Ensuring Efforts to Scale up, Strengthen and Sustain HIV Responses

Accelerating HIV incidence reduction through differentiated service delivery: Scaling up the next wave of the HIV response

Hosted by the Joep Lange Institute

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What's in this meeting report

Section 1 provides:

- an introduction of the overall initiative;
- a summary of recent study findings indicating that although HIV scale-up efforts have shown significant overall success in many countries, major gaps persist that could slow down or reverse progress if not addressed; and
- an overview analysis of how differentiated service delivery (DSD) could help to make HIV responses more efficient, including by improving efforts to locate and respond to micro-epidemics and key and vulnerable populations.

Section 2 discusses the difficulties in measuring HIV incidence and the size of key and vulnerable populations, both of which are vital things to know for future responses.

Section 3 summarizes discussions around **prevention for key and vulnerable populations**, including common barriers and possible solutions. Issues referred to include integration and costing.

Section 4 defines and analyzes the DSD approach. Particular attention is paid to:

- DSD's benefits and concerns in general, and for prevention more specifically:
- the consequences and opportunities for communities; and
- digital and mHealth entry points.

Section 5 consists of a sample list of **suggestions and recommendations** made at the meeting **to move forward a linked DSD–micro-epidemics agenda.**

Section 6 describes a series of high-priority issues and potential follow-up activities for the overall initiative, based on suggestions and outcomes of the first two meetings.

1. Introduction

Ensuring Efforts to Scale up, Strengthen and Sustain HIV Responses is an initiative launched in April 2017 by the Joep Lange Institute. The initiative's overall objectives are 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;
- · efficiently targeting the use of resources; and
- building new and more sustainable approaches for funding.

Three meetings will anchor the initiative's agenda. A comprehensive report and findings from those meetings, along with additional work products to highlight research, communications and advocacy needs and strategies, will be launched at the International AIDS Conference in Amsterdam, July 2018.

Accelerating HIV incidence reduction through differentiated service delivery: scaling up the next wave of the HIV response

The first meeting, held in September 2017, focused on 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. The second meeting centered on measurement of incidence and on approaches and strategies to make responses more efficient, with an emphasis on differentiated service delivery (DSD) and HIV prevention efforts for highly vulnerable populations.

DSD is a high-profile concept that is currently favored by many policy makers, advocates and researchers seeking to improve HIV responses. Its increasing prominence 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 will require considerably less ongoing health system interaction while following through on treatment and prevention interventions. In addition, expectations (e.g., for continued, accelerated scale-up of responses) will be difficult to meet in constrained environments (e.g., stagnant or declining financing for HIV) unless greater cost and quality efficiencies are achieved.

DSD is seen as one approach to provide services to more people for less money. The underlying case for DSD is summarized below. To date, it has mostly been applied to services along the treatment and care cascade, an issue that is noted in the detailed discussion in Section 4.

The gaps that matter: micro-epidemics and key and vulnerable populations

The markers of success for global and national HIV responses obscure some realities that must be better understood and factored into decisions guiding future programming. Even in countries that have met or are close to meeting the UNAIDS Fast-Track initiative's 90-90-90 targets, many individuals and communities are missing or are being left behind. (Box 1 below highlights some notable findings from recent studies exposing critical gaps in responses in some of the world's highest-burden places.)

In most places, those individuals are not being reached even though they should be the highest priority to reach, given that they tend to be the most vulnerable to HIV infection with given that they tend to be the most vulnerable to HIV infection and thus more likely to transmit the virus as well.

No HIV response can be considered a success, regardless of top-level target achievements, when these populations have limited, insufficient or non-existent access to comprehensive HIV prevention, care and support services. No future success in controlling or 'ending' AIDS can be realistically contemplated if such failure persists.

Box 1. What we learned at the 2017 Paris IAC: major gaps within top-level progress

Scale-up prompted in part by the UNAIDS Fast-Track agenda has had remarkable success in many places, including some of the lowest-income, highest-burden countries. Rigorously obtained evidence was presented at the July 2017 International AIDS Conference (IAC) in Paris and at other points in recent months.

Notably, comprehensive recent data have come from findings from the Population-based HIV Impact Assessment (PHIA) Project—funded by PEPFAR, with technical support from CDC and implemented by ICAP at Columbia University—which consists of nationally representative household HIV surveys in 14 countries. Survey outcomes include national HIV incidence among adults, sub-national prevalence of viral load suppression, and HIV prevalence among adults and children.

As of October 2017, PHIA results for six countries had been released. An ICAP news release from 17 October 2017 summarized as follows¹ [*emphasis added*]:

"In Lesotho...results show HIV viral load suppression...has reached over 67 percent among all HIV-positive adults ages 15–59. This finding suggests that Lesotho is on track to achieve epidemic control by 2020, through reaching the UNAIDS 90-90-90 targets and expanding HIV prevention. Full achievement of 90-90-90 is equal to viral load suppression among 73 percent of all people living with HIV.... With the announcement of the [Lesotho] results, *five African countries are now approaching control of their HIV epidemics*: Lesotho, Malawi, Swaziland, Zambia, and Zimbabwe. In addition, Uganda's epidemic has likely stabilized due to increases in coverage of voluntary medical male circumcision for HIV prevention, as well as expansion of HIV treatment, including for pregnant women living with HIV."

While welcome and commendable, a deeper analysis of the overall PHIA results reveal some shortcomings that could restrict further progress. **Young people are being missed**, and this is a serious concern given that 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 2010.²

The gaps start at the very beginning of the HIV treatment cascade. According to pooled PHIA data from Malawi, Zambia and Zimbabwe, nearly 60% of people living with HIV (PLHIV) aged 15–19, and about 50% of those aged 20–24, are *unaware of their HIV status*.³ 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 PLHIV aged 15–24 in Zimbabwe, Malawi and Zambia, respectively.⁴ (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 Zambia.⁵

Epidemics cannot be considered 'in control' given such gaps and disparities. Other presentations at the 2017 Paris IAC 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 PLHIV in the country are not virally suppressed.⁶ 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."⁷

Another important consideration is that although HIV prevalence and risk tend to be greater among adolescent girls and young women, especially in sub-Saharan Africa, *most PLHIV* who have not been diagnosed are male. ICAP's global director, Dr. Wafaa El-Sadr, acknowledged this issue and pointed to the need for greater emphasis on the missing when discussing PHIA findings in October 2017: "It is evident that young people, particularly young men under 35 years of age, are reluctant to get tested for HIV, which hinders efforts to stem the spread of this infection. Reaching them is critically important to achieving the ultimate goal of ending this epidemic."

These examples of incomplete treatment coverage represent a significant prevention shortfall. In many settings, those who are less likely to be diagnosed with HIV and thus less likely to be virally suppressed are often more likely to engage in behaviors that could result in HIV transmission. The imperative to reach them is essential both for their own health as well as the health of their communities.

Finding those left behind is a vital priority for every country. Who and where these missing people are, and why they are missing, varies by context. For scale-up to be effective and sustainable, it makes increasing sense to conceive of several micro-epidemics in each country

¹ http://bit.ly/2y5uuGQ

² The Economist, 'The Dividend is Delayed: Hopes that Africa's dramatic population bulge may create prosperity seem to have been overdone', 8 March 2014.

³ Presentation by Deborah Birx, head of PEPFAR, at the July 2017 International AIDS Conference in Paris. The title of her presentation: 'Knowing who has been left behind and evolving programs so no one is left behind: Using data to focus programs on specific locations and populations for maximal impact 90/90/90 across gender, all age bands and all risk populations.'

⁴ Ibid.

⁵ Ibid.

⁶ Study title: 'Correlates of being outside the 90-90-90 cascade among adults aged 15-64 years in Zimbabwe: Results from the 2015-2016 Zimbabwe Population-based HIV Impact Assessment (ZIMPHIA)'. Authors: Avi J Hakim, Elizabeth Radin, Leala Ruangtragool, Amy Herman-Roloff, Nahima Ahmed, Godfrey Musuka, Hazel Dube, Mutsa Mhangara, Lovemore Gwanzura, Shungu Munyati, Elizabeth Gonese, Amaka Nwankwo-Igomu, Hetal Patel, Katrina Sleeman, Steven Kinchen, Jessica Justman, Beth A Tippett-Barr for the ZIMPHIA Survey Team

⁷ Study title: 'Estimating HIV incidence and the undiagnosed HIV population in the European Union/European Economic Area'. Authors: Ard van Sighem, Anastasia Pharris, Chantal Quinten, Teymur Noori, Andrew Amato-Gauci, and the ECDC HIV/AIDS Surveillance and Dublin Declaration Networks
⁸ http://bit.ly/2y5uuGQ

or region instead of one monolithic one. *These 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. 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.

There is no one-size-fits-all solution to reducing incidence. But regardless of the context, *more information—both quantitative and qualitative—is needed to design, implement and sustain approaches that show impact*. Reliable data and estimates do not always exist about population sizes. Many obstacles and challenges have complex roots that are not always easily evident but should be identified and assessed, including those related to culture and gender. Inaccessibility to relevant HIV and other health and social services among key and vulnerable populations often is much greater due to unique factors such as criminalization, discrimination, and other legal and policy barriers.

Incidence reduction in micro-epidemics also relies on greater attention to prevention. The emphasis on treatment among donors, technical agencies and national HIV and health programs has had remarkable success, as more than 20 million people are now on antiretroviral therapy (ART). A prevention gap persists, however. The contrast could hardly be starker considering the dispiriting fact that the number of annual new HIV infections worldwide has barely budged from 2 million in recent years.

Clearly, despite the substantial effect of ART in preventing onward HIV transmission, treatment alone is insufficient to significantly reduce overall incidence. The preventive benefits of ART are only useful for those who know their HIV status and are successfully initiated into and retained in care. Key and vulnerable populations are far less likely overall to have that knowledge or to be able or willing to get appropriate, acceptable treatment and care. Scale-up of additional prevention interventions is essential in controlling HIV. However, in order for combination scaled up prevention efforts to be successful, they must be designed and introduced after two basic questions are answered: (1) Where are the new infections? (2) How to determine the most effective prevention approaches for any given population and environmental context?

2. Measuring Incidence: Current Tools and Limitations Regarding Microepidemics and Key and Vulnerable Populations

Measuring incidence is difficult in general. Mathematical modelling methods are being used to derive estimates of incidence at regional (SNU-1) and lower-level sub-national levels (e.g., SNU-2), but data and information remain limited. Without the ability to improve incidence measurement at sub-national levels, it is difficult to effectively target HIV prevention and testing services. Significant gaps in information also exist regarding the size and specific risk features among many key populations, due in part to a lack of disaggregated data. Improvements in both areas are needed to be able to target epidemic resources more efficiently and effectively.

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 assays⁹ 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 be 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.

To obtain its population size estimates, UNAIDS uses several mathematical models and provides technical support to country-level processes. Generally speaking, agency software uses a module that relies on multiple inputs to develop estimates, including HIV surveillance data from antenatal care (ANC) services, household surveys and surveys among key populations, as well as case reports and demographic and population size estimates. UNAIDS must rely on what data are available from each country, which sometimes consists of prevalence information only and nothing at all on incidence.

Social media was presented as one option that could help with population size estimates among some key populations. For example, studies have pointed to the potential benefits of analyzing information available through Facebook Adverts Manager or online platforms popular among MSM, including Hornet. According to the findings from one analysis of Facebook information in Nigeria, 3.3 million men appeared to have same-sex interests and profiles of 2.8 million men indicated interest in both men and women. Such information is not generalizable, but it strongly suggests that 'official' data about the number of MSM in Nigeria—about 13,000 according to a method using IBBS data reported through UNAIDS—are widely off the mark (as was already assumed by many observers).

It may be that the most reliable figures around key populations rely on a combination of UNAIDS estimates, results of qualitative in-depth studies (e.g., household surveys), and social media—focused interventions such as those noted above. Using different methodologies for validation seems critical based on the assumption that no one marker has the answer.

The value of detailed research and analysis can be seen in the results of an HIV incidence household survey conducted in Rwanda in recent years, in which 13,000 people were surveyed. Although the survey did not specifically inform about key populations, two notable findings were that overall incidence was higher than previous models had indicated, and that young adults

⁹ Commercially available assays used for cross-sectional incidence testing include LAg-Avidity, BED-CEIA, and Bio-Rad Geenius. Eight other assays for this type of testing were also noted in a meeting presentation. A combination of options is used for most testing. Other assays include: INNO-LIA, BioRad 1 / 2 + O Avidity, Vironostika LS, V3 IDE, Vitros LS, Abbott AxSYM HIV 1 / 2 g Avidity, Bio-Plex Multi-analyte, and Architect Avidity

and single people are among the largest contributors. These findings have major implications for future HIV resourcing and programming—including that young people who initiate ART are likely to be on it for decades. All countries would benefit from having even more detailed incidence information that singles out different key populations.

3. Preventing Infections among Key and Vulnerable Populations: Relevant Barriers and Options

The difficulties in measuring incidence are matched in magnitude by those associated with preventing infections, especially among key and vulnerable populations. Even the most accurate and up-to-date data about population size will make little difference if they are not accessing the services they need. The **multiple barriers** cross most sectors of society, thereby offering important reminders that HIV responses cannot be limited to biomedical interventions. The following are among those that must be addressed directly in most contexts:

- Legal barriers (e.g., criminalization)
- Age of consent laws, many of which turn away vulnerable adolescents and young people
- Unfriendly and non-confidential services, including in clinics and other health facilities
- Lack of targeted services, such as those that respect and acknowledge the specific health and other needs of transgender people and tailor core services in response
- Stock-outs or shortages of antiretroviral drugs, other medicines and diagnostic commodities such as HIV and viral load testing kits
- Lack of knowledge of or access to pre-exposure prophylaxis (PrEP)
- Restrictions on funding of civil society groups, including those working directly with communities and key populations
- Lack of adequate financial and programming resources for prevention in general, and for the most at-risk in particular. The amount of prevention money that reaches key populations is low in most contexts.

Proposed solutions for improved prevention results among key and vulnerable populations also cross multiple sectors. Most will only be useful as part of combination prevention approaches that involve both government structures and independent civil society groups. Some have been proven to be effective and are in various stages of wide use, such as PrEP, condoms and lubricants, safer injection practices and <u>voluntary medical male circumcision</u> (VMMC). Others, including many of those listed below, are newer, less focused on commodities, and have less evidence showing effectiveness (often because their implementation is so limited). Some of these are already relevant in some settings but should be scaled up to have maximum impact:

- Treatment literacy for all people diagnosed with HIV and, where relevant, their partners or caregivers.
- Online platforms to deliver HIV messages and mobilize for testing and other HIV services
- Access to and engagement of community peers
- Easy and consistent access to HIV self-testing kits, including online (ideally)
- Strong and consistent advocacy by community-based groups and key population networks
- Wraparound and one-stop-shop services, all of which are adolescent-friendly
- Identification and use of 'influencers' (e.g., social media stars, sports figures, parents, peers, etc.)

Other potentially useful activities are more strategic in nature. For example, targeted measures (e.g., a tool or survey¹⁰) to track stigma and discrimination could be helpful for policy makers and advocates, and developing prevention cascades relevant for individual contexts could assist in determining the major gaps and specific interventions to bridge them.

Initiatives have been introduced in many places with the specific purpose of reducing transmission risk among key and vulnerable populations. PEPFAR's DREAMS project focuses on adolescent girls and young women in several sub-Saharan Africa countries. In South Africa, the Zimele Project's emphasis on social protection includes using cash interventions to boost empowerment among a similar population. (Other such mechanisms that focus on key and vulnerable populations, either programmatically or in terms of targeted funding, include PEPFAR's Linkages program, the Robert Carr civil society Networks Fund, and the Red Umbrella Fund, which supports organizations led by sex workers.) All initiatives of this sort should be rigorously evaluated and scaled up only if proven effective.

Both DREAMS and the Zimele Project are grounded in the belief that HIV prevention improvements rely on closer integration across numerous sectors that engage adolescents and young women on a regular basis, such as education. 'Multilayering' of services is the process through with HIV responses are being brought to scale among these individuals. A similar 'layering' approach could hold promise for key populations and others at the heart of microepidemics.

¹⁰ Some useful tools of this sort already exist. See, for example: www.unaids.org/sites/default/files/media asset/2017-Global-AIDS-Monitoring en.pdf

Box 2. Costing prevention: factors and complexities

The large and growing number of prevention interventions can lead to competition for resources and prioritization. Quality, effectiveness, acceptability and impact are some factors that should determine access and uptake. All can be difficult to measure—such as, for example, the effectiveness of behavioral interventions. The lack of evidence of effectiveness for such interventions can make cost-effectiveness determination challenging. This is just one of the factors behind the difficulty in measuring costs of individual or comprehensive prevention.

Combination HIV prevention by nature consists of access to numerous support and other services that cover the needs and specific situations of those at risk for and vulnerable to HIV. Programs are more likely to be able to develop viable, sustainable plans when accurate costing data for all such interventions are available in their contexts. These costs vary widely by geography, both among and within countries. Unit cost determination therefore is a highly context-specific endeavor. The complexity is enhanced by the need to cost multisectoral interventions with multiple inputs, which will be more important moving forward.

Costing data tend to be available for prevention interventions that are well-defined, are easily considered health sector costs, are one-off in nature, and are implemented widely—such as HIV testing and counselling (HTC), prevention of mother-to-child transmission (PMTCT) services, VMMC and treatment. Less costing data are available, however, for many behavioral and bio-behavioral prevention interventions, especially those targeted for one or more key populations.

A few studies have given some indication of factors that influence costs. Scale matters, for example, with unit costs declining as uptake increases. Allocation also matters: this refers to the amount and share of resources dedicated to interventions that are evaluated as 'effective' and not so effective in terms of preventive impact.

Evidence also indicates that costs for highly effective yet seemingly expensive interventions, such as PrEP, can be brought down to more manageable and acceptable levels. In Uganda, for example, study results found that PrEP costs were a third cheaper than originally gauged after factoring in policy changes, such as task-shifting, and health care impacts including the need for fewer lab tests and reduced medication costs compared with a baseline of no PrEP.

The context-dependent nature of costing is illustrated by the fact that in South Africa, PrEP originally was listed as 'not cost-effective' in the March 2016 South African HIV and TB Investment Case publication compared with several other prevention-specific interventions (e.g., condom availability) and universal test and treat. Officials put PrEP in that category based on assumptions that it would be a relatively costly intervention, even though they considered it an effective one. A main reason for their caution appeared to be a lack of available public-sector implementation costs.

That example makes the important, linked points that costing can throw a critical intervention off track and that *decisions about interventions should be based on effectiveness as well as costs*. Clearly defining both the impact and the overall cost of an intervention should be undertaken in advance of decision-making.

4. The DSD Approach: Potential Benefits and Concerns for both Treatment and Prevention

4.1 Defining and assessing differentiated service delivery (DSD)

DSD has been defined by the International AIDS Society (IAS) as a "client-centered approach that simplifies and adapts HIV services across the [treatment] cascade to reflect the preferences and expectations of various groups of PLHIV while reducing unnecessary burdens on the health system." The underlying idea is to offer and make available a range of different services contingent upon not only clinical characteristics but also on demographic and other contextual ones (e.g., rural/urban, migrant status, etc.).

DSD marks a departure from the longstanding public health approach to HIV, which has been based on a consistent package of care for all people living with or otherwise affected by HIV. That approach "got us to where we are now", in the words of one Amsterdam meeting participant, by enabling standardized procurement, laboratory planning and health staff training, among other things. Yet today, it is necessary to do things differently to move to the next level to address current, persistent barriers in terms of access (coverage), quality and efficiency.

Differentiated care, as another participant observed, is based on "knowing your clients"— including what their specific needs are and what can make things simpler and better for them. What might be termed 'adaptive care' does not mean personalized service, however, as that would be impractical and impossible to provide for large numbers of clients. Some standardization across DSD models is needed even as individualized methods of follow-up and care are introduced. Even though different models will likely be used in different contexts, some parameters will be needed because the models must fit into health systems.

For HIV treatment purposes, one DSD example has been to divide clients into 'stable' and 'unstable' categories, based on indicators such as viral load levels and treatment adherence history. In some HIV treatment programs, stable clients join peer-based adherence clubs and visit clinics perhaps once every six months or a year. In addition to making care easier for clients, and therefore supporting their efforts to remain adherent and healthy, such 'out-of-facility' components ease burdens on health care facilities and their staff. This can enable nurses, doctors and other facility-based personnel to see more clients and to focus on those with failing regimens or other HIV treatment challenges. Other strategies aimed at reducing client visits include innovative interventions such as ARV-dispensing ATM machines (introduced in South Africa) and, eventually, home-based HIV testing and viral load monitoring.

As these examples indicate, most DSD work to date has focused on treatment. DSD conceivably can also be put to use for prevention purposes—and in some ways, prevention has always been differentiated, as groups and individuals have different risk profiles. More systematic and strategic efforts are now needed to differentiate prevention. Expansive use of differentiated prevention approaches is essential to tackle micro-epidemics and reach key and vulnerable populations.

Learning from treatment-focused interventions is a useful first step: e.g., the success of adherence clubs for people on ART suggests that similar interventions could be used for clients on PrEP. The 'knowing your clients' principle can lead to better understanding of whether and to what extent vulnerable populations such as adolescent girls recognize their HIV risk.

Service delivery should also be influenced by that principle. DSD could *generate more intensified, targeted stigma-reduction actions and interventions* that zero in on health care settings and other sources of stigma and discrimination that disproportionately affect key and vulnerable populations.

It is likely too, for example, that 'knowing your clients' would make peer educators central components of prevention models targeting adolescents and most key populations. 'Prevention literacy' provided by peers and other community-based sources will be just as important as 'treatment literacy'—and for PrEP, among other services, it will share many of the same messages. Treatment education is therefore a cornerstone of DSD. All partners in HIV responses should get more serious about it. Scaling up cannot proceed successfully as long as many people still do not understand things such as the difference between CD4 and viral load, what the pills they are taking are meant to do, what second-line treatment is, etc.

Despite the promise of DSD in general and for prevention specifically, there are many challenges and concerns about structures and impact. *A major concern is whether health systems can handle the complexities and complications that inevitably result from multiple ways of managing clients*. Health care staff must understand different models and properly facilitate care and support across them. DSD can 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. A question to consider is: How much differentiation can a system bear?

That question is relevant not just from a structural or programming perspective. Cost considerations also must be analyzed and taken into account. Some governments might conclude that the overall DSD approach or one or more DSD models are too costly to implement. The latter apparently was the reason given by the Philippines Department of Health when it recently rejected a community-developed proposal for a differentiated approach for MSM and subcategories within that key population.

Another concern is that DSD models will fail to fully consider and accommodate human rights and community engagement. 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 remain stigmatizing and unfriendly. Similarly, opening a clinic in a micro-epidemic area does not quarantee that key populations or others will visit.

4.2 Consequences and opportunities for communities

The community engagement component is far more than incidental. DSD represents a shift toward more 'client-centered' or 'people-centered' care, which is what communities have always sought and fought to achieve. For DSD to work 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.

Investment in communities is required for this to happen. Whatever the models used, DSD will be weak and imperfect if civil society groups and CBOs continue to face funding cuts and close down.

More, better and consistent community systems strengthening (CSS) is another imperative, 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. 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.

The value of community engagement is widely acknowledged across all sectors involved in HIV responses. Less fully understood, if understood at all, is what it means in practice and what might be done to achieve it. This ongoing challenge has created tension between government and civil society sectors in many contexts.

One obstacle is that governments frequently find it difficult to incorporate community approaches into health care systems. Officials often claim that they cannot easily make the case for funding community groups. Among other things, some say that they need better data showing the impact of services provided by communities and that communities do not meet accountability standards (e.g., for providing routine reporting on number of people served and activities undertaken). Many civil society stakeholders reject such assertions, arguing that they have demonstrated the ability to meet such standards and expectations but are still denied funding opportunities.

Disagreements of this sort over what should count as viable, acceptable evidence—or at least evidence of value—of community-led or -influenced interventions represent a notable obstacle to treatment and prevention scale-up. Failure to improve coordination and collaboration could limit the impact of DSD.

Some observers argue that instead of emphasizing communities within DSD, the conceptualization should be community-led approaches that include DSD. In this view, DSD could be a guiding model for HIV and much broader and wider health and development areas—e.g., to address non-communicable diseases (NCDs) and poverty--within an integrated structure that is community-focused and -directed.

4.3 Digital and mHealth entry points

Some existing and new digital and mHealth options could be instrumental in DSD models, especially if they improve access to effective prevention and treatment services for key and vulnerable populations. Substantial attention has focused on adherence to ART, with notable positive outcomes seen in once-a-week check-in through text messaging. Two-way messaging also appears to lead to better impact than one-way. However, other approaches, such as alarms systems and pill-taking reminders, have not been shown to be effective.

These and most other studies of interactive digital approaches to improve care have focused mostly on treatment. *Finding ways to use digital components such as SMS for prevention should now be a critical priority*. Some entry points will not be the same, but learning from what has been shown to work can hasten design and development. One immediately obvious

opportunity would be to adapt ART adherence-improving interventions to PrEP services for prevention. This makes sense from both a health and financial perspective because it is well-known now that adherence is highly cost-effective. Just about any financial and other inputs into improving adherence support will almost certainly be worth it.

5. Suggestions and recommendations to move forward a linked DSD-microepidemics agenda

Accelerating and improving efforts to measure incidence should lead to more targeted, effective HIV responses to micro-epidemics and among key and vulnerable populations. These efforts will be crucial as well to the design and development of DSD models, especially their prevention-focused features. The reverse impact is also likely: developing and introducing DSD models should prompt more attention to the specific needs of key and vulnerable populations and the existing data showing how and by whom they can best be reached.

Whatever form DSD takes in a context, core treatment and care provisions must be accessible and available to all in need. For example, both treatment and prevention outcomes are influenced by access to viral load monitoring and HIV treatment specialists who can assess and respond to treatment failure and drug resistance. Listed below are a sample of suggestions and recommendations raised during the meeting as to how to achieve the shared overall goals.

- More resources should be available for planning and analysis, especially for countries that have less money to conduct comprehensive epidemiological studies or to introduce targeted services for key populations.
- Strategies and interventions should be crafted using real-time data. Making
 decisions based on data that are three, four or more years old can never achieve
 intended impacts given the pace at which epidemics change, including where and
 among whom micro-epidemics exist. Countries and other stakeholders that seek to
 gather and use more recent data will likely need technical support and dedicated
 financing.
- Efforts to determine reliable estimates on key population sizes and risk factors should be undertaken through collaboration with—and leadership by, if necessary—key population groups and other civil society organizations. Such an approach is needed to help craft more acceptable, validated estimates and minimize the highly political nature of counting key populations in many contexts.
- Unique IDs should be introduced and aligned with HIV and health systems. One result could be better case-reporting systems and tracking/monitoring of clients.
- Stronger evidence is needed as to civil society groups' contribution and impact in
 all aspects of HIV responses, including direct service provision and supportive roles in
 HIV prevention and treatment efforts. At the same time, (1) governments and other
 partners must provide clearer guidance as to their expectations for collaboration,
 whether or not funding is involved; and (2) whatever evidence and capacity are required
 of civil society should be the same as for all other partners, including other government
 ones.

- More studies and focus on acute infection could help to track and monitor incidence and epidemics overall.
- Regular, independent country-level monitoring should be undertaken of budgets
 to track targeted funding for key populations in HIV responses. Communities and
 civil society groups are best-placed to take responsibility, but they will need adequate
 resources and at least basic cooperation of relevant government agencies. Many will
 also need training or support to successfully undertake such budget advocacy.
- Greater integration is needed to achieve better HIV prevention results. The most
 effective way to deliver HIV interventions to adolescents, for example, might be to build
 adolescent-friendly services offering a range of things adolescents need for their overall
 health and social well-being—and not rely on an HIV-specific adolescent clinic.
 Expanding this 'layering' approach as widely as possible could result in more extensive
 use of promising interventions such as conditional cash transfers and peer-support
 initiatives for sexual and reproductive health services.

On a programmatic basis, *integrated systems might include joint dashboards* to collect data from a range of different programs. This could promote coordinated, complementary decision-making that addresses gaps in comprehensive HIV prevention efforts.

- Multi-sectoral collaboration through communities of practice could be a useful strategy to prepare for and implement DSD models. In Senegal, for example representatives from government and civil society (including key population groups) meet every three months to share experiences as part of an effort to improve delivery of prevention and access to health care for key populations. Regular engagement of this sort can result in more timely, accurate data and observations on risk and access to care among key and vulnerable populations. In turn, that input can positively influence HIV resourcing and policy decisions.
- DSD-supporting regulatory changes should be pursued. One focus area should be
 on enabling the rapid uptake of evidence-based prevention interventions, both those
 now potentially available and others that are introduced in the future. PrEP should be a
 priority in most contexts, yet in many the legal use of ARVs for non-treatment purposes
 is either unclear or not allowed. Task-shifting, which can be critical for DSD, also can
 require regulatory and legislative changes.

6. Potential Follow-up Activities

Below is a short description of high-priority issues and potential follow-up activities to address them, as suggested by some participants during the first two meetings of the overall initiative. The organizers would like to undertake as many of them as possible, after further investigation of other current efforts in the field, and present the outcomes from the work as part of the preconference at the AIDS 2018 conference.

 Key population size estimation – The challenges of improving understanding of the size and location of key population communities are long-standing. *Proposal*: workshop meeting that would focus on improving methods to document key population size

- estimates at country levels. A report from the meeting would also describe current examples of innovative ways to improve knowledge and methodology.
- 2. <u>Measuring local and sub-national HIV incidence</u> *Proposal*: workshop to discuss methods to improve measurement of HIV incidence at sub-national levels and within key and vulnerable populations. The meeting report would include examples of innovative approaches, recommendations for improving knowledge and methodology.
- 3. <u>HIV prevention cascades and differentiated risk flow charts for key populations and prevention interventions</u> *Proposal*: article development describing current and potential efforts to differentiate HIV transmission risk among key and vulnerable populations along with appropriate interventions for different levels of risk and need.
- 4. <u>Improve the accuracy of unit cost estimates for HIV prevention and key population service delivery</u> *Proposal*: workshop meeting to develop methods for improving the accuracy of cost estimates. A meeting report would provide recommendations and next steps for implementation.
- 5. <u>Monitoring challenges to drug delivery at local levels</u> *Proposal*: survey of community-based organizations to monitor and report on treatment access challenges at local levels and report on methods to monitor stock-outs and shortages of drugs and diagnostics at local levels.
- 6. <u>Transition and scale up of new first-line ART regimens</u>: Transition to a dolutegravir-based first-line regimen could have substantial benefits in treatment outcomes and cost-effectiveness. *Proposal*: article describing the challenges toward scale-up along with a framework to address these and an estimated timeline for implementation.
- 7. Challenges and opportunities in scale up of community-based services *Proposal*: overview article describing: (1) the role of community organizations in service delivery, (2) need for and methods of training and performance monitoring, (3) need for payment for community and peer-providers, (3) methods to address resistance from health systems, (4) integration of social services with health systems, and (5) the need for and approaches to development of sustainable funding mechanisms.
- 8. Development and implementation of reporting mechanisms for community-based service delivery *Proposal*: article describing the need for and challenges of developing and implementing government data collection from community-based service delivery and other DSD approaches. Examples and recommendations would be included. (A workshop meeting approach could be useful here as well).
- 9. Analysis of potential risks and benefits of strategies to integrate HIV into broader development and UHC goals, funding streams, and program development *Proposal*: small meeting of advocates and policy makers to discuss the programmatic value, funding risks and opportunities, and advocacy strategies to determine if and how HIV service provision should and can be incorporated into broader efforts to improve overall development, reduce poverty and improve health.
- 10. *Proposal*: meeting with non-HIV communities/movements about similarities in struggling with ODA/development trends and how to work jointly on this.