



ABRIDGED REPORT

THE GLOBAL HEALTH SECTOR STRATEGY ON HIV/AIDS 2011–2015: AN INTERIM REVIEW OF PROGRESS

MAY 2014

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INTRODUCTION

Three years ago, in May 2011, the 64th session of the World Health Assembly endorsed the *Global Health Sector Strategy on HIV/AIDS 2011–2015* (GHSS). The strategy was developed to guide the expansion of the global human immunodeficiency virus (HIV) response beyond the HIV-specific programmes of the past, by strategically positioning HIV within a rapidly changing health and development agenda.

While building on core HIV programmes, the strategy is designed to maximize linkages and synergies with other key public health areas. These include improving broader health outcomes, strengthening health and community systems for sustainable action, influencing other sectors to adopt pro-health policies and approaches that foster enabling environments, and addressing the underlying social and structural determinants of HIV epidemics.

At the implementation mid-point for the strategy, we can now review progress. Are countries advancing in the right direction? Are the World Health Organization (WHO) and its partners fully exploiting opportunities to accelerate and intensify the response? Is the strategy still fit-for-purpose, given the changing dynamics of HIV epidemics and the global context?

This brief, interim report provides an overview of progress in implementing the strategy over the past three years. It aims to inform global dialogue on the future directions of the HIV response, notably discussions that will take place during the 67th Session of the World Health Assembly in May 2014, during which progress with implementing the strategy will be reviewed.

The report draws largely on data reported by Member States for the end of 2012. A comprehensive update, based on newly submitted end-of-2013 data, will be released in July 2014.

The goals of the strategy are zero new HIV infections, zero AIDS-related deaths and zero discrimination in a world where people living with HIV are able to live long, healthy lives. Reaching those goals requires drastic expansion of the coverage and improvement in the quality of HIV prevention, diagnosis, treatment and care interventions. The strategy was explicitly designed to help achieve those outcomes, and highlights four targets for 2015:

- Reduce new infections—reduce new HIV infections in young people aged 15–24 years by 50% (compared with a 2009 baseline);
- Eliminate new HIV infections in children—reduce new HIV infections in children by 90% (compared with a 2009 baseline);
- Reduce HIV-related mortality—reduce HIV-related deaths by 25% (compared with a 2009 baseline); and
- Reduce tuberculosis-related mortality—reduce tuberculosis (TB) deaths in people living with HIV by 50% (compared with a 2004 baseline).

This report reviews progress made along each of the strategy's four 'strategic directions', and discusses the opportunities that exist for overcoming the remaining challenges to achieve universal access to effective HIV interventions as part of broader universal health coverage.

Strategic direction 1: Optimize HIV prevention, diagnosis, treatment and care outcomes

Appraises the core package of HIV-specific interventions and approaches, how to improve their quality, effectiveness and coverage, how to combine and integrate them into comprehensive programmes for different populations and settings, how to identify and rapidly apply innovations in HIV interventions as new evidence emerges.

Strategic direction 2: Leverage broader health outcomes through HIV responses

Considers how HIV programmes can be linked with other health programmes to maximize both HIV and other health outcomes. The greatest synergies can be achieved by linking HIV with sexual and reproductive health, maternal, newborn and child health, tuberculosis, drug dependence and harm reduction, and blood and injection safety programmes. As more people living with HIV live longer with antiretroviral therapy (ART) and consequently experience health complications related to ageing and HIV therapy, linking HIV and chronic care programmes, notably primary health care and noncommunicable disease (NCD) services, will be critical.

Strategic direction 3: Build strong and sustainable systems

Examines the inter-relationship between HIV-specific programmes, and generic health and community systems. Effective, efficient and comprehensive health and community systems are critical for ensuring accessible, affordable and sustainable HIV services. At the same time, HIV innovations and investments are helping to transform health systems and empower communities in ways that benefit other public health and social areas.

Strategic direction 4: Reduce vulnerability and remove structural barriers to accessing services

Considers the critical roles of other sectors and structural factors in determining individual and population-level HIV vulnerability and risk, the dynamics of HIV epidemics and the feasibility and effectiveness of responses. An effective HIV response depends on enabling environments and should promote health equity, gender equality and human rights, with particular focus on addressing the needs of key populations.

As this report shows, substantial progress has been made in the past few years, particularly in areas where clear service delivery targets have been set—such as HIV treatment, preventing mother-to-child transmission (PMTCT) of HIV, and preventing and treating TB and HIV. But the report also highlights the current unevenness of the HIV response—across different countries, communities, populations and interventions.

A SNAPSHOT OF RECENT PROGRESS

The world has made remarkable inroads against the global HIV epidemic in the past three years. New HIV infections and HIV-related deaths are decreasing at quicker rates than ever before. Treatment programmes have expanded rapidly, with unprecedented growth in the numbers of people receiving life-saving antiretroviral (ARV) drugs and other care. New policies and guidance on HIV prevention, diagnosis and treatment, based on the latest evidence, have been issued to improve the quality of services, enhance the efficiency of programmes, and optimize HIV and broader health outcomes.

Major opportunities have also emerged to further strengthen the response to HIV, including additional evidence of the prevention benefits of ARVs, improved treatment and care approaches, and intensified international efforts to eliminate mother-to-child transmission (EMTCT) of HIV.





The momentum for these gains comes from sustained global and national political commitment, substantial investments of funding and other resources, effective

community mobilization, innovations in science, technology and implementation, and approaches that capitalize on the strengths of different sectors.

Nevertheless, as the 2015 deadline approaches, significant challenges remain. Too many people living with HIV are unaware of their HIV status, and many who present for testing and treatment do so too late to benefit fully from treatment. ART coverage lags in some regions, and important disparities persist, notably for men, pregnant women, adolescents and key populations. In addition, life-long treatment poses novel challenges for individual patients and the communities and health systems they rely on.

And there is the sobering reality that globally more than two million people are newly infected with HIV every year—a number considerably higher than the annual increase in people receiving ART. Significant proportions of new HIV infections are occurring between partners in HIV serodiscordant couples, and key populations continue to experience high HIV prevalence rates in both concentrated and generalized epidemic settings.

Gauging recent progress in the global HIV response

Reduce new HIV infections		Some emerging epidemics, but new infections are declining in more than 56 countries
Reduce new HIV infections in children		Efforts are gathering momentum; reaching the target depends on progress in key countries
Reduce HIV-related mortality		Strong progress due to ART scale-up; on current trends, will exceed target
Reduce TB-related mortality in people with HIV		Fair progress, but mainly in a few countries with large TB burdens

Note: In this document a 'traffic light' graphic is used to summarize progress made under each of the main areas of the HIV response. The grading used is subjective in nature, but aims to visually highlight areas of concern and achievement. The graphics also aim to reflect the varied responses across countries and settings. For each major area, a traffic light grading is provided with a brief rationale for the grading.

Green: On track to meet agreed targets; good programme coverage; evidence of successful implementation of interventions; examples of good practice exist.

Yellow: Progress is lagging; targets could still be achieved with intensified and accelerated action; coverage and quality of programmes need to improve.

Red: Targets are unlikely to be met; substantial overhaul of response may be required

Cross-hatched 'traffic lights' indicate that there are significant variations in the response, including in quality and equitable coverage, and across countries/regions.

Reduce new HIV infections

** TARGET: Reduce new infections—specifically reduce by 50% the percentage of young people aged 15–24 years who are infected (compared with a 2009 baseline)*

Worldwide efforts continue to reduce the number of new annual HIV infections. Globally in 2012, an estimated 2.3 million [1.9 million–2.7 million] people newly acquired HIV – 12% fewer than the estimated 2.6 million [2 million–2.8 million] new infections in 2009. Similarly, the number of new HIV infections among young people aged 15–24 decreased by around 10% from 865 000 to 780 000

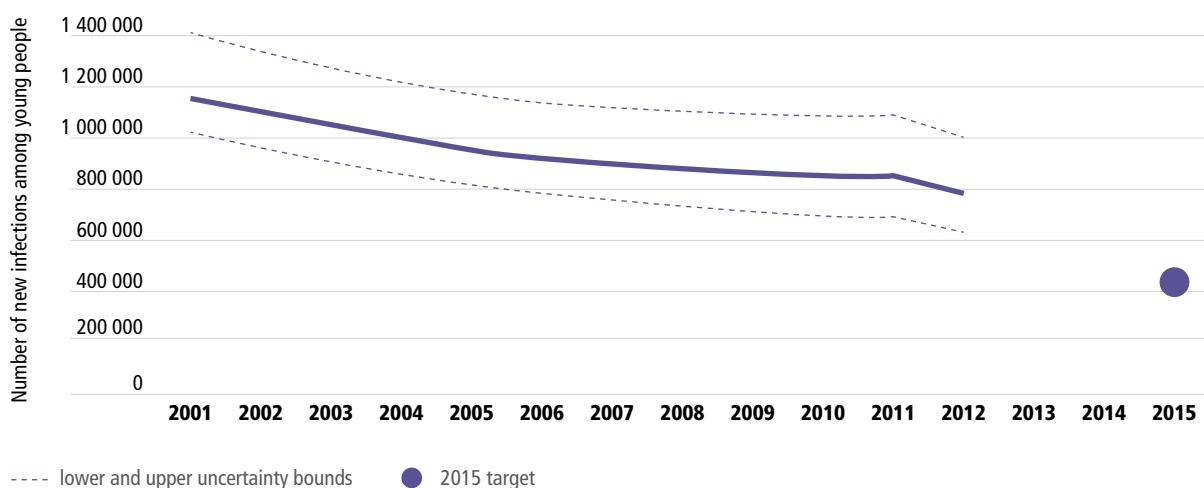
between 2009 and 2012 (see Figure 1), putting the targeted 50% decrease by 2015 out of reach unless prevention efforts are intensified considerably.

The current steady, albeit slow, decrease in new HIV infections has been due largely to reductions in the African Region. Encouragingly, the overall pace at which new infections are decreasing may now be quickening (see Figure 1), as countries continue to scale-up prevention services and focus them more sharply where most HIV transmission is occurring.

The declining trends are not evident, however, in the WHO South-East Asia, European and Eastern Mediterranean Regions, where the key populations

that are most affected by HIV are not being reached in sufficient numbers with HIV prevention, ART and other vital HIV services.

Fig. 1. Estimated number of new infections among young people (15–24 years) globally, 2001–2012



Source: 2013 UNAIDS/WHO estimates.

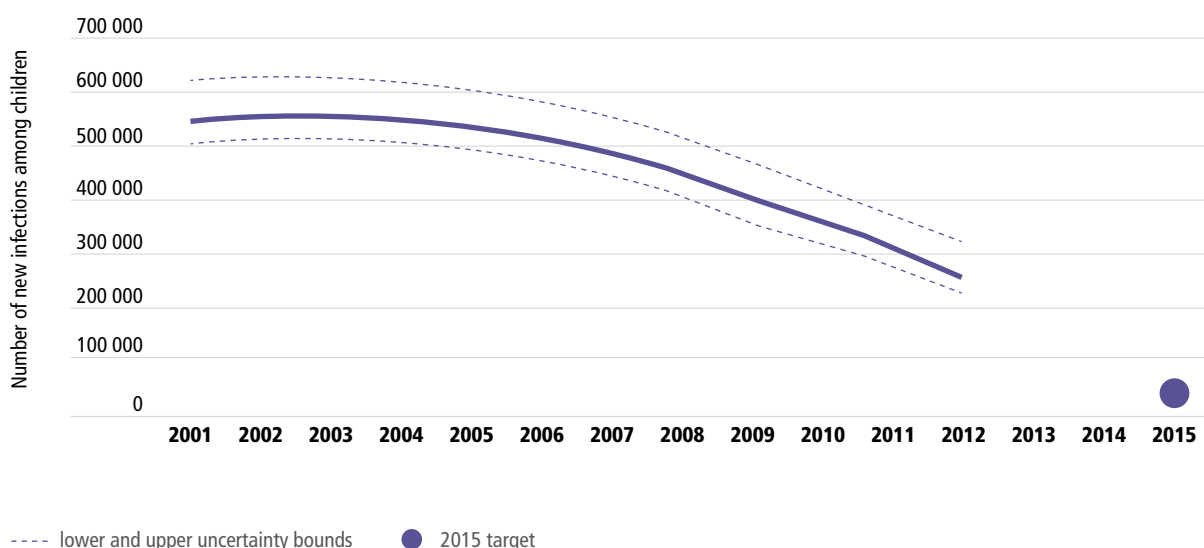
Eliminate new HIV infections in children

** TARGET: Eliminate new HIV infections in children—specifically reduce new HIV infections in children by 90% (compared with a 2009 baseline)*

New HIV infections among children are decreasing at a quicker rate than ever (see Figure 2). The estimated 260 000

new infections [230 000–320 000] globally among children (younger than 15 years) in 2012 were 35% fewer than the 400 000 new infections in 2009 (1). Between 2009 and 2012 more progress was made toward the goal of EMTCT of HIV than during the entire previous decade. Nevertheless, some high-burden countries are lagging behind and need to

Fig. 2. Estimated number of children (under 15 years) acquiring HIV infection due to mother-to-child transmission globally, 2001–2012



Source: 2013 UNAIDS/WHO estimates.

accelerate their efforts drastically if the 2015 global target of reducing new infections in children by 90% is to be reached.

The expansion and improvement of programmes for PMTCT of HIV and the use of more effective ARV regimens helped prevent more than 880 000 children globally from becoming

infected with HIV between 2005 and the end of 2012, including 680 000 new infections in children that were averted between 2009 and 2012 (2). Additional rapid progress is expected with the implementation of the 2013 WHO consolidated ARV guidelines and the move to ART for pregnant and breastfeeding women living with HIV (Option B/B+).

Reduce HIV-related mortality

** TARGET: Reduce HIV-related mortality—specifically reduce HIV-related deaths by 25% (compared with a 2009 baseline)*

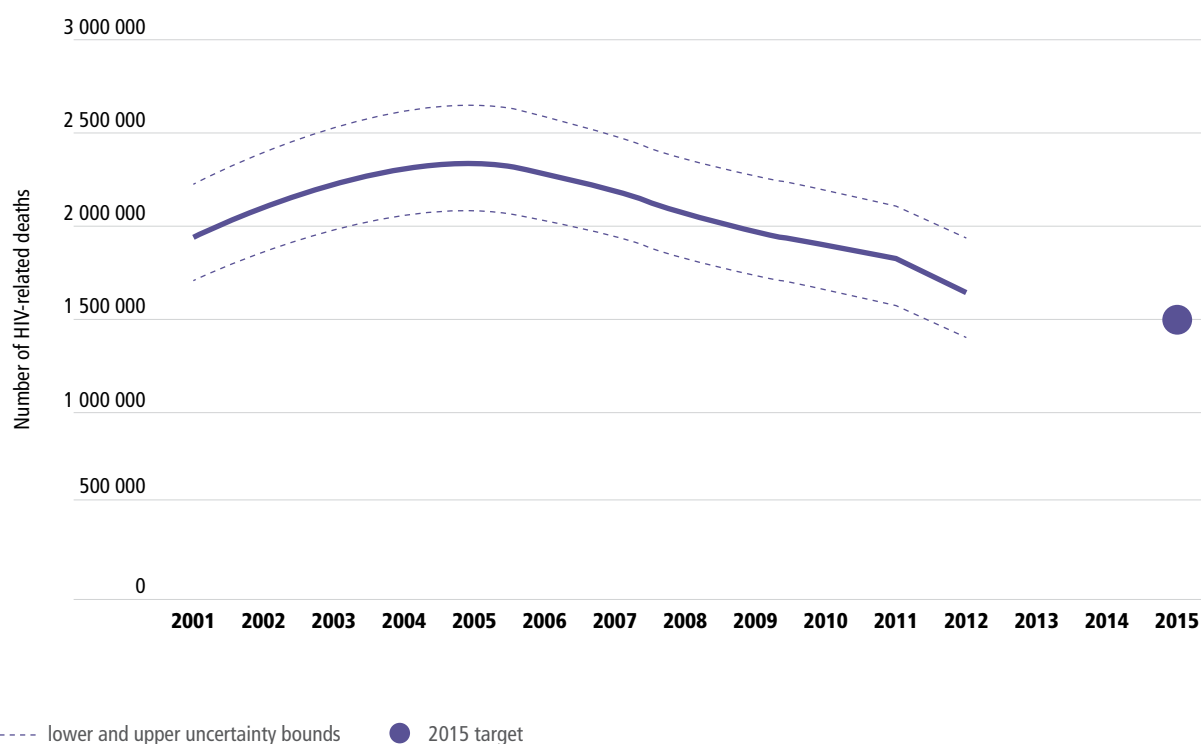
Expanded access to ART and declining incidence of HIV infection have led to a steep fall globally in the number of adults and children dying from HIV-related causes (Figure 3). The estimated 1.6 million [1.4–1.9 million] HIV-related deaths globally in 2012 were 30% fewer than in 2005 and 20% fewer than in 2009 (3). This puts the world on track to exceed the target of reducing HIV-related deaths by 25% by 2015.

In low- and middle-income countries, ART programmes averted an estimated 5.5 million deaths between 1995 and

2012 (3). The drop in HIV-related mortality is especially evident in the regions with the greatest burden of HIV infection. In 2012, an estimated 1.2 million [1.0–1.3 million] people died from HIV-related causes in the African Region, 33% fewer than the 1.8 million [1.6–2.0 million] who died in 2005, and 20% fewer than the 1.4 million [1.3–1.6 million] who died in 2009.

Nevertheless, the number of lives lost each year to HIV remains unacceptably high. This underscores the need to detect infections earlier and to ensure that greater numbers of people eligible for ART start and stay on that treatment. Those improvements are especially vital for adolescents, among whom HIV-related deaths increased by 50% between 2005 and 2012.

Fig. 3. Estimated number of people dying from HIV-related causes globally, 2001–2012



Source: 2013 UNAIDS/WHO estimates.

Reduce TB-related mortality in people with HIV

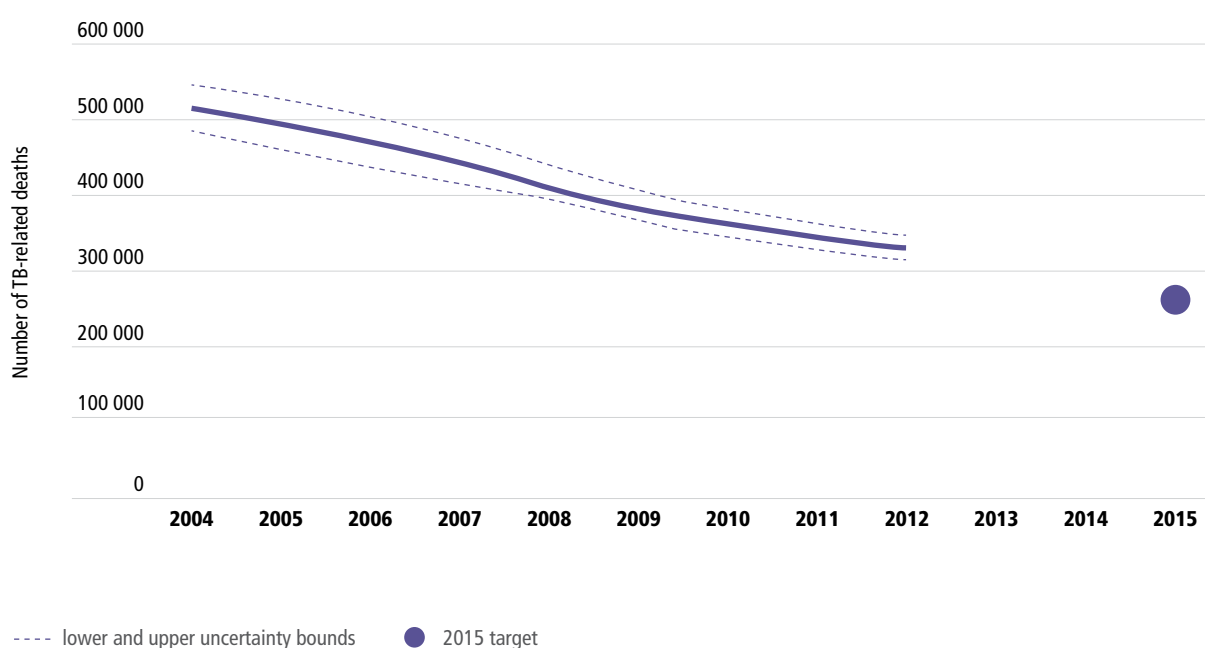
** TARGET: Reduce tuberculosis-related mortality—specifically reduce tuberculosis deaths among people living with HIV by 50% (compared with a 2004 baseline)*

TB-related deaths among people living with HIV have fallen by 36% worldwide since 2004 (4—the result of important improvements in the reach, quality and coordination of HIV and TB services (Figure 4). If those efforts are intensified further, the target of reducing TB

mortality among people living HIV globally by 50% by 2015 could be reached.

WHO estimates that the expansion of collaborative HIV and TB activities (including HIV testing, ART and preventive measures) averted 1.3 million deaths from 2005 to 2012. The scale up is becoming increasingly effective: joint TB and HIV interventions saved the lives of more than 400 000 people in 2011 alone (eight times more than in 2005) (4).

Fig. 4. Estimated number of people with HIV dying from TB globally, 2004–2012



Source: WHO Global TB Programme.

STRATEGIC DIRECTION 1

OPTIMIZE HIV PREVENTION, DIAGNOSIS, TREATMENT AND CARE OUTCOMES

Strategic direction 1 of the Global Health Sector Strategy on HIV/AIDS 2011–2015 focuses on initiatives and systems to improve the quality, effectiveness and reach of HIV-specific interventions and approaches. It features four core elements:

1. Invigorate HIV prevention;
2. Eliminate HIV infections in children;
3. Catalyse the next phase of diagnosis, treatment, care and support; and
4. Provide comprehensive, integrated services for key populations.

Invigorate HIV prevention

Preventing new HIV infections requires that HIV responses prioritize high-quality, evidence-based interventions in the settings and populations where most HIV transmission is occurring. Increasingly, this means reaching populations that are vulnerable to and at high risk of HIV infection, but who are not adequately served by current programmes.

Prevent the sexual transmission of HIV

Along with the natural dynamics of HIV epidemics, changes in sexual behaviour have been central to the observed declines in new HIV infections, especially in countries with a high prevalence of HIV (5). The changes are especially evident among adolescents and young people. Adolescents (aged 10–19 years) are reporting that they have fewer sexual partners, young people (ages 15–24 years) in many low- and middle-income countries report that they are becoming sexually active at later ages than in the past (6), and condom use has increased in many regions.

Condom use can be expanded further

Correct and consistent use of male and female condoms remains one of the most efficient methods to prevent the sexual transmission of HIV (7). Yet, countries reported in 2013 that only 41% of adults with multiple sexual partners said they used a condom at last sex.¹ Condom use appears to be especially low among adolescent girls in the African Region (6). Similarly, among surveyed men who have sex with men, reported median condom use at last anal sex, at about 57%, is low and changed little from 2009 to 2012 (5). Encouragingly, however, the use of condoms and condom-compatible lubricants appears to have become more common during sex work, at least among those sex

workers reached with surveys: median condom use during sex work reported in 2012 was 85% in the 44 countries furnishing those data, up from 78% in 2009 (5).

Concerted action is required in a number of areas if condom programmes are to be optimized. Donor supplies of both male and female condoms need to increase again, and uninterrupted supplies of condoms and lubricants for communities and venues with the greatest need can help to avoid stock-outs. Civil society organizations can play bigger roles influencing community norms, particularly among key populations, in support of expanded condom use.

Even with longstanding prevention tools such as condoms, there are opportunities for innovation to make them more acceptable and effective. New condom materials and designs are being developed, and new marketing methods are being tested. Emulating these and other efforts, such as the Bill and Melinda Gates Foundation's 'Next generation condom' challenge, will help further popularize condom use.

Controlling sexually transmitted infections remains a priority

Preventing and controlling sexually transmitted infections (STIs) remain important components of a comprehensive HIV prevention strategy. In 2012, significant proportions of countries reported offering symptomatic STI treatment for key populations, including for sex workers (57/62 reporting countries), men who have sex with men (44/55 countries) and people who inject drugs (36/44 countries).² Data on services for transgender people were not available. However, it is currently not known how many people belonging to those groups are indeed being reached with services, nor is much known about their quality.

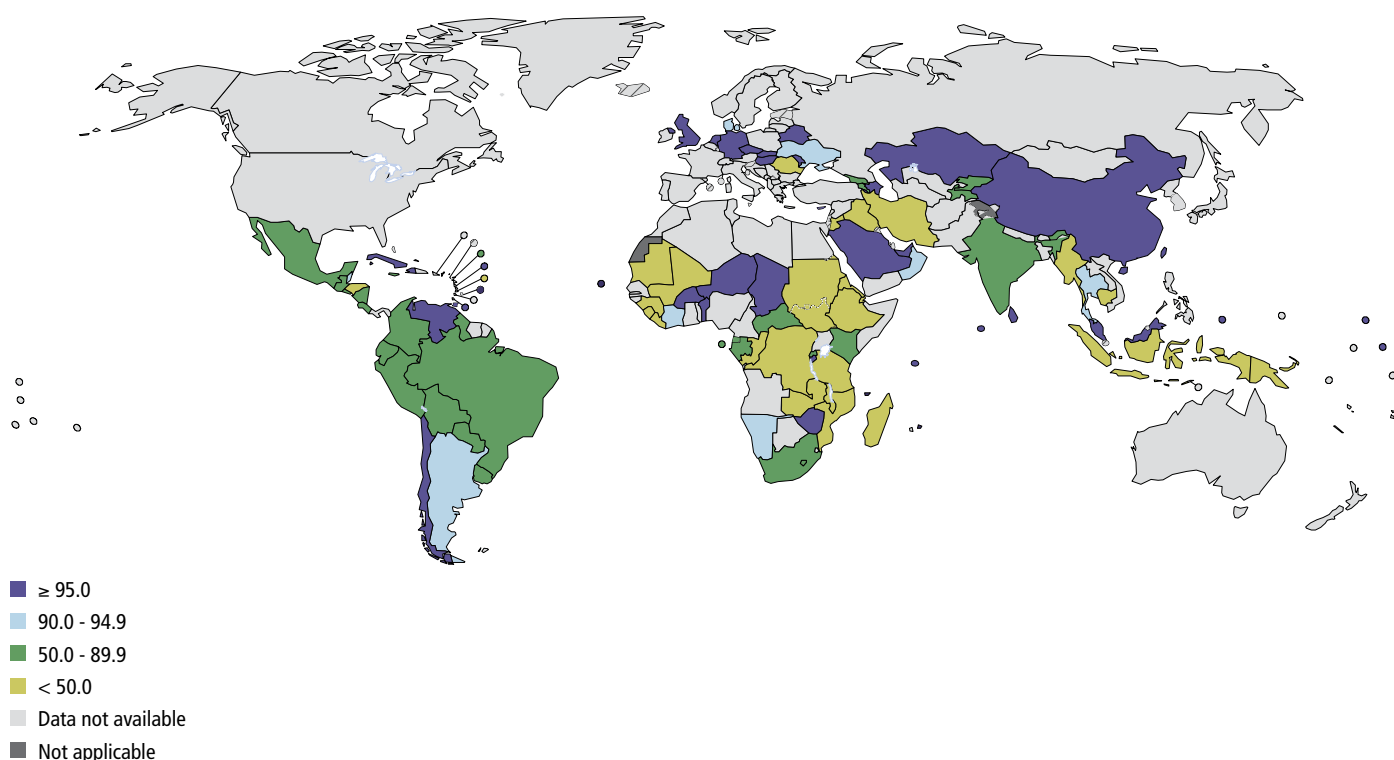
¹ Based on data from the Global AIDS Response Progress Reporting (GARPR) mechanism, an annual data collection exercise jointly undertaken and validated by WHO, UNICEF and UNAIDS, based on a platform managed by UNAIDS.

² Based on data from the GARPR mechanism.

Balancing recent concerns about increases in multidrug resistance to *Neisseria gonorrhoeae* is the improved availability of drugs for herpes and chlamydia, as well as point-of-care testing for syphilis. Countries will be able to respond better to these developments if they update their STI treatment guidelines and services accordingly. WHO has released guidance for STI and HIV management for sex workers (8), and men and transgender women who have sex with men (9), and updated global STI treatment guidelines will be released in 2015.

Syphilis testing during pregnancy is a valuable HIV prevention intervention for pregnant women. Initiatives for the dual elimination of mother-to-child transmission of HIV and syphilis in the Americas, Asia-Pacific, and Africa recognize the role that syphilis plays in increasing mother-to-child transmission of HIV, and the opportunities that exist for common solutions and interventions. In 2012, 57 low- and middle-income countries reported that a median of 81% of women attending antenatal care was tested for syphilis (see Figure 5).

Fig. 5. Percentage of antenatal care attendees tested for syphilis at first visit, 2012



Source: 2013 Global AIDS Response Progress Reporting (WHO/UNAIDS/UNICEF).

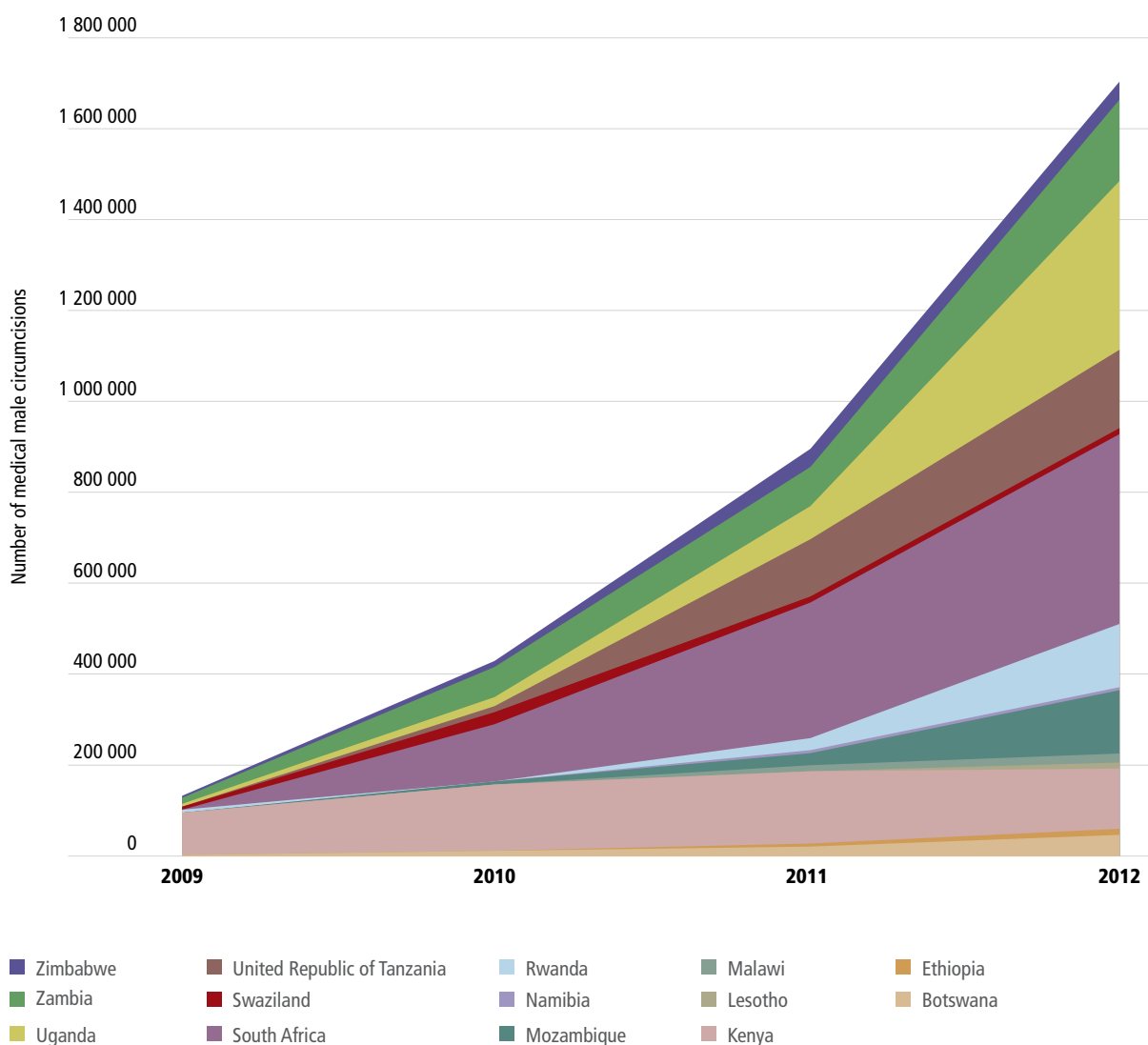
After a slow start, voluntary medical male circumcision has increased

The scale up of voluntary medical male circumcision holds great potential for further reducing new HIV infections. Following recommendations from WHO and UNAIDS in 2007 (10), this procedure has been promoted intensively in 14 priority countries in the African Region.³

Uptake was initially slow, but by the end of 2012 3.2 million males had undergone voluntary medical male circumcision. The number of annual circumcisions performed rose from close to 900 000 in 2011 to above 1.7 million in 2012 (Figure 6) (11). So far, the programmes appear to be most successful in reaching men younger than 25 years.

³ The 14 priority countries in Africa are: Botswana, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Namibia, Rwanda, Swaziland, South Africa, United Republic of Tanzania, Uganda, Zambia and Zimbabwe.

Fig. 6. Annual number of voluntary medical male circumcisions performed in 14 priority countries in the African Region, 2009–2012



Note: Ethiopia numbers only apply to the Region of Gambela.

Source: 2013 Global AIDS Response Progress Reporting (WHO/UNAIDS/UNICEF) and various ministries of health.

Building on this momentum will require overcoming funding and human resource constraints, strengthening commitment among political and community leaders, and avoiding stock-outs of circumcision kits and other supplies (11). Several countries are already allowing cadres of health care workers, besides doctors, to perform medical male surgical procedures. At the same time, easier-to-use male circumcision devices are being developed (11), and WHO pre-qualified the first such device in 2013. Prequalified devices offer the potential of easier medical male circumcision methods that can be performed by mid-level health care workers, thereby expanding service coverage. Strengthened linkages between adolescent and voluntary medical male circumcision could also enhance coverage and would offer

excellent opportunities to reach adolescent males with other relevant prevention and care services.

WHO is supporting countries to boost demand by using fresh advocacy and communication approaches, link their medical male circumcision programmes with adolescent sexual and reproductive health activities, and adopt the use of safe, non-surgical devices. WHO has produced a framework for clinical evaluation of devices for male circumcision and it has developed a programme to prequalify such devices—important contributions to improving the selection and procurement of quality devices. As a longer-term strategy, WHO is promoting the integration of early infant male circumcision into maternal and neonatal health programmes.

Special efforts are needed to reach key populations

Disproportionately high HIV prevalence continues to be reported among key populations, especially men and transgender women who have sex with men, people who inject drugs, sex workers and prisoners. They represent most of the people affected by HIV outside the African Region and an increasingly recognized share of new infections in urban settings within that region. In a majority of low- and middle-income countries, these key populations continue to be poorly served with evidence-based HIV interventions. WHO has issued a series of guidelines for enhancing HIV services for different key populations, which are being consolidated into a single comprehensive guide for release in mid-2014.

Although there has been some progress across all key populations, new and re-emerging HIV epidemics are being witnessed among men who have sex with men in several places—including in parts of Asia (12) and Europe (13), and in Australia (14) and the United States (15, 16). Of particular concern are those communities with recognized successful HIV prevention programmes that are now experiencing increasing HIV incidence. The challenge is to design and implement durable programmes that result in sustained HIV prevention benefits. WHO guidelines in 2012 recommended several options for enhancing prevention efforts in key populations, including ART regardless of CD4 levels for the HIV-positive partner in a serodiscordant relationship (17), and offering ARVs for pre-exposure prophylaxis (PrEP) of HIV for men who have sex with men within the context of demonstration projects (18).

WHO's updated guidelines for a comprehensive harm reduction package for people who inject drugs reiterate the need to implement core interventions such as sterile needle and syringe programmes (NSP), and opioid substitution therapy (OST) for people who use opioid drugs (19). In 2012, 86 countries were implementing NSPs to varying degrees. However, some countries with large HIV burdens in this key population have been scaling back NSP services in the past three years (20).⁴ Seventy-seven countries worldwide provided OST services in 2012, seven more than reported doing so in 2010.

However, the scope and quality of existing NSP and OST services will need to improve if countries are to make a lasting impact on their HIV epidemics. An emerging challenge involves managing co-infections and other co-morbidities such as TB, viral hepatitis B and C and overdoses in an integrated manner.

Intensified action could make a major difference quickly in a number of areas, for example by removing obstacles

that block ready access to services for key populations. Political commitment is required to remove discriminatory laws and practices that hinder—and, in some countries, explicitly prevent—efforts to reach key populations. Of note are legal barriers that are preventing men and transgender women who have sex with men from accessing effective HIV services (5, 21). Strong community involvement has been shown to boost suitable and effective HIV services for key populations (22). Where appropriate, interventions for key populations also could be integrated into other health services.

Highly effective prevention interventions exist for key populations, but these packages could be enhanced with the addition of new interventions, such as the use of ARVs for prevention, including post-exposure prophylaxis (PEP) and PrEP. As with other interventions, these will be most effective if accompanied by strategies that address structural barriers, including violence, stigmatization and criminalization (16).

Making full use of the preventive impact of antiretroviral drugs

ARV drugs offer a powerful addition to current combination HIV prevention strategies and approaches.

Strong, positive evidence in the past three years (23–26) has boosted interest in making greater use of the HIV prevention benefits of ART. Such an approach involves people living with HIV using ART both for their own health and to reduce the risk of HIV transmission to uninfected partners. This is the rationale for providing ART to serodiscordant couples and for considering earlier initiation of ART in some populations and settings. The challenge now is to realize this enormous potential in 'real world' settings (27, 28).

Several countries responded swiftly to the WHO 2012 policy guidance recommending that HIV-positive partners in serodiscordant couples start ART, irrespective of their clinical or immunological status (17). By April 2014, 26 out of 59 surveyed high-burden countries had adopted the provision of ART for serodiscordant couples in their treatment guidelines.⁵

Among the promising new options is the daily use of oral or topical ARVs in HIV-uninfected people who are at high risk of becoming infected, in order to block the acquisition of HIV infection. Several oral PrEP effectiveness trials have yielded promising results (25, 26, 29, 30). In 2012–2013, WHO published guidance on oral PrEP for serodiscordant couples, as well as for men and transgender women who have sex with men, recommending that this intervention be rolled out as demonstration projects in a limited number

⁴ WHO HIV Country Intelligence, unpublished excerpt 15 April 2014

⁵ WHO HIV Country Intelligence, unpublished excerpt 15 April 2014.

of countries to examine critical implementation issues (18). The United States has included PrEP in its HIV prevention portfolio, and demonstration projects are underway in several other countries.

The potential importance of PEP as an ARV-based prevention intervention has been widely recognized for some time. PEP can be used effectively for non-occupational exposures, including following sexual assault, the sharing of drug-injecting equipment and potential exposure through consensual sex. PEP is an important approach to reduce the risk of development of HIV infection in an individual who has been exposed to HIV, and as such is widely considered to be an integral part of the overall strategy for preventing transmission. New WHO PEP guidelines, which focus on recommended PEP regimens and duration of use, will be issued in mid-2014.

Eliminate new HIV infections in children

Implementation of the *Global Plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive* (31) since 2009 has added powerful impetus to scale up highly effective PMTCT interventions, particularly in low- and middle-income countries with high prevalence of HIV.⁶ Seven of the plan's 21 priority countries halved the number of new HIV infections among children from 2009 to 2012.⁷ In the 21 priority countries overall, 64% [58–70%] of pregnant women living with HIV received ARV drugs in 2012, compared with 49% [43–56%] in 2009, and four countries—Botswana, Ghana, Namibia and Zambia—have reached the 90% coverage target⁸, while Mozambique, South Africa, Swaziland and Zimbabwe are close to it.

Despite the progress, an average 16% of children of mothers living with HIV acquired the virus in the 81 low- and middle-income countries that reported data on PMTCT for 2012—well short of the plan's target of reducing MTCT to less than 5% of breastfeeding infants and to less than 2% of non-breastfeeding infants (2).

The WHO 2013 *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection* (32) recommend initiating ART (triple ARVs), either lifelong or during the mother-to-child transmission risk period, for all pregnant and breastfeeding women living with HIV. The new guidelines also recommend that all children under five years of age diagnosed with HIV should be provided with lifelong ART, regardless of their CD4 count or clinical condition (32). The new guidelines, which countries are

rapidly implementing, present a new framework for highly effective interventions that can promote the health of mothers, prevent new infections in children, and provide early ART to those children who are infected.

Further improvement is possible in a number of areas, starting with HIV testing and counselling for pregnant women. Provision of this service has expanded significantly in the past five years in most high-burden countries, but it lags in low-burden and concentrated epidemic settings. In low- and middle-income countries, the roughly 26% of pregnant women who had HIV tests and received their results in 2009 rose to 37% in 2012. However, this increase was most pronounced in high-burden countries, resulting in an increase in the percentage of pregnant women who know their HIV status increasing from 50% in 2009 to 64% in 2012 in the eastern and southern Africa region, which has high HIV prevalence.

Opportunities for greater progress include expanding testing interventions to include re-testing women later in pregnancy after they had initially tested HIV-negative (particularly in high prevalence settings), promoting couples testing and providing ART for HIV serodiscordant couples. Making HIV testing and counselling part of the basic package of services for antenatal care, as recommended in the 2013 consolidated ARV *guidelines* (32), should contribute further to expanded testing coverage.

More can be done, as well, to ensure that women living with HIV who need ART manage to start treatment during pregnancy, and receive the appropriate ARV medicines for PMTCT (33).⁹ The proportion of pregnant women who needed ART for their own health (based on the 2010 guidelines, which recommended ART for women with CD4 cell counts less than 350mm³) and were receiving it in 2012 in low- and middle-income countries was less than for adults overall: 59% [53–64%] versus 64% [61–69%] (33). Pregnant adolescents living with HIV are a particular concern (34). Pending changes in countries' policies, implementation of the 2013 consolidated ARV guidelines is expected to increase uptake of ART rapidly among pregnant and breastfeeding women.

Diagnosing HIV in infants and young children and linking those living with HIV to care continues to pose a major challenge. Early infant diagnosis is expanding in most low- and middle-income countries, but overall only 39% [35%–43%] of HIV-exposed children had access to virological HIV testing within the recommended first two

⁶ The 22 priority countries in the Global Plan are: Angola, Botswana, Burundi, Cameroon, Chad, Côte d'Ivoire, Democratic Republic of the Congo, Ethiopia, Ghana, India, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, South Africa, Swaziland, Uganda, United Republic of Tanzania, Zambia and Zimbabwe.

⁷ Based on GARPR data.

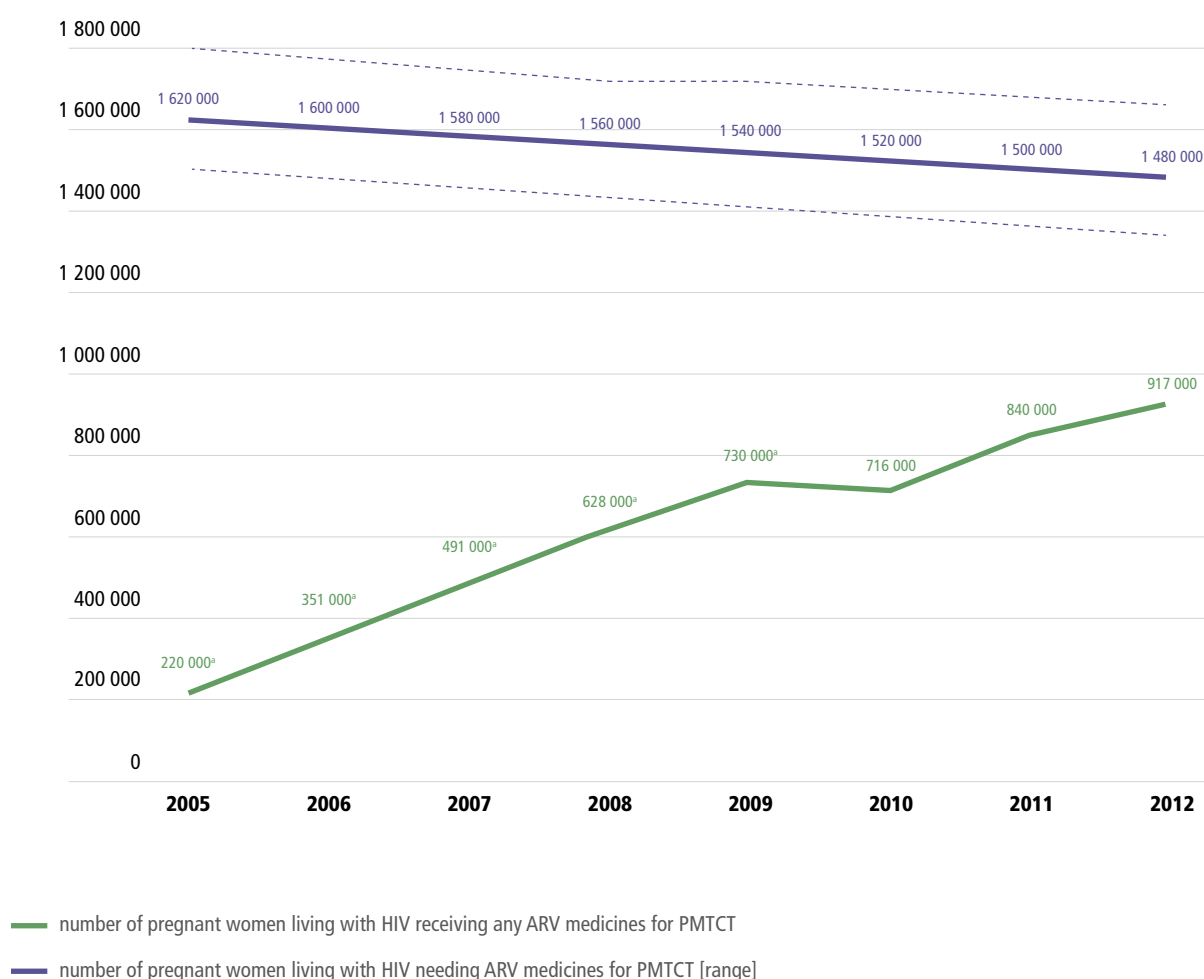
⁸ This refers to the PMTCT ARV coverage target for the perinatal period. Postnatal PMTCT ARV coverage of 90% has not necessarily been met in these four countries.

⁹ Even in areas where the HIV prevalence among pregnant women is as low as 2%, more than one in ten (12%) of all pregnancy-related deaths may be attributable to HIV. That proportion increases to 50% in regions with adult HIV prevalence of 15% or more. See Calvert C, Ronsmans C. The contribution of HIV to pregnancy-related mortality: a systematic review and meta-analysis. *AIDS*. 2013;27(10):1631–9.

months of life in 2012 in the 90 countries reporting those data. Furthermore, in some settings only one third of infants with HIV who are identified through virological testing are promptly referred to treatment facilities to start ART (33).¹⁰ Countries are being supported to scale up early infant testing and to implement more effective follow-up of HIV-exposed infants until a definitive HIV diagnosis can be made. In addition, more efforts are needed to increase provider-initiated testing and case finding of potentially infected children, both through routine child health services and at other venues where children encounter opportunities to receive HIV testing.

Perhaps the most promising recent breakthrough is the decision of many countries to provide lifelong, triple-drug ART to all pregnant and breastfeeding women diagnosed with HIV, regardless of their immune status (known as *Option B+*, which is one of two approaches that WHO now recommends). By April 2014, close to half of the 59 focus countries¹¹ had followed Malawi's early lead by adopting *Option B+* (35), a move that is expected to further reduce the rates of mother-to-child HIV transmission, protect the health of greater numbers of HIV-positive mothers and provide additional prevention benefit against sexual transmission.

Fig. 7. Number of pregnant women living with HIV in low- and middle-income countries receiving and needing antiretrovirals for preventing mother-to-child transmission of HIV, 2005–2012



^a Single-dose nevirapine is still included in the data for the number of pregnant women living with HIV receiving ARV medicines from 2005–2009.

Source: 2013 Global AIDS Response Progress Reporting (WHO/UNAIDS/UNICEF) and 2013 UNAIDS/WHO estimates.

¹⁰ Based on GARPR data.

¹¹ 'Focus countries' refers to countries identified by WHO for intensified HIV-related support, based on their burden of HIV and/or the strategic importance of the HIV response.

Box 1. Closing the treatment gap for children

While the provision of PMTCT services is expanding and improving, large numbers of infants continue to be exposed to HIV, and identifying and linking them to treatment and care remain critical challenges. The number of children (younger than 15 years) receiving ART in low- and middle-income countries increased from 355 000 in 2009 to 647 000 in 2012. However, based on global guidelines valid at the time (36), ART coverage for children was only about half the coverage for adults (33). Greater progress is possible, as shown in Botswana and Namibia where more than 80% of the children eligible for ART are receiving it.

Paediatric ART involves multiple challenges. Early infant diagnosis, although expanding, is mostly limited to urban areas. Other difficulties include the limited availability of fixed-dose combinations, a lack of a palatable formulation suitable for young children and infants, market fragmentation and unreliable supply chains, and hesitancy among non-specialized health care workers in dealing with paediatric HIV. Improvements are underway as new products become available and more efforts are made to simplify and harmonize treatment recommendations. Other opportunities include task-shifting paediatric ART delivery from specialists to non-physicians, and providing paediatric ART at the same sites and with the same providers as other primary health services (37).

Catalyse the next phase of HIV diagnosis, treatment, care and support

Access to ART continues to increase at a remarkable pace. The approximately 9.7 million people receiving ART in low- and middle-income countries at the end of 2012 represented an increase of 1.6 million people in one year—the largest annual increase ever. If this momentum is maintained, there will

be 15 million people on ART by the end of 2015 in low- and middle-income countries (Figure 8) (38). When ART services in high-income countries are also considered, the total number of people on ART reached approximately 10.6 million people globally in 2012.

Box 2. New global recommendations for earlier ART initiation

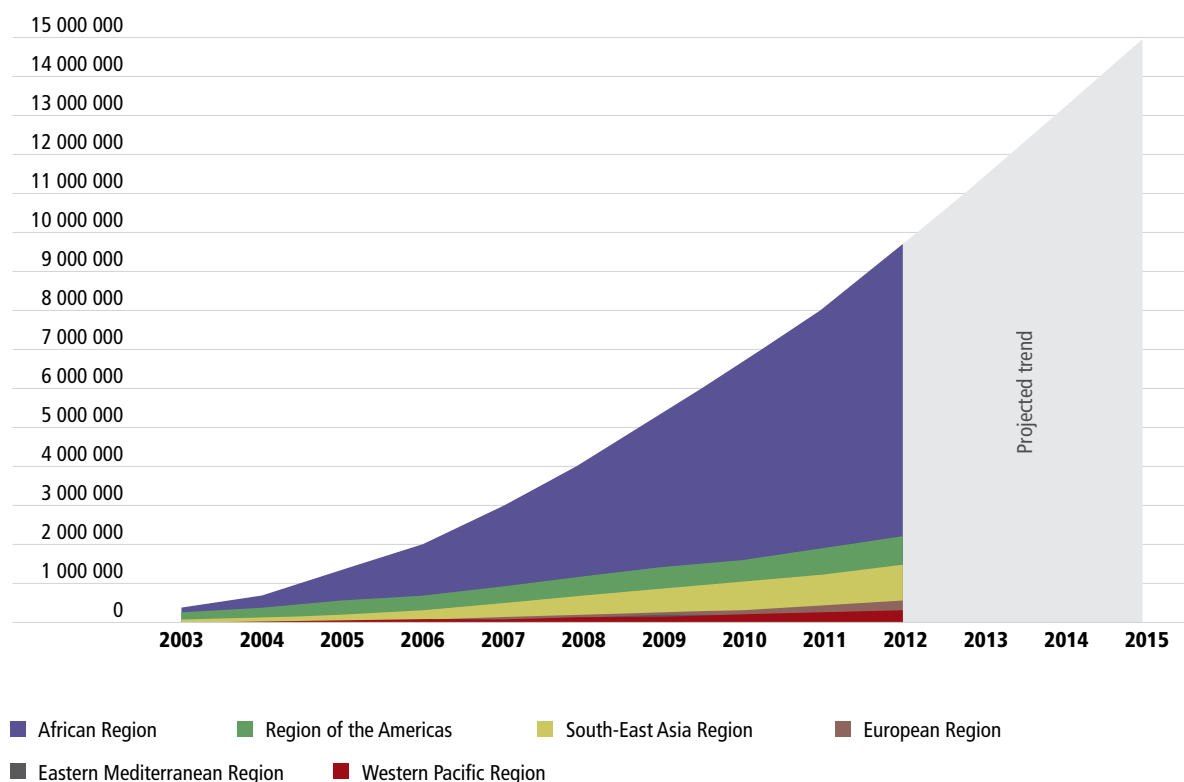
The updated WHO ARV guidelines released in mid-2013 reflect several recent scientific studies that demonstrate the important benefits of starting ART early to reduce mortality, morbidity and infection (32). They recommend earlier initiation of ART at CD4 count ≤ 500 cells/mm³ and initiation of ART regardless of CD4 count. Immediate ART is recommended for HIV serodiscordant couples, pregnant and breastfeeding women living with HIV, people with TB and HIV, people co-infected with HIV and hepatitis B virus (HBV) with severe chronic liver disease, and children living with HIV who are younger than five years. The guidelines also promote the use of more effective, less toxic and simpler regimens, and recommend the adoption of a single first-line regimen¹² for all adults and adolescents. First-line ART should ideally be provided as a fixed-dose combination, which improves adherence and simplifies prescribing (39).

While expanded eligibility for ART provides new opportunities to save lives, it also poses challenges to policy-makers and implementers. If all recommendations were fully implemented, the number of people eligible for ART in low- and middle-income countries will have increased from 16.7 million to 28.6 million in 2013, representing 86% of all people living with HIV in those countries. Hence, WHO is supporting countries to adapt the new guidelines into practical national policies and protocols. By April 2014, 25 of 59 surveyed high-burden countries had adopted at least one of the clinical components of the 2013 guidelines (i.e. ART for adults, paediatric ART, and/or PMTCT), and another 14 countries were in the process of doing so.¹³ Notably, 16 out of 59 focus countries have adopted a CD4 cell count level of 500 as the new threshold for ART initiation, and 39 have moved to TDF/3TC(FTC)/EFV as the preferred first-line regimen.

¹² Tenofovir (TDF) + lamivudine (3TC) or emtricitabine (FTC) + efavirenz (EFV)

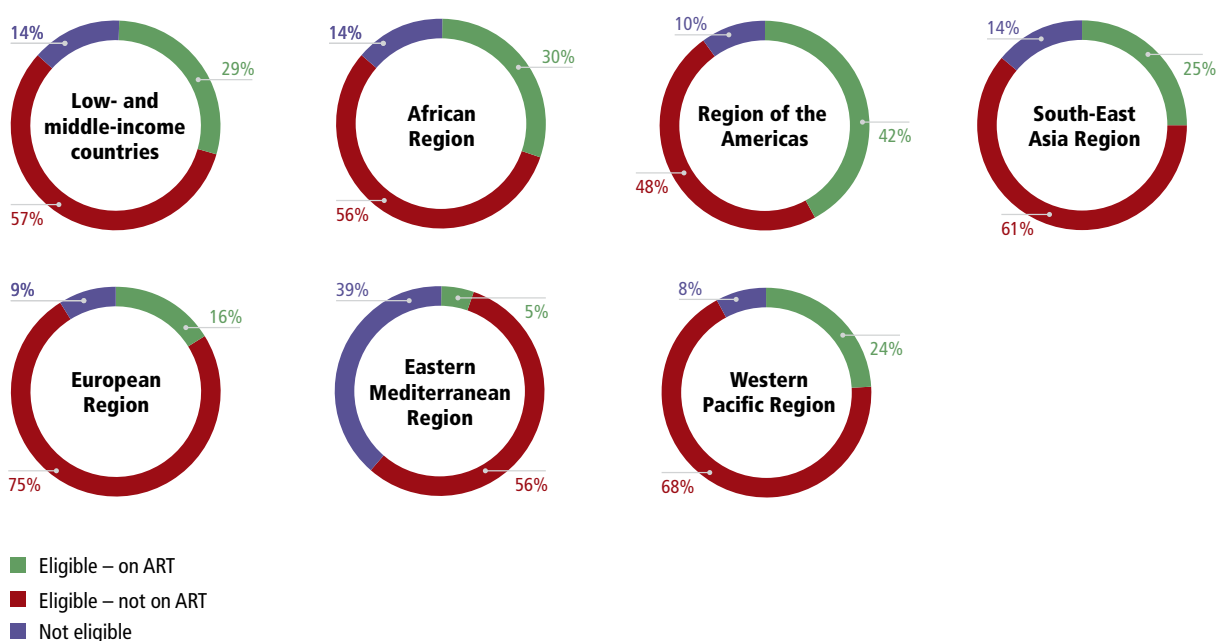
¹³ WHO HIV Country Intelligence, unpublished excerpt 15 April 2014.

Fig. 8. Actual and projected numbers of people receiving antiretroviral therapy in low- and middle-income countries, globally and by WHO Region, 2003–2015



Source: 2013 Global AIDS Response Progress Reporting (WHO/UNICEF/UNAIDS).

Fig. 9. Percentages of people living with HIV in low- and middle-income countries who were eligible for ART* and who were receiving or were not receiving ART, and percentages who were not eligible for ART, 2012



* Eligible according to the WHO 2013 consolidated ARV guidelines

Source: 2013 Global AIDS Response Progress Reporting (WHO/UNICEF/UNAIDS) and 2013 UNAIDS/WHO estimates.

Disparities in antiretroviral therapy coverage

The global scale-up of ART has been impressive, but important disparities persist in access to ART. In most regions, including the African Region, men eligible for ART are less likely to be receiving it than women. The recent treatment gains also are not reaching enough children, adolescents and key populations who face high risk of HIV infection (40).

An estimated 2.1 million adolescents (10–19 years of age) were living with HIV in 2012 (41). ART coverage for adolescents is not known, but HIV-related deaths among adolescents are estimated to have tripled since 2000, making HIV the number two cause of death among adolescents worldwide. In the African Region, HIV accounts for 16% of adolescent mortality (42). This points to a major gap in treatment access (1). In addition, HIV-positive adolescents receiving ART often have lower viral suppression rates compared to both adults and younger children. Maintaining ART adherence among adolescents is a significant challenge (43, 44).

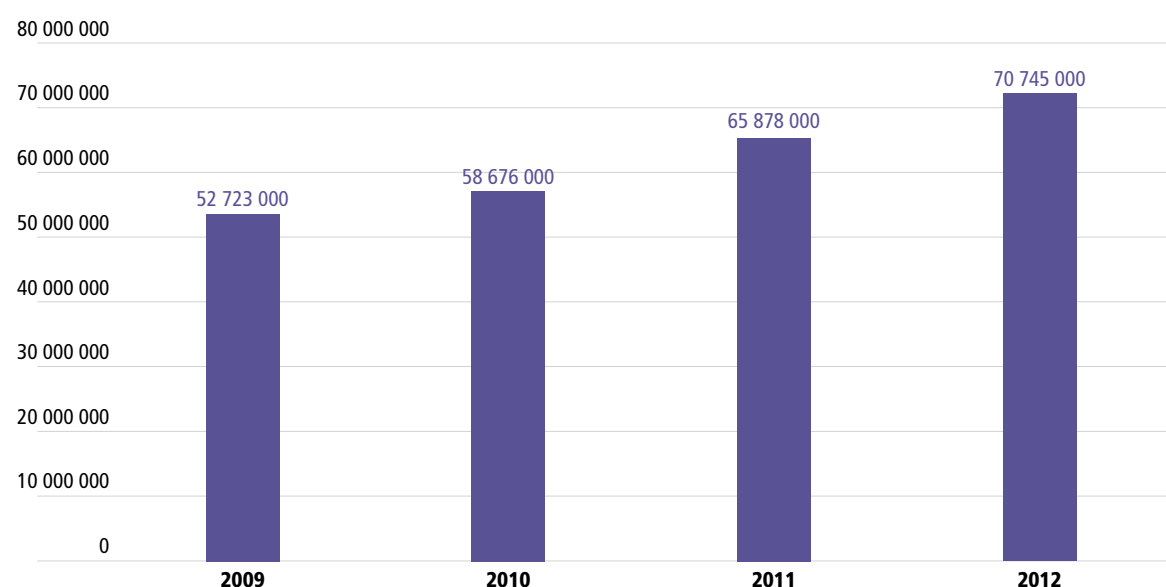
Sex workers, people who inject drugs, men and transgender women who have sex with men, and prisoners, in particular, face a range of social, structural and legal barriers that deny them the full benefits of HIV treatment and care services (33). There is a lack of data

on female sex workers' access to ART, but it is known that ART services tailored for sex workers are exceptional, even in settings with very high HIV prevalence in this population group. Access to ART services for men who have sex with men is also insufficiently documented, while sex disaggregation in routine ART reporting currently does not explicitly reflect transgender people. However, the available evidence indicates that they have poor access to ART—as shown in a recent study from India (45). Similarly, access to ART for people who inject drugs appears to be very limited. For example in the WHO European Region, about 21% of people receiving ART said they had acquired HIV through injecting drug use—a strikingly smaller figure than the estimated 59% of people who were eligible for ART and who had reported injecting drug use (46).

More people are undergoing HIV testing

Maximizing the impact of HIV treatment and care starts with identifying more people in need of ART, doing so before their health declines, and linking them reliably to care services. Uptake of HIV testing and counselling increased by about 34% between 2009 and 2012 in the 58 countries reporting data across that period, as shown in Figure 10.¹⁴ Countries in all regions are diversifying testing approaches and introducing effective testing technologies (including rapid diagnostic tests) (47).

Fig. 10. Number of people aged 15 years and older who received HIV testing and counselling in 58 selected low-and middle-income countries, 2009 – 2012



Source: 2013 Global AIDS Response Progress Reporting (WHO/UNICEF/UNAIDS).

¹⁴ Based on GARPR data.

Although impressive, the increases do not necessarily mean that the people most likely to have acquired HIV are accessing testing and counselling services. In countries with low HIV prevalence or concentrated HIV epidemics, testing still tends to occur mainly via antenatal services and is not necessarily reaching key populations. In addition, HIV testing rates for men are generally lower than for women (48), largely because testing and counselling is still focused around reproductive health services, where routine offers of HIV testing are becoming the norm (49). Overall, it is estimated that about half the people living with HIV globally knew their HIV status in 2012.

Several new testing and counselling approaches are being used more widely. Community-based testing is becoming more widespread, and is highly acceptable and effective in reaching large numbers of first-time testers, diagnosing people living with HIV at earlier stages in their HIV infection, and linking them to care (50). WHO therefore recommends that community-based testing approaches should complement provider-initiated testing and counselling. In addition, in all HIV epidemic settings community-based HIV testing and counselling for key populations is recommended, with linkage to prevention, care and treatment services (32). In 2013, WHO and partners published the first guidelines on HIV testing, counselling and care for adolescents (41).

Other approaches being implemented include combining stand-alone sites, home-based testing, mobile outreach (including couples testing, testing in workplaces, schools and universities and accessible and safe venues for key populations), and special testing events and campaigns (33). The 2012 WHO document *Service delivery approaches to HIV testing and counselling: A strategic policy framework* (51) provides an overview of the diversity of HIV testing and counselling approaches and strategies.

Door-to-door home-based testing, using rapid diagnostic tests, has been shown to increase the reach of HIV testing (5, 52), while community campaigns that combine HIV testing and counselling with screening or prevention services for multiple diseases are proving effective in the Region of the Americas and the African Region (53). Home-based testing also appears to be effective for encouraging more male partners of pregnant women to take HIV tests, and for promoting uptake of PMTCT services (54). Although experience remains limited, self-testing has the potential to reach people who may otherwise not test for HIV and it appears to be highly acceptable (33, 55). However, more data are needed before self-testing for HIV infection can be globally recommended and implemented (56).

Box 3. Meeting the HIV needs of adolescents

Diagnosing and linking adolescents living with HIV to treatment and care are complicated tasks that are compounded by the physical, emotional and social challenges of adolescence. Their access to HIV testing and treatment is hampered further by legal barriers that require a parent or caregiver's consent, which often discourages adolescents from seeking the services they need. If laws and policies on consent to services are reviewed and national HIV responses incorporate more tailored approaches for adolescents, those obstacles may be reduced. The adjustments would include appropriately prioritizing adolescents in national HIV strategies, and making available youth-friendly HIV testing and counselling and treatment services. Improvements can start by involving adolescents more closely in the development of services that reflect their special needs and circumstances.

Other necessary improvements include transitioning adolescents who are in paediatric treatment and care programmes into services that are more appropriate for their age-related needs and circumstances. More tailored adherence and improvements in the sequencing of tolerable and durable first, second- and third-line ARV options will help reduce the disproportionately high rates of poor drug adherence and virological failure among adolescents on ART (44, 57, 58). When youth do attend clinics that provide sexual and reproductive health services (including condoms), and clinics with adolescent support groups, attrition rates before and after ART initiation tend to improve (59).

Strengthening retention in care and adherence to treatment

A clear shift toward earlier initiation of ART is underway, which is vital for successful treatment outcomes. The improvement stems from greater uptake of HIV testing and counselling, and strengthened links between HIV diagnosis and ART initiation. However, significant numbers of adults and children are still dropping out of care at various points along the treatment cascade, from HIV diagnosis to long-term retention in care (60–63). As a result, about one in

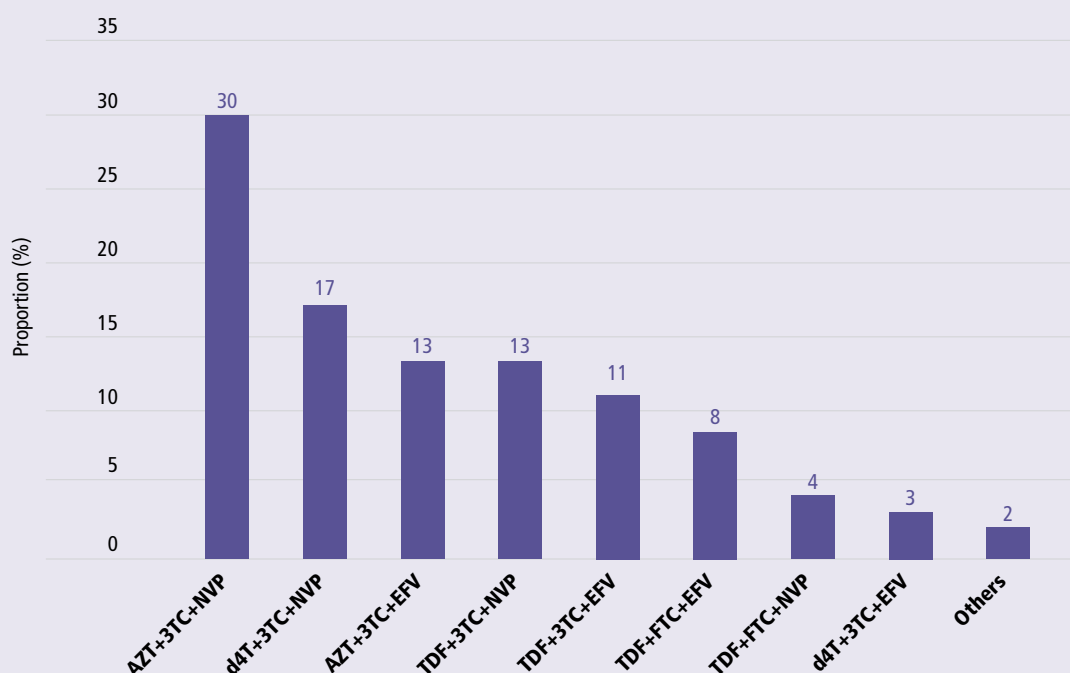
four people in low-income settings initiate ART late, with CD4 counts <100 cells/mm³, according to cohort data, with men more frequently beginning treatment late compared to women (64).

Several approaches for improving pre-ART retention are showing promise. They include reducing the number of clinic visits that are required, cutting waiting times at clinics, using point-of-care CD4 testing, and providing therapeutic services and other benefits (including free co-trimoxazole prophylaxis) as part of pre-ART care (65–68).

Box 4. Getting the best out of HIV treatment

The 2013 consolidated ARV guidelines recommend that eligible patients receive a simplified, daily, single-pill regimen where possible and that countries use fewer first-line regimens. Fixed-drug combinations improve adherence and virological suppression, and simplify procurement and supply management, which can reduce stock-outs (33, 69).

Fig. 11. Proportions of low- and middle-income countries using various first-line antiretroviral regimens, end of 2012



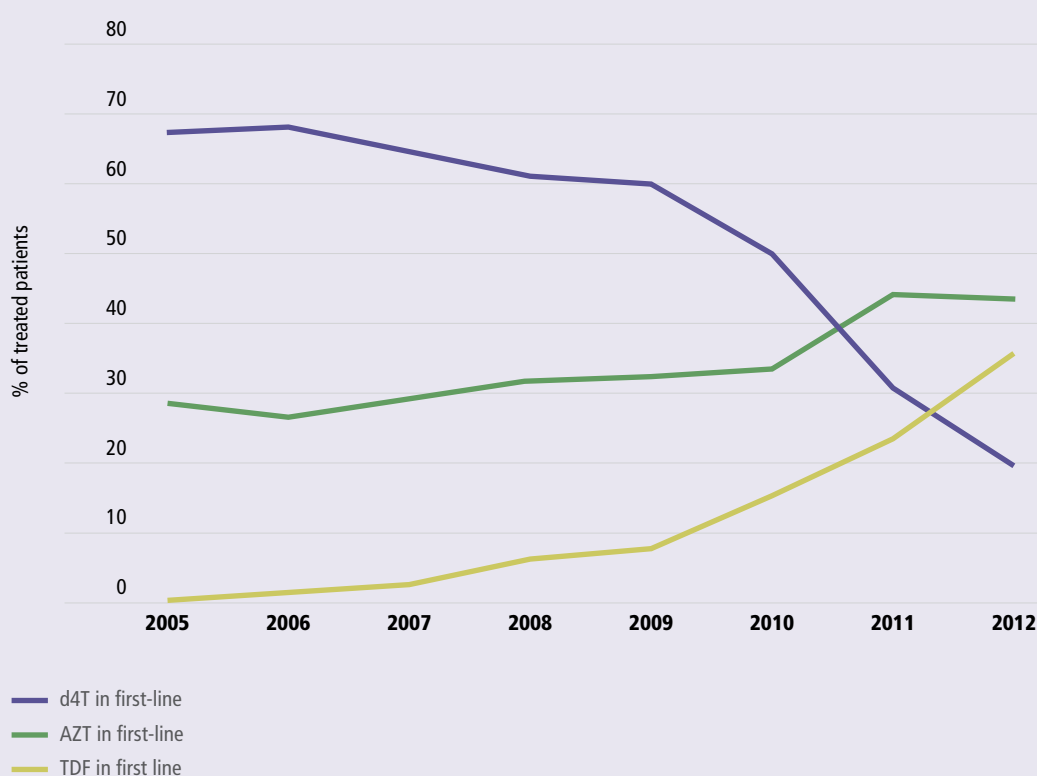
Source: WHO Global ARV survey, 2013.

It was found that a total of 101 different ARV regimens were being used to treat the over 4.9 million people on adult first-line ART in the 69 countries that had detailed ART regimens (Figure 11). The minimum number of regimens used in any one country was 2 and the maximum was 38 regimens; the median was 8 regimens. Although too many different first-line regimens are still being used, most low- and middle-income countries

have indicated that they plan to phase in the recommended first-line regimens, move towards a simplified formulary, and procure fixed-dose combinations when available (35). By April 2014, 39 out of 59 high-burden countries had moved to a recommended first-line regimen of TDF/3TC(FTC)/EFV.¹⁵ Uptake of the preferred first-line treatment regimen is set to continue increasing: ARV procurement data compiled in the Global Price Reporting Mechanism of WHO show that 62% of all ARV regimens contained tenofovir (TDF) in the second half of 2013 and the first quarter of 2014.

Meanwhile, the phasing out of stavudine (d4T), due to commonly reported toxicity issues, continues at an encouraging pace. As Figure 12 shows, the proportion of patients treated with tenofovir-based regimens increased from less than 1% at the end of 2005 to 36% at the end of 2012, and the proportion treated with zidovudine-based regimens increased from 29% to 44% in the same period. Nonetheless, about one million patients were still using d4T as part of first-line therapy at the end of 2012, mostly in countries with large numbers of patients eligible for treatment (35). WHO is recommending a phased approach for replacing d4T, as outlined in the March 2014 supplement to the consolidated ARV guidelines and in a new policy brief on transitioning to new ARV regimens (70, 71). ARV procurement data reported in the WHO Global Price Reporting Mechanism for the second half of 2013 and the first quarter of 2014 indicate that d4T was present in only 2% of the ARV regimes procured (71).

Fig. 12. Evolution of d4T, AZT and TDF in first-line antiretroviral therapy among adults and adolescents, 2005 to end-2012



Source: Results of WHO ARV surveys from 2006 to 2013.

¹⁵ WHO HIV Country Intelligence, unpublished excerpt 15 April 2014.

Once patients are linked to care, the major challenges include retaining them in care and providing them with optimal drug regimens (see box). For people on ART, the attrition rates are initially high and then gradually decline. About one quarter of patients temporarily interrupt treatment (72) and another quarter appear to drop out of care within three years, according to the latest available data (73). Among those lost, up to half (46%) may have died, according to a systematic review of studies in the African Region and in India (74). However recent studies also suggest that some patients shift in and out of care, which suggests that reported attrition rates might be slightly exaggerated (63).

Several methods are being used to improve retention in care. Decentralizing ART services has proved effective (75, 76), as has reducing clinic visits and waiting times (77), and using a model in which stable, long-term patients visit a clinician every six months and collect their medication every two months at a 'fast track' section of the clinic (78). Other options include a national database and a medical alert-type card system¹⁶ that would enable patients to visit any health facility to access their medication (79). Various types of adherence support are also highly effective, including patient education that is tailored for specific groups of patients, treatment support networks and adherence clubs, using mobile-phone text reminders, and providing diary cards and food rations (80).

The 2013 consolidated ARV guidelines recommend the use of viral load testing as the preferred approach to monitoring the success of ART and diagnosing treatment failure, in addition to clinical and CD4 monitoring. As of April 2014, half of 59 focus countries surveyed by WHO have adopted the recommendation to conduct routine viral load monitoring.¹⁷ Point-of-care CD4 testing technology is now available, and point-of care viral load technology is emerging. WHO is working with countries to determine and implement the appropriate combination of diagnostic approaches and technologies within a fully functional health laboratory system.

Monitoring and managing drug resistance and toxicity

As more people start ART earlier and remain on treatment for longer periods, preventing or minimizing serious drug reactions, and monitoring and managing

ARV toxicities has become a priority. Although WHO has determined that the risk of harm from recommended ARV regimens is small, most toxicity studies tend to have limited sample sizes and have been conducted in high-income countries. WHO has produced important technical guidance (81) and is supporting pilot projects to address gaps in toxicity data in several low- and middle-income countries (82). The forthcoming WHO consolidated strategic information guide for HIV in the health sector (due in late 2014) will provide a framework that countries can use to integrate toxicity surveillance within national monitoring and evaluation systems.

Due to the high HIV mutation rate, some degree of HIV drug resistance is anticipated among people receiving treatment, even when appropriate regimens are provided and adherence is achieved (83). Therefore, monitoring the emergence of HIV drug resistance is essential for ensuring the best possible treatment outcomes. The most recent available data indicate that levels of HIV drug resistance in ART-naïve people are increasing in some areas. Drawn from 36 WHO surveys in 12 low- and middle-income countries, the data show the prevalence of HIV drug resistance to any drug among people starting ART ranged from 4.8% [95% CI 3.8%–6.0%] in 2007 to 6.8% [95% CI 4.8%–9.0%] in 2010 (84).

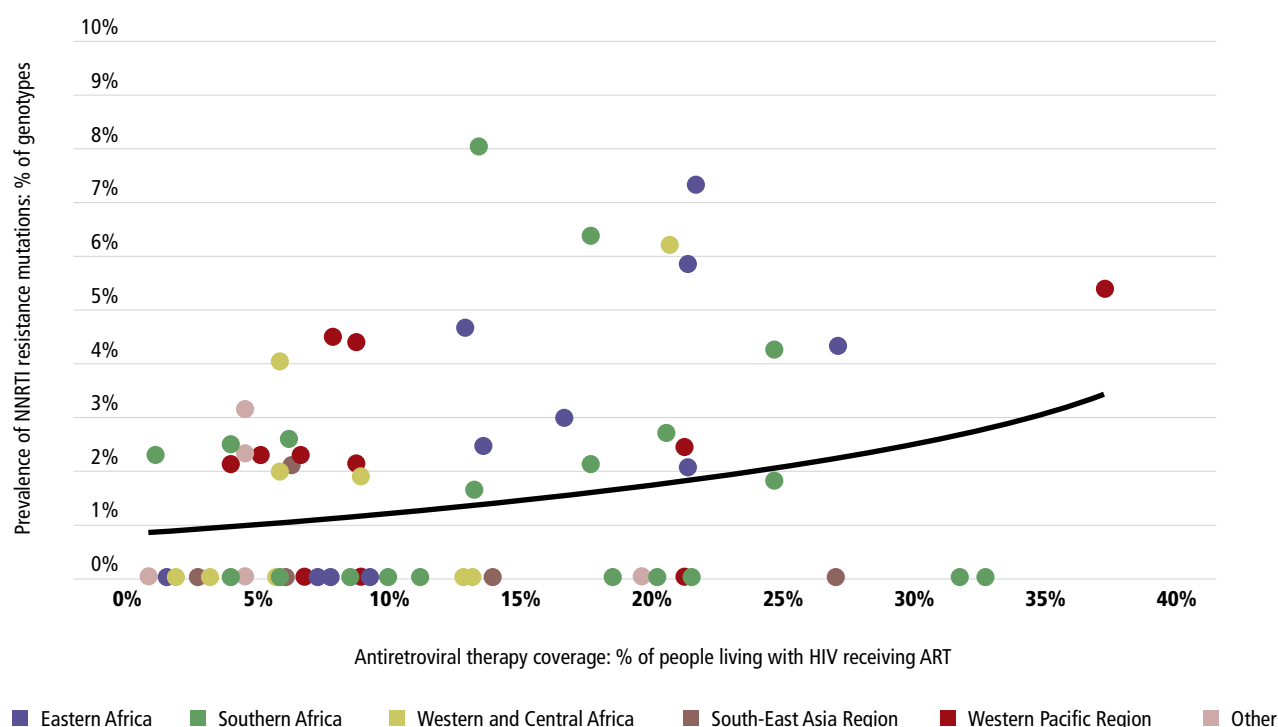
Robust, nationally representative systems for monitoring early warning indicators and prevalence of HIV drug resistance are becoming increasingly important for detecting these patterns, and will perform best if they are integrated into national monitoring and evaluation frameworks. Available data, as depicted in Figure 13, suggest that there is an association between the coverage of ART and an increased prevalence of transmitted drug resistance to non-nucleoside reverse transcriptase inhibitors (NNRTI), such as nevirapine and efavirenz. However, compared with the dramatic expansion of treatment coverage, the observed rise in HIV drug resistance was modest. This implies that the expansion of ART thus far has not triggered unexpected increases in transmitted drug resistance in the areas surveyed.

WHO recently published revised guidance for the surveillance of pre-treatment and acquired HIV drug resistance to assist countries in developing nationally representative estimates of HIV drug resistance (85).

¹⁶ This involves using an electronic chip on a card that contains a patient's medical information, or a bar code on a card that links to an electronic medical record.

¹⁷ WHO HIV Country Intelligence, unpublished excerpt 15 April 2014.

Fig. 13. Relationship between transmitted resistance to NNRTI drugs and antiretroviral therapy coverage, 2004–2010



Source: WHO HIV drug resistance report 2012.

Note: p-value adjusted for region: 0.039. Odds-ratio = 1.4 (95% CI 1.07-1.73)

Strategic Direction 1

OPTIMIZE HIV PREVENTION, DIAGNOSIS, TREATMENT AND CARE OUTCOMES

Increase condom use		Reduced external investments in condom procurement, and mixed trends in condom use
Reduce and manage sexually transmitted infections		Some progress, but the pace needs to quicken
Expand voluntary medical male circumcision		Significant progress in some countries; new male circumcision devices provide opportunities for scale-up, but coverage is still much too low overall
Reach key populations with HIV services		Despite effective interventions, they are not being implemented at sufficient scale
Use antiretroviral medicines to prevent HIV infection		More and more countries are expanding ART eligibility to leverage prevention efforts
Expand coverage of PMTCT services		Major advances in some countries, increasing commitment tied to the Global Plan, but insufficient coverage overall
Expand and improve paediatric treatment		Progress in some regions, but coverage lags behind that of adults
Expand and optimize ART		Strong progress and on track to reach targets
Expand HIV testing and counselling		Progress in diversification of testing and counselling models and new diagnostics, but inadequate coverage
Strengthen retention in care and adherence to treatment		Attritions remains a major problem, but improving regimens and adherence support offer opportunities for progress
Monitor and manage drug resistance and toxicity		Drug resistance still limited, toxicity monitoring systems under development

STRATEGIC DIRECTION 2

ENHANCE BROADER HEALTH OUTCOMES

A significant shift is underway towards greater integration and linkages of HIV with other health programmes and services, as well as with other development sectors.

The evidence shows that integration and linkage can be highly beneficial, especially for enhancing the uptake, suitability, reach and timeliness of services. Improvements have been found in relation to TB and HIV services (1,2), linking PMTCT services with maternal and child health care services (3,4), linking HIV and chronic NCDs (5,6), linking HIV and harm reduction and drug dependence treatment services, and integrating HIV services with primary health care and overall health and community systems (7,8). In addition to improving access to health services, integrated service delivery models may reduce unit costs (9,10).

Decisions on whether to link certain services (for example by locating them together) or to go a step further and fully integrate them need to be carefully considered. Factors such as the disease

burden, the epidemiological context and the status of health care delivery systems should be taken into account. In some settings, referral linkages tend to be more appropriate, acceptable, effective and efficient than full integration of services. The 2013 consolidated ARV guidelines recommend delivery of ART in maternal, neonatal and child health care services in generalized epidemic settings; in TB care where the burden of TB and HIV is high; and, when provided, in OST settings.

Examples of integration are increasing, but there is a dearth of rigorous analysis of how best to integrate HIV services with other health programmes and how to measure the effectiveness of integration. Assessing and analysing the performances of various models of integration more systematically can reduce this knowledge gap. Indicators for gauging the integration of HIV into general health and development sectors are needed, as are methods for integrating the monitoring and evaluation systems of different service channels and platforms (11).

Integrate TB and HIV services

Despite recent progress, there were 320 000 deaths from HIV-associated TB in 2012—equivalent to 1 in 5 of HIV-related deaths and 1 in 4 of TB deaths globally. The vast majority (90%) of those deaths occurred in the African and South-East Asian regions (12, 13).

WHO recommends ART for all TB patients living with HIV, irrespective of their CD4 cell count—in addition to ART scale up at the population level, which will reduce the risk of people living with HIV developing TB (14). However, coverage of ART among people with TB in 2012 was lower than overall ART coverage rate for eligible patients (57% versus 65%) (13). When decentralized and integrated TB and HIV care are provided, service uptake tends to increase and overall patient outcomes tend to improve (15). For example, the delivery of integrated TB and HIV services has been shown to increase ART coverage among TB patients by 60%, to shorten by 72 days the time it takes for treatment to be initiated (16), and to reduce mortality by almost 40% (17). Currently, HIV testing and counselling in TB services, and the provision of cotrimoxazole prophylaxis in TB care settings, appear to be well integrated (12), particularly in the African Region, where 74% of TB patients knew their HIV status in 2012.

There are several models for providing integrated TB and HIV services simultaneously in the same place while paying due

attention to preventing transmission of TB in health facilities and other settings, such as harm reduction facilities. These models are outlined in WHO guidelines issued in 2012 (18).

Globally, more than half of the 59 focus countries surveyed by WHO reported that they were providing TB treatment in ART settings—and close to half were providing ART in TB clinics.¹⁸ However, mismatches between TB and HIV prevention, treatment and care services, and a lack of provision of integrated TB and HIV services, remain important challenges. The recent decision by the Board of the Global Fund to Fight AIDS, TB and Malaria to request countries with large TB and HIV burdens to submit single 'concept notes' provides an opportunity to prioritize the harmonized delivery of integrated TB and HIV services, and to coordinate them with programmes such as maternal and child health and harm reduction services.

WHO is developing technical guidance and support for more effective collaboration and integrated programming for HIV and TB. Key actions include producing programmatic guidelines and supporting implementation of operational tools for TB prevention, diagnosis and treatment within HIV health services. Guidance will also be provided on the joint management of TB and HIV for specific populations and settings, including links with harm reduction and prison health programmes.

¹⁸ WHO HIV Country Intelligence, unpublished excerpt 15 April 2014.

Link HIV with sexual and reproductive health and maternal and child health services ...

There are also opportunities to achieve greater impact by making HIV services part of the core interventions for maternal, newborn and child health services, particularly in settings with a high prevalence of HIV. Among the more obvious examples is the strong integration of PMTCT services in antenatal care, with 70% of the 118 countries that reported data in 2012 stating that they had integrated HIV testing, counselling and ARV provision within antenatal care services to prevent mother-to-child transmission of HIV (12). HIV testing is also being linked with child immunization services, and is being offered in paediatric in-patient wards, nutrition support programmes, community child care services, and other child health services (19, 20). In addition, services for HIV and for STIs, as well as other sexual and reproductive health services, are increasingly being linked or integrated. Two-thirds of 118 countries reported in 2012 that they had integrated

HIV in their sexual and reproductive health services (12).

More can be done to take greater advantage of the benefits of integrating HIV services more effectively with routine maternal and child health services, and with sexual and reproductive services. Integrating HIV testing services with routine infant immunization, for example, can help identify infants who are exposed or have acquired HIV and to link them and their mothers to care services in a timely manner (21). Accelerating access to HIV treatment for children is increasingly recognized as a key driver for improving broader child survival. Making the best use of this 'double dividend' is the central theme of an action framework launched by WHO, UNICEF, the Elisabeth Glaser Pediatric AIDS Foundation and the Government of South Africa at the 17th International Conference on AIDS and STIs in Africa in late 2013 (22).

... and with harm reduction programmes

There are many potential health benefits in linking HIV and harm reduction programmes. Needle and syringe programmes (NSPs) are a key harm reduction intervention for people who inject drugs. They substantially and cost-effectively reduce HIV transmission among people who inject drugs, along with reducing the transmission of other blood borne infections, such as viral hepatitis B and C.

NSPs also provide an ideal platform for delivering HIV and other health services, and for facilitating referrals to drug dependence treatment and opioid substitution therapy (OST) services. NSPs can be tailored to meet the needs of specific populations and settings, including prisons and other closed settings (23, 24). Public health programmes play a key role in working with drug control programmes to advocate for the introduction of NSPs for HIV

prevention and as broader good public health practice.

Wider coverage of OST and stronger integration of HIV, TB and OST services, as recommended in the 2013 consolidated ARV guidelines, hold great promise. As of April 2014, 11 out of 59 surveyed countries were providing ART in OST settings.¹⁹ A recent meta-analysis of studies done in North America, Europe and Asia confirmed that OST was associated with a 54% drop in the risk of HIV acquisition among people who inject drugs, and with enhanced adherence to ART (25). Global coverage of OST among people who inject opioids remains very low, however (26), even though some countries have expanded access in the past three years. These kinds of programmes need to grow in number and scope, with stronger links to HIV testing, care and treatment services (27).

... and with noncommunicable disease programmes

The global burden of NCDs is increasing, including in low- and middle-income countries, and among people living with HIV (28, 29). People living with HIV face increased risks of NCDs as a consequence of their HIV infection, and of side-effects associated with their treatment and with ageing—such as cardiovascular disease, diabetes, liver and pulmonary disease, and a range of non-AIDS associated malignancies (28–31).

More progress can be made in improving understandings of long-term metabolic complications associated with ARV regimens in different age groups, and co-morbidities related to ageing (32). At the same time, closer integration of HIV and various chronic NCD services offers many mutual benefits, for example using HIV services to screen people living with HIV for diabetes and hypertension.

¹⁹ WHO HIV Country Intelligence, unpublished excerpt 15 April 2014.

There are also important opportunities to link clinical and operational HIV guidance more closely to existing WHO recommendations for some major co-infections and co-morbidities—especially in relation to the management of chronic NCDs and HIV and the role of nutrition, integrated service delivery models and operational guidance. WHO

has defined a package of essential NCD interventions for primary health care in low-resource settings (33), and it is integrating key NCD interventions into relevant HIV guidance, such the 2013 consolidated ARV guidelines and the HIV guidelines for key populations.






Improve the management of HIV and viral hepatitis

Despite being a growing cause of morbidity and mortality among people living with HIV, including those on ART²⁰, viral hepatitis epidemics are largely neglected. Most people with chronic hepatitis B (HBV) or hepatitis C (HCV) infection are unaware that they are infected. HBV and HCV are growing causes of morbidity and mortality among people with HIV, including those already on ART. Because the disease is often left untreated or does not completely respond to treatment, chronic hepatitis is a major cause of liver cirrhosis and primary liver cancer in this population. Co-infection with HIV and HCV, which is particularly common among injecting drug users, frequently accelerates HCV-related progression of liver fibrosis and leads to a higher rate of end-stage liver disease and mortality. Viral hepatitis is responsible for an estimated 1.4 million deaths globally each year (34).

New, direct-acting antiviral drugs offer cure rates in excess of 90% for chronic HCV infection and effective treatment for chronic HBV infection. They have the potential to dramatically reduce morbidity and mortality in people living with HIV who are co-infected with HBV and/or HCV. WHO issued guidelines on the screening and treatment of HCV in early 2014 and will be launching guidelines on the screening and treatment of HBV in 2015. WHO guidance on the management of HIV and HBV/HCV co-infection addresses screening, treatment, care and key issues related to drug interactions, notably for ARVs and currently available HCV drugs. The first-line ART regimen recommended by WHO, containing TDF and 3TC, has a significant impact on HBV, and ART initiation is recommended in all people co-infected with HIV and HBV, and showing evidence of severe chronic liver disease, regardless of CD4 count.

Strategic Direction 2

ENHANCE BROADER HEALTH OUTCOMES

Integrate TB and HIV services		Strong model programmes and collaborative policy frameworks, but implementation can broaden
Integrate and link HIV services with maternal and child health, and sexual and reproductive health services		Good models of integrated services (especially for PMTCT), but coverage can widen
Integrate HIV services and harm reduction programmes		Good models of integrated prevention and care, but inadequate coverage and major legal and political constraints
Integrate HIV services and non-communicable disease programmes		Growing awareness needs to be translated into actual services
Integrate HIV and viral hepatitis treatment services		Increasing investments and interest, and new treatments offer hope

²⁰ Hepatitis C (HCV) affected 5–15% of the approximately 35 million people living with HIV worldwide in 2012, and up to 90% of those who injected drugs. See Mathers BM et al. Global epidemiology of injecting drugs use and HIV among people who inject drugs: a systematic review. *Lancet*. 2008;372:1733-1745; and Easterbrook P, Sands A, Harmanchi H. Challenges and priorities in the management of HIV/HBV and HIV/HCV co-infection in resource-limited settings. *Seminars in Liver Disease*. 2012;32:147157.

STRATEGIC DIRECTION 3

BUILD STRONG AND SUSTAINABLE HEALTH SYSTEMS

The principle that everyone should be able to access and use quality health services without risking financial hardship is beyond reproach. Achieving such universal health coverage means that health services must be within reasonable reach of those who need them, and that they should be available on terms and in ways that encourage

and enable people to use the services when needed. In addition, the costs of using those services—including indirect and opportunity costs—should not impose undue hardship on people. The expansion and adaptation of HIV services in recent years have blazed new trails in each of those areas.

Adapt service delivery models

The reach, capacity and impact of HIV services have been enhanced by reducing the numbers of clinic visits and check-ups that are required, decentralizing services down to community level, task-shifting²¹ prudently and strengthening community systems. The combination of task-shifting and decentralization, in particular, is enabling stressed health care systems to expand service delivery points and their human resources further without compromising the quality of care.

These approaches are saving costs and leading to simpler, quicker and improved services that are more accessible and acceptable (1–3), and are associated with an especially strong impact in the provision of ART and PMCT services in several African countries. Shifting the provision of ART to 'lower-level' health facilities has been associated with increased rates of HIV testing, use of antenatal services and ART uptake in some settings in East Africa, for example (4). At the same time, a lack of decentralization and task-shifting in some African

countries and in Asia appears to be inhibiting further expansion of service coverage.

Evidence from the African Region also shows that decentralized ART services may be better for patient retention (5, 6), that the quality of care generally matches or exceeds that provided at hospital-based ART clinics, and that treatment costs are lower in some cases (2, 3, 7). Findings of that nature informed the recommendation in the 2013 consolidated ARV guidelines (8) for decentralizing ART to primary health care settings (9).

However, in using these approaches, care must be taken not to displace costs and obligations elsewhere in the health system or onto communities themselves. Task-shifting has to be accompanied by adequate training, support and remuneration for staff acting in new roles, and those staff should be integrated into health care teams and should be mentored as their responsibilities grow.

Build stronger community systems

As the numbers of people eligible for HIV treatment increase, it is becoming apparent that decentralization and task-shifting within the formal health system may not be sufficient for managing the scale of demand in countries with a high prevalence of HIV. Community health workers are therefore increasingly important for expanding the capacity of stressed health systems to

provide care and support to large numbers of people.

Already, more than half of countries surveyed in the African Region, and 15–30% of countries surveyed in other regions, engage community health workers in ART support.²² A recently published systematic review of 21 studies from Africa (10) found that community health

²¹ The approach involves shifting certain roles from highly qualified health workers (typically few in number) to the more plentiful health workers with shorter training and fewer qualifications.

²² WHO HIV Country Intelligence, unpublished excerpt 15 April 2014.

workers²³ enhanced the reach, uptake and quality of HIV services, as well as the dignity, quality of life and retention in care of people living with HIV. In addition, their presence at clinics was reported to reduce waiting times, streamline patient flow and reduce the workload of health workers.

Involved and empowered community-based groups are a hallmark of successful HIV responses (11). Community-driven treatment literacy and support groups, 'buddy systems' and 'adherence clubs' to support ART patients (12), and community-assisted defaulter tracing procedures are vitally important for treatment programmes (12, 13). Community organizations support—and frequently also provide—HIV services for key populations (14).

There is growing evidence from the African Region of the effectiveness of these methods, especially in ART provision (15, 16). Dispensing ARV medicines in communities, rather than only at clinics and hospitals, appears to improve treatment adherence and seems especially effective in keeping men in treatment (17).

Studies suggest that the use of community workers and peer supporters to deliver HIV services also contributes to reducing stigma (18). The 2013 consolidated ARV guidelines therefore recommend community-supported ART delivery as a strategy to expand care for people receiving ART who are clinically stable (9). Evidence of the feasibility of home-based ART management (19, 20) has opened additional opportunities to strengthen treatment adherence in the years ahead.

Tapping into community systems, however, carries risks and responsibilities. Over-reliance on volunteers and community vitality cannot compensate for a lack of public sector infrastructure and services. The quality and continuity of health services delivered by community health workers, for example, is likely to suffer without sufficient investment in supportive systems and organizational policies, adequate supervision and mentorship, quality training, and programme resources (21–23). Building effective and sustainable community systems requires investing sufficiently in human and financial resources, and strengthening partnerships between community members and the public sector.

Strengthen strategic information

Effective and equitable HIV responses require a strong, up-to-date evidence base. This includes the regular monitoring of epidemic dynamics, the factors influencing epidemics and the performance of HIV responses. Routine health information systems need to track service coverage and quality and analyse data to ensure that lessons are quickly factored into operations. These strategic information needs are becoming more complex as HIV programmes mature. A rich range of innovations have been introduced—and are benefiting both HIV responses and health systems overall.

Understandings of the sources and rates of new HIV infections have improved considerably in the past three years. Dozens of countries have used modes of transmission methodologies to determine the main pathways of HIV transmission and guide their HIV strategies (24). More countries are collecting data and analysing their epidemics in ways that allow them to identify changing risk practices, where HIV is clustering, where localized epidemics may be emerging, where specific populations at high risk of infection are located, where vital HIV services are deficient or absent, and what factors are blocking access or uptake of those services. Key population size estimations and epidemic modelling are more widespread and accurate, and disaggregation of data by sex, age and population is increasing—improvements that are essential for

guiding HIV investments. However, collecting more information on key populations can carry risks with regard to confidentiality, particularly if law enforcement authorities and others use the data to locate, arrest and/or harass certain populations.

The monitoring and evaluation of programme performance and impact is more nuanced, due to the introduction of new indicators. More detailed and reliable information is being collected on cost effectiveness and cost efficiency, pricing and procurement of HIV-related commodities, and monitoring of drug resistance and toxicities.

Many of these advances stem from important new data sets that are being gathered routinely, including the Global AIDS Response Progress Reporting (GARPR) system (which is updated annually) and national mid-term reviews. Among the recent innovations is the Service Availability and Readiness Assessment (SARA), a health facility tool that is designed to assess and monitor service availability, and to assess to what extent services are equipped and ready to provide the interventions that they are supposed to deliver—including services for HIV. SARA can be used to guide the improvement of individual health facilities and to accredit them to provide certain services. When SARA is used in a representative sample of health facilities it also

²³ They included peer health workers, community volunteers, community health workers and lay workers.

offers solid data to inform national planning and direct investments in the health sector.

Countries have increased their use of national surveys such as the Demographic Health Surveys (DHS) and AIDS Indicators Surveys (AIS), and other population-based surveys. By 2012, more than 40 countries had conducted such surveys, some more than once. The use of recently developed technologies

makes it possible for these surveys to include testing to ascertain HIV incidence, viral load and levels of drug resistance. Meanwhile, WHO continues to play a leading role in reporting on the global and regional HIV responses. WHO also maintains key global databases, such as the Global Health Observatory, the WHO HIV Country Intelligence Database and the Global Price Reporting Mechanism for HIV-related medicines and diagnostics.

Health systems financing for a sustained response

HIV responses have continued to lead the way in devising ways to protect people against the financial risks associated with seeking health care. Many HIV services are provided free of charge at point of care, and countries increasingly also use supportive arrangements (such as decentralizing services or offering transport vouchers) to minimize the indirect costs for patients. Direct, out-of-pocket payments (including in situations where health care is nominally 'free') are now widely recognized as compromising uptake of services and threatening the well-being of poor households requiring health care (25).²⁴ These payments are on the decline, and are being replaced with various pooling and pre-payment arrangements,

as well as with conditional cash transfer and voucher systems (26).

These trends are part of a wider shift in an increasing number of countries towards structuring domestic spending on health in ways that can enable everybody to use the full range of health services they need. Experience shows that the best way to achieve this is with compulsory pre-payment of some type—for example taxes and other government charges, social insurance premiums—that are subsequently pooled to spread risks. Contributions should reflect people's ability to pay, which means that there will always need to be subsidies for the poor and vulnerable.

Domestic HIV funding is increasing ...

It is within this context that domestic expenditures on HIV programmes in low- and middle-income countries have increased considerably in recent years. Domestic sources accounted for more than half (53%) of funding for HIV globally in 2012, totalling an estimated US\$ 9.9 billion [US\$ 7.7–12.2 billion] (27). In several regions, domestic expenditure now constitutes the single largest source of funding for HIV treatment programmes.

A growing number of countries are pursuing additional financing methods specifically for their HIV programmes, including dedicated tax levies (such as Zimbabwe's AIDS levy, which made it possible to add an estimated 70 000

people to the country's ART programme in 2012, and the levies imposed on mobile phone use in Rwanda and Uganda) (28,29) and HIV trust funds (27,30). Savings, such as those achieved by reforming South Africa and Swaziland's tender processes in the past three years have also freed up funding to expand treatment coverage further (31).

Overall, an estimated US\$ 18.9 billion [US\$ 16.6–21.2 billion] was available in 2012 for HIV programmes in low- and middle-income countries—up by approximately 10% from 2011 (27), due mainly to increased domestic funding of HIV responses.

... but external support remains crucial for many countries

Despite the increases in domestic funding, in many lower middle-income and low-income countries the

amounts raised are still not sufficient to finance services of adequate quantity and quality for all who need them.

²⁴ An estimated 150 million people suffer financial catastrophe and 100 million people are forced beneath the poverty line each year because of out-of-pocket spending on health. See Xu K, Evans DB, Carrin G, Aguilar-Rivera AM, Musgrove P, Evans T. Protecting households from catastrophic health spending. *Health Aff (Millwood)*. 2007;26(4):972-83.

In 2012, 51 countries relied on international sources for more than 75% of HIV-related spending. ART programmes in particular rely heavily on international funding support. Domestic support for HIV programmes focusing on key populations is especially low, with international sources accounting for at least 90% of such spending in 2010–2011 (27).

Middle-income countries face specific challenges. As domestic economic outputs rise, countries may no longer be eligible for funding from many international development agencies and donors. Furthermore, they may encounter difficulties in negotiating affordable prices for HIV medicines, diagnostics and other commodities if they are then regarded solely as commercial markets rather than recipients of development assistance. However, since middle-income countries are home to a majority of the world's poor—an estimated 960 million people—these shifts are resulting in major health and social inequities, including in relation to HIV services (32).

The main external sources of HIV funding continue to be the US President's Emergency Plan for AIDS Relief (PEPFAR), which provided almost one quarter of total HIV funding available in low- and middle-income countries in 2012), the Global Fund to Fight AIDS, Tuberculosis and Malaria, UNITAID, various United Nations agencies, and European donor countries (27). Some of these funders have introduced innovative financing and purchasing approaches. For example, 65% of the US\$ 1.9 billion mobilized by UNITAID up to the end of 2012 was raised through a levy on airline tickets in a number of countries. Meanwhile, UNITAID's large

purchasing power enables it to negotiate lower prices for quality assured HIV medicines and diagnostics, which influences market dynamics in ways that benefit a wide range of countries in addition to those receiving direct UNITAID support.

Although the funding available for HIV programmes in 2012 fell short of the estimated US\$ 22–24 billion that will be needed annually by 2015 for the global HIV response (33), that target appears to be within reach. However, the 2013 consolidated ARV guidelines, which recommend earlier initiation of ART (thereby making more people eligible for treatment), imply a 5–10% increase in the total resource needs for the HIV response until 2025.

The importance of external funding therefore stands undiminished. However, for sustainability to improve, external funding has to become more predictable, harmonized and aligned with country priorities. Multi-year funding would enable countries to plan ahead with greater predictability. Emerging market economies, along with new private philanthropy, provide opportunities for expanding the donor base. For donor financing to help countries move towards universal health coverage, it should meet the criteria of effectiveness, efficiency and equity—which is more likely when donor aid is used to augment domestic pooled resources (for example in providing budget support) rather than financing fragmented projects. Health inequities need to be addressed, with development assistance reoriented to benefit poor people and communities wherever they are, while prioritizing low-income countries and ensuring that the poor in middle-income countries also benefit (32).

Invest in human resources for health

The recruitment and training of adequate numbers of health workers remains the mainstay of an effective health system. However, funding constraints, staff attrition caused by difficult working conditions, and an exodus of public health workers to high-income countries and to for-profit private facilities continues to weaken health systems in many low- and middle-income countries.

Countries are trying to compensate by expanding their use of task-shifting, deploying community health workers and relying more heavily on community networks and systems, as discussed earlier. However, the fundamental duty of ensuring universal health coverage is dependent on government leadership.

Comprehensive, long-term human resource planning for health services—both public and private—is a prerequisite for fulfilling that duty, as are quality-assurance measures and capacity building, and arrangements for integrating community-based support more solidly into the formal health system. The supply and quality of health workers in public health systems has to improve, and new forms of regional collaboration and coordination in the training and distribution of health workers need to be devised. Ensuring access to HIV prevention, diagnosis, care and treatment for health care workers, particularly in high prevalence settings, should be a core component of human resource planning.

Ensure affordable and reliable supplies of medicines and diagnostics

A comprehensive approach is the most effective way to ensure equitable, reliable and affordable access to HIV medicines and diagnostics. In addition to reducing the prices of commodities, countries are seeking savings by boosting efficiencies in service delivery and reducing wastage, and they are devising methods to achieve reliable and sustainable supplies of health commodities.

Vetting the quality of medicines

Every year, countries spend hundreds of millions of US dollars purchasing HIV diagnostics and medicines through international financing and/or procurement mechanisms. Standardizing and regulating the quality of these products is critically important to avoid wastage and inefficiency and to ensure safe and effective use (34).

By prequalifying diagnostics and HIV medicines, WHO helps ensure that countries and procurement agencies are able to procure medicines and diagnostics that meet international standards of quality, safety and efficacy. ARVs and other HIV-related medicines outlined in WHO guidelines are included on the WHO *List of Essential Medicines*, which informs countries' own national lists for procurement. By end-2013, WHO had prequalified 23 HIV diagnostics and one adult male circumcision device, 234 medicinal products for treating HIV-related conditions, and 12 active pharmaceutical ingredients for use in manufacturing related pharmaceutical products. The pre-qualification of suppliers has also helped put procurement on a more solid footing.

Building reliable supply chains

More accurate planning and more reliable supply chains are vital. Drug stock-outs are a recurring problem that discourages treatment uptake, weakens adherence and sabotages programme effectiveness. They are also an early warning signal for the development of HIV drug resistance. Although still a concern, the proportion of low- and middle-income countries reporting stock-outs declined slightly from 35% in 2011 (38/108 countries) to 30% in 2012 (30/98 countries) (35).

Several ways of avoiding or overcoming stock-outs have proved successful in recent years, including temporarily switching patients to a different ART regimen, transferring ARVs from other health facilities or regions, and purchasing emergency supplies from regional stores

in neighbouring countries (9).

Supported by the Clinton Health Access Initiative, UNAIDS provided funds for children's and second-line ARV medicines to 21 countries in 2012, while the PEPFAR HIV/AIDS Emergency Commodity Fund supported four countries in averting stock-outs of ARV and opportunistic infection medicines by funding the supply of ARVs, test kits and opportunistic infection drugs (9).

Forecasting treatment needs and demand for HIV medicines enables countries to develop reliable procurement plans to avoid stock-outs and wastage, and for manufacturers to plan their production capacity and distribution. Countries can also ease disruptions by ensuring they have sufficient buffer stocks (managed national or even regionally) to cope with any stock-outs that do still occur (9).

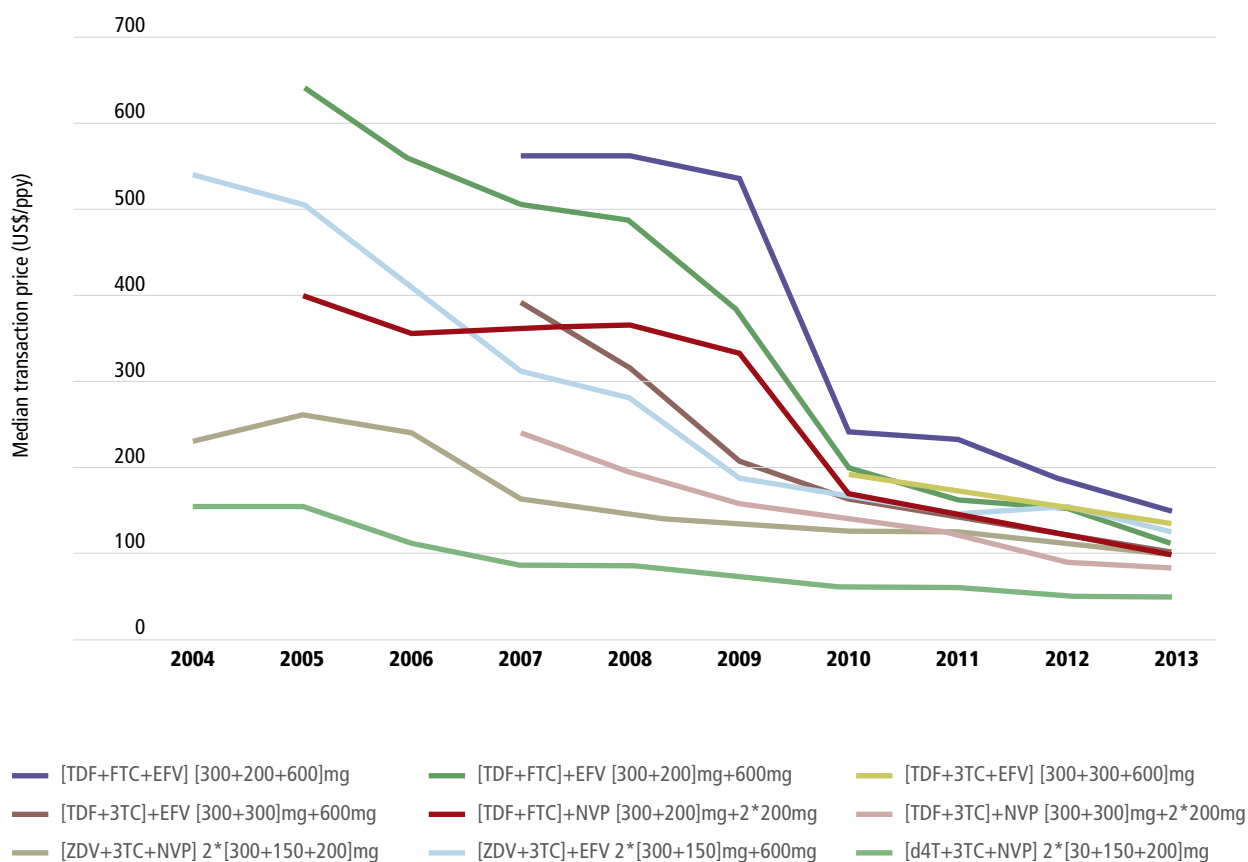
Making treatment affordable

Prices of ARVs continued to decline in the past three years, due to greater predictability of demand, economies of scale (as ART programmes are scaled up), and increased competition among manufacturers.

In 2013, generic manufacturers supplied 98% of all ARVs in low- and middle-income countries, at competitive prices. There has been significant progress in relation to voluntary licensing, partly facilitated through the Medicines Patent Pool (although middle-income countries outside the African Region typically are not benefitting from those arrangements). Buttressing the advances is the WHO Global Price Reporting Mechanism (GPRM) and the Regulatory Status database, which provide key information on manufacturers and prices of HIV medicines, facilitating price negotiations and sustainable supplies.

The cost of first-line ART in low- and middle-income countries has been reduced to a median cost of US\$ 97 for the cheapest, preferred regimen per person per year (36). Prices have continued to decline despite the wider adoption of more expensive TDF-based regimens. The median price per patient year of the WHO preferred first-line regimens is shown in Figure 14. However, there are middle-income countries that pay much higher prices. These tend to be countries with patents or data exclusivity provisions that limit the use of generic products.

Fig. 14. Median prices of WHO preferred first-line regimens per patient year, in US\$, in low- and middle-income countries, 2004-2013



Source: Data from the WHO Global Price Reporting Mechanism.







The prices of second-line regimens also declined substantially between 2010 and 2013, and most low- and middle-income countries can now access second-line treatment at about 330 US\$/patient per year. This development stems largely from the increasing availability of generic formulations. While it is important that second-line regimens become more affordable (9), the delayed diagnosis of treatment failure (often due to limited access to viral load testing) is also hampering their use. However, prices remain an issue in several middle-income countries that continue to pay very high prices. In addition, access to new drugs being used in salvage therapy presents a financial challenge to most low- and middle-income countries.

Deriving the maximum benefits from ART requires that second-line drugs and new drugs (some of which are

likely to be needed in first-line therapy in the future) are available at affordable cost. Limited patent protection on older drugs and voluntary licensing of newer drugs by the originator companies—along with generic competition—have made the current first-line treatment regimens affordable for most low- and middle-income countries. However, a continuing decline in ARV prices is not a foregone conclusion, and there are concerns that patent restrictions and a weakening in generic competition might render ART unaffordable again. Avoiding such outcomes will require continued commitment by all—including the producers—and vigilance from countries and communities. Countries need to ensure that patents are awarded only for genuine innovations, and should be careful about entering into new bilateral and multilateral free trade agreements that include provisions that may disrupt the future availability of affordable medicines (37).

Strategic Direction 3

BUILD STRONG AND SUSTAINABLE HEALTH SYSTEMS

Enhance service delivery methods		New models of service delivery, but infrastructure and basic resources remain inadequate in many countries
Strengthen community systems		Good models for community systems strengthening, but greater funding and capacity building are required
Enhance strategic information		New systems and methodologies being introduced, but data quality needs to improve
Make health systems financing sustainable		Increasing domestic funding and innovative funding channels, but challenges remain especially for low-income countries
Build human resources for health		New approaches to task-shifting and community systems strengthening improving service delivery, but basic capacity constraints remain a concern
Improve access to medicines and diagnostics		Dramatic reductions in prices and innovations in ARV regimens and point-of-care diagnostics

STRATEGIC DIRECTION 4

Reduce vulnerabilities and remove structural barriers

The success of HIV programmes is decided not only by political commitment, and funding of their technical components, but also by the legal, social and economic environments in which they operate. Stigma and discrimination has lessened in some countries, but still

confounds efforts in many places—as do the many laws and practices that deter or deny key populations and people living with HIV adequate access to potentially life-saving services. Gender inequalities and harmful gender norms also continue to stand in the way of more effective HIV responses.

Promote gender equality and remove harmful gender norms

Along with women's greater physiological susceptibility to HIV infection, gender inequalities are among the main factors underlying the disproportionately high HIV incidence among women and girls in settings with generalized HIV epidemics. Prevailing norms of masculinity also increase men's vulnerability to HIV, encouraging high-risk sexual behaviour, and deterring them from seeking timely health care (1). At a minimum, health services need to be provided in a gender-sensitive, confidential and non-judgmental manner, and need to reflect the respective concerns and realities of women and men.

Sex-disaggregated data collection is more common, and upcoming WHO guidance on strategic information will provide guidance for national programmes on appropriate disaggregation, analysis and reporting of data.

Some of the strongest efforts to promote gender equality in relation to the access and use of HIV services are occurring in countries in the African Region that have a high prevalence of HIV. The participation of women's groups and networks in HIV programmes is increasingly being encouraged (2), and efforts to engage men in overcoming harmful gender relations, although mostly small in scale, are also increasing.

Worldwide, one in three women have experienced intimate partner violence in their lifetime, making gender-based violence a problem of epidemic proportions (3). Violence against women is associated with a 1.5-fold greater risk of HIV and other sexually transmitted infections, as well as poorer clinical outcomes for people on ART (3–8). Women from key populations, such as drug users, sex workers and transgender women, are particularly likely to experience violence. Studies have shown a high prevalence of rape, physical violence and other forms of abuse among sex workers (2, 9–12).

These realities are rhetorically recognized, but effective responses to gender-based violence are rare, and few countries have national HIV strategic plans that address gender-based violence. At a minimum, legal recourse and psychosocial support for survivors of gender-based violence should be made more widely available. WHO guidelines recommend that health services (including HIV services) should identify women who are at risk of intimate partner violence, and should provide appropriate clinical and mental health care. WHO guidelines also recommend provision of comprehensive post-rape care that includes PEP for STI and HIV, and emergency contraception to survivors of sexual assault (13).

Various approaches for reducing violence against women, and especially intimate partner violence, have shown promise, including school-based programmes to prevent violence within dating relationships, strategies that combine microfinance support with gender equality training, the promotion of conflict resolution skills in communities, and campaigns to reduce the harmful use of alcohol. Interventions to promote equitable gender norms by working with men and boys, and through community mobilization, have the potential to reduce violence against women and to improve HIV-related outcomes (14). Community empowerment interventions with sex workers are also being implemented and have been shown to be effective in reducing vulnerabilities to HIV.

Structural interventions, such as schemes to empower women economically, have been expanding. Microfinancing schemes and conditional cash transfers are increasingly popular—and apparently effective—tools for improving the well-being and health of impoverished households, and especially women and girls, in low- and middle-income countries (15–17).

Advance human rights and promote health equity

When properly enforced, laws that protect human rights can expand access to important health services and enhance their reach, quality and effectiveness—especially for populations that are at higher risk of HIV infection.

A growing number of countries have removed HIV-related restrictions on entry, stay and residence. From 2000 to mid-2013, the number of countries, territories and areas with HIV-related travel restrictions fell by more than half—from 96 to 43 countries (2, 18).

Many countries have introduced anti-discrimination laws that prohibit discrimination against people in health care contexts (19). Yet protections that exist in letter are not necessarily materializing in people’s lives. More than half (54%) of the 133 countries reporting HIV spending in 2012 did not invest in human rights programmes as part of their HIV responses (2).

HIV-related stigma and discrimination in particular continue to undermine HIV responses, including the provision and uptake of treatment and care (20). Countries are increasingly documenting and publicizing the harmful impact of stigma and discrimination. Findings from those surveys and recommendations from the Global Commission on HIV and the Law have stimulated formal efforts to defuse stigma and discrimination.

Recent years have seen a shift towards introducing legal measures to protect people living with HIV against discrimination. A majority of countries now have anti-discrimination laws to protect people living with HIV (2) and many countries have introduced laws that protect people from discrimination on the grounds of sexual orientation or sexual identity. Although countries are also increasing access to legal aid services to help individuals obtain legal redress when their rights have been violated, these need to be supplemented with practical enforcement mechanisms for anti-discrimination laws.

There is also room for improvement in removing the remaining laws, regulations or policies that impede



effective HIV prevention, treatment, care and support for key populations and vulnerable groups (2). Even when such laws are not routinely enforced, punitive legal environments feed stigma and social marginalization, legitimize discrimination, and facilitate harassment by law enforcement officials, which disrupt the provision of HIV and other health services (21).

Almost all countries maintain laws that criminalize injecting drug use, a majority of countries prohibit or criminalize sex work, and a growing number of countries have or are considering laws that criminalize sexual intercourse between consenting adults of the same sex. These punitive approaches often violate human rights and they undermine public health efforts (22). Yet the public health consequences of homophobic laws and practices are profound: as shown in a recent study from an African country, where men who have sex with men who experienced homophobic abuse were five times more likely to have acquired HIV compared with peers who had escaped such treatment (23).

Several countries have begun shifting towards approaches that are based on public health considerations. A few, mostly high-income, countries have decriminalized the behaviours of certain key populations—notably sex workers and men who have sex with men. WHO guidelines on the prevention and treatment of HIV and other sexually transmitted infections for sex workers (24) and men who have sex with men and transgender people (25), endorsed by the United Nations Development Programme (UNDP), the United Nations Population Fund (UNFPA) and UNAIDS, recommend that countries should work towards decriminalizing these populations and eliminating the unjust application of laws and regulations against them. In 2012, 12 UN system agencies jointly urged the closure of compulsory drug detention and rehabilitation centres (2).

Generally, however, the HIV services for key populations in too many countries continue to operate in legal environments that violate the right to health.

Strategic Direction 4 REDUCE VULNERABILITIES AND REMOVE STRUCTURAL BARRIERS

Advance gender equality and remove harmful gender norms		Increasing awareness and promising approaches, but too little decisive action to enhance gender equality
Safeguard human rights and enhance health equity		Continued stigma and discrimination, disparities in access to essential services, and criminalization of key populations. Progress in a few countries, but worsening situation in some others.

CONCLUSION

The remarkable progress made in the global HIV response over the past three years is beyond question. After 30 years, the HIV epidemic continues to pose new challenges, and the HIV response also continues to generate innovation and leadership in many aspects of public health.

New approaches and technologies provide the world with the tools to effectively prevent, diagnose, treat and care for HIV infection. Diverse funding instruments, including increasing domestic funding, provide us with the means for delivering interventions to increasing numbers of people. Health and community systems are being strengthened to deliver more efficient and sustainable programmes, and broader health efforts are benefitting greatly from HIV investments and learning.

The accomplishments are impressive. The world is on track to reach several of the targets set in the Global Health Sector Strategy on HIV/AIDS 2011-2015, and it appears set to exceed at least one (reducing the number of HIV-related deaths by 50% by 2015).

Approximately 10.6 million people were receiving ART globally at the end of 2012, a number that is expected to have risen to around 12.5 million at the end of 2013.²⁵ Paediatric HIV infections are decreasing at a quicker rate than ever, and joint HIV and TB interventions are averting close to 400 000 deaths annually. The successes in Eastern and Southern Africa have been especially remarkable, and many countries in the Americas and Asia have consolidated the progress made with their HIV responses.

At the same time, there is a sobering reality that new HIV infections still eclipse the numbers of people starting HIV treatment each year. Progress is also uneven, and tends to be slower in areas where the required focus is lacking and where targets are defined less clearly—for example, HIV prevention, improving the quality and efficiency of services, strengthening health and community systems, and creating enabling environments.

A significant number of countries lag behind in delivering core HIV interventions. In many places access to appropriate services for adolescents is inadequate and expansion of paediatric services has not kept pace with those for adults. In addition, certain populations continue to be ignored or discriminated against, and the quality of programmes and impacts achieved vary considerably. The strategic information that is needed to guide more effective policies and programmes also is often missing or of erratic quality.

There have been disturbing reversals on some fronts. Most obvious are policies and practices that contribute to prolonging, escalating or catalysing HIV epidemics among

key populations. Dramatic increases in HIV incidence are occurring in some populations of men who have sex with men, including in communities that had successfully contained epidemics in the past. Barriers continue to block the delivery of evidence-based harm reduction programmes for people who inject drugs, while some countries are imposing increasingly punitive measures against men who have sex with men, and sex workers. Many HIV programmes also continue to ignore the realities and needs of transgender people. These setbacks are undermining the broader progress of the past three years.

Progress in implementing **Strategic direction 1** (Optimize HIV outcomes) has been solid. In the past three years, HIV programmes have benefitted greatly from innovations in prevention (such as the diversified use of ARVs for HIV prevention and the development of male circumcision devices), diagnosis (with emerging point-of-care diagnostics and improving approaches for early infant diagnosis, as well as self- and community-based testing), treatment (with optimized ARV drugs and ART regimens, and improved service delivery models), and care (such as improved management of co-infections including TB). Promising new treatments for chronic HCV infection offer a huge opportunity, if they can be implemented at scale. International PMTCT efforts are intensifying, and countries are increasingly pursuing the goal of dual elimination of HIV and syphilis through strengthened maternal and child health services. Comprehensive packages for specific populations and settings are also more clearly defined and promoted.

However, major challenges remain. The coverage and uptake of core HIV prevention interventions, such as female and male condoms and harm reduction, need to be enhanced. Early diagnosis of HIV infection in infants and paediatric treatments should improve, and quality services must reach adolescents, especially as they transition from child to adult services. Programmes have to identify people living with HIV early so that they can gain the full benefits of ARVs. And adherence and retention in care need to improve to achieve long-term viral suppression.

Actions under **Strategic direction 2** (Leverage broader health outcomes) have led to promising results. Collaboration between HIV and TB programmes has fostered model programmes for integrated HIV and TB service delivery. HIV programmes have stimulated the development and implementation of comprehensive harm reduction programmes for people who use drugs in some countries, including interventions to prevent opioid overdose, as well as prevention and management of HBV and HCV.

The commitment to eliminate new HIV infections in children now also encompasses the elimination of congenital

²⁵ A precise global estimate of the number of people on ART at the end of 2013 based on country reporting will be published by WHO/UNICEF/UNAIDS in July 2014.

syphilis, and the strengthening of maternal and child health services overall. A new focus on NCDs has alerted HIV programmes to the need to address ageing populations of people living with HIV and NCD complications of HIV infection and ART. There appears to be significant progress in successful integration and programme linkages, but widely accepted methods are yet to be settled for measuring such progress, assessing the cost-effectiveness and impact of integrated or linked services, and determining how best to organize such services.

There have been many successes under **Strategic direction 3** (Strong and sustainable systems). However, as with Strategic direction 2, it has been difficult to measure and quantify the overall benefits. HIV programmes have spearheaded innovations in almost all aspects of health and community systems. Despite concerns that the pressures of HIV programmes might overwhelm health systems, in many countries, health services—including primary health care, outreach services and laboratory systems—are now stronger and more versatile. The global HIV response has shown that:

- When the governance and management of health services becomes more inclusive, the reach and quality of those services tend to improve;
- Chronic care systems can provide comprehensive and integrated management across a range of health conditions and populations;
- Access to quality medicines, diagnostics and other commodities can be significantly increased and safeguarded through prequalification, strengthened procurement and supply management systems, interventions that reduce prices, and simplified treatment regimens and monitoring approaches;
- Despite human resource constraints, the prudent use of decentralization and task-shifting, and the deployment of community health workers boost access to and uptake of health services;
- Health information systems for HIV provide critical information that informs broader health policies and planning;
- Health systems financing can be transformed, both at international and domestic levels; and
- Active engagement of affected populations and the broader community contributes to more equitable, acceptable and efficient services.

Finally, under **Strategic Direction 4** (Reduce vulnerability and remove access barriers), HIV investments have elevated advocacy efforts around health equity, gender equality, human rights, vulnerability, stigma and discrimination. Many of the challenges are recognized, effective interventions exist, and political commitment to heed sound public health principles appears to be increasing. However, serious

concerns remain. In too many countries, appropriate action is still irresolute or even entirely absent. Stronger public health advocacy needs to be mobilized to promote appropriate policies and programmes, recognizing that human rights are central to good public health practice.

This review shows that the Global Health Sector Strategy framework has stood the test of time, and that the overall goal, targets and strategic directions have remained relevant over the past three years for guiding the global HIV response.

While attesting to the significant gains made since the launch of the strategy, the review also highlights important questions: Could we have achieved more? Have we fully exploited the many opportunities at hand, and applied new knowledge and tools rapidly enough? Have we made the most efficient use of funds and human resources, and capitalized fully on the considerable political will that has been generated? The answers to these questions, and the other lessons learnt since 2011 should inform implementation of the remaining two years of the strategy, while at the same time preparing us for a new HIV strategy beyond 2015.

The current phase in the global HIV response positions HIV within a much broader health and development agenda. It is clear that the post-2015 development agenda will need to address the unfinished business of the Millennium Development Goals and the HIV universal access commitments. Indeed, health features prominently in the discussions leading to the formulation of the post-2015 sustainable development goals, while HIV is generally recognized as a crosscutting issue that warrants consideration across a range of development areas. Such a perspective has the potential to significantly shift the direction of public health and, with it, the HIV agenda.

Prominent in the emerging thinking is the concept of universal health coverage that ensures all people have access to health services of sufficient quality and do not suffer financial hardship in doing so—a concept that will help guide the next phase of the HIV response.

For years now, HIV responses have been blazing a trail for universal health coverage, showing that well-defined packages of life-saving interventions can be introduced in unfavourable, even hostile, circumstances, and that they can be scaled up and sustained.

By applying the principles of universal health coverage, with a greater emphasis on quality, health equity and social and financial security, HIV responses can be accelerated and strengthened further in ways that benefit the broader public health and development agendas.

ABBREVIATIONS AND ACRONYMS

AIDS	acquired immune deficiency syndrome
AIS	AIDS Indicators Survey
ART	antiretroviral therapy
ARV	antiretroviral
AZT	zidovudine
CPT	co-trimoxazole preventive therapy
d4T	stavudine
DHS	Demographic Health Survey
EFV	efavirenz
eMTCT	elimination of mother-to-child transmission
FTC	emtricitabine
GARPR	Global AIDS Response Progress Reporting
HIV	human immunodeficiency virus
MSM	men who have sex with men
NCD	noncommunicable disease
NNRTI	non-nucleoside reverse transcriptase inhibitors
NSP	needle and syringe programmes
OST	opioid substitution therapy
PEP	post-exposure prophylaxis
PEPFAR	US President's Emergency Plan for AIDS Relief
PMTCT	prevention of mother-to-child transmission
PrEP	pre-exposure prophylaxis
STI	sexually transmitted infection
TB	tuberculosis
TDF	tenofovir
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO	World Health Organization
XTC	lamivudine or emtricitabine

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