the rise.

WHO and UNAIDS are committed to working with countries in the Region to reverse this state of affairs. Specifically, WHO and UNAIDS seek to galvanize an effort to end the HIV treatment crisis in the Region by achieving universal coverage for HIV treatment by 2020. With the aim of strengthening the

WHO consolidated guidelines on the use of antiretroviral medicines for treating and preventing HIV infection: Earlier treatment for HIV infection

Drawing on the accumulated evidence of the therapeutic and prevention benefits of HIV treatment, WHO in 2013 recommended use of a CD4 threshold of 500 cells/mm3 for initiation of HIV treatment, as well as treatment regardless of CD4 count for certain populations (including serodiscordant couples, people with hepatitis B with severe liver disease and/or active tuberculosis, for pregnant and breastfeeding women and children aged five years and below). Globally, the 2013 guidelines revisions effectively increased the number of people eligible for ART from 15 million to 26.7 million. The 2010 guidelines used a CD4 cell count of 350, country-level implementation of the guidelines has varied, with a number of countries using the much lower CD4 threshold of 200 cells/ mm³ for treatment initiation.

Region's contribution towards the 2015 global target of reaching at least 15 million people receiving ART, this regional initiative envisages a proactive approach to extending ART access to an additional 15% of people living with HIV in the Region per year over the next two years.

The framework for accelerating access to HIV treatment outlined in this report describes why this regional initiative is so critical. It describes the HIV treatment coverage gap in the Region (see Figure 1) and the reasons why so few people living with HIV in the Region receive life-preserving treatment services. This framework provides contextual information for the HIV treatment crisis, describing the broader epidemiology of HIV in the Region and the commitments that regional leaders have made to strengthen the HIV response.

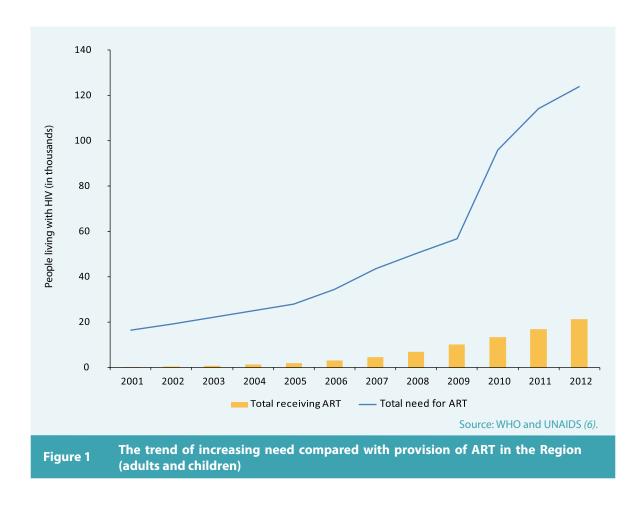
¹ The combined UNAIDS Middle East and North Africa (MENA) Region and WHO Eastern Mediterranean Region (EMR) comprises following countries and territories: Afghanistan, Algeria, Bahrain, Djibouti, Egypt, Iran (Islamic Republic of), Iraq, Jordan, Kuwait, Lebanon, Libya, Morocco, Oman, Pakistan, occupied Palestinian territories, Qatar, Saudi Arabia, Somalia, South Sudan, Syrian Arab Republic, Tunisia, United Arab Emirates and Yemen. Nevertheless, as South Sudan is not part of MENA and leaves the EMR as of January 2014, data and information from South Sudan have not been reflected in this report.

Most importantly, the report focuses on the way forward, identifying the key principles that must guide collective action in the Region and the critical steps needed to end the HIV treatment crisis.

Leaders in the Region have provided a strong foundation on which to end the HIV treatment crisis, having pledged to take specific actions to achieve global and regional HIV targets. In 2013, regional actors need to step forward, working together to translate these commitments into concrete results for people.

The major sources of data presented in this report are the Global AIDS Response Progress Reporting (GARPR) and UNAIDS/WHO HIV estimation and projection exercises, the latest series of both conducted in 2013. However, as some countries in the Region have not

finalized the latter exercise, the estimated number of people living with HIV, number of people eligible for ART and number of HIV-related deaths are based on a subset of countries in the Region. Whenever regional coverage figures are presented, numbers concerning only this subset have been used.²



²The countries in this subset are: Afghanistan, Algeria, Djibouti, Egypt, Iran (Islamic Republic of), Morocco, Pakistan, Somalia, Sudan, Tunisia and Yemen.

A growing regional epidemic



Photo: ©Association LutteContre le Sida, Morocco

In 2012, 347 000 people in the Region were living with HIV, a 127% increase over the number living with HIV in 2001. Even as new infections continue to decline worldwide, there are disturbing signs that the Region's epidemic is worsening. Among the world's regions, HIV incidence is increasing fastest in the Region, with the annual number of new infections rising by more than 124% from 2001 to 2012 (7).

Although, the percentage of the general adult population living with HIV in the Region is among the lowest globally, certain populations have been disproportionately affected. These populations include men who have sex with men, people who inject drugs, prisoners, and sex workers and their clients. Epidemiological studies have documented elevated HIV prevalence among key populations in many settings - with recent surveys reporting levels reaching up to 87% among people who inject drugs and 18% among prisoners in Libya (8), 15.4% among female sex workers in Djibouti, and 13% among men who have sex with men in Tunisia.

Adult HIV prevalence exceeds 1% in Djibouti and parts of Somalia, qualifying them as "generalized" epidemics, although key populations at higher risk of HIV exposure

account for the large proportion of new infections in these countries as well (9). Considerable geographical variation in HIV burden is reported within individual countries.

Within the Region, epidemics vary considerably within and between countries. While key populations have been heavily affected in some settings, surveys suggest very low prevalence in these groups in others (8). In large part, these variations merely reflect the diversity of the Region itself, although they are often amplified by differences in attitudes, policy approaches and service access in different parts of the Region (9).

For the Region as a whole, women account for 38% of the estimated number of adults living with HIV (10), with women's risk tied primarily to risk behaviours by their male sex partners, especially those that belong to key populations. With young people between the ages of 15 and 30 years of age accounting for 20% of the population in many countries, the regional epidemic's future will depend in large measure on success in equipping this new generation with the tools and skills needed to avert HIV transmission (9).

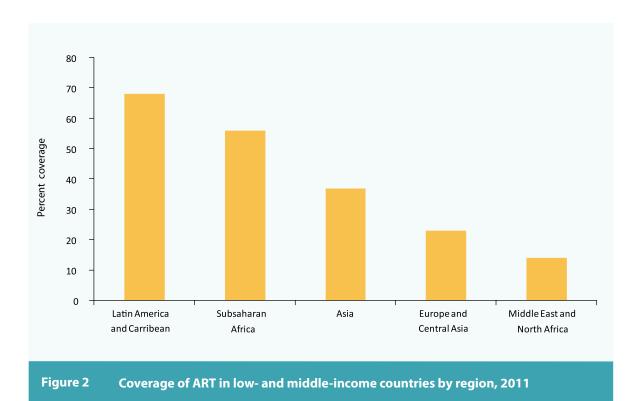
The HIV treatment crisis in the Region

Since the HIV epidemic is expanding rapidly, one might expect that HIV treatment scale-up would be a top priority in the Region. However, treatment coverage is lower in the Region than any other part of the world (Figure 2). While 54% of individuals worldwide who were eligible for ART received it in 2011, only 14% of treatment-eligible people in the Region obtained ART (1). In sub-Saharan Africa, where health systems tend to be far weaker than those in the Region, 56% of those eligible for ART in 2011 received therapy (1).

The absolute number of people receiving ART in the Region increased more than six-fold from 2006 to 2012, including a 26% increase in 2012 alone. However, gains in increasing ART coverage in the Region have been decidedly more modest than in other regions and remain far off the pace required to achieve universal access.

In 2012, 21 527 people (adults and children) in the Region were on ART, out of an estimated 124 000 who were eligible for therapy. Both ART coverage and need for ART vary considerably across the Region. Among low- and middle-income countries, Morocco and Tunisia are the only countries in which ART reached around half of all individuals eligible for treatment under WHO's 2010 HIV treatment guidelines, followed by Lebanon with a treatment coverage exceeding 40%.

Most people in need of ART in the Region reside in countries with comparatively higher HIV prevalence or larger national populations. In 2011, four countries – Islamic Republic of Iran, Pakistan, Somalia and Sudan – accounted for 68% of all individuals in the Region who needed ART under the 2010 WHO guidelines.





The failure to bring ART to scale represents a profound missed opportunity. Not only does ART mitigate the human costs of HIV and enhance the health of national workforces, but it also plays a vital role in slowing the further spread of the virus. Currently, the growth in number of people in need of ART is rapidly outpacing efforts to scale up treatment access in the Region.

The Region also lags behind in preventing mother-to-child transmission. At a time when the number of children who acquire HIV each year globally has rapidly declined, falling by 43% from 2003 to 2011 (1), the Region is the only one that has yet to see a reduction in the number of children newly infected with HIV (7). While 57% of pregnant women living with HIV globally received antiretroviral prophylaxis in 2011 (1), coverage of services to prevent mother-to-child transmission of HIV was only 7.6% in the Region.

In 2012, WHO, UNAIDS, UNFPA and UNICEF launched a regional framework for the elimination of mother-to-child transmission at the 59th Session of the WHO Regional Committee for the Eastern Mediterranean (11). Some progress has been achieved as the number of pregnant women receiving antiretroviral prophylaxis more than doubled between 2009 and 2012, but the pace of service expansion is far too slow to ensure the elimination of new infections among children.

With low numbers of pregnant women having access to HIV testing as part of antenatal care, the number of children exposed to HIV remains unknown. Furthermore, access to early infant diagnosis of HIV is low in the Region and children who become infected also have minimal access to life-saving HIV treatment and care services.

Why regional HIV treatment coverage is so low

Effective scale-up of ART requires addressing each stage of the HIV treatment continuum, including early diagnosis of HIV, linking HIV-positive individuals to care, initiating ART in a timely manner, and ensuring continuity of care and strong treatment adherence. Successful navigation of the HIV treatment continuum is required in order to ultimately achieve complete and durable viral suppression, which dramatically slows HIV disease progression, substantially lowers the odds of HIV-related illness and death, and sharply diminishes the risk of HIV transmission.

To assist countries in exploring the size, and determinants, of the gaps and losses along the HIV treatment and care continuum, WHO has developed guidance and tools for undertaking an evidence-based analysis of the "HIV treatment cascade". Based on such analysis, specific action can be identified and prioritized to close the gaps.

Poor access to HIV testing and counselling

Across the Region, most people living with HIV have yet to know their HIV status. Late diagnosis of infection increases the risk of HIV-related disability and death, reduces the long-term effectiveness of ART and facilitates the continued spread of HIV.

There have been some glimmers of progress in regional efforts to promote knowledge of HIV status, with the number of people tested increasing by 79% in the six countries that submitted testing utilization data through the 2013 Global AIDS Response Progress Reporting (6). However, the absolute number of people accessing HIV testing services remains extremely low, and available data do not indicate whether people accessing testing are those at highest risk.

Several factors contribute to the low uptake of HIV testing in the Region. Awareness of HIV remains low in many countries, and many people do not know of the availability of testing services. Even though effective HIV treatments exist, HIV infection is often portrayed and perceived across the Region as a deadly and frightening infectious disease, deterring many from voluntarily seeking HIV testing and counselling services. Moreover, many people avoid seeking HIV testing due to popular perceptions that associate HIV with criminal or immoral behaviours.

Due to HIV-related stigma and discrimination, many people fear that health care workers, family members and others will react negatively if they test HIV-positive.

Health systems in the Region have inadequately invested in the delivery and promotion of HIV testing services. Per capita, the Region had the lowest number of HIV testing facilities of any region in 2010. The median number of HIV testing facilities in the Region in 2010 (1.1 per 100 000 adult population, based on reports from six countries) was less than one-seventh the number available in low- and middle-income countries generally (8.2 per 100 000 population from 104 countries reporting) (12).

The Region has yet to diversify HIV testing and counselling approaches to ensure services reach those who need it. HIV testing and counselling in the Region is predominantly delivered through traditional client-initiated voluntary counselling and testing (VCT) services. Most of the available VCT services are under-utilized and primarily accessed by individuals who are referred by their health care providers because they present with signs and symptoms suggestive of HIV.

Provider-initiated testing and counselling services are still at nascent stages in the Region. According to recent country reports, only five countries have guidelines for provider-initiated testing and counselling for pregnant women and only three countries for tuberculosis patients.

Non-facility-based outreach and HIV testing and counselling is available in a few countries in the Region, primarily in an attempt to reach key populations at higher risk of HIV exposure. However, coverage for community-based HIV testing and counselling remains extremely low. In many parts of the Region, HIV testing and counselling campaigns are also conducted on an ad hoc basis, often tied to special occasions such as World AIDS Day.

Only three countries (Djibouti, Somalia and Sudan) in the Region have introduced HIV testing strategies that use three serial rapid tests to establish a positive HIV status.

Other countries in the Region continue to rely on more complex and time-consuming laboratory technologies for diagnosis of HIV infection. In these other countries, rapid tests are either not used at all or employed as a first assay only, with confirmation of reactive tests performed with enzyme-linked immunosorbent assay (ELISA) or western blot. Due to the need for confirmation of reactive tests, clients are unable to receive their results at the time of initial testing, requiring them to return at a later time. This approach increases the likelihood that clients will not receive their tests results because they fail to return for the follow-up visit.

The limited resources available for testing in the Region are not used strategically, limiting the reach and impact of testing initiatives. From 1995 to 2008, migrant workers accounted for nearly 60% of HIV tests performed in the Region, compared to 4% for key populations.



Photo: @National AIDS Control Program Saudi Arabia

Inadequate linkage to HIV care, treatment and support

Reliable data are not currently available on rates of linkage to HIV care, treatment and support, although attrition at this stage throughout the Region is believed to be quite high due in large part to the lack of strong referral systems. Once an HIV diagnosis has been made people living with HIV must be linked to HIV care services. To date, chronic life-long HIV care has often been neglected due to a focus on ART. Chronic HIV care should be standardized and include regular assessments for ART eligibility.

WHO recommends that individuals living with HIV have a CD4 cell count test at diagnosis, every 6–12 months prior to initiation of ART, and once ART has been initiated every 6 months, along with a viral load test every 12 months. The 2013 consolidated antiretroviral guidelines increase the importance of regular CD4 testing, calling for initiation of therapy at higher CD4 cell count thresholds.

With the exception of Afghanistan, all countries in the Region have some capacity to perform CD4 tests, although the availability of CD4 laboratory capacity varies considerably across the Region. In Pakistan, for example, the nongovernmental organization Nai Zindagi implemented portable CD4 to reach remote communities. Nevertheless, several countries in the Region (e.g. Somalia, Sudan and Yemen) still struggle to ensure the ready availability of CD4 tests, with technical challenges and shortages of reagents due to supply chain issues.

Obstacles to ART scale-up

Systems are currently in place in all countries across the Region to deliver ART, with 80% of people living with HIV who are known to the health system receiving ART (13). Given the extremely low ART coverage in the Region, these figures underscore that a primary

impediment to accelerated scale-up is the inadequacy of efforts to identify people living with HIV for linkage to HIV treatment.

Challenges faced by countries in the Region in expanding ART access vary. Where access to CD4 tests is limited, many people are not assessed for eligibility for ART. In some countries, the imminent end of Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) financing limits their capacity to recruit new ART patients. In some parts of the Region (e.g. Pakistan), health-care providers defer ART initiation for people who inject drugs until they undergo drug detoxification due to the perception that active drug use is incompatible with treatment adherence.

Ensuring a reliable, ongoing supply of antiretroviral medicines critical is accelerating and sustaining ART scale-up. Although information on the frequency of antiretroviral drug stock-outs is not available for all countries in the Region, there are indications that stock-outs commonly occur in some countries. In 2008-2009, 92% of antiretroviral-dispensing health facilities experienced stock-outs in Djibouti, 20% in the Islamic Republic of Iran, 12% in Somalia and 6% in Sudan, as well as in the only health facility administering ART in Lebanon (13).

Viral load monitoring plays an important role in monitoring treatment success and alerting clinicians to the need to change regimens that are no longer effective. However, several countries (including Somalia and Sudan) have no viral load monitoring capacity at all.

Challenges to retention, adherence and viral suppression

People living with HIV who initiate ART often fail to remain engaged in care. For 2011, eight countries in the Region reported ART retention rates exceeding the global average of 86% (Afghanistan, Djibouti, Egypt, Jordan, Kuwait, Lebanon, Morocco, Qatar), while several (e.g. Sudan, Yemen) reported extremely low rates



(14). Various factors may cause individuals to drop out of HIV care, including difficult life circumstances, household responsibilities, unmanaged side effects associated with antiretroviral medicines, unaffordable out-of-pocket costs, interruptions in supplies of antiretroviral medicines and the perception of those who feel well that they no longer need to take their medicines or seek regular medical monitoring.

As suboptimal treatment adherence is the primary reason for the emergence of HIV drug resistance, adherence support constitutes a fundamental element of effective HIV treatment and care. The ultimate goal of HIV treatment and care is to suppress the virus, which in turn enhances the individual's health and well-being and reduces the risk of onward HIV transmission. Resistance to prescribed regimens and poor treatment adherence are the principal causes of treatment failure, which allows viral replication to rebound, as measured by the patient's viral load (i.e. the amount of virus circulating in plasma).

Countries are advised to implement systems to monitor the emergence of HIV drug resistance (15). Several countries monitor the potential for emergence of HIV drug resistance through early warning indicators. Saudi Arabia has conducted a survey on acquired HIV drug resistance and the Islamic Republic of Iran has investigated transmitted HIV drug resistance (8).

With less than 5% of ART patients in the Region currently receiving second-line regimens, the primary challenge is to ensure ready access to recommended first-line regimens. Over time, however, demand for second- and third-line regimens will inevitably grow, highlighting the need to take steps now to ensure long-term access to a wider array of antiretroviral medicines. Indeed, in some parts of the Region, utilization of second-line regimens is also noteworthy; among ART patients in Morocco, for example, 14% of adults and one-third of children are now on second-line regimens.

Social and systemic impediments

Certain cross-cutting challenges affect outcomes at multiple stages of the HIV treatment and care continuum.

Stigma, discrimination and the lack of an enabling environment

Stigma and discrimination impede testing and treatment scale-up. Reports indicate that stigmatizing attitudes towards people living with HIV are common in the Region. In Pakistan, for example, 26% of people living with HIV reported having been excluded from family activities as a result of their HIV status (16).

As part of the broader society, health care workers often harbour common negative social attitudes towards people living with HIV or marginalized key populations. As a result, people who recognize they may have been exposed to HIV often avoid mainstream health services due to fears that they will be denied health care and HIV treatment, reported to authorities or otherwise harassed (13).

To date, most countries in the Region have yet to implement a sound, human rights-based legal and policy framework related to HIV. Among countries in the Region that provided relevant data to UNAIDS in 2012, most lacked laws or policies prohibiting HIV-related discrimination.³ Similarly, most reporting countries have punitive laws in place against one or more key populations or policies that present obstacles to key populations accessing HIV services.

While a clear global trend towards repeal of HIV-related restrictions on entry, stay and residence is apparent, with the number of countries and territories with HIV-related travel restrictions in place declining from 96 in 2000 to 44 in 2013, many countries in the Region retain policies that are counterproductive to public health efforts.⁴ Migrants who test HIV-

positive under such regulations lose critical employment opportunities and are typically returned to their home countries without appropriate counselling, treatment and care.

Inadequate focus on key populations

Despite clear evidence that transmission among key populations at higher risk of HIV exposure represents an important driving force in many epidemics in the Region, testing and treatment programmes have largely failed to focus on these groups in greatest need. According to country reports to UNAIDS in 2012, countries in the Region are generally failing to reach men who have sex with men with HIV testing services, with most countries reporting no data on testing coverage for this population (1). Across the Region, no country in 2012 reported reaching a majority of people who inject drugs with HIV testing services, with HIV testing coverage data lacking for most countries (1).

Experience in the Region underscores the feasibility of reaching key populations through focused, culturally appropriate and community-centred programmes. For example, Morocco has achieved large-scale HIV service coverage for sex workers, while the Islamic Republic of Iran is in the vanguard of efforts to address the HIV-related needs of people who inject drugs (13). Although they are at high risk, men who have sex with men are least likely to receive focused support for their HIV-related needs in the Region (13).



³ See country progress reports. Available at: http://www.unaids.org/en/dataanalysis/datatools/aidsinfo/.

⁴ Information provided by UNAIDS, 2013.

Health system challenges

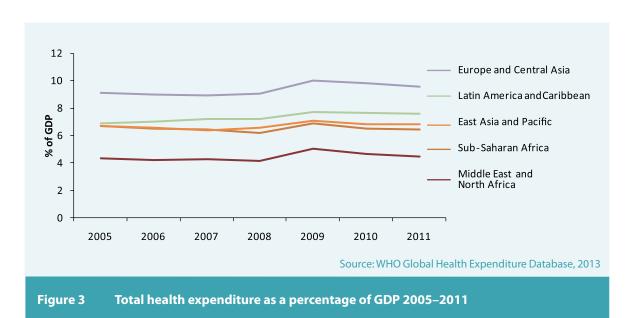
In comparison to other regions, the Region places the lowest priority on health spending (Figure 3). In 2011, the Region allocated 4.4% of public sector resources towards health services, substantially lower than low- and middle-income countries in other parts of the world. Such low levels of investment in health result in extensive infrastructure deficiencies, including inadequate financial and commodity management systems, weak laboratory infrastructure, insufficient information management systems and weak or non-existent mechanisms to involve civil society in health service planning or service delivery.

Health financing mechanisms and social health insurances are yet to be developed in most countries of the Region. As a consequence, out-of-pocket payment and out-of-pocket health spending becomes the main source of financing, limiting the access to healthcare for households.

These systemic weaknesses undermine efforts to bring ART to those who need it.

Supply chain management deficiencies increase the risk of drug stock-outs, underfunding of health systems diminishes capacity to enrol additional patients in ART programmes and weak laboratory infrastructure contributes to inadequate access to essential diagnostic tools, such as CD4 and viral load testing. Likewise, the failure to engage civil society groups as partners in the response inhibits the ability of treatment programmes to reach marginalized populations.

In addition, a shortage of qualified health workers in several countries of the Region functions as a major obstacle to ART scale-up. In five countries (Afghanistan, Djibouti, Islamic Republic of Iran, Sudan and Yemen), four or fewer physicians are available for every 10 000 people. Fifteen countries in the Region have fewer than 20 physicians per 10 000 population, considered by experts to be the minimally-adequate workforce level to permit delivery of basic health services. The health workforce crisis is especially acute in Somalia, where the availability of physicians per 10 000 population is 0.3.



Commitments to strengthen the HIV response

Efforts to end the HIV treatment crisis in the Region have a strong foundation on which to build. National leaders in the Region have made clear, concrete commitments to strengthen the HIV response. Although these commitments demonstrate awareness of the HIV challenge and the determination to take action, the failure of countries to bring ART to scale highlights to need to translate pledges into action.

UN political declaration on HIV and AIDS, 2011

As members of the United Nations (UN) General Assembly, countries in the Region have endorsed the 2011 political declaration on HIV and AIDS (17). Designed to contribute achievement of the 2015 Millennium Development Goal of halting and beginning to reverse the HIV epidemic, the 2011 political declaration pledged UN Member States to take action to achieve specific targets and commitments by 2015 leading to zero new infection, zero AIDS-related death and zero discrimination.

Regional strategy for health sector response 2011–2015

Also, in 2010, the WHO Regional Committee for the Eastern Mediterranean Region endorsed the Regional strategy for health sector response to HIV 2011–2015 (13). Closing gaps in HIV prevention and the HIV treatment and care continuum is the primary aim of this strategy. Ministers of health agreed on a series of actions to achieve a set of prevention and treatment targets by 2015, including that 1) at least 50% of the estimated number of adults and children with advanced

HIV infection will be receiving ART ⁵; and 2) at least 90% of people with diagnosed HIV will be enrolled in HIV treatment and care.

African Union commitments

As Member States of the African Union (AU), African countries in the Region have endorsed a series of commitments made by the AU. In the 2001 Abuja Declaration on HIV/AIDS, Tuberculosis and Other Related Infectious Diseases (18), AU Member States pledged to allocate at least 15% of national public sector expenditure to health. More recently, in the Roadmap on shared responsibility and global solidarity for AIDS, TB and malaria response in Africa (19), AU Member States pledged to: increase domestic resources for HIV, tuberculosis and malaria; diversify funding for responses to these priority diseases; and fully implement the Pharmaceutical Manufacturing Plan for Africa, which envisages strengthened local pharmaceutical manufacturing capacity on the continent and a harmonized approach to medicines regulation.

League of Arab States

The Council of the Arab Ministers of Health, in its 37th session in Amman, endorsed an Arab AIDS Initiative to scaling-up the HIV response at regional and national levels. The corresponding Arab AIDS Strategy 2013–2015 aims to support countries to achieve the goals and targets set forth in the 2011 Political Declaration and to implement actions in accordance with their national situation and resources.

⁵The goal in the regional strategy was developed when WHO's ART guidelines called for initiation of ART in most adults with a CD4 cell count of 350 or less. With the revised 2013 WHO ART guidelines, this goal may need to be revised to reflect moves towards earlier initiation of therapy.

Treatment 2015

UNAIDS and WHO, together with the United States President's Emergency Plan for AIDS Relief (PEPFAR), the Global Fund, and lowand middle-income countries have embraced Treatment 2015, a partnership initiative launched in 2013 to use the 2015 global target of reaching 15 million people with ART as a stepping stone towards universal treatment access (see box 2). The initiative calls for countries to take specific steps to ensure preparedness to rapidly accelerate treatment scale-up. In particular, the initiative recommends specific efforts to: generate robust and sustainable demand for treatment services; make strategic investments to increase uptake of HIV testing and treatment; and use best practices, new technologies and rigorous programme management to deliver HIV treatment to those who need it.

Towards the elimination of mother-to-child transmission of HIV: conceptual framework for the Middle East and North Africa

The Region has embraced the global vision for elimination of new HIV infections among children and keeping their mothers alive (20). It has adopted the overall global goals of reducing the number of new HIV infections among children by 90% by 2015, and reducing the number of AIDS-related maternal deaths by 50%, also by 2015. The framework for action provides the Region with a common systematic approach to the elimination of mother-to-child transmission of HIV.

Treatment 2015: Speed, focus, innovation

Treatment 2015 aims to catalyse swifter progress towards universal treatment access. New ways of thinking and operating will be needed. Specifically Treatment 2015 emphasizes three critical elements of success:

Speed

Rapid scale-up enables responses to outpace the epidemic itself, which in turn ensures that epidemics decline over time rather than expand. In numerous countries where the foundation for an end to the HIV epidemic has been laid, rapid treatment scale-up has led to sharp reductions in AIDS-related deaths and new HIV infections.

Focus

As those currently receiving treatment may be the easiest the reach, further progress towards universal access will demand intensified action to bring HIV testing and treatment services to those who currently lack it. Treatment 2015 calls for all countries to immediately use available data to identify key geographical areas, settings and populations with high HIV prevalence and disproportionate unmet need for HIV treatment. Globally, Treatment 2015 urges particularly intensive focus on 30 countries where 9 out of 10 people with an unmet need for HIV treatment live.

Innovation

New approaches are needed to more swiftly translate scientific advances into concrete action in countries. Innovation should be unleashed to re-conceptualize HIV testing, link individuals to comprehensive treatment and care at an early stage of infection and strengthen community systems.

Accelerating HIV treatment access in the Region: How do we get there?

Treatment coverage is vastly lower in the Region than in any other part of the world. Governments and development partners from the Region should urgently build national and sub-national treatment acceleration plans, translating the 2013 WHO guidance on the use of antiretroviral medicines and the Treatment 2015 initiative into country specific commitments and key actions.

Commit to urgent action

In the Region, successful scale-up of ART will be achieved only through the leadership, determination and cooperation of senior national leaders, health ministries, parliamentarians, health professional groups, the private sector, religious leaders and civil society, especially people living with HIV. Through their many commitments, leaders in the Region have provided a firm foundation on which to build towards universal treatment coverage.

In moving to meet the AIDS commitments that countries have made, all stakeholders in the Region should recognize the emergency posed by the HIV treatment crisis. In addition to rising HIV-related deaths, the failure to bring ART to scale means that the Region is failing to reap the enormous prevention benefits of early therapy.

In prioritizing efforts to close the treatment gap, leaders in the Region should allow evidence to guide the response. Timely access to ART is fundamental to the ability of people living with HIV to achieve the highest attainable standard of health, an internationally recognized human right. Among biomedical HIV prevention tools that have been rigorously evaluated, antiretroviral therapy is highly effective, highlighting the urgent need for the Region to use this powerfully effective tool to curb the epidemic's spread. Efforts to end the HIV treatment crisis should heed the rapidly evolving evidence base on antiretroviral therapy, such as emerging evidence on optimal regimens (20) and programmatic strategies to ensure linkage and retention in care (21).

In view of many competing priorities and limited resources, leaders in all countries should focus on interventions that offer the best value and the greatest impact. With respect to closing the HIV treatment gap, such interventions include HIV testing using a mix of service delivery approaches, efficient linkage of people living with HIV to treatment and care, comprehensive services to deliver high-quality ART in a timely manner, approaches to ensure robust treatment adherence and retention in care, and reliable patient monitoring and follow-up.



For each year through 2015, countries should set ambitious targets for national HIV responses, establishing specific targets for treatment scale-up, tracking progress in expanding treatment uptake, and publishing progress reports. Intermediate and outcome targets should also be put in place. And as the 2015 deadline approaches, new annual targets should be put in place to guide continued scale-up towards the goal of achieving universal treatment coverage by 2020. In implementing strong systems for accountability in the responses, countries should take steps to engage a broad range of strategic stakeholders, including people living with HIV, private sector, clinicians, professional medical and nursing associations, religious leaders, community-based organizations and social service providers.

Rigorous monitoring and reporting systems should be put in place to provide ongoing feedback on regional efforts to close the treatment gap. Results should be monitored at each step of the HIV treatment continuum, from diagnosis of HIV infection through long-term adherence and treatment success. Countries should also commit to annual (and ideally semi-annual) reporting of results, and regional mechanisms should be in place to assess progress, share best practices and agree on changes needed to ensure achievement of the 2020 target. To aid in monitoring, countries should implement the core elements of an HIV surveillance system and estimate the size and service utilization patterns of key populations.

Key recommended action 1

Set ambitious annual targets for HIV testing and treatment at national and local levels, monitor progress closely and take urgent remedial action if targets are not met.

Create demand

As delayed diagnosis of HIV represents the most significant obstacle to treatment scale-up in the Region, countries will need to focus on creating demand for HIV testing. Demand for testing will increase significantly if stigma and discrimination are addressed and if taking an HIV test is a simple, fast, high quality procedure provided in a convenient and supportive environment. To improve uptake of HIV care treatment and care, individuals who have been newly diagnosed with HIV must be effectively linked without delay to easily accessible, high-quality life-long chronic HIV care services.

Address stigma and discrimination

Concerted, continuing, high-level efforts are needed to de-mystify and de-stigmatize HIV in the minds of health-care providers, public health authorities and the public. Community-centred campaigns that educate community members about the benefits and availability of testing and early HIV treatment warrant intensive investment.

Stigma and discrimination in health-care settings nip any demand for HIV testing in the bud and deter people from utilizing existing services. Recognizing that equitable access to essential health services is a human right. To support and accelerate efforts to increase demand for HIV testing and treatment, laws and policies should be in place to prohibit HIV-related discrimination and ensure the availability of health care, legal services and other support to enable people living with HIV to enforce their rights.

Key recommended action 2

Implement bold action plans to overcome stigmatization and discrimination in health services.



Simplify HIV testing

Adopting new and easy-to-use HIV testing technologies, i.e. scaling up rapid testing technologies that permit same-day test results, will be a game-changer in terms of making access to HIV testing easier. The capacity of nongovernmental and private service providers, in addition to the public sector, to administer rapid HIV tests should be developed and quality control systems be put in place. In other regions, countries with similar epidemic contexts have succeeded in identifying people living with HIV largely by using HIV rapid testing technologies in community settings.

Key recommended action 3

Adopt and implement rapid testing technologies that permit same-day test results.

Offer HIV testing in community settings

Mixing a range of approaches and service-delivery models to bring HIV testing close to people in need will increase uptake of HIV testing (22). Given the realities of the HIV epidemic in the Region, where HIV is concentrated among marginalized key populations whose behaviours are frequently criminalized, carefully tailored approaches are required to reach these populations. Experience within the Region and elsewhere shows that offering HIV tests in community settings through community-

based organizations, and private and public providers, facilitates uptake among key populations at higher risk of HIV exposure.

Key recommended action 4

Provide HIV testing services in community settings in order to reach key populations at higher risk of HIV exposure.

Normalize HIV testing in health-care settings

In terms of HIV testing, in place of passive approaches that require individuals to seek an HIV test through their own volition, more proactive strategies are needed, while taking care at all times to ensure that testing services are voluntary and grounded in human rights principles. HIV testing should be normalized in health-care settings and routinely offered as a component of regular health care. Offering testing routinely and free of charge to clients of health services, in particular to pregnant women, tuberculosis patients and sexually transmitted infection (STI) patients, will contribute to earlier HIV diagnosis in people living with HIV who otherwise would not have accessed testing services.

Key recommended action 5

Normalize HIV testing in health-care settings by routinely offering it as a component of regular health care in appropriate services in antenatal, tuberculosis, STI and other relevant services.

HIV testing for prevention of mother-tochild transmission of HIV in Oman

Oman has antenatal care clinic coverage of >99%. Since 2009, pregnant women have been routinely offered an HIV test at their first visit to an antenatal care clinic. The HIV test is part of the standard package of care for all pregnant women. This approach allows women the freedom to "opt out" from taking the test, although uptake of HIV testing has been very high (>90%). From 2009 to September 2012, 90 HIV-infected pregnant women have been identified and received ART interventions for PMTCT. To date, all their babies are free of HIV infection.

Promote uptake of services along the HIV care continuum

Individuals who have been newly diagnosed with HIV must be effectively linked without delay to life-long chronic HIV care services. Ministries of health in collaboration with medical associations, and in consultation with people living with HIV, should develop standardized HIV chronic care packages and equip service providers to implement these packages. High quality counselling and psychosocial support, no or only short waiting times, co-trimoxazole prophylaxis, point-of-care CD4 testing and various methods to encourage regular visits (such as transport allowances) enhance uptake of pre-ART HIV care.

Psychosocial support upon new HIV diagnosis can have a major impact on uptake of, and retention in, lifelong care. Peer support mechanisms help newly-diagnosed individuals cope with their health status, explore disclosure and other important issues, minimize self-stigma, address life circumstances that may interfere with effective HIV care and prepare for initiation of ART. The ability of counsellors and other concerned health workers to support disclosure of HIV status, conduct couples counselling and facilitate partners' HIV testing, requires the attention of HIV programmes in the Region.

In addition, the costs associated with ART should be minimized, arrangements for transportation should be made for patients who may experience difficulty in making clinic appointments and peer-based interventions should be incorporated in clinical settings to support retention in care and patient adherence.

Key recommended action 6

Adopt, client-friendly, standardized, free-ofcharge HIV treatment and care services to facilitate prompt linkage to care upon HIV diagnosis, earlier initiation of ART, treatment adherence and retention in care.



Mobilize sustained investments

Ensure adequate financing of HIV treatment scale-up in the Region

The Region consists partly of low- and lower-middle-income countries, which carry the biggest share of the HIV burden, as well as a number of middle-income and non-Organisation for Economic Co-operation and Development (OECD) high-income countries. Sufficient resources within the Region exist to finance rapid ART scale-up, although, to date, many countries have yet to marshal the political commitment or pursue the strategic approaches required to bring life-saving ART to those who need it.

The task of financing a sound, robust response, including ART scale-up, is entirely manageable. Were the Region to bring its per capita health spending 4.4% of gross domestic product GDP up to the global average of 10%, substantial new resources would be generated to enhance the health and wellbeing of the Region's people. Scale-up of ART would require a relatively modest proportion of these additional health expenditures.

Spending on ART scale-up represents a sound national investment. Each dollar invested in effective testing and treatment programmes can deliver economic returns of up to three times over the next decade in averted treatment costs and strengthened labour productivity (23,24,25). In middle-income countries with concentrated epidemics, such as Tunisia, for example, the discounted cost incurred by an additional infection is estimated to be three times the GDP per capita, amounting to an economic saving of US\$ 16 000 for each infection averted as a result of accelerated ART scale-up.

Middle-income countries with concentrated epidemics from the Region can achieve universal access with an investment of a mere 0.02% of GDP, or 0.07% of government spending (24) – a spending increase that

is less than the Region's historical rate of economic growth. Unlike many other regions, where rapidly expanding epidemics quickly overtook national capacity to respond, the Region possesses the financial means to make the up-front investments that could arrest the epidemic's growth.

Regional solidarity and the robust engagement of international donors will be needed to achieve this aim, as the countries with the largest HIV burden also have the least resources to finance ART programmes.

Key recommended action 7

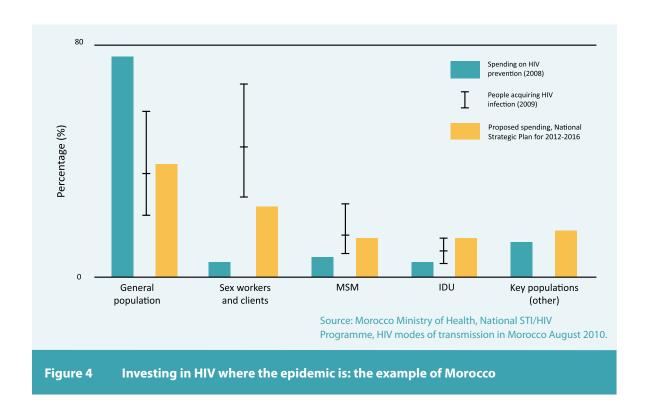
Increase the share of domestic investment for HIV through sustainable and predictable financing mechanisms at country level.

Reduce the cost of antiretroviral medicines

Accelerating ART scale-up and sustaining these gains over time will demand that countries make the most efficient use of available resources. In this regard, substantial potential exists to reduce costs associated with ART, as the Region currently pays the highest median price for antiretroviral medicines among low- and middle-income countries globally-an average 18% higher than the global median price. Similarly, the price paid by middle-income countries in the Region is more than 30% higher than the price paid by middle-income countries worldwide. Aligning median prices would save more than US\$ 2.1 million annually, greatly assisting regional efforts to bring ART to more people who need it.

Key recommended action 8

Reduce costs associated with antiretroviral medicines, including expanded use of generic medicines, exploration of bulk purchasing and investments to build regional pharmaceutical manufacturing capacity.



Enhance efficiency

Efficiency is further enhanced when limited programme resources are focused on the key populations in which national epidemics are concentrated. With the aim of increasing the impact of investments, Morocco used its findings from behavioural and epidemiological studies to revise its national strategic plan and increase the proportion of resources focused on the populations and geographical settings where new infections are occurring (Figure 4).

Key recommended action 9

Track and develop opportunities to increase the efficiency and effectiveness of testing, treatment and care activities, starting with an increased focus of resources on key populations specific for each country and locality.

Involve communities and build their capacity

Achieving testing and treatment scale-up and improving long-term treatment outcomes will only be possible in the Region if community-based organizations are strongly involved

in creating demand, providing testing and psychosocial support, and supporting treatment scale-up. In many countries in the Region, HIV services are already being provided in community settings. These examples need to be replicated. This will require the political will to engage with community-based organizations in the shortand long-term, and strong efforts to build their capacity.

Key recommended action 10

Build community capacity to help design and support testing and treatment scale-up and to improve long-term treatment outcomes.

Build health system capacity to ensure sustainable long-term chronic HIV care

As HIV is becoming a manageable chronic condition, the development of sufficient capacity to deliver chronic HIV care is essential. People living with HIV require care that anticipates their needs at different stages of the HIV care continuum. Compared with the acute care model, planned chronic care models involve the implementation of a robust patient information system



and provide opportunities for prevention, early identification of issues and timely interventions.

Where needed, clinical services should be reorganized with attention paid to adopting protocols for appointments, medication pickup, linkages to and integration with other health services, and other care components that contribute to improved health outcomes. Peer-based interventions should be incorporated in clinical settings to support retention in care and patient adherence. Where successful service delivery models and processes of care are identified in existing systems, HIV programmes can benefit from linking to or integration into these.

Key recommended action 11

Develop health system capacity to deliver chronic care inclusive of HIV.

Deliver results in an equitable manner

Ending the HIV treatment crisis in the Region will demand a strategic, laser-like focus on the right interventions delivered to the right populations in the right manner and at the proper scale.

While effective interventions are known and well-characterized, countries in the Region still struggle with finding the most appropriate ways to deliver them to those in

need. It will be key to success that national programmes reconceptualize and reframe approaches in order to maximize the number of individuals who are diagnosed and treated in a timely manner.

Simplify ART regimens

To accelerate treatment scale-up, countries are recommended to adopt simplified and standardized ART regimens in order to boost rates of treatment adherence and minimize administrative complexity. In its 2013 consolidated antiretroviral guidelines, WHO formally endorsed this approach, recommending that countries adopt a single one-pill, once-daily regimen.

Key recommended action 12

Simplify treatment protocols and move towards fixed dose combinations with "one pill per day" regimens.

Expand eligibility criteria for ART

People enrolled in HIV care must be assessed for ART eligibility immediately and if eligible, ART should be initiated without delay. Early initiation of ART enhances the public health impact of HIV treatment programmes. Action is now needed to bring national treatment guidelines into line with the global recommendations as outlined in WHO's 2013 consolidated guidelines for the use of antiretroviral medicines, including

the earlier initiation of ART (26). According to the new guidelines, initiation of ART is recommended at CD4 \geq 500 and independent of immunological eligibility to people living with HIV in discordant couples, HIV-infected pregnant women, children aged five years and below, and tuberculosis and hepatitis patients.

Key recommended action 13

Offer ART, irrespective of immunological status, to the following groups of people living with HIV: those in discordant couples, pregnant and breastfeeding women, children aged five years and below, those with active tuberculosis and those with hepatitis B with severe chronic liver disease.

Ensure uninterrupted services supported by quality laboratory monitoring

To achieve lasting viral suppression under lifelong ART countries must ensure reliable, uninterrupted treatment supported by quality laboratory monitoring. This involves preventing shortages and stock-outs of laboratory tests and antiretroviral medicines. Stock-outs deter patients from care, cause loss to follow up and treatment interruptions. No treatment programme is credible if health workers and patients are faced with stock-outs.

Sustaining reliable laboratory services, in particular CD4 monitoring, has been challenging for several countries in the Region. This has led to delays in ART initiation and in switching to second-line regimens due to immunological signs of treatment failure. The new WHO guidelines call for monitoring the response to treatment, and diagnosing and confirming treatment failure with viral load testing (26). Sustained CD4 monitoring and viral load testing will require strengthening of the existing laboratory services, while ensuring an appropriate mix of centralized high-volume testing and testing at point of care. The use of dried blood spots as a tool to increase access to viral load testing should be considered.

Decentralized CD4 testing in Pakistan

In Pakistan, the national/provincial HIV/AIDS programmes collaborate with the nongovernmental organization Nai Zindagi to improve access to HIV treatment and care by offering CD4 testing to their clients, who include large numbers of people who inject drugs. The use of WHO prequalified portable CD4 equipment makes it possible for the organization to carry out reliable CD4 testing on site for HIV-positive people who inject drugs, and their spouses and children, thus resulting in a much larger number of people who can access ART.

Key recommended action 14

Avoid service interruptions as a result of stockouts of medicines and laboratory supplies.

Key recommended action 15

Strengthen and expand laboratory services for monitoring of the response to treatment, including CD4 and viral load monitoring.

Decentralize and integrate HIV service delivery

To enhance uptake and increase retention in care, decentralized approaches are needed with respect to testing and treatment, helping bring services closer to the community. Given the deterrents that the key populations at higher risk of HIV exposure face to the use of mainstream health services due to the prevalence of stigma and discrimination, novel community-based channels will often need to be created for outreach and service delivery. Community groups have an especially critical role to play in generating demand for HIV testing, as well as treatment services, among key populations.

The 2013 WHO guidelines for ART recommend that the following options for decentralization of ART initiation and maintenance should be considered: 1) initiation of ART in hospitals

with maintenance of ART in peripheral health facilities; 2) initiation of ART in peripheral health facilities and maintenance in peripheral heath facilities and/or at community level, i.e. in settings such as community-based organizations, outreach sites and health posts (27).

Access to HIV treatment can be enhanced through integration with other services. This is particularly important for countries in the Region with HIV epidemics among people who inject drugs. These countries should consider initiating and maintaining ART in care facilities that provide opiate substitution therapy. In order to make HIV treatment easier accessible for people living with HIV who regularly attend other specialized health services, such as pregnant women, children or those receiving treatment for tuberculosis, countries should consider integrating ART into tuberculosis clinics and selected maternal, neonatal and child health services. To enable decentralization and integration, the guidelines include recommendations

on task shifting, namely that trained nonphysician clinicians, midwives and nurses can initiate first-line ART and maintain ART, and that trained and supervised community health workers can dispense ART between regular clinical visits. These recommendations are relevant in the Region in particular to ensure access to populations that are otherwise difficult to reach.

Key recommended action 16

Decentralize routine patient care and HIV treatment maintenance to selected primary care and community-based settings based on need assessment, with consideration to the involvement of both public and private providers.

Key recommended action 17

Integrate HIV treatment and care in other health services such as mother, neonatal and child health services, tuberculosis clinics and drug use harm reduction services.

Moving forward

Filling the critical treatment gap in the Region is within our reach. Implementing the above recommended actions will require a strong partnership between the stakeholders. WHO and UNAIDS are committed to ensuring that this happens seamlessly.

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