Regional Action Plan for the Implementation of the Global Strategy for Viral Hepatitis

2017-2021

Draft for consultation (2)

WHO Regional Office for the Eastern Mediterranean
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I INTRODUCTION

Viral hepatitis is the seventh-leading cause of mortality globally, responsible for 1.45 million deaths in 2013. According to the global burden of disease data base of 2010, in the WHO Eastern Mediterranean Region viral hepatitis B and C caused more deaths (> 90,000 deaths) than each of HIV, Malaria and Tuberculosis. The consequences of chronic hepatitis B and C infections – cirrhosis and liver cancer – are responsible for 94% of deaths associated with hepatitis infections.

The WHO Regional Committee for the Eastern Mediterranean, at its 56th session in 2009 adopted a bold target, namely, that the percentage of children < 5 years with chronic hepatitis B virus infection would have dropped to less than 1% by 2015 (EM/RC56/R.5 ). Since the adoption of this resolution, the Region has had significant success in fighting viral hepatitis. By end of 2015, the median vaccination coverage of the complete course of childhood vaccination has been 97%. However, 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.

Based on the WHO Global Strategy for Viral Hepatitis, the Regional Action Plan is intended to guide Member States and the WHO secretariat on a roadmap and priority actions towards the achievement of national, regional and global targets. It calls for involving stakeholders from the public and private sectors and civil society in the hepatitis response, strengthening governance and 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.

Hepatitis epidemiology, health systems capacities and the availability of resources vary widely across countries in the Eastern Mediterranean Region. Therefore the Regional Action Plan encourages Member States to develop 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.

II GLOBAL CONTEXT

GLOBAL HEPATITIS BURDEN

The viral hepatitis pandemic takes a heavy toll on lives, communities and health systems. In 2013, the Global Burden of Disease study has recently identified viral hepatitis as the 7th leading cause of mortality globally, superseding each of human immunodeficiency virus (HIV), tuberculosis, and malaria [1,2]. It is responsible for an estimated 1.4 million deaths per year from acute infection and hepatitis-related liver cancer and cirrhosis. Nearly half of this mortality is attributed to hepatitis C virus (HCV) and hepatitis B (HBV), each, while approximately 5% are due to hepatitis A virus and hepatitis E virus [2]. Infection with HBV or HCV causes acute hepatitis, fibrosis, cirrhosis and liver cancer among other forms of disease. Worldwide, approximately 240 million people have chronic hepatitis B virus infection and 130–150 million have chronic hepatitis C virus infection [3]. HCV is estimated to affect 1-3% of the population in most countries globally leading to about 150 million prevalent chronic infections and causing more than half a million deaths ever year [4]. The factors affecting disease burden are manifold and vary across geographic regions.
The First Global Strategy for Viral Hepatitis

Building on the 2012 Prevention and Control of Viral Hepatitis Infection: Framework for Global Action and World Health Assembly resolutions WHA63.18 [5] (2010) and WHA67.6 [6] (2014) on viral hepatitis, WHO has led the development of the first global health sector strategy on viral hepatitis, 2016–2021, with elimination of viral hepatitis as a public health threat by 2030 as its central goal. The strategy is closely aligned with the 2030 Agenda for Sustainable Development and the health targets of the Sustainable Development Goals (SDGs), specifically, SDG 3, which calls for specific action to combat viral hepatitis and achieve universal health coverage; and to related global health strategies and plans, including those for HIV, sexually transmitted infections, blood safety and non-communicable diseases.

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

Ensuring financial security and health equity are key concerns in the 2030 Agenda for Sustainable Development, and universal health coverage provides a framework for addressing them. Universal health coverage (see Figure 1) is achieved when all people receive the health services they need, which are of sufficient quality to make a difference, without those people incurring financial hardship. 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.

While the concept of universal health coverage frames the strategy overall, the continuum of hepatitis services provides the organizing framework for the specific actions to be taken. That continuum spans the entire range of interventions that is needed to achieve the strategy’s targets – from reducing vulnerability, preventing and diagnosing infection, linking people to health services, through to providing treatment and chronic care.

The concept of a public health approach is concerned with preventing infection and disease, promoting health, and prolonging life among the population as a whole. It aims to ensure the widest possible access to high-quality services at the population level, based on simplified and standardized interventions and services that can readily be taken to scale and decentralized, including in resource-limited settings. A public health approach aims to achieve health equity and promote gender equality, engage communities, and leverage public and private sectors in the response.

The global strategy provides:
- A vision of a world where viral hepatitis transmission is halted and everyone living with viral hepatitis has access to safe, affordable and effective care and treatment;
- A goal of eliminating viral hepatitis as a major public health threat by 2030;
- Targets that seek to reduce the number of newly occurring chronic hepatitis infection from the current 6–10 million cases of chronic infection to 0.9 million infections per year by 2030, and to reduce the annual deaths from chronic hepatitis from 1.4 million to less than 0.5 million by 2030, with milestones for 2020 (see annex 1)

### III Regional context

#### Regional hepatitis burden

**Hepatitis C**

In the WHO Eastern Mediterranean Region, it is estimated that a total of 22 million living individuals have been infected with HCV, among whom around 15.4 million are chronically infected. About 80% of these individuals live in Egypt and Pakistan, with each of these countries contributing about 5.1 million and 6.6 million chronic infections, respectively. Additionally, close to half a million chronically infected individuals are found in each of Iran, Saudi Arabia, and Yemen. Consequently, HCV infection is a major cause of liver disease burden in the Region [4].

With the exceptions of Egypt and Pakistan HCV prevalence in the countries of the Region is rather low, in the range of 1% among the general population, comparable to most countries globally. National HCV prevalence is about 10% in Egypt and 5% in Pakistan [4].

The high HCV prevalence levels found among populations with high risk healthcare exposures to HCV, and other populations linked to healthcare, indicate that exposures through less than optimal infection control in healthcare settings are a dominant mode of HCV transmission in the region. Mother-to-child transmission also appears to be a significant mode of HCV transmission in Egypt and Pakistan. Meanwhile, modes of transmission remain poorly characterized in most countries [4].

<table>
<thead>
<tr>
<th>Hepatitis C (HCV-Ab) prevalence</th>
<th>Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>First tier (prevalence &gt; 2%)</td>
<td>Egypt, Pakistan</td>
</tr>
<tr>
<td>Second tier (prevalence 0.6-2%)</td>
<td>Tunisia, Afghanistan, Morocco, Somalia, Sudan, Libya, KSA, Yemen</td>
</tr>
<tr>
<td>Third tier (prevalence ≤ 0.5%)</td>
<td>Lebanon, Iraq, Palestine, UAE, Iran, Jordan, Bahrain, Djibouti, Syria, Kuwait, Qatar</td>
</tr>
<tr>
<td>Injecting drug user population</td>
<td>Pakistan, Iran, Afghanistan, Libya, Morocco, Tunisia, Egypt, Lebanon, Bahrain, Palestine</td>
</tr>
</tbody>
</table>

There are over half a million people who inject drug (PWID) in the Region and about half of them are HCV infected. The mean HCV prevalence among this population was estimated at 45% across EMR countries, comparable to global levels. However, HCV prevalence exceeding 70% has been reported among PWID in several countries including Afghanistan, Iran, Libya, Pakistan, and Saudi Arabia. Considerable HCV prevalence levels are also found among prisoners across the Region [4].
HEPATITIS B

In the Region, the overall HBsAg prevalence is 2.2%, accounting for an estimated 14.8 million people with chronic HBV infection (HBsAg positive individuals). An estimated 80% of all cases in the Region live in eight countries: Pakistan, Sudan, Yemen, Iran, Egypt, Syria, Afghanistan, and Morocco. In 2016, it was estimated that 18.8% of HBsAg positive individuals in the Region were co-infected with Hepatitis D virus (HDV) [3].

<table>
<thead>
<tr>
<th>Hepatitis B (HBsAg seroprevalence)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High endemicity</strong> (prevalence &gt; 8%)</td>
</tr>
<tr>
<td><strong>Intermediate endemicity:</strong> (prevalence 2-8%)</td>
</tr>
<tr>
<td><strong>Low endemicity</strong> (prevalence &lt; 2%)</td>
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</tbody>
</table>

Most countries in the region lack strategic information on the local epidemiology of viral hepatitis because of the lack of adequate surveillance systems. Data gaps present challenges to developing regional epidemiological estimates, including: a lack of studies in the general population across the region, a lack of studies in the general population within certain countries, and a lack of studies reporting data from more recent years. Accordingly, countries need to take the necessary measures to improve their hepatitis surveillance system at national level so that we can have a more reliable and accurate view of the real situation.

National hepatitis responses While HIV programs in EMR have considerably progressed in recent years, programs targeting HCV infection are still lagging in most countries. Roughly two-thirds of viral hepatitis mortality in North Africa and Middle East, the 5th leading cause of death in the region, is attributed to HCV infection [1]. HCV also accounts for 57% of disability-adjusted life years (DALYs) due to viral hepatitis [1].

According to the regional review on hepatitis response conducted by the regional office, almost all of the countries reported having embarked on the prevention and care interventions for viral hepatitis, but implementation of the interventions is still not to scale and approaches are not standardized across the countries.

Thirteen countries (81%) reported having a written strategy or plan for the prevention and control of viral hepatitis. However the strategy documents were not verified. The national strategic plans for each country need to be reviewed and updated, and implementation plans formulated with target indicators for progress. The indicators need to be more linked to the objectives.

Although vaccination programs are being implemented, coverage seems to be inadequate, particularly when it comes to most-at-risk populations, such as sex workers and MSM. Although health-care providers have been identified as populations to be targeted for prevention, coverage is variable and inadequate in most countries.

Many chronically infected persons are unaware of their infection and its consequences, and they risk transmitting the disease to their families and partners. These people do not have timely access to testing, care and effective treatment services to delay disease progression and prevent morbidity, mortality or disability. Ensuring the continued engagement of hepatitis patients with health services along the continuum of care is another challenge.
Even in countries with Hepatitis programs in place, coverage of screening, diagnostic testing and treatment is still very low. For example, 6 countries report screening key populations at higher risk of hepatitis B, such as sex workers or men having sex with men. To enhance case detection, Ministries of Health need to identify and prioritize populations at higher risk for Hepatitis screening, standardize the screening procedures and increase screening coverage. Hepatitis C treatment coverage is in general still very low in the Region. However, since late 2014 remarkable efforts have been made in particular in Egypt and Pakistan to increase access to the new direct acting antivirals. By end of June 2016, 600 000 people have received treatment with DAAs in Egypt and XXXXX in Pakistan. In view of the high number of chronically HCV infected people a continued massive treatment scale-up efforts will be required to reduce the burden of hepatitis sequelae such as liver cirrhosis and cancer.

One of the reasons for poor access and limited treatment coverage is the cost of the treatment options for hepatitis C. The cost per regimen has been reported to range from as low as US$ 150 to as high as US$ 62,000. Thus, although DAAs have been adopted in HCV treatment protocols across the countries of the Region, the costs are prohibitive and unsustainable, regardless of whether the cost is covered by government, health insurance or out-of-pocket payments of patients.

Many countries lack strategic information on local epidemiology of viral hepatitis and on the expected impact and cost-effectiveness of different prevention and care interventions. This is a contributing factor to low national commitment and domestic investment in hepatitis responses.

The region is facing an unprecedented degree of security and displacement challenges. This has drawn the attention in health to emergency relief efforts. Also, the affected countries had to low down scale-up efforts of health sector programs including hepatitis and new, large groups of displaced people have limited access to hepatitis prevention, diagnosis and treatment services.

**IV Regional action plan for Viral Hepatitis in the Eastern Mediterranean 2017-2021 - Overview**

**Vision, goal and targets**

The vision, goal and targets of the Regional action plan are aligned with those of the Global Strategy. Accordingly, the vision is An Eastern Mediterranean Region free of new hepatitis infections and where people living with chronic hepatitis have access to care and affordable and effective prevention, care and treatment. The goal is to eliminate viral hepatitis as a major public health threat by 2030. Targets seek a 10-fold reduction of new infections and a 3-fold reduction of deaths from chronic hepatitis by 2030. These targets will require a radical change in the hepatitis response, and will mean that hepatitis is elevated to a higher priority in public health.

**Purpose and focus**

The purpose of the Regional Action Plan for Viral Hepatitis is to build and keep momentum among WHO Member States for accelerating access to Hepatitis prevention and treatment and to guide Member States, and the WHO secretariat on a roadmap and priority actions towards the achievements of national, regional and global targets. The target audience includes Ministries of Health, policy makers, program officers, health planners and implementing agencies, clinicians, civil society organizations, community groups, WHO partner agencies, the private sector and donors.
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. However, it is important that disease control measures to prevent hepatitis A and E, including surveillance and early warning systems for epidemics of hepatitis A and E, safe water supplies, promotion of hygiene and vaccination are put in place.

**Regional Action Plan Development**

This Regional Action Plan has been developed in consultation with Hepatitis focal points of Ministries of Health, regional Hepatitis experts, civil society representatives and experts from WHO partner agencies. Recommendations for priority actions are based on the burden of disease and its variations between countries in the Region and between populations within countries and gaps in existing programs and resources. The draft Regional Action Plan for Viral Hepatitis has been presented and discussed in the regional strategic and technical consultation meeting held in Morocco from 25 to 27 April 2016. Feedback and comments provided by participants of the meeting have been fully considered in the finalization of the document.

A mid-term review of the implementation of the regional action plan is proposed at the end of 2018 and an end-term review is proposed for 2021.

**V Strategic Directions, Key Actions and Programmatic Milestones**

To achieve the targets of the global targets in the WHO Eastern Mediterranean Region action is required in five areas, referred to as “strategic directions”:

1. Leadership, good governance and advocacy for a coordinated and integrated response
2. Information for focused action
3. Interventions for impact
4. Systems strengthening for equitable access
5. Financing for sustainability

Under each of the strategic directions, specific actions need to be taken by countries, WHO and partners. These actions will be implemented in a phased manner with different starting points for different countries depending on the status of the response to viral Hepatitis in 2016. The speed of scale up of the response towards achieving global targets will depend on many factors: disease burden, political commitment, economic and health system capacity will be key factors. The regional action plan proposes programmatic milestones for 2018 and 2021. If adopted by each country the achievement of those milestones will result in tangible progress towards the global goal of eliminating viral hepatitis B and C by 2030.

**Strategic Direction 1: Leadership, Good Governance and Advocacy for a Coordinated and Integrated Response**

Eliminating viral hepatitis will require commitment of top leadership, coordination of actors within the health sector and beyond, evidence-based policies, consensus between stakeholders on national targets, determination to achieve those targets and funded national action plans.

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The development of effective strategies and policies requires evidence of the effectiveness of interventions, information on local epidemiology, disease burden, health system capacity, cost of interventions etc.; Refer to strategic direction 2.
### PROGRAMMATIC MILESTONES

<table>
<thead>
<tr>
<th>Milestones for the national response</th>
<th>Target year</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 A viral hepatitis health sector coordinating body is actively fulfilling its responsibilities</td>
<td></td>
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<tr>
<td>1.2 A viral hepatitis focal unit (or focal person) has been appointed and is following up on planning, implementation and monitoring of the viral hepatitis response</td>
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<tr>
<td>1.3 National coverage targets for viral hepatitis prevention and treatment interventions have been set with measurable indicators including targets for;</td>
<td></td>
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<tr>
<td>1.3.1 Hepatitis B vaccination of health workers</td>
<td></td>
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<tr>
<td>1.3.2 Safe injections in health care settings</td>
<td></td>
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<tr>
<td>1.3.3 In countries with a significant PWID populations: targets for needles-syringe programmes, opioid substitution therapy and Hepatitis B vaccination</td>
<td></td>
</tr>
<tr>
<td>1.3.4 Hepatitis B and C screening coverage of selected populations</td>
<td></td>
</tr>
<tr>
<td>1.3.5 Hepatitis B and C treatment coverage</td>
<td></td>
</tr>
<tr>
<td>1.4 A plan of action to achieve the national targets has been formulated</td>
<td>2018</td>
</tr>
<tr>
<td>1.5 National policies and guidelines for priority interventions are available and in line with global standards including:</td>
<td></td>
</tr>
<tr>
<td>1.5.1 A policy for Hepatitis B vaccination of health workers</td>
<td></td>
</tr>
<tr>
<td>1.5.2 A policy to integrate Hepatitis B vaccination in HIV services, hemodialysis units and services targeting PWID, MSM and SW is in place</td>
<td></td>
</tr>
<tr>
<td>1.5.3 Policies for screening of selected population groups at increased risk</td>
<td></td>
</tr>
<tr>
<td>1.5.4 A policy for mandatory screening of all blood donations for Hepatitis B and C</td>
<td></td>
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<tr>
<td>1.5.5 A policy for referral of all blood donors with positive screening results for Hepatitis B and C confirmatory testing and case management</td>
<td></td>
</tr>
<tr>
<td>1.5.6 A policy for use of safe injections (or safety engineered devices) in health care settings to prevent transmission of blood borne infections</td>
<td></td>
</tr>
<tr>
<td>1.5.7 Guidelines for diagnostic testing</td>
<td></td>
</tr>
<tr>
<td>1.5.8 Guidelines for Hepatitis B and C case management</td>
<td></td>
</tr>
<tr>
<td>1.6 Advocates from public and private sector, civil society, professional associations, etc. have agreed on a joint awareness raising and advocacy strategy and collaborate on its implementation</td>
<td>2021</td>
</tr>
</tbody>
</table>

### ACTIONS RECOMMENDED FOR MEMBER STATES

**1.1 Establish a coordination mechanism for an integrated hepatitis response**

The coordination mechanism should envisage participation of key stakeholders from government, civil society, academia and the private sector. It should provide a platform for planning, target setting, resource mobilization and monitoring progress in implementation.

The coordination mechanism should include:

- a national multi-sectorial body that guides and oversees the multi-sectoral hepatitis response (e.g. the national inter-ministerial health committee) under the leadership of the Ministry of Health.
- a Ministry of Health internal coordination mechanism that is integrated in the existing governance structure of the health sector.
- a focal unit or person for viral hepatitis to ensure follow up on implementation of national policies by the various actors.

The size of the unit for follow up and program implementation support will vary between countries depending on the capacity needed for this purpose.
1.2 Develop evidence-informed policies for program and service delivery

Policies and standards should be developed or updated in line with global reference guidelines and standards. It is recommended to involve providers and beneficiaries of the interventions in the development of policies to ensure optimal acceptance. There should be national policies and standards for viral hepatitis prevention (immunization for Hepatitis A and B; blood safety, injection safety, injecting drug use harm reduction), Hepatitis B and C testing and case detection and national guidelines for case management of all viral Hepatitis (A, B and D, C, E) and chronic care for cirrhosis and liver cancer. Hepatitis policies should be integrated in relevant existing policies such as blood safety, infection control, antenatal care, and others.

1.3 Set national targets for the prevention and control of viral hepatitis and define measurable indicators for monitoring progress towards their achievement.

National targets should be consensus-based, reflect commitment and ambition and take the reality of health system challenges and financing limitations into account. Interim targets, or “milestones” can mark particular steps on the way towards achieving the national targets. Indicators for monitoring progress towards the achievement of milestones and targets must be defined.

1.4 Develop national plans of action to achieve the national targets.

National action plans provide direction for all actors towards the achievement of national targets. The national hepatitis coordinating body shall oversee the development of national action plans. Action plans shall be developed periodically (e.g. every 2 years) with the involvement of all stakeholders relevant to their successful implementation. National action plans are inclusive of a framework for monitoring and evaluation and a cost estimate.

1.5 Raise awareness of policy makers, communities and health care providers; Build and investment case

In order to achieve success in responding to viral hepatitis, stakeholders must be aware of the extent of hepatitis epidemics, the health consequences and the cost and benefit of a national response. A hepatitis communication strategy tailored to the country context will help to use resources available for this purpose most effectively. Part of the communication strategy is an investment case. The investment case is built on an economic analysis (see 2.3) and will highlight the cost of inaction. Investment cases are used to advocate for priority interventions to prevent new cases and chronic disease.

1.6 Address stigma and discrimination

In order to alleviate structural barriers to access to hepatitis services, stakeholders must ensure appropriate measures to protect people affected by viral hepatitis from stigma and discrimination.

**Actions for the WHO Secretariat**

1.1 Technical cooperation

WHO regional office shall facilitate the establishment of a regional platform of technical expertise to support the implementation of a public health response to viral hepatitis. (A Regional Viral Hepatitis Experts Group).

WHO regional office shall provide necessary tools and material for advocacy and awareness-raising and undertake relevant regional activities that can enhance national efforts.

1.2 Policy advice and dialogue
WHO shall facilitate the dialogue between stakeholders at national and regional level including government institutions, clinical experts, professional associations, academia, private sector, civil society and development partners on WHO recommended policies.

1.3 Norms and standards

WHO Regional and country offices will keep national counterparts up-to-date on WHO global guidance through dissemination and orientation meetings at regional and national levels.

Strategic Direction 2: Information for Focused Action

Reliable strategic information is essential for generating the data for advocacy, target setting, planning for efficient use of resources and monitoring achievements and impact. With limited resources investments need to be strategically targeted to the local epidemic.

In early 2016 WHO published guidance for epidemiological surveillance\(^7\) and program monitoring\(^8\). WHO is proposing global 10 key indicators for Hepatitis burden and response monitoring. Their adoption will enable countries to participate in annual reporting of standardized global indicators. The measurement of those indicators should be integrated in the existing health information systems and tools.

Data sources will include various components of the national health information system including the viral hepatitis data reporting system, the immunization and liver disease reporting (cirrhosis cases and cancer registry) systems, inventory management systems, hospital information systems and antiviral prescribing or ordering data systems, surveys among special population groups at higher risk.

Programmatic Milestones

<table>
<thead>
<tr>
<th>Milestones for the national response</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1 An inventory of existing data and sources of data on viral hepatitis has been made.</td>
<td></td>
</tr>
<tr>
<td>2.2 National key hepatitis indicators have been determined in line with global WHO guidance;</td>
<td>2018</td>
</tr>
<tr>
<td>2.3 A plan for step-wise integration of key hepatitis indicators in national health information system is developed</td>
<td></td>
</tr>
<tr>
<td>2.4 An initial estimate of the prevalence of chronic HBV and HCV infections in the general and or special populations is available;</td>
<td></td>
</tr>
<tr>
<td>2.5 An economic analysis of different intervention scenarios has been carried out and an investment case has been developed (priority in high burden countries).</td>
<td></td>
</tr>
<tr>
<td>2.6 The national health information system measures key disease burden and service coverage indicators;</td>
<td>2021</td>
</tr>
<tr>
<td>2.7 Performance across the viral hepatitis service continuum has been reviewed and barriers to access and retention have been identified (at least once every 2 years)</td>
<td></td>
</tr>
</tbody>
</table>

Action Recommended for Member States

2.1 Strengthen epidemiological data collection on viral hepatitis to enable reliable estimations of the national disease burden and treatment burden.

Key interventions include:
- Assessing existing data, data sources and capacity for viral hepatitis epidemiological surveillance
- Defining a manageable list of national indicators to monitor epidemiological trends - depending of the capacity of the national surveillance system. To ensure standard case definitions are used, WHO global surveillance guidance should be considered and adapted to the national context.

- Gradually building up capacity of the national health information system to enable estimation of the viral hepatitis disease burden including existing (prevalent) and new (incident) hepatitis cases, cases of chronic liver disease and cancer.

- Estimating the treatment need.

- Assessing epidemiological profiles of groups at increased risk to identify country-specific priority groups for testing and treatment.

2.2 *Monitor coverage and quality of a continuum of viral hepatitis services*

The hepatitis service continuum (figure 2, page 13) provides a useful framework of a national hepatitis monitoring and evaluation system. Indicators measure coverage and performance along each step of the cascade. Lost opportunities to engage people with viral hepatitis in the service continuum are identified and resources can be directed towards closing these gaps.

Key interventions include:
- Defining a list of national key indicators to monitor coverage along the hepatitis service continuum.
- Gradually building capacity of the health information system to address data gaps.
- Making use of WHO monitoring and evaluation guidance to ensure that national indicators are in line with standard global indicators.
- Reviewing performance across the viral hepatitis prevention and care continuum and identifying access barriers and factors associated with leakage along the continuum.

2.3 *Carry out economic analysis of viral hepatitis prevention and control in order to build an investment case*

Countries with high burden of viral hepatitis shall carry out an economic analysis to estimate the net cost of different scenarios of viral hepatitis prevention and control, i.e. the difference between (i) the cost of interventions and (ii) the savings gained as a result of the interventions (such as the cost per case or death prevented; the cost per DALY). An investment case can be built on this analysis and will highlight the cost of inaction (see 1.5).

**Actions for the WHO Secretariat**

**Technical cooperation**

The Regional Office and country offices shall provide technical support to member states to

- Assess existing data sources for viral hepatitis surveillance and program monitoring;
- Identify important gaps and develop a plan for gradual strengthening the health information system to accommodate viral hepatitis program data needs;
- Carry out economic analysis and develop an investment case for viral hepatitis;
- Establish baseline values for national indicators;
- Support hepatitis response reviews along the hepatitis prevention and care continuum.
- Build capacity in Hepatitis surveillance and program monitoring.
Policy advice and dialogue

Orient national HIS experts on WHO guidance for Hepatitis surveillance and program monitoring and evaluation.

Leading and convening

Convene stakeholder for consensus building on national disease burden estimates.

Dissemination of evidence and best practices

The Regional Office shall support global monitoring of the hepatitis response, monitor progress toward targets in the Eastern Mediterranean Region and provide feedback to Member States.

Strategic Direction 3: Interventions for Impact

Each country needs to define a set of essential viral hepatitis interventions, services, medicines and commodities. The essential viral hepatitis B and C interventions and services should include the following core viral hepatitis interventions: Hepatitis B vaccination; blood safety, injection safety and universal precautions; harm reduction services for people who inject drugs; and diagnosis and treatment of chronic hepatitis B and hepatitis C virus infections. Interventions for prevention of sexual transmission of hepatitis B virus and hepatitis C virus are important for specific populations.

Elimination of mother-to-child transmission of hepatitis B virus will require a comprehensive approach that includes prevention of hepatitis B virus infection in young women, hepatitis B virus testing, care of pregnant women with chronic hepatitis B virus infection, delivery of hepatitis B virus vaccine to the infant within 24 hours of birth, safe delivery practices, strengthened maternal and child health services, and the development of new interventions to prevent transmission based on antiviral treatment.

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. Effective care and treatment of chronic viral hepatitis is illustrated by the continuum of care diagram (the cascade, 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 link them to care and treatment. Adherence and retention are key to achieving optimum outcomes and maximizing the cost-effectiveness of antiviral therapy.

To have greatest impact, effective interventions should be combined and tailored for the specific population, location and setting. For example, for hepatitis B virus epidemics, in certain countries with high prevalence of this virus, the most significant public health benefits would be seen if the following two approaches were adopted —
and if high coverage rates could be achieved: the focus was on the prevention of early-life infection through birth-dose and childhood vaccination; and deaths were prevented by treatment.

A phased approach towards introducing and scaling up screening, diagnosis, and treatment of hepatitis will help to identify the most suitable service delivery models specific to each country’s health system.

**PROGRAMMATIC MILESTONES AND SERVICE COVERAGE TARGETS**

<table>
<thead>
<tr>
<th>Milestones for the national response</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stopping transmission</strong></td>
</tr>
<tr>
<td>3.1 Policies for key prevention interventions have been developed and endorsed by decision makers (refer to milestones 1.5.1 to 1.5.5)</td>
</tr>
<tr>
<td>3.2 Baseline information on the coverage of preventive interventions is available including:</td>
</tr>
<tr>
<td>3.2.1 Coverage of hepatitis vaccination of health workers</td>
</tr>
<tr>
<td>3.2.2 Percentage of blood donors screened for Hepatitis B and C</td>
</tr>
<tr>
<td>3.2.3 Percentage of health facilities that implement the policy of 100% single use (or safety engineered) injection devices is available</td>
</tr>
<tr>
<td>3.2.4 For countries with significant PWID populations: Coverage of needles-syringe programmes, opioid substitution therapy and HBV vaccination</td>
</tr>
<tr>
<td><strong>Expanding access to a continuum of services for early diagnosis, care and treatment</strong></td>
</tr>
<tr>
<td>3.3 Baseline information on the coverage of Hepatitis diagnosis and treatment interventions is available including:</td>
</tr>
<tr>
<td>3.3.1 Screening coverage (by population to be screened as per national policy)</td>
</tr>
<tr>
<td>3.3.2 Number and percentage of people with chronic Hepatitis B receiving treatment</td>
</tr>
<tr>
<td>3.3.3 Number and percentage of people with chronic Hepatitis C who received a full course of treatment;</td>
</tr>
<tr>
<td>3.3.4 Percentage of people treated for Hepatitis C who are cured</td>
</tr>
<tr>
<td>3.4 Baseline information on deaths from hepatocellular carcinoma, cirrhosis and chronic liver disease attributable to Hepatitis B and C is available;</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Service coverage targets</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stopping transmission</strong></td>
</tr>
<tr>
<td>3.5 A birth dose coverage of ≥ 50 % achieved</td>
</tr>
<tr>
<td>3.6 3-dose hepatitis B vaccination coverage ≥ 90% achieved</td>
</tr>
<tr>
<td>3.7 Hepatitis B vaccination is integrated in at least 50% HIV services and services targeting PWID, MSM and SW.</td>
</tr>
<tr>
<td>3.8 The national target for injection safety in health care settings has been achieved</td>
</tr>
<tr>
<td>3.9 For countries with a public health problem of injecting drug use: The national target for needle-syringe distribution has been achieved</td>
</tr>
<tr>
<td><strong>Expanding access to a continuum of services for early diagnosis, care and treatment</strong></td>
</tr>
<tr>
<td>3.10 The national Hepatitis screening targets for 2021 have been achieved</td>
</tr>
<tr>
<td>3.11 At least 30% of people with chronic Hepatitis B and C have been diagnosed</td>
</tr>
<tr>
<td>3.12 The national Hepatitis B and C treatment targets for 2021 have been achieved</td>
</tr>
</tbody>
</table>
**ACTION RECOMMENDED FOR MEMBER STATES**

Box 1: Key elements of the regional strategy for achieving Hepatitis B control target through vaccination:

1. **Routine infant hepatitis B immunization with high coverage within the first 6 months of life as part of the routine EPI service delivery plan**
   - Administer the birth dose of Hepatitis B vaccine within the first 24 hours of life
   - Ensure completion of the Hepatitis B vaccination schedule within 6 months of birth
   - Achieve and maintain ≥90% coverage with 3 doses of Hepatitis B vaccine as part of the overall global and regional goal to achieve ≥90% coverage with all antigens offered in the national immunization program.

2. **Safeguard vaccine effectiveness by ensuring Hepatitis B vaccine is not frozen during storage and transport and ensuring correct administration of vaccine by IM injection in the thigh or deltoid muscle.**

3. **Plan and implement advocacy and social mobilization to ensure high uptake of vaccine**
   - Advocate decision makers for introduction and expansion of the birth dose of Hepatitis B vaccine nationwide
   - Advocate health sector to increase communication on Hepatitis B vaccine effectiveness and benefit of birth dose of Hepatitis B for prevention of chronic Hepatitis B infection
   - Mobilize the community to increase demand for Hepatitis B vaccine.

4. **Monitor the quality of procured vaccine, cold chain and overall vaccine management at all levels.**

5. **Monitor the vaccination coverage of birth dose and the third dose of Hepatitis B at all administrative levels and take corrective action in underperforming areas.**

6. **Monitor progress towards the regional target of a prevalence of chronic hepatitis B virus infection <1% among children below 5 years of age through conducting sero-surveys.**

3.1 **Improve Hepatitis B vaccination coverage**

It is recommended that countries focus on achieving the target of at least 90% Hepatitis B childhood immunization coverage and on expanding hepatitis B virus birth-dose coverage to provide protection against mother-to-child transmission.

Key interventions include:
- **Routine immunization and birth dose** (see box 1)
- **Targeting of population groups at increased risk of Hepatitis B with vaccination**, such as health workers without prior Hepatitis B vaccination, people who inject drugs, men who have sex with men, sex workers, prisoners and prison personnel. Existing services, such as HIV prevention services for key populations at higher risk provide an opportunity to offer vaccination.

3.2 **Prevention of mother-to-child transmission of hepatitis B**

Perinatal transmission, from an HBsAg positive mother to her new-born, is a particular concern for hepatitis B transmission since 70% to 90% of new-borns infected perinatally become chronic carriers and therefore are at high risk of morbidity and mortality from cirrhosis and liver cancer during later phases of their lives.
Maintenance of hepatitis B control in the population requires effective control of perinatal transmission along with achieving high levels of immunity in children and adolescents through universal immunization.

There are two basic strategies utilised in the Region to prevent perinatal transmission. The first is to immunize all children with a birth dose of monovalent hepatitis B vaccine. It has been addressed above under 3.1. The second is to screen all pregnant women for HBsAg during a prenatal visit and then provide post exposure prophylaxis to the infants of carrier mothers with hepatitis B immune globulin (HBig) plus three or four doses of Hepatitis B vaccine. Twelve countries implement both strategies, that is, universal immunization of all children at birth with Hepatitis B vaccine plus neonatal screening of mothers and addition of HBig to infants of carrier mothers.

Key interventions include:

- Ensure that all infants born in health facilities receive a birth dose within 24 hours of birth. The immunization program must work with maternity and child health care and obstetric staff to integrate the birth dose into essential neonatal care. Infants should not be discharged from the hospital without a birth dose of hepatitis B vaccine;
- Develop strategies to timely administer a birth dose of hepatitis B vaccine to new-borns born at home; (Countries with a significant proportion of home deliveries);
- Countries that decide to continue with maternal screening/prophylaxis without universal birth dose: introduce routine assessments of screening of pregnant women for hepatitis B surface antigen to ensure high coverage, including migrants and socially deprived women;

3.3 Strengthen hepatitis prevention and control measures as an integral part of the national infection control and prevention programme in healthcare settings

Consistent implementation of infection control practices, including safe injection measures in health care settings, will reduce transmission of viral hepatitis and other infections to both users of health care services as well as health care workers.

Key interventions include:

- Develop and disseminate evidence based guidelines for the prevention and management of viral hepatitis
- Develop content of training programmes on IPC to prevent the transmission of viral hepatitis in all healthcare settings
- Address preventive measure that reduce the risk of transmission of viral hepatitis to healthcare workers of all categories
- Establishing/strengthening a national infection prevention and control regulating authority with the ability to:
  - Investigate infection outbreaks in healthcare settings
  - Oversee the implementation of safe therapeutic injection practices

Box 2

The global hepatitis strategy sets a target for increasing the percentage of medical injections administered with safety-engineered injection devices from a baseline of 5% in 2015 to 50% in 2020 and 90% in 2030. It is recommended that countries in the EMR adopt the WHO injection safety policy, with the aim of reducing unnecessary injections and transitioning, where appropriate, to the exclusive use of safety-engineered injection
- Ensure compliance with correct sterilization procedures and medical waste management in both the public and private sectors and the informal health care sector.
- Promote the exclusive use of Safety Engineered Devices and Reuse Prevention devices
- 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
- Promote assessment of IPC/injection safety practices to support with a learning culture

3.4 Ensuring safe blood supply
The World Health Assembly has endorsed three resolutions regarding the safety, quality and availability of blood and blood products in 1975 (WHA28.72), 2005 (WHA58.13) and 2010 (WHA63.12). These call for Member States ... to promote the development of national blood services based on voluntary non-remunerated donation of blood, to take all the necessary steps to update their national regulations on ... testing, to establish quality systems ... including the use of diagnostic [screening] devices to prevent transfusion-transmissible diseases with highest sensitivity and specificity. Ensuring the availability of safe blood and blood products is a vital public health duty for every national government. This responsibility encompasses the establishment of an effective national blood transfusion service that is integrated into the national health system.

Key interventions include:
- Developing and strengthening nationally coordinated blood transfusion service integrated into national health system
- Promoting voluntary non-remunerated donation of blood and blood donor care including referral of blood donors with reactive HBV and HCV screening results for confirmatory testing, evaluation, treatment and care.
- Preventing HBV and HCV transmission through quality-assured screening for HBV and HCV of all % of blood supply collected from voluntary unpaid donors

3.5 Minimizing hepatitis transmission among people who inject drugs through the provision of harm reduction services
A package of harm reduction services for people who inject drugs can be highly effective in preventing the transmission of viral hepatitis A, B and C, as well as HIV and other blood-borne infections.

The package should include:
- Effective opioid substitution therapy for opioid dependent individuals, including in closed settings
- High intensity community and facility based needle and syringe programs, including awareness raising on and promotion of low dead space syringes and other paraphernalia
- Set up infrastructure and service delivery models to reach persons who inject drugs to support easier access to hepatitis screening, care and treatment;

Box 3: While WHO recommends the use of safety-engineered injection devices in health care settings, it acknowledges the necessity to maintain a supply of various types and sizes of disposable syringes and making them available for people who inject drugs.
- Ensuring people who inject drugs have access to hepatitis A and B vaccines
- Ensuring people who use drugs have access to condoms
- Treatment of hepatitis B and C among PWID

3.6 Screening of groups at higher risk for Hepatitis B and/or C

To increase early diagnosis it is recommended that countries establish screening of groups at higher risk. Viral hepatitis screening should be integrated into health settings, where possible incorporating it into existing HIV or related screening strategies (e.g. ANC, healthcare settings, key populations). In particular for groups that are difficult to reach it is important to actively engage them in screening programs (e.g. HIV infected individuals, PWID, men who have sex with men, prisoners).

Key interventions include:
- Identifying populations at higher risk and building consensus on which populations to prioritize for screening – depending on cost-effectiveness analysis and financial and health system capacity.
- Establishing capacity for screening in health settings and outside the health care settings
- Establishing linkages between testing and other prevention and treatment services and ensure referral to treatment and chronic care

3.7 Increasing access to treatment for Hepatitis B and C and care for chronic liver disease

In each country there will be barriers to accessing treatment for people diagnosed with hepatitis B and/or C infection. The barriers will be mostly related to financial or geographical inaccessibility, to cumbersome (non user-friendly) procedures and to fear of stigma. Simplification of case management and decentralization has great potential to overcome such barriers. Partnerships and advocacy to reduce the cost of the drugs will be needed. A phased approach towards introducing screening, diagnosis, and treatment of hepatitis is recommended to give time to determine optimal service delivery models and financing strategies in each country’s context.

Key interventions include:
- Planning for phased implementation of screening, diagnosis, and treatment
- Ensuring access to antiviral therapy for hepatitis B and C in the public sector
- Identifying optimal service delivery models through adapting viral hepatitis care models that have shown success in other countries and developing demonstration projects
- Providing training on case management guidelines for health care workers and promoting adherence to the guidelines

Box 4: Groups at higher risk for whom HCV/HBV testing is recommended may include:
1. People who ever injected drugs,
2. People who were ever on long-term hemodialysis,
3. People living with HIV,
4. People who received blood products / organ transplants before introduction of donor screening,
5. Medical and social workers after needle sticks, sharps, or mucosal exposures to HBV/HCV-positive blood
6. Children born to HBV/HCV-positive
**Actions for the WHO Secretariat**

*Technical cooperation*

The Regional Office and country offices shall provide technical support to member states to

- strengthen national transfusion services
- determining the most appropriate screening policies for the respective country context

*Dissemination of evidence and best practices*

- Promote implementation of safe therapeutic injection practices and of WHO universal precautions and infection control guidelines
- Disseminate and promote evidence based guidance on WHO recommended harm reduction interventions, including OST and NSP to countries
- Disseminate WHO guidelines for screening, diagnostic testing and treatment
- Disseminate WHO guidelines on blood donor selection, blood donor counseling, blood screening and appropriate clinical use of blood and blood products

*Policy advice and dialogue*

- Provide policy advice on effective harm reduction interventions and integrated health service provision to PWID and initiate dialogue with stakeholders on how to address barriers to the implementation of harm reduction.

**Strategic Direction 4: Systems strengthening for equitable access**

**Programmatic Milestones**

<table>
<thead>
<tr>
<th>Milestones for the national response</th>
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</tr>
</thead>
<tbody>
<tr>
<td>4.1 A strategy with targets for achieving the best price for medicines and diagnostics has been formulated and is being pursued.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.2 A system for integrated and inter-linked Hepatitis prevention, testing, care and treatment services at community, primary, secondary and tertiary care levels has been defined (including service package components to be delivered at each level).</td>
<td></td>
<td>2018</td>
</tr>
<tr>
<td>4.3 Core hepatitis competencies of different cadres of health workers at different levels of the health system, considering task shifting options</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.4 Training and supervisory needs of health workers have been defined.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.5 Legal, regulatory and policy barriers have been identified that hinder equitable access to hepatitis services, especially for most-affected populations and other vulnerable groups.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.6 Cost of quality hepatitis diagnostics and medicines has been reduced to ≤ the targeted price.</td>
<td></td>
<td>2021</td>
</tr>
<tr>
<td>4.7 Pre-service and in-service training for health workers has been updated to include training on core hepatitis competences</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.8 Standardized testing algorithms for viral hepatitis surveillance, blood safety, and diagnosis are applied (at least) by all public sector laboratories</td>
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</tr>
</tbody>
</table>

**Action recommended for Member States**

4.1 *Ensuring long-term viability of hepatitis programming through integration*

Viral hepatitis prevention and control should be integrated within Ministry of Health structures and programs to ensure the long term viability of hepatitis interventions. Integration of policies, and service delivery is
required at different levels of the health system, with the relative contributions and roles of primary health care, referral care and hospital care being defined.

Key interventions include:
- Defining appropriate models of integration of Hepatitis prevention, testing, care and treatment services at different levels of the health system (including Hepatitis service package components to be delivered by general health services at each level and by other relevant specialized services).
- Establishing linkages with programmes in other sectors, such as correctional services, police and justice, social welfare, water and sanitation.
- Mainstreaming hepatitis policies in relevant existing policies such as blood safety, infection control, antenatal care, and others. (see strategic direction 1)

4.2 Strengthening community systems: Engaging people at risk of and/or living with Hepatitis in the response.
Key interventions include:
- Recognizing and inviting groups at risk, people living with viral hepatitis and relevant civil society organizations to actively participate in viral hepatitis policy development processes, implementation and in monitoring and evaluation of the response.
- Supporting national patient group formation and mobilization.

4.3 Ensuring access to good quality and affordable hepatitis vaccines, medicines, diagnostics

Effective hepatitis programs are dependent on the uninterrupted supply of quality-assured vaccines, medicines, diagnostics and other commodities. Procurement and supply management systems are required to ensure that the right products are selected, purchased at an affordable price and efficiently delivered to the point of care.

Key interventions include:
- Including the direct-acting antivirals in the essential medicines list as per WHO model list
- Ensuring that intellectual property (IP) issues are not delaying access to medicines and diagnostics by monitoring the IP situation closely and taking all necessary action to ensure access including the application of flexibilities of the TRIPS agreement.
- Pursuing different mechanisms to achieve the best price for medicines and diagnostics, including coordinating procurement between treatment providers to maximize procurement volume and reduced prices.
- Building capacity for pharmaco-vigilance especially for generic products.

4.4 Building the capacity of the health work force

Many essential viral hepatitis interventions are integrated within broader health services and programs, such as programs for child vaccination, blood and injection safety, food safety, water and sanitation, harm reduction for people who use drugs, clinical management of infectious diseases and chronic care for non-communicable diseases. In all such settings, including primary health care, health workers should be knowledgeable about viral hepatitis risk and infection, and the package of essential hepatitis interventions. Community-based and peer-support workers play an important role in reaching marginalized groups, linking people with chronic hepatitis to care, supporting treatment adherence and providing chronic care. Health and community workers should all be competent to work with people living with chronic hepatitis infection and with key populations at higher risk.
Key interventions include:
- Defining the roles and responsibilities of different levels of the health system in delivering hepatitis services, from community-based and primary health services through to tertiary referral centres.
- Ensuring that the national health workforce strategy and/or plan accommodates the needs of hepatitis services.
- Defining the core hepatitis competencies of different cadres of health workers at different levels of the health system, considering task shifting options.
- Defining training and supervisory needs and including viral hepatitis in pre-service and in-service training for health workers accordingly.
- Providing training and appropriate compensation for their work to community-based and peer-support workers.

4.5 Strengthening laboratory capacity

National laboratories should have the ability to adequately support clinical and public health activities aimed at reducing the burden of disease of viral hepatitis. This includes quality diagnosis of acute and chronic hepatitis with timely reporting of results. Blood services should have the capacity to ensure the safety of blood, blood components, and blood products by screening for HBV and HCV.

Key interventions include:
- Developing domestic laboratory network for viral hepatitis with one designated national reference laboratory (quality management system, domestic external quality assurance system). National reference laboratory should establish and maintain a quality management system and participate in a regional or international external quality assessment scheme.
- Establishing a quality monitoring system and a domestic external quality assurance system assessment scheme through the national reference laboratory. Quality monitoring should include community-based facilities using rapid tests.
- Adopt standardized testing algorithms for viral hepatitis surveillance, blood safety, and diagnosis.
- Promote access to new laboratory tests and technologies for more accurate diagnosis of viral hepatitis.

4.6 Promoting an enabling environment (policies, laws, regulations)

The health sector has an obligation to promote an enabling policy environment that reduces people’s vulnerability and risk for hepatitis infection, facilitates access to health services and enhances their reach, quality and effectiveness – especially for most-affected populations. The health sector must ensure that people with viral hepatitis and those at risk are not exposed to stigmatization and discrimination in health care settings.

Key interventions include:
- Identifying and removing legal, regulatory and policy barriers that hinder equitable access to hepatitis services, especially for most-affected populations and other vulnerable groups.
- Putting in place policies that prevent stigmatizing and discriminating attitudes and practices against people living with hepatitis in health care settings.

Actions for the WHO Secretariat

4.1 Leading and convening
- Support affected populations to actively participate in national and regional stakeholder consultations.
4.2 Technical cooperation

The Regional Office and country offices shall provide technical support to member states to
- Develop country-specific access strategies for hepatitis medicines
- Develop the most appropriate service delivery models to facilitate scale-up of Hepatitis testing, treatment and chronic care

STRATEGIC DIRECTION 5: FINANCING FOR SUSTAINABILITY

Adequate investment in the full continuum of hepatitis services is necessary to achieve the targets for 2020 and 2030, and to promote universal health coverage. A sustainable response will require funding the essential hepatitis package through the national health financing system by: mobilizing sufficient and predictable funding; minimizing financial burden for individuals and households through prepayment and pooling; and avoiding wastage in using available funds to enhance efficiency and ensure sustainability.

PROGRAMMATIC MILESTONES

<table>
<thead>
<tr>
<th>Milestones for the national response</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1 An investment case for an enhanced viral hepatitis response has been developed (in high burden countries) based on economic assessment of the burden of viral hepatitis and the cost of inaction (e.g., HCC, cirrhosis)</td>
<td></td>
</tr>
<tr>
<td>5.2 A specific portion of National health budget has been allocated to viral hepatitis prevention, care and treatment</td>
<td>2018</td>
</tr>
<tr>
<td>5.3 Cost-effectiveness analyses of screening and treatment interventions to optimize allocation of resources for viral hepatitis prevention, care and treatment has been carried out</td>
<td></td>
</tr>
<tr>
<td>5.4 A set of essential viral hepatitis interventions, services, medicines and commodities has been defined to be included in the national health benefit package</td>
<td></td>
</tr>
<tr>
<td>5.5 A set of essential viral hepatitis interventions, services, medicines and commodities has been included in the national health benefit package covered by a prepayment arrangement (e.g. government budget or social health insurance)</td>
<td>2021</td>
</tr>
</tbody>
</table>

ACTION RECOMMENDED FOR MEMBER STATES

5.1 Mobilizing resources for action on viral hepatitis

Key interventions include:
- Carry out economic analysis on the burden of viral hepatitis (e.g. hepato-cellular carcinoma, cirrhosis) and its associated interventions (see also strategic directions 1 and 2 on economic analysis and building an investment case)
- Allocate a specific portion of national health budget to viral hepatitis prevention, care and treatment in proportion to countries’ and communities’ disease burden
- Identify additional revenue raising mechanisms to mobilize needed resources for viral hepatitis prevention, care and treatment in proportion to countries’ and communities’ disease burden
- Identify and implement innovative financing mechanism
- Include micro-financing institutions as partners in financing treatment

5.2 Inclusion of preventive, diagnostic and curative services in a national health benefit package

Key interventions include:
- Each country needs to define a set of essential viral hepatitis interventions, services, medicines and commodities relevant to the country context, to be included in the national health benefit package – to be financed from the general budget or a social health insurance arrangement. The benefit package should be covered in manner to minimize out-of-pocket payments, to ensure access to services for all who need them; cover the entire continuum of hepatitis services, including prevention, diagnosis, treatment and care; and enhance financial protection. Selection of essential interventions and services should be through a transparent process, which would take into account the following criteria: efficacy, effectiveness, feasibility, cost, cost-effectiveness, acceptability, relevance, demand and ethics. The selection process would benefit from broad stakeholder engagement, including service providers and affected communities; and should be informed by scientific evidence and good practice. The package should be regularly reviewed to ensure that the selected interventions reflect changes in the country epidemic and context, advances in technologies and service delivery approaches, and evidence of impact or harm. Combinations of interventions should be specifically considered, recognizing that some interventions will only be effective, or achieve maximum impact, if they are delivered in combination with other interventions.

5.3 Monitoring of health expenditure

Key interventions include:
- Ensure integration of health spending on viral hepatitis prevention, care and treatment in the national health accounts (in high burden countries)

5.4 Ensuring value for money in allocating and using the budget for viral hepatitis

Key interventions include:
- Ensure integration of health spending on viral hepatitis prevention, care and treatment in the national health accounts (in high burden countries)
- Identify areas of inefficiency in health workforce mix and health technologies related to viral hepatitis prevention, care and treatment and employ effective measure to address them.
- Conduct cost-effectiveness analysis of screening and treatment interventions to optimize allocation of resources for viral hepatitis prevention, care and treatment.
- Join together, where appropriate, hepatitis with HIV programs to address co-infection and optimize use of resources.

Actions for the WHO Secretariat

5.1 Technical cooperation

The Regional Office and country offices shall provide technical support to member states to:
- Build capacities in conducting economic analysis for developing the investment case for viral hepatitis prevention, care and treatment; as well as, in cost-effectiveness analysis of prevention and treatment interventions.
- Develop country-relevant essential hepatitis package based on country epidemiological profile and socioeconomic imperatives.
- Ensure integration of viral hepatitis prevention, care and treatment interventions, services, medicines and commodities in national health benefit package.

5.2 Information generation and exchange
The Regional Office and country offices shall work to facilitate information sharing on effective, efficient and equitable viral hepatitis prevention, care and treatment interventions, through:

- Arranging for country exchange of experience through study tours and information sharing.
- Convening policymakers and experts to share and discuss up-to-date development in the economics of prevention and control of viral hepatitis.

**VI Monitoring and Evaluation Framework**

The Regional Action Plan adopts the global framework for monitoring and evaluation of the response to viral hepatitis. The framework defines a minimum set of 10 core indicators to monitor and evaluate the health sector response to viral hepatitis B and C along a public health program results chain.

![Diagram of Monitoring and Evaluation Framework](image)

*Figure 3: Global monitoring and evaluation framework for the health sector response to viral hepatitis B and C*
The global framework emphasizes 10 core indicators to monitor progress towards the achievement of the targets set out in the global Hepatitis strategy {1; 8}. In addition WHO proposes 27 indicators: of these, 10 indicators are specific to viral hepatitis and 17 have been used in the past by other programmes, including HIV/sexually transmitted infection (STI) (four indicators), immunization (two indicators), blood safety (two indicators), injection safety and infection control, harm reduction (two indicators) and noncommunicable diseases, cancer (two indicators).

Table 2. List of recommended 10 core indicators to monitor and report progress at global and national levels

<table>
<thead>
<tr>
<th>Indicator number</th>
<th>Indicator name</th>
<th>Programmatic area</th>
</tr>
</thead>
<tbody>
<tr>
<td>C.1 a</td>
<td>Prevalence of chronic HBV infection</td>
<td>Viral hepatitis</td>
</tr>
<tr>
<td>C.1 b</td>
<td>Prevalence of chronic HCV infection</td>
<td></td>
</tr>
<tr>
<td>C.2</td>
<td>Infrastructure for HBV and HCV testing</td>
<td>Immunization</td>
</tr>
<tr>
<td>C.3 a</td>
<td>Coverage of timely hepatitis B vaccine birth dose (within 24 hours) and other interventions to prevent mother-to-child transmission of HBV</td>
<td>Immunization</td>
</tr>
<tr>
<td>C.3 b</td>
<td>Coverage of third-dose hepatitis B vaccine among infants</td>
<td></td>
</tr>
<tr>
<td>C.4</td>
<td>Facility-level injection safety</td>
<td>Injection safety</td>
</tr>
<tr>
<td>C.5</td>
<td>Needle-syringe distribution</td>
<td>HIV, harm reduction</td>
</tr>
<tr>
<td>C.6</td>
<td>People living with HCV and/or HBV diagnosed</td>
<td></td>
</tr>
<tr>
<td>C.7 a</td>
<td>Treatment coverage for hepatitis B patients</td>
<td>Viral hepatitis</td>
</tr>
<tr>
<td>C.7 b</td>
<td>Treatment initiation for hepatitis C patients</td>
<td></td>
</tr>
<tr>
<td>C.8 a</td>
<td>Viral suppression for chronic hepatitis B patients</td>
<td></td>
</tr>
<tr>
<td>C.8 b</td>
<td>Cure for chronic hepatitis C patients treated</td>
<td></td>
</tr>
<tr>
<td>C.9 a</td>
<td>Cumulated incidence of HBV infection in children 5 years of age</td>
<td>Non communicable diseases, cancer</td>
</tr>
<tr>
<td>C.9 b</td>
<td>Incidence of HCV infection</td>
<td></td>
</tr>
<tr>
<td>C.10</td>
<td>Deaths from hepatocellular carcinoma (HCC), cirrhosis and liver diseases attributable to HBV and HCV infection</td>
<td></td>
</tr>
</tbody>
</table>

Data sources for these indicators will include biomarker surveys (specific or combined), cancer registries, vital registration statistics, health-care facility surveys, surveillance and estimates through mathematical modelling.

Countries will need to review their current monitoring system to allow more complete and reliable data collection, data analysis and report progress in the indicators with more focus on the 10 core global indicators.

Progress towards achievement of the programmatic milestones set out for countries in the regional action plan should be monitored by each country and will be monitored by the Regional Office through two regional reviews at the end of 2018 and 2021.
**VII Annex: Global Targets of the WHO Global Health Sector Strategy on Viral Hepatitis, 2016–2021**

The strategy includes both impact (incidence and mortality) and service coverage targets (see figure 4 and table 1).

By 2020, five million people will be receiving treatment for chronic hepatitis B virus infection, three million people will have been treated for chronic hepatitis C virus infection and the number of new cases of chronic hepatitis infection would have been reduced by 30% compared with the number of new cases in 2015. By 2030, the incidence of chronic hepatitis infection will have been reduced by 90% and there will be universal access to key prevention and treatment services.

![Graph showing reduction in hepatitis B and C infections](image)

*Figure 4. Global impact targets and milestones for reducing new cases of and deaths from chronic viral hepatitis B and C infection*

Global impact targets are supported by coverage targets for interventions that are necessary on the way to elimination of viral hepatitis as a public health threat.

**Table 1. Global intervention coverage targets for 2030 and milestones for 2020**

<table>
<thead>
<tr>
<th>Intervention targets (Coverage targets)</th>
<th>Indicator</th>
<th>2030</th>
<th>2020</th>
<th>Baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBV vaccination</td>
<td>Childhod vaccine coverage</td>
<td>90%</td>
<td>90%</td>
<td>81%</td>
</tr>
<tr>
<td>HBV MTCT (mother to child)</td>
<td>Birth dose vaccine coverage (or other approach to prevent MTC)</td>
<td>90%</td>
<td>50%</td>
<td>38%</td>
</tr>
<tr>
<td>Safe injection</td>
<td>Safe injections (needs to cover in and out facility)</td>
<td>90%</td>
<td>50% coverage</td>
<td>5%</td>
</tr>
<tr>
<td>Harm reduction</td>
<td>Number of needles/PWID/year (as part of effective harm reduction package)</td>
<td>300 (75% coverage)</td>
<td>200 (50% coverage)</td>
<td>20</td>
</tr>
<tr>
<td>Testing</td>
<td>Percent of persons with chronic HBV and HCV diagnosed</td>
<td>90%</td>
<td>30%</td>
<td>5%</td>
</tr>
<tr>
<td>HBV Treatment</td>
<td>Treatment eligible persons with chronic HBV treated</td>
<td>80%</td>
<td>Estimated 5m treated</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>HCV Treatment</td>
<td>Treatment eligible persons with chronic HCV treated</td>
<td>80%</td>
<td>Estimated 3m treated</td>
<td>&lt;1%</td>
</tr>
</tbody>
</table>
REFERENCES

1 Global Burden of Disease and WHO/UNAIDS estimates.
3 Epidemiological data review on hepatitis B virus infection in the Eastern Mediterranean region Center for Disease Analysis, Louisville, CO, USA May 2016
4 Characterizing hepatitis C virus infection levels and transmission in the World Health Organization Eastern Mediterranean Region: Implications for strategic action.