

JOEP LANGE
INSTITUTE
REPORT

ENSURING EFFORTS TO SCALE UP, STRENGTHEN AND SUSTAIN HIV RESPONSES

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AIDS
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ACRONYMS AND ABBREVIATIONS

SUMMARY OF THIS REPORT

1. INTRODUCTION AND OVERVIEW

- 1.1 The perils within progress: what treatment scale-up cannot deliver
- 1.2 The rationale and goals of this report: above and beyond Fast-Track

2. CHALLENGES TO A SUSTAINABLE AND EFFECTIVE GLOBAL HIV RESPONSE

- 2.1 The stalled and volatile state of HIV financing
- 2.2 Ensuring quality of HIV treatment delivery
 - 2.2.1 Consistency of drug supply
 - 2.2.2 HIV drug resistance (HIVDR)
 - 2.2.3 Overburdened health systems and underfunded support systems
- 2.3 Reinvigorating HIV primary prevention
 - 2.3.1 Prevention funding gaps
 - 2.3.2 Lack of data on population sizes and HIV incidence

3. GUIDING PILLARS OF A FRAMEWORK FOR IMPROVED, LONG-TERM RESULTS

- 3.1 Differentiated service delivery
 - 3.1.1 Simplicity within complexity: can DSD contribute to improved responses for all?
 - 3.1.2 What to look out for: challenges in the DSD approach and models
- 3.2 Community engagement
 - 3.2.1 Components of a vibrant community-based response: examples from the field
 - 3.2.2 Barriers and other challenges to enhanced community engagement
- 3.3 Integration
- 3.4 Financing
 - 3.4.1 The importance of multiple sources
 - 3.4.2 Options and opportunities for sustainable future financing

4. CONCLUSION AND RECOMMENDATIONS

ANNEXES

- Annex 1. Methodology
- Annex 2. Options and recommendations to improve measurement of HIV incidence
- Annex 3. Toward a more perfect UHC: challenges and concerns for HIV inclusion and integration
- Annex 4. What community leadership can accomplish: successful shift to government funding for key population prevention services in Macedonia
- Annex 5. Country examples of insurance schemes that are critical components of UHC efforts

Nduku Kilonzo
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**“We are not on
track of ending
AIDS by 2030.
This report really
begins to ask:
what do we need
to do differently
and how do we
get there?”**

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ACRONYMS AND ABBREVIATIONS

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ART =	antiretroviral therapy
ARV =	antiretroviral drug
CBO =	community-based organization
CHW =	community health worker
DSD =	differentiated service delivery
Global Fund =	Global Fund to Fight HIV, Tuberculosis and Malaria
JLI =	Joep Lange Institute
MIC =	middle-income country
MSM =	men who have sex with men
NCD =	non-communicable disease
ODA =	official development assistance
PEPFAR =	US President's Emergency Plan for AIDS Relief
PMTCT =	prevention of mother-to-child transmission
PrEP =	pre-exposure prophylaxis
SDG =	Sustainable Development Goal
UNAIDS =	Joint United Nations Programme on HIV/AIDS
WHO =	World Health Organization

Note on text: All '\$' figures are US dollar amounts.

SUMMARY OF THIS REPORT

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Driven by the UNAIDS Fast-Track initiative, the rapid scale-up of HIV treatment is transforming the lives of millions of people worldwide. But it is not sufficient on its own, no matter how many countries achieve the 90-90-90 targets or how quickly they get there. This report offers a broad framework for building on and expanding the Fast-Track successes so that the main goal can realistically be met: epidemic control, defined as eliminating new infections and ensuring all people living with the virus have access to the quality treatment and support services they need.

The information, analysis and observations in this report are based on seven consultations with a wide range of policy makers, scientists, advocates and service providers over a year through April 2017. The overall initiative was convened and supported by the Joep Lange Institute.

The report focuses primarily on identifying challenges, gaps, and weaknesses in the current response that must be confronted not only so that scale-up can continue, but so that overall approaches are strengthened, expanded and sustained in diverse contexts across an increasingly integrated health and development environment.

Key challenges and gaps

Challenges discussed in this report that could jeopardize efforts control the epidemic and to provide all people initiated on antiretroviral therapy (ART) with high-quality treatment and care include the following:

- stalled and declining funding for HIV responses
- rising rates of HIV drug resistance
- drug shortages and stock-outs
- overburdened health systems
- inadequate support for community systems
- lagging success in primary prevention
- failure to reach and support the most vulnerable, including key populations

Framework for the future

Potential solutions exist for all the challenges mentioned above. Each is likely to be needed, but none will be sufficient on their own to build, strengthen and sustain the kind of HIV responses ultimately needed. **This report proposes that most challenges and solutions be considered through the lens of four themes or pillars that should guide future work: differentiated service delivery (DSD), strengthened community systems, integration, and innovative and sustainable financing approaches.** All four are approaches through which fundamental changes can be made that collectively create a framework that could turn the tide everywhere, for everyone.

Recommendations

There is no magic bullet in this report, or anywhere else, that will solve all the current barriers described to ensure the quality of HIV treatment, prevention and care services that reach all in need and can reasonably be sustained. However, there are many steps that can be taken to lay the groundwork for achieving the kind of thorough, quality-centered framework required for ultimate success. **In Section 4, this report presents a series of specific, targeted actions and decisions that should be taken within the recommended priority challenge areas below:**

- reinvigorating primary HIV prevention
- improving data collection on HIV incidence and population size, to better target prevention spending and interventions
- preventing a resurgence of HIV in middle-income countries (MICs)
- scaling up resources for community-based responses
- strongly and quickly confronting HIV drug resistance
- realizing the promise of new and mobile technology
- developing HIV-inclusive universal health coverage (UHC) platforms and schemes

Mark Dybul
Professor, Joep Lange Chair and Fellows Program

**“What we really
need is people
who are willing
to see and hear
the world in a
fundamentally
different way”**

1. INTRODUCTION AND OVERVIEW

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1.1 The perils within progress: what treatment scale-up cannot deliver

Snapshot from a year in the global HIV epidemic

The estimated number of people living with HIV topped 100 million for the first time as the year came to an end. It was widely assumed, though, that this milestone was reached years before, as HIV estimates have become increasingly unreliable due to challenges with measuring incidence and prevalence, especially in key populations. The majority of those newly infected do not know their status and have little incentive to find out because no viable treatment options exist: HIV strains resistant to most available drugs predominate, and effective new antiretroviral combinations are years away from development and availability because the pharmaceutical industry, citing insufficient profit incentive, stopped developing new HIV drugs.

Annual deaths from AIDS have risen steadily for a decade, surpassing 4 million the previous year. Pervasive AIDS-related fear, prejudice, intolerance and bigotry likely mean, however, that far more people died from HIV-related causes that were hidden or obscured.

Fear and stigma also have contributed to ongoing failure, and often simple abandonment, of traditional prevention efforts. Globally, annual new infections started increasing years ago after stalling for a time at about 2 million. The estimate for the past year—also thought to be highly imprecise—was that about 5 million people were newly infected. Pre-exposure prophylaxis (PrEP) long ago became useless in the era of blanket drug-resistance. Requesting or using a condom is rare and frowned upon, given renewed emphasis on abstinence and shaming of people with sexually transmitted infections and unwanted pregnancies. Prevention of mother-to-child transmission (PMTCT) efforts are increasingly failing, reversing trends in which several countries had claimed elimination of vertical transmission: Last year an estimated 500,000 babies were born with HIV. Among adolescents, HIV is by far the most important killer.

In a growing number of countries, uncontrolled HIV epidemics have led officials to resort to laws and policies to criminalize behaviors that risk transmitting HIV. People living with HIV and others assumed to be highly vulnerable to HIV and likely to have it, including members of key populations, are prohibited from having sex outside of marriage. Several nations now have laws and policies mandating that people identified as (or accused of being) gay or transgender must be arrested and put to death. Many have introduced, expanded and institutionalized methods identified years ago as being politically popular in the Philippines and other places to deal with drug users: immediate removal from society altogether (i.e., sanctioned killing by the state).

Those lucky enough to avoid such fates typically have their housing, education and employment opportunities curtailed and regulated, with enforcement by the police and armed forces. Most are denied access to health services of any kind, although in many middle- and lower-income countries health options are limited even for those not living with HIV or subject to official discrimination (excluding the small minority who can afford private care). The failure of high-profile universal health coverage (UHC) efforts—due in part to faltering economies, inefficient insurance systems and negative demographic trends attributed to newly surging HIV epidemics—put to rest hopes raised a decade ago about eventual access to and availability of comprehensive health services for all.

The snapshot above is from the year 2030. Or rather, it could be. Such a doomsday scenario, which evokes the early years of the HIV response, may seem implausible or overly pessimistic given recent successes. But some version is not so far-fetched if those successes are not built upon and maintained.¹

Under the guidance and influence of the 2030 Agenda for Sustainable Development and its wide-ranging Sustainable Development Goals (SDGs), the world today is at a critical point in the nexus of HIV, health and broader development. With the current focus on integration and universal health

coverage (UHC), countries, donors and international institutions must determine where, how and to what extent HIV can be integrated into the future health and development architecture.

Such structural and conceptual evolutions present myriad opportunities to expand, improve and sustain HIV responses. But these opportunities cannot be recognized and exploited without more careful thinking and prioritization, followed by suitably aggressive action to ensure that all countries will accommodate a framework and momentum for truly comprehensive and transformative HIV responses. Failure to achieve this objective could stall or reverse some of the phenomenal successes over the past two decades, thereby leading to a downward spiral to environments not far removed from the devastating 2030 scenario presented above.

The successes are worth recalling to put in perspective both what has been gained and what could be lost. For example, more than half of the world's 37 million people living with HIV have initiated antiretroviral therapy (ART).² The roll-out and prioritization of PMTCT services have averted an estimated 2 million new infections in children since 2000—1.6 million of them since 2010 alone.³ According to a recently released Global Burden of Disease Study, years of life affected by disease or early death fell by 44% for HIV/AIDS between 2006 and 2016.⁴

The rapid scale-up of ART in recent years is a main factor in these successes. This scale-up has accelerated both in terms of programming emphasis and impact (i.e., numbers) since the launch in 2014 of the Fast-Track initiative by the Joint United Nations Programme on HIV/AIDS (UNAIDS). A core part of this initiative is the so-called 90-90-90 targets calling on countries to aim for 90% of people living with HIV to be diagnosed, 90% of those diagnosed to be accessing ART, and 90% of those accessing treatment to achieve viral suppression by 2020.⁵ Some countries—including several low-income ones with high HIV burdens—have achieved, or are close to achieving, one or more of these targets.⁶

The benefits of target-motivated treatment scale-up to both individuals and the public health are enormous. An important concern, though, is that countries are using these core targets as the sole or primary gauge of the scope and effectiveness of their overall epidemic responses. Yet, reliance on these blunt indicators is a limited strategy because they reflect progress in only a narrow set of treatment areas and only in terms of sheer numbers (quantity).

Treatment initiation is a means, not an end. **Despite the powerful, proven value of treatment as a way to prevent HIV transmission, treatment on its own will not be able to lower HIV incidence to the levels needed for epidemic control, however 'control' is defined.**⁷ Some 2 million new infections every year worldwide⁸ underscore the weakness of prevention programs overall. Moreover, quality of treatment is just as important as quantity, especially when considering the success of longer-term responses relies on high rates of adherence and retention in care—which in turn are dependent on a full range of drugs and services being consistently available, accessible and acceptable to all in need.

Meeting the 90-90-90 targets is not the end of AIDS. The millions who are on treatment must take quality ART consistently for the rest of their lives, which in most cases should mean multiple decades. Given current trends and trajectories in new infections and ART scale-up, a world in which 40 million people or more are on HIV treatment until at least the year 2075 is not far off. Planning now is needed for long-term, sustainable solutions to maintaining treatment effectiveness and improving prevention efforts.

1.2 The rationale and goals of this report: above and beyond Fast-Track

In 2016, at a General Assembly High Level Meeting on HIV, UN member states released an unprecedented Political Declaration on HIV and AIDS and committed to achieving the Fast-Track targets proposed by UNAIDS two years earlier. This ambitious set of HIV treatment and prevention targets is aimed at ending the HIV epidemic as a public health threat by 2030.⁹ Modelling developed for the Fast-Track initiative estimates that rapid scale-up and sustained viral suppression could reduce both HIV deaths and rates of new infections by 500,000 by 2020, with an 81% global reduction in AIDS deaths and 89% reduction in new infections by 2030. The Fast-Track initiative further asserts that if new infection rates are not significantly reduced within the projected time frame, the HIV epidemic will rebound and progress made to date will be undone.¹⁰

The Fast-Track initiative is more than a set of aspirational goals. At both global and national levels, it is setting the foundation upon which HIV strategic planning and evaluation are built.¹¹ Fast-Track, in other words, is embedded in the global HIV response.

This report starts from the premise that the Fast-Track initiative may not be sufficient on its own to guide and direct the kind of comprehensive responses needed to avoid even a tiny echo of the doomsday 2030 scenario above. One reason is that the initiative is only being implemented selectively in many countries, with important prevention, human rights and social support targets ignored or forgotten as emphasis focuses on treatment progress. Another reason is that target-based approaches set at a global level suggest that ‘one size fits all’ strategies are appropriate for every context. Countries must have programmatic and financial space to look beyond, including more deeply into what is driving their epidemics and how the specific factors and conditions can be addressed more directly, effectively and equitably.

Globally, annual AIDS deaths were estimated at 1 million in 2016, a decline of 48% from a peak in 2005 and HIV prevalence has fallen or remained relatively stable over the past few years in most countries, including many higher-burden ones in sub-Saharan Africa¹². Results from ongoing comprehensive Population-based HIV Impact Assessments (PHIAs) indicate that several low-income countries with substantial HIV epidemics have come close to achieving at least one (and often at least two) of the three main 90-90-90 treatment targets.¹³

These relatively positive trends and numbers obscure others that should be cause for great concern in all countries. Since the 90-90-90 targets were introduced by UNAIDS in 2014, a growing body of information has become available about the effectiveness of program scale-up. Despite great progress, most countries are struggling to fill gaps in their HIV treatment cascades—a model that outlines the sequential steps or stages of HIV medical care that people living with HIV go through from initial diagnosis to achieving the goal of viral suppression, and shows the proportion of individuals living with HIV who are engaged at each stage.¹⁴ There is conflicting data regarding the real-world effect of treatment on HIV incidence.¹⁵ There are reports that the ever-increasing number of clients is overwhelming some health facilities and workers, increasing crowding and wait times.¹⁶ HIV program data are raising concerns about gaps in quality, including suboptimal retention rates.¹⁷ Drug-resistance rates are increasing, including rising rates of pre-treatment and acquired drug resistance, with children and adolescents at increased risk.^{18,19,20}

The goal of controlling the HIV epidemic by 2030 is laudable and potentially achievable, at least when defined as eliminating new infections and ensuring all people living with the virus have access to the quality treatment and support services they need. However, this goal will be difficult to reach if there are insufficient resources available and/or if programs do not have the capacity to adequately scale up health and support services to tens of millions more people over the coming years. Setting programmatic targets based on the Fast-Track initiative without sufficient resources to achieve them could overwhelm health systems and lead to reduced quality of care that could ultimately harm clients and undermine public health goals.

The intention of this report is not to dispute the Fast-Track goals. Rather, it is to encourage critical analysis of their impact and feasibility as more information is gathered, with responses to that information influencing the development and implementation of improved strategies for increased effectiveness.

The report aims to support the development of HIV response frameworks that reflect the implementation of long-term and sustainable results. It focuses primarily on identifying challenges, gaps, and weaknesses in the current response that must be confronted not only so that scale-up can continue, but so that overall approaches are strengthened, expanded and sustained in diverse contexts across an increasingly integrated health and development environment.

Many of the shortcomings—and proposed solutions to them—are well known and have received extensive attention. This report seeks to present them collectively, to show how and why they are linked and interdependent, and to propose a set of priority recommendations that reflect the realities and expectations of the current HIV and development domains.

Lillian Mworeko

Executive Director, International Community of Women Living
with HIV & Chair Joep Lange Preconference AIDS2018

**“Global Goals
will only be
achieved when
investments are
put in community
responses and
structures”**

2. CHALLENGES TO A SUSTAINABLE AND EFFECTIVE GLOBAL HIV RESPONSE

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2.1 The stalled and volatile state of HIV financing

No realistic scenario for future HIV responses can ignore the constraining impact of funding shortfalls. To meet the Fast-Track goals, UNAIDS estimated in 2014 that investment in HIV programs in low- and middle-income countries (LMICs) would need to increase by about one third, from approximately \$19.2 billion available in 2014 to \$26.2 billion by 2020.²¹ This overall escalation would require more external and domestic funding, including total annual international donor assistance for the HIV response that would be at least \$2.8 billion higher in 2020 compared with 2014 levels. In 2015, however, donor investments for the HIV effort were \$1 billion *lower* than the previous year, the first time in five years that such levels declined.²²

The HIV funding landscape was given a comprehensive, historical view in a landmark global health financing report released in April 2018 by the Institute for Health Metrics and Evaluation (IHME).²³ The study tracked health spending in 188 countries and logged it by disease. Among the notable findings were the following, all of which are relevant for the observations in this report:

- HIV and AIDS received the largest share, 26.8%, of global health spending between 2000 and 2015. The report's authors concluded that the annualized increase of 11.9% in funding for HIV and AIDS has "mitigated a major global health crisis."
- Most money for HIV is domestically sourced. Governments financed 57.6% of the \$562.6 billion spent on HIV/AIDS worldwide from 2000 through 2015.
- Global HIV/AIDS spending peaked at \$49.7 billion in 2013, decreasing to \$48.9 billion in 2015.
- In 2015, low-income and lower-middle-income countries represented 74.6% of all HIV/AIDS disability-adjusted life-years, but just 36.6% of total HIV/AIDS spending.
- In 2015, \$9.3 billion (or 19%) of HIV/AIDS financing was spent on prevention, and \$27.3 billion (or 55.8%) was dedicated to care and treatment.

The 2018 IHME report documents major investments to HIV responses, generating incalculably beneficial impacts on the health and well-being of societies and individuals worldwide. Yet the findings above and others in the IHME report underline several imbalances and gaps that could derail successful and sustainable responses moving forward. For one, overall HIV spending has plateaued, at best. Second, prevention spending continues to lag, never yet having come close to the minimum 25% share of all HIV resources that UNAIDS has stated should be the minimum level.²⁴ Third, resources allocated to HIV tend to be concentrated in wealthier countries even though the greater needs are in poorer ones. Fourth, recent declines in development assistance for health, including for HIV, leave the most vulnerable people even more exposed because this source currently constitutes the majority of HIV spending each year in low-income countries and countries with extremely high HIV prevalence. Commenting on these findings, the report's authors observed:

Despite the considerable domestic response to HIV/AIDS, many low-income and middle-income countries remain dependent on development assistance for health to fund HIV/AIDS programmes.... Domestically sourced resources are crucial to the long-term sustainability of HIV/AIDS programmes, but governments in low-income countries often have constrained fiscal space, generally driven by low government revenue.... Additional cuts to development assistance could hasten this decline [in external funding for HIV], and risk slowing progress toward global and national goals.

The current dominant understanding of aid, which has endured since World War II, has certainly helped promote and achieve significant successes in development. But with the exception of a few important elements, including a call for global solidarity with the world's poorest people, the description of development aid is no longer fit for purpose. While the global development agenda has evolved into the Sustainable Development Goals (SDGs) to reflect the changing realities and priorities of countries, official development assistance (ODA) has failed to evolve along with it.

Rather than facilitate the ambitious 2030 Agenda for Sustainable Development, it may in fact be holding back progress by failing to inspire key stakeholders or to reflect the changing reality of financing needs in development. The traditional emphasis for aid on ending extreme poverty persists, but this focus fails to take into account that increasing global equality is central to the 2030 Agenda and leads to conclusions that restrictions should be placed on investments in some middle-income countries. Similarly, an 'us and them' optic continues to be applied to aid, casting countries as recipients of aid rather than the partners, the relationship suggested by the SDGs.

For this and other reasons, people living with, affected by and vulnerable to HIV in many wealthier countries, including those classified as middle-income by the World Bank, have good reason to be apprehensive about the future. The Global Fund and many bilateral donors are pulling out of many middle-income countries (MICs) as they shift HIV spending priorities to lower-income ones. However, more than half of the world's people living on less than \$2 per day and a full 70% of the world's people living with HIV live in these 'middle-income' contexts. Many MICs' health systems lack sufficient funding and programming to reach key and vulnerable populations with quality HIV prevention, treatment, and care. Reduction of Global Fund and other international support for HIV programs from MICs has had a negative impact on quality of HIV services and engagement of key and vulnerable populations in health.²⁵ The result has been slower progress and reversals in efforts to diagnose and treat people and prevent new infections.

In addition to rapidly declining donor funding, countries classified as middle-income by the World Bank are also often ineligible to benefit from lower drug prices through voluntary licenses or other price-lowering mechanisms developed by pharmaceutical companies and/or the Medicines Patent Pool. This lack of access to affordable medicines will create barriers to national domestic funding of HIV programs at sufficient scale for most of the world.

The failure of effective planning for transitions away from external assistance in such environments has proved devastating for members of key populations in countries such as Romania and Serbia.²⁶ Yet even if transition plans are in place, often there is little guarantee that the promised domestic funding will be available or that it will be used for the most urgent HIV prevention and treatment purposes, such as harm reduction services for people who inject drugs.

Unappealing decisions: the destructive and short-sighted consequences of insufficient HIV funding

The consequences of the overall funding cuts for HIV have already forced many countries to make some tough decisions about the services made available, such as by delaying or restricting access to second-line ART regimens or pre-exposure prophylaxis (PrEP). Academic models looking at the bigger picture suggest a grim longer-term forecast if current trends continue because there are few good options as available HIV funds decline.

One model presented as part of this report's consultative process compared the implications of maintaining the current standard strategy (the benchmark) in two countries, South Africa and Côte d'Ivoire, with potential 'scale-back strategies' that could be necessitated by funding cuts. The benchmark itself would result in some 3.24 million new transmissions and 4.26 million new AIDS deaths over 10 years. Every scale-back strategy would result in even more HIV transmissions, more deaths, and fewer years of life over a 10-year horizon.²⁷

Another modelling study discussed at a consultation considered what the impact would be across sub-Saharan Africa should the US government adopt proposed steep cuts in external HIV funding. A top-level finding is that a likely consequence would be an epidemic that looks more like it did in the early 2000s than today. The modelers also noted that real or threatened reduced funding could prompt governments to make more short-sighted decisions, often due to what they consider necessity. This could mean, for example, that many prevention mechanisms that could show full benefit over the longer term would be de-prioritized as governments look to achieve shorter-term impact.

The success of the Fast-Track initiative is based on the ability to support a comprehensive program of HIV treatment, prevention and social support. If countries are unable to support such a comprehensive response because of lack of financial or human resources, then how do they set

HIV spending priorities? UNAIDS, WHO and others should provide guidance to support this kind of difficult decision-making. These are difficult discussions in which people are reluctant to engage. However, the failure to make rational decisions about spending priorities can lead to serious and detrimental outcomes.

Nevertheless, these types of decisions have long been made and will continue to be made as countries set HIV response agendas and priorities regardless of the funding environment. Important questions remain as to whether it is possible to influence such priority-setting; who or what will be influential (and how); whether human rights and equity considerations are reflected in decisions; and whether decisions make sense objectively in terms of epidemiological, financing, and social realities.

2.2 Ensuring quality of HIV treatment delivery

The constrained decision-making parameters necessitated by inadequate financing are important underlying factors in the numerous other challenges discussed in this report. Perhaps the biggest overall potential threat that links all components of HIV responses, especially as rapid scale-up continues, is the **quality of services**. Speed and progress toward meeting scale-up targets are important priorities as well, but for many—including people already on ART, those who will be initiated as scale-up continues, and those at relatively high risk of infection—ensuring the quality of services is a matter of life or death. One overarching concern about quality is that it can erode slowly over time as pressures on health systems increase. The outcomes of eroding service-delivery quality may not be noticed until the harm has been done.

However quality is defined, funding realities cannot be ignored when quality-improving strategies and actions are proposed and implemented. That is one reason the interconnectedness of all aspects of HIV responses, including quality-related issues, must be recognized and reflected in a comprehensively coordinated, integrated framework. For example, inadequate funding of support services can lead to poor ART adherence, thus exacerbating drug resistance, which in turn can weaken prevention efforts, and so on. Possible solutions to one or more challenges will have impacts elsewhere, most often positively from the perspective of improved response outcomes but also potentially negatively if resources are shifted from other important areas to concentrate on discrete problems and gaps. Solutions thus are as interconnected as challenges.

Some of the many quality-related issues that are challenges to sustainable and effective HIV responses are summarized below. Potential solutions for addressing these challenges are described later in the document.

2.2.1 Consistency of drug supply

Stock-outs of antiretroviral drugs (ARVs) and other HIV service commodities are regularly reported around the world, as described below. Stock-outs are often the result of badly designed or poorly functioning supply chains, particularly at the lowest level—the ‘last mile’ before the drugs and other commodities are in the hands of clients.

The magnitude of the problem is evident in numerous reports—many of which are prepared by community groups monitoring stock-outs—about shortages in diverse settings worldwide. Stock-outs have been reported in recent years in many countries, including those as diverse as the Democratic Republic of Congo (DRC),²⁸ South Africa,²⁹ India,³⁰ Ukraine³¹ and Argentina.³² Examples include:

- In Uganda, the government in October 2017 reportedly instructed district officials to reduce supplies of ARVs to two weeks per individual, a development that prompted civil society groups and people living with HIV in the country to warn that as many as one million Ugandans could develop resistance to first-line ART.³³
- In Russia, ITPCru, a country-wide network of HIV treatment activists, developed a website, www.pereboi.ru, through which people throughout the country could report on shortages of HIV, HCV and tuberculosis medications. In 2017, a record number of reports of shortages of medicines in the country were received, with 509 reports of disruptions in the supply of ARV drugs and frequent delays in timely analysis of CD4 and/or viral load testing from 45 regions of the country.³⁴

- The situation in Venezuela is particularly serious, with reports of no available ARV treatment in the nation and rising rates of HIV-related illness and death.³⁵

The consequences of stock-outs are destructive for clients' health and countries' ability to minimally meet the needs of people living with HIV or to prevent the emergence of more complex and expensive challenges to their HIV responses. Shortages also often erode clients' confidence in the system that encouraged them to initiate ART, which may make them more likely to abandon care altogether. As the Ugandan example above specifically notes, stock-outs are, as one report termed them, "early warning indicators for HIV [drug] resistance" because they raise the risk of weak adherence and retention. As a result, when drug supplies are not consistently available, earlier ART initiation is not only worthless to many clients, but also potentially dangerous for them.

2.2.2 HIV drug resistance (HIVDR)

Drug resistance is the dark underbelly of rapid and mostly beneficial treatment scale-up.³⁶ The WHO's HIV Drug Resistance Report 2017 documents steadily increasing drug resistance since 2001 in low- and middle-income countries among individuals starting first-line ART.³⁷ This has particularly been seen in South America and in Eastern and Southern Africa, with pre-treatment drug-resistance (PDR) levels exceeding 10% to WHO-recommended first-line ARVs in 6 of 11 countries in that African region as per recent national surveys.³⁸

Most PDR is concentrated among non-nucleoside reverse transcriptase inhibitors (NNRTIs)—and especially efavirenz—with rates of resistance among nucleoside reverse transcriptase inhibitors (NRTIs) and protease inhibitors (PIs) remaining relatively low (below 5%).

PDR has been proven to significantly affect ART outcomes, including by inducing increased viral failure, reduced CD4 recovery, and accumulation of additional drug resistance. If current levels of PDR over 10% continue, 16% of AIDS deaths (890,000), 9% of new infections (450,000), and 8% (\$6.5 billion) of ART program costs in sub-Saharan Africa in 2016–2030 will be attributable to HIVDR.³⁹

Projections such as those are why WHO recommends switching to different first-line drug regimens when PDR levels greater than 10% are reached. High and rising PDR thus further strains programming and financing by raising the number of people who must be started on or switched to other more expensive and harder to obtain first-line or to second-line regimens. Even such switches might not benefit some clients. Although data on long-term ART clients are still scarce, reports of second-line failures due to extensive drug resistance and documented 'untreatable' HIV are emerging.⁴⁰

Most HIV drug resistance stems from inconsistent adherence to ART regimens, with resistant strains then often transmitted to others. Poor adherence can occur for various reasons, including clients who report late to collect treatment, take 'treatment holidays' or share pills. Food insecurity, alcohol and depression also reduce a client's adherence to treatment. The side effects of treatment are often cited as a key reason for low adherence rates. Despite rising drug-resistance rates, adherence support and treatment literacy services remain underfunded.

The price of medicines can further disincentivize client adherence, especially in countries where clients must contribute co-payments or cover the full cost of certain medicines. As with other medicines that must be taken regularly, sometimes clients simply forget, an unsurprising fact when HIV treatment must be taken for one's entire lives even when other events affect their ability to remember to take their medications. Systemic challenges including drug supply chain problems (stock-outs), lack of laboratory monitoring, stigma and/or insufficient health care workers are also contributing to increased HIV drug-resistance rates.

In 2017, WHO launched its Global Action Plan (GAP) on HIV Resistance 2017–2021, which provides the most comprehensive strategic response to HIVDR to date.⁴¹ The GAP's strategic objectives focus on improvements in five areas: prevention and response, monitoring and surveillance, research and innovation, laboratory capacity, and governance and enabling mechanisms.

The leadership of WHO on this issue is to be commended. While welcome and undeniably beneficial, including its role in raising awareness about the issue, the GAP does not (and perhaps cannot) provide useful suggestions for individual clients who are making personal treatment decisions, including whether to go on ART or to switch regimens. More guidance on such issues would be of great assistance not only for those clients but also for facility-based health care workers involved in clients' care and community-based groups supporting them.

Closer attention and consideration should be given to treatment initiation advice and options. There is no question that earlier ART initiation, regardless of CD4 cell count, is beneficial both for a client's long-term HIV prognosis and as a prevention intervention. But, for some individuals, it might not always be the wisest decision, given the underuse and lack of adherence services coupled with gaps in the drug supply chain in many contexts.

It can be reasonably assumed that drug resistance will decline due to proposed plans to replace efavirenz (EFV) with dolutegravir (DTG) in first-line regimens, as clinical trial data have indicated that DTG is a 'better' drug in that it has fewer side effects and a higher threshold to development of resistance.⁴² Opportunities for both more robust and less expensive regimens have increased with the announcement, in September 2017, of a pricing agreement that will make a generic, single-pill regimen containing DTG available to public sector purchasers in low- and middle-income countries for around \$75 per person, per year.⁴³ In July 2017, WHO recommended switching clients who are currently on EFV-containing first-line regimens to TLD, the new DTG-containing regimen.

However, DTG is a relatively new drug and more information is needed about its safety. In May 2018, the US Food and Drug Administration (FDA) and the European Medicines Association (EMA) both issued alerts regarding the development of serious birth defects associated with DTG use in Botswana. More information is needed to determine if and how this will affect the use of DTG-containing regimens as the standard first-line treatment. If, in fact, DTG is seen as a drug that women of child-bearing age cannot use safely, then the primary strategy for addressing the current and looming crisis of ARV drug resistance is in jeopardy.

In any case, switching first-line protocol regimens poses additional challenges to already constrained health systems in resource-limited settings. Therefore, the 'technical solution' of switching drugs should be supported by simultaneous increased efforts with respect to ART drug adherence, information provision to clients and providers, improved supply chain management, etc.

2.2.3 Overburdened health systems and underfunded support systems

The rapid scale-up and earlier use of treatment is essential to prevent illness and HIV transmission. However, the success of the ongoing scale-up has also led to increasing reports about overburdened health care systems and workers, with consequences including extended wait times and limited ability to provide the client-centered care needed to ensure treatment effectiveness.⁴⁴ In addition, the emphasis on rapid scale-up of treatment initiation has come at the cost of reductions in the delivery of critical enabling support services, which for many are as important as pills for maintaining good health and quality of life. Ensuring the quality of HIV care and treatment has become much harder as a result.

In 2013, according to a WHO survey, there were 17.4 million fewer health workers worldwide than were needed to provide essential primary health care services, with the most acute health workforce shortages occurring in Africa and South East Asia.⁴⁵ WHO projects that the global unmet need for trained health care workers will decline by only 17% from 2013 to 2020, leaving the world 14.5 million workers shy of what is required to achieve SDG 3. In Africa, there will be a projected gap of nearly 1.1 million doctors by 2030. For residents of many countries, the shortfall in sheer numbers is only part of the problem because of where and how existing personnel are concentrated. In Kenya, for example, 46% of doctors are located in or around Nairobi, home to only 19% of the national population.⁴⁶ In Angola and South Africa, only 15% and 17% of health workers, respectively, serve the rural areas where roughly half the population lives.⁴⁷ PEPFAR has invested in health care worker training, bringing 190,000 new personnel into the field in sub-Saharan over the past few years.⁴⁸ This is good news, but not good enough to fill the gap.

Task-shifting, which includes moving tasks traditionally conducted by physicians to nurses and community health workers (CHWs) and peer-based service providers, has helped to alleviate the burden on physicians and built additional client capacity in many health programs. But, many of these nurses and other workers are now also overwhelmed with the numbers of people and tasks for which they are responsible.

UNAIDS in 2017 offered an ambitious plan to encourage the addition of 2 million CHWs across sub-Saharan Africa over the next two years.⁴⁹ It estimates that their recruitment, training, compensation and support will cost \$4.3 billion to \$6.1 billion depending on specific country program configuration and the need for complementary investments in enabling infrastructure such as health posts. However, these additional resource requirements are not included in the estimated resource needs outlined in the Fast-Track initiative.

In addition to increasing burdens on health systems and health care workers, entities that provide **critical enabling services** are underfunded. These services are strategies, activities and approaches that aim to overcome the full range of major barriers to uptake of HIV services, including the myriad ones outside of the health system. Such barriers include many that can be characterized as human rights failures or abuses, such as social exclusion and marginalization, criminalization, stigma and inequity. They disproportionately affect key populations, who may be reluctant or unable to seek out services due to fear of arrest or harassment.

Critical enablers might include, for example, advocacy and policy work to decriminalize activities such as sex work; remove or reform age of consent policies for HIV testing, ART initiation, and access to sexual and reproductive health services; and reduce stigma, discrimination and violence by sensitizing health care workers, law enforcement personnel, and parliamentarians, among others. Critical enablers also include provision of support services for adherence, treatment literacy, transportation, food security, and mental health. Voluntary efforts by people living with HIV have yielded many of the self-care models that have proven so effective, such as adherence clubs and community distribution of medicines. But, sustaining such efforts over the long term requires sufficient funding and institutional support.

To achieve the 90-90-90 targets, UNAIDS estimates that funding community-delivered services will need to increase about four-fold during the next five years.⁵⁰ However, there is little to no data of aggregated funding levels going towards critical enabling services. Meanwhile, community-based organizations (CBOs) report decreased funding levels in most regions. Further, leading global measures of human rights have reported worsening rights-related situations in every region of the world, and HIV programs serving key and vulnerable populations routinely report rights violations as a barrier for people to access services.^{51,52,53}

2.3 Reinvigorating HIV primary prevention

More than 2 million people worldwide were newly infected with HIV last year. That number has been more or less the same for each of the past several years, and new figures to be reported by UNAIDS in July 2018 will show only a small decline from the previous years. **As a result, the core 2020 Fast-Track prevention target—to lower annual new infections to 500,000 that year—is off track by a wide margin.** This ongoing plateau in new infections is attributed to poor results among adolescents and adults. Annual new infections among children have continued to decline sharply, largely due to the success of PMTCT programming. However, of those children who are born HIV-positive (still ~200,000 per year), about half experience HIV drug resistance within the first 18 months of life.⁵⁴

Some success has been achieved in preventing HIV transmissions. The estimated number of new adult HIV infections declined by more than 20% in 57 countries between 2000 and 2015, and the number of new infections stabilized in 20 countries. In Eastern and Southern Africa, the UN region with the greatest burden, annual new adult HIV infections have declined by over 50% in Malawi, Namibia, and Tanzania and by 48% in South Africa. But infections increased by more than 20% in 30 countries.⁵⁵ Although weak prevention results are evident everywhere, regional differences persist. Of note is that annual new infections are increasing in some places where epidemics are highly concentrated among key populations, including Eastern Europe and Central Asia.

Coverage with proven prevention tools, services and effective interventions remains low. Among the examples:⁵⁶

- The number of condoms available in Africa covers only about half the current need.
- Uptake of PrEP is less than 5% of the global target.
- Almost half (43%) of countries with injecting drug use do not have any needle/syringe programs. This is one reason that less than 1% of people who inject drugs live in an area where this is sufficient coverage of a full suite of harm reduction services that are needed for adequate combination prevention.
- Only about 38% of people living with HIV are virally suppressed, well below the level needed for the prevention effect of treatment to have an impact on HIV incidence.

Micro-epidemics are characterized by troublingly high HIV incidence and typically involve one or more key or vulnerable populations, such as men who have sex with men (MSM), sex workers, people who inject drugs, and adolescent girls and young women. Uptake challenges are evident among these groups in regard to case identification, late diagnosis, lack of knowledge and other prevention failures, treatment initiation, retention and adherence. Often, the greatest vulnerability and most intense micro-epidemics are within sub-populations that are rarely described or highlighted, such as migrant MSM or adolescent girls living in rural, impoverished areas who are not in school.

Key populations remain at much higher risk of HIV infection. A UNAIDS report from 2016, based on comprehensive reviews and analysis, noted the following: “Recent studies suggest that people who inject drugs are 24 times more likely to acquire HIV than adults in the general population, sex workers are 10 times more likely to acquire HIV and gay men and other MSM are 24 times more likely to acquire HIV. In addition, transgender people are 49 times more likely to be living with HIV and prisoners are five times more likely to be living with HIV than adults in the general population.”⁵⁷

Many of these figures and trends indicate that meeting prevention targets will become increasingly more difficult to achieve. Reaching key populations effectively is almost always harder to accomplish and more expensive. In addition, reaching adolescents and young adults, particularly those who are members of key population groups, will require new strategies for raising HIV awareness and engagement in health services. Other important factors are lack of political leadership, including in regard to resourced commitments to programming for prevention generally and key populations in particular.

Among the most problematic barriers are policies that criminalize or discriminate against people because of behaviors including sex work, drug use and gay sex, and lack of critical documentation that matches a person’s gender (important for many transgender individuals). Research indicates that removing such barriers can have a noticeable impact on HIV transmission and reduce HIV programming costs over time. For example, studies have shown that making sex work safer (e.g., by decriminalizing it) could lead to a greater reduction in transmission than providing ART to HIV-positive sex workers.⁵⁸

Meanwhile, examples of the negative consequences of failing to remove policy and legal barriers are common everywhere, including in some of the wealthiest and supposedly more ‘advanced’ settings. In the United States, the lack of syringe-exchange programs, which are illegal in the state of Indiana, was a key reason behind a sudden spike in HIV infections associated with injecting drug use in a rural part of the state in 2015. Even when faced with signs of the crisis, the governor at the time—Mike Pence, who is now the US vice president—waited a few months before signing an emergency executive order allowing the county to start syringe exchange.⁵⁹ More than 200 people have been diagnosed with HIV since the outbreak began.

In addition to key populations, young women in particular are disproportionately vulnerable to HIV, as indicated by the following:⁶⁰

- In 2016, new infections among young women aged 15–24 were 44% higher than men their age. In Eastern and Southern Africa, young women made up 26% of new HIV infections that year despite only accounting for 10% of the population.

- In West and Central Africa, 64% of new HIV infections among young people in 2015 occurred among young women. The difference is particularly striking in Cameroon, Côte d'Ivoire and Guinea, where adolescent girls aged 15–19 are five times more likely to be infected with HIV than boys of the same age.
- Women comprise a rising proportion of people living with HIV in Eastern Europe and Central Asia, where the population most affected by HIV is people who inject drugs (the majority of whom are men). In Russia, for example, the number of young women living with HIV aged 15–24 is double that among men of the same age.

Another important consideration is that although adolescent boys and young men face lower levels of risk and vulnerability compared with their female counterparts, at least in sub-Saharan Africa, they are less likely to know their HIV status. This points to prevention and information failures specific to both young males and females at a time when countries can afford it the least from long-term perspectives. Africa as a continent is the youngest on average in the world, with the majority of people in some countries younger than 20. According to one projection, the number of Africans between 15 and 24 years of age could reach 450 million by 2050, compared with about 200 million in 2010.⁶¹

Box 1: What do population-based surveys tell us about who is missing from care?

Evidence of notable gaps can be seen in results released since mid-2017 from the extensive Population-based HIV Impact Assessment (PHIA) surveys conducted by ICAP in collaboration with PEPFAR and ministries of health.⁶² The findings indicate that, at least in the survey results released thus far, there is much to be optimistic about in general, as they show strong and positive impact from HIV responses in recent years.

Yet, significant age-related gaps in progress can be seen in most surveyed countries. For example, according to pooled PHIA data from Malawi, Zambia and Zimbabwe, nearly 60% of people living with HIV aged 15–19, and about 50% of those aged 20–24, are unaware of their HIV status.⁶³ Unsurprisingly, the results remain troubling further down the line as the majority of these young people do not have suppressed viral loads: 2016 PEPFAR data of viral load suppression in the community by age groups show levels of just 46%, 48% and 34% among people living with HIV aged 15–24 in Zimbabwe, Malawi and Zambia, respectively.⁶⁴ (Comparable figures for those aged 25 and above are 63%, 70% and 64%.)

Data from those three countries also make alarmingly clear the substantially elevated risk for HIV among young women. Compared with young men, the rate of new HIV infections in young women is 5 times greater in Zimbabwe, 8 times greater in Malawi, and 14 times greater in Zambia⁶⁵

Epidemics cannot be considered 'in control' given such gaps and disparities. Presentations at the 2017 International AIDS Conference (IAC) in Paris highlighted some numbers that suggest that epidemic control is not feasible even with the current scale-up approaches and can only be achieved through more targeted, precise efforts. According to findings from one study in Zimbabwe, 465,000 of the estimated 1.15 million people living with HIV in the country are not virally suppressed.⁶⁶ Testing gaps (which are closely related to viral non-suppression gaps) are also evident in places where HIV epidemics are commonly thought to be controlled or essentially insignificant, such as Europe. Among the main conclusions from a study of HIV incidence in that region, presented at the 2017 IAC, were that "a substantial number of people in the EU/EEA are living with undiagnosed HIV" and "a significant proportion are estimated to have late stage infection, suggesting more efforts are needed to test and diagnose these people."⁶⁷

2.3.1 Prevention funding gaps

In its 2016 Prevention Gap Report, UNAIDS stated that there is a declining trend in the percentage of total resources dedicated for a wide range of prevention services, including PMTCT.⁶⁸ Prevention-relevant resources reportedly reached about 20% in recent years—short of the commitment made within the 2016 Political Declaration on HIV and AIDS to ensure that financial resources for HIV prevention are adequate and constitute no less than a quarter of AIDS spending globally.

Not only does primary prevention remain significantly underfunded generally, but funding allocations are misaligned when compared with the number of estimated new infections worldwide and in whom those infections occur, including gay men and other MSM, people who use drugs, sex workers, and transgender people. HIV prevention services accounted for 20%–23% of the total resources provided by PEPFAR from 2012 to 2014. However, if expenditures for PMTCT and voluntary HIV testing and counselling are excluded from these amounts, the prevention share was 13%–16% of the total, including only 4% for services focused on key populations.⁶⁹

A study of Global Fund grants approved over the 2014–2016 allocation period further reveals the level of underinvestment in key populations.⁷⁰ Of the \$5.9 billion approved in new grants over that period, \$724 million (12%) was specifically dedicated to programs intended for *all* key populations. Programs funded included costs for HIV testing services as well as expenses associated with research, training, and management. Less than 10% of funding earmarked for key populations was to support interventions targeting upstream factors like community organizing and mobilization, promoting supportive legislation, sensitizing against anti-stigma and discrimination, or mitigating violence.

2.3.2 Lack of data on population sizes and HIV incidence

Responding to the full suite of challenges faced by key populations, young people and others in micro-epidemic ‘hotspots’ is made more difficult by the lack of reliable data and information about many of these groups. This is particularly true for key population sizes and HIV incidence. A review of country reports as part of the Global AIDS Reporting process from 2006–2015 found, for example, that in 2015, just 25% of countries reported on indicators specific to MSM, 21% on indicators specific to people who inject drugs, and fewer than 25% on indicators specific to sex workers.⁷¹ Over the course of the 10 years surveyed, the share of submitted progress reports that reported on these key populations never exceeded 50% on MSM, 45% among sex workers, or 30% among people who inject drugs.

Incidence refers to the occurrence of new cases of disease or injury in a population over a specified period of time. Because they expose trends and higher-risk areas and populations, comprehensive HIV incidence estimates are central to efforts to identify who is ‘missing’ in HIV responses. To obtain its population size estimates, UNAIDS uses several mathematical models and provides technical support to country-level processes. It must rely on what data are available from each country, which sometimes consists of prevalence information only and nothing at all on incidence.

In the absence of improved incidence measurement at sub-national levels, it will remain difficult to effectively target HIV prevention and testing services. Efforts to do so for key and vulnerable populations is especially problematic if not impossible when it is not clear where they are, their population size, or their specific risk factors.

Population-based HIV Impact Assessments (PHIAs)⁷² and other surveys can provide some information about who is disproportionately affected by national epidemics and where they live. But many surveys do not include HIV incidence estimates, and those that do include them often can only provide estimates at national levels due to the large sample size requirements for HIV incidence estimation. The PHIA surveys, for example, were not meant to provide demographic information about key populations. Such estimates therefore are too general in scope to be of maximum use for resource prioritization.

Participants in the consultation process for this report presented several technical options and recommendations for how HIV incidence measurement might be improved. Several of these recommendations are listed in Annex 2.

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**“We need to
identify new
innovations, we
need to take some
of the evidence
we have at hand
and take that
evidence off the
shelf and take it
to action”**

3. GUIDING PILLARS OF A FRAMEWORK FOR IMPROVED, LONG-TERM RESULTS

3. GUIDING PILLARS OF A FRAMEWORK FOR IMPROVED, LONG-TERM RESULTS

Potential solutions exist for all the challenges mentioned in Section 2. Each is likely to be needed (and many are presented as recommendations in Section 4), but none will be sufficient on their own to build, strengthen and sustain the kind of HIV responses ultimately needed. **This report proposes that most challenges and solutions be considered through the lens of four themes or pillars that should guide future work: differentiated service delivery (DSD), strengthened community systems, integration, and innovative and sustainable financing approaches.** All four are approaches through which fundamental changes can be made that collectively create a framework that could turn the tide everywhere, for everyone. The progress required to reach such goals relies on there being more of all four of them: more integration, more financing for HIV, more DSD in programming, and more engagement and leadership of communities.

The four pillars are distinct, yet also interdependent, overlapping and mutually reinforcing. One example of the chain of connections: More integration within HIV responses and externally—e.g., HIV integration with broader health and development—could lead to more funding being allocated for HIV, including from development areas and resources associated with education, labor and youth, among others. More funding on HIV-relevant programming and interventions in turn should lead to more money being available for and allocated to communities for their essential work. Increased financial space and capacity for communities would make DSD more effective and sustainable because communities must be extensively involved if DSD approaches are to be successful.

3.1 Differentiated service delivery

Differentiated service delivery (DSD) is a high-profile approach to program design that is intended to improve the coverage, quality and impact of HIV service delivery. It is based on the underlying idea of meeting clients' preferences and expectations at different stages of their HIV 'journey' in as simplified a way as possible, and ideally while reducing unnecessary burdens on the health system.⁷³

In general, DSD program models seek to balance client-centered HIV treatment and prevention services with the public health approach so critical to delivery of high quality services at scale. Key themes and elements include:

- The primary goal of DSD is to provide responsive and **client-centered services** tailored to meet the needs of specific client groups/categories in order to improve their ability to effectively engage in HIV treatment and prevention services.
- A second goal is related to **quality**. Because the majority of clients on ART are stable and doing well, DSD can simplify treatment services for large numbers of people living with HIV by shifting services to the community and decreasing the frequency of health facility, laboratory and pharmacy visits. Early data suggest that these more flexible and responsive treatment models improve retention in care and adherence to ART. In addition to improving quality of life for clients, these changes may also ease burdens on health care facilities and their staff, allowing them to see more clients and to focus on those with more intensive needs.
- A third goal is related to **value**. Improving the efficiency of HIV programs will enable existing resources to reach more clients, improving coverage of key elements of the HIV response and contributing to epidemic control. Simplification should not be construed as endorsing a shrinking or smaller pool of services available for clients, stable or not. The comprehensive view of DSD provides a wide range of critical enabling services (e.g., adherence support, legal services and mental health and social services), but with the understanding that only those individuals with a specific need will use them, and perhaps only for a limited period of time.

3.1.1 Simplicity within complexity: can DSD contribute to improved responses for all?

DSD's current favor stems from growing recognition that HIV service delivery can be structured to better meet the needs of an increasingly diverse client base, some of whom require more intensive engagement with health and social systems and others who require considerably less health system interaction to achieve viral suppression. Successful DSD depends on maintaining a high quality of services and an approach that is structured to meet the different needs of people along different parts of the HIV treatment cascade. In practice this means taking into account what a client needs, if the individual is at higher or lower risk of HIV disease progression, is symptomatic or asymptomatic, lives nearby or far away, has TB or other physical or mental health issues, and other structural considerations that could affect treatment or prevention outcomes such as income, education and awareness, and family support.

Most of the initial differentiated ART (DART) models are based on the observation that clients who are stable and doing well on treatment do not need—and often do not want—intensive monitoring or frequent visits to health facilities. Instead, DSD offers a more tailored approach. Many DART models therefore divide clients into 'stable' and 'unstable' categories, based on variables such as extent of immunosuppression (CD4 count), presence/absence of viral suppression, treatment adherence history, comorbid health conditions, age (e.g., adolescent vs. adult) and presence/absence of pregnancy. 'Stable' clients are then eligible for DART models including:

- Facility-based individual models, e.g., fast-track appointments and extended appointment spacing;
- Facility-based group models, e.g., adherence clubs or family group models;
- Community-based individual models, e.g., community ART pick-up (as had been done in models in places including South Africa and the Democratic Republic of the Congo);
- Community-based group models, e.g., community ART groups.

Example of DSD in practice

In Botswana, PEPFAR's LINKAGES project is using differentiated ART service delivery approaches to improve care and treatment for two key populations, MSM and female sex workers. A key component is the 'one-stop shop' approach to provide integrated clinical services in the community through outreach at mobile clinics or drop-in centers. By offering HIV testing and ART services in the same location, the project also aims to accelerate ART initiation. Results seem promising. The proportion of MSM who were diagnosed with HIV and then initiated on treatment increased from 38 percent in the first year of the project to 58 per cent in the second. Results among sex workers increased by 12 percent over the same period.⁷⁴

One advantage of DSD is that it can simplify delivery of treatment services for the majority of clients as ART scale-up continues, particularly for clients at low risk of HIV disease progression, who will be a large and increasing number of those on treatment as 'test and treat' scale-up accelerates. This can ease the burden on health facilities, enabling health workers to see more clients and to focus on those with more intensive needs.

Providing less intensive services and/or services in the community and doing so in such settings rather than at health facilities should not be equated with providing inferior care. Improved linkage between community and facility services is required, and peer-based linkage support, treatment literacy, transportation and child care, nutritional support, counselling and mental health, substitution therapy, and legal services may all be required to achieve treatment success even where DSD models are operational.

The issue of inferior care is important because it is highly relevant to what DSD models and approaches offer clients who are not 'stable' or who have needs and challenges that might require more targeted consideration, including key populations and adolescents. Each population, or even sub-sets of individual populations, may want or need specially tailored models to help ensure maximum effectiveness.

The concept of differentiated services is also relevant for HIV primary prevention. To be more effective globally and in more contexts, primary prevention must ensure access to a full range of interventions with proven benefits. But not all people will want or need all these interventions. Nearly all individuals in both high and low prevalence settings can benefit from a basic package of services that includes information, condoms and HIV testing, for example. But only some—and often only a small number—will at any given time need or benefit from other services such as syringe exchange, PrEP or mental health care. The simplicity is in the basic services being widely and easily available, while the complexity lies in the availability of targeted, discrete interventions to the specific populations and individuals who need them wherever they may be and regardless of how few will take them up. In discussing the use of DSD concepts for primary prevention, participants at the consultations informing this report considered the development of a needs assessment for those seeking out HIV prevention support and subsequent referral to the services deemed valuable for that client.

Examples of DSD-related improvements in quality and costs

In Cameroon, results from a pilot program found that a peer navigation system was associated with an increase in linkage to care from 39% to 82% among HIV-positive MSM and female sex workers.⁷⁵

A trial in South Africa found that the probability of linkage to care was significantly higher among individuals who were followed up after initial referral to care with phone calls and home visits.⁷⁶

Multi-month scripting (MMS), fast-track refills (FTRs), and community ART groups (CAGs) are three models of differentiated care for HIV used in Malawi. According to analysis, “Annual per patient costs of MMS, FTRs and CAGs are similar and represent an estimated 10% reduction compared with a monthly clinical visit policy. These reductions are largely driven by decreased visit frequency and the delegation of some service delivery tasks to lower level cadres.”⁷⁷

For DSD to be effective for either treatment or prevention purposes, people from communities, including key population groups, should be systematically engaged in policy development, design, implementation, and monitoring and evaluation. More, better and consistent community systems strengthening (CSS) is thus another core priority, as communities themselves must be trained and educated before they support others to maximize DSD opportunities and deliver relevant services themselves. The findings of a rapid assessment recently undertaken among people living with HIV and community groups in several African countries are instructive.⁷⁸ Most respondents did not know what DSD was as a concept or might be in practice, though they expressed interest in knowing more. The most popular potential benefits revolved around saving time and costs (e.g., for transport) with clinic visits and ART collection. Options that many respondents particularly liked included community drug distribution points (CDDPs) and a fast-track window within clinics.

3.1.2 What to look out for: challenges in the DSD approach and models

Despite the promise of DSD, there are many challenges and concerns about how to appropriately incorporate DSD into health systems. A major concern is handling the complexities and complications that inevitably result from having multiple ways of managing clients. Health care staff must understand different models and properly facilitate care and support across them. DSD can also create challenges for routine monitoring and adequate, timely tracking of client records and oversight. A recent study in Malawi found that mischaracterization of clients was common, with (for example) ‘unstable’ clients being referred to differentiated services such as adherence clubs that should be reserved for ‘stable’ ones.⁷⁹ A question to consider is: How much differentiation can a system bear? Answers to that question will always be context-specific, as should all DSD approaches.

Many of the challenges faced in the adoption and scale-up of DSD have been outlined in an article by El-Sadr, et al.⁸⁰: Priority actions to make DSD models as effective as possible include:

- Adjusting national guidelines to describe the package and schedule of care for each category of clients.
- Training of health care providers so that clients can be directed toward the appropriate services based on stage of HIV disease, response to treatment, viral suppression, prior adherence with clinic visits, comorbid illnesses, pregnancy status, and psychosocial needs.
- Developing streamlined cross-referral mechanisms with clear criteria and defined systems to ensure smooth transfers from low-intensity to high-intensity tracks and vice versa.
- Developing new systems for drug procurement, distribution, and tracking, and for laboratory specimen collection based on clients' location of care and frequency of visits.
- Re-designing national monitoring and evaluation systems to collect information from diverse locations, utilizing novel methods and a diverse workforce.
- Shifting funding from health systems toward community systems for testing, linkage and retention services and drug delivery systems. Also required to make such shifts useful will be extensive training and supervision modules for community- and peer-based service delivery programs.

As noted by El-Sadr, et al.:⁸¹

For differentiated care approaches to succeed, they must adhere to the principles of the public health approach. For each category of patients, a systematic, evidence-based, and algorithmic approach is needed, with clear delineation of how, where, and by whom the services will be provided. It will also be important to balance increased programmatic complexity with the constraints imposed by fragile health systems, most notably the scarcity of physicians and nurses and the current limits of procurement and laboratory systems. Evaluating both pilot programs and large-scale initiatives will be needed to identify best practices, assess programmatic and economic efficiencies, explore potential unintended consequences, and elicit feedback from patients and communities.

Another concern is that DSD models will fail to fully consider and accommodate human rights. Task-shifting to make services simpler and more efficient will not necessarily lead to better outcomes for key populations, for example, if the services provided are stigmatizing and unfriendly. Similarly, opening a clinic in a micro-epidemic area does not guarantee that key populations or others will visit.

And finally, one question that deserves careful consideration by all partners in HIV response is how and whether DSD actually cuts costs and increases efficiencies. Studies such as the one conducted in Malawi aimed at reducing monthly clinic visits (see box within this sub-section) indicate where and how costs can be reduced. Yet such cost reductions are for health systems only, and may not consider what else might be needed for DSD to work in the way it should: to improve the quality and effectiveness of HIV services for all people in need and at risk.

3.2 Community engagement

Communities have long been central to the HIV response, and community-based responses continue to affect every aspect of the HIV response. They create the demand for services, implement prevention, testing, linkage to care, treatment literacy and adherence support services, and provide the critical enabling social services and advocacy without which health services cannot be effective. Without strong and well-resourced community systems, the promise of DSD approaches cannot be realized, targets for zero discrimination cannot be met, and the promise to 'leave no one behind' cannot be fulfilled. AIDS cannot be ended without affected communities serving as the foundation to the HIV response.

A World Bank study of HIV service delivery from 2010 to 2012 found the following:⁸²

Community-based efforts are a "cornerstone" of the response to AIDS and represent substantial value relative to financial investment in the sector. Studies from countries as diverse as Cambodia, South Africa, the United Republic of Tanzania and Zimbabwe point to the effectiveness and cost-efficiency of community-based HIV services. The report concluded that community responses to HIV work with and complement public systems; achieve scale; lead to better policies for greater treatment access; promote human rights, equity and quality of services; ensure that limited resource allocations reach those in need; and provide the evidence base that helps inform the development of effective policies and services.

Box 2. A defining challenge: what constitutes ‘community-based responses’ to HIV?

There is no single globally accepted definition of ‘community’ or what might rightly and appropriately be considered a ‘community-based response’ in the HIV world. This lack of consensus continues to be a major challenge to data collection (including in regard to resource amounts), analysis and advocacy since results and assertions can be widely varying.

The following definition, from a 2015 UNAIDS document, defines community responses as such: “In the context of HIV, a community response is the collective of community-led activities in response to HIV. These activities include: (1) advocacy, campaigning and participation of civil society in decision-making, monitoring and reporting on progress made in delivering HIV responses; (2) direct participation in service delivery; (3) participatory community-based research and (4) community financing.”⁸³ This definition will be used for the purposes of this report.

In addition to independently based CBOs and networks, community-based approaches to service delivery include those embedded within health systems. This is an important and large area of community contribution to the HIV response and includes such activities as home-based counselling and testing, peer-based linkage to care and adherence support services, support groups, treatment delivery systems such as community adherence groups, etc.

3.2.1 Components of a vibrant community-based response: examples from the field

The term ‘community-based’ can refer to two different yet often linked or complementary concepts and interventions: activity driven by communities, which typically refers to independent CBOs and networks, and delivery within communities, which can be undertaken by such independent entities as well as others (including from the health system). A robust community-based response of both kinds is required to address each of the challenges described earlier in this report. Community-driven activity in particular can be critical for reaching the most vulnerable and marginalized. An example from the field of such activity is associated with each challenge listed below. Annex 5 includes a lengthier example of how community leadership achieved a successful shift to government funding for key population prevention services in Macedonia.

People who are ‘missing’ from HIV services. In Kenya, Nairobi-based LVCT Health implements one of the country’s major key population prevention programs, using a peer-led approach for outreach. To better reach clients ‘where they are’ and in a convenient manner, it focuses on service location and convenience such as extended working hours or home delivery of condoms. Steps taken in response have included providing services at night at MSM hot spots and paying for a room in a bar to provide clinical services for sex workers, who can stop by between clients. Evidence and observations to date indicate improvements in PrEP uptake and adherence and higher levels of viral suppression among MSM and female sex workers.⁸⁴

Controlling drug resistance: simplified drug delivery, treatment literacy and adherence support. Community-based services have been at the forefront of adherence support work in many countries. CBOs provide treatment literacy to clients to help build informed decision-making and follow through on treatment decisions. Community-based monitoring can also identify and address eroding quality of HIV services. West and Central Africa overall had one of the world’s worst ART uptake rates in 2016, when just 36% of adults living with HIV were on treatment. To help improve the situation, the ITPC Regional Community Treatment Observatory in West Africa, a project supported by the Global Fund, is extending community-based monitoring of HIV treatment to 11 countries in the region and thus is seeking to improve both the quality of treatment and its reach.

Stopping drug stock-outs and shortages. The Stop Stockouts Project (SSP) undertakes comprehensive community-based monitoring of stock-outs of ARVs and other essential medicines

in South Africa. It is a consortium of six civil society organizations whose members provide expert advice, technical support and advocacy to reduce stock-outs across the country through community engagement, a case management database (hotline reporting and hot spotting) and a telephonic survey to review the state of healthcare and medicine stockouts in national health facilities in district and sub-district hospital and clinics.⁸⁵

Critical enablers. The supporting services offered by many CBOs—including in areas such as nutrition, legal issues and rights, transportation, referrals for other health and welfare concerns, among others—can be the difference between a thriving, retained HIV client and one who drops out of care altogether. In South Africa, the Zimele Project has designed and implemented ‘cash transfers’ as a way to empower adolescent girls and young women.⁸⁶

Advocacy to protect human rights. In Senegal, one way that implementers are seeking to make the environment safer for key populations and more conducive for their ability to obtain HIV and broader health services is to engage with parliamentarians and host workshops with Muslim religious leaders on key populations and HIV. Such conversations have already shown some promising results, including a ‘gentleman’s agreement’ that the civil society-led program targeting key populations will not be stopped as long as engagement continues.⁸⁷

Advocacy for resource mobilization. Advocacy at national and global levels is crucial to ensure a well-resourced and equitable global HIV response. Community leadership has been a key player in Global Fund replenishment processes, participation on its country coordinating mechanisms (CCMs), developing and implementing transition plan in MICs, and in monitoring government budgets and spending.

3.2.2 Barriers and other challenges to enhanced community engagement

Despite the importance of the role that community-based efforts play in effective HIV responses, the CBOs and other independent entities at the center of many of them continue to face funding challenges in nearly every context, with many organizations forced to reduce operations or shut their doors completely over the past few years. The extent of the funding crisis cannot easily be quantified, however, because readily available data on funding for community-based HIV responses do not exist in most countries and tracking at global levels has been inadequate.

UNAIDS acknowledges and has publicized the importance of substantial increases in resources allocated towards community-based efforts, concluding that “to achieve the bold HIV treatment and prevention targets set in 2014, investments in community mobilization and services must increase *more than threefold* between 2015 and 2020.”⁸⁸ According to the UNAIDS Strategy 2016–2021, the increase should be even greater through 2030: The Strategy aims for “comprehensive systems for health” that integrate community service delivery and for community-based HIV service delivery to move from a global average of 5% in 2013 to cover at least 30% of all service delivery by 2030.⁸⁹

These estimates do not include essential funding for global and regional advocacy, community mobilization and capacity-building efforts to mobilize resources; ensure consistent, equitable and high-quality service delivery; and protect human rights. The extent of demand for such services can be seen from the results of a recent round of grant making conducted by the Robert Carr civil society Network Fund (RCNF), which supports global and regional community-based HIV networks. Funding requests from eligible proposals totaled approximately \$70 million over a three-year period, but RCNF only had about \$24 million available for disbursements.

Funding challenges for independent groups operating in the community space are more severe, chronic and complicated due to restrictions often placed on the use of funds. Many donors, for example, specify that funds can only be used for activities directly related to one or more project, which leaves many groups without the necessary core funding to pay for salaries, rent or other basic administrative functions.

Few donors are ready and willing either to pay for advocacy work, often because they claim that such work cannot be evaluated or measured for impact. That challenge constrains the scope of

networks of people living with HIV and key populations to undertake some of their most important and potentially influential efforts, such as advocating for legal and policy reform that can improve their constituents' overall health and well-being (and thus contribute to improved HIV responses). Funding for human rights advocacy has always been far below the estimated needs and has been cut even further in the past few years.⁹⁰

One proven way to meet such needs is community-driven grant making, which refers to a system in which donors provide a pot of money and representatives from key population networks, CBOs and similar independent entities have the role and responsibility of soliciting proposals and making funding decisions. This system often can more easily and efficiently provide funding and support for organizational and network development as well as advocacy work. RCNF is one such example.

More sources and more money are urgently needed, however. External donors could make a big difference by relaxing strict policies on what financial assistance can be used for, setting aside more funds for community-based responses, and more actively seeking new and diverse recipients through calls for proposals. Additional funding from governments could be facilitated through broader introduction of social contracting mechanisms, in which governments formally link with civil society groups in HIV responses through contractual arrangements for the provision of HIV prevention, treatment and other services. In many settings, new laws and policies might be required to allow and guide this process. Moreover, for such a promising approach to be useful, social contracting mechanisms must be relatively flexible in terms of indicators and measures of effectiveness to enable such organizations to meet contractual obligations. (Social contracting is also discussed in Section 3.4 of this report, which centers on financing.)

The structural barriers that limit the effectiveness of community-based services are not only due to insufficient funding. The work of CBOs and many other local civil society groups is often not given the level of respect it deserves because of heightened emphasis by governments and other funding sources (e.g., external donors) on evidence of impact and efficiency. Such an emphasis, while welcome in general, puts most community-based groups at a disadvantage because much of the work they do is not easily translated and filtered into existing reporting systems that governments use to collect HIV and other health information and to evaluate impact. The result in many contexts is a lack of viable reporting mechanisms vis-à-vis community-based service delivery, which has the effect of minimizing communities' value and deprioritizing their access to funding.

This challenge is significant even in countries such as Kenya where community-based responses have continued to play major roles in the overall response relative to many other places. Kenya's National AIDS Control Council (NACC) has a community-reporting tool known as CAPR (Community AIDS Programs Reporting) that is supposed to allow CBOs and other CSOs to give a comprehensive picture of the kind of work they do and its value. Yet in the opinion of many advocates and representatives of groups in that sector, the CAPR is missing some important indicators that could reflect more extensively and accurately the full scope of HIV-relevant services, especially those offered by communities. They also consider the current tool's focus solely on numbers to be limiting because it does not provide opportunities for community groups to describe the bulk of their work that cannot be easily recorded in a strict quantitative manner.

A solution that can have substantial conceptual impacts (e.g., in increasing understanding and appreciation for communities' role) as well as tangible impacts would be for all reporting mechanisms to include qualitative indicators and measures in addition to quantitative ones. Qualitative indicators can help to give a better understanding of the value of the work of CBOs and other independent groups in reaching out to, engaging with, and supporting people to get tested for HIV; helping them make and follow through on treatment decisions; providing access to the full range of prevention tools; and offering information that is relevant to their specific risks and needs of their clients. Much of this work cannot be captured effectively, if at all, with purely quantitative indicators. The development of metrics that can reward the success CBOs can achieve could provide incentive for governments and others to include them in pay-for-performance schemes.

Some caveats must be acknowledged and taken into consideration if and when the roles and responsibilities of CBOs and other civil society groups increase in HIV responses. Some CBOs may

not have the staffing, systems or processes in place to quickly expand their work; many, therefore, could require intensified financial and other support to get to that point. Also, not all CBOs that currently focus on HIV or hope to do so are committed to human rights and evidence-based service delivery. Some civil society groups in places such as Uganda have been at the forefront of efforts to marginalize, harass or imprison people living with HIV or members of key populations. Due diligence is always needed for civil society partners as with representatives of all other sectors in HIV responses.

3.3 Integration

The value of continued vertical HIV programming is still apparent, particularly in relation to advocacy for resources and responding to continued stigma and discrimination associated with HIV. Moving forward, however, changes in the political landscape are forcing the HIV community to reconsider the relationship between HIV responses and broader health and social development. Most notably, realistic considerations of long-term strategies for effective HIV treatment and new approaches for engagement in HIV prevention strategies may necessitate a more integrated approach.

Thus, although some specialized HIV services are still critical for responses, HIV treatment, prevention and support services have been and will continue to be integrated within broader health, development, financing, and social systems. Changes in the political landscape and the priorities of both donor and implementing countries—as seen, for example, through the launch in 2015 of the 2030 Agenda for Sustainable Development—make continued consolidation of more integrated approaches to HIV responses inevitable. But, in addition to this inevitability, the time is right to explore such integration as a way to build upon and sustain the progress made to date.

There are several ways of thinking about HIV-relevant integration, including integration of HIV within primary care and other health care services (e.g., for TB and sexual and reproductive health); integration of HIV services within other areas of development and social welfare (e.g., schools); and integration of HIV within broader funding and structural mechanisms for health and development. **Below are examples of areas in which integration of HIV-related concerns could produce more effective and efficient outcomes:**

Improved health outcomes through integrated service delivery: Integration of HIV health services into primary health care and into areas with high rates of co-morbidity could lead to improved health outcomes overall and HIV specifically. These other areas include TB, hepatitis C (HCV), cervical cancer, sexual and reproductive health, mental health, and drug treatment services. Integration of HIV care within primary health could better link HIV health needs to health services for non-communicable diseases (NCDs), an area of increasing concern as people living with HIV grow older and NCDs are massively on the rise in lower-income countries. HIV testing programs can and should include TB and HCV testing, NCD tests with available interventions such as glucose and blood pressure tests, pap smears, etc.

Community systems and health systems: As described in greater detail in Section 3.2, expanding HIV prevention, treatment and social service delivery through the scale-up of community-based approaches offers substantial opportunities for a more sustainable and more effective HIV response. To realize these opportunities, greater integration between community and health systems is essential. Making this possible requires that governments acknowledge the potential for community systems to create greater demand for health services, improve on treatment and prevention outcomes, and provide essential critical enabling social services. Viable integration of community and health systems also relies on community organizations developing and complying with standardized reporting methods regarding client outcomes and organizational performance. Health systems also must be willing to transfer resources into the community sector.

Universal health coverage: The SDGs galvanized momentum toward universal health coverage (UHC), with countries around the world now committed to its achievement and implementing a range of approaches aimed at doing so. All HIV services should be integrated within UHC scale-up and all associated structures and systems, as well-designed UHC platforms could greatly benefit people living with and affected by HIV. But for that to be the case, such platforms must include and

reflect core principles of the most effective, acceptable and sustainable HIV responses, including full inclusion ('leaving no one behind'), human rights, transparency and accountability, and the open, accepted and adequately resourced engagement of non-state actors such as civil society groups and communities. Many of these principles are reflected in the UHC2030 global compact, a multistakeholder platform that is promoting political commitment to UHC.⁹¹

Such 'lessons learned' from HIV responses underscore how and why the expertise and experience developed over the years in HIV responses can strengthen and help to guide the implementation, expansion and improvement of UHC. The reliance is two-way in a more integrated development world: *progress in HIV cannot be achieved without moving towards UHC, and UHC efforts will fail if frameworks do not include the HIV response.*

Community mobilization and socialization⁹² for HIV prevention among key and vulnerable populations: Efforts to prevent HIV transmission have primarily been provided through HIV-specific programming and through resources from HIV-specific budgets. As targeted prevention efforts increasingly focus on key populations, adolescents and young adults, integration of such efforts within broader attempts to mobilize these communities might provide a more effective method of engagement in HIV information dissemination and prevention activities. The majority of those prioritized to be reached are young and many are facing multiple challenges and needs—including related to health, economic opportunity, societal expectations and pressures, sexual exploration, homophobia and transphobia, gender-based violence, etc. Therefore, great potential value might be found in integrating HIV specific messaging and prevention services within broader community mobilization and socialization approaches. To be effective, such efforts depend on more information about what motivates young people toward health services and acceptance of health information. HIV-specific programming may be exactly what these populations do not want to be associated with. They may be more open to HIV services when included as part of a broader attempt to address their needs, wants and desires.

Multi-sector engagement in health, education, and rights: Ideally, integration within governments will extend beyond health ministries. Resources and valuable entry points for HIV prevention and awareness are likely to exist within education ministries, for example, including in reaching highly vulnerable adolescent girls. Initiatives funded and implemented by housing and labor ministries, among others, often help to weaken or removal structural determinants that contribute to greater HIV risk and vulnerability, including poverty and joblessness. Targeting such efforts toward adolescents and young people in addition to key populations almost certainly boosts the quality of overall HIV responses. Diffusion of HIV-relevant efforts in such ways can help to increase overall support and financing for the response in efficient and cost-effective ways.

Integration of all the types mentioned above represents an opportunity to finally 'normalize' HIV service delivery and set it on firm, sustainable financial and programmatic ground. However, the opportunity will be squandered and people's health and lives put at unnecessary risk if all essential components of quality HIV responses are not integrated and sustained as well. A critical goal, therefore, must be to ensure that specific HIV experience and expertise are supported and incorporated into broader service delivery.

Discussions around integration and HIV should proceed with caution, however, regardless of the promises and opportunities. There is limited data about the effectiveness of comprehensive and extensive integrated strategies involving HIV services, and some major risks must be considered—such as the possibility of decreased HIV program quality and impact. Also, integrating HIV into primary care may not be simple, valuable or advisable in settings where primary care currently offers minimal services with minimal quality. Such settings are not likely to be appropriate for chronic care conditions such as HIV treatment and prevention. Integration could mean weakened and not improved HIV service provision.

To help recognize and avoid such risks, more attention and resources should be directed toward evaluation and implementation science research on HIV-relevant integration.

3.4 Financing

More and more carefully directed financing is a relevant part of most solutions for the challenges referred to in Section 2 and to better support, facilitate and connect the other three main pillars of a comprehensive framework for future HIV responses. This message is in direct contrast to the currently reality, which is characterized by a stark disconnect between the funding expectations associated with the Fast-Track scale-up agenda and already lagging HIV financing.

Most modeling by UNAIDS and other sources has concluded that financing of the global HIV response today is inadequate and would need to increase considerably for there to be any possibility of meeting the Fast-Track targets and exhibiting other signs of overall progress in controlling epidemic.^{93,94} The quality of responses almost certainly will be further compromised and eroded unless the trajectory changes. As scale-up continues, countries are still needing to spend more every year on case identification, linkage to care and providing ever larger numbers of people with quality ART that must be taken for the rest of their lives. Yet countries are already facing significant financial constraints as a consequence of the huge gap between funding needs and availability that threatens to widen even further. These financing gaps will ultimately inhibit efforts to halt new infections meaningfully and be a factor behind growing levels of negative health outcomes, including more illness and death, even as treatment scale-up continues. How and from where countries will find the money necessary to escalate responses while improving them are open questions that at the moment have no easy answers in many places.

In general, and as suggested in this section, sufficient and sustainable future financing for HIV relies not only on raising more money, but also on using existing and additional money better. Ideally, evidence of the latter will help make the former easier as governments, donors and other funding sources see the social, health and economic value of boosting their HIV-related financing. One major challenge is that many governments lack the political will to provide sufficient funding for HIV programming, especially services targeted at key populations. Financing options that can address that complex and often intractable obstacle perhaps might have the most direct and long-lasting impact on improved HIV responses in certain countries.

3.4.1 The importance of multiple sources

Official development assistance (ODA) and other forms of external funding for HIV have been mostly flat after steadily rising for more a decade through 2008. Some of the HIV financing gap from donors' retrenchment and refocusing is being filled by domestic sources (e.g., from government budgets), which currently account for more than 50% of HIV programming costs across low- and middle-income countries.

Expanded domestic responsibility is supported by most advocates and technical partners in the belief that such funding is the most sustainable longer-term source. It cannot and should not be the only source, however. For numerous reasons, external funding for HIV must remain available and robust as scale-up continues and quality-driven HIV response frameworks are rolled out and entrenched. Although some countries have made significant progress toward domestically financing much of their HIV responses (e.g., South Africa), many others continue to rely heavily on external funding from sources such as the Global Fund and PEPFAR. In Mozambique and Zimbabwe, for example, more than 90% of the hundreds of millions of dollars spent annually on HIV responses is funded by donors.⁹⁵

An evolved vision for aid would emphasize increasing global equality; it would address mutually beneficial global public goods; it would bring to an end persistent 'us and them' implications; it would be a permanent mechanism for the correction of distributive asymmetries and market failures at international level; and it would incorporate sharing knowledge and experiences and promoting standards and rules rather than emphasize only financial transfers. Such a vision could garner broad support nationally and internationally, but it needs to be championed.

Important opportunities exist now to reshape aid. For example, definitions of ODA are currently being reviewed to reflect the SDGs. Convening a conversation between African ministers, civil society and Development for Assistance Committee (DAC)⁹⁶ donors is essential as part of this process, to improve the effectiveness of aid. DAC donors must be challenged and not left to

redefine aid in isolation. To utilize the opportunities available now, and to shape the aid narrative in the future, it is necessary to articulate a clear problem statement and solution.

Continued and sufficient external funding is also needed because some countries that conceivably could afford to fund most or all of their HIV responses are unwilling to do so. This is where equity concerns become paramount, including about how and for which purposes domestic funding is allocated. Examples abound of countries in which domestic funding—no matter how substantial overall—fails to support targeted services and interventions for key populations. The Russian government, for example, currently budgets about \$350 million for the HIV response,⁹⁷ a paltry sum in light of a continually growing HIV crisis in which more than 100,000 people are newly infected each year and overall HIV prevalence is increasing. Although Russia's epidemic is concentrated among people who inject drugs, the government refuses to fund the provision of opioid substitution therapy (OST) and greatly restricts syringe exchange programs.

Substantial evidence exists of the negative health, social, legal and economic consequences members of key populations in particular face in countries such as Russia where the Global Fund and other donors have withdrawn. CBOs and other civil society groups in such places often are the only providers of prevention and treatment services and support for key populations. External donors, most notably the Global Fund, often are or have been their primary or sole funding source. They frequently have no option but to reduce services or close down completely when external funding is no longer available. In Montenegro, for example, HIV infections among MSM started rising after the Global Fund withdrew a few years ago and many civil society groups providing services for them lost the bulk of their funding.⁹⁸

The administrative costs of a Global Fund grant for relatively small programs such support for MSM-related services in Montenegro may be prohibitive, and government-led allocations of such funding to MSM-led organizations may be hindered by political resistance. Small grants, administered by a regional or national network of community organizations may be a better option to provide funding at lower costs, with improved technical support, and with improved knowledge about which organizations are best-suited to provide such services as local levels. Multiple community-led grant making mechanisms have shown that such an approach is feasible and effective.⁹⁹

3.4.2 Options and opportunities for sustainable future financing

Establishing a sustainable financing framework for HIV is a key priority for quality scale-up. The complications and barriers of ensuring sufficient funding for HIV responses from domestic and external sources have for years prompted attention and consideration toward other financing options and opportunities among policy makers, donors and health and finance ministries. Some approaches are based on tapping more extensively into sources that currently comprise smaller shares of HIV financing (e.g., the private sector), while others rely on a range of tools and approaches to leverage more money for co-financing HIV responses that are loosely categorized as innovative financing. Some are a combination of both.

Direct budget support is the most efficient and effective source of additional domestic funds for national HIV responses. For political and other reasons, such as competing demands for the use of relatively modest budgets and the challenges of maintaining accountability at the level of national budgets, this is not always a realistic option. **Taxation policies** have the same problem to some extent, although there are some examples of targeted levies raising small amounts of funds this way—e.g., Zimbabwe's AIDS Trust Fund, which was introduced in 2000 and in recent years has contributed annual sums of about \$35 million.¹⁰⁰

Such limitations are why renewed attention has turned to the broad area of **innovative financing**, which runs the gamut from smaller, targeted, discrete interventions (e.g., voucher programs for one highly vulnerable population such as adolescent girls) to large-scale national insurance schemes that aim to cover a core set of health costs for most or all the population, including people living with HIV to integrating HIV treatment into digital mobile healthcare exchange wallets, creating a bottom-up payment system. Such approaches to financing can serve to allocate risk and burden more efficiently. Innovative financing approaches also can provide incentives by encouraging health and social systems to institute promising approaches to treatment and prevention services, which in

the case of HIV might include increased uptake of testing, more consistent condom use, and other such changes that can mitigate the impact of the epidemic. Such initiatives should be evaluated regularly and extensively to help determine effectiveness, efficiency and adaptability.

In addition, innovative financing approaches can support the development of effective service delivery models, which can then be scaled up for broader use. More importantly, they can create politically palatable mechanisms to encourage greater domestic resources mobilization. For example, country finance ministers may balk at funding increases for health ministries, but they might be willing to pay for actual reductions in HIV incidence or vouchers that only become a draw on the Treasury when people from higher risk populations use them to get tested for HIV.

As discussed in regard to integration, the global commitment to reach UHC goals provides both opportunities and challenges for the global HIV response. All components of HIV responses, including whatever kind of innovative financing options are used, therefore should fit within and be integrated into and embedded within UHC structures to the fullest extent possible. To date, however, that has proved difficult to achieve in practice—a situation that deserves careful attention across from all people and institutions involved in HIV responses. (Annex 3 provides a list of some important considerations that should guide future discussions of HIV and UHC.) Reviewing global guidance on UHC, including that developed by WHO, should be a first step in any effort to determine how linkages between HIV and UHC can be ensured.

Insurance schemes are one example of a financing mechanism and instrument that several countries have been using in recent years to move closer to achieving UHC. What can and has been done regarding integrating HIV services into such schemes depends on factors including epidemiological burden, income and other economic conditions, and political will and support.

Annex 5 includes examples of how national health insurance schemes in some developing countries have dealt with HIV to date, and they give some idea of what has been happening at country level at the nexus of insurance, UHC and HIV. The good news is that UHC-focused efforts have already begun and that policy makers recognize the gaps that must be addressed for HIV to be included and integrated moving forward. The less promising news, as the examples indicate, is that many of the ambitious efforts have encountered challenges associated with insurance schemes' structural and financial stability and expansion of coverage, with HIV services proving to be particularly difficult to support directly. One way to address this is through the use of external donor funding that could be applied directly through the insurance scheme for HIV services, using a mechanism like mobile vouchers to ensure accountability.

Such gaps and challenges underscore why insurance schemes alone are insufficient in creating demand for and providing access to services and information that benefit HIV outcomes. A range of innovative financing tools holds promise in addressing some of the HIV and other health needs that cannot be met through insurance schemes and commonly used HIV funding sources such as external donors and domestic resources (e.g., direct government budget support or taxation levers). Several of those tools are summarized below. Increased uptake of some or all of them rightly should depend on the outcome of more extensive and thorough evaluations.

- **Pay-for-performance** models tie funding to achieving agreed-upon clear and measurable results. Such models could prove particularly useful in paying for primary prevention interventions and programs and for services provided through community systems (many of which are prevention-oriented). Many of these activities, such as keeping girls in school, may not be specific health services, but are necessary to improve health outcomes. They include efforts to change behavior, provide social support, increase demand for and sustained engagement in health services, and address social determinants that have negative impacts on health.

In most pay-for-performance instruments, the parties—those paying for the services and those providing the services—agree to a funding amount and a set of indicators and results. (Both the payee and payor could be from any sector—public at any government level, private, civil society, donor, etc.). Payments are not made upfront, as in grants; instead, they are only released after results are achieved.

This model can also be combined with a **social impact bond** or other source of upfront payment from a third party, which would receive a return on its investment when the agreed-upon results are met. In social impact bonds, governments are the outcome payer and the risk of success is held by the private investors, which in different settings have included banks or private foundations. According to one analysis of this option, “Social impact bonds would be particularly suitable for financing preventative interventions that reduce future burden of disease, especially for effective interventions that are under-utilized or inefficiently delivered (such as prevention of mother to child transmission, harm reduction, voluntary male circumcision, condom distribution and use) to bring health, economic and social benefits and achieve returns beyond the costs.”¹⁰¹

- Some pay-for-performance instruments are versions of **social contracting**, which refers to formal arrangements for a government to transfer public funds to civil society implementers for targeted interventions such as key population services and community-based work among adolescents and young people. Social contracting agreements typically are results-based relationships in that they include targets and indicators. Some, though, provide for all or part of the payment upfront, which can be essential for many community and civil society groups that operate on shoestrings and would find it hard to pay salaries and deliver services even with the eventual possibility of payment later down the line.
- **Vouchers** could be a valuable method to support and sustain community-based services (especially for prevention) among key and vulnerable populations. They could be used when members of these populations experience financial barriers that prevent them from access to a full range of support services and information they might need. For a relatively small amount of money value, vouchers could have substantial impact in places where out-of-pocket payments are high and/or are the primary mode of health funding. Mobile payment mechanisms can be particularly useful here as a method to integrate outreach to key populations into national UHC systems.
- The highly specific nature of some proposed financing options for community-based services underscores the potential ability to adapt and mix-and-match from a large overall menu. A **sustainability bridge fund**, for example, could focus on financing to provide time-bound grants for civil society in countries about to transition from, or which are no longer eligible for, Global Fund support. The funding could be restricted for activities for which no funding exists, such as community-based and civil society advocacy. Such a mechanism could be performance-based, which among other things could help to demonstrate the effectiveness of community-based services for key populations.
- For insurance-strengthening purposes in particular, **risk pool** development can be useful, depending on the context. People living with HIV and other high-cost conditions could be covered separately from the general insured population with specialized funds, thereby easing pressure on the main insurance scheme. Risk pools of this sort are likely to be most useful in countries with relatively high HIV burdens. This approach has been tried out on occasion already. In 2006, for example, a successful pilot with HIV risk equalization funding was performed in Namibia, with 15% of formal sector employees enrolling in a general health insurance scheme with HIV risk being covered by the fund. Ultimately, though, it was crowded out by public sector funding through Global Fund and PEPFAR.¹⁰² Again, mobile payment mechanisms can be a useful mechanism here. If, for example, someone receives a positive HIV test, they could automatically get credited with funds to pay for a basket of HIV-specific services alongside their entitlement from the standard UHC system.
- Maximizing opportunities in a landscape of limited financing also could include more targeted and systematic focus on lowering the cost of essential medicines and other commodities. Access to generic medications is a main component of the success to date of HIV treatment scale-up. **Voluntary and compulsory licenses** can be used under global trade rules by countries seeking to import or produce generic medications or to secure lower prices of HIV drugs and other commodities. However, MICs, collectively home to the majority of people living with HIV, are increasingly left out of these solutions. For many MICs and other countries, future HIV financing could be much more optimistic if global trade policies were more flexible.

Different contexts will require different solutions, approaches and ideas to finance HIV services. Each country—and often each sub-national unit—has different needs, expectations and priorities. Identifying the most valuable financing tools and models, whether deemed ‘innovative’ or not, requires tailoring any such mechanism to the context. Especially important upfront is clear understanding among all involved as to the main objectives, including the scale and scope of the financing effort. Among the other factors governments, donors, technical agencies and others should consider are:

- country income level (e.g., low-income, lower-middle income, middle-income, etc., as designation directly affects eligibility for external donor support);
- extent and share of external funding for HIV (e.g., from the Global Fund and PEPFAR) and current share of all sources of HIV funding, such as from domestic resources and external support;
- HIV burden (e.g., overall prevalence, prevalence among key populations and highly vulnerable groups such as adolescent girls and young women, incidence overall and among targeted groups);
- political will, including whether governments are able and willing to allocate public resources to programs for key populations and others (including in transition environments);
- the strength and capacity of the financial sector, regulators, health systems, civil society and communities; and
- legal, social and cultural obstacles such as criminalizing environments for some key populations and restrictive rights and access for women.

David Barr
HIV treatment advocate and educator

“We need to have frank, honest discussions about what is not working and how to address the shortcomings. If we don’t address them we can’t reach our goals of ending AIDS.”

4. CONCLUSION AND RECOMMENDATIONS

4. CONCLUSION AND RECOMMENDATIONS

There is no magic bullet in this report, or anywhere else, that will solve all the current barriers described to ensure the quality of HIV treatment, prevention and care services that reach all in need and can reasonably be sustained. Many of the ideas offered here have been described previously, some since the beginning of the epidemic. This goes beyond pills and condoms, as important as they are, to include real human rights protection; recognition of the value that communities play in improving engagement in health; and an acknowledgment that everyone everywhere has a right to good health and safety regardless of where they live, who they love, or their age, gender or economic status. **Perhaps the greatest challenge to ending AIDS is that it depends primarily on one precondition that has often been lacking: ongoing political will to fully fund and implement the tools, programs and policies that are proven effective.**

This report offers the opportunity to examine the potential solutions to a broad set of problems and show how these problems and solutions are interrelated, how the changing political and environmental landscape are creating unavoidable changes in the shape of the global HIV response, and how that response fits within broader health, development and human rights mechanisms.

The framework of solutions proposed here also is meant to address a longer-term view of a sustainable HIV response. Meeting the Fast-Track targets is not the end of AIDS. While the targets are extremely useful in setting and achieving milestones, the HIV global response must now be centered on development of long-term and sustainable approaches based on the decades of commitment required to reach and maintain control of the epidemic and secure the lives of people living with HIV for decades to come. For these ideal outcomes to be achieved, UNAIDS and its partner agencies, donors, civil society and implementing countries must develop more sophisticated country-specific strategies based on realistic trajectories and evidenced-based approaches for decreasing HIV incidence; implement comprehensive treatment delivery that includes critical enabling support services; and exhibit a true commitment to human rights that addresses gender inequity and violence and discrimination and criminalization of key populations.

There are many steps that can be taken to lay the groundwork for achieving the kind of thorough, quality-centered framework required for ultimate success. A sampling of those actions and decisions are presented as suggestions to address the recommended priority challenge areas below. Based on the main themes and gaps arising from the consultation process for this report, they are proposed to help guide future work by all stakeholders in HIV responses in coordinated, collaborative and integrated ways. Additional recommendations can be found throughout the body of this report and in the reports from the consultative meetings that informed this report, which are available on the Joep Lange Institute website at www.joeplangeinstitute.org.

Three important overarching points about collaboration, integration and acting on evidence are worth re-emphasizing, as they are relevant for all efforts.

- **Continued progress cannot be made on HIV, with or without UHC platforms in place, unless there is sufficient money for prevention and other key non-treatment services upfront.** Supporting a robust 'infrastructure for prevention' will require integrating non-state actors in ways that allow them to grow while retaining the independent, separate qualities that make them effective.
- **South-South cooperation and learning should be emphasized and supported.** The extensive and impressive work at local levels around the world is often poorly recognized or highlighted. For example, there is much that other countries can learn from their counterparts' experiences in designing and implementing a range of financing mechanisms that aim to expand and sustain HIV responses. There is space for valuable lessons both negative and positive, and

from countries with small, concentrated epidemics as well as those with, large generalized ones. In Macedonia, for example, as discussed in Annex 4, civil society advocates used strong analysis and evidence to convince the government to agree to cover community groups' HIV prevention and advocacy work. In Kenya, the struggles to identify ways to finance and cover huge epidemics of HIV and non-communicable diseases (NCDs) in insurance schemes are highly instructive (see Annex 5), as are policy makers' and advocates' determination to find solutions.

- **More research and analysis are needed to answer some of the important questions around community-based services, DSD and integration.** Evidence and data can help to better determine, for example, the strengths and weaknesses of specific HIV interventions provided by CBOs in a range of settings; which DSD models work best; and the effect of integration of HIV into primary care on the quality of HIV services. Results from more extensive and comprehensive research in such areas should influence decision-making and advocacy.

The priority challenge areas below each have recommendations for different constituencies that should have responsibility for taking them forward. The constituencies are in bold text when associated with a specific recommendation.

(1) Reinvigorate primary HIV prevention

The global HIV community agrees that funding for HIV prevention must be larger overall as well as in terms of its share of all HIV funding. But there is little space in most countries to boost their support or shares as they are focusing on meeting the Fast-Track 90-90-90 treatment targets while neglecting the Fast-Track primary prevention and other stigma and social support targets. Without an increased effort to reduce HIV transmission, epidemic control is not possible. The number one priority in HIV prevention is to address the gaps in services and impact among key populations, young women and girls. This requires a **significant increase in funding**. In addition:

- **Governments**, in an effort to meet public health and human rights goals, should eliminate laws and policies that discriminate and/or criminalize consensual sexual behavior, drug use and eliminate bans on effective prevention activities such as syringe exchange and substitution therapy.
- The potential of PrEP to prevent transmission among those most vulnerable is a particularly compelling, yet underutilized. As a core component of their HIV prevention efforts, **governments** should seek to rapidly scale up PrEP access that is accompanied with quality support services and diagnostic testing.
- **UNAIDS, the World Bank, and the Global Fund** should take an active role in proposing innovative financing tools and helping countries design and roll out those identified as being context-relevant and feasible. Ultimately, such solutions should be country-developed and -owned, but that should not preclude external or other partners from providing more targeted guidance and advice. Pay-for-performance funding coupled with social impact bonds is a promising, yet mostly unexplored method of funding these services, as are mobile vouchers.
- The **Global Fund, PEPFAR and other donors** should develop ways to more successfully incentivize countries to focus more on primary prevention—and to do so using evidence-informed, targeted ways to have the most impact. Thus, for example, support would end for abstinence programs and would be scaled up for PrEP, condom availability and harm reduction. The **Global Fund** should seek to boost prevention funding in its grants, perhaps by setting strict minimum targets both for proposals and signed agreements.
- **Research and academic institutions** have key roles to play in conducting research to better understand where and how to engage people in prevention interventions, which interventions are most effective and cost-effective, and how to measure success.

(2) To better target prevention spending and interventions, improve data collection on HIV incidence and population size

It is not possible to control the HIV epidemic without more and better information to guide decision-making about how and where to prioritize prevention interventions, particularly information about key populations, adolescents, and young adults. Improved, targeted data on HIV incidence and key population sizes, disaggregated by sex, age and demographics, are needed to identify micro-epidemics and 'hotspots' at national and sub-national levels.

- **Governments** should commit to gathering such data consistently and making the results publicly available, including through their progress reporting to the United Nations.
- **UNAIDS, WHO and other UN agencies**, in conjunction with **research institutions**, should more proactively encourage and support such efforts, offering technical support and advice and facilitating referrals for expertise and funding.
- **Community-based groups** should be involved in data-gathering processes, as they are likely to have deeper knowledge about and closer links with affected communities. The involvement of communities also lends legitimacy to data-collecting efforts and increases the likelihood that governments will be held accountable if they do not respond responsibly or effectively to the findings.
- **Donors**, such as the Global Fund, should prioritize funding proposals based on a country's presentation of sufficient data about population sizes and incidence measurement at sub-national levels, including that of key populations

(3) Prevent a resurgence of HIV in middle-income countries (MICs)

The withdrawal of external donor support from MICs undermines global efforts to gain control of the HIV epidemic and commitments to 'leave no one behind'. The use of gross national income (GNI) and disease burden are insufficient indicators to provide the Global Fund and other donors with sufficient information to assess the ability and willingness of a country to sustain its HIV response.

- **The UN**, in consultation with international financial institutions, should develop transparent measurements of progress on sustainable development that go beyond per capita income. These should recognize poverty in all of its forms and dimensions and the economic, social and environmental dimensions of domestic output and structural gaps at all levels. Additional criteria to be considered could include fiscal space, economic growth, health spending, inequality, willingness to pay, debt to gross domestic product (GDP) ratio, etc.
- **Governments** in both MICs and lower-income countries should not assume that external financing will always be available and thus begin transition planning as soon as possible. As they reduce dependency on external donors, they should prioritize efforts to allocate adequate levels of domestic funding to address HIV and other health needs, including those of key populations.
- **The Global Fund and other donors** should develop bridge funding mechanisms for MICs facing transition as one option. But the concept of 'bridge' might not be sufficient in places where the other end of the metaphorical bridge, domestic financing and support, is uncertain or unlikely. The funding and support strategies and approaches implemented should be designed to be used and prioritized for as long as the gaps exist, regardless of how long that might take.
- **Donors** also should jointly agree on strategies to support CBOs and other civil society groups in such countries not only to sustain what was started by the Global Fund and others, but to preserve progress made to date and expand and strengthen it. Such funding should include support for advocacy to encourage transition planning and implementation.

(4) Scale up resources for community-based responses

As this report has made clear, quality HIV responses across the board cannot be built and sustained without strengthened community-based responses. The Global Fund and most other donors and grantmaking institutions have consistently and publicly agreed with that assessment. Now is the time for them to back up their words with more forceful action.

- **Governments** should support community-based services for HIV treatment, prevention and support through funding, capacity building and technical support to CBOs and other independent entities engaged in HIV work. Such services should work in partnership with health systems. Social impact bonds tied to performance-based funding are one method to be explored to finance and expand community-driven work.
- **Governments** should also review and update existing laws and regulations in order to provide social contracting mechanisms and to broaden the role that civil society can play in health services delivery, including drug dispensary and HIV testing and counselling.
- **The Global Fund and other donors** should develop and support funding mechanisms for CBOs working at national, regional and global levels to advocate for human rights protections and provide technical support to local community-based service providers. Community-driven grants

programs, such as the Robert Carr civil society Networks Fund, are a useful method to support these activities. They deserve and require greater investment.

- **CBOs and civil society groups** must ensure that they establish the systems and procedures necessary to show how, why and where they are using increased funding, with extra effort made to develop impact indicators that highlight both priority quantitative and qualitative issues that collectively provide a full picture of the scope and breadth of their work. In most contexts, the development of such indicators should be done in collaboration with government agencies to which CBOs are reporting.

(5) Confront HIV drug resistance (HIVDR)

In July 2017, WHO launched the Global Action Plan on HIVDR (2017–2022) in an effort to raise awareness about HIVDR. Yet the scope and threat of HIVDR still have not received the attention they deserve, including in terms of their impact on the future of treatment scale-up and the quality of HIV responses overall. Growing rates of drug resistance represent a real and significant threat to the continued success of the HIV response.

- **WHO** should take the lead in developing simplified messaging regarding HIVDR to help those outside of the research community understand its relevance and importance, including all donors, government health officials and policy makers, CBOs and other CSOs.
- **Governments** should (1) invest in increased laboratory capacity to better detect drug resistance and expand access to viral load testing; (2) invest in community-based, mobile technology-based and other adherence support services; and (3) ensure that supply chains can provide ARVs consistently without stock-outs or shortages at clinics. Better data management is one potentially useful approach to strengthening supply chains. India, for example, recently has put in place a new client identification system that makes it possible to see when and from where each individual client gets a standard ARV supply.¹⁰³ And, governments and donors must commit to ensuring access to second- and third line regimens so that treatment options are available for people with HIVDR.
- **CBOs and other CSOs** should make it a priority to provide information to communities on the risks of HIVDR as well as help to monitor it, including among those only recently initiated on treatment. Communities also have a key role to play in monitoring and reporting on drug stock-outs and shortages. Several models are already in use, and funding should be made available to scale up these programs in every country. CBOs should prioritize increasing their capacity to provide treatment literacy and adherence support services.
- **WHO, UNAIDS, governments and researchers** should initiate a rapid, comprehensive analysis of DTG to give a more thorough understanding of its risks and opportunities, including for treatment-naïve individuals.
- **Research institutions and industry** should prioritize the development of new and more affordable technologies for drug-resistance monitoring.

(6) Realize the promise of new and mobile technology

Digital technologies deserve special attention and focus as potential solutions for building and sustaining comprehensive, quality HIV responses. Options that are carefully designed, tested and evaluated can help boost access, uptake and success by enhancing HIV service delivery convenience and confidentiality among clients.

Parts of the critical architecture are already in place and broadly acceptable. For example, mobile phone coverage is extensive across sub-Saharan Africa and most other places where HIV is a severe health concern. Solutions associated with mobile phones therefore offer notable and numerous opportunities to ‘democratize’ health and improve HIV programming. Mobile phones and their users can be harnessed for encouraging people to get HIV tests, to promote ART and PrEP adherence through text messaging, to monitor and report stock-outs, and to send results of diagnostic tests, among many other options. Innovations of this sort also could have beneficial financial implications and factor into DSD models—for example, as increased efficiencies quicken the pace of results delivery and decision making among both clients and health systems personnel.

- **WHO** should develop guidelines for using mobile phones and other digital solutions and be transparent at all stages, thereby helping promote crowd-sourced solutions. For example, WHO

indicators for quality of care by providers could be supplemented with a new set of mobile phone-based early warning indicators (EWIs) that are used by clients and communities to report on quality of care in a geo-targeted and real-time manner. Heat maps and benchmarks of community-supported quality of care could be constructed, using centralized data depots at WHO.

- **Governments and donors** should set up and strengthen links with private-sector partners with expertise and experience in digital technologies that are acceptable and adaptable in specific contexts, including resource-constrained ones. In particular, linkage to mobile phone providers will allow for using new sets of data that can help target HIV treatment and prevention efforts and identify vulnerable populations as well as potential hotspots of HIV. Companies such as Safaricom in Kenya have had great success innovating and expanding mobile-payment systems, for example.
- Part of these efforts may require greater upfront and future rewards. **Governments, donors and other external partners (e.g., foundations)**, also should establish and prioritize incentive-based programs that reward new and promising digital solutions targeted toward improving overall HIV responses and the experiences of the most vulnerable and key populations in particular. Models that might prove promising include work done by Unitaid and others to promote new point-of-care (POC) diagnostic options.
- **Entrepreneurs in mobile technologies** should be stimulated to come up with digital solutions that support HIV prevention, ART supply chain management, HIV treatment and care and empower individuals as well as communities in monitoring and securing determinants of quality of care. Innovative digital pooling of public and private funds through mobile healthcare exchange platforms (such as M-TIBA in Kenya¹⁰⁴) can potentially strengthen HIV responses and leverage total amount of money in the system.

(7) Develop HIV-inclusive UHC platforms and schemes

HIV responses cannot continue to scale up and improve unless they are fully integrated into all UHC structures and systems. Equally important is that UHC targets cannot be achieved without covering HIV. This is undeniable not only in countries with high HIV burdens. In countries with concentrated HIV epidemics, for example, the most vulnerable and hard-to-reach individuals for HIV services (e.g., key and marginalized populations) are also the most difficult and hard-to-reach for UHC—and often for the same reasons. Insurance schemes and other UHC-enhancing mechanisms must be inclusive of HIV for the final UHC targets to eventually be met.

All partners involved in UHC development and financing must make this a priority.

- HIV treatment and prevention should be included in UHC-driven insurance schemes as quickly as feasible.
- The Global Fund, World Bank and other donors should consider funding all aspects of comprehensive HIV care through UHC schemes to allow those schemes to stabilize as they grow.
- UHC must include more than access to health and treatment services, as coverage for prevention interventions is vital.
- Any UHC scheme must include key and marginalized populations if it is to succeed and be truly universal.
- High drug prices in middle-income countries will undermine the stability of UHC schemes. Access to generic medications and/or reduced pricing should be extended to MICs if their UHC goals are to be met.
- Community advocates should be involved in all aspects of UHC program development, implementation and monitoring.

Micheal Merson

Former director of the World Health Organization's Global Program on AIDS and founding director of the Duke University Global Health Institute

“We need to remind people, particularly the youth, how AIDS in the past devastated many communities around the world and still is a threat to our health security today.”

ANNEXES

ANNEXES

Annex 1. Methodology

This report is based on input provided during a series of meetings and consultations organized through an initiative launched in April 2017 by the Joep Lange Institute (JLI). Titled **Ensuring Efforts to Scale up, Strengthen and Sustain HIV Responses**, the initiative's overall objectives as articulated at the beginning were to describe challenges to meeting current HIV targets and articulate an approach for the HIV response that takes sharp aim at:

- reducing the number of new HIV infections, with a focus on key populations, adolescents and young adults;
- streamlining and improving service delivery to sustain the overall quality of treatment;
- efficiently targeting the use of resources; and
- building new and more sustainable approaches for funding.

Members of a Planning Committee met in April 2017 to define the initiative's broad scope and objectives. A total of seven consultations on different topics relevant to the objectives anchored the initiative's agenda. The consultations took place between September 2017 and April 2018.

Three of the seven meetings were larger-scale, bringing together more than 30 participants from across a range of sectors—including government, donor, research/science, multilateral and technical agencies, and civil society. Topics included (1) the potential impact of reduced funding for HIV on countries' efforts and ability to scale up their responses and how limited resources can best be used effectively and responsibly; (2) approaches and strategies to maximize the potential benefits of differentiated service delivery; and (3) identifying and leveraging current and innovative financing options and opportunities.

Three other meetings were planned and organized to respond to priority areas of more intensive work, as identified by participants at the first two larger meetings. The range of participants was similar, but total participation in each consultation was smaller. Topics included HIV incidence measurement; reporting mechanisms that can help to promote increased funding and other resources to communities; and HIV prevention in an era of DSD, with a focus on key populations. The seventh contributing meeting, held in March 2018, focused on strategies and advocacy to address growing rates of HIV drug resistance. It was organized by JLI, the Partnership to Inspire, Transform and Connect the HIV response (PITCH) project and the World Health Organization (WHO), and was hosted at the Netherlands Ministry of Foreign Affairs.

Initiative organizers prepared summary reports of discussions at all seven consultations that were subsequently reviewed by participants. Those individual reports form the basis of this comprehensive one.

Annex 2. Options and recommendations to improve measurement of HIV incidence

As part of the consultative process for this overall report, the Joep Lange Institute (JLI) held a technical meeting to discuss the need for and methods to improve measurement of HIV incidence particularly at sub-national levels and among key and vulnerable populations. (The full meeting report for that gathering, held in January 2018, can be found at the JLI website (www.joeplangeinstitute.org) The topic of HIV incidence is discussed in this main report in Section 2.2.3.

As noted at the technical meeting, one main challenge with measuring incidence is that most methods require huge sample sizes and have other limitations. Longitudinal cohort studies can take at least a year, for example, and imprecision is common among cross-sectional incidence assays¹⁰⁵ and age-based prevalence models. One possible idea to explore for 'local incidence' in the future is an approach called 'small area estimation'. It too has drawbacks, however, including that the results are not generalizable. Age-based prevalence is another possible approach. Through this method, for example, prevalence in 16-year-olds minus prevalence in 15-year-olds would equal incidence.

Additional surveillance methods, such as case reporting with unique identifiers, could promote better understanding of micro-epidemics. Yet such solutions do not necessarily address the other part of problem: whatever the methods used, incidence estimates for key populations depend on the availability and quality of input data. Challenges in finding and counting key populations are likely to persist regardless of what kind of model or models are used. Some of the strongest obstacles are stigma and discrimination (including in health facilities) and criminalization, both of which contribute to selection bias because people choose not to be part of studies. Undercounts are common, or—just as problematically—highly assumed to be common.

Listed below are summaries of several **recommendations** identified by participants at the January 2018 technical meeting.

- **Use the absolute number of unsuppressed people in a defined population as a measure for HIV transmission risk.** Rather than incidence, viral load suppression is a potential factor that could determine where the needs are greatest and where resources and attention should be directed in HIV responses. High rates of poor viral suppression in geographic areas and among populations signal urgent places to focus. Ramped up and routine viral load testing therefore is an essential priority.
- **Stimulate point-of-care (POC) viral load determination as a measure for HIV acute infection.** Accurate and reliable POC options do not yet exist. Qualitative DNA tests are used for infants, but they have not been used to find acutely infected adults. Another area to consider might be incorporating IP-10 into a two-stage process. IP-10 screening would be followed by a POC test for confirmation.
- **CD4 determination at HIV diagnosis should be continued, as it can serve as a proxy for early infection.** CD4 cell testing at the time of HIV diagnosis still offers valuable information for clinical decision-making in addition to incidence trends.
- **Building incidence into case-based surveillance: Outcome indicators should be redefined to include measures from infection to diagnosis and subsequent care.** Broadening the pool of data in this way can help to ensure that as much information as possible is available for case-based reporting.
- **Assess whether self-testing can be used as a strategy for incidence identification.** Self-testing is a potentially valuable area that should be researched and developed further, to consider how and if it could be an alternative strategy for incidence identification. It is rolling out now in several countries, including as pilot initiatives.
- **Use big data analysis/machine learning to 'heat map' (predict) HIV incidence in geographic areas and among populations.** This would rely on a wide range of statistical, geographic, epidemiological and other data. The goal is to use data that already exist to predict areas with higher risk of incidence. One proposal is to conduct an experiment by focusing on countries where PHIA have been undertaken. The findings from this kind of big data analysis could then be validated with PHIA results.
- **Measuring extent of migration is an important complementary step to measuring HIV incidence.** Migration in and out of a discrete survey area or behavior can be a major mitigating factor in measuring incidence.

Annex 3. Toward a more perfect UHC: challenges and concerns for HIV inclusion and integration

The movement toward and focus on universal health coverage (UHC) could be transformative for HIV programming and people living with HIV. Unfortunately, the transformative effects could be either (or both) positive and negative. The following are some observations about UHC that are of relevance to HIV programming and should be taken into consideration by policy makers, advocates and donors involved in both areas:

- Out-of-pocket (OOP) expenses for health services remain extremely high in some countries that have moved toward UHC, including countries such as Ghana and Senegal that are discussed in this report. This situation has the effect of limiting benefits and access, especially among the poorest and most vulnerable.
- Due to considerations about financial expense and stability, some UHC initiatives (e.g., national insurance schemes) might not cover some or many important HIV services, including ART provision. Addressing such gaps with realistic, costed plans that look to the long term is necessary to avoid major problems as donors withdraw or are otherwise unwilling to support such components of HIV and health responses.
- Numerous options exist to pay for UHC. With few exceptions, most countries will have to do it themselves with domestic resources—such as direct budget allocations, specialized levies (e.g., ‘sin’ taxes on tobacco or alcohol), or insurance schemes that require participants to pay premiums and create risk pools where the more affluent support the poor.
- Inclusion in UHC is sometimes constrained by what is politically palatable. This can mean, for example, that governments are not willing to pay for or subsidize services for socially and politically marginalized groups such as HIV key populations. Existing and additional donors (external or internal) might need to be used strategically to support services for these populations as HIV is integrated into UHC efforts.
- Civil society organizations (CSOs) have long been best placed to provide the highest-quality and most acceptable services in certain areas of responses to HIV and other health priorities (including TB). UHC services and platforms that do not involve CSOs therefore by nature have serious shortcomings. Policies should be in place that allow and clarify government transfer of funds to civil society (e.g., social contracting mechanisms) as part of comprehensive UHC provision.

Annex 4. What community leadership can accomplish: successful shift to government funding for key population prevention services in Macedonia

Macedonia is an example of how strong community engagement and leadership can ensure better quality HIV responses for all. In 2017, the Global Fund withdrew from the country. Its support had provided the primary source of funding for HIV prevention and advocacy work by key populations and communities. While the HIV epidemic in Macedonia is small, advocates were concerned that the withdrawal of prevention services from communities at higher risk of HIV infection would lead to a rise in transmission. While the Macedonian government continued to be directly responsible for ART provision, it was reluctant or unwilling to cover costs for prevention services among key populations due to many such populations being criminalized and an alleged lack of evidence of value and effectiveness. (It should be noted that unlike many other countries in its region, Macedonia supports opioid substitution therapy directly from government funds.)

A group of community advocates used strong analysis and evidence to convince the government to agree to cover community groups' HIV prevention and advocacy work.

The process included several steps, starting with a continuous multi-stakeholder discussion about sustainability three years before the Global Fund left. The advocates studied the budget cycle and developed extensive and accurate information about service delivery costs.

A political crisis delayed success, but ultimately the Ministry of Health agreed on a substantial allocation of funds for key population-specific advocacy and prevention services in the 2018 budget. The first group of civil society organizations received funds for activities for the last quarter of 2017.

Annex 5. Country examples of insurance schemes that are critical components of UHC efforts

Listed below are examples from countries that have implemented national health insurance schemes. These initiatives are now core components of their efforts to achieve universal health coverage (UHC). Each has dealt with HIV in different ways. All the examples are based on presentations by participants from respective countries in the consultative process behind this overall report:

- Significant scale-up of **Kenya's** main health insurance scheme, the National Hospital Insurance Fund (NHIF), over the past two years has resulted in it covering about 25% of the population. The NHIF currently does not cover HIV, largely because HIV services are still mostly funded directly by donors. Covering HIV services through the national scheme has been considered, including by policy makers at NHIF, but it would be a huge, expensive and complicated undertaking. HIV clients are involved, however, in some initiatives aimed at making NHIF more accessible and efficient. For example, a pilot project that integrates vertical HIV funding into horizontal health care through a digital mobile health care exchange wallet, and is and linked to NHIF, is ongoing in a Nairobi hospital. Some 2,500 people living with HIV are involved.
- The government in **Senegal**, which has had a basic national insurance scheme for several years, in November 2017 finalized a National Health Financing Strategy (NHFS) to guide progress to UHC. As of the beginning of 2018, more than 1,000 people living with HIV (along with some 2,300 beneficiaries including their spouses and families) reportedly had joined the overall health scheme by early 2018, a development that signals commitment by the scheme's administrators to provide comprehensive coverage for them in the context of UHC. Despite such targeted efforts to support people living with HIV, along with many other countries Senegal's overall efforts to achieve UHC are facing resource challenges associated with provision of HIV treatment, care and support.
- **Ghana** was the first sub-Saharan Africa state to introduce a national health insurance scheme, in 2003. It is currently funded by a combination of earmarked value-added tax (VAT) revenues; contributions from formal sector workers through a social insurance contribution; payment of premiums; and some donor funds. About 40% of Ghanaians currently are enrolled. The current package of interventions in the national insurance scheme is fairly basic, covering some common conditions such as malaria and diarrheal diseases. HIV medications are not covered, but the government remains focused on trying to find ways to cover HIV costs when donor funding declines. Discussions to date have included 'sin' taxes, increased premiums, and government earmarking.
- Several countries in **South East Asia** also have national health insurance schemes of varying depth and scope, many of which are intended to deliver UHC. How and whether they cover HIV services also varies:
 - **Indonesia's** scheme is compulsory and covers basic services for everyone. Some HIV-related services are covered, including HIV testing and counselling and treatment for opportunistic infections and sexually transmitted infections. HIV treatment is not covered, however, because of its expense; instead, it is subsidized by the government and donors.
 - **Thailand** has three main insurance schemes, including one for government employees, one for the private sector, and one under the auspices of the National Health Insurance Office (NHSO). HIV treatment and other services are subsidized by the government through a separate scheme altogether.
 - In the **Philippines**, all HIV services except testing are supported through insurance schemes. The Philippine Health Insurance Corporation (PhilHealth), the main national insurance provider, offers a specialized HIV package for a set fee. It covers treatment, diagnostic tests and provider visits. Separating out HIV this way is viewed as stigmatizing by some observers, including members of some key populations who are concerned about having any of their identifying information associated with separate schemes.

ENDNOTES

- ¹ For an example of the world retreating from a global health campaign against an epidemic with disastrous consequences, see a description of the resurgence of malaria in the 1960s and 1970s in Cohen JM, Smith DL, Cotter C, et al. Malaria resurgence: a systematic review and assessment of its causes. *Malaria Journal* 2012;11:122. www.malariajournal.com/content/11/1/122
- ² UNAIDS. UNAIDS announces nearly 21 million people living with HIV now on treatment. Press release. November 2017. www.unaids.org
- ³ UNAIDS. Prevention gap report. 2016. www.unaids.org/en/resources/documents/2016/prevention-gap
- ⁴ Global Burden of Disease Health Financing Collaborator Network. Spending on health and HIV/AIDS: domestic health spending and development assistance in 188 countries, 1995–2015. *The Lancet*. Volume 391, No. 10132, p1799–1829, 5 May 2018.
- ⁵ UNAIDS. Ambitious treatment targets: Writing the final chapter of the AIDS epidemic. 2014 www.unaids.org/sites/default/files/media_asset/JC2670_UNAIDS_Treatment_Targets_en.pdf
- ⁶ UNAIDS. Ending AIDS: Progress toward the 90-90-90 targets. Global AIDS update. June 2017. page 31. www.unaids.org/sites/default/files/media_asset/Global_AIDS_update_2017_en.pdf. PHIA results can be found at <http://phia.icap.columbia.edu/>
- ⁷ PEPFAR, for example, defines epidemic control in standard epidemiologic terminology: the point at which new HIV infections have decreased and fall below the total number of deaths among HIV-infected individuals. More detailed analysis and discussion of 'epidemic control' can be found in a report from an October 2017 UNAIDS Science Panel meeting in Glion, Switzerland, available at www.unaids.org/en/resources/documents/2017/glion_oct2017_meeting_report
- ⁸ UNAIDS. Fact sheet: Latest statistics on the status of the AIDS epidemic. Accessed May 2018. www.unaids.org/en/resources/fact-sheet
- ⁹ Political Declaration on HIV and AIDS: On the fast-track to accelerate the fight against HIV and to end the AIDS epidemic by 2030. 2016. www.unaids.org/sites/default/files/media_asset/2016-political-declaration-HIV-AIDS_en.pdf
- ¹⁰ It is important to note that many upper-middle and high-income countries, such as Russia, are not included in the Fast-Track projections despite having large numbers of people living with HIV and rising infection rates. It is unclear how continued HIV transmission and disease in these countries will affect the projections to end AIDS as a public health threat by 2030.
- ¹¹ The two largest and most influential HIV donors, the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), use Fast-Track targets in their review of grant applications and program plans and to measure program effectiveness. The WHO Global Health Sector Strategy on HIV 2016–2021 has based its recommendations on Fast-Track data. The Global Fund has also relied on Fast-Track cost estimate data in its 2017–2019 investment case.
- ¹² UNAIDS. Fact sheet: Latest statistics on the status of the AIDS epidemic. Accessed May 2018. www.unaids.org/en/resources/fact-sheet
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Khama Rogo

Head of Health in Africa Initiative, IFC/World Bank Group

“Thinkers are many. But it’s thinkers who turn their thinking into action who make social justice happen”

JOEP LANGE INSTITUTE REPORT

The Joep Lange Institute aims to make health markets work for the poor. Digital technology can revolutionize healthcare, connecting those who are currently excluded to better quality care and more equitable finance. We identify and accelerate innovative (digital) solutions and advocate to scale those that have real impact. Ultimately, we believe that the question isn't whether or not inclusive healthcare is possible. It's whether there is enough political will to make it happen.

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