
Draft global health sector strategies

Viral hepatitis, 2016–2021

Report by the Secretariat

1. The Executive Board at its 138th session in January 2016 noted an earlier version of this report, which annexed a summary of the draft global health sector strategy on viral hepatitis, 2016–2021, and provided web links to the full version of the draft strategy in all official WHO languages.¹ The Executive Board recommended that the Sixty-ninth World Health Assembly consider the draft strategy and that the Secretariat draft a resolution for its possible adoption. The full version of the strategy included at the Annex has been updated.² The revised draft strategy reflects changes to the overall vision and 2020 targets. The present version also introduces additional detail including: a description of the populations most affected and at risk; tailoring of responses to the country context; highlighting the importance of comprehensive viral hepatitis prevention, including safe food and water, and harm reduction for people who inject drugs; interventions related to alcohol use; prevention and management of coinfections; the use of the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health; research towards hepatitis C vaccine; and reporting arrangements.
2. In May 2010, the Sixty-third World Health Assembly adopted resolution WHA63.18 on viral hepatitis, which, inter alia, urged Member States to support or enable an integrated and cost-effective approach to the prevention, control and management of viral hepatitis. To facilitate implementation of the resolution, the Secretariat established the global viral hepatitis programme. In 2012, the Secretariat issued a framework for global action to prevent and control viral hepatitis infection,³ which has since provided guidance for the hepatitis programme.
3. Recognizing the need for an intensified and expanded global hepatitis response, in May 2014, a follow-up resolution was adopted by the Sixty-seventh World Health Assembly. Resolution WHA67.6 requested the Director-General, inter alia, to provide the necessary technical support to enable Member States to develop robust national viral hepatitis prevention, diagnosis and treatment strategies with time-bound goals.

¹ Document EB138/30.

² The updated draft strategy (see the Annex) incorporates Member States' comments – both those provided during the discussions at the 138th session of the Executive Board and those contributed as additional input, see the summary records of the Executive Board at its 138th session, ninth meeting (document EB138/2016/REC/2). Specifically, sections of the draft strategy that were revised include: 1.3; 3.3; 3.4; 4.0; 4.2.5; 4.3.3; 4.5.1; and 5.2.

³ Prevention and control of viral hepatitis infection: framework for global action is available at: <http://www.who.int/hiv/pub/hepatitis/Framework/en/> (accessed 2 April 2016).

4. In September 2014, in response to resolution WHA67.6, the Secretariat initiated work on a global health sector strategy on viral hepatitis for the period 2016–2021. Two other global health sector strategies covering the same period were also drafted: on HIV¹ and on sexually transmitted infections.² The three draft strategies were developed together, using a common framework and a coordinated consultation process.

5. In September 2015, the United Nations General Assembly adopted the 2030 Agenda for Sustainable Development,³ which enshrines 17 Goals and associated targets. Of particular relevance to the preparation of the draft strategy on viral hepatitis is target 3.3: “By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases.”

6. The draft strategy on viral hepatitis responds to resolution WHA67.6, which requests the Director-General, *inter alia*, to examine the feasibility of and strategies needed for the elimination of hepatitis B and hepatitis C, with a view to potentially setting global targets; and is also in line with target 3.3 referred to above. A goal of the draft strategy is to eliminate viral hepatitis as a public health threat by 2030, and to contribute to the achievement of universal health coverage. The Secretariat’s draft strategy on viral hepatitis is presented in the Annex of this report.

7. The draft strategy provides a framework for concerted action by the Secretariat and Member States at the global, regional and country levels. It is based on existing good practices and available evidence on the effectiveness of hepatitis-related approaches and interventions in the health sector.

8. The broad consultative process⁴ that led to the draft strategy involved all key partners, including Member States, organizations in the United Nations system and other multilateral agencies, donor and development agencies and initiatives, civil society, nongovernmental organizations, scientific and technical institutions and networks, and the private sector. Numerous stakeholder consultations were held, and more than 100 Member States participated in consultations that were held in all WHO regions from April to July 2015. To supplement those consultations and ensure the broadest participation, the Secretariat hosted a public online consultation for six weeks from April to June 2015. An official technical briefing on the three draft strategies (viral hepatitis, HIV and sexually transmitted infections) was held during the Sixty-eighth World Health Assembly.⁵

9. As referred to previously, the process of developing the draft strategy on viral hepatitis was managed together with two other health sector strategies for the same period.⁶ The universal health

¹ See document EB138/29.

² See document EB138/31.

³ United Nations General Assembly resolution A/RES/70/1 – Transforming our world: the 2030 Agenda for Sustainable Development, see http://www.un.org/ga/search/view_doc.asp?symbol=A/RES/70/1&Lang=E (accessed 30 March 2016).

⁴ Information on the consultation process and draft strategy documents is available at: <http://www.who.int/hiv/pub/hep-strategy-background/en/> (accessed 2 April 2016).

⁵ A report of the technical briefing is available at: http://www.who.int/hiv/strategy2016-2021/ghss_wha_2015_story/en/ (accessed 2 April 2016).

⁶ The two other global health sector draft strategies for the period 2016–2021 are on HIV and sexually transmitted infections. The draft strategies are available in the annex to the respective documents, see document A69/31 on HIV and document A69/33 on sexually transmitted infections.

coverage framework provided a common structure for the three strategies, and a cross-cluster working group was established to facilitate the process. Substantial input was provided from across the three levels of the Organization by contributors working in areas that have significant involvement in hepatitis-related activities. The process was enhanced by input from a civil society reference group on viral hepatitis convened by WHO and the WHO Scientific and Technical Advisory Committee on Viral Hepatitis.¹

ACTION BY THE HEALTH ASSEMBLY

10. The Health Assembly is invited to adopt the draft global health sector strategy on viral hepatitis, 2016–2021.

¹ The WHO civil society reference group advises the WHO global hepatitis programme, and the WHO strategic and technical advisory group advises the Director-General.

ANNEX

**DRAFT GLOBAL HEALTH SECTOR STRATEGY ON VIRAL
HEPATITIS, 2016–2021 – THE FIRST OF ITS KIND**

1. Viral hepatitis is an international public health challenge, comparable to other major communicable diseases, including HIV, tuberculosis and malaria. Despite the significant burden it places on communities across all global regions, hepatitis has been largely ignored as a health and development priority until recently. It will no longer remain hidden, however, with the adoption of the resolution on the 2030 Agenda for Sustainable Development.¹ Target 3 is of particular relevance: it calls for specific action to combat viral hepatitis.²

2. This is the first global health sector strategy on viral hepatitis, a strategy that contributes to the achievement of the 2030 Agenda for Sustainable Development. It covers the first six years of the post-2015 health agenda, 2016–2021, building on the *Prevention and Control of Viral Hepatitis Infection: Framework for Global Action*,³ and on two resolutions on viral hepatitis adopted by the World Health Assembly in 2010 and in 2014.⁴ The strategy addresses all five hepatitis viruses (hepatitis A, B, C, D and E), with a particular focus on hepatitis B and C, owing to the relative public health burden they represent.

3. The strategy describes the contribution of the health sector to combating viral hepatitis, towards its elimination as a public health threat. It promotes synergies between viral hepatitis and other health issues, and aligns the hepatitis response with other global health and development strategies, plans and targets. It positions the response to viral hepatitis within the context of universal health coverage – an overarching health target of the 2030 Agenda for Sustainable Development. The strategy outlines a way ahead, and provides:

- A vision of a world where viral hepatitis transmission is halted and everyone living with viral hepatitis has access to safe, affordable and effective care and treatment;
- A goal of eliminating viral hepatitis as a major public health threat by 2030;
- Targets that seek to reduce the incidence of chronic hepatitis infection from the current 6–10 million cases of chronic infection to 0.9 million infections by 2030, and to reduce the annual deaths from chronic hepatitis from 1.4 million to less than 0.5 million by 2030. Achieving these targets will require a radical change in the hepatitis response, and will mean that hepatitis is elevated to a higher priority in public health responses.

¹ United Nations General Assembly resolution A/RES/70/1 – Transforming our world: the 2030 Agenda for Sustainable Development, see http://www.un.org/ga/search/view_doc.asp?symbol=A/RES/70/1&Lang=E (accessed 2 April 2016).

² Sustainable Development Goals, target 3.3: “By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases.”

³ *Prevention and Control of Viral Hepatitis Infection: Framework for Global Action*, see <http://www.who.int/hiv/pub/hepatitis/Framework/en/> (accessed 3 April 2016).

⁴ Resolution WHA63.18 was adopted in 2010, and resolution WHA67.6, in 2014.

4. The strategy must exploit new opportunities, including: increasing public awareness; advances in hepatitis medicines, diagnostics and other technologies; and strengthening commitment to achieve health equity. The strategy defines a set of priority actions for countries to undertake, and counterbalances this with a set of priority actions for WHO to undertake, in support of countries.

5. Priority actions are organized under five strategic directions, which are:

Strategic direction 1 – Information for focused action: developing a strong strategic information system to understand viral hepatitis epidemics and focus the response;

Strategic direction 2 – Interventions for impact: defining essential, high-impact interventions on the continuum of hepatitis services that should be included in health benefit packages;

Strategic direction 3 – Delivering for equity: strengthening health and community systems to deliver high-quality services to achieve equitable coverage and maximum impact;

Strategic direction 4 – Financing for sustainability: proposing strategies to reduce costs, improve efficiencies and minimize the risk of financial hardship for those requiring the services;

Strategic direction 5 – Innovation for acceleration: promoting and embracing innovation to drive rapid progress.

Outline of the strategy

6. The strategy has five major components:

1. **Towards eliminating viral hepatitis** – reviews the current status of viral hepatitis epidemics and responses, identifies opportunities and challenges for the future, and argues the case for adequate investment in the health sector response to viral hepatitis;

2. **Framing the strategy** – describes the three organizing frameworks for the strategy (universal health coverage, the continuum of hepatitis services and the public health approach);

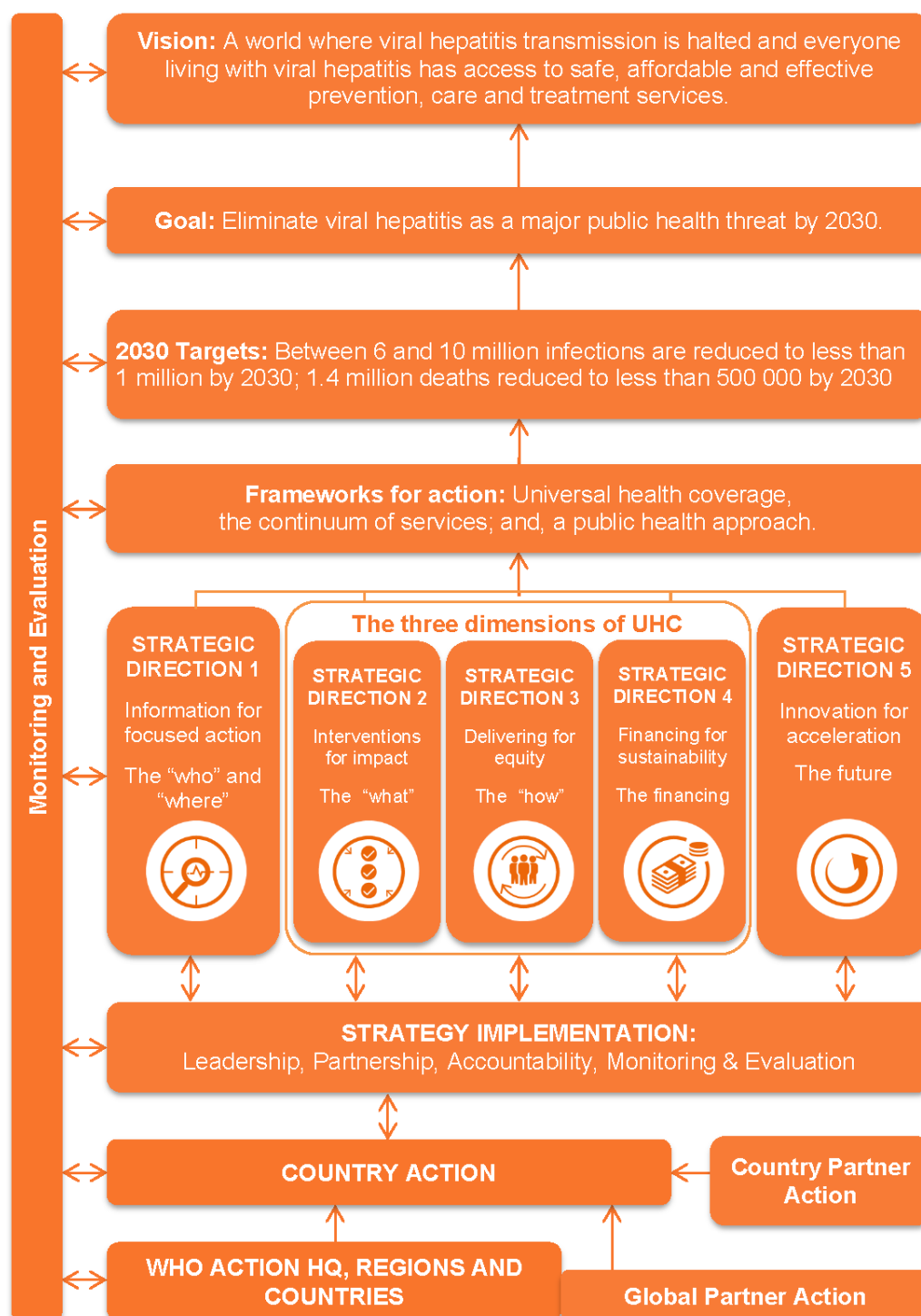
3. **Vision, goal, targets and guiding principles** – presents a set of impact and service coverage targets for 2020 and 2030 to drive the response;

4. **Strategic directions and priority actions** – recommends actions to be taken by both countries and WHO under each of **five strategic directions**; and

5. **Strategy implementation: leadership, partnerships, accountability, monitoring and evaluation** – outlines key elements of strategy implementation, including strategic partnerships, monitoring and evaluation and costing.

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Figure 1. Framework for the global health sector strategy on viral hepatitis, 2016-2021



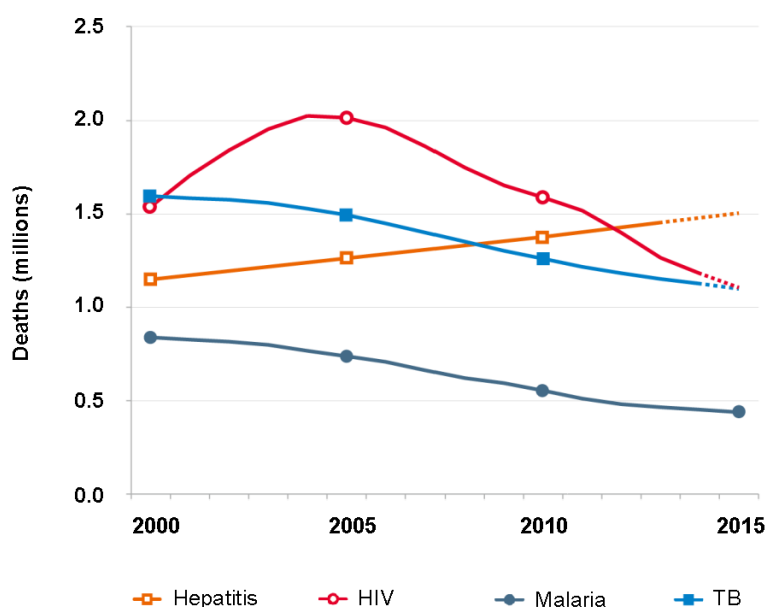
1. TOWARDS ELIMINATING VIRAL HEPATITIS

7. The need for a global health sector strategy on viral hepatitis stems from the scale and complexity of the hepatitis pandemic, along with growing recognition of its massive public health burden and the huge opportunities for action. To date, few countries have seized these opportunities; action has tended to be fragmented and inadequate. The time has come for a coherent public health response that prioritizes effective interventions, promotes service delivery approaches that ensure quality and equity, takes programmes to scale to achieve sustained impact at the population level, and establishes clear stakeholder responsibility and accountability.

1.1 A major public health burden

8. The viral hepatitis pandemic takes a heavy toll on lives, communities and health systems. In 2013, viral hepatitis was the seventh highest cause of mortality globally. It is responsible for an estimated 1.4 million deaths per year from acute infection and hepatitis-related liver cancer and cirrhosis – a toll comparable to that of HIV and tuberculosis (Figure 2). Of those deaths, approximately 47% are attributable to hepatitis B virus, 48 % to hepatitis C virus and the remainder to hepatitis A virus and hepatitis E virus. Viral hepatitis is also a growing cause of mortality among people living with HIV. About 2.9 million people living with HIV are co-infected with hepatitis C virus and 2.6 million with hepatitis B virus.¹

Figure 2. Estimated global number of deaths due to viral hepatitis, HIV, malaria and TB, 2000–2015



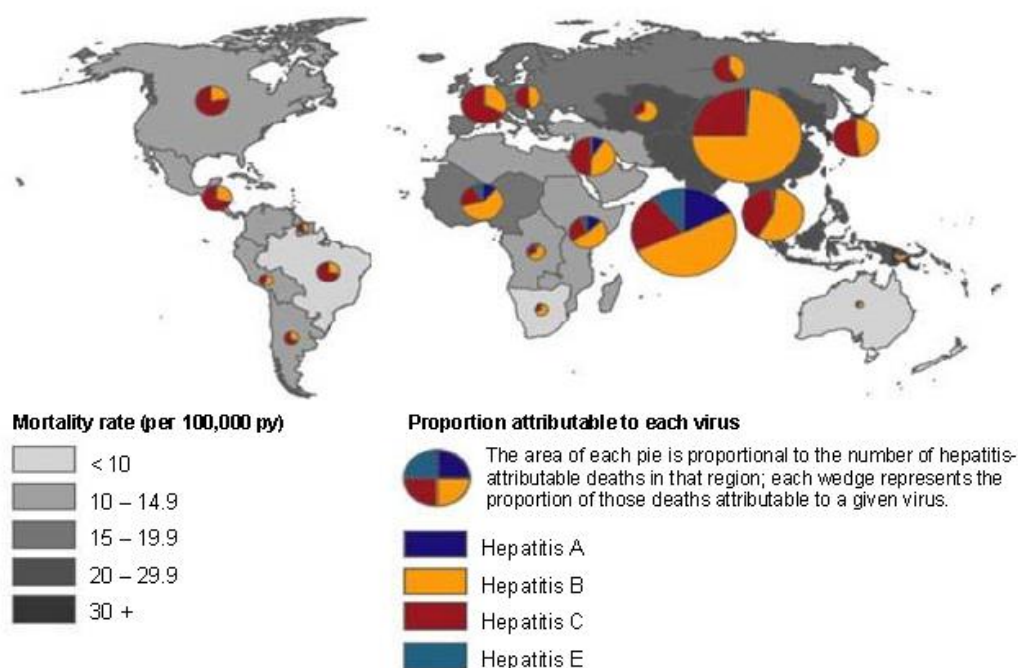
Source: Global Burden of Disease and WHO/UNAIDS estimates, see <http://ihmeuw.org/3pms>, <http://ihmeuw.org/3pmt> (accessed 2 April 2016).

¹ Global Burden of Disease and WHO/UNAIDS estimates.

9. Worldwide, approximately 240 million people have chronic hepatitis B virus infection and 130–150 million have chronic hepatitis C virus infection. Without an expanded and accelerated response, the number of people living with hepatitis B virus is projected to remain at the current, high levels for the next 40–50 years, with a cumulative 20 million deaths occurring between 2015 and 2030. The number of people living with hepatitis C virus is actually increasing, despite the existence of an effective cure. A stepped-up global response can no longer be delayed.

10. The five hepatitis viruses (A, B, C, D and E) are very different, with different modes of transmission, affecting different populations and resulting in different health outcomes. An effective response requires a range of common actions, while at the same time delivering tailored interventions for each of the viruses (see Figure 3).

Figure 3. Regional distribution of viral hepatitis deaths



Source: Global Burden of Disease, see <http://vizhub.healthdata.org/gbd-compare/#settings=f53a9677cb8e4ff596bc37f980aa0276322ecc39> (accessed 2 April 2016).

11. Viral hepatitis B and C are blood-borne infections, with significant transmission occurring in early life and through unsafe injections and medical procedures, and less commonly through sexual contact. Hepatitis B virus prevalence is highest in sub-Saharan Africa and east Asia, where between 5–10% of the adult population is chronically infected. Mother-to-child transmission of hepatitis B virus is a major mode of transmission in high prevalence settings. High rates of chronic infections are also found in the Amazon region of South America and the southern parts of eastern and central Europe. In the Middle East and the Indian subcontinent, an estimated 2–5% of the general population is chronically infected. Immunization is the most effective strategy for prevention of hepatitis B virus infection.

12. Hepatitis C is found worldwide. The most affected regions are central and east Asia and north and west Africa, where most infections are caused by unsafe medical injections and other medical procedures. Hepatitis C virus epidemics related to injecting drug use occur in all regions, with an estimated 67% of people who inject drugs having been infected with hepatitis C virus. Comprehensive prevention strategies for both hepatitis B virus and hepatitis C virus should include assurance of safe blood products, safe injection practices, harm reduction services for people who inject drugs and promotion of safe sex.

13. Hepatitis D is transmitted through contact with infected blood. It only occurs in people who are already infected with hepatitis B virus and can therefore be prevented through hepatitis B virus vaccination and other prevention efforts.

14. Viral hepatitis A and E are food- and water-borne infections that can result in acute outbreaks in communities with unsafe water and poor sanitation. They do not result in chronic infection or chronic liver disease and there is no specific treatment. Prevention is through improved sanitation, food safety and vaccination.

1.2 There are unprecedented opportunities to act

15. Ending hepatitis epidemics as a major public health threat is feasible with the tools and approaches currently available and in the pipeline. Opportunities exist for enhancing and expanding the response by investing in **five core intervention areas**:

Vaccines – Effective vaccines are available for preventing viral hepatitis A, B and E infections, with a range of countries already implementing large-scale and inexpensive hepatitis B virus childhood vaccination programmes;

Prevention of mother-to-child transmission of hepatitis B virus – Timely hepatitis B virus birth-dose vaccination is a key intervention for preventing the transmission of the virus from mother to infant at birth, which could be enhanced through antenatal testing and the use of antiviral drugs;

Injection, blood and surgical safety – transmission of viral hepatitis B and C in health care settings can be stopped through the rigorous application of universal precautions for all invasive medical interventions, promotion of injection safety measures and securing the safe supply of blood products;

Harm reduction for people who inject drugs – Ensuring access to sterile injecting equipment and effective drug dependence treatment can prevent and control epidemics of viral hepatitis B and C among people who inject drugs, as part of a comprehensive package of interventions for the prevention, treatment and care of HIV, viral hepatitis and other blood-borne infections among people who inject drugs;¹

¹ WHO's comprehensive package for the prevention, treatment and care of HIV and viral hepatitis among people who inject drugs includes the following interventions: needle and syringe programmes; opioid substitution therapy and other drug dependence treatment; HIV testing and counselling; antiretroviral therapy for people with HIV; prevention and treatment of sexually transmitted infections; condom programmes for people who inject drugs and their sexual partners; targeted information, education and communication for people who inject drugs and their sexual partners; vaccination, diagnosis and

Treatment – New oral, well-tolerated medicines and treatment regimens for people with chronic hepatitis C virus infection can achieve cure rates of over 90%. Effective treatment is also available for people with chronic hepatitis B virus infection, although for most people such treatment needs to be lifelong.

16. To have greatest impact, effective interventions should be combined and tailored for the specific population, location and setting. For example, for hepatitis B virus epidemics, in certain countries with high prevalence of this virus, the most significant public health benefits are likely to be achieved by focusing efforts on reducing deaths by the prevention of early-life infection through birth-dose and childhood vaccination, and the treatment of people with chronic hepatitis infection.

1.3 Clearing a path for success

17. New opportunities provide hope for the elimination of viral hepatitis as a public health threat. Some very significant barriers need to be addressed, however, in order to realize this goal:

Leadership and commitment is uneven – Exceptional leadership in the hepatitis response is emerging from a range of countries. Civil society, too, has mobilized a global hepatitis movement. As a consequence viral hepatitis has been elevated to a public health priority. However many countries – and the international community as a whole – are yet to act with the determination and urgency required to eliminate hepatitis epidemics. Few countries have national viral hepatitis strategies or plans, and even fewer have designated units and budgets within their health ministries to lead, guide and coordinate their hepatitis responses and to be held accountable by its citizens.

Data are inadequate – The true public health dimensions and impact of hepatitis epidemics are poorly understood in many countries. National and subnational data are often lacking or inadequate and hepatitis surveillance programmes are weak, making it difficult to plan for focused action and prioritize the allocation of resources.

Coverage of prevention programmes is limited – Prevention programmes, particularly for specific populations that are most affected and at risk, are often of limited scope and coverage. Between 2000 and 2010, there was a reduction of 91% in hepatitis B virus infections and a reduction of 83% in infections of hepatitis C virus due to unsafe injections. However, medical injections still account for an estimated 1.7 million new hepatitis B virus infections annually and between 157 000 and 315 000 new hepatitis C virus infections annually. Global coverage of harm reduction programmes for people who inject drugs, including needle and syringe programmes, is less than 10%. By 2014, global childhood hepatitis B virus vaccination coverage had increased to over 82%, however, coverage of hepatitis B virus birth-dose lagged behind at just 38%.

Most people do not know their hepatitis status – Simple and effective hepatitis testing strategies and tools are lacking, with less than 5% of people with chronic hepatitis infection knowing their status. For this reason, diagnosis often occurs late and appropriate tests to assess liver disease and guide treatment decisions, including when to start treatment, are seldom available.

treatment of viral hepatitis; prevention, diagnosis and treatment of tuberculosis, and prevention and management of drug overdose.

Few have access to treatment and care services – Of those people with chronic viral hepatitis infection, it is estimated that less than 1% have accessed effective antiviral therapy. Those with complications of chronic hepatitis infection, including end-stage cirrhosis and hepatocellular carcinoma, may not be able to access basic care, notably palliative and end-of-life care.

Medicines and diagnostics are unaffordable for most – The development of highly effective treatment regimens, including direct-acting antiviral medicines, has revolutionized the treatment of chronic hepatitis C virus infection, and there is a long development “pipeline” of additional promising options. The high prices of new medicines are a major barrier to access in most countries. Treatment for chronic hepatitis B virus infection is lifelong for most people. The challenges will be to ensure that such medicines are affordable and that those people in need of treatment have access to those medicines without experiencing financial hardship.

A public health approach to hepatitis is lacking – A reorientation of hepatitis programmes towards a comprehensive public health approach will be critical if hepatitis elimination is to be achieved. This will require people-centred health services that can reach those populations most affected, well-functioning laboratories to ensure high-quality testing and treatment monitoring, a secure supply of affordable medicines and diagnostics, an appropriately trained health workforce, adequate public funding for essential interventions and services and active involvement of affected communities.

Structural barriers increase vulnerability and prevent equitable access to services – Human rights violations, along with widespread stigma and discrimination, continue to hinder access to health services for populations that may be criminalized and marginalized and who are at higher risk of hepatitis infection, including people who inject drugs, men who have sex with men, prisoners and sex workers.

18. Responses to hepatitis can learn from successful public health programmes in other areas, including those for HIV, tuberculosis, immunization and chronic care. Innovative HIV service delivery approaches can be adapted to reach specific populations (see text box). Quality improvement and price-reduction strategies that have enabled rapid expansion of HIV treatment coverage provide lessons for increasing access to affordable hepatitis C virus treatment. Immunization programmes can demonstrate how a range of strategies can be used to reach all communities and ensure access to effective, safe and affordable vaccines.

Populations most affected and at risk

Each country should define the specific populations within their country that are most affected by viral hepatitis epidemics and the response should be based on the epidemiological and social context. In many countries, much transmission of hepatitis B virus and hepatitis C occurs in health care settings and therefore specific populations for focused attention include people who have been exposed to viral hepatitis through unsafe blood supplies and unsafe medical injections and procedures. In settings with high hepatitis B prevalence, mother-to-child transmission of hepatitis B is likely to be a major mode of transmission, along with early childhood infection among those who have not been vaccinated. Populations exposed through sexual transmission may include young people and adolescents, men who have sex with men, sex workers, transgender people and prisoners. People who inject drugs are at high risk of hepatitis C infection and hepatitis B infection because of the shared use of contaminated injecting equipment and blood. Mobile populations, and people affected by conflict and civil unrest may be at particular risk of all forms of viral hepatitis infection because of their living conditions, lack of access to clean water and safe food and medical services that cannot maintain effective infection control measures.

People who will require specific attention include those with coinfections such as: hepatitis B and C combined; viral hepatitis and tuberculosis; and HIV and viral hepatitis.

19. The challenges described above are holding back country responses, however, the fact that so much room for improvement exists marks a significant opportunity for countries. Increasingly, people with chronic hepatitis infection and affected communities are demanding action. There is a clear imperative to act now. Many of the actions required are comparatively simple to undertake and will profoundly impact on hepatitis epidemics and other health and development priorities.

2. FRAMING THE STRATEGY

20. The viral hepatitis strategy is designed to contribute to the attainment of the 2030 Agenda for Sustainable Development, and specifically, to health-related Goal 3 (target 3.3). The strategy describes priority actions required to achieve the global hepatitis targets and how the hepatitis response can contribute to the achievement of universal health coverage, other health targets and the broader 2030 Agenda. It is aligned with other relevant health strategies and plans, including those for HIV, sexually transmitted infections, safe injections, blood safety, vaccines, tuberculosis and noncommunicable diseases, and responds to the requirements of World Health Assembly resolutions on viral hepatitis that were adopted in 2010 and 2014.¹

21. The strategy draws on three organizing frameworks: universal health coverage; the continuum of hepatitis services; and the public health approach.

2.1 2030 Agenda for Sustainable Development – providing direction

22. The 2030 Agenda for Sustainable Development is ambitious and far-reaching. Health is a major goal in this post-2015 agenda, reflecting its central role in alleviating poverty and facilitating development. The health-related goal (Goal 3) addresses a range of health challenges that are critical for development, notably, target 3.3 on communicable diseases, which includes combating viral hepatitis epidemics. Effectively combating such epidemics will also impact on other health targets, including reducing maternal mortality (target 3.1), reducing mortality from noncommunicable diseases (target 3.4), preventing and treating substance use disorders (target 3.5), achieving universal health coverage (target 3.8), access to affordable medicines and vaccines (target 3.b) and health financing and

¹ Resolution WHA63.18 (2010) and resolution WHA67.6 (2014).

health workforce (target 3.c). In addition to its impact on health-related Goal 3, combating viral hepatitis epidemics will contribute to ending poverty (Goal 1), ending hunger (Goal 2), managing water and sanitation (Goal 6), reducing inequality in access to services and commodities (Goal 10), promoting inclusive societies that promote non-discrimination (Goal 16), and financing and capacity building for implementation (Goal 17).

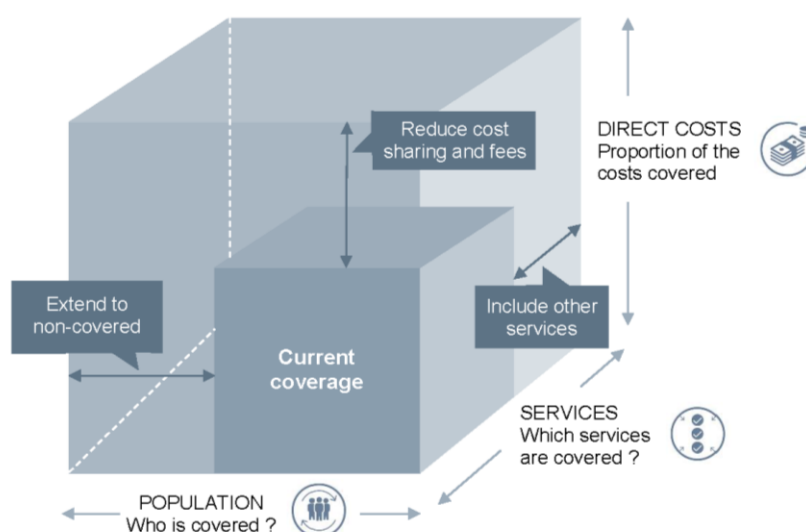
2.2 Universal health coverage – an overarching framework

23. At the global level, 150 million people experience financial catastrophe and 100 million people suffer impoverishment every year as a result of out-of-pocket health expenses. Ensuring financial security and health equity are key concerns in the 2030 Agenda for Sustainable Development, and universal health coverage provides a framework for addressing them. Universal health coverage (see Figure 4) is achieved when all people receive the health services they need, which are of sufficient quality to make a difference, without those people incurring financial hardship. Universal health coverage comprises three major, interlinked objectives:

- (1) Expanding the range of services provided – Improving the range, quality and availability of essential health services that are needed;
- (2) Covering the populations in need of services – Improving the equitable and optimal uptake of services in relation to need;
- (3) Reducing the direct costs of services – Providing financial protection for those who need the services.

24. As resources, efficiencies and capacities increase, the range of services provided can be expanded, the quality can be improved, and more populations can be covered with less direct costs to those who need the services – a progressive realization of universal health coverage.

Figure 4. The three dimensions of universal health coverage



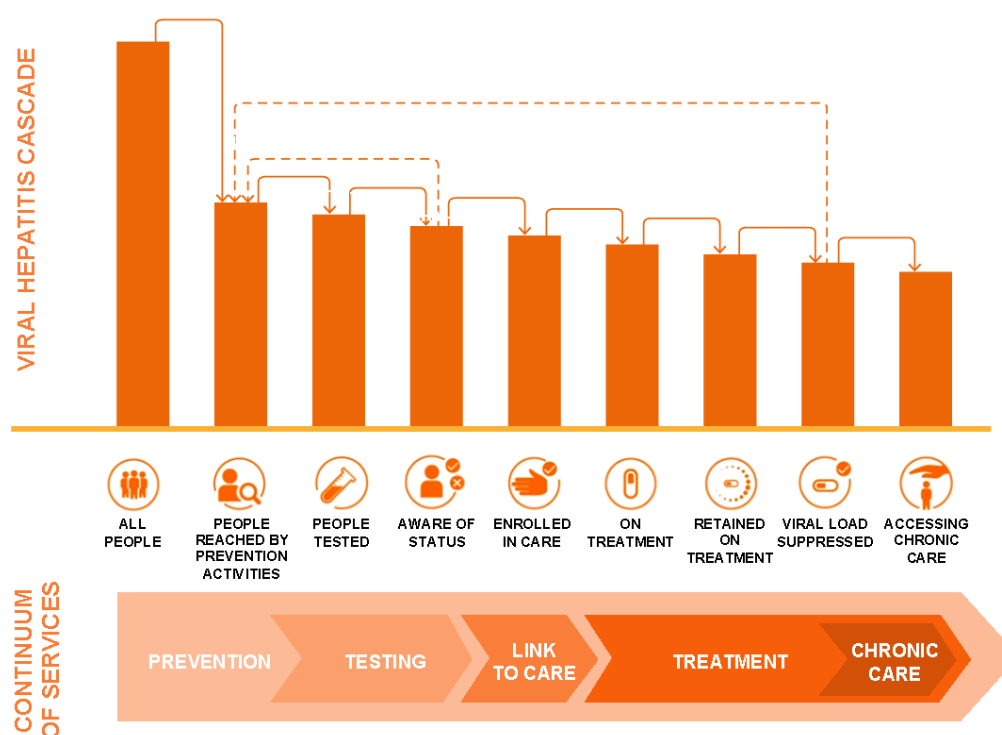
2.3 The continuum of hepatitis services – an organizing framework

25. While the concept of universal health coverage frames the strategy overall, the continuum of hepatitis services that are needed to curb the epidemic provides the organizing framework for the specific actions to be taken (see Figure 5). That continuum spans the entire range of interventions that is needed to achieve the strategy’s targets – from reducing vulnerability, preventing and diagnosing infection, linking people to health services, through to providing treatment and chronic care. The strategy defines the essential services and interventions that need to be delivered along this continuum and the strategic information that is needed to focus interventions for maximum impact.

2.4 A public health approach

26. The strategy is based on a public health approach that is concerned with preventing infection and 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 and decentralized, 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.

Figure 5. The continuum of viral hepatitis services and the retention cascade



3. GLOBAL VISION, GOAL AND TARGETS

27. The strategy outlines a global vision, a global goal, and a set of global targets that are aligned with the 2030 Agenda for Sustainable Development and relevant World Health Assembly resolutions.

3.1 Global vision

28. A world where viral hepatitis transmission is halted and everyone living with viral hepatitis has access to safe, affordable and effective prevention, care and treatment services.

3.2 Goal

29. Eliminate viral hepatitis as a major public health threat by 2030.¹

3.3 Targets for 2020 and 2030

30. Countries can contribute to the elimination of viral hepatitis as a major global public health threat if they act with enough resolve to achieve a set of ambitious targets for 2020 and 2030. These targets (see Table 1) apply to everyone at risk of viral hepatitis infection: children, adolescents and adults; rich and poor; women and men; and all populations affected and at risk.

¹ Goal 3 of the 2030 Agenda for Sustainable Development calls for combating hepatitis and in 2014, the World Health Assembly in resolution WHA67.6 requested that WHO examine the feasibility of viral hepatitis elimination. WHO modelling and analysis suggest that the effort to combat viral hepatitis could secure elimination as a public health threat when five synergistic service coverage targets in prevention and treatment are reached (see Table 1). WHO has defined the elimination of viral hepatitis as a public health threat as achieving a 90% reduction in new chronic infections and a 65% reduction in mortality.

Table 1. Global hepatitis strategy targets at a glance

TARGET AREA	BASELINE 2015	2020 TARGETS	2030 TARGETS
Impact targets			
Incidence: New cases of chronic viral hepatitis B and C infections	Between 6 and 10 million infections are reduced to 0.9 million infections by 2030 (95% decline in hepatitis B virus infections, 80% decline in hepatitis C virus infections)	30% reduction (equivalent to 1% prevalence of HBsAg ¹ among children)	90% reduction (equivalent to 0.1% prevalence of HBsAg among children) ²
Mortality: Viral hepatitis B and C deaths	1.4 million deaths reduced to less than 500 000 by 2030 (65% for both viral hepatitis B and C)	10% reduction	65% reduction
Service coverage targets			
Hepatitis B virus vaccination: childhood vaccine coverage (third dose coverage)	82% ³ in infants	90%	90%
Prevention of hepatitis B virus mother-to-child transmission: hepatitis B virus birth-dose vaccination coverage or other approach to prevent mother-to-child transmission	38%	50%	90%
Blood safety	39 countries do not routinely test all blood donations for transfusion-transmissible infections 89% of donations screened in a quality-assured manner ⁴	95% of donations screened in a quality-assured manner	100% of donations are screened in a quality-assured manner
Safe injections: percentage of injections administered with safety-engineered devices in and out of health facilities	5%	50%	90%
Harm reduction: number of sterile needles and syringes provided per person who injects drugs per year	20	200	300
Viral hepatitis B and C diagnosis	<5% of chronic hepatitis infections diagnosed	30%	90%
Viral hepatitis B and C treatment	<1% receiving treatment	5 million people will be receiving hepatitis B virus treatment 3 million people have received hepatitis C virus treatment (Both targets are cumulative by 2020)	80% of eligible persons with chronic hepatitis B virus infection treated 80% of eligible persons with chronic hepatitis C virus infection treated

¹ The abbreviation “HBsAg” refers to hepatitis B virus surface antigen. It should be noted that some of WHO’s regional committees have already endorsed region-specific targets. 1% is to be taken as the global average.

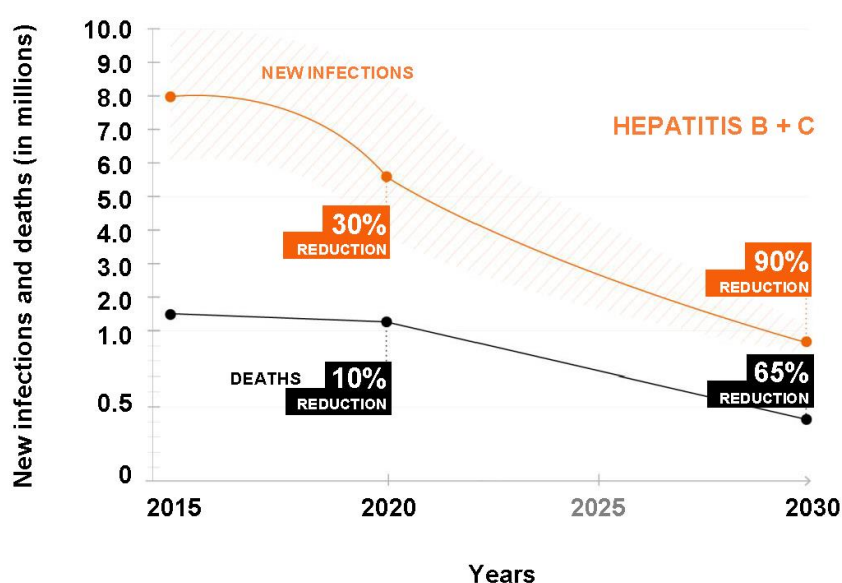
² Documentation of the 0.1% HBsAg will require development of new methods for validation that should be developed in the light of all available efforts to eliminate mother-to-child transmission of the hepatitis B virus, such as the use of the hepatitis B vaccine and anti-viral medicines.

³ WHO/UNICEF coverage estimates 2013 revision, July 2014, see: http://apps.who.int/immunization_monitoring/globalsummary/timeseries/tswucoveragebcg.html (accessed 1 April 2016).

⁴ Global database on blood safety, Summary Report 2011, see: http://www.who.int/bloodsafety/global_database/GDBS_Summary_Report_2011.pdf?ua=1 (accessed 1 April 2016).

31. The strategy includes both impact (incidence and mortality) and service coverage targets (see Table 1). By 2020, five million people will be receiving treatment for chronic hepatitis B virus infection, three million people will have been treated for chronic hepatitis C virus infection and the number of new cases of chronic hepatitis infection would have been reduced by 30% compared with the number of new cases in 2015. By 2030, the incidence of chronic hepatitis infection will have been reduced by 90% and there will be universal access to key prevention and treatment services.

Figure 6. Targets for reducing new cases of and deaths from chronic viral hepatitis B and C infection



3.4 Country targets for 2020

32. Informed by global goals and targets, countries should develop as soon as practicable ambitious national goals and targets for 2020 and beyond, taking into consideration the country context, including the nature and dynamics of country viral hepatitis epidemics, populations affected, structure and capacity of the health care and community systems, and resources that can be mobilized. Targets should be feasible and developed based on country realities, the best possible data available on the viral hepatitis situation, trends and responses, and monitored through a set of standard and measurable indicators. The targets should apply to everyone.

4. STRATEGIC DIRECTIONS AND PRIORITY ACTIONS

33. To achieve the 2030 Agenda for Sustainable Development, action is required in five areas, referred to as “strategic directions”. Under each of the strategic directions, specific actions should be taken by countries, WHO and partners. This draft strategy outlines those priority actions to be taken by countries and by WHO. The proposed actions are intended to guide country efforts, with countries

selecting and implementing those actions that are most appropriate to their respective hepatitis epidemics, national priorities and country contexts, taking into consideration national policies, jurisdiction and legislation.

4.1 Strategic directions

34. The five strategic directions that guide priority actions by countries and by WHO are presented below:

Strategic direction 1: Information for focused action (know your epidemic and response).

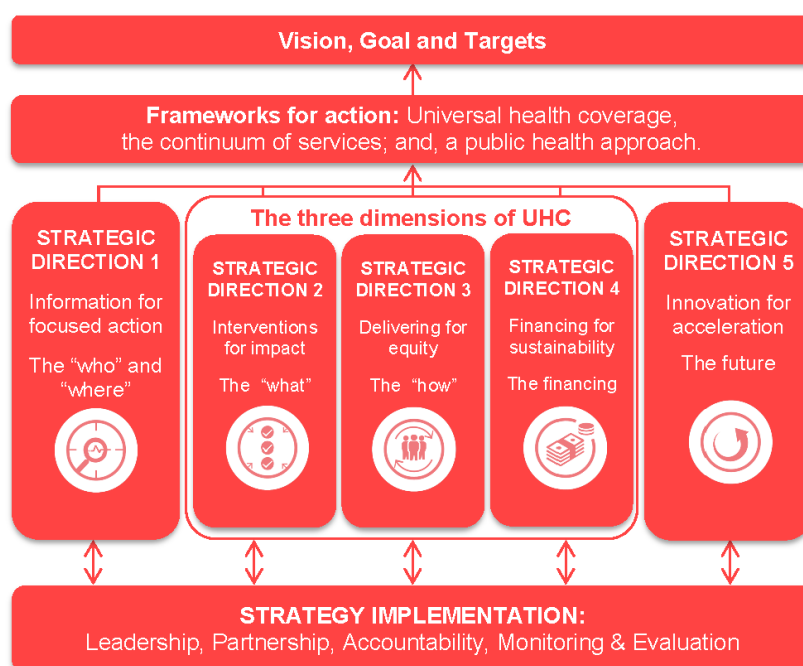
Strategic direction 2: Interventions for impact (covering the range of services needed).

Strategic direction 3: Delivering for equity (covering the populations in need of services).

Strategic direction 4: Financing for sustainability (covering the financial costs of services).

Strategic direction 5: Innovation for acceleration (looking towards the future).

Figure 7. The five strategic directions of the Global health sector strategy on viral hepatitis, 2016–2021



35. Each of the strategic directions addresses a specific set of questions:

Strategic direction 1 – What is the situation? – Focuses on the need to understand the viral hepatitis epidemic and response as a basis for advocacy, political commitment, national planning, resource mobilization and allocation, implementation, and programme improvement.

Strategic direction 2 – What services should be delivered? – Addresses the first dimension of universal health coverage by describing the essential package of high-impact interventions that need to be delivered along the continuum of hepatitis services to reach country and global targets, and which should be considered for inclusion in national health benefit packages.

Strategic direction 3 – How can these services be delivered? – Addresses the second dimension of universal health coverage by identifying the best methods and approaches for delivering the continuum of hepatitis services to different populations and in different locations, so as to achieve equity, maximize impact and ensure quality.

Strategic direction 4 – How can the costs of delivering the package of services be met? – Addresses the third dimension of universal health coverage by identifying sustainable and innovative models for financing of hepatitis responses and approaches for reducing costs so that people can access the necessary services without incurring financial hardship.

Strategic direction 5 – How can the trajectory of the response be changed? – Identifies where there are major gaps in knowledge and technologies, where innovation is required to shift the trajectory of the viral hepatitis response in order for those responses to be accelerated and in order for the 2020 and 2030 targets to be achieved.

4.1 STRATEGIC DIRECTION 1: Information for focused action

Know your hepatitis epidemic and response in order to implement tailored investments

36. Global leaders have recognized viral hepatitis as an international public health and development priority by explicitly including it under target 3.3 of the 2030 Agenda for Sustainable Development. However, such global recognition has not necessarily resulted in country action. Few countries have national hepatitis strategies, plans and budgets. A robust strategic information system that analyses and translates up to date data on viral hepatitis into usable information can leverage much-needed political commitment. Such a system is essential for generating the necessary data to create awareness and advocate for action and resources, to set national targets, to plan for a focused response, to implement programmes most efficiently in order to achieve greatest impact, and to monitor and improve quality and outcomes.

4.1.1 Understanding the epidemic and the response – data for decisions

37. With limited resources interventions, services and investments need to be strategically targeted to the local epidemic. Timely and reliable data, with an adequate level of “granularity”, are essential to identify “hotspots”, the main modes of transmission and risk factors, the specific populations that are vulnerable, at risk and affected, the health burden in terms of cirrhosis and hepatocellular carcinoma, and the coverage and quality of essential hepatitis services. Such data make it possible to proactively focus high-impact interventions more precisely and effectively, and to deploy or adapt services to reach greater numbers of people in need. Community and stakeholder involvement in collecting and analysing the data is important for improving the quality and relevance of the information. The

rigorous application of ethical standards in gathering and using data is important so as not to compromise the confidentiality and safety of individuals and communities. The hepatitis information system should be fully integrated into the broader national health information system to ensure standardized and coordinated reporting and to maximize efficiencies.

38. Monitoring and understanding the response to viral hepatitis is critical for informing more strategic investments in hepatitis services, and for maximizing their effectiveness, responsiveness and cost-effectiveness. The hepatitis service continuum provides a good framework for establishing a national hepatitis monitoring and evaluation system, with indicators measuring coverage and performance along each step of the “cascade”. Resources can then be directed to address any significant “leaks” in the cascade, to improve retention in care.

Priority actions for countries

- **Integrate viral hepatitis strategic information activities and indicators** within national health information systems and tools, including for outbreak surveillance, and monitoring and evaluation of the national hepatitis response.
- **Assess the national hepatitis burden**, including the numbers of persons with chronic hepatitis and hepatocellular carcinoma and cirrhosis attributable to hepatitis B virus and hepatitis C virus, assessing trends over time, using sub-national and disaggregated data.
- **Monitor access to, uptake and quality of vital hepatitis services**, disaggregated by different populations and geographic locations to guide service improvement.

Priority actions for WHO

- **Develop and update normative guidance and tools** on hepatitis surveillance, and monitoring and evaluation, including surveillance of acute disease and defining a standardized set of core indicators across the continuum of hepatitis services.
- **Support countries to strengthen their health information systems and to use strategic information tools** for setting targets, planning, implementing, and monitoring and evaluating their hepatitis responses.

4.1.2 Implement evidence-based national hepatitis plans

39. The national hepatitis response should be guided by a national plan with a well-defined governance and management structure that can ensure a coordinated and efficient response and clear accountability. Strategic planning processes should enable meaningful inputs from all key stakeholders on policy development, service planning and resource allocation.

40. Informed by current data, national plans and investment cases can be used to mobilize political commitment, define and budget for tailored packages of interventions and services, define responsibilities and allocate resources across the different levels of the health system, and identify potential and reliable sources of funding. Such hepatitis plans, efforts and other activities should be fully aligned and appropriately integrated with broader national health and development strategies and plans, with the goal of achieving universal health coverage. Regular reviews of the national hepatitis response are essential in order to ensure that the national plan is current and “fit for purpose”.

41. Concerted advocacy efforts, particularly by political and community leaders, and a sound communication strategy are required to increase public and political awareness of the public health

importance of viral hepatitis, to generate resources and to mobilize action. World Hepatitis Day provides an opportunity each year to raise public awareness, however, a broader and intensified communication strategy is required to generate the interest required to elevate and accelerate the hepatitis response to reach the global targets.

Priority actions for countries

- **Establish a national governance structure and coordination mechanism** to oversee the national hepatitis response, integrated within the national health programme.
- **Develop a national plan on viral hepatitis with a budget** based on the global health sector strategy on viral hepatitis and integrate it into the broader national health programme.
- **Set national targets and define indicators** based on global targets and indicators, to monitor and evaluate, and to report on the national hepatitis response.
- **Regularly review the national hepatitis response** and revise the national plan as necessary.
- **Raise national awareness on viral hepatitis**, by promoting the national plan, celebrating World Hepatitis Day (July 28), and engaging community and political leaders advocates and “champions”.

Priority actions for WHO

- **Develop and update guidance** and tools on national strategic planning, including guidance on setting national hepatitis targets, costing, programme implementation and review, and monitoring and evaluation.
- **Provide technical assistance to countries** to set ambitious but achievable national targets and develop national plans and activities with budgets.
- **Regularly report on the global viral hepatitis situation and response**, including progress towards the achievement of 2020 and 2030 targets at the global and regional levels.
- **Increase global awareness on viral hepatitis** through such activities as World Hepatitis Day and high-level meetings, such as the Global Hepatitis Summit.

4.2 STRATEGIC DIRECTION 2: Interventions for impact

People should receive the full range of hepatitis services they need

4.2.1 Defining an essential benefit package for viral hepatitis

42. Each country needs to define a set of essential viral hepatitis interventions, services, medicines and commodities relevant to the country context, to be included in the national health benefit package. The benefit package should be covered in whole, or in part, through public funding so as to minimize out-of-pocket payments, ensure access to services for all who need them, and cover the entire continuum of hepatitis services, including prevention, diagnosis, treatment and care. Selection of essential interventions and services should be through a transparent process, which would take account of the following criteria: effectiveness, cost, cost-effectiveness, acceptability, feasibility, relevance, demand and ethics. The selection process would benefit from broad stakeholder engagement, including service providers and affected communities, and should be informed by scientific evidence and good practice. The package should be regularly reviewed to ensure that the selected interventions

reflect changes in the country epidemic and context, advances in technologies and service delivery approaches, and evidence of impact or harm. Combinations of interventions should be specifically considered, recognizing that some interventions will only be effective, or achieve maximum impact, if they are delivered in combination with other interventions.

4.2.2 Essential interventions for viral hepatitis

43. The essential package of viral hepatitis interventions and services should include all **five core viral hepatitis interventions**: vaccination, particularly for hepatitis B virus, and where appropriate, hepatitis A virus; injection, blood and surgical safety and universal precautions; prevention of mother-to-child transmission of hepatitis B virus; harm reduction services for people who inject drugs; and treatment of chronic hepatitis B virus and hepatitis C virus infection. In addition, ensuring high levels of sanitation and access to safe food and water is essential for preventing and controlling epidemics of hepatitis A virus and hepatitis E virus. Interventions for prevention of sexual transmission of hepatitis B virus and hepatitis C virus are important for specific populations. Hepatitis prevention interventions also contribute to broader health outcomes, including the prevention of HIV, sexually transmitted and other blood-borne infections described below. The relative composition and balance of the interventions will vary by country, based on the country context and epidemic dynamics, including the prevalence of the various types of viral hepatitis. Particular focus should be given to interventions targeting viral hepatitis B and C infection, given their relative health burden, as compared with viral hepatitis A, D and E infection.

4.2.3 Preventing transmission

Using vaccines

44. Effective vaccines exist for preventing viral hepatitis A, B and E infections. Hepatitis B virus immunization is a critical intervention for the elimination of hepatitis B virus epidemics. Wider provision of the existing, safe and effective hepatitis B virus vaccine, including through universal childhood vaccination and by delivery of birth-dose, will drastically reduce new hepatitis B infections, reducing rates of chronic illness and death. The strategy calls for an increase in routine childhood hepatitis B virus vaccination coverage from 82% in 2015 to 90% by 2020, which will require strengthening of overall childhood immunization programmes along with specific efforts to target hepatitis B virus vaccination for those people at increased risk. Depending on the country context, hepatitis A virus vaccination may be included in routine childhood immunization programmes, and may also be considered an appropriate intervention in response to outbreaks in specific communities.

Priority actions for countries

- **Implement a comprehensive hepatitis B virus immunization programme**, based on WHO guidance: inclusion of hepatitis B virus vaccine in national childhood immunization schedules; strengthening hepatitis B virus birth-dose programmes; consideration of catch-up hepatitis B virus vaccination for children or adolescents with low coverage; and offering hepatitis B virus vaccination to people who are at increased risk of acquiring and transmitting the virus.
- **Consider the role of viral hepatitis A and E vaccination** in a comprehensive hepatitis prevention strategy and national immunization programme, based on the country context, following WHO guidance.

Priority actions for WHO

- **Promote enhanced access to all hepatitis vaccines**, including through international agencies that procure vaccines or advocate for vaccine access.
- **Develop and update guidance on the most effective use of all hepatitis vaccines** (viral hepatitis A, B and E), improving hepatitis B virus birth-dose coverage, and vaccination for specific populations at high risk.
- **Support the evaluation of new hepatitis vaccines and vaccination approaches**, in association with the Strategic Advisory Group of Experts (SAGE) on immunization, including evaluation of products that do not require a supply cold chain.

Improving blood safety

45. The risk of transmission of viral hepatitis B and C (as well as HIV and other blood-borne infections) through the transfusion of contaminated blood and blood products is extremely high, and, despite being preventable, still occurs because of the absence, or poor quality, of screening in blood transfusion services. Ensuring the availability of safe blood and blood products is a vital public health duty for every national government. Countries should work towards self-sufficiency in safe blood and blood products, aiming for 100% of donations from regular, voluntary, and non-remunerated blood donors.

Priority actions for countries

- **Establish and implement national policies and practices on blood safety** based on WHO guidance, which promotes the rational use of blood and blood products to prevent unnecessary blood transfusions and ensure reliable screening of blood for viral hepatitis B and C.
- **Implement quality control measures for laboratory testing of viral hepatitis B and C** to ensure a reliable supply of quality-assured screening assays.
- **Establish systems of surveillance, haemovigilance and monitoring** of the incidence and prevalence of viral hepatitis infections in blood donors and on post-transfusion hepatitis risk.

Priority actions for WHO

- **Provide updated guidance** to countries on the management of safe blood supplies and the strengthening of linkages between blood transfusion services and viral hepatitis services.
- **Support countries, with tools and technical assistance**, to establish systems of surveillance, haemovigilance and monitoring of supplies of blood and blood products.

Enhancing infection prevention and control in health care settings

46. Consistent implementation of infection control practices, including safe injection measures in health care and community settings, will reduce transmission of viral hepatitis and other infections to both users of health care services as well as health care workers. This hepatitis strategy sets a target for increasing the percentage of medical injections administered with safety-engineered injection devices from a baseline of 5% in 2015 to 50% in 2020 and 90% in 2030.

47. An estimated 15.7 billion injections are administered annually in low- and middle-income countries, with many injections being unsafe and/or unnecessary. Despite a major decline since 2000, about 5.5% of injections in 2010 were still being administered with reused injecting equipment. It is estimated that over 90% of injected medications used in primary care for therapeutic purposes can be administered orally. Reducing unnecessary injections remains a vital challenge, along with staff training in safe injections practices, and effective sharps and waste management. The WHO injection safety policy and global campaign, launched in 2015, aims to address this major public health risk.¹

Priority actions for countries

- **Strengthen and sustain routine infection prevention and control practices** in health care settings (public and private), including in laboratories.
- **Implement the WHO injection safety policy**, with the aim of reducing unnecessary injections and transitioning, where appropriate, to the exclusive use of safety-engineered injection devices.
- **Ensure access to appropriate injection equipment for people who inject drugs** that meet their needs, including low dead-space syringes.
- **Provide health workers with free immunization** against vaccine-preventable diseases, including, where appropriate, hepatitis B virus vaccine, and provide hepatitis B virus post-exposure prophylaxis as necessary.

Priority actions for WHO

- **Update normative guidance on:** standard precautions and effective disinfection and sterilization methods; safe injection practices and alternatives to injections; infection control inside and outside health care services; and for specific procedures, including endoscopy, tattooing and cosmetic procedures.
- Support countries to **fully implement WHO's injection safety policy** and global campaign, and other infection control measures, and monitor its implementation and impact.

Preventing mother-to-child transmission of viral hepatitis

48. Transmission of hepatitis B virus in highly endemic areas often occurs from infected mothers to their infants during the perinatal period. Elimination of mother-to-child transmission of hepatitis B virus will require a comprehensive approach that includes prevention of hepatitis B virus infection in young women, hepatitis B virus testing, care of pregnant women with chronic hepatitis B virus infection, delivery of hepatitis B virus vaccine to the infant within 24 hours of birth, safe delivery practices, strengthened maternal and child health services, and the development of new interventions to prevent transmission based on antiviral treatment.

49. Birth-dose vaccination is a key intervention for prevention of hepatitis B virus infection in infants. However, its delivery can be a challenge in communities where a large proportion of births occur outside of health facilities. As a result, global coverage is only around 38%. This strategy calls for the expansion of interventions to prevent mother-to-child transmission of hepatitis B virus to achieve a coverage of 50% by 2020 and 90% by 2030.

¹ For information on WHO's injection safety policy and global campaign, see http://www.who.int/injection_safety/global-campaign/en/ (accessed 3 April 2016).

Priority actions for countries

- **Provide timely administration of hepatitis B virus birth-dose vaccine** with special attention given to those births occurring outside of health care settings and in remote areas.
- **Update national policies and guidelines** on maternal and neonatal health, based on evolving WHO guidance on elimination of mother-to-child transmission of viral hepatitis.

Priority actions for WHO

- **Advocate for** enhanced access to and uptake of hepatitis B virus birth-dose vaccination, including through international advocacy, advising on procurement policies of international agencies and providing implementation guidance on delivering vaccines in different settings.
- **Develop and update global guidance on** a comprehensive package of interventions to eliminate mother-to-child transmission of hepatitis B virus, including the possible role of perinatal use of antiviral drugs and on viral hepatitis testing for pregnant women, mothers and infants.

Providing harm reduction services

50. A package of harm reduction services for people who inject drugs can be highly effective in preventing the transmission and acquisition of viral hepatitis A, B and C, as well as HIV and other blood-borne infections. Such a package should be integrated into a comprehensive set of services for the prevention and management of substance use disorders. WHO, UNODC and UNAIDS have defined a set of interventions and services that should be included in a comprehensive package for people who inject drugs.¹ Included in the package are five intervention areas that will have greatest impact on hepatitis epidemics: sterile needle and syringe programmes, opioid substitution therapy for opioid users, risk reduction communication, hepatitis B vaccination, and treatment of chronic hepatitis infection.

51. The hepatitis C virus is more easily transmissible than HIV, therefore harm reduction services should include provision of all injecting paraphernalia, including mixing containers and solutions. This hepatitis strategy calls for a major increase in provision of sterile needles and syringes to people who inject drugs, from an estimated baseline of 20 needles and syringes per person who injects drugs per year to 200 by 2020 and 300 by 2030. Current coverage of these interventions is too low to have a significant impact on hepatitis epidemics. Ensuring sufficient coverage of other harm reduction interventions depends on overcoming legal and societal barriers.

¹ For the WHO, UNODC, UNAIDS technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users – 2012 revision, see http://www.who.int/hiv/pub/idu/targets_universal_access/en/ (accessed 1 April 2016).

Priority actions for countries

- **Implement a comprehensive package of harm reduction services, where appropriate**, based on the WHO package of evidence-based harm reduction interventions for people who inject drugs, taking into account the domestic context, legislation and jurisdictional responsibilities.
- **Address legal and institutional barriers** to the provision of harm reduction services.
- **Link hepatitis and harm reduction services** to facilitate integrated prevention, treatment and care for people who use drugs.

Priority actions for WHO

- **Develop and update policies and guidance** on evidence-based prevention and management of viral hepatitis B and C infection for people who inject drugs and for non-injecting drug users, including people who use cocaine and amphetamine-type stimulants.
- **Provide advocacy and technical support to countries to mobilize commitment** and resources for recommended harm reduction interventions.

Promoting safer sex

52. Although sexual transmission of viral hepatitis B and C plays a minor role in most hepatitis epidemics, specific attention should be given to certain populations, particularly men who have sex with men and who have not been vaccinated against hepatitis B virus, and in heterosexual persons with multiple sexual partners. Safer sex practices, including minimizing the number of sexual partners and consistently and correctly using male and female condoms, offer powerful protection against viral hepatitis B and C and HIV infection, and a range of other sexually transmitted infections. In some populations, problem alcohol and other drug use can exacerbate certain vulnerabilities and sexual risk behaviours. Such factors should be considered when designing services.

Priority actions for countries

- **Intensify condom programming** to increase demand and supply of male and female condoms and water-soluble lubricants in both traditional and non-traditional outlets, especially for populations most at risk of viral hepatitis B and/or C infection.
- **Ensure that the national hepatitis B virus vaccination policy** includes persons at increased risk of acquiring hepatitis B virus infection through sexual contact.

Priority actions for WHO

- **Advocate for** increased investments in male and female condom programmes and their integration into hepatitis prevention services.
- **Provide guidance on standards for, and procurement and supply** of quality-assured male and female condoms and lubricants.

Ensuring access to safe food and water

53. An estimated 748 million people lack access to an improved source of drinking water, and 2500 million people, more than one third of the global population, live without basic sanitation facilities. In settings with very poor sanitary conditions and hygienic practices, most children acquire hepatitis A virus at an early age and achieve immunity. Outbreaks in such settings tend to be rare. However, where sanitary conditions are variable, children are often exposed to infection as they grow older, and large outbreaks may occur. Assuring access to safe food, drinking water and sanitation systems can dramatically reduce the transmission of viral hepatitis A and E. Specifically, actions should include a focus on hygiene as a priority in all settings through alignment with efforts to address Goal 6 of the 2030 Agenda for Sustainable Development, which includes the following 2030 targets:

- achieve universal and equitable access to safe and affordable drinking water for all;
- achieve access to adequate and equitable sanitation and hygiene for all and end open defecation, paying special attention to the needs of women and girls and those in vulnerable situations;
- support and strengthen the participation of local communities in improving water and sanitation management.

Priority actions for countries

- **Work with water and sanitation departments** to ensure access to safe drinking water and sanitation systems, particularly in high-risk settings such as under-serviced neighbourhoods, and camps for internally displaced persons or refugees.

Priority actions for WHO

- **Update guidance** on risk assessment and management of water supplies, sanitation, hygiene and food safety, and promote and support country implementation of the guidance.

4.2.4 Diagnosing hepatitis infection

54. Early diagnosis of hepatitis infection is critical for effective treatment and care. Yet globally, less than 5% of persons with chronic viral hepatitis are aware of their status. Awareness is lacking, reliable diagnostics that are appropriate for the setting of intended use and testing services are not sufficiently available, and laboratory capacity is weak. Increasing early diagnosis requires overcoming those shortcomings, using effective testing approaches, quality-assured diagnostics, and linking the results of testing to treatment and care services. The strategy calls for a major increase in diagnosis of chronic viral B and C infection, with 30% of people infected knowing their status by 2020 and 90% by 2030.

Priority actions for countries

- **Integrate viral hepatitis testing** into national hepatitis policies and guidelines that defines, among other things, priority populations and locations for testing, testing approaches and strategies.
- **Strengthen the national laboratory system** to provide quality diagnosis of acute and chronic hepatitis with timely reporting of results and ensure the reliable supply of quality-assured (WHO prequalified) diagnostics.
- **Establish key linkages between testing and other services** to improve referral and access to quality-assured treatment and other support services.

Priority actions for WHO

- **Regularly update guidance** on hepatitis testing approaches, strategies and diagnostics, incorporating the latest innovations.
- **Support country adaptation and implementation** of WHO policies and guidelines on viral hepatitis diagnostics, testing approaches and strategies.

4.2.5 Enhancing hepatitis treatment and chronic care

Expanding treatment

55. Effective antiviral agents against viral hepatitis B and C have the potential to dramatically reduce morbidity and mortality, including among people co-infected with HIV. Not all people with chronic hepatitis infection require, or are eligible for, treatment. Individuals need to be assessed for liver disease to determine whether treatment is indicated, and if not eligible for treatment, regularly monitored to determine when treatment should be initiated. Direct-acting antivirals for the treatment of chronic hepatitis C virus have cure rates exceeding 95%, with pan-genotypic regimens becoming available. Effective treatment is available for chronic hepatitis B virus infection, although lifelong treatment is usually required. WHO guidelines for treatment of chronic viral hepatitis B and C infection promote a public health approach with a move towards simpler and safer oral treatment regimens.

56. According to 2014 WHO guidelines, of the 130–150 million people living with chronic hepatitis C virus infection, only 26–30 million are eligible for treatment. Nevertheless, less than 1% of people with chronic hepatitis infection are receiving treatment. The strategy calls for 5 million people with chronic hepatitis B virus infection to be on treatment by 2020, and for 3 million people with chronic hepatitis C virus to have been treated by 2020. By 2030, treatment coverage for both chronic viral hepatitis B and C infection should reach 80% of eligible persons.

Providing chronic care

57. People with chronic hepatitis infection may require care for a range of health and psychosocial problems. In addition to liver cirrhosis and hepatocellular carcinoma, people with chronic hepatitis infection may experience extrahepatic manifestations of their infection, including insulin resistance and diabetes. Alcohol use, smoking and obesity may complicate chronic infection. An assessment of alcohol intake is recommended for all people with chronic viral hepatitis infection followed by the offer of a behavioural alcohol reduction intervention for those people with moderate-to-high alcohol intake.

58. Persons living with viral hepatitis B or hepatitis C may also have coinfections, including HIV, tuberculosis or other hepatitis viruses (hepatitis B, C and D). About 3 million people living with HIV are co-infected with hepatitis C and 2.6 million with hepatitis B. Treatment regimens that do not cover coinfection expose those patients to a progression of their chronic liver disease. The effective management of HIV-hepatitis B and HIV-hepatitis C coinfection is important to secure the health gains acquired through HIV treatment. This requires testing services that can ensure a linkage with adapted care.

59. Persons at increased risk of hepatitis C infection are often also at higher risk of tuberculosis, particularly people who inject drugs. Two out of three people who inject drugs and who develop tuberculosis will also be infected with hepatitis C. Dual infection with hepatitis B and hepatitis D can lead to severe chronic hepatitis. In countries where the prevalence of hepatitis D coinfection makes it a public health problem, specific approaches are needed. For all types of coinfections, co-management needs to take into consideration the side-effects and interactions of the drugs used to treat HIV, tuberculosis and viral hepatitis.

60. In addition to antiviral treatment, chronic care is required for many, including the management of decompensated liver disease and hepatocellular carcinoma. Treatment of advanced liver cirrhosis and hepatocellular carcinoma, including liver transplantation and chemotherapy, is very limited in most low- and middle-income settings, highlighting the need to provide access to good quality palliative and end-of-life care.

Priority actions for countries

- **Prioritize hepatitis treatment** by including access to antiviral treatment for people with chronic viral hepatitis B and C infection as a central component of the national hepatitis strategy and plan.
- **Establish national hepatitis treatment and care guidelines, plans and protocols** based on WHO hepatitis treatment and care guidelines.
- **Provide quality treatment that** ensures standardized care of people with chronic hepatitis infection, including appropriate disease staging, timely treatment initiation, patient and drug toxicity monitoring, management of liver cirrhosis, hepatocellular carcinoma and liver failure.
- **Address common comorbidities**, including HIV infection and risk factors that may accelerate progression of liver disease, including alcohol use and provide palliative and end-of-life care, including access to adequate analgesia.

Priority actions for WHO

- **Advocate** for adequate investments to scale up viral hepatitis B and C treatment to reach global targets.
- **Develop and regularly update consolidated guidelines** for the prevention, diagnosis, treatment and care of chronic hepatitis infection, including advanced liver disease and major comorbidities, and provide support to countries for their adaptation and implementation.
- **Provide technical support to countries** to develop costed national hepatitis treatment plans and guidelines.

4.3 STRATEGIC DIRECTION 3: Delivering for equity

All people should receive the hepatitis services they need, and such services should be of adequate quality

61. Large proportions of people at high risk of, or living with, chronic hepatitis infection do not have access to prevention services, remain undiagnosed, do not use or adhere to treatment, and cannot access chronic care services. Furthermore, existing hepatitis services seldom address critical underlying factors that can generate health inequities, such as poverty, discrimination and criminalization, drug dependence and poor mental health. Interventions and services, where they exist, are often poorly targeted and fail to reach those who are at greatest risk or who are most affected. Such factors lessen the overall impact of interventions and services. The impact of hepatitis responses is also dependent on the quality of hepatitis medicines and diagnostics, interventions and services. When hepatitis services are available, issues of affordability, accessibility and acceptability can prevent their optimal utilization.

62. An effective hepatitis response requires robust and flexible health systems that can sustainably deliver people-centred care across the full continuum of services to those populations, locations and settings in greatest need. The hallmarks of such health systems are: a strong health information system; efficient service delivery models; appropriately trained and distributed workforce in adequate numbers and with an appropriate skills mix; reliable access to essential medical products and technologies; adequate health financing; and strong leadership and governance. Hepatitis interventions are most effective when they occur in appropriate social, legal, policy and institutional environments, which encourage and enable people to access and use services. Those interventions need to be grounded in an enabling environment that promotes health equity and human rights, that features well-supported health and community systems, and that makes it possible to harness the strengths and contributions of partners, especially those in civil society.

4.3.1 Adapting viral hepatitis services

63. An efficient health system should be able to deliver essential hepatitis services to different populations and settings, reinforce strategic linkages between different health services, ensure quality of the services and actively engage communities. The roles and responsibilities of different levels of the health system in delivering hepatitis services need to be defined, from community-based and primary health services through to tertiary referral centres.

Tailoring services for different populations and locations

64. Not all hepatitis interventions and services will be required by all populations and in all locations and settings. Strategic information gathered on affected populations, risk factors and locations should help guide the adaptation and implementation of the essential hepatitis package to specific populations, country settings and contexts. Depending on the country context and epidemiology, priority might be given to certain age groups (such as those born between certain dates), certain high prevalence groups (such as incarcerated persons, people who inject drugs, migrants, haemodialysis patients, people who undergo skin-piercing procedures including tattooing, some indigenous communities, sex workers and men who have sex with men), people at a certain stage of hepatitis disease (such as advanced liver fibrosis), or others. It is important to have strategic information systems sensitive enough to identify these groups in order to deliver services for the highest impact.

Linking and integrating hepatitis services with other health services

65. Greater integration and linking of viral hepatitis services with other relevant health services (including for sexually transmitted infections, HIV, broader sexual and reproductive health, harm reduction and drug use disorders, alcohol use disorders, blood safety, cancer prevention and management, and noncommunicable diseases) can speed up progress towards key milestones and targets, and increase efficiency, reach, acceptability and savings. Investments in hepatitis programmes may also facilitate the prevention and management of other major health conditions. Linkages at different levels of the health system are required, with the relative contributions and roles of primary health care, referral care and hospital care being defined. Appropriate models of integration and linkage will depend on the country context and health system, and should be informed by operational research. Linkages are also required with programmes in other sectors, such as correctional services, police and justice, social welfare, water and sanitation, and housing.

Strengthening community-based services

66. Community-based services provide opportunities to reach marginalized groups, improve acceptability and utilization of services, facilitate decentralization of services to provide more equitable access, enhance the quality and impact of services, improve efficiencies and reduce costs. There are considerable opportunities to support communities to expand their capacity and provide services across hepatitis prevention and care continuum. Lessons can be learnt from community-based services addressing other health issues, such as HIV and palliative care.

Involving people living with viral hepatitis

67. Actively engaging affected populations in developing strategies and programmes should result in better targeted and acceptable services. Affected populations can also act as a powerful force in addressing discrimination, criminalization and harmful socioeconomic and cultural norms that help generate health inequities.

Ensuring the quality of interventions and services

68. Rapid expansion of programmes to improve coverage should not compromise the quality of services, nor contribute to inequities in access to services and health outcomes. Quality can be optimized by ensuring that interventions and services conform to national and international norms and

standards, are continuously monitored and improved, and are made more acceptable and accessible to patients' needs and preferences.

Priority actions for countries

- **Define populations and locations** that are most affected and require intensified support, and prioritize them in the national hepatitis response while minimizing the risk of stigmatization.
- **Build community capacity** to deliver quality community-based hepatitis services, supported by legal and regulatory frameworks and appropriate financial incentives.
- **Decentralize and expand hepatitis services** to include, where appropriate, services in custodial settings, refugee camps and places of humanitarian concern.
- **Identify good models of integrated and linked service delivery** through operational research, including linkages with other key health areas.
- **Improve the quality of services** by setting national norms and standards for services, integrating quality indicators into strategic information systems and promoting the adoption and implementation of WHO guidelines.
- **Regularly undertake hepatitis “cascade analyses” for different populations and settings** to determine the quality of services, assess service utilization and acceptability, identify major weaknesses and propose possible remedial actions.

Priority actions for WHO

- **Provide guidance on implementation of models of integrated and linked service delivery**, and community-based services for the prevention and management of viral hepatitis.
- **Promote the WHO cascade monitoring and evaluation framework** as a key component of national hepatitis monitoring and evaluation systems, and provide technical assistance to countries in analysing their hepatitis prevention, treatment and care cascades.
- **Provide guidance on quality assurance and quality improvement systems**, including for hepatitis services and for hepatitis commodities.

4.3.2 Strengthening human resources for hepatitis

69. Many essential viral hepatitis interventions are integrated within broader health services and programmes, such as programmes for child vaccination, blood and injection safety, food safety, water and sanitation, harm reduction for drug users, clinical management of infectious diseases and chronic care for noncommunicable diseases. In all such settings, including primary health care, health workers should be knowledgeable about viral hepatitis risk and infection, and the package of essential hepatitis interventions. They should be competent to work with people living with chronic hepatitis infection and those most affected and at risk. Defining the core hepatitis competencies of different cadres of health workers at different levels of the health system will help define those tasks which can be shifted and to what level, along with defining training, accreditation and supervisory needs. Issues related to viral hepatitis should be included in pre-service and in-service training for health workers. Community-based and peer-support workers play an important role in reaching marginalized groups, linking people with chronic hepatitis to care, supporting treatment adherence and providing chronic care. Those workers should receive regular training, mentoring and supervision and appropriate

compensation for their work. Given the risk of viral hepatitis transmission in health care settings, health workers should be protected by comprehensive occupational health and safety programmes.

Priority actions for countries

- **Ensure that the national health workforce strategy and plan** addresses the needs of hepatitis services, including integrating hepatitis content into the training of health workers and defining core competencies relevant to delivering hepatitis services at different levels of the health system.
- **Identify opportunities for task-shifting and task-sharing** to extend the capacity of the health workforce and provide community health workers with sufficient support.
- **Implement occupational health measures** that address the risk of viral hepatitis transmission within health care settings and address the needs of health workers living with viral hepatitis.

Priority actions for WHO

- **Provide policy and technical guidance** aimed at building a competent workforce that can effectively deliver a public programme for addressing viral hepatitis.
- **Provide guidance on occupational health** and safety policies relating to viral hepatitis.

4.3.3 Ensuring access to good quality and affordable hepatitis vaccines, medicines, diagnostics and other commodities

70. Effective hepatitis programmes are dependent on the uninterrupted supply of quality-assured vaccines, medicines, diagnostics and other commodities. Robust procurement and supply management systems are required to ensure that the right products are selected, purchased at a reasonable price and efficiently delivered to the point of care. Disruptions in supply, including stockouts, of hepatitis medicines contribute significantly to the risk of treatment failure.

71. Accurate forecasting of country and global needs of all hepatitis commodities is required to inform the readiness and capacity of manufacturers to meet expected needs. Local manufacturing capacity should be considered, where economic analysis shows there is potential to reduce prices and guarantee supply. National hepatitis and broader health plans and budgets should address procurement and supply chain management needs. Medicines, vaccines, diagnostics and other commodities will constitute an increasingly important component of national hepatitis budgets, particularly as treatment is expanded. WHO hepatitis guidelines, the WHO list of essential medicines, WHO hepatitis testing strategies and the WHO list of prequalified products can guide countries in the selection of the right products which are of sufficient quality. The procurement and supply management of hepatitis commodities should be integrated into the broader national procurement and supply management system.

72. The demand for affordable treatment for viral hepatitis B and C infection requires comprehensive price reduction strategies for medicines, diagnostics and health commodities, including for those medicines and diagnostics in the development pipeline. Strategies include fostering generic competition, including through voluntary licences, and using the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health. That would include compulsory licences and filing patent oppositions, differential pricing and direct price negotiations with manufacturers, as well as local manufacturing in accordance with the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, which also notes that intellectual

property rights are an important incentive for the development of new health care products. Different measures may have to be taken for different medicines and different countries, noting the differences in access barriers in low-income and lower middle-income countries as compared with upper middle-income countries.

73. There are also many opportunities to save on procurement of hepatitis commodities and improve efficiencies in supply management, such as bulk procurement with staggered deliveries for short shelf-life commodities, advanced purchasing and improved forecasting to avoid wastage through expired products.

Priority actions for countries

- **Strengthen the national hepatitis procurement and supply management structures and processes** by ensuring that they are integrated into the broader national procurement and supply management system while promoting incentives for continued innovation.
- **Ensure the procurement of quality-assured hepatitis vaccines, medicines, diagnostics, condoms, and other hepatitis-related commodities**, including through the use of WHO prequalification.
- **Plan and implement a hepatitis medicines and commodities access strategy** to reduce prices of hepatitis-related commodities, including, where appropriate, through implementation of flexibilities of the TRIPS Agreement, in accordance with the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.
- **Safeguard and expand availability of WHO-prequalified generic products** through the expansion of licence agreements and timely registration at national level.

Priority actions for WHO

- **Advocate for comprehensive strategies to reduce prices** of viral hepatitis vaccines, medicines, diagnostics and other commodities.
- **Forecast demand** for, access to and uptake of commodities for hepatitis and major comorbidities and use this information to advocate for adequate manufacturing capacity of producers.
- **Promote the WHO prequalification programme** to allow fast-track registration of priority medicines and commodities, and to safeguard and expand availability of quality-assured medicines and diagnostic products.
- **Provide guidance on hepatitis product selection** by national programmes, donors and implementing agencies through the generation and dissemination of strategic information on prices, manufacturers, regulations and patent landscapes of hepatitis commodities.
- **Provide technical support to countries** to forecast the need for essential hepatitis commodities, include them in their national procurement and supply management plans and develop a strategy for negotiating price reductions with manufacturers.
- **Support regulatory authorities** in pre-market assessment and registration of new hepatitis medicines and diagnostics, with post-market surveillance.
- **Assess the quality and performance** of commercially available hepatitis diagnostics and issue appropriate recommendations.

4.3.4 Promoting an enabling environment

74. As with other public health programmes, the hepatitis response requires an enabling environment of policies, laws and regulations that support the implementation of evidence-based policies and programmes, and promote and protect human and health rights, reduce stigma and ensure health equity. The health sector has a compelling obligation to ensure that such an environment exists. When properly enforced, laws and policies can reduce people's vulnerability and risk for hepatitis infection, expand access to health services and enhance their reach, quality and effectiveness – especially for most-affected populations. However, legal, institutional and other barriers may prevent certain groups of people from accessing effective interventions and using health services such as adolescents, prisoners, people who use drugs, men who have sex with men, sex workers and transgender people.

75. People with viral hepatitis and those at risk may be exposed to stigmatization, discrimination and social marginalization, further impeding their access to hepatitis services. Many of these barriers can be overcome if existing models of service delivery are reviewed and adapted to meet the needs of affected populations. Others may require the reform or removal of certain laws, regulations and policies.

Priority actions for countries

- **Use public health evidence to shape pro-health laws** and actions in all relevant sectors that will enable an effective hepatitis response.
- **Remove legal, regulatory and policy barriers** that hinder equitable access to hepatitis services, especially for most-affected populations and other groups at risk.
- **End policies and practices that condone or encourage stigma and discrimination against people at risk for hepatitis or living with hepatitis**, especially in health care settings and places of employment.
- **Create institutional and community environments** that make it safe for people to access hepatitis services, involving communities in the planning and delivery of services to improve their reach, quality and effectiveness.
- **Address gender inequality** by integrating evidence-based interventions into national hepatitis plans and strategies.

Priority actions for WHO

- **Advocate for the use of public health evidence** to shape pro-health laws and actions based on medical ethics, human rights and public health principles.
- **Develop and promote WHO policies and guidelines** that explicitly address gender inequality, gender-based violence, stigma and discrimination, human rights, the health of marginalized populations, and public health alternatives to criminalization.
- **Provide technical assistance to countries** to review policies and laws and develop programmes that advance gender equality, empower women and girls, and promote human rights and health equity, particularly for young people and most affected populations.

4.4 STRATEGIC DIRECTION 4: Financing for sustainability

People should receive the hepatitis services they need without experiencing financial hardship

76. Adequate investment in the full continuum of hepatitis services is necessary to achieve the targets for 2020 and 2030, and to promote universal health coverage. A sustainable response will require funding the essential hepatitis package through the national health financing system, mobilizing new and predictable funding, minimizing the financial burden for individuals and households through prepayment and pooling, achieving savings and avoiding wastage, and using available funds efficiently and equitably. Increasing access to high quality and affordable medicines and diagnostics for viral hepatitis B and C infection, coupled with standardized and simple treatment protocols, is critical.

77. Financing for a sustainable hepatitis (and broader health) response requires action in three areas:

Revenue raising to pay for viral hepatitis interventions and services, with an emphasis on improving domestic tax collection (including both general revenues and compulsory health insurance contributions) supplemented by external sources, such as donor grants, and private revenues as relevant;

Financial risk protection and pooling, including establishing equitable mechanisms to pool funds across the health system to ensure adequate coverage along the hepatitis services continuum, reducing financial barriers to services while providing financial risk protection;

Improving efficiency in the use of health system resources to enable greater effective coverage of hepatitis services, by reducing the costs of medicines, diagnostics and other commodities and by reducing duplication of underlying subsystems with other programmes and the wider health system, such as strategic information, human resources and procurement and supply management.

78. The national health financing systems should address viral hepatitis along with all other priority national health issues, avoiding fragmented funding channels while aiming to achieve health equity.

4.4.1 Increasing investments through innovative financing and new funding approaches

79. Unlike the other major communicable diseases, such as HIV, tuberculosis and malaria, there has been very little external development assistance funding for comprehensive viral hepatitis responses. Similarly, most countries do not have dedicated hepatitis budgets or programmes. Therefore, new sources of funding will be required for countries to launch, accelerate and sustain public health responses to viral hepatitis, and these resources will need to be substantial if the ambitious global targets are to be realized.

80. Strategies to increase investment in hepatitis need to be part of broader efforts to increase overall investments in health, so that all priority health services can be scaled up towards universal health coverage. Public, domestic funding will be central to funding essential viral hepatitis services in all countries and to ensure the long-term sustainability of such services. Public spending on health can be increased either by raising more tax revenues (increasing a government's fiscal capacity) or by allocating a greater share of overall government funds to health (giving health a greater priority in the public budget). Health ministries need to actively engage with ministries of finance on issues related to

budgets, public financial management systems, and fiscal space concerns, with the aim of having a minimum 5% of the gross domestic product allocated for public spending on health. Hepatitis investment cases should be developed and used to advocate for and negotiate a fair allocation of public resources for viral hepatitis.

81. Many low- and lower middle-income countries will rely on external funding to expand their hepatitis responses over the period of the strategy. Revenue flows from such sources need to be fully aligned with national hepatitis and broader health sector priorities, programmes and plans. Stability and predictability of these revenue flows are essential to minimize the risk of service interruption. The coordination of hepatitis interventions and services with other health programmes and the overall health system will reduce inefficiencies and, as a result, maximize intended results.

4.4.2 Addressing financial and other barriers to access and provide financial risk protection

82. Health financing systems that minimize out-of-pocket payments for all essential health services increase access to these services and prevent impoverishment. To minimize catastrophic health payments, out-of-pocket spending should be limited to less than 15–20% of the total health spending.

83. Treating chronic hepatitis infections, especially new treatments for hepatitis C, and care for cirrhosis and cancer is currently unaffordable for many people. Essential viral hepatitis interventions, across the continuum of hepatitis services, should be included in the national health benefit package and be provided free of charge. In addition, the provision of supportive arrangements (such as decentralizing services or offering transport vouchers) to minimize the indirect costs for people using services can improve service uptake and impact. User fees result in inequities in access to hepatitis treatment, undermine service use, contribute to poor treatment adherence, increase risks of treatment failure, and constitute unnecessary financial burdens on households.

84. Financial risk protection and access to needed services for people at risk and living with hepatitis will depend on a broader, robust and fair national health financing system. Public financing systems for health, involving predominant reliance on revenues raised from general taxation and/or payroll taxes for compulsory health insurance, are the most equitable and efficient systems. Such prepayment mechanisms should be based on an ability to pay, with broad pooling of the revenues to enable benefits to be provided to those in need, including those who cannot afford to contribute to the system.

4.4.3 Reducing prices and costs, and removing inefficiencies

85. Fiscal constraints require that countries select the most effective interventions and approaches, target those activities to the populations and settings where they will have greatest impact, reduce the prices of medicines and other health commodities, and increase the efficiency of services. Programmes that can demonstrate “value for money” and efficiency gains are better positioned to argue for fair allocation of resources and external financial support. The potential for efficiency gains across programmes needs to be explored.

86. Good programme management can improve the efficient flow, allocation and utilization of resources from national budgets or external sources to service delivery. This includes better coordination of donor funding and alignment with national plans and the broader health system, pooling of resources, performance-based funding and increased accountability at all levels and across all stakeholders, including implementers and funders.

87. Opportunities to reduce cost through improving the efficiency of services and improving the selection, procurement and supply of affordable vaccines, medicines, diagnostics and other health commodities are described under strategic direction 3.

Priority actions for countries

- **Develop a robust viral hepatitis investment case** to advocate for adequate allocation of domestic resources and to mobilize external funding support.
- **Estimate national hepatitis resource needs** and develop a plan for filling any resource gap through raising new funds and allocating adequate health resources to hepatitis.
- **Reduce financial barriers**, including phasing out direct, out-of-pocket payments for accessing hepatitis and other health services.
- **Provide universal protection against health-related financial risk**, covering all populations, and identify the most appropriate way for achieving such protection, including public compulsory health financing systems.
- **Monitor health expenditures and costs and cost-effectiveness of hepatitis services** through the national monitoring and evaluation system to identify opportunities for cost reduction and saving.
- **Strengthen coordination with other health programmes:** Identify opportunities for improving system-wide efficiencies by consolidating underlying health systems, such as those for strategic information, human resources and procurement and supply management.

Priority actions for WHO

- **Estimate and regularly review resource needs** for a comprehensive viral hepatitis response at the global level to achieve the 2020 and 2030 targets.
- **Advocate for full funding of the viral hepatitis response** by building political commitment for sustained financing and national ownership, fair allocation of government resources to hepatitis and inclusion of essential hepatitis services into national health benefit packages.
- **Support countries to develop investment cases** and funding proposals to mobilize external funding for viral hepatitis responses.
- **Provide guidance and tools for assessing and monitoring health service costs** and cost-effectiveness, and support countries to adopt the WHO Health Accounts Country Platform.¹

4.5 STRATEGIC DIRECTION 5: Innovation for acceleration

Elimination of viral hepatitis epidemics will require new technologies and approaches

88. Research and innovation provide opportunities to change the trajectory of the global hepatitis response, improve efficiency and quality of services and maximize impact. It is unlikely that the ambitious targets set for 2020 and 2030 can be achieved if we are limited to existing medicines, technologies and service delivery approaches. Innovations are required along the entire continuum of

¹ The WHO Health Accounts Country Platform is available at: http://www.who.int/health-accounts/platform_approach/en/ (1 April 2016).

prevention, diagnosis, treatment and care services. They need to be backed with operational research and collaboration between researchers and policy-makers to ensure that research findings are translated into practice rapidly and on a scale sufficient to have the desired impact.

89. This strategic direction outlines areas where research and innovation will play a key role in accelerating the hepatitis response. Whereas WHO has an important role in convening partners and promoting and shaping a global research agenda, much leadership will rest with others, including research institutions and private industry. WHO also has a responsibility to monitor the development of new vaccines, medicines, diagnostics, other commodities and service delivery approaches, and, where appropriate, to rapidly integrate them into WHO guidelines. Countries have a critical role in defining priorities for innovation, facilitating research, documenting early implementation experiences and leading on operational research. Given the 15-year time horizon for achieving the 2030 targets, short-, medium- and long-term research priorities should be considered. This strategy focuses on the short- and medium-term priorities.

4.5.1 Optimizing prevention

90. In addition to the existing technologies for preventing viral hepatitis infections, there are major opportunities for improving and expanding the package of prevention interventions for viral hepatitis.

91. **Injection equipment:** Effective implementation of the WHO injection safety policy and global campaign will require innovations in safety-engineered injection equipment, that is affordable, to prevent re-use. Harm reduction programmes would benefit from new designs of needles and syringes that minimize the “dead space” where blood may remain after use.

92. **Hepatitis vaccines:** Hepatitis B virus vaccination programmes would be greatly enhanced by the development of a more heat-stable and freeze-stable vaccine and simplified delivery systems for hepatitis B virus birth-dose. The development of effective therapies for hepatitis C has paradoxically led to a reduction in efforts to find an HCV vaccine and that this trend needs to be reversed. The development of an effective hepatitis C vaccine would be a powerful addition to the hepatitis prevention intervention portfolio and would complement new advances in hepatitis C virus treatment.

93. **Using antiviral medicines for prevention:** The potential role of pre-exposure and post-exposure-prophylaxis for preventing viral hepatitis B and C acquisition should be considered, noting the experience from the HIV response. Similarly, more research is required on the use of antiviral drugs for preventing mother-to-child transmission of hepatitis B virus, which would be an important complement to hepatitis B virus birth-dose vaccination. The impact of expanded coverage of viral hepatitis B and C treatment on viral hepatitis B and C prevention should be assessed.

94. **Prevention benefits of treatment:** Assess the potential prevention benefits of expanded coverage of viral hepatitis B and C treatment on viral hepatitis B and C transmission.

4.5.2 Optimizing testing and diagnostics

95. There are huge opportunities to improve viral hepatitis diagnostics technologies, strategies and approaches, essential for rapidly expanding viral hepatitis testing services and ensuring accurate and reliable diagnosis, clinical assessment and patient monitoring. Simple technologies are required to ensure that testing services can reach remote areas and hard-to-reach populations. Priority should be given to the development of rapid diagnostic tests for diagnosing viral hepatitis B and C infection,

point-of-care tests for monitoring hepatitis B and hepatitis C viral load (and hepatitis C virus antigen) to guide treatment decisions, and simplified methods for reliably assessing liver fibrosis and cirrhosis.

4.5.3 *Optimizing medicines and treatment regimens*

96. The development of highly effective medicines to treat chronic hepatitis C infection has been a “game-changer” in tackling hepatitis C epidemics. There is also an impressive pipeline of new medicines, combinations and candidate molecules under development that promise to offer more effective, potent, tolerable and safer oral drugs and treatment regimens. Priority should be given to the development of affordable, simple pangenotypic regimens for hepatitis C virus. Progress in the development of medicines to treat chronic hepatitis B infection has been less rewarding, with a “cure” yet to be found. Elimination of viral hepatitis B and C epidemics will require safe and effective curative treatments. The development of long-acting treatment formulations should improve treatment adherence. In addition, new medicines and other treatments are required to improve the management of complications of chronic viral hepatitis infection, including treatments for chronic liver disease, liver failure and hepatocellular carcinoma.

4.5.4 *Optimizing service delivery*

97. Few countries have public health programmes that deliver comprehensive hepatitis services, apart from childhood hepatitis B virus vaccination programmes. Various obstacles exist in the efficient delivery of hepatitis B virus vaccine at birth, a key intervention for preventing mother-to-child transmission of hepatitis B virus. Harm reduction services that have been effective in preventing HIV epidemics among people who inject drugs have been less successful in preventing hepatitis C virus epidemics, even though the key interventions are the same. Early diagnosis and staging of chronic hepatitis disease is compromised by both the lack of simple and reliable diagnostics and effective testing services that can reach those populations and locations most affected. In 2015, less than 1% of people with chronic hepatitis infection were receiving treatment, mostly through individual clinical care.

98. Gaps in the response, such as those outlined above, highlight challenges in service delivery that require careful analysis and new service delivery approaches. Large-scale treatment and care of people with chronic hepatitis will require a new public health approach to service delivery, including simplified and standardized treatment regimens and protocols, and decentralized care, including at the primary health care level and in the community. Investment in operational research is required to assess different service delivery models and opportunities for improving service delivery quality. Expanded treatment, particularly for lifelong hepatitis B virus treatment, will require strategies and approaches to maximize treatment adherence and retention in care, monitor patients for treatment outcomes and failure, and monitor for drug toxicity and the emergence of drug resistance.

5. STRATEGY IMPLEMENTATION: PARTNERSHIPS, ACCOUNTABILITY, MONITORING AND EVALUATION AND COSTING

99. Effective implementation of the strategy depends on concerted action from all stakeholders in the health sector response to viral hepatitis. Success requires strong leadership and partnerships to ensure policy and programme coherence. Within the health sector, linkages across different disease-specific and cross-cutting programmes need to be established and strengthened.

5.1 Collaboration with partners

100. WHO has an important convening role: it brings together different constituencies, sectors and organizations in support of a coordinated and coherent health sector response to viral hepatitis. In addition to its Member States, the Secretariat works closely with other key partners, including:

Multilateral and bilateral donor and development agencies, funds and foundations: Unlike other major communicable diseases, such as HIV, tuberculosis and malaria, there are very few major donor agencies supporting viral hepatitis. The GAVI Alliance plays a critical role in supporting routine childhood immunization programmes, with hepatitis B virus vaccine included in the pentavalent vaccine. A key challenge over the coming years will be to mobilize the involvement of other major donor and development agencies in the hepatitis response.

Civil society: Civil society has played a lead role in getting viral hepatitis on the global health and development agendas, with strong leadership from hepatitis patient groups, treatment advocates and public health activists. WHO has established a Civil Society Reference Group on Viral Hepatitis, which brings together representatives from a broad range of hepatitis-related civil society constituencies and networks. The Reference Group advises WHO on its hepatitis policies and programme of work, and facilitates dissemination and implementation of WHO policies and guidance. Civil society is represented in all WHO technical working groups, including those for the development of WHO policies, guidelines and tools. A range of civil society organizations have official relations with WHO, enabling them to attend as observers various WHO governing body meetings.

Technical partners: WHO has established a Strategic and Technical Advisory Committee on Viral Hepatitis, which comprises a range of technical experts from national hepatitis programmes, implementing organizations, research institutes and civil society to advise the Director-General on the Organization's hepatitis policies and programme of work. Technical partners play a critical role in WHO working groups that are responsible for developing WHO policies and guidelines.

5.2 Monitoring, evaluating and reporting

101. Implementation of the strategy will be monitored at three levels, using existing mechanisms:

- Monitoring and evaluating of progress towards global goals and targets;
- Monitoring and evaluating the response at country level;
- WHO's framework for results-based management.

102. A number of targets will be monitored through the use of the existing Global AIDS Response Progress Reporting system and the Monitoring and Evaluation Accountability Framework that supports the implementation of the Global Vaccine Action Plan 2011–2020.

5.2.1 Monitoring and reporting progress towards global goals and targets

103. At the global level, regular reviews are planned to assess progress on the various commitments and targets. These reviews will build on the data received from countries through various existing monitoring and evaluation mechanisms.

104. Progress at global and regional levels in moving towards the targets set out in this strategy will be regularly assessed. Comparisons between and within countries – “benchmarking” – will also be used to assess performance in reaching targets. The strategy is designed to be sufficiently flexible to incorporate additional priorities or fill gaps in the health sector response to hepatitis that may be identified. WHO will continue to work with its partners to provide support to countries for the harmonized and standardized collection of data on core indicators, and in the preparation of global and regional reports.

105. WHO will develop a monitoring and accountability framework for the strategy in consultation with key stakeholders, building on existing strategic information and reporting systems. It will also monitor and share data on the uptake of its guidelines on viral hepatitis, as well as on progress in implementation of the strategy, in order to highlight barriers and promote best practices.

5.2.2 Monitoring and evaluating the response at country level

106. Progress in implementing the health sector response to viral hepatitis should be assessed with indicators on availability, coverage outcome and impact, taking into consideration other relevant recommendations for monitoring implementation. Progress towards the 2030 Agenda for Sustainable Development, in particular the health-related goals, will be tracked and reported.

107. Indicators for monitoring the strengthening of health systems derive from a common platform for monitoring and evaluating national health strategies, known as the Country Health Systems Surveillance platform, coordinated by WHO. Instruments are also available for measuring progress in implementing policy, legal and structural measures for enhancing the hepatitis response.

5.2.3 WHO’s framework for results-based management

108. WHO’s Twelfth General Programme of Work, 2014–2019, provides high-level strategic vision for the work of WHO. The Programme of Work outlines six areas of work. Most activities related to viral hepatitis fall under Category 1 on *Communicable Diseases*. However, other important hepatitis-related activities fall under other categories, notably Category 2 on *Noncommunicable Diseases* (including cancer, substance use and chronic care), Category 3 on *Promoting Health through the Life-course* (including maternal, adolescent and child health) and Category 4 (including access to medicines and diagnostics, integrated service delivery, strategic information and human resources). Under Category 1 “HIV and viral hepatitis” has its own area of work for which biennial workplans are developed with a set of agreed outcomes and budget. This strategy covers three biennia (2016–2017, 2018–2019 and 2020–2021). Workplan implementation is monitored through a mid-term review at the end of the first year of each biennium and progress towards the achievement of each of the outcomes is reported at the end of each biennium.

5.3 Implementing the strategy at the national level

109. The global strategy is intended to guide the development and implementation of national hepatitis strategies, efforts and activities. Broad buy-in through the preparation process will assist in effective implementation. In order to enable country ownership, national hepatitis strategies or plans should be aligned with existing plans such as national development plans, national health sector strategies and other disease strategies. They should also, to the extent possible, align with national planning and financial cycles.

5.4 Accountability

110. Well-functioning and transparent accountability mechanisms, with strong civil society participation, are vital, given the range of partners and stakeholders needed for an effective viral hepatitis response. Important building blocks include nurturing strong leadership and governance that involve full engagement with all relevant stakeholders, setting clear targets, using appropriate indicators to track progress, and establishing transparent and inclusive assessment and reporting processes.

5.5 Costing estimates for implementing the strategy

111. The Global health sector hepatitis strategy 2016–2021 would be expected to deliver a 30% reduction in new cases and a 10% reduction in the number of hepatitis-related deaths by 2020, and a 90% reduction in new cases and a 65% reduction in hepatitis-related deaths by 2030.

112. The main interventions are testing and treatment (for both hepatitis B virus and hepatitis C virus) (with 8 million people treated by 2020, and 80% of those eligible treated by 2030), hepatitis B virus vaccination (with 90% coverage by 2020) and prevention of mother-child transmission (with 50% coverage by 2020, with birth-dose vaccination, and 90% by 2030, incorporating both birth-dose vaccination and additional interventions including peri-partum antivirals), harm reduction among people who inject drugs (providing sterile injecting equipment and opioid substitution therapy) and measures to maximize blood and injection safety.

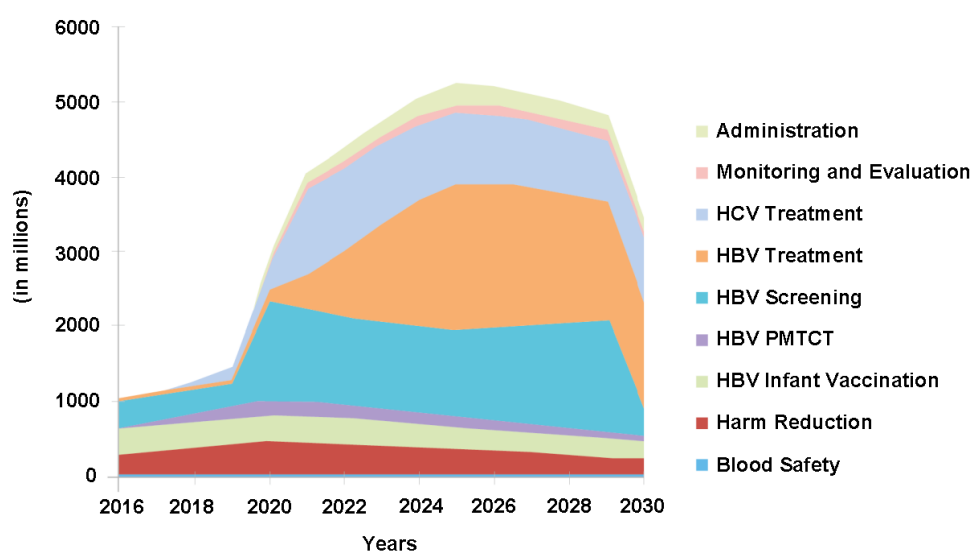
113. The costs of some interventions are assumed to be shared across different parts of the health sector: 25% of the estimated cost of outreach to people who inject drugs and opioid substitution therapy are incorporated under this strategy, as the costs are also reflected in the HIV strategy; 10% of the estimated cost of the blood and injection safety costs are incorporated; and only 10% and 50% of the anticipated testing costs, for Africa and elsewhere, respectively, are incorporated in the hepatitis strategy as costs of active testing campaigns are also incorporated in the HIV strategy.

114. In low- and lower-middle income countries, the full costs of the intervention are considered additional costs for the health sector. However, in upper-middle income and higher-income countries, intervention costs are expected to be partially or fully offset by savings made in reduced care needs for those with advanced disease or by replacing alternative less effective treatments already in use. Therefore, the costing of this strategy includes 100% of the cost for low- and lower-middle income countries and 25% of the costs of the upper-middle income countries. It does not include the cost of high-income countries.

115. The total cost of implementing this strategy for the period 2016–2021 is US\$ 11 900 million. (Figure 8) The peak annual cost in this period is 2021, and the value is US\$ 4100 million. In the years following 2021, annual costs continue to grow and peak in 2026 at US\$ 5200 million. Costs decline to US\$ 3500 million per year in 2031. The principal drivers of cost are hepatitis B virus treatment, screening and hepatitis C virus costs. Costs decline in the future largely due to reduced need for hepatitis B virus testing and lower hepatitis B virus treatment loads (due to reduced rates of new cases, and the introduction of a cure for persons on antivirals).

116. For comparison, the cost in the period 2016–2021 across all low- and middle-income countries (full costs included for those countries but no costs for high-income countries) is US\$ 19 300 million. In this scenario, the annual cost in the strategy period peaks at US\$ 7100 million. In the years following 2021, annual costs continue to grow, peaking at US\$ 8800 million in 2025, and then declining.

Figure 8: The cost of implementing the global health sector strategy on viral hepatitis, 2016–2030 (US\$ million)



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