Health systems implications of the 2013 WHO consolidated antiretroviral guidelines and strategies for successful implementation

Charles Holmes\textsuperscript{a}, Yogan Pillay\textsuperscript{b}, Albert Mwango\textsuperscript{c}, Jos Perriens\textsuperscript{d}, Andrew Ball\textsuperscript{d}, Oscar Barreneche\textsuperscript{e}, Steven Wignall\textsuperscript{f}, Gottfried Hirnschall\textsuperscript{d} and Meg C. Doherty\textsuperscript{d}

Introduction

To successfully implement the 2013 WHO consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection at country level, the implications for national and regional health systems need to be considered and addressed. The guidelines target the entire continuum of care for the HIV-infected individual, and in some cases, their partners, and those with unknown status. The guidelines include not only a more inclusive treatment initiation threshold of CD4\textsuperscript{+} T-cell count of 500 cells/\mu l or less for adults and adolescents, treatment for life for pregnant and breastfeeding women (or treatment for the duration of pregnancy and breastfeeding regardless of CD4\textsuperscript{+} T-cell count), treatment regardless of CD4\textsuperscript{+} T-cell count for children under 5 years of age, discordant couples, those co-infected with either tuberculosis (TB) or severe hepatitis B virus (HBV), and diversification of effective strategies to reach those with unknown status through couples testing and community-based testing.

These changes, if fully enacted, will lead to an increase in treatment eligibility of over 60\%, from 17.6 million globally, to 28.6 million globally, with variation in that increase by epidemic type and other epidemiologic factors [1]. However, within these increases in volume, health systems will be serving a healthier mix of patients starting antiretroviral therapy (ART), and greater proportions of pregnant women and children, and sexual partners seeking care together.

The increased patient volumes and changes in the composition of those seeking care will require rapid attention to existing care delivery strategies in order to ensure that newly diagnosed individuals are served with the maximum efficiency and effectiveness, and others entering or already within the system under existing guidelines are not harmed. Additionally, to be successful over the long term, health systems and HIV programs will need strengthened adherence-support strategies. Systems of care that may already be stressed need to be further augmented through innovations, and in many cases provided with additional resources in order to become more efficient, resilient, robust and effective. The ‘Operations’ and ‘Service delivery’ sections (Chapter 9) of the guidelines address these challenges through recommendations for innovations in the models of service delivery, laboratory diagnostics and treatment delivery in the form of fixed-dose combinations (FDCs) to improve the efficiency, reach and quality of the prevention, care and treatment cascade. There are also potential gains from implementing the guidelines that could accrue to and strengthen health systems and communities, such as a healthier and more productive workforce and fewer new HIV infections, especially in newborns, and HIV-related hospitalizations, and these benefits must also be factored into HIV program and country-level decision-making surrounding adoption and adaptation of the new guidelines [2].

Our objective was to examine the implications of the new guidelines across the continuum of care for each of the...
elements of national health systems, starting with governance and the role of strategic planning and policy, and including diversification of service delivery models, generation and use of data, healthcare financing, human resource capacity, and supply chains for therapeutic and diagnostic commodities.

**Governance, strategic planning and policy**

The progress of discovery and change in the HIV epidemic have demanded a high degree of engagement with evolving evidence, as reflected in part by the 10 guidance documents on antiretroviral drug use issued by WHO since 2000. To date, national governments, with the support of civil society and cooperative partners, have employed a variety of approaches to new guideline adoption. Whereas earlier approaches often focused largely on clinical issues, there is now a need for much broader adoption processes to consider the complex interplay between clinical objectives, operational feasibility, issues related to equity, affordability and health systems capacity.

In order to consider, adopt and implement new national guidelines with a broad coalition of support, Ministries of Health must take a strong leadership and governance role. When performed well, the key elements of the process at national level include the following:

1. An inclusive and transparent consultative process that draws upon the best available resources, including program experts and managers, healthcare providers, civil society including people living with HIV, community and faith-based groups, key populations, technical specialists, other relevant government Ministries (e.g. Finance), budget experts and economists, researchers, academics, and health-related professional associations.
2. Assembly, analysis and presentation of relevant clinical, programmatic and financial information.
4. Clear decision-making mechanisms that allow consideration of competing demands.
5. Clear articulation of roles and responsibility of various partners, in order to ensure accountability and oversight of the processes of change.
6. Ensuring that the case for health in national development, including the potential benefits and risks of potential guidelines changes, is clearly communicated early and often to political leadership and external development partners.

The recent process of developing and adopting new guidelines for antiretroviral drug use in pregnant and breastfeeding women in Zambia provides an instructive example of the range of activities needed to ensure that guidelines changes are made with broad stakeholder and health systems support (Fig. 1) [3,4]. National governments and civil society are encouraged to learn lessons from peers, and to participate in WHO’s regional guidelines dissemination workshops that are designed to support strong national processes of guidelines change.

**Diversification and integration of service delivery models to manage patient volumes and improve retention and quality**

The expansion of HIV testing, care and eligibility for ART will require national governments and partners to consider how best to augment or modify their current health systems to accommodate increased volumes and new categories of patients, and to ensure retention across the care and treatment cascade. There is currently an over-reliance on a limited number service delivery models in many countries. Maximum expansion capacity and quality can be achieved by ensuring that a carefully selected variety of models are put in place and adapted strategically to take account of geography, epidemiology and local needs. Thus, it is an opportune time for governments and funders to focus on previously piloted models that are appropriate for scale-up, and to ensure that the most effective models are scaled up systematically in order to provide substantial complementary capacity to absorb new patients and provide ongoing care.

Within the new guidelines, there is an increased emphasis on the importance of expanded national HIV testing and counseling strategies in order to identify ‘as many people living with HIV as early as possible after acquiring HIV infection, and link them appropriately and in a timely manner to prevention, care and treatment services’. The reality of most HIV-testing programs in most generalized epidemics is that they have been largely dominated by provider-initiated testing (most typically healthcare provider-initiated), which has been favored because of the ease of linkage to services and for its high yield and cost-effectiveness. However, it often identifies people living with HIV late in the course of HIV disease, in particular, men and adolescents, as well as key populations, who have low utilization of healthcare services.

With the guidelines’ strong recommendation for community-based HIV testing and counseling with linkage to prevention, care and treatment services, governments should consider systematically expanding a number of approaches tailored for their settings, including mobile, door-to-door, index, campaign, workplace and school-based HIV testing and counseling approaches, and other strategies that ensure the inclusion of underserved groups such as children, adolescents and men. It is also important...
to recognize that the yield of nonclinic-based testing can be lower and more expensive from a human resource perspective, requiring a careful balance to be struck. For concentrated and low-level epidemics, governments are urged to consider guidelines that reflect WHO’s strong recommendation to increase the number and diversity of the facilities in which provider-initiated testing and counseling are available, including sexually transmitted infection clinics, hepatitis and TB sites, antenatal care settings and services for key populations, notably MSM, transgender people, sex workers and people who inject drugs (Fig. 2) [5].

The capacity of national health systems to absorb the greater numbers of healthier, pregnant and individuals accompanied by partners eligible for treatment will be directly related to the extent to which ART sites are diversified, decentralized (and in some cases integrated into primary care services) and generally expanded. Extending care through different models will also relieve traditional ART sites and higher-level facilities and allow a greater focus on the sickest patients, especially in high-burden generalized epidemics. Models for consideration and rapid scale-up include ART initiation and maintenance for mothers and children in high HIV-prevalence settings integrated into antenatal care, and maternal and child health clinics, and for HIV/TB co-infected individuals into TB clinics, and other approaches that reduce the need of patients to come to clinics through community-based treatment clubs with rotating
Indonesia is still facing a growing HIV epidemic with an estimated nearly 600,000 people living with HIV in 2013. Most of the country (with the exception of Papua and West Papua provinces in the east where the epidemic is described as low-level generalized) is experiencing a concentrated epidemic particularly affecting populations such as people who inject drugs (PWID), SW and MSM. Epidemiological data confirm this trend in particular among MSM. According to Integrated Biological and Behaviour Survey (IBBS) data, in 2011 the prevalence of HIV among MSM was 12%, increasing from 5% in the previous survey conducted in 2007. Similarly, the prevalence of syphilis among MSM grew from 4 to 13%; and in Jakarta alone, HIV prevalence increased from 8 to over 17%. These data are consistent with low condom use reported. Added to this, progress on coverage of HIV treatment has been slow with an estimated 20% of those who need treatment (under the 2011 national treatment guidelines criteria of eligibility at 350 CD4) accessing ART by the end of 2013.

In response to this situation, the Ministry of Health and its partners decided to intensify its response giving particular focus to increasing coverage of HIV prevention and promotion of early treatment services with focus on key populations. This included the adoption of a Continuum of Care service delivery model of promoting district-level partnerships between public health services and civil society organizations as a way to increase HIV service utilization and supported starting ART regardless of CD4+ T-cell count for special groups such as sero-discordant couples, pregnant women, TB/HIV and hepatitis B/HIV co-infected patients and members of key populations living with HIV. This strategy is included in road map developed after a national consultation on scaling up antiretroviral drugs for treatment and prevention, which was endorsed by Ministerial Decrees.

In Indonesia, there are several encouraging examples of increased HIV service utilization; in particular, HIV testing and early treatment implemented in partnership of civil society organizations and the public health sector such as for MSM population in Bali. It is estimated that there are over 14,000 MSM in Bali many of whom have never been tested for HIV. Bali Medika Clinic (BMC), a community-run clinic, has provided free, friendly, comprehensive, ‘one hour – one stop’ STI and HIV diagnostic services in Kuta, Bali since October 2012. BMC works together with Yayasan Gaya Dewata, a local MSM organization, and two NGOs (Bali Peduli and Bali Rainbow Community) interested in supporting the MSM community in Bali. National and local public health authorities are partners in this project providing support for HIV testing reagents, antiretrovirals and some STI drugs for the clinic.

Following the recent Ministry of Health recommendation the BMC started to offer ART regardless of CD4+ in September 2013. From October 2011 through December 2013, 2140 new patients have been enrolled. There are 314 HIV+ individuals (19.5%) of whom 165 (58.3%) have initiated ART and 140 (84.9%) have continued ART and 15 (9.1%) were lost to follow-up. Median CD4 at ART initiation was 303 in a subset of HIV+ patients enrolled since September 2013. The Ministry of Health is currently considering supporting the replication of similar clinics providing services for MSM in partnership between civil society and public health sector in other cities of Indonesia.

Fig. 2. Innovative service delivery models to increase diagnosis and early antiretroviral therapy (ART) initiation among key populations in Indonesia.
antiretroviral drug pick-up and home delivery, especially in remote rural areas. A systematic review on the impact of decentralization of ART delivery identified evidence from both randomized controlled trials and observational studies, and found that patients initiated at a hospital and maintained at a health center were more likely to be retained [6]. No difference in attrition was observed between those initiated and maintained on ART at a hospital compared to at a health center. Comparable attrition was observed after 12 months in the two trials in which ART maintenance was in the community [6]. Regions with measurable injection drug use may also consider the new strong recommendation for ART initiation integrated into clinics and sites in which opioid substitution therapy (OST) is provided. In areas with strong general outpatient services, integration of HIV services may yield greater equity with other health services, and may more directly enable HIV’s chronic care models to benefit care and management responses to other chronic diseases such as diabetes and hypertension.

These integrated sites must also be capacitated with on-site laboratories and referrals with a rapid turnaround for results reporting, especially for viral load, CD4 T-cell count testing, TB testing and safety laboratories. Tiered laboratory systems must work closely with program leadership to ensure strategic investments in the best technologies for sites providing ART. Intentional analyses should be conducted to balance the convenience of point-of-care (e.g. CD4 T-cell testing) technologies with the use of centralized high-throughput instruments. With anticipated rapid expansion of demand for viral load testing, it is essential to use internationally acceptable methods to locally validate the use of dry blood spots, as a means of viral load testing, which will allow expansion of this capacity without phlebotomy and cold chain capacity – the imminent availability of point-of-care viral load testing will also strengthen the health system’s ability to provide good quality care. It is also critical to close the loop with results reporting via short message service or other secure electronic communication.

Existing and new models also need to be chosen in order to intentionally retain patients in care and treatment, and ensure adherence to ART. Structural interventions such as increasing access points and decentralization through community-based models can address some of the most commonly cited reasons for disengagement with care (e.g. transport expenses, overcrowding of vertical sites). At an individual level, substantial evidence has demonstrated the benefits of two-way mobile phone text message systems, and WHO has made a strong recommendation for consideration of this approach [7]. As with numerous other proven methodologies, very few countries have systematically evaluated the needs of various vulnerable groups such as pregnant women, adolescents, key populations and healthy individuals starting ART and systematically taken appropriate packages of cost-effective adherence and retention interventions from the pilot phase, to scale.

Generation and use of data for monitoring, evaluation, efficiency and quality improvement

National and regional health systems of program monitoring and evaluation are fundamental to public health approaches to HIV prevention, care and treatment, and other chronic illnesses. When they work well, systems of measurement serve to provide actionable data for decision-making, starting with the clinician and service delivery sites, to regional and national program managers, related sectors (e.g. Ministries of Finance), and development partners [8]. Although the HIV response has focused substantial investments on monitoring and evaluation, the nature of the emergency response combined with weak health systems and the sheer volume of chronically ill patients have resulted in greater than expected challenges for many national systems. These challenges have been highlighted in recent studies demonstrating serious gaps in the ability of these systems to report on indicators that meaningfully measure program quality, and a lack of consistent data use at the site and regional levels to improve program quality [9].

With the influx of individuals seeking testing and care, and through sites and models not traditionally reporting on ART use (e.g. community-based antiretroviral drug pick-up and antenatal care sites), there are actions that must be taken coincident with guidelines adoption to ensure effective monitoring and evaluation of program quality. National governments and supportive cooperative partners must redouble efforts to harmonize and strengthen platforms for the regular use of data at multiple levels of the health system to ensure that guidelines changes are implemented as expected and that quality of care and patient outcomes are not compromised. Optimal models include monthly or quarterly meetings convened by the Central Ministry of Health, provincial health offices and development partners (including their implementing partners) to review care and treatment cascade performance at the sub-national and local levels. These processes should be linked to performance against prespecified targets and quality improvement processes that ensure clinical sites regularly review their performance on critical elements of the care and treatment cascade and have flexibility to design affordable solutions to common barriers to quality and access to technical assistance as needed.

Refocusing on data use also helps to concentrate attention on the volume and types of indicators being collected and the information systems that underlie data collection. A proliferation of potential indicators over the years has in
some cases drawn attention away from those indicators considered highest priority at regional and national levels, and countries are encouraged to select their most critical indicators [harmonized with the Global AIDS Response Progress Reporting (GARPR) process] and ensure adequate performance in collecting the indicator [10]. WHO’s early warning indicators for HIV drug resistance represent another system of key performance indicators designed to inform quality improvement of ART services at facility level, with built-in capability for district and national-level aggregation of the results for program management purposes.

National governments and development partners also need to ensure information systems are operating sufficiently to allow regular reporting and use of the data. There are numerous open source and proprietary systems in use, although few are fully integrated across the cascade of care and treatment and supported at a national level. WHO is working with numerous countries to improve integration of systems using the ‘Three Interlinked Patient Monitoring Systems (3IPMS)’ for HIV care/ART, a series of generic tools and guidelines to help countries develop and implement a system that collects patient and population-level outcomes and assesses the impact in an integrated fashion across ART, maternal and child health (MCH)/prevention of mother-to-child transmission (PMTCT), and TB/HIV [11]. In 2014, WHO will release consolidated strategic information guidance that will bring together a globally endorsed minimum set of indicators across the continuum of prevention, treatment and care; these will highlight the key measures of quality HIV programs. With this effort, HIV program managers will have access to the critical indicators within one document, harmonized with other global indicators.

When regular data are not sufficient to draw conclusions about specific and important areas of the program, other methods may be employed, including use of representative sampling methodologies to collect more detailed information on critical issues that can herald problems with program quality, and qualitative information, before traditional indicators and targeted implementation science studies to evaluate the success of critical program changes (e.g. studies evaluating outcomes of pregnant women starting ART above CD4+ T-cell count of 350 cells/μl) [12].

Estimating funding needs, diversifying financing models and gaining efficiency

The HIV response requires ongoing and detailed attention to financing streams to ensure the sustained availability of funding for effective interventions, and with the right timing. Although the new guidelines will have much greater impact on health and incidence of new infections and have the potential to reduce out-year costs, the upfront costs of their implementation are substantially higher [1]. Ministries of Health and Finance have three critical joint challenges with regards new guideline adoption: to estimate the epidemiological and financial impacts of potential guidelines changes in order to assist with local planning and prioritization, to secure diverse funding streams to support ongoing and planned changes to programs, and to ensure the efficient use of available funds.

Estimation of the costs of potential guidelines changes can be accomplished using a variety of models, and some countries have been making these types of projections for years. As described in section 10.8 of the guidelines, the Spectrum suite of models is one of the most commonly used, and its AIDS impact, goals and resource needs models can be used to estimate the impact of guidelines changes on number of deaths, number of infections, and the associated marginal costs of changing guidelines or approaches in a variety of epidemic types [13]. Other projection models include the One Health Tool, and models developed by the Clinton Health Access Initiative (CHAI), and US President’s Emergency Plan for AIDS Relief (PEPFAR), each with various features and potential advantages [14]. Countries are encouraged to consider that any model is only as good as its ease of use, level of support, and structure; attention must be paid in particular to ensuring the soundness of local epidemiological information, programmatic inputs, and unit costs.

Although donor funding has comprised the bulk of funding for the HIV response over the first 10 years of the response in many low and some middle-income countries, leading national governments have begun to increase their share [15]. The ability of the domestic funding in low and middle-income countries to further support the HIV and broader health response will be increasingly important, especially if traditional donor funding continues to plateau. These new guidelines present a singular case for changing the course of the HIV epidemic, and further domestic resource mobilization may be compelled by the idea of ‘buying impact,’ (e.g. investing more in antiretroviral drugs in the next year may reduce HIV incidence so that future generations are less at risk for infection). These arguments may also be helpful in encouraging the contributions of private sector, innovative financing schemes such as the Pledge Guarantee for Health (PGH), and as motivation for development of national insurance schemes that have the potential to provide a more sustainable tool for the HIV response and general health [16,17]. The African Union has illustrated a commitment to working with member states to increase domestic funding for HIV.

Establishing regular methods for reviewing the efficiency by which the healthcare system uses resources to produce
key outputs and outcomes will also help to justify and further motivate resource investments. For instance, being able to track the range of expenditures required to provide ART to an individual, or provide an HIV testing and counseling service, by province or region, allows examination of outliers, and for refocusing activities [18]. Development partners have made investments in developing these methods over recent years, and national governments are encouraged to join joint exercises to better understand and direct resource use as the new guidelines are implemented.

Ensuring adequate human resource capacity to support evolving service delivery models

Shortages of trained personnel to deliver the range of services required to deliver quality healthcare are a chronic bottleneck in many countries. Clinics, in many low and middle-income countries, with thousands of patients, are in some cases staffed by only 1–2 clinical officers and nurses, leading to long wait-times and frustrations for patients and a lack of attention to quality improvement. Fortunately, the new guidelines have streamlined many of the main HIV interventions (e.g. a single first-line recommended regimen, available in one pill once daily for HIV-infected adults), and a focus on ensuring patients start ART before they develop complicated HIV-related illnesses. These ‘simplifying’ trends will further allow national programs to shift routine care delivery to personnel who require less training and to diversify service delivery models and expand community delivery of treatment. The new guidelines also include recommendations for task shifting ART initiation to trained nonphysician clinicians, and for trained and supervised community health workers to dispense ART between regular clinic visits. South Africa has been a leader in generating the evidence for these recommendations and has successfully leveraged task shifting as a means of increasing the number of sites and providers able to serve HIV-infected individuals (Fig. 3) [19–24].

Even as countries rapidly adapt and scale-up new models of delivery, the guidelines changes provide a good opportunity to evaluate the current deployment of various levels of personnel, and to use accepted rapid evaluation tools to assess estimated future requirements. For instance, the CHAI has developed tools that allow national governments to estimate the need for additional healthcare workers based on various guidelines choices. These tools can also help countries to model approaches to distributing and deploying healthcare workers,
including laboratory staff [25]. These projections can form the basis for discussions with professional societies, schools of nursing, pharmacy, laboratory and medicine, and training programs for other cadres, including community health workers and peer educators.

In order to realize the full potential of the health workforce, including substantial numbers of new types of health workers, governments must commit to regular monitoring of program performance and ongoing support for the development of healthcare workers. It is also important to reform regulatory frameworks to enable state support and recognition for new types of health workers that have proven themselves essential to the HIV response, including peer counselors and community health workers. These cadres with the closest links to communities have often been considered volunteers, but now are increasingly relied upon for long-term delivery of services and must receive compensation or incentives, and opportunities for career growth [26].

**Ensuring national supply chains are prepared for the increase in volumes and changes in the mix of commodities**

Many of the critical interventions outlined in the new guidelines are reliant on a consistent supply of essential commodities. Although national supply chains have improved tremendously in the past 10 years of the global HIV response, especially for antiretroviral drug supplies, there remain serious challenges in ensuring that clinics have adequate stocks [27]. For example, interruptions of rapid test kit supplies at the site level undermine the efficiency and effectiveness of PMTCT, ART, and testing and prevention programs [28]. With more frequent and expanded testing capacity underlying plans for reaching individuals before their CD4+ T-cell count falls below 500 cells/μL (in the case of adult treatment), and rapid expansion of viral load capacity, countries will want to ensure that test kits and related commodities are treated with the same sense of urgency as antiretroviral drugs.

Critical activities for the rollout of new guidelines include assessment of the capacity of the infrastructure and human resource capacity for storage, transport and data management of the national supply chain(s) for medicines and diagnostics. Specific considerations need to include decisions on antiretroviral drug selection that maximize the use of fixed-dose formulations in order to ensure adherence and simplify supply chains; the potential for viral load testing to drive up demand for second and possibly third-line regimens; estimated quarterly requirements for additional HIV rapid test kits (and other point of care diagnostic supplies such as point-of-care CD4+ T-cell and TB molecular testing reagent cassettes, and pediatric and adult antiretroviral drug formulations given planned pace of scale-up; assessments of the causes of site-level supply shortages, and targeted deployment of available technical assistance resources; and monthly national reviews of site-level stocks of select commodities, with accountability placed at the highest levels of government and donor agencies.

Countries will likely have the greatest success with ensuring regular supplies of key commodities such as HIV rapid test kits, antiretroviral drugs and critical laboratory reagents if their demand projections are regularly updated, communicated to their suppliers (manufacturers or supply agents), and fed into global market surveys. The latter is important because the organizations maintaining them (WHO and the Global Fund to fight AIDS, TB and malaria) work with major donors to forecast the demand for various types of products, which enables the manufacturers to anticipate the demand for their products. In addition, the Coordinated Procurement Planning Initiative uses this information and financial risk assessment to help prevent national-level stock-outs. Reporting of stock-outs by users of health services as well as civil society organizations should be encouraged by national governments to ensure that stock-outs are known as early as possible so that action may be taken.

In conclusion, the new WHO consolidated guidelines reflect not only evolving clinical science, but also advances in the science and practice of service delivery and program implementation. The most effective processes of guidelines change are convened by government, and reflect transparent, data-driven, consultative processes in which benefits, risks, and priorities can be weighed by multisectoral partners with a stake in the outcome. It is expected that most countries will determine that there is a need to make investments in the diversification of service delivery models, use and collection of data, development of human resources, and supply chains in order to accommodate increased patient volumes and to maintain quality across the care and treatment cascade. If implemented thoughtfully, and with careful regard for the essential elements of national health systems, the new guidelines could yield substantial impacts for individuals living with HIV and public health.

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**Conflicts of interest**

There are no conflicts of interest.

**References**


