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Reaching the 95-95-95 targets: How can industry contribute?

Session 1: HIV testing strategies to reach key populations

Roundtable, 18 April 2023

Background

On 9 June 2021, United Nations Member States adopted a political declaration[i] calling on countries to provide access to people-centred and effective HIV combination prevention options for 95% of all people vulnerable to acquiring HIV within all epidemiologically relevant groups, age groups and geographic settings. The declaration also calls on countries to ensure that 95% of people living with HIV know their HIV status, 95% of people who know their status are on HIV treatment, and 95% of people on HIV treatment are virally suppressed. This declaration reinforces and accelerates the UNAIDS Fast-Track strategy to end the AIDS pandemic by 2030[ii], adopted on 18 November 2014, which included achieving the 90-90-90 testing and treatment targets by 2020.

Globally and at regional levels, the 90-90-90 testing and treatment targets were missed. However, progress has been steady and, at the end of 2020, 84% (67-98%) of people living with HIV knew their status; among those who knew their status, 87% (67-98%) were on treatment; and 90% (70-98%) of those on treatment were virally suppressed[iii] . At least eight countries in settings as diverse as Botswana and Switzerland[iv] had achieved the 90-90-90 targets on

time, showing that with sufficient funding, political will, policies and evidence-informed interventions, the targets were not overly ambitious.

The 2025 95-95-95 targets extend the 90-90-90 targets to include meeting women's needs for HIV and sexual and reproductive health services, promoting the use of appropriate and prioritized person-centred combination prevention by people vulnerable to acquiring HIV, and adopting an integrated approach to well-being and healthcare, as well as addressing social and legal barriers that limit access to and use of HIV services.

Learning from both the successes and failures towards reaching the 2020 targets is essential to increase the chance of ending AIDS as a global public health threat by 2030. Success will require commitment from all stakeholders in the HIV response. The Industry Liaison Forum at IAS – the International AIDS Society – is organizing a series of online roundtables to explore important gaps and how the biomedical industry can actively contribute to achieving the 95-95-95 target by 2025.

The series will have three events, each focusing on one of the specific 95-95-95 targets.

Agenda

Welcome and opening remarks Helen McDowell, ViiV Healthcare, Industry Co-Chair
Testing strategies for vulnerable populations Cheryl Johnson, Technical Officer, HIV Testing Services, WHO
Community perspective: Current barriers to HIV testing Omar Syarif, GNP+
HIV testing among transgender women attending the Tangerine Community Health Clinic, Bangkok, Thailand Rena Janamnuaysook, Tangerine Health Clinic, Bangkok, Thailand
Challenges of registering new products Duncan Blair, Abbott

Panel Discussion
Mapping the way forward: Reaching key populations & overcoming testing barriers *Facilitator:* Helen McDowell
Panellists:
  • Antons Mozalevskis, WHO
  • Jennifer Sherwood, amfAR
  • Tafadzwa Dzinamarira, ICAP, Columbia University
  • Samuel Boova, Beckman Coulter Life Sciences
  • Ombeni Mwerinde, Unitaid

Summary and closing remarks Helen McDowell, ViiV Healthcare, ILF Industry Co-Chair

Opening and welcome

Despite progress with HIV testing technology and uptake, many individuals vulnerable to HIV acquisition do not know their HIV status, in particular, people in key populations that face stigma and discrimination. This first Industry Liaison Forum (Forum) event reviewed current knowledge on key populations and HIV testing, as well as barriers to HIV testing and outreach strategies, with the aim of identifying areas where the pharmaceutical industry can contribute to improving testing strategies and uptake of HIV testing.

Summary of the presentations

Testing strategies for vulnerable populations
Cheryl Johnson, Technical Officer, HIV Testing Services, WHO

This presentation laid the key groundwork for the rest of the session, focusing on differentiated testing services for key and vulnerable populations. It is important to recognize the significant progress that has

been made in the field of HIV testing since the start of its roll out when only a small number of people had access to testing and could become aware of their status. Decentralized testing and rapid testing were the initial steps that led to significant gains.

Several new testing approaches, such as self-testing, social network testing and index testing, have emerged with a focus on ensuring that individuals who may not have access to service delivery are tested. These approaches have been effective in increasing the number of people who know their HIV status and have facilitated the scaling up of antiretroviral therapy (ART), with 84% of people living with HIV globally now aware of their status.

- A significant gap remains, with 16% of people living with HIV undiagnosed. Men, adolescents and migrants are some of the key populations that are being left behind, and more effort is required to reach low HIV incidence by 2030.

- Lessons learnt from treatment scale up can help in reaching out to those who do not or cannot yet access HIV testing services.

- The World Health Organization (WHO) testing strategy recommends neutral HIV testing prevention and care approaches that provide a pathway to prevention and treatment, especially for those vulnerable to acquisition, such as key populations.

- A focus on balancing efficiency and impact is needed.

- About 70% of new acquisitions occur in key populations that require tailored delivery services. Differentiated testing delivery services can be broken down into multiple pillars to ensure that they reach the right people. Ensuring linkage to care is also important and is the responsibility of the testing programme.

Creating a supportive environment for testing is just as crucial as the testing method itself. To achieve this, WHO has established a framework that focuses on various essential enablers, one of which is the "Undetectable equals Untransmittable" (U=U) message. By incorporating this message, key populations are more likely to be encouraged to undergo testing, whether it is through self-testing or provider-based testing. However, provider-based testing is generally more widely accepted and leads to a higher rate of uptake.

Currently, many testing programmes utilize either rapid tests or self-testing due to their scalability and affordability, making them ideal for a

range of settings. Furthermore, these testing methods offer accurate diagnosis, with the added benefit of allowing for same-day treatment initiation. With approximately 20 WHO prequalified HIV rapid test kits, three dual HIV/syphilis test kits and six HIV self-test kits, WHO provides essential guidance to adapt testing strategies and select appropriate products for testing programmes.

HIV rapid testing is gaining momentum, with dual testing becoming more common. However, despite stable product prices, cost remains high, which creates difficult choices and impedes the widespread implementation of recommended testing strategies.

To implement testing strategies, WHO recommends cost-efficient virtual interventions and peer-led strategies. In addition to standard facility- and community-based approaches, partner services and self-testing are also critical strategies that can be utilized in both clinical settings and the community.

- *Partner services*, which involve a trained healthcare professional offering voluntary testing to the partners of consenting clients who have been diagnosed with HIV or other viral infections, have proven to be effective in vulnerable populations. It is a voluntary approach and is part of a continuum of support from healthcare providers.

- For key populations, the most effective approach is a *social networking strategy* as it enables reaching out to a comprehensive network. Index testing, followed by provider-assisted referral, remains highly effective and should be prioritized in vulnerable populations.

- *Self-testing* is a useful tool that can increase engagement, autonomy, access and equity while also improving the quality and efficiency of care by reducing costs for both individuals and the health system. Furthermore, self-testing is a crucial component of a broader framework of self-care. However, developing a linkage to care strategy for those who test positive is essential, and community involvement is necessary in this regard. Pre-exposure prophylaxis (PrEP) provides an excellent example of how self-testing programmes can be developed to suit the needs of individuals.

In combination with other approaches, an integrated, broad approach to sexual health services delivered in an enabling environment will contribute to accelerating and scaling up HIV testing, with the ultimate goal of achieving the first 95 target.

Community perspective: Current barriers to HIV testing
Omar Syarif, GNP+

GNP+ is a global network of people living with HIV established in 1992. The network operates through two offices and several remote locations. The presentation focuses on three major barriers to increasing HIV testing uptake: legal environment, stigma and discrimination. Omar highlighted the need for an enabling environment, including a supportive legal environment, to address these barriers.

- The first barrier is a *repressive legal environment*, which can drive people underground and away from services: 128 countries criminalize drug use and possession for personal use; 153 countries criminalize sex work; more than 70 countries criminalize same-sex practices, with harsh punishments, including the death penalty; and 92 countries criminalize HIV transmission. This creates difficulties for key populations to access facility-based HIV services as most are operated by governments, and the risk of criminalization and punishment is threatening.

- The second major barrier to accessing HIV services is current *programme design*, which relies heavily on facility-based services, many of which are operated by the government. This creates barriers for key populations who fear encountering problems with law enforcement. The programme design should be improved to better meet the needs of the target populations, and this issue is now widely recognized in the global HIV response and in the latest political declaration on HIV and AIDS. Member States set the target of increasing the proportion of HIV services delivered by communities, ensuring community led organizations deliver30% of testing and treatment services and 80% of HIV prevention services for key population by 2025.

- The third barrier is *stigma and discrimination*. Omar presented data from the stigma index study collected in 2021 and 2022 to illustrate the barriers faced by the community in accessing treatment due to the current set up. The data provide snapshots of the current situation in each country and are not meant for comparison. The data show that there are major issues with the current set up of testing services, with a significant percentage of people being tested without their knowledge or being forced into testing. The data also show examples of stigma and discrimination, particularly in government facilities.

The community has a huge distrust of healthcare workers due to their own experiences or those of their peers. Going to government facilities for treatment exposes them to the risk of discrimination and unequal treatment. This shows that the current programme design is not meeting the needs of the target population.

Another major issue is related to funding. Over the past seven to 10 years, there has been a lack of adequate funding for HIV and AIDS programmes. Despite the increasing need, resources have remained stagnant, which has made it difficult to achieve the targets for the programme. This is especially concerning if we want to reach the 95-95-95 targets by 2030. Currently, the two main funders in the HIV and AIDS response are the Global Fund and PEPFAR, but even their funding schemes have limitations.

PEPFAR is a government-to-government funding programme that gives the government more control over how funding is used. However, with flatline funding and increasing needs, community programmes are often left out. The Global Fund mechanism is more engaging in how the funding is utilized, but most of the control still lies with government institutions. When it comes to efficiency, outreach programmes are often the first to be cut.

To increase the uptake of HIV testing among key populations, there is a need to address the issues of stigma and discrimination in healthcare facilities, as well as the flatlined funding landscape. These two issues are interconnected and have a significant impact on the effectiveness of HIV testing programmes. It is crucial to use resources more efficiently and find innovative ways to address the needs of key populations.

Omar emphasizes that based on his experience and observations, most of the funding for HIV and AIDS is spent on commodities. There is a need to work together to reduce high spending on commodities, which could be achieved by revisiting the pricing strategies of the industry. Revising pricing strategies could be the biggest contribution industry can make to the community and could be a game changer in using resources for important programmes. Omar hopes that the Forum will address and make recommendations on drug pricing. As a representative of the people living with HIV community, he is looking forward to having this conversation with the Forum on drug pricing.

HIV testing among transgender women attending the Tangerine Clinic, Bangkok, Thailand
Rena Janamnuaysook, Tangerine Clinic, Institute of HIV Research and Innovation Bangkok, Thailand

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The presentation focused on how the Tangerine Clinic implemented strategies to increase access to HIV testing, PrEP and sexual health services for trans women in Bangkok, Thailand. There are an estimated 300,000 trans women in Thailand, with 62,000 sexually active and 13,000 vulnerable to HIV acquisition. HIV prevalence among trans women in Thailand is approximately 17%. Stigma and discrimination against trans individuals and HIV status remain a challenge in healthcare settings in Thailand, with studies showing negative experiences and lack of counselling on gender-affirming care and hormone use.

When Rena joined the Thai Red Cross Research Center's Anonymous Clinic, one of the largest HIV testing sites in Thailand, in 2015, she noticed that no trans clients were coming for HIV testing because the services provided did not meet the specific needs of the trans community. While the clinic's list of sexual health services may have seemed comprehensive to some, it was inadequate for trans individuals.

As a result, the Tangerine Clinic was established in late 2015 after consultations with the trans community. The clinic provides a range of services that cater for the unique needs of trans individuals, such as gender-affirming care, hormone therapy and monitoring, as well as sexual health services. In addition, it offers mental health and well-being services, minor gender-affirming surgery and aesthetic services. The clinic also partners with a nearby hospital for referrals to genital surgery. Plans include integrating viral hepatitis C services and harm reduction services into its offerings.

The Tangerine Clinic has provided services to over 5,000 trans individuals, with 4,800 being trans women. Uptake of HIV testing is high among these women, with 93% receiving testing, of whom almost 10% tested positive. A total of 90% of those who tested positive initiated antiretroviral therapy, with most starting treatment on the day of diagnosis; 97% of them achieved viral suppression. Among those who tested HIV negative, 11% were linked to post-exposure prophylaxis (PEP) and 24% to pre-exposure prophylaxis (PrEP) services.

In total, 30% of trans women tested positive for either chlamydia or gonorrhoea, and around 10% tested syphilis reactive. In terms of demographic and risk characteristics, the median age of women attending the clinic was 26 years old, and more than half had education levels below a Bachelor's degree. Almost 24% were unemployed at baseline and almost 40% reported depressive symptoms. Additionally, 18% reported engaging in sex work, and almost 10% reported using amphetamine type stimulants. These data highlight the importance of having a trans-led health clinic that is accessible for the trans population in Thailand.

The Tangerine Clinic provides services for the trans population in Bangkok and beyond. In its eighth year, the clinic is led by a team of trans healthcare providers who are nurses, counsellors and physicians proud to serve their community with gender-sensitive services.

The Tangerine Clinic reaches the trans community through online outreach and social media platforms using trans social influencers called "Friends of the Tangerine" to spread the word about its services and encourage its followers to use the clinic.

Rena emphasizes the role of HIV self-testing, implemented at the Tangerine Clinic less than a year ago. HIV self-testing is an innovative tool that normalizes HIV and empowers key populations and should be made available and included in national healthcare benefits to increase testing coverage and frequency. The clinic uses a status-neutral approach to self-testing, and those who screen reactive are linked to confirmatory testing and HIV treatment if necessary. For those who screen non-reactive, the clinic offers PrEP based on an assessment of the client's behaviours. The clinic uses telehealth for counselling and can deliver self-testing kits and medications through motorbike or Uber-like Grab delivery. The results of testing are sent to clients via an application, email or phone.

Rena added that the focus should shift from the number of self-test kits distributed and returned to national CD4 counts at diagnosis and ART initiation, and the continuation rate of PrEP use from clients using HIV self-testing with telehealth.

Rena concluded with three key takeaway messages. First, integrated gender-affirming care and trans-competent providers increase access to HIV testing, PrEP and other health services among trans populations. Second, health services should be organized around the health needs of the people rather than focusing on individual diseases. Last, trans-led and trans-owned programming is crucial to the HIV community and should be sustained.

Challenges of registering new products
Duncan Blair, Abbott

Duncan focused on the challenges and opportunities of providing new innovations to those who need them. He acknowledged the importance of WHO's technical leadership in HIV self-testing and the role of self-testing in improving access to healthcare. He highlighted the institutional barriers faced by marginalized communities and the importance of tailored service delivery. He also noted the relevance of different service

delivery methods, including the use of HIV self-testing, in providing context.

Industry's key role is in developing, manufacturing and supplying healthcare products. There are additional roles that industry can play, such as community and healthcare provider education, policy debates and scientific contributions. However, the fundamental focus is delivering critical healthcare products.

Innovation is a crucial aspect of industry's role in delivering health products. The use of HIV rapid tests has enormously expanded access to HIV testing, yet conventional healthcare provider testing models have limitations, particularly for marginalized communities; different delivery models may be required. Product innovation, including around HIV self-testing, is important and requires investment by developers, which itself necessarily requires some assessment of the risk associated with those investments. Complicated and unpredictable regulatory processes can present a significant challenge and lead to unnecessary duplication, which slows down access and increases costs. To avoid this, there should be a focus on avoiding unnecessary duplication of regulatory effort and incentivizing investment in further innovation.

Regulations play an important role in ensuring the quality and safety of healthcare products, including HIV self-tests. However, implementing regulation is a complex process that requires significant expertise and resources. Collaboration between manufacturers, regulators and stakeholders is necessary to ensure that healthcare products benefit everyone.

Governments need to invest in resources to ensure effective regulation. However, lack of domestic regulatory capacity is a significant challenge, particularly in low-income countries, where many still lack fully functional regulatory systems, particularly in the diagnostic space. This can make the process of delivering health products for use opaque, costly, time consuming and highly variable. Greater emphasis on clearly defined regulatory pathways is needed to improve access to critical healthcare products.

The process of product registration can vary greatly depending on the jurisdiction in which it is being registered, making it challenging for companies operating in countries where the requirements for study design and execution are not well established or defined. This challenge is amplified when a product has to be registered across multiple countries, which is necessary to achieve equity of access. The associated investments

needed in terms of time, finances and opportunity costs can be significant. Further, uncertainty associated with individual outcomes in different countries and the need for duplicate efforts across multiple countries presents a significant challenge, risk and barrier for developers and suppliers of health products.

The WHO pre-qualification process is an important and respected standard for quality and safety, but it doesn't guarantee local registration and uptake. Complying with local regulations is also needed for market access, and regulatory harmonization efforts have not been effective. More effort is needed to move towards a concept of regulatory reliance where the complex workload associated with regulation is shared between jurisdictions or agencies, but enabling ultimate decisions to remain with individual states. It is important to avoid adding complexity that does not bring added value, and innovation is needed to address gaps in suitability for certain interventions or health products.

In conclusion, Duncan said that an effective and efficient regulatory system, whether domestic, regional or international, which does not compromise on quality but always strives for efficiency, is needed to expand access to healthcare products. The goal is to avoid unnecessary duplication of regulatory effort, which slows down access and disincentivizes investment in further innovation.

Panel discussions

Helen McDowell introduced the panel discussions, noting that there are clear examples of WHO guidance and evidence supporting testing and self-testing, as well as community-centred care to reach key populations. Challenges have also been highlighted, including the need for better linkage to care and the role of technology in testing processes. The impact of diversifying testing strategies and delivery methods will be the focus of the next roundtable in the series.

What do we know about the impact of diversifying delivery approaches and strategies?

Ombeni Mwerinde, Unitaid: It is important to acknowledge the wealth of information and best practices available to programmes in areas where progress has been slow in addressing HIV. Understanding end-user uptake dynamics and preferences is crucial for effective delivery, and solutions should be tailored to address barriers specific to each community. It is important to recognize that consumers have diverse needs. Diversifying delivery approaches requires country-specific and context-specific solutions as what works in one country may not work in

another. It is important to have comprehensive options that span facility and community approaches and private and public sector approaches, and that adopt public and private partnership models. Cheryl's presentation emphasized these points.

Integrating HIV testing services with other health services, such as in HCV, HBV, TB and STI settings and paediatric clinics, can offer many advantages. Decentralizing testing outside of the health system has also been proven to increase testing uptake. Task sharing and task shifting have been shown to benefit key populations, as well as lay providers and pharmacies. Services should be simplified and easily accessible, as well as provide privacy and confidentiality and be available at convenient times. Integrating HIV testing with other health and social services in one-stop shops or drop-in centres at community levels and venues has also been effective. Peer-led testing approaches and social networking have reached clients who may not have been reached otherwise. It is important to adapt existing information and practices to the local context rather than reinvent the wheel.

Jennifer Sherwood, amfAR: It is important to diversify approaches and increase client choice to improve uptake of services and ensure that services are friendly and safe for clients. It is not enough to just drive people towards services; there is a need to make sure that they feel comfortable and supported when they arrive.

amfAR is involved in several community-led monitoring projects around the world. The data from these projects is incredibly useful in examining the factors that contribute to different client preferences and choices. The Ritshidze community led monitoring project in South Africa aims to identify service gaps and preferences among key populations. The project found that overall satisfaction and acceptability of HIV testing were higher at drop-in centres and mobile clinics than at public health facilities. However, 70% of key populations surveyed were not aware of drop-in centres or mobile clinics near them. This presents a challenge as efforts to expand community-based testing services must be balanced with improving the safety and friendliness of public health services. The Ritshidze project also revealed a high level of service denial at public health facilities.

What is the role of industry in enabling and driving more demand and supporting communities?

Antons Mozalevskis, WHO: The industry has a role in developing new user-friendly products and ensuring their registration and pre-qualification.

The industry could support demonstration projects or provide funding for community-based organizations to develop projects that aim at demand generation. Diversifying testing modalities (blood versus saliva), not only services, can increase the uptake of HIV testing. The industry can also play a role in developing dual tests for HIV and other infections, which are recommended for key populations.

Tony Boova, Beckman Coulter Life Sciences: As an industry partner and manufacturer, the company supports education, training and advocacy primarily focused on HIV testing. It recognizes the need to reach key populations and other underserved communities and believes that civil society can play a critical role in achieving this goal. Additionally, the company is committed to developing new products and testing modalities that are more user friendly and diversified to increase HIV testing uptake. To reach underserved populations, such as key populations, it recognizes the need for more involvement from civil society. In the past, it has successfully worked with community organizations that have a strong influence on these populations. It believes that industry can support these organizations by providing resources, such as funding or technical expertise, to help develop and implement effective outreach programmes.

Beckman Coulter Life Sciences launched a community recognition award to find individuals doing volunteer work targeting key populations. This allowed it to identify small organizations, some registered charities and some not, that have significant influence in their communities. The company partnered with these organizations to create a more friendly environment for key populations. This is a foundational opportunity for industry partners to get involved and leverage civil society organizations to create a more friendly environment. Community groups play a vital role in achieving a safe environment as they are trusted and have a deep understanding of the needs and challenges of their communities.

Another example is by driving more demand for testing in one country. The company supported community groups to become more efficient by bringing testing services closer to the client and by working closely with national referral laboratories to create a more centralized testing system. However, to address the challenges of access to testing, there is a need to continue to work towards creating a national footprint of testing modalities and services. Centralized testing will remain a cornerstone of laboratory testing, but we need to ensure that more testing options are available to people across the country.

![IAS logo]

Tony agreed with Duncan that there is a need to find ways to streamline the process of registering new products. Bringing a product to the market requires a significant investment, and numerous regulatory compliance requirements must be met, which leads to duplications. Therefore, it is crucial to harmonize these regulations to ensure better and quicker access. Addressing these challenges can go a long way in improving access to new products.

What do we know about the driving factor for people to utilize HIV self-testing?

Tafadzwa Dzinamarira, ICAP, Columbia University: As highlighted by previous speakers, key populations face multiple barriers when it comes to HIV testing. These include stigma, fear of discrimination and the threat of harassment and violence, particularly in countries that criminalize these populations. Even when accessing health services, the quality of care can be compromised by judgemental attitudes among healthcare providers. These and other social and legal barriers lead to lower uptake of HIV services, which in turn amplifies vulnerability to HIV and poor outcomes among key populations living with HIV.

Consequently, HIV self-testing presents an attractive option for key populations as it allows them to personalize and individualize their testing experience and can be carried out privately and conveniently. In the countries where ICAP is working with key populations, it has found remarkable uptake where self-test kits have been ordered online, via social media, and delivered directly to people's homes. Community centres and peer support groups are also providing HIV self-tests, and in some cases, they are available in vending machines. Privacy, convenience, pain-free testing and ease of use are some of the motivators that we can leverage to scale up testing among key populations using HIV self-testing.

Concluding remark

In conclusion, Helen McDowell said that numerous insightful examples and diverse topics were covered during the meeting, ranging from regulatory and policy issues to legal and criminalization matters. However, the key takeaway is that we must take more action – and it must be driven by the community. This is critical if we want to achieve the 95% target, especially among key populations.

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i   Political Declaration on HIV and AIDS: Ending Inequalities and Getting on Track to End AIDS by 2030. https://www.unaids.org/en/resources/documents/2021/2021_political-declaration-on-hiv-and-aids.

[ii] Fast-Track - Ending the AIDS epidemic by 2030. https://www.unaids.org/en/resources/documents/2014/JC2686_WAD2014report.
[iii] 2021 UNAIDS Global AIDS Update — Confronting inequalities — Lessons for pandemic responses from 40 years of AIDS. https://www.unaids.org/en/resources/documents/2021/2021-global-aids-update.
[iv] Marukutira, T. et al. A tale of two countries: progress towards UNAIDS 90-90-90 targets in Botswana and Australia. Journal of the International AIDS Society 21, e25090 (2018).