

Regional Action Plan for Viral Hepatitis in the Western Pacific 2016–2020



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A priority action plan for awareness, surveillance, prevention
and treatment of viral hepatitis in the Western Pacific Region

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ABBREVIATIONS

CTC	controlled temperature chain
EQAS	external quality assurance system
GHP	Global Hepatitis Programme
HAV	hepatitis A virus
HBsAg	hepatitis B surface antigen
HBV	hepatitis B virus
HCC	hepatocellular carcinoma
HCV	hepatitis C virus
HDV	hepatitis D virus
HEV	hepatitis E virus
IPC	infection prevention and control
NSP	needle-and-syringe programme
OST	opioid substitution therapy
PCR	polymerase chain reaction
PWID	people who inject drugs
QMS	quality management system
RED	Reaching Every District
STI	sexually transmitted infection
TB	tuberculosis
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UHC	universal health coverage

FOREWORD

Viral hepatitis is the seventh-leading cause of mortality globally, responsible for 1.45 million deaths in 2013. One quarter of the world's population lives in the Western Pacific, but the Region bears 40% of the world's deaths caused by hepatitis. Hepatitis kills more than 1500 people every day in the Region.

Our work has been impressive: we have successfully reduced childhood transmission of hepatitis B through infant vaccination, with 30 out of 37 countries and areas having reached the 2012 milestone of less than 2% chronic hepatitis B prevalence among 5-year-old children and 13 countries and areas having already reached the goal of less than 1% prevalence. Millions of people will never face the ravages of hepatitis B as a consequence of these visionary decisions made 13 years ago, endorsing the ambitious goal at the fifty-fourth session of the WHO Regional Committee meeting in 2003.

Even with these successes, however, millions of people across the Region continue to live with chronic hepatitis infection and the risk of cirrhosis and liver cancer. We now need the same resolve to provide treatment for the millions of adults living with hepatitis B and C.

We now have effective medicines to manage and treat chronic viral hepatitis. However, the high prices of these medicines are a major barrier for access to treatment across our Region. We need innovative approaches to ensure that the people of our Region can benefit from these life-saving medicines.

As we work on these challenges, we must not forget the issue of stigma. The stigma of hepatitis can prevent many from taking employment or leading a normal life with normal relationships. Like most types of discrimination, stigma is curable with information and understanding. We must commit to reducing stigma as part of the fight against viral hepatitis.

The *Regional Action Plan for Viral Hepatitis in the Western Pacific 2016–2020*, approved by Member States at the sixty-sixth session of the WHO Regional Committee in 2015, provides a systematic approach to priority areas for action by countries to reduce the impact of viral hepatitis, with a focus on chronic hepatitis B beyond immunization and hepatitis C. It was developed through extensive Member State and expert consultations.

It is intended to guide Member States in developing country-specific national hepatitis responses based on the needs and priorities of people living with hepatitis or at risk for viral hepatitis, as well as the capacity of the national health sector to address these needs. Through implementation of this action plan, the Western Pacific Region may continue to lead global hepatitis action, addressing the challenge of eliminating new infections and restoring health to millions of people living with hepatitis.



Shin Young-soo, MD, Ph.D.
Regional Director

EXECUTIVE SUMMARY

Viral hepatitis is the seventh-leading cause of mortality globally, responsible for 1.45 million deaths in 2013. The countries of the WHO Western Pacific Region bear almost 40% of the global mortality burden, accounting for more than 1500 deaths every day. The consequences of chronic hepatitis B and C infections – cirrhosis and liver cancer – are responsible for 94% of deaths associated with hepatitis infections. Liver cancer is the second most common cause of cancer deaths in the Asia–Pacific region, and approximately 78% of liver cancer cases are a result of chronic viral hepatitis B or C.

The WHO Regional Committee for the Western Pacific, at its fifty-fourth session in 2003, set a goal to reduce the prevalence of chronic hepatitis B infection among 5-year-old children to less than 1% (WPR/RC54.R3). In 2005, the Regional Committee established a milestone of reducing chronic hepatitis B infection among 5-year-old children to less than 2% by 2012 (WPR/RC56.R8).

Since the adoption of these resolutions, the Region has had significant success in fighting viral hepatitis. By 2012, the Region as a whole – as well as 30 out of 37 countries and areas – were verified to have met the 2% interim target. Building on these gains, the sixty-fourth session of the WHO Regional Committee in 2013 set a target date of 2017 for reducing chronic hepatitis B infection rates to less 1% among 5-year-old children (WPR/RC64.R5). Thirteen countries have already reached the 2017 goal. Full achievement of this goal will ultimately save millions of lives.

Even with reductions in childhood prevalence, millions of people across the Region continue to live with chronic hepatitis infection and the risk of cirrhosis and liver cancer. The *Regional Action Plan for Viral Hepatitis in the Western Pacific 2016–2020* provides an approach specific to viral hepatitis in the Western Pacific Region, reaching beyond immunization and including building awareness and knowledge among stakeholders, strengthening public policy, generating data to better understand hepatitis epidemics, enhancing prevention strategies, and improving access to affordable screening, diagnosis and treatment of hepatitis B and C.

Cognizant of variations in hepatitis epidemiology and the availability of resources across countries in the Western Pacific Region, the *Regional Action Plan for Viral Hepatitis in the Western Pacific 2016–2020* is intended to guide Member States in developing country-specific national hepatitis responses based on the needs and priorities of people living with hepatitis and populations at risk for viral hepatitis, as well as the capacity of the national health sector to address these needs.

PART A. Background

1. Viral hepatitis epidemiology

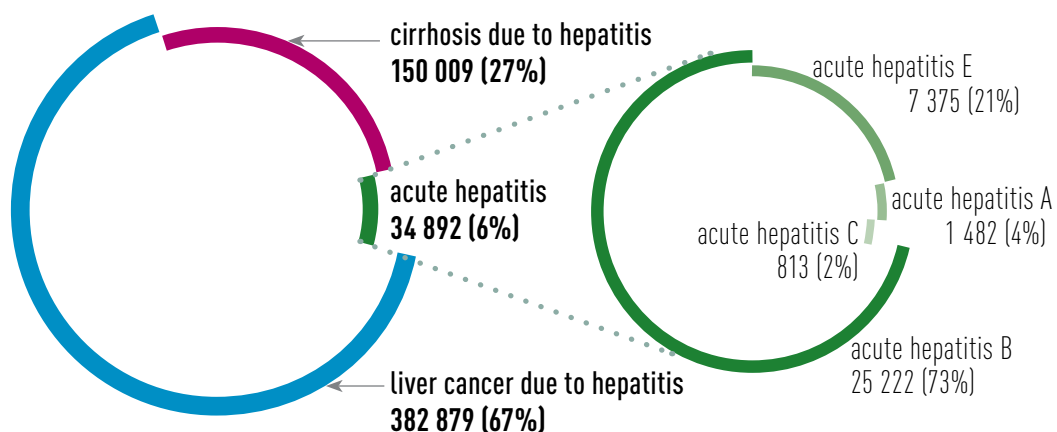
Globally, viral hepatitis is now responsible for 1.45 million deaths every year – higher than the 1.3 million deaths from HIV/AIDS and 1.3 million deaths from tuberculosis (TB). Viral hepatitis is the seventh-highest cause of mortality globally, approximately 48% of those deaths are from hepatitis B, 48% from hepatitis C, and the remainder from acute hepatitis A and E.

Mortality from viral hepatitis in the Western Pacific Region is now higher than mortality from HIV/AIDS, malaria and TB combined. Compared with other WHO regions, the Western Pacific has the highest number of viral hepatitis-related deaths per year, accounting for approximately 39% of global mortality due to hepatitis. That translates to more than 1500 deaths every day, 47% from chronic hepatitis B and 47% from chronic hepatitis C.

The consequences of chronic hepatitis B and C infection – cirrhosis (end-stage liver fibrosis) and liver cancer – are responsible for 94% of deaths associated with hepatitis infections, illustrated in Figure 1. Liver cancer is the second most common cause of cancer deaths in the Asia-Pacific region, and approximately 78% of liver cancer cases are a result of chronic viral hepatitis B or C. China alone accounts for over 50% of the global liver cancer burden. The majority of cases of liver cancer can be prevented through effective prevention and treatment of hepatitis B and C.

The epidemiology of HIV and hepatitis is closely related to shared transmission routes. The HIV-hepatitis coinfection is associated with more rapid progression of liver-related disease and poor outcomes in HIV and interferon-based hepatitis treatment, though less so with new direct acting antivirals. While the burden of hepatitis B virus (HBV) infection in HIV populations is similar to the overall population burden of HBV, the burden of hepatitis C virus (HCV) in specific HIV-infected key populations, such as people who inject drugs (PWID), is over 90% in a number of countries.

FIGURE 1. Mortality from viral hepatitis in the Western Pacific Region in 2013



Source: GBD 2013 Mortality and Causes of Death Collaborators. Global, regional, and national age/sex specific all-cause and cause-specific mortality for 240 causes of death, 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013. *The Lancet*. 2015 Jan 10; 385(9963):117–71.

2. Action on viral hepatitis to date

The Western Pacific Region has seen recent successes in the fight against viral hepatitis. In 2003, the Western Pacific was the first WHO region to include infant hepatitis B immunization in the national immunization programmes of all its Member States. The Western Pacific Region was also the first to set the goal of reducing the prevalence of hepatitis B infection, as indicated by the seroprevalence of hepatitis B surface antigen (HBsAg), to less than 2% among children 5 years of age by 2012 and to less than 1% prevalence by 2017, through universal three-dose hepatitis B and birth-dose vaccination of infants. The Region has largely reached the 2012 interim milestone, and 13 countries have reached the 2017 goal.

Despite this success with vaccinations, there remains a substantial cohort of infected individuals with progressive liver disease who were born prior to vaccination availability and developed chronic hepatitis B infection through mother-to-child or childhood infection. Of this cohort, 15–25% will – without treatment – die from complications associated with chronic hepatitis B. There is no vaccine for hepatitis C. The limited investment in a public health response to viral hepatitis contrasts sharply with HIV/AIDS and TB, despite the high burden of disease and mortality.

The World Health Assembly provides a mandate for action

The World Health Assembly has now issued two resolutions on viral hepatitis – WHA63.18 (Viral hepatitis) in 2010 and WHA67.6 (Hepatitis) in 2014. These resolutions call on Member States to develop and implement coordinated multisectoral national strategies to prevent, diagnose and treat viral hepatitis based on the local epidemiological context, among other activities. In addition, the resolutions call on WHO to support these efforts. While several countries in the Region have developed comprehensive national hepatitis strategies, there has been no coordinated regional response to viral hepatitis, related liver disease, and consequent morbidity and mortality.

In response to the 2010 World Health Assembly resolution, the Global Hepatitis Programme (GHP) launched *Prevention and Control of Viral Hepatitis Infection: A Framework for Global Action* in 2012 (1). The four axes of this global hepatitis framework provided a structured approach to viral hepatitis prevention and control activities. Viral hepatitis activities in the Region need such an approach to address all aspects of viral hepatitis control, including awareness, surveillance, prevention and management for all hepatitis viruses (A–E).

The GHP has issued guidance to Member States, including *New recommendations in the updated WHO guidelines for the screening, care and treatment of persons with chronic hepatitis C infection* (2), *Waterborne outbreaks of hepatitis E: recognition, investigation and control* in 2014 (3) and *Guidelines for the prevention, care and treatment of persons with chronic hepatitis B infection* in 2015 (4). For the HIV–HBV coinfection, *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection* (5) recommend immediate initiation of antiretroviral therapy in HIV–HBV coinfecting individuals with severe liver disease regardless of CD4 count. While HIV–HBV coinfecting individuals should be a priority for hepatitis care and treatment, early access to effective HBV treatment and, especially, HCV treatment remains very limited in much of the Western Pacific Region.

The Global Health Sector Strategy for Viral Hepatitis

The *Global Health Sector Strategy for Viral Hepatitis 2016–2021* was drafted in response to WHA67.6 and intends to position the viral hepatitis response in the post-2015 health and development agenda. The strategy builds on WHO's *Prevention and Control of Viral Hepatitis Infection: Framework for Global Action* (1) with the central goal of the elimination of viral hepatitis transmission by 2030. Through key dimensions of universal health

coverage (UHC), the strategy aims to define the essential services and interventions that people should receive, as well as identify measures that can be taken to ensure and improve the quality of services and programmes, describe how the coverage of services can be expanded to ensure equity and maximum impact, and propose strategies to minimize the risk of financial hardship for those requiring the services. The strategy is designed to meet the complex challenges of preventing, diagnosing and treating viral hepatitis in rapidly evolving contexts.

The global strategy, based on the principles of UHC, promotes a long-term, sustainable response through strengthening health and community systems, tackling the social determinants of health that both drive the epidemic and hinder the response, and protecting and promoting human rights and gender equity as essential elements of the health sector response. It calls on the world to build on the collaboration, innovation and investment that have forged hard-won progress in order to establish the foundation for success over the next six years. As resources, efficiencies and capacity increase, the range of services provided can be expanded, with improved quality, and can cover more populations with fewer direct costs to those who need the services – a progressive realization of the goal of UHC.

3. Coordination between regional and global action plan development

The *Global Health Sector Strategy for Viral Hepatitis 2016-2021* is an overarching framework that provides a series of strategic directions covering high-level key domains in the viral hepatitis response.

The *Regional Action Plan for Viral Hepatitis in the Western Pacific 2016–2020* provides priority areas for action by countries in addressing the national burden of viral hepatitis, with a focus on chronic hepatitis B (beyond success in immunization) and hepatitis C. Hepatitis B and C account for more than 90% of the hepatitis mortality burden in the Region. This plan recommends actions for Member States and supporting actions for WHO to achieve consensus targets.

The target audience includes ministries of health, policy-makers, programme officers, clinicians, nongovernmental organizations, health planners and those implementing health plans, the private (non-profit and profit) sector, donors, community groups and civil society organizations.

TABLE 1. Alignment of the Regional Action Plan for Viral Hepatitis in the Western Pacific priority areas with the Global Health Sector Strategy for Viral Hepatitis strategic directions

PRIORITY AREAS OF ACTIONS	Corresponding strategic directions (SD)
PRIORITY AREA 1: Broad-based advocacy and awareness	SD1. Strategic information for focus and accountability
PRIORITY AREA 2: Evidence-informed policy guiding a comprehensive and coordinated hepatitis response	SD1. Strategic information for focus and accountability
	SD2. Interventions for impact
	SD4. Financing for sustainability
PRIORITY AREA 3: Data supporting the hepatitis response	SD1. Strategic information for focus and accountability
PRIORITY AREA 4: Stopping transmission	SD3. Delivering for equity
	SD4. Financing for sustainability
	SD5. Innovation for acceleration
PRIORITY AREA 5: An accessible and effective treatment cascade ^a	SD3. Delivering for equity
	SD4. Financing for sustainability
	SD5. Innovation for acceleration

a. A cascade is a succession of steps in a process, each of which triggers or initiates the next stage.

Regional milestones and targets

Regional milestones and targets are intended to be nearer-term targets than the global hepatitis strategy targets. This is the minimum set of regional milestones and targets that take into account intercountry variability in viral hepatitis epidemiology, context and response, specific national milestones and targets may vary.

TABLE 2. Regional hepatitis milestones and targets

2017 MILESTONES	2020 TARGETS
ADVOCACY AND AWARENESS	
Initiate specific advocacy activities that go beyond recognition of World Hepatitis Day (28 July) are initiated to increase awareness.	Report card on specific awareness and advocacy activities is completed.
National task force is established with a designated focal point within the ministry of health, with representation from affected communities.	
EVIDENCE-BASED POLICY	
	A costed and funded national hepatitis action plan with targets.
DATA AND SURVEILLANCE	
National disease burden estimate and investment case.	
WHO viral hepatitis surveillance guideline is adapted to local context. Laboratory or clinical reporting mechanisms are established.	Member States have a national hepatitis infection and disease surveillance programme that can inform disease burden estimates and monitor the health sector response to viral hepatitis.
National hepatitis reference laboratories are established.	Hepatitis surveillance is linked to the liver cancer registry, treatment registry, immunization data and vital statistics registry.
Regional hepatitis laboratory network is established.	
STOPPING TRANSMISSION	
– Immunization	
Achieve prevalence of HBsAg in 5-years-old of < 1%.*	In countries that have achieved <1% in children under 5 years, further reduce mother-to-child transmission.
Achieve birth-dose hepatitis B vaccination coverage of at least 95%.* Achieve three-dose hepatitis B vaccination coverage of at least 95%.*	
National policy of vaccinating health-care workers against hepatitis B is established in > 80% of countries.	National policy of vaccinating health-care workers, medical/health students against hepatitis B is established in all countries. Hepatitis B vaccinations are integrated into HIV, harm-reduction, and sexually transmitted infection (STI) services.
– Prevention (health-sector transmission)	
	Safe injection policies for transmission of hepatitis B and C in health-care settings are established in all countries.

* Agreed to in 2003 and 2013 (resolutions WPR/RC54.R3 and WPR/RC64.R5).

2017 MILESTONES	2020 TARGETS
<p>– Prevention (high-risk adult populations)</p> <p>Countries with populations of PWID have policies supporting harm-reduction programmes including needle-and-syringe programmes and opioid substitution treatment.</p>	<p>Countries with harm-reduction programmes access 60% of PWID with a comprehensive package of harm-reduction services and 50% of people dependent on drugs with substitution treatment.</p>
TREATMENT CASCADE	
<p>– Treatment (screen/test/diagnose)</p> <p>Obtain baseline data for national hepatitis screening, care and treatment cascade.</p>	<p>30% of the estimated population living with HBV-HCV are diagnosed.</p>
<p>– Treatment (eligibility)</p> <p>Obtain baseline data as above.</p>	<p>50% of the eligible population for treatment begin on treatment.</p>
<p>– Viral suppression (HBV) and cure (HCV)</p> <p>Obtain baseline data as above.</p>	<p>90% of those on HBV or HCV treatment obtain viral suppression (HBV) or are cured (HCV).</p>

Development of the Regional Action Plan

The World Health Assembly resolutions on viral hepatitis, WHA63.18 in 2010 and WHA67.6 in 2014, called for Member States to develop and implement multisectoral national strategies to prevent, diagnose and treat viral hepatitis based on the local epidemiological context and for WHO to support these efforts.

The *Regional Action Plan for Viral Hepatitis in the Western Pacific 2016–2020* was developed following recommendations from the first Meeting of the Informal Expert Working Group on Surveillance, Prevention and Management of Viral Hepatitis in the Western Pacific Region in Manila, Philippines, in April 2014. Experts from eight countries attended the meeting. Following the development of a preliminary draft of the action plan, there were consultations – including virtual consultations – and feedback was sought from regional experts and affected communities.

Recommendations in the Regional Action Plan for priority activities are based on regional immunization targets, gaps in programmes and resources covering these activities, as well as the burden of disease in certain settings and subpopulations. Although not listed among the Region’s new priority activities, efforts to ensure food and water safety as global public goods should continue. Countries should also conduct other viral hepatitis prevention, diagnosis and treatment activities as recommended by the *Global Health Sector Strategy on Viral Hepatitis 2016–2021*. Midterm and end-term reviews of implementation of the *Regional Action Plan for Viral Hepatitis in the Western Pacific 2016–2020* are recommended.

PART B.

The Regional Action Plan

1. Vision, goals and principles

VISION

A Western Pacific Region free of new hepatitis infections, where people living with chronic hepatitis have access to care and affordable and effective treatment.

GOALS

Within a health systems framework and using a public health approach, the goals of the *Regional Action Plan for Viral Hepatitis in the Western Pacific 2016–2020* are:

- to reduce transmission of viral hepatitis,
- to reduce morbidity and mortality due to viral hepatitis.

PRINCIPLES

1. Universal health coverage
2. Government stewardship and accountability
3. Evidence-based interventions, services and policies
4. Protection and promotion of human rights, gender equality and health equity
5. Partnership, integration and linkage with relevant sectors, programmes and strategies
6. Meaningful involvement of people living with viral hepatitis, key populations and affected communities

2. Priority areas and actions

PRIORITY AREA 1

Broad-based advocacy and awareness

Objective 1.1 Empower communities and providers by increasing awareness about viral hepatitis

Knowledge about the prevention and treatment of viral hepatitis and liver disease, with the exception of the need for HBV immunization, is low among stakeholders in many parts of the Region. Communities, health-service providers and governments must be aware of the extent of national and community hepatitis epidemics and the consequences of viral hepatitis infection and related liver disease. They must undertake public and provider awareness education and training campaigns in viral hepatitis. Targeted awareness building is needed among public health policy- and decision-makers.

2017 MILESTONES

- Specific advocacy activities that go beyond recognition of World Hepatitis Day are initiated to increase awareness.
- National task force is established with designated focal point within the ministry of health, with representation from affected communities.

2020 TARGET

- Report card on specific awareness and advocacy activities is completed.

ACTIONS RECOMMENDED FOR MEMBER STATES

1. Develop a multisectoral national hepatitis task force to coordinate a public health awareness and communication strategy:
 - a. Membership should include policy-makers, health-care providers and their associations, as well as researchers, media, civil society, and affected communities.

- b. The communications strategy should be targeted specifically towards populations at risk of viral hepatitis, their providers and policy-makers. In high-prevalence countries, this may mean the general population.
 - c. Stigma and discrimination should be specifically addressed in the awareness and communications strategy. All awareness-building actions should have a strong emphasis on being culturally appropriate and avoid reinforcing stigma and discrimination.
2. Support national patient-group formation and mobilization:
 - a. Affected groups or those at risk of infection should be recognized and invited to actively participate in viral hepatitis policy and the guideline development processes.
3. Integrate viral hepatitis prevention and treatment into health professional training curricula to promote the development of a hepatitis literate workforce.
4. Recognize and carry out hepatitis activities annually – including high-quality public and provider awareness-building and service announcements – on World Hepatitis Day (July 28).

WHO SUPPORTING ACTIONS

1. Develop communications plan to support the actions of Member States in building community and provider awareness of viral hepatitis and its health consequences, including dissemination of this regional action plan.
2. Engage patient and affected population groups to actively participate in WHO consultations and regional guidance development.
3. Support Member States to develop a health workforce literate in viral hepatitis prevention, diagnosis and treatment.
4. Annually develop a World Hepatitis Day toolkit for use in countries. Where possible, align major hepatitis policy and disease burden estimate announcements with World Hepatitis Day (July 28).

PRIORITY AREA 2

Evidence-informed policy guiding comprehensive and coordinated hepatitis action

Objective 2.1 A national action plan

National-level policy is the most effective mechanism for affecting change at the population level. In the context of limited domestic and external resources, action to address hepatitis needs to be optimized to ensure a coordinated and, where possible, integrated policy framework supporting evidence-informed and cost-effective programmatic responses. The development and maintenance of efficient hepatitis programmes is dependent on the early identification of secure and sustainable funding mechanisms.

2020 TARGET

- A costed and funded national hepatitis action plan with clear targets.

ACTIONS RECOMMENDED FOR MEMBER STATES

1. Develop a comprehensive national hepatitis action plan in partnership with key stakeholders, including affected communities:
 - a. Each Member State may establish a task force (including appointing a designated organizational structure within the ministry of health) to develop a costed and funded national hepatitis action plan with representation of affected communities.
 - b. A national action plan, developed through a consensus-based process including ongoing involvement of affected communities, can support national responses to viral hepatitis and HIV/hepatitis coinfections. The plan should include specific indicators for measuring progress and related targets to be achieved over the life of the action plan.
 - c. The national action plan should be linked programmatically to other key strategies and disease action plans, including, but not limited to, HIV.
 - d. Stigma and discrimination should be specifically addressed in the national action plan.
 - e. Efforts should be made to institutionalize viral hepatitis control, individualized within ministry of health structures, to ensure the long-term viability of hepatitis actions, including identifying a focal point in the ministry of health (at the national and subnational levels) to coordinate all viral hepatitis and HIV–hepatitis

coinfection-related activities, as well as the development and implementation of a national action plan addressing awareness, surveillance and prevention.

- f. Regular high-level meetings should be held among representatives of all departments of government relating to viral hepatitis policy, including those working in infection control, harm reduction, drug policy, food, water, blood safety, HIV, immunization and cancer.
- g. Address regulatory issues including, where appropriate, early registration based on stringent regulatory agency approval, collaborative regulatory processes such as WHO prequalification mechanisms, and intensive pharmacovigilance, especially for generic products.
- h. Ensure pool procurement mechanisms for medicines and diagnostics can be utilized in national planning.

2. Mobilize resources for action on viral hepatitis:

- a. Allocate a specific portion of the national health budget to viral hepatitis prevention, care and treatment in proportion to the disease burden of countries and communities, including HIV–hepatitis coinfections.
- b. Join together, where appropriate, hepatitis programmes with HIV programmes to address coinfections and optimize the use of resources.
- c. Conduct cost-effectiveness analysis of screening and treatment interventions to optimize allocation of resources.
- d. Through advocacy and partnerships, for example, with the pharmaceutical industry, influential global donors, patient advocacy groups, professional societies and others, explore opportunities to increase access to affordable hepatitis medications.

WHO SUPPORTING ACTIONS

1. Provide technical assistance to develop national hepatitis action plans and support countries to engage with regional and global policy initiatives.
2. Work with Member States to address the HIV/hepatitis coinfections through HIV programming and vice versa.
3. Identify and work with potential donors to identify funding sources for viral hepatitis activities. Ensure hepatitis policy development takes a whole-of-system approach, working across diseases to optimize the cost-effective use of limited country resources.
4. Support national planners to strengthen regulatory and procurement issues in hepatitis planning, including collaborative registration processes such as WHO prequalification procedures, pharmacovigilance and pooled procurement mechanisms.

PRIORITY AREA 3

Data supporting the hepatitis response

Objective 3.1 National disease burden estimates and investment case

To support budget allocations and attract investments for policies supporting a comprehensive programmatic response to hepatitis, the disease burden of viral hepatitis and HIV–hepatitis coinfections must be established, together with a costed proposed policy response.

2017 MILESTONE

- National disease burden estimates and investment case.

ACTIONS RECOMMENDED FOR MEMBER STATES

1. Develop national estimates of disease and treatment burdens for viral hepatitis and HIV–hepatitis coinfections. Focus initially on chronic hepatitis B and C (and D if relevant):
 - a. Use disease burden models, adapted to the local epidemiology context, to develop estimates.
 - b. Include consensus-building consultations in the process of deriving estimates to ensure stakeholders are in agreement with national disease burden estimates.
 - c. Calculate the national treatment burden for chronic hepatitis B and C using national or WHO hepatitis treatment eligibility criteria, with high-quality local data.
 - d. Identify gaps in knowledge of disease burden and develop an operational research agenda to address these gaps.
2. Develop a country-specific investment case for action on hepatitis:
 - a. Focus initially on chronic hepatitis B and C, informed by the local epidemiological context.
 - b. Include agreed national estimates of disease and treatment burdens and various care packages and coverage and pricing scenarios tailored to the local epidemiological and socioeconomic situation.
3. Achieve stakeholder consensus on data.
4. Identify country-specific priority groups for testing and treatment based on local epidemiology and liver disease patterns. Ideally, these should be identified in

conjunction with the above national disease burden estimates:

- a. Develop epidemiologic profiles for high-risk groups for incident infections and for the outcomes of chronic infection.

WHO SUPPORTING ACTIONS

1. Support the development of national estimates of disease and treatment burdens:
 - a. Provide technical support to develop robust data inputs to estimate the hepatitis disease burden.
 - b. Support consensus building on national estimates of the disease burden through stakeholder consultations with community engagement.
 - c. Support the development of plans and implementation of continual data gathering and validation to maintain up-to-date estimates.
2. Support Member States to identify priority groups for testing and treatment based on an analysis of the local epidemiology and liver disease burden profile.
3. Assist Member States to develop a national investment case for comprehensive hepatitis B and C action using existing models, where possible, to allow comparison between countries and calculation of regional investment needs.
4. Work with countries to undertake a national or subregional assessment of current capacity for a comprehensive hepatitis response, including the public health sector response and the role of the private sector.

Objective 3.2 Standardized surveillance and data collection activities

In much of the Western Pacific Region, there are limited or no data on the extent of viral hepatitis epidemics and consequent liver disease. A functional and reliable surveillance system is fundamental to understand hepatitis epidemiology in real time and inform programmatic responses. Targeted programmatic monitoring and robust evaluation provide a strong feedback mechanism to improve programmatic effectiveness and efficiency.

Innovative and economical approaches to viral hepatitis surveillance have been described that are appropriate to the resources and epidemiological patterns in individual countries. The inclusion of such surveillance in existing systems could be a way to reduce costs. A detailed description of approaches to the selection of indicators and surveillance processes is presented in the WHO guidance on *Technical*

considerations and case definitions to improve surveillance for viral hepatitis: technical report (5) and Monitoring and evaluation for viral hepatitis B and C: recommended indicators and framework.(6)

2017 MILESTONES

- WHO viral hepatitis surveillance guideline is adapted to local context.
- Laboratory or clinical reporting mechanisms are established.
- National hepatitis reference laboratory is established.
- Regional hepatitis laboratory network is established.

2020 TARGETS

- Member States have a national hepatitis infection and disease surveillance programme that could inform disease burden estimates.
- Hepatitis surveillance is linked to existing liver cancer registry, treatment registry, immunization data and vital statistics registry.

ACTIONS RECOMMENDED FOR MEMBER STATES

1. Coordinate viral hepatitis surveillance using existing infrastructure:
 - a. Assess current hepatitis and related communicable diseases data sources and surveillance, including HIV.
 - b. Move towards test-result reporting through laboratory reporting to a central registry:
 - minimize additional workloads through a case reporting system and use standard case definitions nationally and among countries;
 - use unique identifiers, where available, to allow “deduplication”;
 - report negative and positive tests; and
 - link to existing reporting systems where possible.
 - c. Strengthen the laboratory role in public health surveillance and response to outbreaks and changes in infection and disease epidemiology.
 - d. Centralize data management of all hepatitis test reporting and surveillance.
 - e. Link cancer registry data for liver cancer to viral hepatitis reporting systems.
2. As part of the national hepatitis action plan, review national surveillance guidelines for viral hepatitis or adapt WHO viral hepatitis surveillance guidelines appropriate to local epidemiology and resource availability to ensure standard case definitions nationally and among countries.

3. Develop a domestic laboratory network for viral hepatitis, linked to a regional laboratory network:
 - a. Establish WHO external quality assurance for hepatitis network laboratories.
 - b. Designate one national reference laboratory – quality management system (QMS), domestic external quality assurance system (EQAS) – with the following responsibilities:
 - oversee domestic EQAS and provide QMS including community-based facilities using rapid tests; and
 - participate in a WHO accreditation programme.
 - c. Set up domestic hepatitis test kit validation process or link to a WHO-endorsed external test validation process.
4. Adopt standardized testing algorithms for viral hepatitis surveillance, blood safety and diagnosis.
5. Triangulate viral hepatitis data reporting system with immunization and liver disease reporting (cirrhosis cases and cancer registry), and consider integrating other currently available data, such as inventory management systems, hospital information systems, and antiviral prescribing or ordering data systems.

WHO SUPPORTING ACTIONS

1. Provide technical support to Member States to collate viral hepatitis data sources to:
 - a. establish gaps and priorities in current surveillance data for viral hepatitis;
 - b. expand existing disease reporting and surveillance systems so that they may also be utilized for viral hepatitis surveillance; and
 - c. establish systems for viral hepatitis surveillance, moving towards centralized test reporting.
2. Develop a toolkit for surveillance activities, including key indicators, which can be used to analyze trends over time and between populations and countries.
3. Support, with Member States, the development of a regional laboratory network to provide laboratory technical assistance to domestic laboratory networks, and domestic laboratories, on viral hepatitis.
4. Support the establishment and maintenance of robust EQAS and QMS mechanisms for domestic hepatitis laboratories.
5. Support the use of pre-qualified viral hepatitis test kits in domestic laboratories through processes to increase the proportion of manufacturers seeking WHO pre-qualification for their testing products.

6. Support the dissemination and adaptation of WHO viral hepatitis surveillance guidelines to local contexts.
7. Develop and disseminate screening and testing guidance to support standardized algorithms for detection and diagnosis of viral hepatitis.

Objective 3.3 Research

In the Western Pacific Region there remain substantial gaps in our understanding of hepatitis, particularly for the epidemiology of hepatitis and related liver disease and cancer, as well as in the arenas of operational research, implementation science and health economics analysis for screening, care and treatment. Research partnerships provide an opportunity for the sharing of knowledge and expertise, as well as access to relevant and specific data.

ACTIONS RECOMMENDED FOR MEMBER STATES

1. Promote regional research and partnerships in viral hepatitis:
 - a. Designate centres of excellence in viral hepatitis research and training.
 - b. Support research and policy networks in viral hepatitis.
2. Promote and support research in hepatitis screening, care and treatment:
 - a. focused on country-specific issues,
 - b. including operational/implementation science research,
 - c. including health economic analysis to support programme implementation.

WHO SUPPORTING ACTIONS

1. Support the research agenda by identifying policy and programmatic research gaps during hepatitis consultations and policy document formulations. Bring together researchers and policy-makers to foster the development of evidence to inform policy.
2. Identify key gaps in hepatitis research, focusing on public health issues, and support domestic and international collaborations in hepatitis research, including translation and implementation science research agendas.

PRIORITY AREA 4.

Stopping transmission

There are three major domains of action required to stop viral hepatitis transmission: hepatitis B immunization, prevention of health-care associated transmission, and high-intensity harm reduction.

TARGET

- In line with the proposed *Global Health Sector Strategy for Viral Hepatitis, 2016–2021*, countries of the Western Pacific Region undertake to eliminate the transmission of hepatitis resulting in chronic infection by 2030.

Objective 4.1 Hepatitis B immunization

Immunization is fundamental to eliminating hepatitis B transmission. Universal infant immunization with three to four doses of hepatitis B vaccine, with the first dose provided within 24 hours of birth, is the most cost-effective hepatitis B prevention and control strategy. This strategy provides the earliest possible protection to future birth cohorts and reduces the pool of chronic carriers in the population. Timely vaccination of newborn infants – ideally within 24 hours of birth – can prevent perinatal transmission of hepatitis B.

In 2003, the fifty-fourth session of the WHO Regional Committee for the Western Pacific set a goal to reduce the prevalence of chronic hepatitis B infection among 5-year-old children to less than 1% (WPR/RC54.R3). In 2005, a milestone with an interim target of reducing chronic HBV infection among 5-year-old children to less than 2% by 2012 was established (WPR/RC56.R8) – the first WHO region to do so. Striving to build upon these gains, the sixty-fourth session of the WHO Regional Committee for the Western Pacific in 2013 agreed to the goal of reducing chronic HBV infection to less than 1% among 5-year-old children by 2017 (WPR/RC64.R5). Achievement of this goal will translate to averting an additional 60 000 hepatitis B-related deaths per birth cohort in the Region.

Thirty out of 37 countries and areas have reached the 2012 milestone. Thirteen countries have already reached the 2017 target. Therefore, it is timely that the Western Pacific Region moves beyond immunization to a comprehensive approach to viral hepatitis, which includes screening, diagnosis, and treatment of hepatitis B and C. A number of countries in the Western Pacific Region have adopted the goal of elimi-

nation of mother-to-child transmission of HIV and congenital syphilis, as well as achievement of hepatitis B control targets. Adoption of the target of the elimination of chronic hepatitis B transmission aligns the Region with the policies of these countries and the Global Strategy targets.

2017 MILESTONES

- Achieve prevalence of HBsAg in 5-year-olds of less than 1%.[◊]
- Achieve birth-dose hepatitis B vaccination coverage of at least 95%.[◊]
- Achieve three-dose hepatitis B vaccination coverage of at least 95%.[◊]
- National policy of vaccinating health-care workers against hepatitis B is established in > 80% of countries.

[◊] Agreed to in 2003 resolution WPR/RC54.R3 and 2013 resolution WPR/RC64.R5

2020 TARGETS

- In countries that have achieved less than 1% prevalence in children under 5 years, mother-to-child transmission is reduced to less than 2%.
- National policy of vaccinating health-care workers, medical/health students against hepatitis B is established in all countries.
- Hepatitis B vaccinations are integrated into HIV, harm reduction, and STI services.

ACTIONS RECOMMENDED FOR MEMBER STATES

The following recommended actions are detailed in *Hepatitis B Control Through Immunization: A Reference Guide (8)*, except where indicated by an asterisk (*).

1. Vaccination of infants

- a. Strengthen routine immunization services to achieve and sustain at least 95% coverage with three doses of hepatitis B vaccine by 1 year of age in each birth cohort at the national level, and at least 85% coverage in each district.
- b. Focus efforts on poor-performing districts and high-prevalence groups, identified through improved data collection, mapping and regular analysis of subnational and district-level coverage data.
- c. Deliver a timely birth dose (within 24 hours of birth), with a target of reaching at least 95% of births at the national level and at least 85% coverage in each district.
- d. Coordinate with maternal and child health programmes to improve access to immunization and other neonatal care interventions for births outside of health

facilities: Reaching Every District (RED) strategy and novel strategies to increase penetration of birth-dose coverage including:

- promoting the appropriate use of controlled temperature chain (CTC) for hepatitis B vaccine to increase birth-dose coverage in health facilities with no continuous cold chain;
- ensuring availability of vaccine and standing orders for administration of the birth dose in the delivery room or postnatal ward for all newborn infants; and
- working closely with prevention of mother-to-child transmission (PMTCT) initiatives in HIV and STI programmes.*

2. Vaccination of priority adult population groups

- a. Immunize high-risk population groups, including health workers, men who have sex with men, sex workers, PWID, frequent recipients of blood/plasma transfusions, and any other population groups coming in regular contact with blood products. (Consider rapid HBV vaccination regimens in PWID.)
- b. Advocate national policies requiring free and universal hepatitis B vaccination of health-care workers.

3. Vaccine supply and quality

- a. Eliminate vaccine stock-outs at the national and district levels through improved training in vaccine management.
- b. Prevent vaccine freezing through improved training in temperature monitoring.
- c. Promote use of CTC for delivery of the hepatitis B birth dose.

4. Advocacy and social mobilization

- a. Increase awareness among decision-makers, health workers and caretakers of the risks and consequences of HBV infection and the need for hepatitis B vaccination through:
 - community and civil society engagement;
 - use of media outlets;
 - education materials; and
 - mass awareness campaigns such as World Hepatitis Day and World Immunization Week.

5. Measurement of programme performance and impact

- a. Measure programme performance through monitoring of immunization coverage rates, including establishment of systems to monitor hepatitis B birth-dose coverage at the district level.

- b. Measure impact through HBsAg seroprevalence survey.
- c. Verify the attainment of regional goals.

WHO SUPPORTING ACTIONS

The following recommended actions are detailed in *Hepatitis B Control Through Immunization: A Reference Guide (8)*, except where indicated by an asterisk (*).

1. Provide technical support to Member States to:
 - a. collate hepatitis B data sources (vaccination and seroprevalence data);
 - b. improve hepatitis B vaccination coverage;
 - c. conduct quality hepatitis B seroprevalence surveys; and
 - d. promote effective strategies for controlling hepatitis B through immunization.
2. Provide regional guidance for hepatitis B control including:
 - a. up-to-date information on effective strategies for controlling hepatitis B through immunization;
 - b. advocacy material for promoting hepatitis B immunization;
 - c. field guide for hepatitis B birth-dose vaccination;
 - d. guidelines for verifying achievement of the regional hepatitis B control goal;
 - e. recommendations and supporting documents for regional hepatitis B resolutions; and
 - f. assessing the place of antiviral therapy in preventing vertical transmission of HBV infection in pregnant women at higher risk of HBV transmission.*
3. Conduct operational research to identify new effective strategies for increasing hepatitis B vaccination coverage.
4. Coordinate the process of verifying achievement of the regional goal including country-level verifications by an independent expert resource panel and estimations of the impact of vaccination at the regional level.

Objective 4.2 Health-care associated transmission

Hepatitis C infection acquired during health care remains a concern in a number of countries in the Region, in both the public and private sectors, including among para-health practitioners and a variety of other services including those using injection equipment, such as tattoos and acupuncture. High rates of HCV transmission among PWID and within closed settings are of particular concern across the Region.

While transmission of hepatitis C in health-care settings likely has been substantially reduced in the Western Pacific Region through improved blood screening programmes, the use of single-use medical injection, and general infection and control initiatives, prevalent infections are largely a consequence of transmission related to health and para-health care during the mid to late 20th century.

2020 TARGET

- Safe injection policies for prevention of transmission of hepatitis B and C in health-care settings are established in all countries.

ACTIONS RECOMMENDED FOR MEMBER STATES

1. Ensure safe blood supply, including appropriate indications for use
 - a. Support the implementation of *Universal Access to Safe Blood Transfusion: WHO Global Strategic Plan 2008–2015*.
 - b. Strengthen national blood product screening policies that include screening for HBV and HCV in blood and blood products, tissues and organs.
 - c. Address unnecessary use of blood products to reduce blood product use.
 - d. Develop a national transfusion service with full authority and responsibility to ensure safe blood supply integrated into national health system.
2. Reduce transmission and strengthen infection control and prevention (IPC) measures for hepatitis in health-care settings
 - a. Improve understanding at all levels of the health system of the preventable causes of viral hepatitis transmission in health settings.
 - b. Establish or strengthen a national IPC regulating authority to:
 - investigate infection outbreaks in health-care settings;

- oversee the implementation of safe therapeutic injection practices, where appropriate, of WHO prequalified or equivalent safety-engineered injection devices, including reuse-prevention syringes and sharp injury prevention devices for therapeutic injections and develop related national policies; and
 - ensure correct sterilization procedures and medical waste management in the public and private sectors and the informal health-care sector.
- c. Ensure adequate funding for single-use disposable injection equipment in all public health facilities and adherence to measures to prevent the reuse of such equipment.
 - d. Reduce unnecessary injections in health facilities.
 - e. Ensure adoption of standard precautions in all health facilities, including training in and monitoring of health-care workers adherence to standard precautions.

WHO SUPPORTING ACTIONS

1. Support safe blood supply in countries
 - a. Provide technical assistance to develop or strengthen national transfusion services with full authority and responsibility to ensure a safe blood supply integrated into the national health system, including addressing blood screening capacity deficits to ensure universal screening of donated blood.
 - b. Provide technical assistance to countries to reduce unnecessary use of blood products.
2. Support IPC in health-care settings
 - a. Provide technical support to countries to develop and maintain appropriate regulatory structures for effective IPC in the health system.
 - b. Provide technical support to outbreak investigation related to health-care setting viral hepatitis transmission.
 - c. Promote implementation of safe therapeutic injection practices (9).
 - d. Promote implementation of WHO universal precautions and infection control guidelines (10,11).

Objective 4.3 Full harm-reduction measures

Effective harm-reduction interventions are available in many jurisdictions in the Region; however, only full participation in harm-reduction interventions (12) is associated with a reduction in HCV incidence, and full participation by PWID in harm-reduction interventions is limited across the Region.

2017 MILESTONE

- Countries with populations of PWID have policies supporting harm-reduction programmes including needle-and-syringe programmes and opioid substitution therapy.

2020 TARGET

- Countries with harm-reduction programmes access 60% of PWID with comprehensive package of harm-reduction services and 50% of people dependent on drugs with substitution treatment.

ACTIONS RECOMMENDED FOR MEMBER STATES

1. Minimize hepatitis C transmission among PWID through the provision of effective high coverage and intensified harm-reduction interventions:
 - a. Make available effective opioid substitution therapy (OST) to opioid-dependent individuals, including in closed settings.
 - b. Implement high-intensity community- and facility-based needle-and-syringe programmes (NSPs), including low dead-space syringes.
 - c. Ensure PWID have access to condoms.
 - d. Set up infrastructure and service delivery models to reach PWID to support easier access to hepatitis screening, care and treatment.

WHO SUPPORTING ACTIONS

1. Support Member States to implement and maintain effective harm-reduction interventions for PWID:
 - a. Provide evidence-based guidance on recommended harm-reduction interventions, including OST and NSP, is country-specific although some guidance and support dissemination of these recommendations.

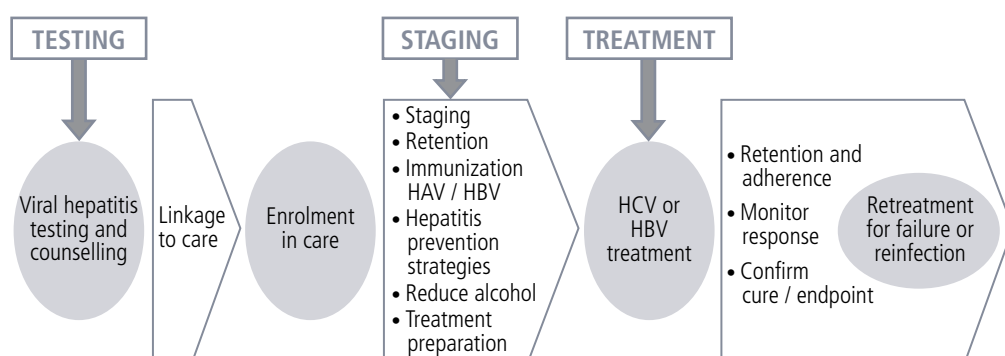
- b. Advocate to mobilize commitment and resources for evidence-based public health policies to reduce viral hepatitis transmission, in particular hepatitis C, among PWID.
- c. Provide technical support to countries to address barriers to implementation of effective harm-reduction interventions and integrated health service provision to PWID.

PRIORITY AREA 5

An accessible and effective treatment cascade

The chronic viral hepatitis cascade shows the steps in effective care and treatment (Fig. 2). Each step relies on sustaining the preceding step. Early diagnosis is important to identify new cases and to begin prevention programmes and the timely initiation of treatment. Following enrolment in care and treatment, adherence and retention are keys to achieving optimum outcomes and maximizing the cost-effectiveness of antiviral therapy.

FIGURE 2. The chronic viral hepatitis continuum



TARGET

- Member States develop country-specific screening, care and treatment milestones and targets for hepatitis B and C.

Objective 5.1 Access to and retention within the viral hepatitis treatment cascade

People living with chronic viral hepatitis can only be cured or have their risk of disease progression reduced through screening, diagnosis, care and effective antiviral treatment. Identifying high-risk subpopulations and implementing screening in these groups are key activities. Screening activities need to be linked to counselling, and care and treatment programmes. The process of identifying priority populations should include addressing barriers to screening, care and treatment, including the affordability of treatment.

High prices for new effective hepatitis medicines are a major impediment to access to treatment across the Region. While competition from antivirals entering the market will likely reduce prices in time, specific mechanisms may be employed now to address high prices. Systematic engagement of all stakeholders to work towards lower prices is fundamental to an accessible and effective viral hepatitis treatment cascade.

Each country will have unique barriers to treatment. For example, primary care providers in most countries are not equipped to treat and do not have access to medications. Capacity-building among such providers could enhance linkages to care. Providers should also be aware of the need to assess all infected people for chronic disease and for treatment. Partnerships and advocacy to reduce the cost of drugs will be needed. A phased approach is recommended towards introducing screening, diagnosis and treatment of hepatitis to determine service delivery models and financing strategies tailored to country-specific health systems, based on high-quality data. Actions will include support for access to screening, care and treatment for viral hepatitis by providing affected populations with access to affordable, effective care and antiviral therapy, where indicated. These actions will minimize loss along the screening, care, and treatment cascade continuum.

2016 MILESTONES

- Obtain baseline data for national hepatitis screening, care and treatment cascade.

2020 TARGETS

- 30% of the estimated population living with HBV/HCV are diagnosed.
- 50% of the eligible population for treatment begin treatment.
- 90% of those commenced on HBV or HCV treatment obtain viral suppression (HBV) or are cured (HCV).

ACTIONS RECOMMENDED FOR MEMBER STATES

1. Identify people infected with hepatitis B and C early:
 - a. Integrate viral hepatitis screening into health settings, where possible incorporating into HIV or related screening strategies (e.g. antenatal care, health-care settings, key populations).
 - b. Engage high-risk populations¹ in appropriate and targeted screening programmes, e.g. HIV-infected individuals, key populations and prisoners.
2. Ensure screening is directly linked to staging and treatment programmes:
 - a. Include provision of testing results and staging disease in hepatitis testing².
 - b. Ensure direct contact between hepatitis screening initiatives and antiviral hepatitis treatment programmes so that eligible patients are offered treatment.
 - c. Link existing services and programmes – e.g. maternal and child health, HIV, substance use or noncommunicable diseases – to hepatitis screening and care.
 - d. Link liver cancer screening initiatives to viral hepatitis programming, focusing on individuals with advanced liver disease at high risk of liver cancer.
3. Increase access to effective antiviral treatment for affected populations:
 - a. Ensure access to antiviral therapy for hepatitis B and C in the public sector.
 - b. Adapt viral hepatitis care models from countries with programmes.
 - c. Ensure national treatment guidelines are developed through community consultation and are consistent with WHO guidelines and recommendations.
 - d. Promote adherence to WHO guidelines by providing training in these guidelines and related screening, care and treatment for health-care workers.
 - e. Develop demonstration initiatives for integrated screening, care and treatment in high-burden, high-capacity areas:
 - ensure demonstration initiatives include community-based viral hepatitis care (pilot and/or demonstration projects, testing, counselling, vaccination and treatment);
 - integrate hepatitis screening into health service provision and other settings that serve at-risk populations;
 - identify barriers to access to diagnosis, management and treatment; and
 - take action to ensure equitable access for all those affected.
 - f. Plan for phased implementation of screening, diagnosis and treatment initiatives.
 - g. Ensure affordability of private sector treatment provision through adequate oversight.

1. Key populations for hepatitis infection include migrant populations (domestic and international), PWID, men who have sex with men, sex workers and transgender people, although these may be country specific and include health workers. Additional epidemiological studies may be required to identify these populations.

2. By non-invasive means, e.g. APRI or FIB-4 biochemical algorithms.

4. Monitor and evaluate country-specific viral hepatitis treatment cascades:
 - a. Identify key indicators, adopted or adapted from WHO key indicators, to measure success across the viral hepatitis screening, care and treatment cascade.
 - b. Identify access barriers and factors associated with retention and loss to follow-up along the viral hepatitis cascade.
 - c. Develop country-specific indicators for the number of people living with hepatitis B and C and for treatment uptake at the national and subnational levels.
 - d. Perform a country-specific analysis of access to treatment and develop cost-effectiveness and economic analyses on the cost of the burden of disease, e.g. hepatocellular carcinoma (HCC), cirrhosis and treatment.

5. Make available safe, affordable quality diagnostics and medicines to support antiviral therapy:
 - a. Initiate dialogue with stakeholders, e.g. pharmaceutical industry and major external funders, including the Global Fund to Fight AIDS, Tuberculosis and Malaria, to improve access to affordable medicines.
 - b. Ensure the intellectual property environment fosters development of and facilitates access to affordable medicines and diagnostics, recognizing the Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities.
 - c. Explore different mechanisms to achieve the best price for medicines and diagnostics, including TRIPS flexibilities and where appropriate consistent with the WHO's *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*, coordinating procurement between treatment providers to maximize procurement volume and reduced prices.
 - d. Facilitate transparent and accountable distribution chains to improve access in public and private markets.
 - e. Rationalize diagnostics with available resources by coordinating diagnostic procedures across providers, e.g. polymerase chain reaction (PCR) confirmation only is available centrally, whereas rapid test antigen or antibody testing can occur in peripheral facilities.

WHO SUPPORTING ACTIONS

1. Develop and disseminate WHO viral hepatitis testing guidance, and emphasize the integration of recommended hepatitis screening and testing strategies into existing programmes:
 - a. Support the efforts of countries to adapt the WHO hepatitis surveillance guidelines to the local epidemiological and socioeconomic context.
 - b. Support advocacy efforts, including in communities, to increase hepatitis testing uptake among key populations and individuals with severe liver disease who may require immediate treatment.

- c. Support countries to validate testing algorithms for viral hepatitis.
 - d. Support countries to require the use of pre-qualified hepatitis testing kits to optimize testing strategies among affected populations.
2. Develop guidance on recommended interventions and programme considerations to optimize engagement and retention of individuals in the screening, care and treatment cascade:
 - a. Support hepatitis programme and service provision integration to reduce costs and increase programme efficiency.
3. Support the development of national hepatitis clinical guideline documents, adapted from or aligned with WHO-recommended hepatitis B and C treatment guidance.
4. Support the development of demonstration screening, care and treatment initiatives in high-burden, high-capacity areas:
 - a. Work with countries to identify potential sites for demonstration initiatives.
 - b. Provide technical assistance to optimize the effectiveness of the initiatives.
 - c. Support robust monitoring and evaluation of these initiatives to inform broader phased roll-out.
5. Support the efforts of countries to access affordable diagnostics and antiviral medicines:
 - a. Provide advice on intellectual property issues regarding antiviral medications, including TRIPS flexibilities.
 - b. Facilitate collaborative regulatory procedures, such as WHO pre-qualification mechanisms, in particular for generic medicine manufacturers.
 - c. Provide technical advice on joint procurement mechanisms and access to generic antiviral medicines.

Major challenges for reaching these targets:

- No baseline data
- Resource constraints
- Infrastructure constraints
- Inadequate awareness
- High cost for diagnostics and drugs
- Stigma and discrimination

ANNEX 1. Table of actions

PRIORITY AREA	OBJECTIVE	ACTIONS RECOMMENDED FOR MEMBER STATES	WHO SUPPORTING ACTION
1. Broad-based advocacy and awareness	1.1 Empower communities and providers by increasing awareness about viral hepatitis	1. Develop a multisectoral national hepatitis task force	1. Develop hepatitis communications guidance
		2. Support formation and mobilization of national patient group	2. Engage patient and affected population groups
		3. Integrate viral hepatitis prevention and treatment into health professional training	3. Support the development of hepatitis-literate health workforces
		4. Recognize and carry out hepatitis activities on World Hepatitis Day	4. Develop World Hepatitis Day toolkit to support Member States' activities
2. Evidence-informed policy guiding a comprehensive and coordinated hepatitis action	2.1 A national action plan	1. Develop a comprehensive national hepatitis action plan	1. Provide technical assistance to develop national hepatitis action plans
		2. Mobilize resources for action on viral hepatitis	2. Address HIV/hepatitis coinfection 3. Identify and work with potential donors 4. Strengthen regulatory and procurement issues
3. Data supporting the hepatitis response	3.1 National disease burden estimates and investment case	1. Develop national estimates of disease and treatment burden for viral hepatitis and HIV–hepatitis coinfections	1. Support the development and consensus building on national estimates of the disease and treatment burden
		2. Develop a country-specific investment case for action on hepatitis	2. Support the identification of country-specific priority groups for testing and treatment
		3. Achieve stakeholder consensus on data	3. Support the development of a national investment case for comprehensive hepatitis B and C action
		4. Identify country-specific priority groups for testing and treatment based on local epidemiology and liver disease patterns	4. Work with countries to undertake a national or subregional assessment of current capacity for a comprehensive hepatitis response
	3.2 Standardized surveillance and data collection activities	1. Coordinate viral hepatitis surveillance utilizing existing infrastructure	1. Provide technical support to Member States to collate viral hepatitis data sources
		2. Adapt or adopt WHO viral hepatitis surveillance guidelines	2. Develop a toolkit for surveillance activities, including recommended key indicators
		3. Develop domestic laboratory network for viral hepatitis, linked to a regional laboratory network	3. Support the development of a regional laboratory network
		4. Adopt standardized testing algorithms for viral hepatitis surveillance, blood safety and diagnosis	4. Support the establishment and maintenance of robust EQAS and QMS mechanisms for domestic hepatitis laboratories.
		5. Triangulate viral hepatitis data reporting system with immunization and liver disease reporting	5. Support the use of pre-qualified viral hepatitis test kits in domestic laboratories
			6. Support the dissemination and adaptation of WHO viral hepatitis surveillance guidelines
			7. Develop and disseminate screening and testing guidance

PRIORITY AREA	OBJECTIVE	ACTIONS RECOMMENDED FOR MEMBER STATES	WHO SUPPORTING ACTION
3. Data supporting the hepatitis response (continued)	3.3 Research	<ol style="list-style-type: none"> Promote regional research and partnership in viral hepatitis Promote and support viral hepatitis research 	<ol style="list-style-type: none"> Bring together researchers and policy-makers to foster the development of evidence to inform policy Identify key gaps in hepatitis research and support collaborations
	4. Stopping transmission	<p>4.1 Elimination of chronic hepatitis transmission</p> <ol style="list-style-type: none"> Hepatitis B control through immunization: <ul style="list-style-type: none"> achieve high coverage (95%) with a timely birth dose and the three-dose infant vaccination series implement health-worker hepatitis B vaccination policies ensure regular supply of vaccine and quality vaccine management conduct necessary communication and advocacy for hepatitis B vaccination conduct high-quality performance monitoring and measurement of impact through periodic serosurveys <p>4.2 Health-care-associated transmission</p> <ol style="list-style-type: none"> Ensure safe blood supply including appropriate indications for use Reduce viral hepatitis transmission in health-care settings <p>4.3 Full participation in harm-reduction measures</p> <ol style="list-style-type: none"> Minimize hepatitis C transmission among PWID through the provision of effective high-intensity harm-reduction interventions 	<ol style="list-style-type: none"> Support Member States to achieve hepatitis B control through immunization: <ul style="list-style-type: none"> provide technical support to collate and manage HBV immunization data sources and conduct surveys; provide regional normative guidance for hepatitis B control; identify and support countries to implement effective strategies for increasing hepatitis B vaccination coverage; and coordinate the process of verifying achievement of the regional goal including country-level verifications by an independent expert resource panel and estimations of the impact of vaccination at the regional level Support safe blood supply in Member States Support strengthening infection prevention and control in health-care settings Support Member States to implement and maintain effective high-intensity harm-reduction interventions for PWID
5. An accessible and effective treatment cascade	5.1 Access to and retention within the viral hepatitis treatment cascade	<ol style="list-style-type: none"> Identify people infected with hepatitis B and C early Link hepatitis screening to staging and treatment programmes Increase access to effective antiviral treatment for affected populations Monitor and evaluate country-specific viral hepatitis treatment cascades Make available safe, affordable quality diagnostics and medicine 	<ol style="list-style-type: none"> Develop and disseminate WHO viral hepatitis testing guidance, and emphasize the integration of recommended hepatitis screening and testing strategies into existing programmes Develop guidance for hepatitis programming to optimize engagement and retention in the hepatitis treatment cascade Support the development of national hepatitis clinical guideline documents, adapted from or aligned with WHO-recommended hepatitis treatment guidance. Support the development of demonstration screening, care and treatment initiatives in high-burden, high-capacity areas Support the efforts of countries to access affordable diagnostics and antiviral medicines

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