

Regional Action Plan for Viral Hepatitis in the Western Pacific

Draft for virtual consultation

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

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VISION

A 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 goal of the Western Pacific Regional Action Plan for Viral Hepatitis is:

- 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.

INTRODUCTION

BACKGROUND

CHRONIC 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). Viral hepatitis is the 8th highest cause of mortality globally, approximately 48% from HBV, 48% from HCV, and the remainder from acute hepatitis A and E.

Mortality from viral hepatitis in the Western Pacific Region is now higher than that of HIV, tuberculosis and malaria combined. Compared with other geographical 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 accounting for more 1500 deaths every day, 94% from chronic hepatitis B and C – shared equally.

The consequences of chronic hepatitis B and C infection which are cirrhosis (end-stage liver fibrosis) 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. China alone accounts for over 50% of the global liver cancer burden. To date, the majority of liver cancer can be prevented through available effective prevention and treatment of hepatitis B and C.

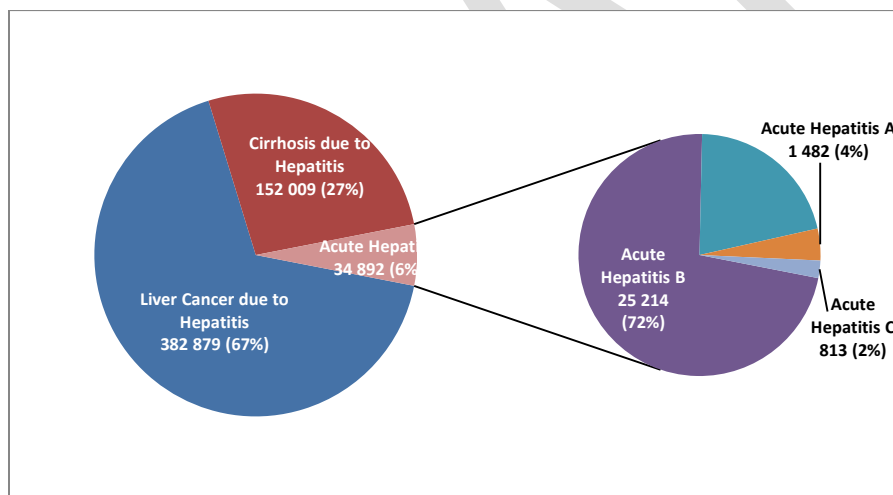


Figure 1 - Mortality from viral hepatitis in the Western Pacific Region in 2013¹

The epidemiology of HIV and hepatitis is closely related to shared transmission routes. HIV-hepatitis coinfection is associated with more rapid progression of liver-related disease and poor outcomes in HIV and interferon-based hepatitis treatment. While the burden of HBV infection in HIV is similar to the population burden of HBV, the burden of HCV in specific HIV infected key populations, such as people who inject drugs, is over 90% in a number of countries.

ACTION ON VIRAL HEPATITIS TO DATE

¹ 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. *Lancet*. 2015 Jan 10;385(9963):117-71.

The Western Pacific Region has seen recent success in action on viral hepatitis. In 2005, the WHO Western Pacific Region became the first WHO Region to have infant hepatitis B immunization included in the national immunization programs 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 < 2% among children at least 5 years of age by 2012 and to < 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 twelve countries have already reached the 2017 goal.

Despite this success in vaccination, 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 these individuals, 15 – 25% will, without treatment, die from complications associated with chronic hepatitis B. In addition, there is no vaccine for hepatitis C. Furthermore, in many countries, low levels public health investment in a comprehensive response to viral hepatitis contrasts sharply to substantial funding to fight HIV/AIDS and tuberculosis, despite the often higher burden of hepatitis-related disease and mortality.

The World Health Assembly has now issued two resolutions regarding viral hepatitis - (63.9 in 2010) and (67.6 in 2014). These call for Member States to develop and implement coordinated multisectoral national strategies for preventing, diagnosing, and treating viral hepatitis based on the local epidemiological context, among other activities, and for the World Health Organization to support these efforts. To date, while several countries in the Region have developed comprehensive national hepatitis strategies, there has been no coordinated regional response to this burden of viral hepatitis, related liver disease and consequent morbidity and mortality.

In response, the Global Hepatitis Program (GHP) launched the *Prevention and Control of Viral Hepatitis: A Framework for Global Action* in 2012. The four axes of the WHO 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).

In 2014, the Global Hepatitis Programme released *Guidelines for the screening, care and treatment of persons infected with hepatitis C* and *Waterborne outbreaks of hepatitis E: recognition, investigation and control* followed by the *Guidelines for the prevention, care and treatment of persons with chronic hepatitis B infection* in 2015.

For HIV – hepatitis coinfection, the *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection* recommended immediate initiation of antiretroviral therapy in HIV-HBV coinfecting individuals with severe liver disease regardless of CD4 count. While HIV-hepatitis 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.

THE GLOBAL HEALTH SECTOR STRATEGY FOR VIRAL HEPATITIS

The Global Health Sector Strategy for Viral Hepatitis 2016–2021 was drafted in response to WHA resolution 67.6 and intends to position the viral hepatitis response in the post-2015 health and development agenda. The strategy builds on the WHO Framework for Global Action on Prevention and Control of Viral Hepatitis Infection. Through the three dimensions of universal health coverage², the strategy aims to define the essential services and interventions that people should receive, as well as identify measures that can be taken to assure 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.

² The three universal health care dimensions are equity (inclusiveness), services (prevention, treatment, rehabilitation), and financial protection (from health care associated costs).

The Global strategy, based on universal health coverage framework, 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 to date, establishing the foundation for success over the next six years. Noting Member States varying economic and infrastructure contexts, as resources, efficiencies, and capacity increase, the range of services provided can be expanded, with improved quality, and cover more populations with fewer direct costs to those who need the services – a progressive realization towards universal health coverage.

A REGIONAL HEPATITIS ACTION PLAN

The Global Health Sector Strategy on Viral Hepatitis (GHSSVH) is an overarching framework, which provides a series of strategic directions covering high level key domains in the viral hepatitis response³.

This Regional Action Plan for Viral Hepatitis is a five year plan seeking to provide concrete, prioritized, and actionable items for consideration by countries. In addressing the national burden of viral hepatitis, with a focus on chronic hepatitis B and C, which account for the vast majority of mortality burden in the Region.

This Regional Action Plan for Viral Hepatitis seeks to support of Member States' efforts in the development of comprehensive hepatitis strategies and to build on regional success in hepatitis B immunization in the Western Pacific. Implementation of recommended **Member State Actions supported by WHO actions aims to achieve consensus targets**.

Regional Action Plan for Viral Hepatitis priority area	Corresponding Global hepatitis health sector strategy strategic direction
Broad-based advocacy and awareness	Creating an enabling environment for greater impact (cross cutting)
Evidence informed policy guiding a comprehensive hepatitis action	Information for focus (SD1) Finance for sustainability (SD4)
Data supporting the hepatitis response	Interventions for impact (SD2) Information for focus (SD1) Delivering for equity (SD3)
Stopping transmission	Information for focus (SD1) Delivering for equity (SD3) Innovation for acceleration (SD5)
An accessible and effective treatment cascade	Information for focus (SD1) Interventions for impact (SD2) Innovation for acceleration (SD5)

PURPOSE AND FOCUS OF THE ACTION PLAN

³ The Global Health Sector Strategy on Viral Hepatitis is currently available for consultation at <http://www.who.int/hiv/proposed-hep-strategy2016-2021/en/>

This is an actionable framework aimed at providing tangible implementation pathways at the country and regional level.

Purpose:

The Regional Action Plan for Viral Hepatitis has the purpose to address the tremendous burden of morbidity and mortality from viral hepatitis, by providing guidance priority activities, for countries to address hepatitis beyond success in hepatitis B immunization.

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

Focus:

The focus of this action plan is chronic hepatitis B and C, as the vast majority of morbidity and mortality from viral hepatitis is associated with chronic hepatitis B and C infections.

TARGETS AND MILESTONES

REGIONAL

Regional milestones and targets are intended to be nearer term targets than the 2030 Global Health Sector Strategy for Viral Hepatitis.

Table 1 - Regional Hepatitis milestones and targets

These milestones and targets should be considered as the minimal set of milestones and targets. Noting intercountry variability in viral hepatitis epidemiology, context and response, specific national milestones and targets may vary.

Policy, advocacy and finance

Milestones (2017)	Targets (2020)
<ul style="list-style-type: none"> Initiative specific advocacy activities which go beyond recognition of World Hepatitis Day in increasing awareness 	<ul style="list-style-type: none"> Report card on specific awareness and advocacy activities carried out
<ul style="list-style-type: none"> A national disease burden and investment case estimate 	<ul style="list-style-type: none"> A costed and funded national hepatitis plan with clear targets
<ul style="list-style-type: none"> National taskforce established with designated focal point within MoH with representation from affected communities 	

Data and Surveillance

Milestones (2017)	Targets (2020)
<ul style="list-style-type: none"> WHO viral hepatitis surveillance guideline adapted to local context Laboratory or clinical reporting mechanisms 	<ul style="list-style-type: none"> Member States to have a National hepatitis infection and disease surveillance program that could inform disease burden estimates

established	
<ul style="list-style-type: none"> National hepatitis reference laboratory established 	<ul style="list-style-type: none"> Hepatitis surveillance linked to existing liver cancer registry, treatment registry, immunization data and vital statistics registry
<ul style="list-style-type: none"> Regional laboratory network established 	

Prevention

	Milestones (2017)	Targets (2020)
Immunization	<ul style="list-style-type: none"> Achieve prevalence of HBsAg in 5 year olds of < 1%* 	<ul style="list-style-type: none"> In countries that have achieved <1% in children under 5 years, reduce mother-to-child transmission to less than 2%
	<ul style="list-style-type: none"> Achieve Birth dose hepatitis B vaccination coverage of at least 95%* Achieve 3 dose hepatitis B vaccination coverage of at least 95%* 	
	<ul style="list-style-type: none"> National policy of vaccinating health care workers against hepatitis B established in >80% of countries 	<ul style="list-style-type: none"> National policy of vaccinating health care workers, medical/health students against hepatitis B established in all countries Hepatitis B vaccinations integrated into HIV, harm reduction, and STI services
Health sector transmission		<ul style="list-style-type: none"> Safe injection policies for prevention of health sector hepatitis B and C transmissions established in all countries
High risk adult populations	<ul style="list-style-type: none"> Countries with populations of PWID have policies supporting harm reduction programmes including NSP and OST 	<ul style="list-style-type: none"> Countries with harm reduction programs access 60% of PWID with comprehensive package of harm reduction services and 50% of people dependent on drugs with substitution treatment

* already agreed to in Resolutions WPR/RC54.R3, WPR/RC64.R5

Screening, care and treatment

Note for both of hepatitis B and C **each country to develop country specific screening care and treatment milestones and targets**

	Milestone (RAHVH ⁴)	Target (RAPVH ¹)	Target (GHSSVH ⁵)
	2016	2020	2030
Screening/testing/diagnosed	Obtain baseline data for National hepatitis screening care and treatment cascade	30% of the estimated population living with HBV/HCV are diagnosed	90 %
Eligible treatment	Obtain baseline data as above	50% of the <i>eligible</i> ** population for treatment are commenced on treatment	90 %
Viral suppression (HBV) / cure (HCV)	Obtain baseline data as above	90% of those commenced on HBV or HCV treatment obtain viral suppression (HBV) or cure (HCV)	90 %

** initial estimates In the Western Pacific are that 10 – 30% of people living with chronic viral hepatitis B or C would fulfil eligibility criteria according to WHO recommendations, although for hepatitis C, eligibility varies depending on resource constraints. i.e. The eligible population for treatment is estimated to be ~ 3 – 10% of the estimated population living with chronic hepatitis B or C.

GLOBAL

The following are the proposed (draft) GHSSVH targets⁶:

Table 2 - Global hepatitis proposed (draft) milestones and targets

	2020	2030
Expand and enhance services		
HBV vaccination	<ul style="list-style-type: none"> Greater than 90% coverage in infants 50% coverage in healthcare workers 	<ul style="list-style-type: none"> 90% coverage in healthcare workers
HBV birth dose vaccination	<ul style="list-style-type: none"> 80% coverage 	
Blood safety		<ul style="list-style-type: none"> Zero new infections due to unsafe

⁴ Regional Action Plan for Viral Hepatitis in the Western Pacific

⁵ Global Health Sector Strategy for Viral Hepatitis, inserted here for reference only.

⁶ Taken from the Global Health Sector Strategy on Viral Hepatitis is currently available for consultation at <http://www.who.int/hiv/proposed-hep-strategy2016-2021/en/>

Safe medical practices	<ul style="list-style-type: none"> • 75% reduction in new infections due to unsafe medical practices 	blood transfusions
Harm reduction services	<ul style="list-style-type: none"> • 50% of people who inject drugs reached 	
HBV and HCV diagnosis		<ul style="list-style-type: none"> • 90% of chronic hepatitis diagnosed
HBV and HCV treatment		<ul style="list-style-type: none"> • 90% of eligible treated • 90% treated are virally suppressed (HBV) or cured (HCV)
Reduce new infections		
New HBV infections	<ul style="list-style-type: none"> • 20% reduction 	<ul style="list-style-type: none"> • 90% reduction
New HCV infections	<ul style="list-style-type: none"> • 50% reduction 	<ul style="list-style-type: none"> • 70% reduction
Mother-to-child transmission of HBV		<ul style="list-style-type: none"> • 95% reduction
Reduce deaths		
HBV-related deaths		<ul style="list-style-type: none"> • 60% reduction
HCV-related deaths		<ul style="list-style-type: none"> • 60% reduction

TIMELINE

The Region Action Plan for Viral Hepatitis is a five year plan.

DEVELOPMENT OF THE PLAN

The World Health Assembly has endorsed two resolutions regarding viral hepatitis in 2010 (WHA63.18) and 2014 (WHA67.6). These call for Member States to develop and implement multisectoral national strategies for preventing, diagnosing, and treating viral hepatitis based on the local epidemiological context, among other activities, and for the World Health Organization to support these efforts.

This plan 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 attended by experts from eight countries. Following a preliminary draft of the Regional Action Plan, consultation and feedback from regional experts and affected communities was sought to revise the preliminary draft after feedback.

Recommendations for priority activities were based on regional immunization targets, gaps in existing programs and resources covering these activities, and the burden of disease in certain settings and sub-populations. 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 WHO Global Viral Hepatitis Programme.

This draft Regional Action Plan for Viral Hepatitis is the primary focus of the initial Member State consultation on the draft Regional Action Plan for Viral Hepatitis in the Western Pacific.

Should this Regional Action Plan for Viral Hepatitis receive Member State endorsement, following endorsement of this Action Plan, a mid-term review is proposed. At the conclusion of the Action Plan, an end-term review is proposed.

PRIORITY AREAS AND ACTIONS

1. BROADBASED ADVOCACY AND AWARENESS

"BREAKING THE SILENCE"

1.1 EMPOWER COMMUNITIES AND PROVIDERS BY DECREASING IGNORANCE ABOUT VIRAL HEPATITIS

Strategic objective: Undertake public and provider awareness education and training campaigns in viral hepatitis. Targeted awareness building among public health policy and decision makers.

RATIONALE

With the exception, perhaps, of HBV immunization, viral hepatitis infection and liver disease, prevention and treatment literacy is low among the general community, the affected populations, providers, and policymakers in many parts of the Region.

In order to achieve success in responding to viral hepatitis, communities, health service providers, and their Governments must be aware of the extent of countries' and communities' hepatitis epidemics and the health consequences of viral hepatitis infection and related liver disease.

TARGET

Recognize and carry out activities on World hepatitis day

Milestones (2017)	Targets (2020)
<ul style="list-style-type: none"> Initiative specific advocacy activities which go beyond recognition of World Hepatitis Day in increasing awareness 	<ul style="list-style-type: none"> Report card on specific awareness and advocacy activities carried out
<ul style="list-style-type: none"> National taskforce established with designated focal point within MoH with representation from affected communities 	<ul style="list-style-type: none">

MEMBER STATE RECOMMENDED ACTIONS:

1. Develop a multi-sectorial 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, researchers, media, civil society, and the affected community.

- 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. In addition, 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 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 on World Hepatitis Day** and beyond
 - a. Conduct high quality public and provider awareness building, service announcements, and activities each World Hepatitis Day
 - b. Ensure advocacy and awareness building activities for hepatitis occur beyond World Hepatitis Day

WHO SUPPORTING ACTIONS

1. Develop communications guidance to support Member States action on building community and provider awareness of viral hepatitis and its health consequences, including dissemination of this Regional Action Plan for Viral Hepatitis.
2. Engage patient and affected population groups to actively participate in WHO consultations and Regional guidance development
3. Develop World Hepatitis Day toolbox developed annually for use in countries. The tool box is a suite of measures are provided all of which can be developed to various levels of complexity depending on resource availability in Member States.
4. Align, where possible, major hepatitis policy and disease burden estimate announcements with World Hepatitis Day (July 28).

2. EVIDENCE INFORMED POLICY GUIDING COMPREHENSIVE HEPATITIS ACTION

"COORDINATED ACTION"

2.1 A NATIONAL ACTION PLAN

RATIONALE:

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 coordinated and, where possible, integrated policy framework supporting evidence informed and cost-effective programmatic responses. The development and maintenance of efficient hepatitis programs is dependent on the early identification of secure and sustainable funding mechanisms.

TARGET:

Milestones (2017)	Targets (2020)
	<ul style="list-style-type: none"> A costed and funded national hepatitis plan with clear targets

MEMBER STATE RECOMMENDED ACTIONS:

1. **Develop a comprehensive National Hepatitis Action Plan** in partnership with key stakeholders, including affected communities
 - a. It is recommended that all Member States establish a taskforce (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 Hepatitis Action Plan, developed through a consensus based process, including ongoing involvement of affected communities, should then provide the cornerstone for guiding national responses to viral hepatitis and HIV – hepatitis coinfections. This 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 also sub-national levels) to coordinate all viral hepatitis and HIV-hepatitis coinfection related activities as well as the development and implementation of national action plan addressing awareness, surveillance, prevention.

- f. Regular high-level meetings should be held between representatives of all sections of Government relating to viral hepatitis policy, such as infection control, harm reduction and drug policy, food, water and blood safety, HIV, immunization, and cancer.
- g. Addressing 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. Ensuring 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 National health budget to viral hepatitis prevention, care, and treatment in proportion to countries' and communities' disease burden, including the context of HIV-hepatitis coinfections. This may be better directed at augmenting existing front-line services where available.
- b. Join together, where appropriate, hepatitis with HIV programs to address co-infection and optimize 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 pharmaceutical industry, influential global donor, patient advocacy groups, professional societies, and others) explore opportunities to increase access to affordable hepatitis medications

WHO SUPPORTING ACTIONS

1. Actively support the development of National Hepatitis Action Plans by providing technical assistance in the development of National Action Plans and supporting the engagement of countries' in Regional and Global policy initiatives.
2. Work with Member States to address hepatitis coinfection through HIV programming and vice versa.
3. Actively 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 use of limited country resources
4. Provide National planners with support to strengthen regulatory and procurement issues in hepatitis planning, including collaborative registration processes such as WHO prequalification procedures, pharmacovigilance, and pooled procurement mechanisms

3. DATA SUPPORTING THE HEPATITIS RESPONSE

"UNDERSTAND YOUR EPIDEMICS"

3.1 NATIONAL DISEASE BURDEN ESTIMATES AND INVESTMENT CASE

RATIONALE

In order to support budget allocation and attract investment to effect policy supporting a comprehensive programmatic response to hepatitis, the disease burden of viral hepatitis and viral hepatitis HIV coinfections must be established, together with a costed proposed policy response.

TARGET

Milestones (2017)	Targets (2020)
<ul style="list-style-type: none"> A national disease burden and investment case estimate 	

MEMBER STATE RECOMMENDED ACTIONS:

1. Develop **National estimates of disease and treatment burden** for viral hepatitis and HIV-hepatitis coinfections. Initial focus should be on chronic hepatitis B and C (and D, if relevant).
 - a. These estimates should use existing disease burden models, adapted to the local epidemiology context.
 - b. The process of deriving estimates should include a consensus building consultation to ensure key stakeholders are in agreement with National disease burden estimates.
 - c. The National treatment burden for chronic hepatitis B and C should be calculated based on National or WHO hepatitis treatment eligibility criteria, using high quality local data.
 - d. Identify gaps in knowledge of disease burden and accordingly develop an operational research agenda to address gaps
2. Develop a **country specific investment case** for action on hepatitis.
 - a. Initial focus should be chronic hepatitis B and C, informed by the local epidemiological context
 - b. The investment case should include:
 - i. Agreed National estimates of disease and treatment burden
 - ii. Various care packages, 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. Epidemiologic profiles should be developed for high risk groups for both incident infections and for the outcomes of chronic infection

WHO SUPPORTING ACTIONS:

1. **Support the development of National estimates of disease and treatment burden** through
 - a. The provision of technical support to assist in developing robust data inputs to estimate hepatitis disease burden
 - b. Supporting consensus building on National estimates of disease burden through stakeholder consultation with community engagement
 - c. Supporting the development of plans for/Implement continual data gathering and validation to maintain up-to-date estimates
2. **Provide support to 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 sub-regional assessment of current capacity** for a comprehensive hepatitis response, including the public health sector response and the role of the private sector

3.2 STANDARDIZED SURVEILLANCE AND DATA COLLECTION ACTIVITIES

RATIONALE

In much of the Western Pacific Region, there is limited or no data on the extent of viral hepatitis epidemics and consequent liver disease. An effective surveillance system is fundamental to understanding hepatitis epidemiology in real-time and informing programmatic responses and needs to be tailored to the local epidemiological context. Targeted programmatic monitoring and robust evaluation provide a strong feedback mechanism to improve programmatic effectiveness and efficiency.

TARGET

Milestones (2017)	Targets (2020)
<ul style="list-style-type: none"> • WHO viral hepatitis surveillance guideline adapted to local context • Laboratory or clinical reporting mechanisms established 	<ul style="list-style-type: none"> • Member States to have a National hepatitis infection and disease surveillance program that could inform disease burden estimates
<ul style="list-style-type: none"> • National hepatitis reference laboratory established 	<ul style="list-style-type: none"> • Hepatitis surveillance linked to existing liver cancer registry, treatment registry, immunization data and vital statistics registry
<ul style="list-style-type: none"> • Regional laboratory network established 	

MEMBER STATE RECOMMENDED ACTIONS:

1. **Coordinate viral hepatitis surveillance utilizing 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.
 - i. The case reporting system should minimize additional workload and utilize standard case definitions nationally and between countries.
 - ii. Unique identifiers should be used, where available, to allow deduplication
 - iii. Both negative and positive tests should be reported.
 - iv. Where possible, link to existing reporting systems
 - c. Strengthen laboratory's role in public health surveillance and response to outbreaks and changes in infection and disease epidemiology
 - d. Centralise 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** to the domestic context, to ensure standard case definitions nationally and between countries.
 3. Develop domestic **laboratory network for viral hepatitis**, linked a to regional laboratory network
 - a. Establish WHO EQA for hepatitis network labs
 - b. Designate one national reference laboratory (QMS, domestic EQAS)
 - i. The reference laboratory should oversee domestic EQAS and provide QMS including community-based facilities using rapid tests.
 - ii. The reference laboratory should participate in a WHO accreditation program
 - c. Domestic hepatitis test kit validation process or linkage to an WHO endorsed external test validation process
 4. **Adopt standardized testing algorithms** for viral hepatitis surveillance, blood safety, and diagnosis.
 5. Triangulation of 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 but not limited to 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 exist viral hepatitis data sources** to establish:
 - a. Gaps and priorities in current surveillance data for viral hepatitis
 - b. Existing disease reporting and surveillance systems that may also be utilized for viral hepatitis surveillance
 - c. Through building capacity, systems for viral hepatitis surveillance, moving towards centralized test reporting
2. **Develop a tool kit 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 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 surveillance, screening, and testing guidance** to support standardized algorithms for detection and diagnosis of viral hepatitis

3.3 RESEARCH

RATIONALE

There remain substantial gaps in our understanding of hepatitis, particularly for epidemiology of hepatitis and related liver disease and cancer in the Western Pacific and 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.

MEMBER STATE RECOMMENDED ACTIONS:

1. **Promote regional research and partnerships in viral hepatitis**
 - a. Designate Centers of Excellence in viral hepatitis research and training, where indicated
 - 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 program 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.
 - a. Including translation and implementation science research agendas

4. STOPPING TRANSMISSION

4.1 ELIMINATION OF CHRONIC HEPATITIS TRANSMISSION

RATIONALE

Universal infant immunization with three doses of hepatitis B vaccine, with the first dose provided within 24 hours of birth, is the most cost-effective 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.

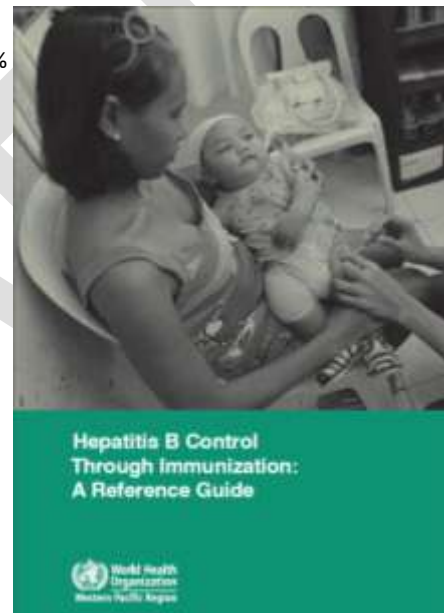
In 2003, the fifty-fourth session of the WHO Regional Committee for the Western Pacific set a goal to reduce the prevalence of chronic hepatitis B infection among 5-year-old children to < 1% (WPR/RC54.R3) in 2005 an interim milestone of reducing chronic HBV infection among children to < 2% by 2012 was established (WPR/RC64.R5) – the first region to do so. By 2012, the Region, as a whole and 30 countries and areas, were estimated to have met the milestone. Striving to build upon these gains, in 2013, the sixty-fourth session of the WHO Regional Committee for the Western Pacific has now resolved to meet the goal of reducing chronic HBV infection to < 1% among 5-year-old children by 2017 (WPR/RC64.R5). Achievement of this goal will translate to an additional 60,000 hepatitis B-related deaths averted per birth cohort in the Region.

Thirty out of 37 countries and areas have reached the 2012 milestone. Eleven countries have even 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 elimination of mother-to-child-transmission of HIV and congenital syphilis and hepatitis B control targets. Adoption of the target of the elimination of chronic hepatitis B transmission aligns the Region with these countries' policies and the GHSSVH targets.

Healthcare acquired HCV infection 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 utilizing injection equipment, such as tattoos and acupuncture. High rates of HCV transmission among people who inject drugs and within closed settings (such as prisons) are of particular concern across the Western Pacific.

To date, while transmission of hepatitis C in health care settings is likely substantially reduced in the Western Pacific through improvement in blood screening programs, the use of single-use medical injections and general infection and control initiatives, prevalent infections are largely a consequence of health and para-health care related transmission during the 20th century. Effective harm reduction interventions are available in many jurisdictions in the Western Pacific; however, only full participation in harm reduction interventions⁷ is associated with reduction in HCV incidence, and full participation by PWID in harm reduction interventions is limited across the Region.



⁷ High intensity needle and syringe programs combined with therapeutic dosages of opioid substitution therapy.

TARGET

In line with the proposed GHSSVH, the countries of the Western Pacific undertake to eliminate the transmission of hepatitis resulting in chronic infection.

	Milestones (2017)	Targets (2020)
Immunization	<ul style="list-style-type: none"> Achieve prevalence of HBsAg in 5 year olds of < 1%* 	<ul style="list-style-type: none"> In countries that have achieved <1% in children under 5 years, reduce mother-to-child transmission to less than 2%
	<ul style="list-style-type: none"> Achieve Birth dose hepatitis B vaccination coverage of at least 95%* 	
	<ul style="list-style-type: none"> Achieve 3 dose hepatitis B vaccination coverage of at least 95%* 	
	<ul style="list-style-type: none"> National policy of vaccinating health care workers against hepatitis B established in >80% of countries 	<ul style="list-style-type: none"> National policy of vaccinating health care workers, medical/health students against hepatitis B established in all countries Hepatitis B vaccinations integrated into HIV, harm reduction, and STI services
Health sector transmission		<ul style="list-style-type: none"> Safe injection policies for prevention of health sector hepatitis B and C transmissions established in all countries
High risk adult populations	<ul style="list-style-type: none"> Countries with populations of PWID have policies supporting harm reduction programmes including NSP and OST 	<ul style="list-style-type: none"> Countries with harm reduction programs access 60% of PWID with comprehensive package of harm reduction services and 50% of people dependent on drugs with substitution treatment

* already agreed to in Resolutions WPR/RC54.R3, WPR/RC64.R5

MEMBER STATE RECOMMENDED ACTIONS:

Figure 2 - Hepatitis Control Through Immunization - a reference guide WPRO 2015⁸

The following recommended actions are detailed in the WPRO publication Hepatitis Control Through Immunization - a reference guide, except where indicated by ''.*

- 1 Hepatitis B control through immunization**
 - a. Vaccination of infants**
 - i. Strengthening of 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.
 1. Focus efforts on poor-performing districts and high-prevalence groups, identified through improved data collection, mapping and regular analysis of subnational/district-level coverage data.
 - ii. Delivery of 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.
 - iii. Coordination with maternal and child health programmes to improve access to immunization and other neonatal care interventions for births outside of health facilities.
 1. **Reaching every district (RED) strategy**
 2. Novel strategies to increase penetration of BD coverage including:
 - a. **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
 - b. **Ensure availability of vaccine and standing orders** for administration of birth dose in the delivery room or postnatal ward for all newborn infants.
 - c. **Work closely with PMTCT initiatives in HIV and STIs programmes***
 - b. Vaccination of priority adult population groups**
 - i. Immunization of high-risk population groups, including health workers, men who have sex with men, sex workers, people who inject drugs, frequent recipients of blood/plasma transfusions, and any other population groups coming in regular contact with blood and blood products.
 1. Consider rapid HBV vaccination regimens in people who inject drugs
 - ii. Advocating for national policies requiring free and universal hepatitis B vaccination of health-care workers.
 - c. Vaccine supply and quality**
 - i. Elimination of vaccine stock-outs at the national and district levels through improved training in vaccine management.
 - ii. Prevention of vaccine freezing through improved training in temperature monitoring.
 - iii. Promotion of use of controlled temperature chain for delivery of hepatitis B birth dose.
 - d. Advocacy and social mobilization**
 - i. Increasing awareness among decision-makers, health workers, and caretakers of the risks and consequences of HBV infection and the need for hepatitis B vaccination through:
 1. Community and civil society engagement,
 2. Use of media outlets,
 3. Education materials,
 4. Mass awareness campaigns such as World Hepatitis Day and World Immunization Week.

⁸ Available at http://www.wpro.who.int/hepatitis/hepatitis_resource_publication/ref_guide/en/

e. Measurement of programme performance and impact

- i. Measurement of programme performance through monitoring of immunization coverage rates, including establishment of systems to monitor hepatitis B birth dose coverage at the district level.
- ii. Impact measurement through hepatitis B surface antigen (HBsAg) seroprevalence surveys.
- iii. Verification

- 2 Ensuring **safe blood supply**, including appropriate indications for use
 - a. Support the implementation of the WHO Global Strategic Plan (2008-2015) for universal access to safe blood transfusion
 - b. Strengthen national blood product screening policies that include screening for HBV and HCV in blood and blood products, tissues, and organs
 - c. Reducing the use of blood products by addressing unnecessary use of blood products
 - d. Develop national transfusion service with full authority and responsibility to ensure safe blood supply integrated into national health system
- 3 Reduce transmission and strengthening infection control and **prevention measures for hepatitis in healthcare settings**
 - a. Improve understanding at all levels of the health system on the preventable causes of viral hepatitis transmission in health settings
 - b. Establishing or strengthening a National infection prevention and control regulating authority with the ability to:
 - i. Investigate infection outbreaks in healthcare settings
 - ii. 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
 - iii. Ensure correct sterilization procedures and medical waste management in both 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 re-use of such equipment
 - i. Reducing unnecessary injections in health facilities
 - d. Ensure adoption of standard precautions in all health facilities, including training in and monitoring of health care workers adherence to standard precautions
- 4 Minimizing hepatitis C transmission among people who inject drugs through the provision of effective high coverage and intensity **harm reduction** interventions
 - a. Effective opioid substitution therapy for opioid dependent individuals, including in closed settings
 - b. High intensity community and facility based needle syringe programs, including low dead space syringes
 - c. Ensuring people who use drugs have access to condoms
 - d. Set up infrastructure and service deliver models to reach persons who inject drugs to support easier access to hepatitis screening, care, and treatment;

WHO SUPPORTING ACTIONS

Figure 3 - Hepatitis Control Through Immunization - a reference guide WPRO 2015

The following recommended actions are detailed in the WPRO publication Hepatitis Control Through Immunization - a reference guide,, except where indicated by ''*

- 1 Hepatitis B Control Through Immunization**
 - a. **Provide technical support** to Member States to:
 - i. Collate existing hepatitis B data sources (vaccination and seroprevalence data)
 - ii. Improve hepatitis B vaccination coverage
 - iii. Conduct quality hepatitis B seroprevalence surveys
 - iv. Promote effective strategies for controlling hepatitis B through immunization
 - b. **Provide regional guidance for hepatitis B control** including:
 - i. Up-to-date information on effective strategies for controlling hepatitis B through immunization
 - ii. Advocacy material for promoting hepatitis B immunization
 - iii. Field guide for hepatitis B birth dose vaccination
 - iv. Guidelines for verifying achievement of the regional hepatitis B control goal
 - v. Recommendations and supporting documents for regional hepatitis B resolutions
 - vi. Assessing the place of antiviral therapy in preventing vertical transmission of HBV infection in pregnant women at higher risk of HBV transmission*
 - c. **Conduct operational research** to identify new effective strategies for increasing hepatitis B vaccination coverage
 - d. **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.
- 2 Support safe blood supply in countries** by:
 - a. Providing technical assistance to develop or strengthen national transfusion service with full authority and responsibility to ensure safe blood supply integrated into national health system including addressing blood screening capacity deficits to ensure universal screening of donated blood
 - b. Providing technical assistance to countries to reduce unnecessary use of blood products
- 3 Support infection prevention and control in health care settings** by:
 - a. Providing technical support to countries to develop and maintain appropriate regulatory structures for effective infection prevention and control within the health system
 - b. Providing technical support to outbreak investigation related to healthcare setting viral hepatitis transmission.
 - c. Promote implementation of safe therapeutic injection practices⁹
 - d. Promote implementation of WHO universal precautions and infection control guidelines^{10,11}
- 4 Support Member States to implement and maintain effective harm reduction interventions** for PWID by:

⁹ Best practices for injections and related procedures toolkit http://www.who.int/injection_safety/9789241599252/en/

¹⁰ Aide memoire: Infection control standard precautions in health care http://www.who.int/csr/resources/publications/4EPR_AM2.pdf and

¹¹ Essential environmental health standards in health care http://whqlibdoc.who.int/publications/2008/9789241547239_eng.pdf

- a. Providing evidence based guidance on recommended harm reduction interventions, including OST and NSP to countries, and supporting dissemination of these recommendations
- b. Advocating with Member States and key stakeholders to mobilize commitment and resources for evidence based public health polices to reduce viral hepatitis transmission, in particular hepatitis C, among people who inject drugs
- c. Providing technical support to countries to address barriers to implementation of effective harm reduction interventions and integrated health service provision to PWID.

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5. AN ACCESSIBLE AND EFFECTIVE TREATMENT CASCADE

“ACCESSIBLE TREATMENT”

Effective care and treatment of chronic viral hepatitis is illustrated by the continuum of care diagram (*the cascade*) below (figure 2). Each step is contingent upon the achievement and maintenance of the prior one. Early diagnosis is important in order to identify new cases and institute positive prevention programs, as well as timely initiation of treatment, where indicated. Following enrolment in care and treatment, adherence and retention are key to achieving optimum outcomes and maximizing the cost-effectiveness of antiviral therapy.

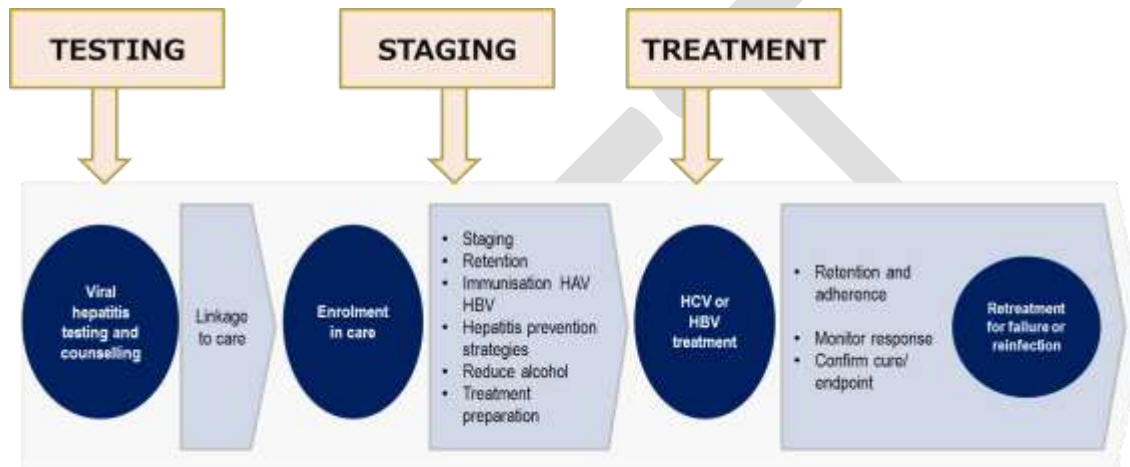


Figure 4 - the chronic viral hepatitis cascade

5.1 ACCESS TO AND RETENTION WITHIN THE VIRAL HEPATITIS TREATMENT CASCADE

RATIONALE

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 then implementing screening in these groups is a key activity. Screening activities need to be linked to counselling as well as care and treatment programs. The process of identifying priority populations should include addressing current barriers to screening, care, and treatment, including the affordability of treatment.

Each country will have unique barriers to treatment, which should be identified. 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 linkage to care as will provider education in the need to assess all infected persons for chronic disease and for treatment. Partnerships and advocacy to reduce the cost of the drugs will be needed. A phased approach towards introducing screening, diagnosis, and treatment of hepatitis to determine service delivery models and financing strategies tailored to country- specific health systems will be proposed, based on high quality country specific data is recommended.

TARGET

Support access to screening, care, and treatment for viral hepatitis by providing affected populations with access to affordable, effective care, and antiviral therapy, where indicated. Minimize loss along the screening, care, and treatment continuum.

Note for both of hepatitis B and C Member States **to develop country specific screening care and treatment milestones and targets**

	Milestone (RAHVH ¹²)	Target (RAPVH ¹²)	Target (GHSSVH ¹³)
	2016	2020	2030
Screening/testing/diagnosed	Obtain baseline data for National hepatitis screening care and treatment cascade	30% of the estimated population living with HBV/HCV are diagnosed	90 %
Eligible treatment	Obtain baseline data as above	50% of the <i>eligible</i> ** population for treatment are commenced on treatment	90 %
Viral suppression (HBV) / cure (HCV)	Obtain baseline data as above	90% of those commenced on HBV or HCV treatment obtain viral suppression (HBV) or cure (HCV)	90 %

** initial estimates are that 10 – 30% of people living with chronic viral hepatitis B or C would fulfil eligibility criteria according to WHO recommendations, although for hepatitis C, eligibility is variable depending on resource constraints. i.e. this is estimated to be ~ 3 – 10% of the estimated population living with chronic hepatitis B or C.

The major challenges for reaching these targets are:

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

MEMBER STATE RECOMMENDED ACTIONS:

1. **Early identification** of persons infected with hepatitis B and C
 - a. Integrate viral hepatitis screening into health settings, where possible incorporating into existing HIV or related screening strategies (e.g. ANC, healthcare settings, key populations²)
 - b. Ensure high-risk populations¹⁴ are actively engaged in appropriate and targeted viral hepatitis screening programs (e.g. HIV infected individuals, key populations, prisoners)
2. Ensure **screening is directly linked to staging and treatment programs**
 - a. Hepatitis testing should also include provision of testing results and staging disease¹⁵

¹² Regional Action Plan for Viral Hepatitis in the Western Pacific

¹³ Global Health Sector Strategy for Viral Hepatitis

¹⁴ Key populations for hepatitis infection include includes migrant populations (domestic and international), people who inject drugs, men who have sex with men, sex workers, transgender persons. May be country specific and include health workers. Additional epidemiological studies may be required to identify these populations.

- b. Viral hepatitis screening initiatives should have direct contact with antiviral hepatitis treatment programs for those eligible to be offered treatment.
 - c. Linkages should be built with existing service and programmes, e.g. maternal and child health, HIV, substance use, or non-communicable disease linkages to hepatitis screening and care
 - d. Liver cancer screening initiatives should be linked with 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 developed with community consultation and are consistent with WHO guidelines and recommendations. Promote adherence to these guidelines.
 - i. Provide training in these guidelines and related screening, care, and treatment for health care workers
 - d. Develop demonstration projects for integrated screening, care, and treatment initiatives in high burden capacity geographic areas
 - i. Ensure these demonstration initiatives have community-based viral hepatitis care that includes testing, counselling, vaccination, and treatment.
 - ii. Integrate hepatitis screening into health service provision and other settings that serve at-risk populations
 - iii. Countries should identify barriers to access to diagnosis, management, and treatment and take action to ensure equitable access for all those affected
 - e. Plan for phased implementation of screening, diagnosis, and treatment initiatives for hepatitis
 - f. Where private sector treatment provision occurs, ensure affordability is optimized through adequate oversight
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 leakage along the viral hepatitis cascade
 - c. Develop country-specific indicators for number of people living with hepatitis B and C and for treatment uptake at the national and sub-national level
 - d. Perform a country-specific analysis of access to treatment and develop cost effective and economic analysis on cost of burden of disease (e.g., HCC, cirrhosis) and treatment
5. **Procure affordable diagnostics and medicines** to support affordable antiviral therapy
- a. Initiate dialogue with stakeholders (e.g., pharmaceutical industry, major external funders including the Global Fund) to improve access to affordable medicines
 - b. Ensure intellectual property issues are not delaying access to medicines and diagnostics.
 - c. Explore different mechanisms, including TRIPS flexibilities where appropriate, to achieve the best price for medicines and diagnostics, including coordinating procurement between treatment providers to maximize procurement volume and reduced prices.
 - d. Ensure transparent accountability for distribution chains are set up to ensure access in public and private markets.
 - e. Rationalize diagnostics with available resources by coordinating diagnostic procedures across providers (e.g. PCR confirmation only is available centrally, whereas rapid test antigen or antibody can occur in peripheral facilities).

WHO SUPPORTING ACTIONS:

¹⁵ By non-invasive means e.g. APRI or FIB-4 biochemical algorithms.

1. **Develop and disseminate WHO viral hepatitis testing guidance**, with an emphasis on integrating recommended hepatitis screening and testing strategies into existing screening programs
 - a. Support countries to adapt the WHO guidelines hepatitis surveillance guidelines to the local epidemiological and socioeconomic context
 - b. Support advocacy efforts, including by community group involvement, 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 increase to optimize testing strategies among affected populations
2. **Develop guidance on recommended interventions and programmatic considerations** to optimize engagement and retention of individuals within the screening, care, and treatment cascade
 - a. Support hepatitis program and service provision integration into existing services to reduce costs and increase programmatic 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 geographic areas**
 - a. Work with countries to identify potential sites
 - b. Provide technical assistance during the development of those sites to optimize the effectiveness of the interventions
 - c. Support robust monitoring and evaluation of these demonstration projects to inform broader phased roll-out
5. **Support countries to access affordable diagnostics and antiviral medicines** by:
 - a. Providing advice on intellectual property issues regarding antiviral medications, including TRIPS flexibilities
 - b. Facilitating collaborative regulatory procedures, such as the WHO prequalification mechanisms, in particular for generic medicine manufacturers
 - c. Providing support and technical advice on joint procurement mechanisms and access to generic antiviral medicines

ANNEX 1 – REGIONAL MILESTONES AND TARGETS

These milestones and targets should be considered as the minimal set of milestones and targets. Noting intercountry variability in viral hepatitis epidemiology, context and response, specific national milestones and targets may vary.

POLICY, ADVOCACY AND FINANCE

Milestones (2017)	Targets (2020)
<ul style="list-style-type: none"> Initiative specific advocacy activities which go beyond recognition of World Hepatitis Day in increasing awareness 	<ul style="list-style-type: none"> Report card on specific awareness and advocacy activities carried out
<ul style="list-style-type: none"> A national disease burden and investment case estimate 	<ul style="list-style-type: none"> A costed and funded national hepatitis plan with clear targets
<ul style="list-style-type: none"> National taskforce established with designated focal point within MoH with representation from affected communities 	

DATA AND SURVEILLANCE

Milestones (2017)	Targets (2020)
<ul style="list-style-type: none"> WHO viral hepatitis surveillance guideline adapted to local context Laboratory or clinical reporting mechanisms established 	<ul style="list-style-type: none"> Member States to have a National hepatitis infection and disease surveillance program that could inform disease burden estimates
<ul style="list-style-type: none"> National hepatitis reference laboratory established 	<ul style="list-style-type: none"> Hepatitis surveillance linked to existing liver cancer registry, treatment registry, immunization data and vital statistics registry
<ul style="list-style-type: none"> Regional laboratory network established 	

PREVENTION

Milestones (2017)	Targets (2020)
<p>Immunization</p> <ul style="list-style-type: none"> Achieve prevalence of HBsAg in 5 year olds of < 1%* 	<ul style="list-style-type: none"> In countries that have achieved <1% in children under 5 years, reduce mother-to-child transmission to less than 2%
<ul style="list-style-type: none"> Achieve Birth dose hepatitis B vaccination coverage of at least 95%* 	
<ul style="list-style-type: none"> Achieve 3 dose hepatitis B vaccination coverage of at least 95%* 	

	<ul style="list-style-type: none"> National policy of vaccinating health care workers against hepatitis B established in >80% of countries 	<ul style="list-style-type: none"> National policy of vaccinating health care workers, medical/health students against hepatitis B established in all countries Hepatitis B vaccinations integrated into HIV, harm reduction, and STI services
Health sector transmission		<ul style="list-style-type: none"> Safe injection policies for prevention of health sector hepatitis B and C transmissions established in all countries
High risk adult populations	<ul style="list-style-type: none"> Countries with populations of PWID have policies supporting harm reduction programmes including NSP and OST 	<ul style="list-style-type: none"> Countries with harm reduction programs access 60% of PWID with comprehensive package of harm reduction services and 50% of people dependent on drugs with substitution treatment

* already agreed to in 2013 Resolution WPR/RC64.R5

SCREENING, CARE AND TREATMENT

Note for both of hepatitis B and C **each country to develop country specific screening care and treatment milestones and targets**

	Milestone (RAHVH ¹⁶)	Target (RAPVH ¹²)	Target (GHSSVH ¹⁷)
	2016	2020	2030
Screening/testing/diagnosed	Obtain baseline data for National hepatitis screening care and treatment cascade	30% of the estimated population living with HBV/HCV are diagnosed	90 %
Eligible treatment	Obtain baseline data as above	50% of the <i>eligible</i> ** population for treatment are commenced on treatment	90 %

¹⁶ Regional Action Plan for Viral Hepatitis in the Western Pacific

¹⁷ Global Health Sector Strategy for Viral Hepatitis, inserted here for reference only.

Viral suppression (HBV) / cure (HCV)	Obtain baseline data as above	90% of those commenced on HBV or HCV treatment obtain viral suppression (HBV) or cure (HCV)	90 %
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** initial estimates In the Western Pacific are that 10 – 30% of people living with chronic viral hepatitis B or C would fulfil eligibility criteria according to WHO recommendations, although for hepatitis C, eligibility varies depending on resource constraints. i.e. The eligible population for treatment is estimated to be ~ 3 – 10% of the estimated population living with chronic hepatitis B or C.

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ANNEX 2 - INDICATORS

Regional Action Plan for Viral Hepatitis proposed indicators for monitoring health sector response to Viral Hepatitis. These are adapted from and reflect the Global hepatitis indicators

	Domain	Indicator and definition
1	Morbidity (incidence proxy)	Prevalence of Hep B infection in 5-year-old children Percentage of 5-year-old children HBsAg positive
2	Morbidity (Prevalence)	Prevalence of viral Hepatitis B or Hepatitis C infection <ul style="list-style-type: none"> • Number and proportion of adults and children living with Hepatitis C or Hepatitis B • Number and proportion of adults and children living with HIV who are coinfecting with hepatitis B or C
3	Mortality	Mortality rate by hepatocellular carcinoma (HCC) and liver disease: <ul style="list-style-type: none"> • Number of deaths from HCC and cirrhosis • Proportion of HCC attributable to HBV/HCV/HDV • Proportion of deaths from cirrhosis attributable to HBV/HCV/HDV
4	Policy	National Hepatitis Action Plan
5	Testing (screening)	Hepatitis B and C screening and testing <ul style="list-style-type: none"> • Number of adults and children who were screened for hepatitis B and hepatitis C • Proportion of estimated populations of adults and children living with HBV or HCV who were screened for hepatitis B and hepatitis C
6	Prevention (vaccination)	Vaccination coverage HBV newborn (mother to child transmission) <ul style="list-style-type: none"> • Percentage of newborns receiving HBV vaccine birth dose (BD) within 24 hours Vaccination coverage HBV children <ul style="list-style-type: none"> • Number of third doses of Hep-B vaccine (HepB3) administered to children Vaccination coverage health workers <ul style="list-style-type: none"> • Proportion of health care workers completed hepatitis B immunization
7	Prevention (injection safety)	Facility level injection safety Percentage of health care facilities where all therapeutic injections are given with new, disposable, single-use injection equipment
	Prevention (infection control)	Sterilization procedures Proportion of facilities with at least one updated TST spot register or analogous register if sterilization in use

8	Prevention (blood safety)	Blood screening coverage Percentage of blood units screened for HBsAg, HCVAb, HIV Percentage of blood units screened for HBV DNA, HCV RNA
10	Prevention (harm reduction PWID)	NSP coverage The number of needles and syringes distributes per PWID per year by NSPs.
11	Treatment and care	Treatment coverage Hep B and Hep C Percentage of treatment-eligible people living with hepatitis B or C who are commenced on treatment (based on national hepatitis B or C treatment guidelines);
12	Treatment and care	Viral suppression or cure Hep B and Hep C Proportion of patients achieving treatment hepatitis B and C treatment endpoints - HBV DNA viral load suppression or loss of HBsAg - HCV Sustained virologic response (SVR)

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ANNEX 3 - TABLE OF ACTIONS

Priority area	Goal	Country action	WHO supporting action
1 Broadbased advocacy and awareness	Empower communities and providers by decreasing ignorance about viral hepatitis	Develop a multi-sectorial National Hepatitis Task Force to coordinate a public health awareness and communication strategy.	Develop hepatitis communications guidance
		Support National patient group formation and mobilization	Support patient and affected population groups to actively participate in WHO hepatitis consultations and Regional guidance development
		Integrate viral hepatitis prevention and treatment into health professional curricula training to promote the development of a hepatitis literate workforce	Develop core training curricula components
		Recognize and carry out hepatitis activities on World Hepatitis Day and beyond	Develop World Hepatitis Day toolbox which can be adopted at various levels of complexity depending on resources
2 Evidence informed policy guiding comprehensive hepatitis action	A National Action Plan	Develop a comprehensive National Hepatitis Action Plan in partnership with key stakeholders	Provide technical assistance in the development of National Action Plans
		Mobilise resources for action on viral hepatitis	Work with potential donors to identify domestic and external funding sources for viral hepatitis activities.
3 Data supporting the hepatitis response	National disease burden estimates and investment case	Develop national estimates of disease and treatment burden for viral hepatitis	Technical support to assist in developing robust data inputs to estimate hepatitis disease burden
		Achieve stakeholder consensus on data	Support consensus building on National estimates of disease burden through supporting stakeholder consultation
		Identify country specific priority groups for	Provide technical support to identify country specific

		hepatitis testing and treatment	priority groups for hepatitis testing and treatment
		Based on disease burden estimates develop a country specific investment case for action on hepatitis	Technical support to assist in developing robust data inputs and economic analyses for the investment case
		Assess current capacity for a comprehensive hepatitis response	Work with countries to undertake a National or sub-regional assessment of current hepatitis response capacity
	Standardized surveillance and data collection activities	Coordinate viral hepatitis surveillance utilizing existing infrastructure	Technical support to identify and collate existing viral hepatitis data
		Adapt or adopt WHO viral hepatitis surveillance guidelines	Develop a tool kit for surveillance activities
		Develop domestic laboratory network for viral hepatitis	Support development of regional laboratory network, establishment and maintenance of robust EQAS and QMS, and the use of pre-qualified viral hepatitis test kits
		Triangulate viral hepatitis data reporting system with immunization and liver disease reporting	Support the dissemination and adaptation of WHO viral hepatitis surveillance guidelines
	Research	Promote regional research and partnership in viral hepatitis	Identify policy and programmatic research gaps between consultations and policy document formulation
		Promote and support research	Identify key gaps in hepatitis research and support collaborations
4 Stopping Transmission	Elimination of chronic hepatitis transmission	<p>Hepatitis B control through immunization by achieving high coverage (95%) with a timely birth dose and the three dose infant vaccination series.</p> <p>Implement health worker hepatitis B vaccination policies.</p> <p>Ensure regular supply of vaccine and quality vaccine management.</p> <p>Conduct necessary communication and advocacy for hepatitis B vaccination.</p> <p>Conduct high quality performance monitoring and measurement of impact through periodic</p>	<p>Providing technical support to collate and management HBV immunization data sources and conduct surveys.</p> <p>Provide regional normative guidance for hepatitis B control.</p> <p>Identify and support countries to implement effective strategies for increasing hepatitis B vaccination coverage.</p> <p>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.</p>

		serosurveys.	
		Ensure safe blood supply	Technical support to strengthen National transfusion service and reduce unnecessary use of blood products
		Strengthen infection prevention and control measures for hepatitis in healthcare settings	Support infection prevention and control in health care settings
		Minimizing hepatitis C transmission among people who inject drugs	Technical support for the implementation and implementing and maintaining effective harm reduction interventions
5	An accessible and effective treatment cascade	Access to and retention within the viral hepatitis treatment cascade	Early identification of persons infected with hepatitis B and C
		Link hepatitis screening to staging and treatment programs	Support adaption or adoption of WHO viral hepatitis testing guidance
		Increase access to effective antiviral treatment in a phased manner	Develop guidance for hepatitis programming to optimize engagement and retention in the viral hepatitis cascade
		Monitoring and evaluation of the demonstration treatment cascades to inform phased national response	Technical support for the development of demonstration integrated screening, care and treatment initiatives in high burden high capacity geographic areas. Support development of national hepatitis clinical guidelines aligned with or adapted from WHO hepatitis clinical guidance.
		Procure affordable diagnostics and medicines	Technical support for robust monitoring and evaluating of demonstration screening, care, and treatment initiatives.
			Provide support and technical advice to countries to identify regulatory barriers to access and procure affordable diagnostics and antiviral medicines