Virtual Meeting of the WHO Strategic and Technical Advisory Committee on HIV and Viral Hepatitis (STAC-HIVHEP)

28-30 October 2020

Background Reference Paper

	Contents
Exe	cutive summary
Pref	ace
1.	Rationale for global strategic responses to HIV, viral hepatitis and STIs
2.	Vision, goal and targets1
3.	Strategic directions and priority actions1
4.	Information for focused action1
5.	Interventions for impact1
6.	Delivering for equity1
7.	Financing for sustainability2
8.	Innovation for acceleration2
9.	Updating the framing of the strategies2
10.	Strategy implementation3

Executive summary

The World Health Organization (WHO) Department of Global HIV, Hepatitis and Sexually Transmitted Infections (STIs) Programmes (HHS) has initiated a process to develop and propose new strategies to follow the 2016–2021 global health sector strategies on HIV, viral hepatitis and sexually transmitted infections (STIs).

This paper has been developed to inform discussions on post-2021 strategies at the 28–30 October 2020 virtual meeting of the WHO Strategic and Technical Advisory Committee on HIV and Viral Hepatitis (STAC-HIVHEP). The STAC-HIVHEP will be asked to advise WHO on four key inter-related issues: (1) identification of themes and principles that should be foremost in the post-2021 strategies; (2) implications of the COVID-19 pandemic for WHO's work to address HIV, viral hepatitis and STIs; (3) the challenge of maintaining disease-specific focus areas while also advancing universal health coverage (UHC); and (4) the challenge of reviving the global response to STIs.

Global efforts to eliminate HIV, viral hepatitis and STIs were already faltering in 2019, with the pace of progress not sufficient to meet key targets associated with the 2030 Sustainable Development Goals (SDGs). With the onset of the COVID-19 pandemic in 2020, and the associated strain on health systems, there is widespread concern that progress may be halted and even reversed on several fronts. The development of new WHO global health sector strategies on HIV, viral hepatitis and STIs is occurring at an opportune time, not only because the initial impact of COVID-19 can be taken into account in these strategies but also because they can be aligned with other key processes underway including the development of the UNAIDS post-2021 global AIDS strategy and a new strategy's 2025 targets will be incorporated into the next WHO global health sector strategy on HIV, while new 2025 targets will be developed for hepatitis and STIs.

All three of the post-20201 WHO strategies will be fully aligned with other major global health strategies, the Declaration of Astana on primary health care (PHC), the 2019 United Nations political declaration on universal health coverage, and WHO's Thirteenth General Programme of Work 2019–2023 (GPW13). The new strategies furthermore will seek to align with the approach described in the Pan-American Health Organization (PAHO) Disease Elimination Framework and with an initiative underway within the WHO division of UHC and communicable and noncommunicable diseases (UCN) to develop a global framework for multi-disease elimination.

While the way forward on new strategies will be decided in consultation with Member States and other stakeholders, WHO is considering recommending that the structure of the 2016–2021 strategies be retained, with essential disease-specific interventions and priority actions again highlighted as key components of the strategies.

The three current strategies share five common strategic directions: information for focused action, interventions for impact, delivering for equity, financing for sustainability, and innovation for acceleration. The October 2020 meeting of the STAC-HIVHEP is asked to take into account major developments since the adoption of the current strategies, including developments that relate to the guidance provided under each strategic direction as well as developments in the global health landscape. A new STAC will be convened in 2021 to include STIs and to provide guidance on the specific content of new strategies.

At this stage it is important that the STAC reflect on the strategic landscape for the three disease areas taking into account recent data on epidemiological trends, including data showing that HIV prevention efforts are making little impact, particularly among key populations, and that treatments for hepatitis B virus and hepatitis C virus are reaching more people. In the STI field, progress has been made in generating global baseline incidence data for chlamydia, gonorrhea, syphilis and trichomoniasis, laying the foundation for a more informed global response to STIs in the post-2021 era.

Across the HIV, viral hepatitis and STI fields, new evidence regarding community-based service delivery and differentiated care provides key learnings about how to maximize the impact of interventions while also delivering people-centered services that more fully embody human rights-based approaches to health.

Shifts in donor funding – especially for health systems in middle-income countries – underscore the imperative to pursue sustainable disease funding strategies that are aligned with the financing objectives of national health systems and with efforts to advance universal health coverage and primary health care. In the post-2021 HIV, viral hepatitis and STI strategies, there will be opportunities to provide more robust guidance on financing to national health systems and other stakeholders, while promoting a health systems framework as the basis for decision-making.

Preface

This background paper has been prepared by the World Health Organization (WHO) Department of Global HIV, Hepatitis and Sexually Transmitted Infections Programmes (HHS) as a reference document to inform discussions at the 28–30 October 2020 virtual meeting of the WHO Strategic and Technical Advisory Committee on HIV and Viral Hepatitis (STAC-HIVHEP).

At the meeting, STAC-HIVHEP members, informed by internal discussions and augmented by inputs from expert observers and WHO staff members, will be invited to provide strategic advice to WHO on the proposed WHO 2022–2030 global health sector strategies on HIV, viral hepatitis and sexually transmitted infections (STIs). This will be facilitated through a focused discussion seeking advice and responses to the following questions:

DRAFT Background paper – WHO STAC-HIVHEP 28-30 October 2020 virtual meeting updated 21 October

- What critical elements, themes or principles should be highlighted in the 2022–2030 global health sector strategies on HIV, viral hepatitis and sexually transmitted infections?
- In the context of the COVID-19 pandemic, what should WHO do to maintain and further accelerate and expand access to HIV, viral hepatitis and STI prevention, testing and treatment services, medicines, diagnostics and other commodities?
- How best should WHO focus on disease specificity while also building sustainable, peoplecentered health systems that make clear contributions to universal health coverage (UHC) and primary health care goals?
- How can WHO raise the profile of and address the unmet challenges of STIs?

Annex A provides a summary of responses and actions to the STAC-HIVHEP recommendations from the last face-to-face meeting in 2017.

The planning process for post-2021 strategies is in the inception phase and the rationale for future strategies will be discussed at the WHO Executive Board in January 2021.

While the way forward on new strategies will be decided in consultation with Member States and other stakeholders over the course of 2021 and presented to the World Health Assembly in outline in 2021 and in full in 2022, WHO is considering recommending that the structure of the 2016–2021 strategies is retained and that the essential disease-specific interventions are maintained with renewal and expansion of interventions and approaches to service delivery based on new evidence and new targets and goals. A number of critical elements have emerged since the 2016 adoption of the strategies that require reflection and incorporation into the strategies' content and framing. These include: new epidemiological trend data across the disease areas; increasingly regionalized epidemics; the development and agreement of 2025 targets for HIV to bridge the gap between 2020 targets and 2030 goals; new global political commitments including those linked to primary health care and universal health coverage; the WHO 13th General Programme of Work which introduced the new "Three Billions" targets; the transformed operational and resource environment as a result of the COVID-19 pandemic; shifts in donor funding especially for middle-income countries; advances in science, technology and innovation including for Hepatitis C curative treatment; and advances in service delivery and practice with a greater emphasis on community-based service delivery and differentiated service delivery (DSD) models.

To achieve synergies across the three disease strategies, the same general structure is utilized across all 2016–2021 strategy documents, with five common strategic directions (Figure 1).

Figure 1. Common key elements of the global health sector strategies on HIV, viral hepatitis and sexually transmitted infections



Source: Global health sector strategy on HIV 2016–2021: towards ending AIDS (World Health Organization, 2016)

This background paper has been organized to correspond to the content, including the five strategic directions, of the 2016–2021 strategies. While this structure is not intended to serve as a point-by-point review of the existing strategies, key issues have been highlighted that may have significance for STAC-HIVHEP members as they consider the four central questions outlined above¹ at the 28–30 October 2020 meeting.

¹ 1. What critical elements, themes or principles should be highlighted in the 2022–2030 global health sector strategies on HIV, viral hepatitis and sexually transmitted infections?; 2. In the context of the COVID-19 pandemic, what should WHO do to maintain and further accelerate and expand access to HIV, viral hepatitis and STI prevention, testing and treatment services, medicines, diagnostics and other commodities?; 3. How best should WHO focus on disease specificity while also building sustainable, people-centered health systems that make clear contributions to universal health coverage/primary health care goals?; 4. How can WHO raise the profile of STIs and address the unmet challenges of STIs?

The October 2020 meeting of the STAC-HIVHEP is asked to take into account major developments since the adoption of the current strategies and offer general and broad advice at the start of the strategies' development process. A new STAC will be convened in 2021, to include greater representation from the STI field, to discuss the content of new strategies, including interim 2025 targets and the impact of COVID-19 for all three areas, in more detail.

1. Rationale for global strategic responses to HIV, viral hepatitis and STIs

The 2016–2021 strategies open with a brief overview of the status of the global HIV, viral hepatitis and STI pandemics, as well a,s, identifying barriers to progress and opportunities for accelerating progress in each of the three fields. This section of the STAC-HIVHEP reference document outlines key issues and evolutions in the 2020 context.

Progress in relation to the 2016–2021 strategies

Since the 2016–2021 global health sector strategies on HIV, viral hepatitis and STIs were introduced, progress has been observed on key disease elimination efforts. Among the most prominent achievements, antiretroviral therapy is benefitting far more people living with HIV as a result the expansion of treatment for all ('Treat All' recommendation in 2016) and progress toward the ambitious 90–90–90 HIV testing and treatment targets. More than 25 million people received antiretroviral treatment in 2019, up from 18 million people in 2016. In the viral hepatitis field, breakthroughs in direct-acting antiviral treatments for hepatitis C virus (HCV) infection from 2011 onward have facilitated the scale-up of HCV treatment programmes that are achieving high cure levels, with global efforts to lower the prices of direct-acting antivirals being crucial to this progress. The number of people starting hepatitis C treatment increased from 1.1 million in 2015 to 2.1 million in 2017. The proportion of children under five years of age chronically infected with hepatitis B virus (HBV) dropped to just under 1% in 2019 down from around 5% in the pre-vaccine era of the last millennium (the period between the 1980s and the early 2000s) – marking one of the few 2020 SDG targets to be reached. All low- and middle-income countries have now included syphilis screening in their antenatal care packages since 2017, and 132 of 185 countries have prevalence reporting for syphilis among adult women enabling a national estimate of the prevalence of syphilis among women and global estimation of congenital syphilis for monitoring progress towards eliminating mother-to-child transmission.

WHO will report the following summary updates on each disease areas to its Executive Board in January 2020:

HIV: The global health sector strategy on HIV is aligned with the goals and targets of the UNAIDS 2016–2021 Strategy: On the Fast Track to end AIDS. Since 2016 treatment scale-up has continued rapidly, with 25.4 million people receiving treatment by 2019, compared with 18.2 million in 2016. Progress has been guided by new WHO policies and guidelines, including those on: treatment for

all, the use of optimized antiretroviral drugs and formulations for treatment and prevention; patient monitoring and case surveillance; HIV-related drug resistance; key populations; HIV selftesting and partner notification; managing advanced HIV disease; and sexual and reproductive health and rights of women living with HIV, with implementation of the latter supported in collaboration with an official WHO advisory group of women living with HIV convened in 2019. Monitoring the uptake and implementation of WHO HIV guidance is now routine and has demonstrated country impact: by June 2020, 96% of 137 low- and middle-income countries were following HIV "treat all" guidance, 72% had fully implemented routine viral load testing, 78% had included dolutegravir in first-line antiretroviral therapy combinations and 63% had either implemented or were developing a policy on HIV self-testing. While AIDS-related mortality has declined there were still an unacceptable 690,000 AIDS-related deaths in 2019 compared to 1 million in 2016. And HIV prevention is facing a crisis with 1.7 million new infections in 2019 compared to 1.8 million new infections in 2016. Prevention remains a key challenge and in 2019 the proportion of new adult HIV infections among key populations and their sexual partners was 62% globally reaching 99% in several regions. While there are some encouraging developments in HIV prevention, including through the provision of 20 million voluntary medical male circumcisions in East and southern Africa and the expansion and increased uptake of pre-exposure prophylaxis among groups with high levels of incidence, structural and political barriers still inhibit the roll-out of proven interventions to key populations.

Viral hepatitis: The 2020 and 2030 goals for viral hepatitis include targets for hepatitis B infant and birth-dose vaccination, blood and injection safety, harm-reduction measures among persons who inject drugs, and testing and treatment coverage. Since publication of the first global hepatitis report in 2017 progress has been supported by WHO's normative work including the third 2018 update to guidelines on care and treatment of hepatitis C; guidelines on care and treatment of hepatitis B infection; guidelines on viral hepatitis testing; and on surveillance for viral hepatitis. In 2020, 93 countries reported that viral hepatitis plans were in place, compared with only 17 in 2012. The number of persons starting hepatitis C treatment, predominantly with the new curative direct-acting antiviral medicines, increased from 1.1 million in 2015, to an estimated total of 5 million treated today. This was supported by a substantial price reduction through generic drug competition, with costs declining for the most common regimen (sofosbuvir/daclatasvir) in low and middle countries to less than \$200 between 2014 and 2017 and less than \$50 in some countries. For chronic hepatitis B infection, where less than 20% of those infected are estimated to require treatment over their lifetime, the number of persons on lifelong treatment increased from 1.7 million in 2015 to 4.5 million people in 2017, representing an increase in coverage from 8% to 16%. Between 2004 and 2017, the annual cost of treatment with generic tenofovir disoproxil difumarate (TDF) for hepatitis B decreased from US\$ 208 to US\$ 28 per year. With the expiration of the drug patent in 2017, all countries can now procure generic versions of TDF, which will further increase access to hepatitis B treatment. The proportion of children under five years of age chronically infected with HBV dropped to just under 1% in 2019 down from around 5% in the pre-vaccine era of the last millennium marking – one of the few 2020 targets to be successfully reached. Equitable access to timely birth dose for prevention of HBV infection in early childhood for those living many African countries and harm reduction for people who inject drugs lags behind significantly and requires urgent attention.

Sexually transmitted infections. Since 2016 progress has been made in the generation of global baseline incidence data. In 2019, WHO published estimates as of 2016 for four curable infections: chlamydia, gonorrhoea, syphilis and trichomoniasis. Total estimated incident cases were 376.4 million chlamydia cases; 86.9 million gonorrhoea cases; 156 million trichomoniasis cases; and 6.3 million syphilis cases. According to maternal syphilis estimates derived from the WHO developed Spectrum-STI modelling tool and based on national time trend estimation for 205 countries, there were 988 000 global maternal syphilis cases in 2016 resulting in more than 661 000 cases of congenital syphilis, with 355 000 of these occurring as adverse birth outcome and 306 000 nonclinical congenital syphilis cases (infants without clinical signs born to un-treated mothers). Thirtytwo of the 64 countries monitoring gonorrhoea antimicrobial resistance reported decreased susceptibility or resistance to extended-spectrum cephalosporins, last-line treatment in Neisseria gonorrhoeae. Between 2006 and 2017, more than 100 million adolescent girls worldwide received at least one HPV vaccine dose, 95% were in high-income countries. Access to HPV vaccination is improving, in 2019, more than 65% of the girls being vaccinated each year were living in low- and middle- income countries. Responses from a survey assessing progress towards 2020 targets indicated that knowledge and use of the global health sector strategy and WHO treatment guidelines were 92% and 84% respectively among the 112 Member States responding; surveillance or monitoring for sexually transmitted infections are in place in 87% of reporting countries and more than 70% of countries provide services or links to primary, HIV, reproductive health, family planning, and pre- and post-natal care services. Development of new diagnostic tests and vaccines for sexually transmitted infections has advanced, an independent laboratorybased evaluation of near point-of-care tests was completed, and new treatment options for syphilis and gonorrhoea are being explored.

These and other disease specific accomplishments, however, are offset by many signs that the HIV, viral hepatitis and STI fields need to make major course corrections. Even prior to the COVID-19 pandemic, the pace of progress in reducing new HIV infections, increasing access to treatment and ending AIDS-related deaths was slowing. HIV prevention stood out as an especially problematic area: from 2016 to 2016 the annual number of new HIV infections decreased only slightly, from 1.8 million to 1.7 million.

Advances in hepatitis prevention, testing and treatment were failing to reach the 290 million people unaware they are living with viral hepatitis. And more than one million STIs continued to be acquired every day worldwide with more than 350,000 adverse birth outcomes including 200,000 stillbirths and newborn STI-related deaths occurring annually. With progress now further slowing as a result of COVID-19, there are concerns that gains made to date may be reversed.

WHO's mid-term <u>Progress report on HIV, viral hepatitis and sexually transmitted infections, 2019:</u> <u>accountability for the global health sector strategies, 2016–2021</u> provides further insight into the situation as reported in 2019. Among its key messages:

- The global number of people acquiring HIV is declining, but not rapidly enough. The focus on HIV prevention is insufficient, and the number of people newly infected with HIV would need to decline significantly to achieve global 2020 targets. Mortality from HIV has declined but is still too high.
- Global targets for reducing mortality from viral hepatitis will not be met without massively accelerating universal access to testing, hepatitis B treatment and hepatitis C cure. The global incidence of hepatitis B virus infection is declining overall towards achieving the strategy targets, with progress in immunization and prevention, but not for people who inject drugs.
- Sexually transmitted infections are not declining globally except for slow declines in congenital syphilis. In several countries, sexually transmitted infections are increasing. ... The global response to sexually transmitted infections is in crisis after years of neglect. Opportunities to link with HIV and broader sexual and reproductive health services must be seized to revive progress.
- Over half of the people newly infected with HIV are members of key populations or their sexual partners: men who have sex with men, sex workers, people who inject drugs, transgender people, migrants and people in prisons. Almost one quarter of the people newly infected with hepatitis C virus globally inject drugs, and more than half the people who inject drugs have chronic hepatitis C virus infection. STI incidence among adolescents is the highest compared with other age groups. Nevertheless, these groups have the least access to health-care services.

Additional findings from the progress report are presented in Figure 2 and Table 1.





Source: Progress report on HIV, viral hepatitis and sexually transmitted infections, 2019: accountability for the global health sector strategies, 2016–2021 (World Health Organization, 2019).

Table 1. Mid-term findings regarding progress under five strategic directions of 2016–2021 strategies

HIV	Viral hepatitis	Sexually transmitted infections			
Global reporting mechanisms are well established, and major investments have been made in granular, routine data systems. Challenges: Strengthening data on key populations; and improving the governance of data use for improving programmes.	A global reporting system was established in 2018, and the first baseline estimates of disease burden were developed for 2015. 	Efforts have been made to strengthen global reporting mechanisms, disease burden estimates and, recently, Spectrum modelling. Challenges: Country capacity for surveillance and monitoring remains insufficient and has not benefited from investment in HIV data systems.			
Interventions fo	r impact				
HIV	Viral hepatitis	Sexually transmitted infections			
Strong progress has been made towards achieving the 90–90–90 targets and improvements in life expectancy among people living with HIV in countries with a high burden of HIV infection. Service delivery has been diversified with new testing approaches and differentiated care. Challenges: Implementing effective HIV prevention to reduce incidence and improving the targeting and quality of testing. There are gaps in reaching key populations and underserved areas and critical gaps in harm reduction.	Strong progress has been made in delivering prevention interventions such as the hepatitis B vaccine together with early but expanding testing and treatment access, including a cure for hepatitis C. Challenges: Providing timely birth doses of the hepatitis B vaccine in Africa and the need to massively expand access to diagnosis, treatment and cure.	Strategy actions to update the completed treatment guidelines and global surveillance of antimicrobial resistance are in place. Momentum is increasing to tackle human papillomavirus and cervical cancer. Challenges: Implementation of available diagnostics and treatment has stalled, and synergy with HIV has been weak, including tackling HIV as a sexually transmitted infection.			
Delivering for equity					
HIV	Viral hepatitis	Sexually transmitted infections			
Differentiated and client-centred models of service delivery are helping to improve outreach; HIV commodity prices have declined and civil society has supported access globally. Challenges: Making universal health coverage work for key, overlooked and underserved populations and interarting HV into emergency	Progress in price reductions and initiatives to expand access make it feasible to rapidly scale up diagnosis, treatment and cure from 2020 to 2030. Challenges: Harm-reduction services and access to treatment for people who inject drugs are particularly lacking. Task-shifting will be needed to support the massive projected	Progress has been made among pregnant women for syphilis screening, treatment and dual elimination with HIV. Strong progress in reducing vertical transmission of syphilis. There is stagnation for many sexually transmitted infections and among many populations.			

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HIV	Viral hepatitis	Sexually transmitted infections
Funding for HIV has benefited from major resource mobilization efforts, supported by strong investment frameworks and estimates of the resources needed. Access to basic HIV services is free of user charges in most countries with a high burden of HIV infection. Challenges: Sustaining funding and civil society support and monitoring health expenditure and costs within programmes.	The first global costing of hepatitis has been completed. Drug prices have declined significantly in the past three years, supported by generic manufacturing. Challenges: Chronic lack of funding for hepatitis programmes and the need for additional civil society advocacy, including to include hepatitis in domestic health funding	International funding and domestic resource allocation for sexually transmitted infections have been limited, resulting in large funding gaps despite the high levels of morbidity and mortality these diseases cause. Challenges: Despite the relative affordability of many interventions, funding for sexually transmitted infections is in crisis and has not benefited from synergy with the HIV response.
Innovation for a	icceleration	
Innovation for a	viral hepatitis	Sexually transmitted infections
Innovation for a HIV HIV There has been a strong focus on innovation, especially in treatment, testing and diagnostics. Challenges: Implementation of innovations at scale for testing and further innovations in HIV prevention and vaccines, including addressing the social determinants of health.	Viral hepatitis The main approaches and tools to eliminate viral hepatitis are already available, but implementation varies Challenges: Additional research to find a functional cure for hepatitis B virus, affordable point-of-care tests and a vaccine for hepatitis C.	Sexually transmitted infections Several innovations are in use or in the pipeline to improve the response to sexually transmitted infections, including new rapid and point-of-care tests and new treatments and vaccines. Challenges: Further innovation in new, rapid and affordable point- of-care tests and new approaches to tackle social and behavioural determinants of sexually transmitted infections and HIV, adapted to each generation.
Innovation for a	Viral hepatitis The main approaches and tools to eliminate viral hepatitis are already available, but implementation varies. Challenges: Additional research to find a functional cure for hepatitis B virus, affordable point-of-care tests and a vaccine for hepatitis C.	Several innovations are in use or in the pipeline to improve the response to sexually transmitted infections, including new rapid and point-of-care tests and new treatments and vaccines. Challenges: Further innovation in new, rapid and affordable point- of-care tests and new approaches to tackle social and behavioural determinants of sexually transmitted infections and HIV, adapted to each generation.

Source: Progress report on HIV, viral hepatitis and sexually transmitted infections, 2019: accountability for the global health sector strategies, 2016–2021 (World Health Organization, 2019).

The COVID-19 pandemic

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Global progress toward HIV, viral hepatitis and STI elimination has been greatly threatened by the emergence of COVID-19. The overburdening of health systems with COVID-19 cases, coupled with other effects of the COVID-19 pandemic including limitations on movement and health worker quarantines, illnesses and deaths, has undermined access to a wide range of health services. COVID-19 is additionally impacting both the production and distribution of health commodities, potentially leading to increases in costs and to challenges with supply issues. It has been estimated that the final cost of exported

antiretroviral medicines from India could be between 10% and 25% higher than normal prices. This situation has severe consequences for the global HIV, viral hepatitis and STI responses. For example, recent modelling has estimated that a six-month complete disruption in HIV treatment could lead to more than 500,000 additional deaths from AIDS-related illnesses in sub-Saharan Africa alone between 2020 and 2021. Should services to prevent mother-to-child transmission of HIV be halted for six months, the estimated increases in new child HIV infections would be 162% in Malawi, 139% in Uganda, 106% in Zimbabwe and 83% in Mozambique.

A WHO survey carried out in April–June 2020 provides further insight into the vulnerabilities that health systems are facing as they try to maintain HIV, viral hepatitis and STI services in the context of COVID-19. Seventy-three countries reported being at risk of stock-outs of antiretroviral medicines, while 36 countries were already experiencing disruptions in the provision of HIV treatment services. Ten countries reported disruptions in hepatitis B testing, and six, in hepatitis C treatment initiation. Sixteen countries reported STI service disruptions. Seventeen countries reported disruptions in services for key populations. Numerous countries also reported experiencing other types of service disruptions with implications for the HIV, viral hepatitis and STI fields, including disruptions in tuberculosis case detection and treatment, family planning services, harm reduction services, and diagnosis and treatment of noncommunicable diseases and cancers.

Although the future course and duration of the global COVID-19 pandemic are unknown, STAC-HIVHEP is encouraged to consider the significance of the post-2021 HIV, viral hepatitis and STI strategies being introduced at a time when health systems worldwide may still be heavily affected by this new pandemic. Implications extend well beyond the delivery of health services and commodities to encompass governance, financing, and all other core areas of health system functioning. Until an effective COVID-19 vaccine reaches most of the world's population, national and subnational health systems may be contending with fluid situations that call for ongoing adjustments in the allocation of health resources in relation to where and to what extent COVID-19 cases are increasing or decreasing. This uncertainty should be taken into account in the design of the next HIV, viral hepatitis and STI strategies. At the same time, there are important questions to consider regarding how the HIV, viral hepatitis and STI fields can align their resources and efforts with the global response to COVID-19 in order to achieve synergies that will optimize health outcomes broadly.

2. Vision, goal and targets

The 2016–2021 strategies are framed around attaining the goals of the 2030 Agenda for Sustainable Development and position the strategies within three important frameworks: universal health coverage, the continuum of services, and the public health approach. This background paper reflects on these concepts in the current environment.

The 2016–2021 strategies present a vision and central goal of each strategy (Figure 3), along with specific time-bound targets such as targets relating to mortality, prevention, treatment and service coverage.



Figure 3. Vision and goals of the 2016-2021 global health sector strategies

Sources: Global health sector strategies on HIV, viral hepatitis and STIs 2016-2021 (World Health Organization, 2016)

Establishing 2025 Targets

While the overarching vision and 2030 goals and targets remain relevant there are currently no agreed mid-term milestones to help drive targets between the 2020 targets and 2030 for the three disease areas.

WHO is working with UNAIDS to develop 2025 HIV targets and estimates of the resources needed for the global AIDS response up to 2030. The outputs from the process will guide the multisectoral response from 2021 to 2030. In the last 20 years, global health sector strategies have aligned to the multisectoral targets and goals developed in partnership with UNAIDS.

WHO has also convened expert meetings on viral hepatitis and STIs to identify strategic milestones for these epidemics. WHO proposes initiating processes in 2021 to develop 2025 targets for viral hepatitis and STIs while recognizing challenges in ensuring meaningful baseline data in the context of STIs and welcoming STAC-HIVHEP advice in this regard. Figure 4 illustrates categories and top-line 2025 targets for HIV.

Figure 4: Recently agreed top-line 2025 targets for HIV, proposed as part of UNAIDS strategy development process

Categories and top-line 2025 targets						
	HIV services	5	Integration		Social enablers	
95–95–95 testing and treatment targets achieved within all sub- populations and age groups.	95% of women of reproductive age have their HIV, sexual and reproductive health and family planning needs met, and 95% of HIV- avpoced	95% of people at risk of HIV infection use appropriate, prioritized, person-centred and effective combination prevention options	Adoption of people-centred and context-specific integrated approaches that support the achievement of 2025 HIV targets and result in 90% coverage of TB, STI, viral hepatitis, human papillomavirus, cervical cancer, mental health, cardiovascular disease, diabetes and sexual and gender-based violence services among people living with HIV and all populations at substantial risk of HIV infection.	for removing so an enabling envir Less than 25% of countries have punitive legal and policy environments	25–25–25 targets cial and legal imped onment limiting ac of HIV services Less than 25% of people living with HIV and key populations experience	diments towards cess or utilization Less than 25% of women, girls and key populations experience
	exposed children are tested.	options.		that deny access to services.	stigma and discrimination.	gender inequality and violence.
				Achieve SDG targe 1, 2, 3, 4, 5, 8, 10,	ets critical to the H . 11, 16, 17) by 203	IV response (i.e. 0

3. Strategic directions and priority actions

The three 2016–2021 strategies present priority actions for countries and for WHO, with these actions framed by five strategic directions:

- Information for focused action (know your epidemic and response)
- Interventions for impact (covering the range of services needed)
- Delivering for equity (covering the populations in need of services)
- Financing for sustainability (covering the financial costs of services)
- Innovation for acceleration (looking towards the future)

Many of these actions remain timely and are likely to be incorporated into the post-2021 strategies with minor updating, while new actions will need to be added.

The following sections describe how concepts and evidence relating to the strategic directions have evolved in ways that should be taken into account during the planning of the next strategies.

4. Information for focused action

There are three main ongoing priorities: ensuring a focus on impact; defining a path towards public health elimination with critical milestones; and securing disaggregated data to leave no one behind. In

addition, there is a need for better integration to support country monitoring and evaluation systems, including:

- District- and local-level data, with sufficient disaggregation by population to leave no one behind;
- Electronic reporting and interoperability of data systems, including between disease specific and broader health systems;
- Protection, security and use of individual-level data to support service provision; and
- Country analytical capacity to better use data, including at district level and among nongovernmental organizations and civil society.

A particularly important challenge that warrants attention in the next strategic cycle is extending facility reporting into communities to support improved prevention, testing (including self-testing) and treatment (including differentiated care).

5. Interventions for impact

One of the strengths of the 2016–2021 global health sector strategies is that they present robust packages of public health interventions across the service delivery spectrum in the fields of HIV, viral hepatitis and STIs, accompanied by corresponding recommended actions for countries and for WHO. Intervention areas addressed in the three strategies are summarized in Box 1. Many of the key "interventions for impact" in all three disease fields have remained the same since the time the strategies were introduced, and thus much of the current content relating to these interventions will be considered for inclusion in the 2022–2030 strategies, with appropriate updating to reflect the latest scientific evidence.

Box 1. Key intervention areas

Global Health Sector Strategy on HIV 2016–2021 interventions for impact:

- Defining an essential benefit package for HIV
- Reducing HIV vulnerability and HIV transmission and acquisition
 - Male and female condoms and lubricants
 - Harm reduction for people who inject drugs
 - Antiretroviral-based prevention
 - Prevention of HIV infection in infants
 - Voluntary medical male circumcision
 - Injection and blood safety
 - Behaviour change interventions
 - Prevention and management of gender-based and sexual violence
- Expanding HIV testing
- Expanding antiretroviral therapy, managing comorbidities and providing chronic care
 - Expand antiretroviral therapy coverage
 - Prevent and manage HIV and tuberculosis coinfection
 - Prevent and manage HIV and viral hepatitis

- Address other HIV coinfections
- Prevent and manage HIV drug resistance
- Provide person-centred chronic care for people living with HIV

Global Health Sector Strategy on Viral Hepatitis 2016–2021 interventions for impact:

- Defining an essential benefit package for viral hepatitis
- Preventing transmission
 - Birth dose hepatitis B vaccination and 3 doses of infant vaccination
 - Harm reduction for people who inject drugs
 - Antiviral prophylaxis for prevention of mother to child transmission
 - Injection and blood safety
 - Hepatitis C treatment as prevention in key populations
- Expanding hepatitis B and C testing
- Expanding hepatitis C curative treatment, and long-term suppressive antiviral therapy for chronic hepatitis B infection, and managing advanced liver disease
 - Expand coverage of curative treatment of HCV infection
 - Expand coverage of long-term suppressive antiviral therapy for chronic hepatitis B infection
 - Prevent and manage advanced liver disease
 - Monitor for and manage hepatocellular carcinoma

Global Health Sector Strategy on Sexually Transmitted Infections 2016-2021 interventions for impact:

- Defining an essential benefit package for sexually transmitted infections
- Preventing transmission
 - Revitalize condom promotion and programming
 - Scale up HPV vaccination
 - Link HIV prevention with STI prevention interventions
- Early diagnosis and treatment
 - Targeted STI screening and treatment for specific populations (key populations, adolescent, pregnant women)
 - Effective STI case management for symptomatic STIs
 - Expedited partner management
 - Integrate STI services in key populations including pre-exposure prophylaxis, family planning, adolescent and maternal and child health services and primary health care
 - Access to quality medicines, vaccines and diagnostics
- Elimination of cervical cancer
- Elimination of mother-to-child transmission of syphilis and HIV
- Control antimicrobial resistance in Neisseria gonorrhoeae and other STIs

Many of the interventions described in the strategies will be included in the WHO UHC Compendium planned for publication in December 2020. While much of the existing content remains valid there have been a number of clinical and public health advances since 2016 that will likely be reflected in the updated descriptions of interventions, and other advances that may warrant the introduction of new interventions

in one or more of the three disease areas. WHO envisages that any changes to these sections will involve additions rather than reviews of the current interventions described. To summarize key advances to date: Following the positive opinion from the article 58 EMA process on the dapivirine vaginal ring (DPV-VR), a new WHO recommendation for the use of this female-controlled prevention method is currently under consideration. Although of likely modest efficacy compared with oral pre-exposure prophylaxis (PrEP), supporting an additional choice for women vulnerable to HIV has been identified as important by women's groups. WHO will continue to review the evidence and provide guidance for other long-acting PrEP products and MPTs as this become available.

The need for greater integration of HIV and STI services into contraception services has long been recognized and highlighted by results from the Evidence for Contraceptive Options and HIV Outcomes (ECHO) study. Following this, WHO has worked with colleagues from UNAIDS to provide <u>integration</u> guidance and to influence countries and donors including the Global Fund to Fight AIDS, Tuberculosis and Malaria to address this gap. Post-ECHO support for high-burden HIV countries is ongoing.

Integration of HIV services with other areas with clear overlap of interests as non-communicable diseases (NCDs) and mental health disorders (MHDs) have been promoted by WHO in last years and specific recommendations on assessment of cardiovascular risk and depression were included in WHO HIV guidelines. In 2019, an expert scoping consultation reviewed current WHO norms and policies for the prevention and management of major NCDs and MHDs, and prioritized the technical areas for the co-management of these conditions in people living with HIV. One of the key outputs of the meeting was the inclusion of hypertension and diabetes as a short-term priority for integration with HIV services. More recently, WHO establish a interdepartmental technical working group (TWG) to develop the operational framework on integration of preventative, curative and rehabilitative services, for NCDs, TB, HIV and SRH, addressing comorbidities throughout the health system. It also advocates a health systems approach.

Update and uptake of ART and care recommendations. The WHO recommendations on antiretroviral therapy has been periodically updated and moved towards earlier treatment initiation, use of less toxic more robust ARV regimens and simpler monitoring of the HIV treatment response. In 2016, WHO released Consolidated Guidelines on the use of antiretroviral drugs for preventing and treating HIV infection. Since that time, several specific guidelines in different areas have been developed in response to new evidence and opportunities to improve outcomes. In 2017, WHO established a package of interventions for managing patients with advanced HIV disease and rapid initiation of ART, including same day start. In 2018/2019, dolutegravir (DTG) containing regimens were included as the preferred 1st and 2nd line therapy and PEP. The guidelines for diagnosis, prevention and management of cryptococcal disease in PLHIV was also reviewed. Since the launch of 2016 consolidated guidelines, more than 100 countries have adopted Treat All policy, transitioned to DTG containing regimens in 1st line ART and implemented routine HIV viral load monitoring in their national HIV treatment programmes. More than 90% of LMICs has adopted ART maintenance at community level policies as multi-month dispensing of ART refills and reduced frequency of clinical visits in those patients doing well on ART. In October 2020, the update of clinical recommendations (use of point-of-care technologies for early infant diagnosis and viral load monitoring,

timing of ART in TB/HIV coinfection) and service delivery recommendations (frequency of clinical visits and ART dispensing; tracing strategies for reengagement to care, adherence measurement, specimen collection by lay providers; diagnostic integration across HIV, TB, Hep and STIs; integration of HIV/NCD care and family planning programmes; psychosocial interventions for adolescents with HIV) were reviewed, and a new consolidated version of the HIV guidelines is planned to be launched in early 2021.

Effective management of STIs. STI treatment guidelines have been updated for priority STIs including Neisseria gonorrhoeae (NG), Chlamydia trachomatis (CT), Herpes Simplex Virus type 2 (HSV) and Treponema pallidum(syphilis). Due to emerging resistance to the last-line treatment in gonorrhoea, updating treatment guidelines are underway with additional treatment guidelines for Human Papilloma Virus (HPV), Trichomonas vaginalis (TV), Bacterial vaginalis (BV) and Mycoplasma genitalium (MG) being updated. WHO is also reviewing the focus STIs and adding an additional viral STI to the priority list: human T-lymphotropic virus type 1 (HTLV-1), for which guidance will be developed in 2021.

STI syndromic management approach promoted widely for settings with limited resources, have poor performance characteristics in women. Near-patient point of care tests (POCT) molecular assays for CT/NG/TV are commercially available and provide an opportunity for improving STI management. The prices of these near POCTs remain the barrier for uptake in resource-constrained settings. This is driving the development of lower-cost solutions. In September 2020, evidence-based recommendations are being made by WHO to upgrade standard of care and STI case management of symptomatic STIs, including recommendations on the use of point-of-care- test if laboratory capacity is available. Guidelines on STI management of asymptomatic STIs and strengthening STI service delivery are being planned in 2021. These STI guidelines will be consolidated into a comprehensive guideline.

6. Delivering for equity

The 2016–2021 strategies address the importance of adapting services for different populations and locations; strengthening human resources for health; securing good-quality commodities; and creating and sustaining an enabling environment.

Key populations in the HIV response are defined by United Nations agencies as men who have sex with men, sex workers, people who inject drugs, transgender people and people in prisons or other closed settings. They are defined as such because they may engage in behaviors that put them at increased risk for HIV. Additionally, their behaviors are criminalized in many settings and there are other structural barriers which can hinder access to health services. Importantly, while these five groups were initially defined as "key" in the HIV response, they have broader health needs than those related to HIV and are also affected by STIs and viral hepatitis.

In 2014 the first consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations (Consolidated KP HIV guidelines) were published by WHO. These were updated in 2016 (https://www.who.int/publications/i/item/consolidated-guidelines-on-hiv-prevention-diagnosis

treatment-and-care-for-key-populations). These guidelines focused on HIV, while addressing STIs and hepatitis, along with other HIV comorbidities and sexual and reproductive health interventions.

Acknowledging the need for integration, universal health coverage and person-centred care in 2020, WHO brought HIV, viral hepatitis and STIs together into the Global HIV, Hepatitis and Sexually Transmitted Infections Programme. In 2020-2021, the consolidated guidelines for key populations will be updated and will be the first guideline to give equal focus to HIV, STIs and viral hepatitis. Several new recommendations will be considered and existing ones updated. The working title for the updated guidelines is: Consolidated Guidelines for HIV, viral hepatitis and STIs: prevention, testing, treatment and care for key populations (Consolidated KP HIV, VH and STI guidelines). Involvement of communities and key population networks will be central to the development of the guidelines.

7. Financing for sustainability

The fourth strategic direction of the three 2016–2021 global health sector strategies addresses improving efficiencies and developing innovative financing mechanisms. However, the content of this part of the strategy is not as well developed when it comes to considering sustainable solutions to resourcing disease elimination efforts.

This is an area of the post-2021 strategies that might be strengthened through referencing the health system building blocks framework discussed earlier in this paper. For example, addressing the challenge of sustainable financing through a health systems lens calls attention to the significance of leadership and governance, which in the context of financing point to issues such as government accountability for spending and civil society participation in financial decision-making.

Ensuring countries achieve the impact they desire in HIV, viral hepatitis and STI requires a lens that appreciates how both disease-specific and systems-based resources and finances can be put to more strategic use and better integrated. For example, working toward greater financial sustainability also requires attention to how health information systems and the health workforce systems for disease areas and for broader health can be further integrated.

STAC-HIVHEP is invited to consider how the post-2021 strategies might utilize the health system building blocks framework, developments in global and national approaches to achieving universal health coverage, and other tools to provide stakeholders with suggested actions that can be taken to address the broad range of obstacles to developing financially sustainable approaches and to eliminating HIV, viral hepatitis and STIs.

8. Innovation for acceleration

HIV innovations: WHO has already championed HIV self-testing (HIVST) as a way to reach people who are at risk from HIV but not currently accessing testing – for example men and people from KP. WHO has

guidance and four HIVST kits have been prequalified. There has been significant increase in policy uptake, implementation and access. WHO has worked with Unitaid to support large scale HIV implementation programmes in several countries to provide information on acceptability, uptake, linkage and impact. Self-testing for HCV has also been shown to be safe, acceptable and effective from studies which WHO has supported through Unitaid. HIVST has been noted by countries and programmes to be an important opportunity to continue access to testing during COVID-19 restriction coupled with online support, virtual tools and community and pharmacy delivery. WHO will be developing guidelines and supporting a pathway for HCVST prequalification. WHO has supported guidance and prequalification of dual tests (HIV-and syphilis) and continues to explore further opportunities for multiplex testing.

Many service delivery innovations which use virtual platforms and digital tools have been developed and embraced by young people and KP groups to provide prevention information, help people consider risk and deliver support to understand about and deliver products. This area is fast moving and has huge potential to reach people more broadly and to increase access to information and services and decrease the strain on health services.

The pipeline for biomedical HIV prevention is exciting with several long acting PrEP products in various stages of development. CAB-LA has been shown to be highly effective for men (HPTN085) and the trial in women (HPTN084) will likely release result by end 2020/early 2021. There are unresolved safety concerns for CAB-LA which will have to be considered. Other promising products include BNAbs and implants and WHO continues to review evidence and data. Two BNAbs phase 2b proof of concept studies - AMP (HVTN 703/HPTN 081 for women and (HVTN 704/HPTN 085 for men) - will report out soon and several combination BNAb trials are underway. The vaccine trial pathway has been long and generally disappointing. The HVTN 702 (Uhambo) HIV preventative vaccine was stopped for futility. However, the HVTN 705(Imbokodo) and HVTN 706(Mosaico) trials are ongoing with results expected in 2022 and 2023 WHO continues to engage in this area through HSS with IVB.

Viral hepatitis innovations: WHO has been promoting progressive simplification of HCV through simplified algorithms, decentralised testing and treatment, integrated care and treatment with harm reduction or with HIV care at ART sites, and task-shifting to non-specialists. In addition, WHO has established simplified HCV service delivery models with implementation and evaluation of a community-based "educate, test and treat" model for elimination HCV in high prevalence rural settings in Egypt and Pakistan. These showed high uptake of testing, linkage, treatment and cure among 300,000 adults across 73 villages, and led to a reduction in incidence. WHO has also worked with FIND supported by Unitaid on development of a lower cost RDT version of the HCV core-antigen test, evaluation of use of point-of-care HCV viral load to promote access to care and treatment in 3 countries, and of prototype HCV self-testing (acceptabliity and useability) in five countries. The evidence generated from these studies will provide the foundation for new WHO guidance. WHO is also working with collaborators on the development of long-acting DAAs to promote further treatment access.

STI innovations: Benzathine penicillin remains to be the treatment of choice for syphilis. Globally syphilis rates are increasing and quality- assured Benzathine Penicillin shortage are being experienced in many countries. HHS continue to support pre-qualification process of quality assured active product ingredient of Benzathine penicillin. Dual HIV-syphilis tests have been pre-qualified by WHO and have been recommended for antenatal screening to increase coverage of syphilis antenatal screening. In addition, pre-qualification of diagnostic tests for Neisseria gonorrhoeae and Chlamydia trachomatis are being planned. Due to emerging antimicrobial resistance in Neisseria gonorrhoea, WHO in partnership with the Global AMR Research and Development Partnership and FIND is facilitating the development of new gonorrhoea treatment accompanied by a sound access strategy and stewardship framework. Appropriate STI diagnosis is crucial and point-of-care tests (POCTs) is essential to ensure immediate diagnosis and treatment in resource-constrained settings. In line with this, WHO is working with partners to facilitate the development of low-cost, rapid POCT for identification of *N. gonorrhoeae* and *C. trachomatis* and identification of antimicrobial resistance/susceptibility in gonorrhoea. Work is underway to identify barriers in implementing STI testing in resource-poor settings and to develop an investment case for STI POCT to facilitate STI testing in selected countries.

Development of new STI vaccines is a key innovation for achieving sustainable global STI control. Priority roadmap activities for WHO include developing preferred product characteristics (PPCs) and conducting full public health value assessments for STI vaccines. STI vaccine development has been most advanced for HSV, with several candidates in Phase I/II trials, but in the past 1-2 years, activity related to vaccines for gonorrhoea has dramatically increased, given the rising threat of gonococcal AMR and new evidence suggesting licensed meningococcal B vaccines may provide some cross-protection against the closely-related N. gonorrhoeae. In 2019, WHO PPCs for HSV prophylactic and therapeutic vaccines, which were developed through a global stakeholder process and public consultation. In 2020, PPC for gonorrhoea vaccines will be released.

9. Updating the framing of the strategies

The 2030 Agenda for Sustainable Development and WHO's GPW13

The 2030 Agenda for Sustainable Development, adopted by the United Nations General Assembly in September 2015, put forth among the 17 Sustainable Development Goals (SDGs) a broad health goal as well as other goals that will be served through efforts to end the HIV, viral hepatitis and STI pandemics (e.g., ending poverty, achieving gender equality).

The three 2016–2021 Global Health Sector strategies took direction from how the SDGs conceptualized key health-related targets under the broad health goal: "Ensure healthy lives and promote well-being for all at all ages." It is anticipated that this goal and the Sustainable Development Agenda more generally will continue to factor prominently in the formulation of the 2022–2030 HIV, viral hepatitis and STI strategies.

In addition, the World Health Organization's Thirteenth General Programme of Work 2019–2023 (GPW13) commits WHO to three strategic priorities that are explicitly tied to the Sustainable Development Agenda, reinforcing the centrality of the SDGs as a guiding force in the global health field and fully aligning WHO's efforts with efforts to achieve the SDGs. The GPW13 strategic priorities are achieving universal health coverage, addressing health emergencies, and promoting healthier populations. These priorities have corresponding targets known as the "Three Billions":

- One billon more people benefitting from universal health coverage
- One billion more people better protected from health emergencies
- One billion more people enjoying better health and well-being

The Three Billions targets and GPW13, like the SDGs, will inform the conceptualization of the next global health sector strategies on HIV, viral hepatitis and STIs. Given that the strategies are organized around "actions for countries" and "actions for WHO" an exercise will be undertaken to ensure clear links to the GPW13 and greater accountability is built into the shaping and monitoring of WHO actions. WHO has developed a number of outcome delivery areas and detailed output indicators based on the GPW13 which enables countries to track how well WHO is delivering on its workplan progress using the associated outcome indicators. The 46 outcome indicators, include 39 which are SDG indicators and seven non-SDG indicators, which were approved in World Health Assembly resolutions including, for example, in relation to antimicrobial resistance and ensuring essential health services for vulnerable populations. An outcome and accountability framework Outcome (Figure 5) helps WHO monitor and evaluate its contribution to achieving the health-related SDGs.



Figure 5. WHO Outcome Framework

Universal health coverage and primary health care

The three 2016–2021 global health sector strategies recognized universal health coverage as an overarching framework and were synergistic with the goals of UHC as they are stated in <u>Target 3.8 of the</u> <u>Sustainable Development Goals</u>:

Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.

By now it is well recognized that progress in specific disease areas can contribute to UHC, and also that progress toward UHC can create new opportunities to work toward disease-specific targets. However, there is not yet widespread understanding of how stakeholders might utilize specific mechanisms underlying this dynamic in order to improve health outcomes at national and subnational levels. The post-2021 global health sector strategies on HIV, viral hepatitis and STI present an important opportunity for WHO to provide leadership in this regard.

STAC-HIVHEP is invited to consider how key elements in the ongoing drive toward UHC may be more effectively leveraged in strategic planning to end the epidemics of HIV, viral hepatitis and STIs.

In 2019, the <u>United Nations General Assembly adopted a resolution committing Member States to</u> <u>accelerate efforts around UHC</u>, and WHO's <u>GPW13</u> strongly affirms both the central place of UHC in the global health agenda and WHO's role in advancing UHC, as noted earlier in this paper. Current approaches to pursuing UHC may point to ways in which the post-2021 strategies for HIV, viral hepatitis and STIs can be more fully merged with the UHC movement as it is being shaped by global and national stakeholders including WHO, national governments and civil society.

Most notably, WHO stresses that strengthening health systems is fundamental for moving toward universal health coverage. Strengthening health systems requires attention to improving the performance of all of the core functions of health systems, which in itself entails consideration of how health system functions are integrated with each other. Siloed approaches to health system financing and to the health workforce, for example, generate inefficiencies in both of these areas. The WHO health systems building blocks framework is identified as a potentially valuable tool for health system strengthening in a later section of this paper; here we examine selected core functions as they relate to the task of developing post-2021 HIV, viral hepatitis and STI strategies that simultaneously advance UHC and disease-specific goals.

WHO worked closely with UNAIDS in 2019 to develop a background document and key inputs into a thematic Programme Coordinating Board (PCB) session on universal health coverage and many key issues are explored in the key PCB background document: <u>Thematic segment: delivering on SDG3: strengthening</u> and integrating comprehensive HIV responses into sustainable health systems for Universal Health <u>Coverage</u>

During the 2019 thematic session WHO proposed the following areas of focus to help support disease specific programmes to align more efficiently in the context of UHC: improve health system strengthening literacy among disease stakeholders; ensure a better mix, distribution and capability of human resources for health; invest to improve disease surveillance; collaborate with other areas of health to reduce fragmentation; advocate for sustainable health; understanding different financing approaches and mixes.

Building on the historic 1978 Alma-Ata declaration, the 2018 Global Conference on Primary Health Care endorsed a new declaration emphasizing the critical role of primary health care around the world. The <u>Declaration of Astana</u> has renewed political commitment to primary health care from Governments, non-governmental organizations, professional organizations, academia and global health and development organizations.

New strategies for HIV, hepatitis and STIs must reflect the key components of the PHC and UHC declarations including their focus on improved country-led accountability frameworks, inclusive governance and community engagement and sustainable financing options and approaches that support and promote country ownership over donor priorities and reporting.

The public health approach and the health system building blocks

The 2016–2021 global health sector strategies for HIV, viral hepatitis and STIs all made reference to framing disease elimination efforts within a public health approach, describing this concept in similar terms. As stated in the HIV strategy:

The strategy is rooted in a public health approach that is concerned with preventing disease, promoting health, and prolonging life among the population as a whole. It aims to ensure the widest possible access to high-quality services at the population level, based on simplified and standardized interventions and services that can readily be taken to scale, including in resource-limited settings. A public health approach aims to achieve health equity and promote gender equality, engage communities and leverage public and private sectors in the response. It promotes the principle of health in all policies through, where necessary, legal, regulatory and policy reforms. It aims to strengthen integration and linkages between HIV and other services, improving both impact and efficiency.

While many of these elements of a public health approach are embodied in the 2016–2021 strategies, STAC-HIVHEP is invited to consider what taking a public health approach should signify in the post-2021 strategies. The health system building blocks framework, introduced by WHO in 2007 to advance health systems strengthening efforts, remains a widely referenced model for describing the core functions of health systems (Figure 6). Although, the three 2016–2021 strategies did not explicitly reference this framework, the health systems building blocks may be useful for encouraging greater recognition of how multiple elements of health systems are implicated in efforts to achieve specific health outcomes.

STAC-HIVHEP may consider whether more explicit presentation and referencing of the links between disease efforts and of the health system building blocks, or similar frameworks, could help strengthen elements of a sustainable public health approach to eliminating HIV, viral hepatitis and STIs.





Source: A new era for the WHO Health Systems Building Blocks? https://healthsystemsglobal.org/news/a-new-era-for-the-who-health-system-building-blocks

Integration and linkages

Two closely related elements of the public health approach, integration and linkages, are particularly notable in the context of the drive toward universal health coverage and ensuring people-centered quality services. While the 2016-2021 strategies place important emphasis on programme-programme integration and linkages in areas that have demonstrated some success, for example TB-HIV and HIV-SRHR, they placed less emphasis on the opportunities for linkage and integration in relation to health systems functions.

A 2020 article *Tailored HIV programmes and universal health coverage* in the WHO Bulletin² explores areas of both divergence and convergence between an increasing donor-led focus on HIV microtargeting and broader UHC offers and proposes the following areas of convergence that also provide ideas for hepatitis and STIs:

• Use of common clinical platforms

Stronger primary health-care systems, if prioritized through national UHC financing strategies, provide additional routes to deliver targeted HIV services to those patients with less intense clinical needs.

² https://www.who.int/bulletin/volumes/98/2/18-223495/en/

• Health-care worker performance

Improvements in national systems would support pre-service education and performance management (e.g. systems of incentivizing, mentoring, supervising) for health-care workers.

• Information systems and data use

Responsive electronic information systems (e.g. systems that are networked, include unique patient identifiers and promote subnational data use) are fundamental to both targeted HIV interventions and outcome-based programming for noncommunicable diseases, civil registration and vital statistics programmes and other elements of UHC.

• Laboratory systems

Improvements in laboratory systems (e.g. equipment, sample transportation systems, staff and information systems) through microtargeting of high-volume sites for HIV service delivery could benefit UHC delivery and management of other noncommunicable diseases throughout a region.

• Community delivery systems and civil society

Microtargeting of HIV services as well as integrated disease management and prevention services are highly reliant on well managed community systems to deliver focused messages and interventions into communities, with support from civil society.

• Supply-chain management

HIV microtargeting and many UHC goals require strong, yet responsive, supply chains that are held accountable by providers and society. Greater integration of health services and joint performance management could yield substantial health benefits.

While the existing global health sector strategies do promote synergies, linkage and integration it is clear that further strengthening across the functional areas of health is possible.

There are several key areas and opportunities for integration of HCV with other diseases, especially HIV and TB, include integrating HCV and HBV testing into existing testing activities in the community, antenatal clinics or in prisons; integrated serological testing using combo assays for HIV, HBV and syphilis; use of multi-disease laboratory based as well as point-of-care viral load platforms such as the GeneXpert for HIV and HCV; and delivery of HCV care integrated with harm reduction, in prisons and within primary care. There is a need for further pilot studies to examine the impact and cost efficiencies of delivery of integrated testing, lab services and service delivery models.

Since 2016, integration and linkages have been strengthened with tuberculosis; sexual and reproductive health and cervical cancer; mental health and other non-communicable diseases; vaccines and innovations including the development of broadly neutralizing antibodies (bNAbs) against HIV as therapeutics and prevention tools; and antimicrobial resistance. Key joint or common achievements include the validation of the elimination of mother-to-child transmission of HIV and/or syphilis in 10 countries or areas and a regional framework adopted for the triple elimination of mother-to-child transmission of HIV, hepatitis B and syphilis in Asia and the Pacific 2018–2030; Publication of new treatment guidelines for HIV infection, hepatitis C, syphilis, Chlamydia trachomatis infection, genital herpes and gonorrhea; the use of a dual HIV/syphilis rapid diagnostic testing in antenatal services; and

updating of the WHO Model List of Essential Medicines to include new treatments for sexually transmitted infections, the first combination therapy effective against all six genotypes of hepatitis C virus, and antiretroviral drugs for children and for the use as pre-exposure prophylaxis to prevent HIV infection.





Alignment and synergies across the three disease areas and tuberculosis

While all three strategies are already well aligned with the End TB Strategy which was developed a year in advance of the 2016-2021 strategies, and progress has been made in addressing HIV-associated TB (Table 2), there are some areas that could be further highlighted. For example, despite scale-up of ART, TB is still the leading cause of hospitalization and death among PLHIV. Joint HIV and tuberculosis programming continues to make sense in countries with the highest burden of tuberculosis and HIV coinfection which further strengthens integration, enhancing access to life-saving interventions, while maximizing efficient use of resources. The strategies should continue to promote intensified implementation and uptake of key interventions including systematic TB screening among PLHIV, TB preventive treatment, HIV testing and timing initiation of ART and look to highlight interdependencies with STIs and hepatitis including through the development of polyvalent or integrated diagnostic platforms for combined diagnosis of HIV and coinfections, such as TB, viral hepatitis and syphilis.

	<u>2016</u>	<u>2019</u>	2020 Target
Percentage reduction in TB/HIV	48% (TBC)	63% (TBC)	75%
Mortality since 2010			
Percentage of AIDS deaths due	37% (TBC)	30% (TBC)	
to TB			
% PLHIV who knew their status	74% (62-87)	81% (68-95)	90%
% Estimated PLHIV with TB who	47% (TBC)	56% (TBC)	90%
were notified and knew they			
were HIV-positive			
ART among notified HIV-	85%	88% (TBC)	
positive TB patients			
% TPT among PLHIV newly on	42%	50% (TBC)	
ART			
Progress to HLM TPT target		5.3 million	6 million
		(TBC)	

Table 2. Progress made to address HIV-associated TB since 2017

WHO describes SRHR/HIV linkages as bidirectional and involving synergies in policy, programmes, and service delivery that support comprehensive sexual and reproductive health needs and rights of all people, including people living with HIV, within a framework of gender equality and human rights. SRHR/HIV integration is a subset of SRH/HIV linkages which occurs at the service delivery level and can be understood as joining operational programmes to ensure effective outcomes through many modalities (multi-tasked providers, referral, one-stop shop services under one roof, etc.) Linkages with SRHR are also clearly evident in STIs and viral hepatitis.

The new strategies will also seek to align with the approach described in the PAHO Disease Elimination Framework adopted by the regional committee in 2019 (CE164/16) and with an initiative underway within the WHO division of UHC and communicable and noncommunicable diseases (UCN) to develop a global framework for multi-disease elimination (Box 2).

Box 2. The Global Framework for Multi-disease Elimination

More than 30 diseases have been targeted for "elimination" (including HIV, hepatitis B&C and STIs) and four diseases have been targeted for eradication at the global level. Each disease area has typically developed its own targets, strategies and processes according to the specific needs of each individual disease. This has led to a proliferation of elimination terminology, evidence requirements and confirmation processes (i.e. validation, verification, certification) that are used inconsistently or in contradictory ways across disease programmes. Additionally, many countries have multiple diseases they are targeting for elimination. Without guidance countries risk setting up a series of vertical elimination programmes. This represents a missed opportunity to identify

and capitalize on synergies between programmes to address multiple diseases in a more coherent, holistic, people-centred approach in the context of Universal Health Coverage.

In 2019, recognizing some of these challenges, the Pan-American Health Organization (PAHO) adopted a Regional framework to harmonize regional disease elimination approaches and targets. Based on the PAHO experience, WHO is now considering developing a Global Framework for Multi-disease Elimination (GFME).

The GFME could be used for both communicable and some non-communicable diseases and conditions, including those not currently targeted for elimination if elimination targets subsequently become feasible. The framework would aim to guide actions at country, regional and global levels to facilitate and accelerate disease elimination efforts across multiple diseases at the same time.

The objectives of a framework would be to:

- guide countries or regional organizations to develop integrated multi-disease elimination strategies, through a people-centred approach in the framework of UHC, based on global commitments and standards and adapted to the local context;
- identify programme synergies and optimize effectiveness, efficiency and impact through integrated approaches to multi-disease elimination that also address other health priorities;
- guide countries on how best to integrate elimination of multiple diseases or health conditions into broader national health and development strategies and plans according to local contexts, disease burden and other considerations – and to subsequently develop a locally appropriate 'pathway to multi-disease elimination';
- harmonize disease elimination definitions, governance structures and validation processes globally;
- provide an overview of all diseases currently targeted for elimination or eradication through WHO or other United Nations commitments or processes; and
- outline the potential roles and responsibilities of countries, WHO and partners to support multi-disease elimination efforts in countries and regions.

The strategies promote important synergies and opportunities for linkage and integration across the diseases and other health areas. During the implementation period a number of joint advances have been made, including: participation of 60 countries in the Global Antimicrobial Resistance Surveillance System and publication of guidelines and a global action plan on HIV drug resistance; validation of the elimination of mother-to-child transmission of HIV and/or syphilis in 10 countries or areas1 and endorsement by the Regional Committee for the Western Pacific of a regional framework for the triple elimination of mother-to-child transmission of HIV, hepatitis B and syphilis in Asia and the Pacific 2018–2030;2 publication of new treatment guidance for HIV infection, hepatitis C, syphilis, *Chlamydia trachomatis* infection, genital herpes and gonorrhoea; publication of advice on the use of a dual HIV/syphilis rapid diagnostic test in antenatal services; and updating of the WHO Model List of Essential Medicines to include new treatments

for sexually transmitted infections, the first combination therapy effective against all six genotypes of hepatitis C virus, and antiretroviral drugs for use as pre-exposure prophylaxis to prevent HIV infection.

Integrated people-centred health services and differentiated service delivery

WHO promotes Integrated people-centred health services as a key feature of robust and resilient health systems and central to progressing towards universal health coverage. Integrated people-centred health services means putting people and communities at the centre of health systems, and empowering people to take charge of their own health rather than being passive recipients of services. Evidence shows that health systems oriented around the needs of people and communities are more effective, cost less, improve health literacy and patient engagement, and are better prepared to respond to health crises.HIV responses in particular have been led by key principles of meaningful community engagement and a growing hepatitis community continues to advocate for stronger hepatitis programming. While STIs may not have an easily identifiable overarching "community" there are some exceptions – strong youth and female advocacy around cervical cancer and other cancers related to HPV has supported work on HPV vaccine promotion and prevention and HTLV1, a little known sexually transmitted infection, has a robust community of people living with HTLV1 supported by researchers and specialist clinicians.

On 16 October 2020 WHO convened 65 members of former civil society reference groups for HIV and hepatitis, the WHO advisory group of women living with HIV and community and civil society representatives who had formally engaged with WHO in recent years for a virtual exchange of ideas in advance of the meeting of the Strategic and Technical Committee on HIV and Viral Hepatitis (STAC-HIVHEP). During discussion meeting participants stressed the importance of WHO securing support for 2022-2030 strategies and described the impact of COVID-19 on the disruption of essential HIV, hepatitis and STI services exacerbated by the influence of populist challenges to science, community organizing and rights. WHO was also encouraged to be bolder in highlighting the countries, regions and populations were progress is unacceptably slow, including as a result of policy and financial barriers. Other issues raised during the meeting included:

- Future strategies must urgently prioritize key populations for all three disease areas, universal health coverage and should include further focus on criminalization, prisoners, social determinants and people in humanitarian crises including displaced and migrant populations;
- Re-focus on prevention, including primary prevention, across the disease areas with a clear focus on reaching priority populations first and enhancing support to innovation;
- The importance of raising the profile of HTLV1 as a sexually transmitted infection and encouraging expanded HTLV1 testing and prevention programming including through safer sex and condom promotion with links to other disease areas and sexual reproductive health and rights;
- COVID-19 mitigation approaches should continue to promote and support funding for community delivery of services including for testing, harm reduction and other prevention services and the distribution of medicines for HIV and viral hepatitis;

- WHO should ensure that guidance on all disease areas and on COVID-19 seeks to ensure women's sexual and reproductive health and rights by maintaining essential services and ensuring an increased focus on gender based and intimate partner violence and mental health;
- Participants shared perspectives on how "COVID criminalization" was impacting on sex workers, people who use drugs and other key populations and called for further attention on the health of prisoners in context of COVID-19;
- WHO was asked to optimize all options to secure lower commodity prices including for middleincome countries and to apply the learning and expertise from HIV and hepatitis access strategies to emerging COVID-19 commodities;
- Essential HIV, hepatitis and STI services and interventions need to be included in all essential UHC packages in all countries with WHO support including through the planned UHC Compendium;
- WHO has an important role in ensuring that community-based data generation and digital approaches are valued and supported and that funders see the value in community-based and community-led responses.

Differentiated services. As national responses to the disease areas evolve towards providing proven treatments to all people in need, services will be challenged to manage an increasing number of patients requiring treatment and an increasingly diverse set of patient needs. For HIV differentiated care involves the provision of different care packages to patients on antiretroviral therapy based on the stage of their HIV disease, their stability on treatment and their specific care needs. Patients who are stable on treatment, for example, may be moved to community-based care and multi month dispensing of medications, enabling overburdened clinical care settings to focus on patients who are unwell either because they are unstable on antiretroviral therapy or because they present to the clinic with an advanced stage of HIV disease or major comorbidities.

Differentiated service delivery (DSD) also offers opportunities to reduce the burden on stretched health systems during COVID-19. Patients with stable treatment or prevention needs can be prescribed medications and commodities for 3-6 months to reduce the need for clinic and pharmacy visits and interactions.

Expanding DSD for children, adolescents and pregnant women. Following the release of the 2016 recommendations in support of a more differentiated approach to HIV care, specific efforts were made to tailor DSD to families with a particular focus on pregnant women, children and adolescents. Implementation of these recommendations has been delayed. Most recently, increasing evidence, growing implementation experience and the pressure put by COVID on the health systems have overall resulted into a more widely and rapid adoption of DSD models for these vulnerable populations.

Given our inability to reach the 2020 targets for elimination of new paediatric HIV infections, focus has been on building national capacity for better data use to facilitate more nuanced planning for DSD for adolescent and young women in general as well those in key populations, to reach the last 7 to 15% of

women not accessing ART during pregnancy. There was also stronger engagement of civil society to improve EMTCT indicator coverage as well the national assessments for validation of EMTCT.

DSD models to provide HIV care to children living with HIV has been received with reluctance due to the lack of specific evidence and the desire to follow them up more closely in the context of formulation changes and poor retention. Following experiences from countries such as Malawi, which demonstrated the feasibility of MMD for children, more countries have initiated pilot implementation of DSD models for children. As of July 2020, more than 16 priority countries have reported full adoption of DSD for children and have started to implement MMD (3 monthly). More experience and evidence to support how DSD models would be implemented for the pediatric population as still needed.

Despite myriad challenges, some key progress has been made on DSD for adolescents. Following the Zvandiri trial that showed peer driven models of care improved important HIV outcomes including viral suppression, WHO developed and disseminated a technical document on peer driven models of care to support country adaptation and adoption of such models of care. The model has now been either shared or formally adapted beyond its Zimbabwe origins to other countries.

10. Strategy implementation

This part of the three 2016–2021 strategies addresses collaboration with partners; global and country accountability; monitoring, evaluation and reporting; and costing estimates for implementing the strategies.

The strategies' framework has informed country-led implementation of the health sector programmes for HIV, viral hepatitis and STIs. Efforts have been made to align national targets with those of the strategies. In addition, countries have also mobilized domestic and external resources, they have worked on strengthening implementation capacity and they have set up systems for monitoring and evaluating implementation progress. WHO support to countries has been focused on providing evidence based normative guidance on prevention, case finding, treatment and care. WHO has also supported the development of national strategic and implementation plans, training of programme managers and service providers, and resource mobilization including price negotiations. WHO has about 150 staff members working on HHS around the world in either full-time or part-time basis. These staff members are distributed between HQ, the six regional offices and 107 countries.

Under the strategies' framework, key partnerships have been strengthened since 2016 resulting in: the signing of a Memorandum of Understanding between WHO and the Global Fund to Fight AIDS, Tuberculosis and Malaria to improve country impact of the Fund's investments; the signing of a Memorandum of Understanding between WHO and UNODC that makes a commitment to joint action on HIV, viral hepatitis and tuberculosis among people who use drugs; co-signature of a joint United Nations statement on ending discrimination in health care settings; joint advocacy with the World Hepatitis Alliance to drive action to tackle viral hepatitis; and award signing of a grant from Unitaid to WHO to

promote research and innovation in HIV and hepatitis C prevention, diagnosis and treatment. Strengthened intersectoral collaboration for the disease areas has also been fostered in the context of the UNAIDS Joint Programme; ensuring links and contributions to a number of WHO-led intersectoral initiatives including the UHC 2030 Partnership, The Global Action Plan on healthy lives and well-being, and more recently, on multisectoral efforts focused on COVID-19 and its impact. WHO is also actively supporting post-2021 strategy development processes led by UNAIDS and the Global Fund to Fight AIDS, Tuberculosis and Malaria.

WHO plans to publish a progress report at the 74th World Health Assembly to review the successes and challenges in implementing the global health sector strategies, 2016-2021 on HIV, hepatitis and sexually transmitted infections (STIs) – including against the 2020 targets. The report will provide important data and analysis to inform 2022-2030 strategies – including ideas for ensuring a strengthened accountability framework for both country actions and WHO actions.