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# Action plan for the health sector response to viral hepatitis in the WHO European Region

DRAFT



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## Abbreviations

AIDS	acquired immunodeficiency syndrome
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
EECA	eastern Europe and central Asia
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
EU	European Union
GARPR	Global AIDS Response Progress Reporting
HCC	hepatocellular carcinoma
HIV	human immunodeficiency virus
HAV	hepatitis A virus
HBV	hepatitis B virus
HCV	hepatitis C virus
HDV	hepatitis D virus
HEV	hepatitis E virus
IDU	injecting drug use
IEC	information, education and communication
IPC	infection prevention and control
MSM	men who have sex with men
OST	opioid substitution therapy
PLHIV	people living with HIV/AIDS
PWID	people who inject drugs
SSP	Sanitation Safety Planning
STI	sexually transmitted infection
SW	sex worker
TB	tuberculosis

TRIPS trade-related aspects of intellectual property rights  
UNAIDS Joint United Nations Programme on HIV/AIDS  
UNICEF United Nations Children's Fund  
WSP Water Safety Plan  
WHO World Health Organization

## Contents

Executive summary.....	6
1. Introduction .....	7
Epidemiology and burden of viral hepatitis .....	7
Response to viral hepatitis in the WHO European Region: achievements and remaining challenges .....	9
2. The action plan for the health sector response to viral hepatitis .....	11
Purpose.....	11
Development of the Action plan.....	12
3. Vision, goal and targets.....	12
Vision.....	12
Goal.....	13
Targets.....	13
4. Strategic directions and priority actions.....	14
4.1 Strategic direction 1: Information for focused action .....	14
Data for informed decisions .....	14
Evidence based national planning.....	16
National viral hepatitis communication and awareness strategy as an integrated component of the national action plan.....	16
4.2 Strategic direction 2: Interventions for impact.....	17
Hepatitis control through immunization (HAV and HBV).....	18
Prevention of mother-to-child transmission of hepatitis B .....	19
Blood and tissue safety.....	20
Injection safety and infection prevention and control (IPC) in and out of health care settings.....	21
Prevention of HBV and HCV transmission associated with injecting drug use .....	22
Prevention of sexual transmission of viral hepatitis and other sexually transmitted infections .....	23
Prevention: ensuring food safety and water safety .....	24
Diagnosing hepatitis virus infections.....	25
Enhancing chronic hepatitis care and treatment.....	26
4.3 Strategic direction 3: Delivering for equity.....	27
Identifying populations and locations most affected and tailoring hepatitis services.....	28
Strengthening human resources.....	28
Promoting an enabling environment: overcoming legal barriers, and taking an evidence-based and integrated service delivery approach .....	29
4.4 Strategic direction 4: Financing for sustainability .....	30
Increasing investments including through innovative funding approaches ...	30
Ensuring access to good quality and affordable vaccines, medicines and diagnostics – reducing prices and costs, and removing inefficiencies.....	30
4.5 Strategic direction 5: Innovation for acceleration.....	31
5. Implementation .....	32

5.1 Partnerships .....	32
5.2 Monitoring and evaluation .....	33
References .....	33
Annex. Summary of proposed milestones and targets.....	35

## **Executive summary**

Viral hepatitis is a global public health threat that, until recently, has not received sufficient attention. In the WHO European Region, an estimated 171 000 people die each year from viral hepatitis-related causes, generally due to late effects of chronic hepatitis B and hepatitis C. It is estimated that more than 13 million people in the European Region are living with chronic hepatitis B virus (HBV) infection and more than 15 million with chronic hepatitis C virus (HCV) infection.

This is the first Action plan for the health sector response to viral hepatitis in the WHO European Region. It is aligned with both the 2030 Agenda for Sustainable Development and Health 2020, the European policy for health and well-being. This new Action plan addresses all five hepatitis viruses with a particular focus on HBV and HCV and adapts the Global Health Sector Strategy on Viral Hepatitis 2016–2021, adopted by the Sixty-ninth World Health Assembly in May 2016, to the political, economic and epidemiological contexts of the European Region.

The overall goal of the Action plan is the elimination of viral hepatitis as a public health threat in the European Region by 2030, by reducing morbidity and mortality due to viral hepatitis and its complications, and ensuring equitable access to recommended prevention, testing, care and treatment services for all. This will require a coordinated, comprehensive and integrated health system response, including national planning informed by strategic information and based on the local context, awareness raising, prevention of transmission, and improved access to diagnosis, treatment and care of viral hepatitis. Equity is critical and the most affected groups and those most at risk of viral hepatitis infection must receive special attention.

The Action plan sets regional milestones and targets across the continuum of viral hepatitis services and proposes priority actions for Member States, accompanied by supporting actions for WHO, under five strategic directions: information for focused action; interventions for impact; delivering for equity; financing for sustainability; and innovation for acceleration.

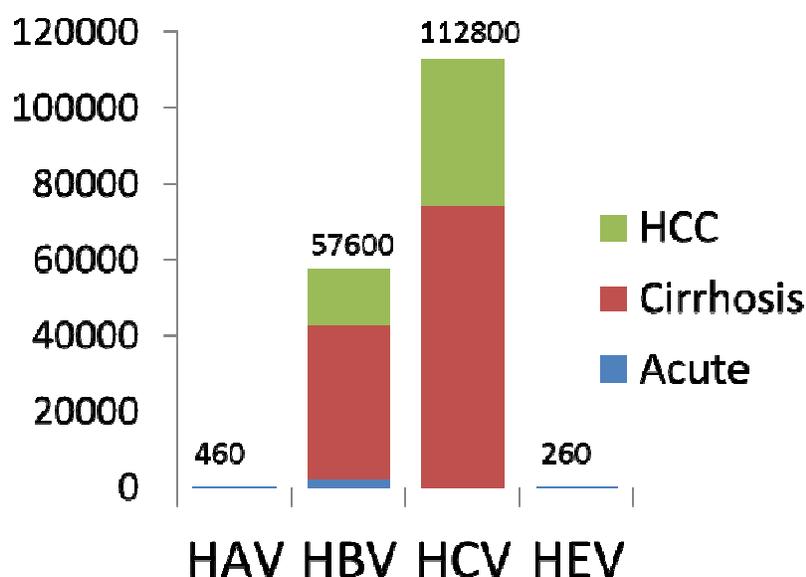
The Action plan has been developed through a Region-wide participatory process, and was finalized after consideration by and guidance from the Twenty-third Standing Committee for the Regional Committee for Europe. This background document is submitted to complement the working document (EUR/RC66/10), a draft resolution (EUR/RC66/Conf. Doc./6) and the financial and administrative implications for the Secretariat (EUR/RC66/10 Add.1) for consideration by the 66<sup>th</sup> session of the Regional Committee for Europe.

## 1. Introduction

### Epidemiology and burden of viral hepatitis

Viral hepatitis is a leading cause of mortality globally that until recently did not receive sufficient attention as a public health priority until recently. In the WHO European Region, an estimated 171 000 people die annually from viral hepatitis-related causes (approximately 2% of all deaths) or more than 400 deaths per day (1). Approximately 98% of these deaths are due to late effects of chronic hepatitis B and hepatitis C (estimated 56 000 and 112 500 deaths in 2013, respectively) and the remainder are attributable to acute viral hepatitis infections (Figure 1). It is estimated that more than 13 million people in the European Region are living with hepatitis B virus (HBV) infection and more than 15 million with chronic hepatitis C virus (HCV) infection (2).

**Figure 1. Mortality from viral hepatitis in the WHO European Region, 2013 (1)**



HAV: hepatitis A virus; HBV: hepatitis B virus; HCC: hepatocellular carcinoma; HCV: hepatitis C virus; HEV: hepatitis E virus.

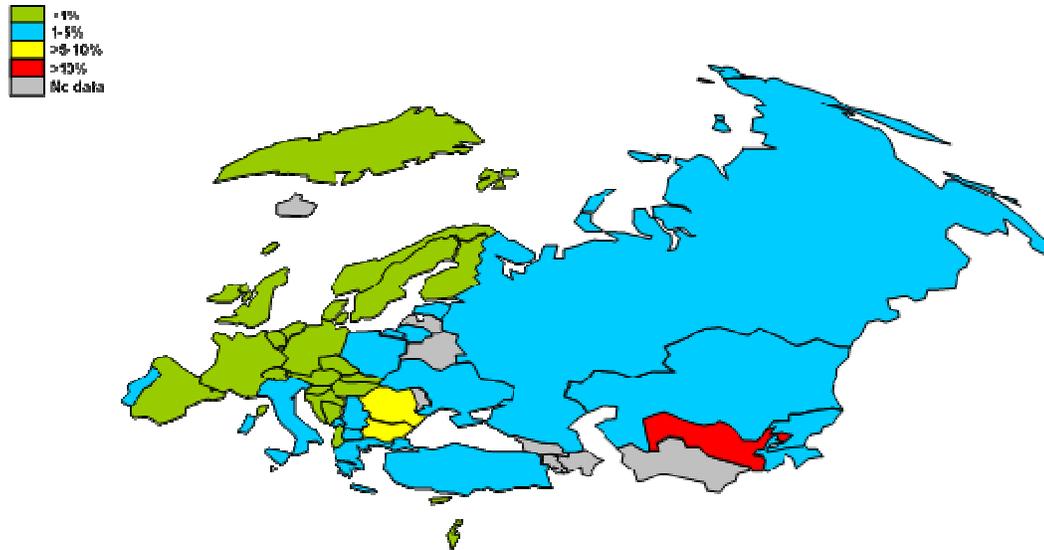
The five hepatitis viruses – hepatitis A virus (HAV), HBV, HCV, hepatitis D virus (HDV) and hepatitis E virus (HEV) – differ with regard to transmission routes, affected populations, geographic distribution and socioeconomic environments, and result in a range of health outcomes. Hepatitis A and E are associated with food- and water-borne transmission and typically resolve without long term pathology. HBV, HCV and HDV are blood-borne infections with a high risk of transmission through unsafe injections and other medical practices, sexual contact, and sharing equipment for injecting drug use. In addition, HBV transmission can occur from-mother-to-child and horizontally through household contacts in early childhood. HBV, HCV and HDV often result in

chronic infection which may remain undetected for decades, though lead progressively to liver cirrhosis and cancer.

HAV infections remain a challenge for many countries with tens of thousands of cases occurring annually, resulting in hundreds of deaths, mostly in vulnerable age groups (the elderly and children below 1 year of age), and almost exclusively in lower- and middle-income countries. The incidence of hepatitis A in the WHO European Region has been decreasing since the 1990's, with the majority of the countries having a low-endemicity profile. However, incidence, transmission source, and risk groups vary widely between countries, with eastern Europe and central Asia being the most affected.

The epidemiology of hepatitis B in the Region is diverse, indicated by HBsAg prevalence that ranges from extremely low (<0.1%) in northern Europe to high (>10%) in countries in central Asia (Figure 2). Despite a decrease in incidence since 2000 and the positive impact of vaccination on seroprevalence in younger age groups, many Member States in the eastern and southern part of the European Region still face a heavy burden due to of chronic HBV infection in older age cohorts. In most countries of western and northern Europe, the majority of cases are now registered as imported (3), and the burden is considerably higher among immigrants from countries with high prevalence (4). Certain groups, such as people with multiple sexual partners, men who have sex with men (MSM), people who inject drugs (PWID), and health care workers are at increased risk of HBV infection.

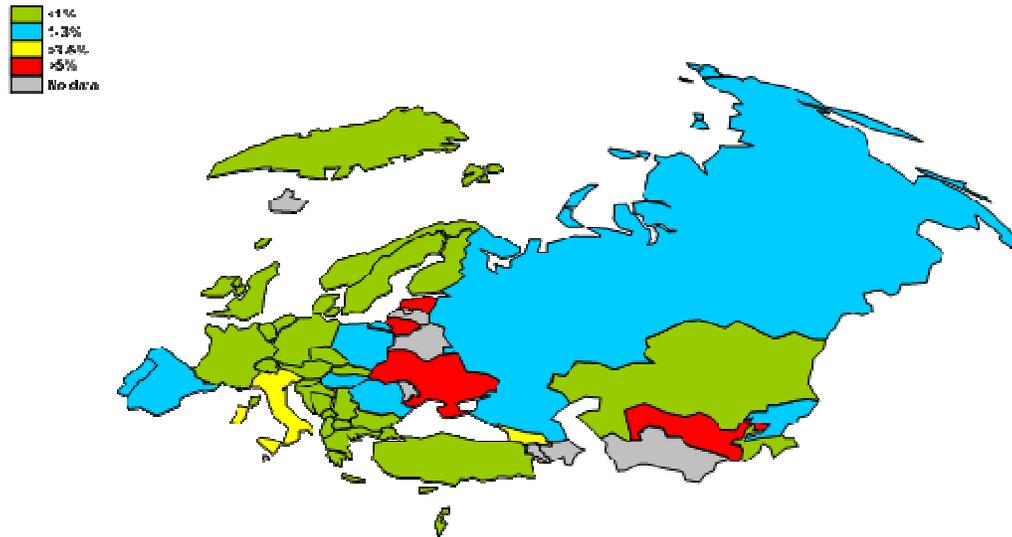
**Figure 2. Prevalence of hepatitis B surface antigen (HBsAg) in the WHO European Region, 2013 (2)**



The epidemiology of hepatitis C in the WHO European Region ranges substantially from countries with very low prevalence (<0.5%) in some northern, western and central European countries to high prevalence (>5%) in some countries in southern and eastern Europe and central Asia (Figure 3). The burden of chronic hepatitis C is disproportionately high in HIV infected populations among PWIDs and MSM. Historically new infections typically occurred through blood transfusions and other

forms of nosocomial transmission, though injection drug use now accounts for 80% of new HCV infections with a known transmission route in European Union/European Economic Association (EU/EEA) countries (5). In several Member States transmission due to unsafe procedures in and outside health care settings continues to play an important role.

**Figure 3. Prevalence of antibodies to hepatitis C virus (anti-HCV) in the WHO European Region, 2013 (2)**



HDV infection occurs either as co-infection (with HBV) or as super-infection in patients with chronic hepatitis B. Most countries do not have reliable data on HDV prevalence; however it is known to be endemic in some countries of eastern Europe and central Asia (6). HDV infection accelerates progression of liver disease and is increasingly difficult to treat.

HEV infection is the most common cause of acute viral hepatitis. The infection is usually asymptomatic and until recently the majority of cases were considered to be associated with travel to endemic regions. However, recent studies show that in the last years there has been an increase in the number of autochthonous cases, including outbreaks related to consumption of pig meat and wild animal meat products in several countries in the Region (7). Certain population groups are also more vulnerable to hepatitis E infection resulting from blood transfusion (such as transplant patients receiving immunosuppressive treatment).

### **Response to viral hepatitis in the WHO European Region: achievements and remaining challenges**

The epidemiology and burden of viral hepatitis across the Region is diverse, with very low prevalence of chronic hepatitis B and C among the general population in northern Europe and high prevalence in many countries in southern and eastern Europe and

central Asia. In addition to this geographical variability, specific populations can be more affected by, or be at higher risk of, viral hepatitis infection<sup>1</sup>.

Progress has been achieved in some Member States with regard to enhancing political commitment to control viral hepatitis, as evidenced by an increase in the number of countries developing national hepatitis prevention and control strategies and action plans. Many countries, however, still have not prioritized viral hepatitis as a public health threat and lack national strategies and well-funded action plans.

There are significant gaps in viral hepatitis surveillance in many Member States, particularly where disease burden, including viral hepatitis-related liver cirrhosis and cancer, information is scarce, and challenges persist in assuring high quality, validated diagnostic assays. This results in poor epidemiological baselines and undermines specific and targeted response efforts.

The majority of Member States in the European Region have successfully implemented universal childhood HBV immunization programmes and achieved 90% or higher coverage with three doses of the HBV vaccine. Two countries implement universal vaccination of teenagers and six Member States with very low HBV endemicity do not implement universal vaccination, thereby relying on selective immunization of people who are at high risk for HBV infection, including health care workers. Increasing anti-vaccination sentiment and vaccine hesitancy negatively affect hepatitis B vaccine uptake in many countries of WHO European Region. The monitoring of knowledge and attitudes and health-seeking behaviours are limited, which compromises the ability of authorities to effectively address public concerns.

All Member States implement strategies to prevent perinatal transmission of HBV, through either universal newborn vaccination or universal screening of pregnant women and targeted prevention of transmission from mothers living with chronic HBV infection. However, some countries still do not have effective systems to monitor the coverage of screening pregnant women, and timeliness and completeness of post-exposure prophylaxis of newborns.

For hepatitis A, several countries with intermediate endemicity have introduced hepatitis A vaccination into routine childhood immunisations, while others effectively implemented targeted vaccination strategies for groups at higher risk and also as an outbreak control measure.

Infection prevention and control in health care settings, including blood and injection safety, have improved significantly in the Region over recent decades. Nosocomial transmission of viral hepatitis, however, continues to play an important role in some Member States, particularly in eastern Europe and central Asia. In some

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<sup>1</sup> **Populations most affected and at higher risk.** Each country should define the specific populations within their borders that are most affected by viral hepatitis epidemics and the response should be based on the epidemiological and social context. These could differ according to different local contexts but may include: (a) people who have been exposed to viral hepatitis through unsafe blood supplies and unsafe medical injections and procedures; (b) transgender people and men who have sex with men; (c) sex workers; (d) prisoners; (e) people who inject drugs; (f) migrant and other mobile populations and people affected by conflict and civil unrest. People who will require specific attention include those with coinfections such as: hepatitis B and C combined; viral hepatitis and tuberculosis; and HIV and viral hepatitis (8).

countries, non-medical settings such as cosmetic and tattoo facilities have been associated with poor infection control owing to inadequate disinfection and sterilization practices thereby increasing the risk of transmission of blood-borne hepatitis viruses.

The incidence and prevalence of viral hepatitis among certain most affected and at risk populations, particularly people who inject drugs and prisoners remain high in many countries (2, 9), and access to prevention and harm reduction services varies widely across the Region. In some countries, legal barriers and challenges hamper effective viral hepatitis and HIV prevention measures, such as needle and syringe programmes and opioid substitution therapy among people who inject drugs, while in others, the sustainability of harm reduction programmes is seriously threatened by the withdrawal of international funding, from the Global Fund to Fight AIDS, Tuberculosis and Malaria.

The influx of migrants, refugees and asylum seekers to the WHO European Region poses health challenges for the displaced individuals and their host communities. This changes the epidemiology of the virus as migrant populations often lack access to healthcare so their vaccination status, prevalence, and incidence may go underreported and unreported. Many western European countries have experienced a rise of chronic HBV infections associated with migrants who move from countries of high-intermediate to low endemicity. Strategies and interventions tailored for these migrant populations need to be prioritized (4).

The burden of comorbidities and co-infections, for chronic hepatitis patients is high. Alcoholic liver disease remains the main cause of liver cirrhosis in many countries of the Region and its co-morbidity with chronic viral hepatitis is not uncommon. The burden of HCV/HIV co-infection is particularly high in eastern Europe and central Asia. Of an estimated 2.3 million people globally living with HIV and co-infected with hepatitis C 27% are in eastern Europe and central Asia (10).

Rapid progress in the development of treatments for chronic viral hepatitis infections in recent years has made it possible to cure chronic HCV infection in more than 90% of patients, and to effectively control chronic HBV infection through suppression of viral replication, thus resulting in a substantial reduction in viral hepatitis-related morbidity and mortality. Affordability and sustainability of treatment, as well as treatment access remain major obstacles in most Member States, particularly as the cost of novel direct-acting antiviral therapies for chronic HCV infection remains extremely high.

## **2. The action plan for the health sector response to viral hepatitis**

### **Purpose**

This Action plan advocates for the elimination of viral hepatitis as a public health threat in the European Region by 2030. It provides the framework for a comprehensive health sector response to viral hepatitis, including evidence-informed national planning based on local contexts and needs, awareness raising, prevention of transmission, diagnosis, care and treatment of viral hepatitis, with special attention to the populations most affected and at higher risk of viral hepatitis infection. Recognizing variations in viral

hepatitis epidemiology and availability of resources across the countries in the European Region, the Action plan is intended to guide Member States in developing country-specific national viral hepatitis prevention and control strategies and plans. While the Action plan addresses all five hepatitis viruses, its major focus is on HBV and HCV, given the high public health burden they represent in the Region.

The Action plan is built around three organizing frameworks: universal health coverage; the continuum of viral hepatitis services; and the promotion of a public health approach. It proposes that countries address their hepatitis-related priorities through the application of scientific evidence and technical knowledge with full involvement of civil society, most importantly people living with chronic viral hepatitis, taking a whole-of-society approach, ensuring respect for human rights, gender equality and equity. It suggests the adoption of a whole-of-government approach using a multisectoral partnership model.

## **Development of the Action plan**

Member States discussed and requested the development of the Action plan for the health sector response to viral hepatitis in the European Region at the regional consultation for the global health sector strategies on HIV, viral hepatitis and STIs, held in Copenhagen, Denmark, in June 2015.

This Action plan adapts the Global Health Sector Strategy on Viral Hepatitis 2016–2021 (8), endorsed by the Sixty-ninth World Health Assembly in resolution WHA69.22, to the epidemiological, social and political contexts of the countries of the European Region. It also aligns with the 2030 Agenda for Sustainable Development and Health 2020, the European policy framework for health and well-being (11), the European Vaccine Action Plan 2015–2020 (12); the Action plan for sexual and reproductive health: towards achieving the 2030 Agenda for Sustainable Development in Europe – leaving no one behind (13) and the Action plan for the health sector response to HIV in the Region (14).

This Action plan has been developed through a Region-wide participatory process drawing on the expertise of an advisory committee. Feedback has been sought formally through direct correspondence with Member States, major partners and civil society, including patient organizations. The plan has also been the subject of a broader public web-based consultation.

## **3. Vision, goal and targets**

### **Vision**

The vision for 2030 is a WHO European Region in which the transmission of new hepatitis infections is halted, testing is accessible, and all people living with chronic hepatitis have access to care and affordable and effective treatment.

## Goal

The goal for the Action plan is **the elimination of viral hepatitis as a public health threat in the European Region by 2030<sup>2</sup>** through:

- reduction of transmission of hepatitis viruses;
- reduction of morbidity and mortality due to viral hepatitis and its complications and;
- ensuring equitable access to comprehensive prevention, and recommended testing, care and treatment services for all.

## Targets

The Action plan suggests regional targets across the continuum of viral hepatitis services for 2020 with milestones for 2018 (see Annex), which will guide Member States in setting national targets in accordance with the local context and will be used to monitor the implementation of the Action plan.

Seven regional targets, to be achieved by 2020, are essential for achieving the ambitious goal of hepatitis elimination. The first five targets listed below relate to prevention while targets six and seven relate to testing and treatment:

1. 95% coverage with three-dose HBV vaccine for infants, in countries that implement universal vaccination;
2. 90% coverage with interventions to prevent mother-to-child transmission of HBV: hepatitis B birth-dose vaccination or other approaches;
3. 100% of blood donations screened using quality assured methods;
4. 50% of injections administered with safety-engineered injection devices;<sup>3</sup>
5. at least 200 sterile injection equipment kits distributed per person per year for people who inject drugs, as part of comprehensive package of harm reduction services;<sup>4</sup>
6. 50% of people living with chronic HBV and HCV infections are diagnosed and aware of their condition; and
7. 75% treatment coverage of people diagnosed with HBV and HCV infections who are eligible for treatment.

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<sup>2</sup> Elimination of viral hepatitis as a public health threat has been defined as the 90% reduction in number of new chronic hepatitis B and C infections and 65% reduction in number of deaths by 2030, with milestones for 2020 defined as 30% and 10% reductions, respectively (8). Each Member State, however, will need to define specific national targets concerning mortality and incidence for 2020 and beyond, based on local epidemiological context and best available baseline data.

<sup>3</sup> Safety-engineered injection devices: injection devices (for example, syringes) that have been engineered so they cannot be re-used and don't lead to accidental needle stick injuries among health workers (see [http://www.who.int/injection\\_safety/global-campaign/en/](http://www.who.int/injection_safety/global-campaign/en/)).

<sup>4</sup> A comprehensive package of evidence-based interventions to reduce harm associated with injecting drug use is outlined in the WHO, UNAIDS, UNODC technical guide for countries on setting targets for universal access to HIV prevention, treatment and care for injecting drug users. Since blood-borne transmission is common to HIV and hepatitis viruses, interventions effective in preventing HIV among people who inject drugs also help to prevent HCV/HBV transmission (15).

Guided by regional goal and targets, Member States should develop national goals and targets for 2020 and beyond. Such goals and targets should take into consideration the local context of each Member State, should be based on the best available data, and monitored through a set of measurable indicators. The targets should apply to everyone, with a particular focus on those populations most affected and most at risk of transmission.

## 4. Strategic directions and priority actions

To achieve the 2020 and 2030 targets and goals, action is required in five strategic directions. These aim to maximise the synergies between viral hepatitis and other settings within national health system, and to align the health sector response with other relevant regional and global health and development strategies, plans and targets. They intend to provide guidance to countries on how to prioritise viral hepatitis and broader health investments based on national epidemiological context and needs and through recommended priority health sector policies, interventions, and approaches.

The five strategic directions are:

1. **Information for focused action** (know your epidemic and response – the “who” and “where”);
2. **Interventions for impact** (defining an essential package of interventions – the “what”);
3. **Delivering for equity** (identifying the best approaches for delivering services, ensuring equity and quality – the “how”);
4. **Financing for sustainability** (identifying sustainable and innovative models for financing viral hepatitis responses – the financing);
5. **Innovation for acceleration** (addressing gaps that require innovative approaches – the future).

Aligning with the global vision of the elimination of viral hepatitis as a public health threat by 2030, the Action plan identifies intervention targets for 2020, with milestone targets for 2018 (see Annex), which will guide Member States in setting national targets in accordance with the local context.

### 4.1 Strategic direction 1: Information for focused action

*Develop strong strategic information systems to understand viral hepatitis epidemics and focus the response*

Strategic direction 1 focuses on the need to generate and use high-quality strategic information about the viral hepatitis epidemics and response as a basis for focused national strategic planning, urgent and accelerated programme implementation, and advocacy to raise political commitment.

#### *Data for informed decisions*

Robust national hepatitis strategic information systems that generate timely and high quality data about the epidemics and the interventions in place to respond to the

epidemics provide the basis for a comprehensive situation analysis and are critical to inform programme decision making and structure services according to needs and available resources. Such data make it possible to proactively focus high-impact interventions more precisely and effectively, and to deploy or adapt services to reach greater numbers of people in need.

Monitoring and understanding the response to viral hepatitis is critical for informing more strategic investments in hepatitis services, and for maximizing their effectiveness, responsiveness and cost-effectiveness. The hepatitis service continuum provides a good framework for establishing a national hepatitis monitoring and evaluation system, with indicators measuring coverage and performance along each step of the “cascade”.

The rigorous application of ethical standards in gathering and using data is important so as not to compromise the confidentiality and safety of individuals and communities. Greater community and stakeholder involvement in collection and analysis of the data has the potential to improve the quality and use of information.

2018 Milestones	2020 Target
<ul style="list-style-type: none"> <li>• Harmonized surveillance objectives and case definitions aligned with current WHO technical considerations adopted</li> <li>• National disease burden estimated and investment case developed</li> </ul>	<ul style="list-style-type: none"> <li>• Member States to have a national hepatitis infection surveillance programme (strategic information framework) that can detect outbreaks in a timely manner, assess trends in incidence, inform disease burden estimates and effectively track “in real time” the viral hepatitis diagnosis, treatment and care cascade, including in specific vulnerable populations</li> </ul>

Member States should consider the following priority actions:

- Assess and strengthen current viral hepatitis and related communicable disease data sources and surveillance systems;
- Adapt WHO-compatible case definitions for viral hepatitis surveillance; and ensure that the viral hepatitis surveillance system serves its main purposes<sup>5</sup>;
- Develop national estimates of the disease burden of chronic viral hepatitis (including incidence, prevalence and mortality for the general population, and populations most affected and at higher risk for viral hepatitis infection);
- Link and integrate viral hepatitis strategic information systems with broader health information systems, including those focusing on coinfections and other comorbidities (particularly HIV, tuberculosis and STIs), and expand the cross-border sharing of information to ensure service continuity for refugees, migrants and other mobile populations;
- Create or improve central registers at the national level for chronic viral hepatitis, cirrhosis and HCC, ensuring rigorous application of ethical standards in gathering and using data;

<sup>5</sup>The viral hepatitis surveillance system should be able (a) to detect outbreaks, monitor trends in incidence and identify risk factors for new infections; (b) to estimate the prevalence of chronic infections and monitor trends in the general population and in sentinel groups; and (c) to estimate the burden of sequelae of chronic hepatitis, including cirrhosis and hepatocellular carcinoma (16).

- Develop a country-specific investment case for action on viral hepatitis;
- Achieve stakeholder consensus on data.

WHO and partners will provide:

- Assistance to the Member States in implementing and adapting the WHO technical guidance on viral hepatitis surveillance (16);
- Methodological and technical assistance in improving surveillance systems, conducting sero-surveys and modelling exercises, including support in data interpretation;
- Support in the development of national estimates of transmission, disease burden, and number of infected persons receiving recommended treatment annually;
- Collaboration closely with ECDC, EMCDDA and other regional agencies to optimise the data collection, harmonize case definitions, improve data collection and analysis; and prevent double-reporting.

### ***Evidence based national planning***

National planning processes should be based on the best available data generated by strategic information systems. It should enable input from all key stakeholders – including civil society – on policy development, service planning and resource allocation, and should ensure coordination and alignment of the viral hepatitis response with the broader health sector. It should advocate for political commitment for sustained financing and national ownership.

#### **2018 Milestone**

- A costed and funded national hepatitis plan with clear targets or a viral hepatitis response plan integrated into a broader health strategy or action plan

Member States should consider the following priority actions:

- Establish a national governance structure and coordinating mechanism to oversee the national hepatitis response, integrated with the national health programme;
- Develop a national action plan for viral hepatitis by bringing together relevant sectors, with a budget and timeframe for achieving targets and milestones;
- Establish monitoring and evaluation mechanisms, which should be implemented in partnership with key stakeholders, including affected communities.

WHO and partners will provide:

- Advocacy for implementation of comprehensive, costed, multi-sectoral national plans as cost-effective and cost-saving approach in response to viral hepatitis and technical assistance in national planning, using the WHO national planning manual (17).

### ***National viral hepatitis communication and awareness strategy as an integrated component of the national action plan***

The lack of awareness about viral hepatitis and stigma associated with chronic viral hepatitis B and C often lead to widespread discrimination and prevent people living with chronic hepatitis from being diagnosed and seeking care. Targeting undiagnosed patients will require a reduction of stigma in combination with effective case finding,

testing, and increased public and professional awareness. Systematic methods to monitor the knowledge, attitudes and health-seeking behaviours relating to HBV and HCV should also be developed to enable authorities to effectively address this public health concern.

2018 Milestone	2020 Target
<ul style="list-style-type: none"> <li>World Hepatitis Day marked in all Member States</li> </ul>	<ul style="list-style-type: none"> <li>National viral hepatitis communication and awareness strategy adopted in a majority of Member States</li> </ul>

Member States should consider the following priority actions:

- Educate and train health professionals, decision makers, the media, and the public to create awareness, increase knowledge, and improve attitudes and practices that aid in viral hepatitis prevention;
- Address stigma and discrimination through comprehensive awareness and communication strategies;
- Reduce language and cultural barriers that exist in populations with regards of access to services of prevention and treatment;
- Create specific awareness campaigns and anonymous free viral hepatitis testing programmes, which cover the general population but also the specific risk groups according to the epidemiological situation in a country

WHO and partners will provide:

- Communication guidance to support the Member States, including annual World Hepatitis Day toolkit and information package for use in countries in a range of languages;
- Engagement of patient and affected population groups to actively participate in the regional guidance development and promote co-operation of the civil society and governmental sector in viral hepatitis prevention and control;
- Examples of targeted awareness campaigns for different settings and various risk groups.

## 4.2 Strategic direction 2: Interventions for impact

*People should receive all the hepatitis services they need*

Each country should define a set or package of essential interventions, services, medicines and commodities relevant to the country context, to be included in the comprehensive health sector response to viral hepatitis. These essential interventions should be included in the national health benefit package with no out-of-pocket expenses to ensure affordability and the overall sustainability of the health sector response to viral hepatitis. These interventions should cover the entire continuum of hepatitis services, including prevention, diagnosis, treatment and care through integrated service delivery and using a public health approach and within the context of universal health coverage.

### Prevention

There are three major domains of action required to prevent viral hepatitis transmission that are essential in achieving the ambitious goal of elimination: hepatitis B immunization, including measures for prevention of mother-to-child transmission, prevention of healthcare associated transmission, and high-intensity prevention of transmission associated with injection drug use. Additional domains of action include: prevention of sexual transmission of viral hepatitis and ensuring food and water safety.

### ***Hepatitis control through immunization (HAV and HBV)***

High coverage with three doses of hepatitis B vaccine among infants has the greatest impact on the burden of disease and should be the essential foundation of a hepatitis B prevention programme. Universal childhood vaccination ensures protection to the entire next generation before risk behaviour starts, without discriminating between country of birth or sexual preference. The improvement of hepatitis B vaccination coverage should be considered in the context of strengthening of national immunization programmes and increasing uptake of all routine childhood immunizations.

Hepatitis A vaccination provides long-lasting protection against hepatitis A in children and adults. National level hepatitis A vaccination programmes should be considered for countries with intermediate levels of endemicity in the context of comprehensive viral hepatitis prevention, which includes improvement of hygiene, sanitation, and outbreak control.

2018 Milestone	2020 Target
<ul style="list-style-type: none"> <li>• 90% coverage with three doses of HBV vaccine in countries that implement universal childhood vaccination</li> <li>• National guidelines on high risk group HAV and HBV vaccination developed and implemented</li> </ul>	<ul style="list-style-type: none"> <li>• 95% coverage with three doses of HBV vaccine in countries that implement universal childhood vaccination</li> <li>• ≤0.5% HBsAg prevalence in vaccinated cohorts</li> <li>• 80% of health-care workers vaccinated against HBV</li> </ul>

Member States should consider the following priority actions:

- Based on scientific advice provided by national immunization advisory bodies consider introduction of universal childhood hepatitis B vaccination in countries that do not implement it;
- Improve HBV vaccination coverage by monitoring public perceptions, knowledge and attitudes, and developing tailored and innovative strategies to create demand for vaccination among all population groups as it is outlined in the European Vaccine Action Plan (12).
- Based on considerations of local epidemiology consider catch-up vaccination strategies targeted at older age groups as a supplement to universal childhood vaccination;
- Define country-specific risk groups according to local context and develop national policy on vaccination of high-risk individuals against hepatitis B. The health care workers who are at high risk for hepatitis B infection, and, rarely, can transmit it to patients, should be prioritized in all countries;

- Define local HAV disease burden by using data from viral hepatitis surveillance or population-based sero-surveys, and develop adequate HAV vaccination strategies. Member States that have intermediate HAV incidence should consider integrating HAV vaccination into their national immunization programmes. Countries with low and very low endemicity should consider targeted vaccination of high risk groups.

In line with the European Vaccine Action Plan WHO and partners will provide:

- Support to Member States in setting evidence-based policies on HBV and HAV vaccination;
- Guidance and tools to generate and maintain demand for immunization services and address vaccine hesitancy;
- Advocacy and guidance on how to reach high risk populations in accordance with resolution 140730 of the 64<sup>th</sup> session of the WHO Regional Committee for Europe.

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

Perinatal transmission, from an HBsAg positive mother to her new-born, is a major 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 through universal immunization.

There are two basic strategies utilized in the Region to prevent perinatal transmission. The first is to ensure that all children are vaccinated with a dose of monovalent hepatitis B vaccine within 24 hours after birth. The second is to screen all pregnant women for HBsAg prenatally and then provide post exposure prophylaxis to the infants of carrier mothers with HBV vaccine birth dose and hepatitis B immune globulin (HBIG). Twelve countries implement both strategies, that is, universal immunization of all children at birth with HBV vaccine plus neonatal screening of mothers and addition of HBIG to infants of carrier mothers.

<b>2018 Milestone</b>	<b>2020 Target</b>
<p>For countries that implement universal newborn vaccination:</p> <ul style="list-style-type: none"> <li>• 85% coverage with timely HBV birth dose vaccination</li> </ul> <p>For countries that implement screening of pregnant women and post-exposure prophylaxis of newborns:</p> <ul style="list-style-type: none"> <li>• 85% coverage with screening in pregnant women and 90% coverage with post-exposure prophylaxis in infants born to infected mothers</li> </ul>	<p>For countries that implement universal newborn vaccination:</p> <ul style="list-style-type: none"> <li>• 90% coverage with timely HBV birth dose vaccination</li> </ul> <p>For countries that implement screening of pregnant women and post-exposure prophylaxis of newborns:</p> <ul style="list-style-type: none"> <li>• 90% coverage with screening in pregnant women and 95% coverage with post-exposure prophylaxis in infants born to infected mothers</li> </ul>

Member States should consider the following priority actions:

- In countries that implement universal newborn immunization, monitoring of timeliness of HBV vaccine birth dose to ensure that all children are vaccinated within 24 hours after birth. The countries with a significant proportion of home deliveries should develop strategies to timely administer the birth dose of HBV vaccine to infants born at home.
- In countries that do not implement universal newborn immunization, establishment of systems to assess coverage of screening of pregnant women for HBV and post exposure prophylaxis of new-borns. Efforts should be made to achieve high screening coverage among pregnant women from ethnic minorities, immigrants, undocumented migrants, and marginalized groups.
- Creating partnerships with appropriate professional organisations, maternal and child health champions and other stakeholders to increase awareness among women of reproductive age about burden of hepatitis B and the importance of hepatitis B vaccination to protect their children in order to support the national immunization programme.

WHO and partners will provide:

- Advocacy and technical support to countries in defining national strategies to prevent perinatal HBV transmission and establishing effective systems to monitor and evaluate coverage for preventive interventions.

### ***Blood and tissue safety***

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

2018 Milestone	2020 Target
<ul style="list-style-type: none"> <li>• All countries have effective haemovigilance systems in place and all donations are tested at least with serological methods for HBV and HCV infection</li> </ul>	<ul style="list-style-type: none"> <li>• All donated blood tested with NAT-screening methods for HBV and HCV</li> <li>• All donated blood from non-remunerated donors</li> </ul>

Member States should consider the following priority actions:

- Harmonize national legislative acts with the WHO Global Strategic Plan (2008–2015) for the Universal Access to Safe Blood transfusion<sup>6</sup>;
- Develop nationally coordinated transfusion and transplantation services with full authority and responsibility to ensure safe blood supplies are integrated into national health system;
- Standardize donor selection and blood testing processes;
- Strengthen the quality control system for blood production and testing.

<sup>6</sup> <http://www.who.int/bloodsafety/StrategicPlan2008-2015AccessSafeBloodTransfusion.pdf>

WHO and partners will provide:

- Guidance to countries on the management of safe blood and tissue supplies and the strengthening of linkages between blood transfusion and transplantation services and viral hepatitis services;
- Promote development and use of blood and blood products substitutes.

***Injection safety and infection prevention and control (IPC) in and out of health care settings***

2018 Milestone	2020 Target
<ul style="list-style-type: none"> <li>• Safe injection policies and IPC rules for preventing transmission of blood-borne infections in health sector (including in prisons) in place and implemented</li> <li>• National disinfection and sterilization protocols for non-health care settings (cosmetic and tattoo facilities) developed and implemented</li> </ul>	<ul style="list-style-type: none"> <li>• 50% of injections administered with safety-engineered devices in and out of health care facilities</li> </ul>

Member States should consider the following priority actions:

- Establish or strengthen a national infection prevention and control regulating authority, covering medical and non-medical settings, including prisons;
- Regularly revise and update, according to latest evidence available, national sterilisation and disinfection guidelines in healthcare settings (including healthcare settings in prisons), specifically covering injection safety, endoscopic procedures, dental and oral health, haemodialysis and other potential sources of exposure to blood borne infections;
- Improve understanding at all levels of the healthcare system, including auxiliary and cleaning personnel, on viral hepatitis and other blood borne infection transmission risks and infection control principles;
- Develop or strengthen national sterilisation and disinfection guidelines in non-medical settings (tattooing, piercing etc. facilities) and ensure the effective monitoring and control mechanisms are in place;
- Develop, where appropriate and based on latest scientific evidence, national guidance on post-exposure prophylaxis of parenteral hepatitis viruses;
- Reduce unnecessary injections in and outside of healthcare facilities;
- Implement measures to promote universal use of safety-engineered devices (e.g. reuse prevention and needle-stick injury protection syringes) for all therapeutic injections

WHO and partners will provide:

- Guidance on standard precautions and effective disinfection and sterilization methods; safe injection practices and alternatives to injections (17); infection prevention and control inside and outside health care services; and for specific procedures, including endoscopy, tattooing and cosmetic procedures;
- Technical assistance to develop and maintain appropriate regulatory structures for effective IPC in the health system;

- Promotion for implementation of safe injection practices, including introduction of non-reusable injection devices and WHO universal precautions and infection control guidelines.

### ***Prevention of HBV and HCV transmission associated with injecting drug use***

People who inject drugs remain the key risk group for HCV infection in most European countries due to lack of awareness and wide-spread unsafe injection practices such as injection equipment sharing. A package of harm reduction services for people who inject drugs can be highly effective in preventing the transmission and acquisition of viral hepatitis A, B and C, as well as HIV and other blood-borne infections. Such a package should be integrated into a comprehensive set of services for the prevention and management of substance use disorders. HCV is more easily transmissible than HIV; therefore harm reduction services should be up-scaled and include provision of all injecting paraphernalia, including mixing containers and solutions.

2018 Milestone	2020 Target
<ul style="list-style-type: none"> <li>• Policies developed and implemented to support a comprehensive package for infection prevention and harm reduction among people who inject drugs including: needle and syringe programmes (NSPs); opioid substitution therapy (OST) and other evidence-based drug dependence treatment targeted information; education and communication (IEC) for people who inject drugs and HAV and HBV vaccination</li> </ul>	<ul style="list-style-type: none"> <li>• A comprehensive package of harm reduction services to all persons who inject drugs, including*:               <ul style="list-style-type: none"> <li>- At least 200 syringes distributed per PWID per year</li> <li>- At least 40% of opioid dependent PWID receive opioid substitution therapy</li> <li>- HBV and HAV vaccination</li> </ul> </li> <li>• 90% of PWID receiving targeted IEC provided by NSPs, drug treatment service sites (including OST) and other services targeting PWID</li> </ul>

\* A comprehensive package of evidence-based interventions to reduce harms associated with injecting drug use is outlined in the WHO, UNAIDS, UNODC technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users(15). Since blood-borne transmission is common to HIV and hepatitis viruses, interventions effective in preventing HIV among people who inject drugs help to prevent HCV/HBV transmission. Because HCV is more virulent than HIV, however, higher levels of intervention coverage may be necessary to achieve comparable reductions in incidence.

The WHO, UNAIDS, UNODC guidance (15) suggests a target of 200 syringes distributed per PWID per year based upon studies in developed-country settings and mathematical modelling investigating the levels of syringe distribution and its impact on HIV transmission. The guidance notes that levels required for the prevention of HCV are likely to be much higher. The 40% OST target is based on levels of coverage achieved in countries with well-established OST programmes.

Member States should consider the following priority actions:

- Implement a comprehensive, interdisciplinary infection prevention and harm reduction programme based on the WHO package of interventions (14), with integrated services for people who inject drugs, including treatment for HCV

infection and effective measures to prevent re-infection, as well as harm reduction interventions;

- Implement measures aimed on prevention of initiation of drug use, including promotion of healthy life-styles;
- Support high-intensity outreach- and facility-based programmes for the distribution of sterile injection equipment kits, including low dead-space syringes in the community and in prisons where this is appropriate;
- Make effective drug treatment including OST available to opioid dependent individuals, ensuring equivalence of services in prisons, and make safe-injection sites accessible, where this is appropriate;
- Assess and address accordingly the risk of transmission, associated with new injection drug practices, including injection of amphetamine and other stimulant drugs, and image and performance enhancing drugs; as well as other types of drug consumption (including “snorting”);
- Implement inter-disciplinary approach and integration of services for PWID; including testing and treatment for viral hepatitis, HIV and tuberculosis infection, drug dependence treatment and mental health;
- Consider routine testing for hepatitis B and C virus infections not only as individual benefit for linkage-to-care but also as testing-for-prevention approach among PWID.

WHO and partners will provide:

- Promote and update policies and guidance on evidence-based prevention and management of viral hepatitis and other blood-borne infections for people who inject drugs, including people who use cocaine (including intranasal consumption practices) and amphetamine-type stimulants;
- Provide advocacy and technical support to mobilise commitment and resources for recommended harm reduction interventions;
- Create a stakeholder network to assure coordination of effective policies and health policy development.

***Prevention of sexual transmission of viral hepatitis and other sexually transmitted infections***

Although sexual transmission of viral hepatitis viruses plays a minor role in most hepatitis epidemics, specific attention should be given to certain populations, particularly high-risk behaviour MSM, but also heterosexual persons with multiple sexual partners. In low-endemicity countries, sexual contact constitutes one of the main transmission routes for HBV infection among persons who have not been vaccinated, and there is an increase in reporting of acute HCV outbreaks in some groups of (mainly HIV-positive) MSM in a number of western European countries. Progress on reducing sexual transmission of viral hepatitis is hard to measure in most settings, therefore reduction of other STI infections will serve as indicator for reducing sexual transmission of hepatitis.

2018 Milestone	2020 Target
<ul style="list-style-type: none"> <li>• 90% of countries provide STI services or links to such services in all primary, HIV, drugs, reproductive and perinatal care</li> </ul>	<ul style="list-style-type: none"> <li>• Access for all individuals to a full range of services relevant to STIs, including HIV and HBV and HCV, and access to condoms,</li> </ul>

services	testing and counselling
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Member States should consider the following priority actions:

- Guarantee the provision of comprehensive and evidence-based sexual and reproductive health, including health promotion, education, prevention, diagnosis and management of STIs for all persons;
- Ensure dedicated services for those who may have difficulties accessing sexual and reproductive health services, including adolescents and elderly, migrants and asylum seekers, people living with HIV, MSM and transgender persons, PWID, incarcerated persons, and people engaged in sex work;
- Develop and implement strategies to strengthen sexual partner management; ensuring patient confidentiality and linkage to counselling and treatment of partners;
- Develop and implement targeted awareness campaigns for specific populations-at-risk for STI, including viral hepatitis (particularly MSM, transgender people and sex workers).

WHO and partners will provide:

- Updated guidance on STI prevention, including new evidence-based interventions and STI prevention packages for different epidemic contexts<sup>7</sup>, giving particular attention to vulnerable populations, adolescents and women.

### ***Prevention: ensuring food safety and water safety***

Although the burden of viral hepatitis A and E is relatively low in the WHO European Region, waterborne and foodborne cases and outbreaks continue to occur, sometimes causing large multi-national outbreaks. There is strong evidence that faecally contaminated food and water are common sources of infection. In areas with poor sanitation, children are often infected at early ages and become immune for life without clinical symptoms of disease. In areas with adequate sanitation, infection tends to occur later in life. Hepatitis A and E show long persistence in water supplies and moderate persistence to chlorine. Control measures to reduce potential risk from hepatitis A and E focus on prevention of source water contamination by human and animal waste, followed by adequate treatment and disinfection. Use of contaminated water in the production of fruits and vegetables can also cause foodborne hepatitis. Furthermore, there is increased reporting of autochthonous cases of hepatitis E related to mainly pork meat consumption associated with specific meat and meat production traditions. Ensuring food safety and access to safely managed water and sanitation services can significantly reduce the transmission of HAV and HEV.

Member States should consider the following priority actions:

- Ensure collaboration and information-sharing between the health, environment, food safety and agriculture sectors;
- Develop and implement policies and regulations on food safety that will address the safety of the food in a whole-food-chain approach including primary production, the food industry, and food handlers;

<sup>7</sup> <http://www.who.int/reproductivehealth/topics/rtis/stis-new-treatment-guidelines/en/>

- Develop and promote recommendations and raise awareness among the general public on food safety and water safety, including the importance of applying the WHO Five Keys to Safer Foods and the WHO Five Keys to Growing Safer Fruits and Vegetables<sup>8</sup>;
- Ensure uptake of Water Safety Plans<sup>9</sup> and Sanitation Safety Planning<sup>10</sup> approaches in policy and practice, including in high-risk settings and camps for internally displaced persons and refugees;
- Establish and/or maintain effective surveillance, outbreak response and reporting systems for HAV and HEV infections

WHO and partners will provide:

- Promote guidance and scale-up of risk assessment and management approaches (i.e. WSPs and SSP) in water supply and sanitation;
- Update and promote guidance on food safety related issues;
- Provide technical assistance to Member States

## Diagnosing hepatitis virus infections

Early diagnosis of hepatitis infection is critical for effective treatment and care. Yet, the majority of people who are living with viral hepatitis are not aware of their infection. Reliable diagnostics that are appropriate for the setting of intended use and testing services are not sufficiently available, and laboratory capacity is weak in some Member States. Increasing early diagnosis requires overcoming those shortcomings, using effective testing approaches, quality-assured diagnostics and linking the results of testing to treatment and care services.

2018 Milestone	2020 Target
<ul style="list-style-type: none"> <li>• High quality viral hepatitis testing and diagnosis services are available and accessible for all</li> <li>• All countries have national HBV and HCV testing policies, aligned with WHO guidelines</li> <li>• All countries have estimated the diagnosis rate and the proportion of patients diagnosed at late stage of viral hepatitis-related liver disease (cirrhosis or HCC)</li> <li>• all health care workers know their viral hepatitis B and C sero-status</li> </ul>	<ul style="list-style-type: none"> <li>• 50% of all persons with chronic HBV, HCV and HDV diagnosed</li> <li>• 75% of estimated number of patients at late stage of viral hepatitis-related liver disease (cirrhosis or HCC) diagnosed</li> </ul>

Member States should consider the following priority actions:

<sup>8</sup> <http://www.who.int/foodsafety/consumer/5keys/en/>

<sup>9</sup> The Water Safety Plans (WSPs) require a risk assessment encompassing all steps in water supply from catchment to consumer, followed by implementation and monitoring of risk management control measures: [http://www.who.int/water\\_sanitation\\_health/dwq/WSP/en/](http://www.who.int/water_sanitation_health/dwq/WSP/en/)

<sup>10</sup> The Sanitation Safety Planning (SSP) is a step-by-step risk based approach to assist in the implementation of the 2006 WHO Guidelines for Safe Use of Wastewater, Excreta and Greywater: [http://www.who.int/water\\_sanitation\\_health/publications/ssp-manual/en/](http://www.who.int/water_sanitation_health/publications/ssp-manual/en/)

- Develop and rollout national viral hepatitis testing and diagnostic guidelines in accordance with WHO guidance and local policies that identify and target high risk groups and high risk behaviours;
- Offer hepatitis testing as part of a yearly health check-up to all clients at drugs services on an ‘opt-out’ basis;
- Test all prisoners on entry into prison for viral hepatitis on ‘opt-out’ basis;
- Strengthen the national laboratory system to provide quality diagnosis of acute and chronic hepatitis;
- Ensure availability and access to good quality and affordable diagnostics/testing, including diversified testing approaches (outreach programme, self-testing);
- Assure confidentiality of test results and sharing of test results that avoid stigma and promote linkages to recommended care and treatment;
- Ensure continuous education of healthcare professionals, including General Practitioners and non-communicable disease specialists, on viral hepatitis testing and diagnosis-related issues.

WHO and partners will provide:

- Updated guidance on viral hepatitis testing approaches;
- Technical assistance in adopting and implementing WHO policies and guidelines on viral hepatitis diagnostics, testing approaches and strategies

## Enhancing chronic hepatitis care and treatment

Effective antiviral agents against viral hepatitis B and C have the potential to dramatically reduce morbidity and mortality, including among people co-infected with HIV. Direct-acting antivirals for the treatment of chronic hepatitis C virus have cure rates exceeding 95%, with pan-genotypic regimens becoming available. Effective treatment is available for chronic hepatitis B (8).

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

Treatment of advanced liver cirrhosis and hepatocellular carcinoma, including liver transplantation and chemotherapy, is very limited in most low- and middle-income settings, highlighting the need to provide access to good quality palliative and end-of-life care.

2018 Milestone	2020 Target
<ul style="list-style-type: none"> <li>• National hepatitis treatment and care updates, in line with WHO guidelines established and regularly updated</li> <li>• Baseline estimation of people</li> </ul>	<ul style="list-style-type: none"> <li>• Treatment for chronic HBV, HCV and HDV infection, in line with international standards, is available and affordable for all</li> <li>• 90% of diagnosed patients with</li> </ul>

<p>who need to receive treatment for chronic HBV, HCV and HDV infection obtained, preferably by liver disease stage</p>	<p>chronic HBV, HCV and HDV infections are linked to care and adequately monitored</p> <ul style="list-style-type: none"> <li>• 75% of the diagnosed patients with chronic HBV and HDV infection, who are eligible for treatment, begin treatment and among those on long-term treatment for HBV, 90% obtain viral suppression</li> <li>• 75% of the diagnosed eligible patients with chronic HCV infection receive effective treatment and at least 90% of them are cured</li> </ul>
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\*All patients with chronic HCV infection are eligible for treatment, however in resource constrained settings, treatment prioritisation might be needed.

Member States should consider the following priority actions:

- Establish and regularly update national hepatitis treatment and care protocols, in line with WHO guidelines using a public health approach;
- Include HBV and HCV (and HDV) medicines in the national essential medicines list or any positive list of reimbursed medicines;
- Provide quality treatment that ensures standardised care of people with chronic viral hepatitis, including disease staging, patient and drug toxicity monitoring, management of late stage liver disease;
- Address common comorbidities and co-infections that may accelerate progression of liver disease, or increase the risk of reinfection with HCV, including alcohol and substance use;
- Ensure post-treatment / post-cure monitoring of the patients at risk for HCC;
- Make use of patient-registry data to identify gaps in care quality and persons who become re-infected and in need of prevention interventions and re-entry into care.

WHO and partners will provide:

- Regularly updated and disseminated consolidated guidelines for the prevention, diagnosis and treatment of chronic viral hepatitis;
- Technical support to countries in updating and optimising their treatment protocols and plans for chronic viral hepatitis.
- Advocacy for adequate investments to scale up chronic hepatitis treatment;
- Advocacy for public health approach and continuity of chronic hepatitis care and treatment;

### **4.3 Strategic direction 3: Delivering for equity**

*All people should receive the hepatitis services they need, and such services should be of sufficient quality to have an impact*

Strategic direction 3 responds to the need for an enabling environment and optimization of service delivery using a public health approach under a model of universal health coverage. Interventions to address viral hepatitis and the health and community-based systems that provide them should respect the principles of equity and human rights. The

continuum of hepatitis services should be people-centred, integrated, accessible, equitable and community-based and of a high-quality to ensure that no one is left behind.

### ***Identifying populations and locations most affected and tailoring hepatitis services***

The WHO European Region represents a great diversity in terms of epidemiologic situation, socio-economic and political context, which calls for the need to identify populations most affected by viral hepatitis and the essential set of interventions, services, medicines and commodities relevant to the country context.

Member States should consider the following priority actions:

- Define the populations and locations that are most affected and require intensified support, and prioritise them in the hepatitis response while minimising the risk of stigmatisation based on the best epidemiological evidence from available sources of strategic information;
- Support involvement of civil society in the national response to viral hepatitis by creating the platform for civil society, and by building community capacity to deliver community-based viral hepatitis services;
- Provide patient-oriented and integrated services: in particular, consider integrating services for PWID, to make treatment of infections (HIV, tuberculosis, viral hepatitis) available at harm reduction and drug treatment/OST services;
- Regularly undertake “hepatitis cascade” analysis for different populations and settings to determine the quality of services and propose possible adjustments

WHO and partners will provide:

- Technical assistance to countries in analysing their hepatitis prevention, care and treatment cascades in the general population and in specific vulnerable groups;
- Guidance on implementation of models of integrated and linked service delivery, and community based services for the prevention and management of viral hepatitis.

### ***Strengthening human resources***

Many essential viral hepatitis interventions are integrated within broader health services and programmes, thus providing opportunities for effective task shifting and task sharing. In all such settings, including primary health care, health workers should be knowledgeable about viral hepatitis risk and infection, and the package of essential hepatitis interventions. They should be competent to work with people living with chronic hepatitis infection and those most affected and at risk. Issues related to viral hepatitis should be included in pre-service and in-service training for health workers.

Community-based and peer-support workers play an important role in reaching marginalized groups, linking people with chronic hepatitis to care, supporting treatment adherence and providing chronic care. Those workers should receive regular training, mentoring and supervision and appropriate compensation for their work.

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

Member States should consider the following priority actions:

- Ensure that national health workforce strategy and educational curriculum addresses sufficiently the needs of hepatitis services;
- Identify opportunities for task-shifting and task-sharing, for example involving general practitioners in viral hepatitis care and treatment;
- Involve community-based organisation and peer-support workers in providing viral hepatitis services, particularly in the context of vulnerable populations (such as people who inject drugs, Roma population and migrants);
- Raise awareness and educate healthcare workers on viral hepatitis-related issues, to reduce the stigma and discrimination of people affected by viral hepatitis, and also improve occupational health and safety of the health workers

WHO and partners will provide:

- Provide guidance and technical assistance in capacity building and educating and training competent workforce that can effectively deliver viral hepatitis services

***Promoting an enabling environment: overcoming legal barriers, and taking an evidence-based and integrated service delivery approach***

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

Member States should consider the following priority actions:

- Use public health evidence to inform laws affecting health of the people and actions (including legal regulation of drug use) in all relevant sectors that will enable an effective hepatitis response;
- Ensure that legal and regulatory frameworks uphold human rights for populations affected by and at risk of hepatitis virus infections and facilitate involvement of civil society at all levels of viral hepatitis response;
- Address gender inequities, including gender based discrimination of MSM and transgender persons; and age-based inequality (including lack of paediatric viral hepatitis services and age restriction for chronic HCV treatment) by integrating evidence-based interventions into national hepatitis plans and strategies;

WHO and partners will provide:

- Advocacy for public health approach and universal health coverage framework;
- Promotion of WHO guidelines that address gender inequality, human rights, stigma and discrimination, the health of vulnerable populations and public health alternatives to criminalisation
- Facilitation of partnerships and encouragement for Member States to create an enabling environment for accessible, equitable and affordable viral hepatitis services through multisectoral collaboration and the engagements of civil society, including patient organizations

#### **4.4 Strategic direction 4: Financing for sustainability**

Strategic direction 4 identifies the need for sustainable financing models for the health system response to viral hepatitis and approaches for reducing costs so that people can access the services they need without incurring financial hardship. This is possible when integrated and linked services are delivered under a model of universal health coverage.

Adequate investment in the full continuum of hepatitis services is necessary to achieve the targets for 2020 and move towards the global goal of elimination of viral hepatitis as a public health threat by 2030. WHO European Member States are diverse in terms of political and socio-economical context and the organisation of the health systems varies. Some priority actions may be more relevant for the EU/EEA Member States of the WHO European Region (e.g. joint procurement procedure), others – will specifically apply to lower-middle income countries from the eastern part of the Region.

##### ***Increasing investments including through innovative funding approaches***

Member States should consider the following priority actions:

- Develop a viral hepatitis investment case to advocate for adequate allocation of domestic resources, monitor the efficiency of interventions, health expenditures and cost-effectiveness of services, taking into account direct and indirect costs of burden of disease;
- Explore innovative funding approaches in service delivery to maximize the cost efficiency of the response (e.g. social impact bonds, “hepatitis fund”, public-private partnerships, “brand marketing”);
- Ensure sustainable financing to all essential viral hepatitis response-related services, including harm reduction.

WHO and partners will provide:

- Support to countries for developing investment cases;
- Facilitation of best practice sharing among Member States;
- Advocacy for sustained financing and national ownership through building political commitment

##### ***Ensuring access to good quality and affordable vaccines, medicines and diagnostics – reducing prices and costs, and removing inefficiencies***

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

Member States should consider the following priority actions:

- Address regulatory issues including, where appropriate, early registration based on stringent regulatory agency approval, collaborative regulatory processes such as WHO prequalification mechanisms, and intensive pharmacovigilance;

- Ensure a strong focus on procurement and price negotiations: assess feasibility of joint procurement of medicines and diagnostics; and/or joint negotiations, transparency in drug pricing and sharing information between Member States,
- Assess possible price reduction strategies, including differential pricing initiatives, such as including viral hepatitis in Affordability Index (for EU Member States), price controls, joint negotiation, managed entry agreements, voluntary licensing and the use of Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities where appropriate;
- Monitor efficiency of interventions, health expenditures and cost-effectiveness of the services, taking into account direct and indirect costs of burden of disease;
- Strengthen the coordination between viral hepatitis services and relevant health interventions and programmes, including HIV, STIs, cancer prevention, blood and tissue safety, alcohol and drug use disorders and mental health thereby improving people-centred care, optimize the use of resources and explore mechanisms to assure best prices for medicines and diagnostics;
- Reallocate funds to remove inefficiencies

WHO and partners will provide:

- Advocacy for public health approach and universal health coverage framework;
- Advocacy and guidance on the use of comprehensive strategies to reduce prices for viral hepatitis medicines and diagnostics;
- Guidance on viral hepatitis product selection by national programmes, based on WHO guidelines, public health approach and transparency;
- Assistance for assessing and monitoring health service costs, and cost-effectiveness of the services;
- Promotion of information sharing on medicines and diagnostics prices (e.g. through on-line tools);
- Economic experts to support a finance reallocation process

#### **4.5 Strategic direction 5: Innovation for acceleration**

Research and innovation provide opportunities to change the trajectory of the regional and national health sector response to viral hepatitis, improve efficiency and quality of services and maximize impact. Innovations are required along the entire continuum of prevention, diagnosis, treatment and care services. They need to be backed with operational research and collaboration between researchers and policy-makers to ensure that research findings are translated into policies rapidly and on a sufficient scale to achieve the desired impact.

Member States should play a critical role in defining priorities for innovation, facilitating research by establishing multisectoral inclusive partnerships and collaborative opportunities focused on innovation and best practice. These should include collaborating with public and private sector organizations, documenting early implementation experiences, and taking the lead on operational research.

Member States should consider the following priority actions:

- Prioritise viral hepatitis as a research area and provide public funding to targeted projects, increasing transparency, and promoting a public health approach;

- Incentivise alternative research and development models to prevent private-sector driven research bias;
- Disseminate research finding quickly and efficiently;
- Introduce and integrate innovations in care and treatment while removing those which are outdated and no longer qualified under best-practice;
- Ensure operational research (e.g. on service integration feasibility and effectiveness) and other studies are included in the development of viral hepatitis policies.

WHO and partners will provide:

- Advocacy for innovative evidence-based effective interventions, including assessing potential benefits of expanding coverage of HBV and HCV treatment on transmission, point-of-care testing, non-invasive stage of the disease determination, and monitoring of the viral load, among others;
- Facilitation of investment into research to collect evidence and recommendations;
- A compendium of best practices on innovations and new technologies updated and shared on a regular basis;
- Technical support, including with support of the WHO Collaborating Centres, for introducing/implementing innovative technologies, e.g. new treatment regimens, telemedicine, services provision models.

## **5. Implementation**

Member States will be supported by the Regional Office and partners to develop ambitious national goals and targets for 2020 and beyond guided by global and regional goals and targets. National goals and targets should reflect the country context and be based on the best possible data available on the viral hepatitis situation, trends and responses, and monitored through a set of standard and measurable indicators. The targets should apply to all populations, with a specific focus populations most affected and at higher risk.

### **5.1 Partnerships**

Effective implementation of this Action plan requires the establishment of strong governance processes, a “whole of government” approach with multisectoral engagement, and ongoing political commitment and resources at the highest levels. This should include strong partnerships and involvement of civil society, including patient organizations, to ensure that linkages across disease-specific and cross-cutting programmes are established and strengthened.

In addition to working with the ministries of health of Member States, the Regional Office will work closely with other key stakeholders and partners, including United Nations agencies, the European Commission and its institutions, particularly the ECDC and EMCDDA, WHO collaborating centres, research institutions, national institutes of excellence, civil society including patient organizations, and other partners and technical experts.

## 5.2 Monitoring and evaluation

In 2016 WHO published a monitoring and evaluation framework for HBV and HCV with 10 core (global) indicators (18). These core indicators are intended to facilitate the generation, collection and analysis of standardized data and monitoring of the response nationally, regionally and globally. Three of the core indicators (HBV vaccination coverage, injection safety and needle–syringe distribution) are already collected through the UNICEF/WHO Joint Reporting Form on Immunization (19), the joint UNAIDS/WHO/UNICEF Global AIDS Response Progress Reporting (GARPR) (20) while diagnosis data are collected through the annual WHO European Communicable Diseases Reporting Form and the ECDC Hepatitis B and C Surveillance in Europe.

No regionally or globally coordinated reporting mechanism on the health sector response to viral hepatitis has been implemented so far but is likely to be established as an integral process with existing relevant reporting mechanisms to support monitoring of the Global Health Sector Strategy implementation. In the meantime, WHO will support countries to build national capacity to monitor and evaluate country responses and will collate the data reported nationally on a regular basis to measure progress at regional and global levels.

Progress at the global and regional levels in moving towards the targets set out in this Action plan and the Global Health Sector Strategy will be regularly reviewed and assessed, including through Global Hepatitis Report and reports to the Regional Committee for Europe at its 69th and 72nd sessions in 2019 and 2022, respectively, on implementation of this Action plan.

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## Annex. Summary of proposed milestones and targets

2018 MILESTONES	2020 TARGETS
<b>SURVEILLANCE AND DATA</b>	
<ul style="list-style-type: none"> <li>Harmonized surveillance objectives and case definitions aligned with current WHO technical considerations adopted</li> <li>National disease burden estimated and investment case developed</li> </ul>	<ul style="list-style-type: none"> <li>Member States to have a national hepatitis infection surveillance programme (strategic information framework) that can detect outbreaks in a timely manner, assess trends in incidence, inform disease burden estimates and effectively track “in real time” the viral hepatitis diagnosis, treatment and care cascade, including in specific vulnerable populations</li> </ul>
<b>EVIDENCE-BASED POLICY</b>	
<ul style="list-style-type: none"> <li>A costed and funded national hepatitis plan with clear targets or a viral hepatitis response plan integrated into a broader health strategy or action plan</li> </ul>	
<b>AWARENESS</b>	
<ul style="list-style-type: none"> <li>World Hepatitis Day marked in all Member States</li> </ul>	<ul style="list-style-type: none"> <li>National viral hepatitis communication and awareness strategy adopted in a majority of Member States</li> </ul>
<b>IMMUNIZATION</b>	
<ul style="list-style-type: none"> <li>90% coverage with three doses of HBV vaccine in countries that implement universal childhood vaccination</li> <li>National guidelines on risk group HAV and HBV vaccination developed and implemented</li> </ul>	<ul style="list-style-type: none"> <li>95% coverage with three doses of HBV vaccine in countries that implement universal childhood vaccination</li> <li>≤0.5% HBsAg prevalence in vaccinated cohorts</li> <li>80% of health care workers vaccinated against HBV</li> </ul>
<b>PREVENTION OF MOTHER-TO-CHILD TRANSMISSION OF HBV</b>	
<p>For countries that implement universal newborn vaccination:</p> <ul style="list-style-type: none"> <li>85% coverage with timely HBV birth dose vaccination</li> </ul> <p>For countries that implement screening of pregnant women and post-exposure prophylaxis of newborns:</p> <ul style="list-style-type: none"> <li>85% coverage with screening in pregnant women and 90% coverage with post-exposure prophylaxis in infants born to infected mothers</li> </ul>	<p>For countries that implement universal newborn vaccination:</p> <ul style="list-style-type: none"> <li>90% coverage with timely HBV birth dose vaccination</li> </ul> <p>For countries that implement screening of pregnant women and post-exposure prophylaxis of newborns:</p> <ul style="list-style-type: none"> <li>90% coverage with screening in pregnant women and 95% coverage with post-exposure prophylaxis in infants born to infected mothers</li> </ul>
<b>BLOOD SAFETY</b>	
<ul style="list-style-type: none"> <li>All countries have effective haemovigilance systems in place and all donations are tested at least with serological methods for HBV and HCV infection</li> </ul>	<ul style="list-style-type: none"> <li>All donated blood tested with NAT-screening methods for HBV and HCV</li> <li>All donated blood from non-remunerated donors</li> </ul>
<b>INFECTION PREVENTION AND CONTROL IN HEALTH CARE SETTINGS AND BEYOND</b>	
<ul style="list-style-type: none"> <li>Safe injection policies and IPC rules for preventing transmission of blood-borne infections in health sector (including in prisons) in place and implemented <ul style="list-style-type: none"> <li>National disinfection and sterilization protocols for non-health care settings (aesthetic cosmetology and tattoo facilities) developed and implemented</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>50% of injections administered with safety-engineered devices in and out of health care facilities</li> </ul>
<b>PREVENTION AMONG PEOPLE WHO INJECT DRUGS</b>	
<ul style="list-style-type: none"> <li>Policies developed and implemented to support a comprehensive package for infection prevention and harm reduction among people who inject drugs including: needle and syringe programmes (NSPs); opioid substitution therapy (OST) and other evidence-based drug dependence treatment targeted information, education and communication (IEC) for people who inject drugs and HAV and HBV vaccination</li> </ul>	<ul style="list-style-type: none"> <li>A comprehensive package of harm reduction services to all persons who inject drugs, including: <ul style="list-style-type: none"> <li>At least 200 syringes distributed per PWID per year*</li> <li>At least 40% of opioid dependent PWID receive opioid substitution therapy</li> <li>HBV and HAV vaccination</li> </ul> </li> <li>90% of PWID receiving targeted IEC provided by NSPs, drug treatment service sites (including OST) and other services targeting PWID</li> </ul>

2018 MILESTONES	2020 TARGETS
<b>PREVENTION OF SEXUAL TRANSMISSION</b>	
<ul style="list-style-type: none"> <li>90% of countries provide STI services or links to such services in all primary, HIV, drugs, reproductive and perinatal care services</li> </ul>	<ul style="list-style-type: none"> <li>Access for all individuals to a full range of services relevant to STIs, including HIV and HBV and HCV, and access to condoms, testing and counselling</li> </ul>
<b>DIAGNOSING HEPATITIS VIRUS INFECTIONS</b>	
<ul style="list-style-type: none"> <li>High quality viral hepatitis testing and diagnosis services are available and accessible for all</li> <li>All countries have national HBV and HCV testing policies, aligned with WHO guidelines</li> <li>All countries have estimated the diagnosis rate and the proportion of patients diagnosed at late stage of viral hepatitis-related liver disease (cirrhosis or HCC)</li> <li>All health care workers know their viral hepatitis B and C sero-status</li> </ul>	<ul style="list-style-type: none"> <li>50% of all persons with chronic HBV, HCV and HDV diagnosed</li> <li>75% of estimated number of patients at late stage of viral hepatitis-related liver disease (cirrhosis or HCC) diagnosed</li> </ul>
<b>ENHANCING CHRONIC HEPATITIS CARE AND TREATMENT</b>	
<ul style="list-style-type: none"> <li>National hepatitis treatment and care updates, in line with WHO guidelines established and regularly updated</li> <li>Baseline estimation of people who need to receive treatment for chronic HBV, HCV and HDV infection obtained, preferably by liver disease stage</li> </ul>	<ul style="list-style-type: none"> <li>Treatment for chronic HBV, HCV and HDV infection, in line with international standards, is available and affordable for all</li> <li>90% of diagnosed patients with chronic HBV, HCV and HDV infections are linked to care and adequately monitored</li> <li>75% of the diagnosed patients with chronic HBV and HDV infection, who are eligible for treatment, begin treatment and among those on long-term treatment for HBV, 90% obtain viral suppression</li> <li>75% of the diagnosed eligible patients with chronic HCV infection receive effective treatment and at least 90% of them are cured</li> </ul>

HAV: hepatitis A virus; HBV: hepatitis B virus; HCC: hepatocellular carcinoma; HCV: hepatitis C virus; HDV: hepatitis D virus; HIV: human immunodeficiency virus; IEC: information, education and communication; IPC: infection, prevention and control; NAT: nucleic acid testing; NSP: needle and syringe programme; OST: opioid substitution therapy; PWID: people who inject drugs; STIs: sexually transmitted infections

\* A comprehensive package of evidence-based interventions to reduce harms associated with injecting drug use is outlined in the WHO, UNAIDS, UNODC technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users (15). Since blood-borne transmission is common to HIV and hepatitis viruses, interventions effective in preventing HIV among people who inject drugs help to prevent HCV/HBV transmission. The guidance notes that because HCV is more virulent than HIV, however, higher levels of intervention coverage may be necessary to achieve comparable reductions in incidence.

The WHO, UNAIDS, UNODC guidance (15) suggests a target of 200 syringes distributed per PWID per year based upon studies in developed-country settings and mathematical modelling investigating the levels of syringe distribution and its impact on HIV transmission. Levels required for the prevention of HCV are likely to be much higher. The 40% OST target is based on levels of coverage achieved in countries with well-established OST programmes.

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