

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



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Abstract

This first Action plan for viral hepatitis in the WHO European Region adapts the Global Health Sector Strategy on Viral Hepatitis, 2016–2021 to the context of the European Region. The plan was developed through a participatory process, finalized and endorsed at the 66th session of the WHO Regional Committee for Europe, along its resolution EUR/RC66/R10. While the Action plan addresses all five hepatitis viruses, its major focus is on hepatitis B and C, given the high public health burden they represent in the Region. The goal of the Action plan is elimination of viral hepatitis as a public health threat in the WHO European Region by 2030 through the reduction of transmission, morbidity and mortality due to viral hepatitis and its complications, and by ensuring equitable access to comprehensive prevention, recommended testing, care and treatment services for all.

Keywords

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Foreword



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Viral hepatitis is a global public health threat which, until recently, has not received adequate attention. An estimated 15 million people in the WHO European Region are living with chronic hepatitis B virus infection and 14 million are estimated to be living with chronic hepatitis C virus infection. In addition, about 171 000 people die from viral hepatitis-related causes in the Region every year.

This is the first Action plan for the health sector response to viral hepatitis in the WHO European Region developed to facilitate the implementation of the Global Health Sector Strategy on Viral Hepatitis 2016–2021 in our Region. By endorsing this plan at the 66th WHO Regional Committee, Member States committed to eliminate viral hepatitis as a public health threat by 2030 through providing access to affordable and effective immunization, testing, treatment and care.

The Action plan is fully aligned with the 2030 Agenda for Sustainable Development, and Health 2020, the European policy for health and well-being in the 21st century. It sets regional milestones and targets across the continuum of viral hepatitis services and proposes priority actions for Member States, accompanied by WHO supporting actions.

It is time to join our forces to achieve viral hepatitis elimination!

Dr Zsuzsanna Jakab

WHO Regional Director for Europe

Preface

This very first Action plan for the health sector response to viral hepatitis in the WHO European Region has been developed through a truly inclusive consultative approach. It draws on the expertise of an advisory committee and has benefited from the input of Member States, major partners and civil society, including patient organizations which represent the people who live with viral hepatitis in Europe. The Action plan provides the framework for a comprehensive health sector response to viral hepatitis; it comprises evidence-informed national planning based on local contexts and needs, awareness-raising, prevention of transmission, diagnosis, and care and treatment, with special attention to the populations most affected and at risk of infection. The framework of the plan is built on three organizing principles: universal health coverage; the continuum of viral hepatitis services; and the promotion of a public health approach. Recognizing variations in viral hepatitis epidemiology and the availability of resources across the countries of the WHO European Region, the Action plan is intended to guide Member States in developing country-specific national strategies to control and prevent viral hepatitis.

Failure to combat viral hepatitis risks undermining the achievement of the 2030 Agenda for Sustainable Development, compromising health security and the reduction of inequalities in the WHO European Region. In line with the Sustainable Development Goals, this Action plan calls for action across sectors and settings to eliminate viral hepatitis as a public health threat.

Dr Nedret Emiroğlu

Director, Division of Health Emergencies and Communicable Diseases

Abbreviations

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
HCC	hepatocellular carcinoma
HAV	hepatitis A virus
HBsAg	hepatitis B surface antigen
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
NSP	needle and syringe programme
OST	opioid substitution therapy
PLHIV	people living with HIV
PWID	people who inject drugs
STI	sexually transmitted infection
TB	tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
UNODC	United Nations Office on Drugs and Crime

Executive summary

Viral hepatitis is a leading cause of mortality globally – a global public health challenge that has, until recently, been largely ignored as a health and development priority. This first Action plan for viral hepatitis in the WHO European Region adapts the Global Health Sector Strategy on Viral Hepatitis 2016–2021, endorsed by the Sixty-ninth World Health Assembly in resolution WHA69.22, to the epidemiological, social and political contexts of the countries of the WHO European Region.

The Action plan is structured around five strategic directions: information for focused action; interventions for impact; delivering for equity; financing for sustainability; and innovation for acceleration. While the Action plan addresses all five hepatitis viruses, its major focus is on hepatitis B and C, given the high public health burden they represent in the Region.

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. The goal of the Action plan is the elimination of viral hepatitis as a public health threat in the European Region by 2030; this is to be achieved by reducing transmission of hepatitis viruses; reducing 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.

This Action plan provides the framework for a comprehensive health sector response to viral hepatitis; it comprises evidence-informed national planning based on local contexts and needs, awareness-raising, prevention of transmission, diagnosis, and care and treatment of viral hepatitis, with special attention to the populations most affected and at risk of viral hepatitis infection. Recognizing variations in viral hepatitis epidemiology and the availability of resources across the countries of the European Region, the Action plan is intended to guide Member States in developing country-specific strategies and plans, aligned with national priorities, policies and legislation, to prevent and control viral hepatitis. The plan was developed through a participatory process across the Region, finalized following guidance from the 23rd Standing Committee for the Regional Committee for Europe, and endorsed in September 2016 at the 66th session of the WHO Regional Committee for Europe, by means of Regional Committee resolution EUR/RC66/R10.



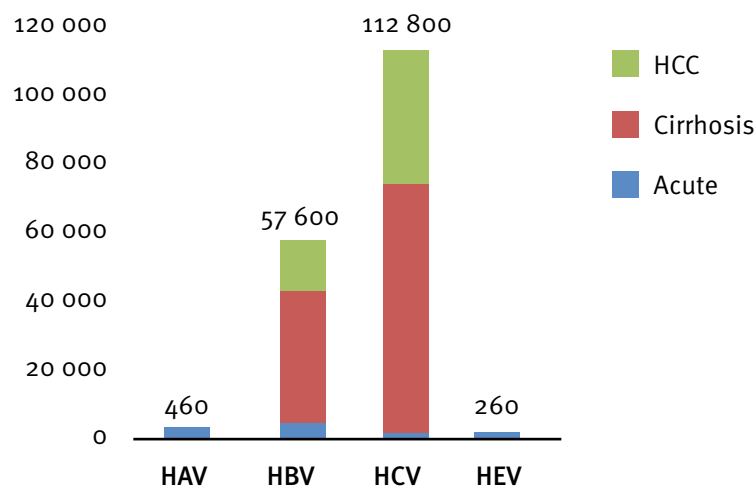
Introduction

Epidemiology and burden of viral hepatitis

Globally, viral hepatitis is a leading cause of mortality which, until recently, had not received the attention as a public health priority it deserved. In the WHO European Region, an estimated 171 000 people die annually from viral hepatitis-related causes – more than 400 deaths a day, or approximately 2% of all deaths (1). Approximately 98% of these deaths are due to late effects of chronic hepatitis B and hepatitis C (estimated deaths in 2013, 56 000 and 112 500 respectively), while the remainder are attributable to acute viral hepatitis infections (Fig. 1). It is estimated that approximately 15 million people in the European Region are living with hepatitis B virus (HBV) infection and about 14 million with chronic hepatitis C virus (HCV) infection (2).

The five hepatitis viruses – hepatitis A virus (HAV), HBV, HCV, hepatitis D virus (HDV) and hepatitis E virus (HEV) – differ with respect to their transmission routes, affected populations, geographical distribution and socioeconomic environments, and result in a range of health outcomes. Hepatitis A and E are associated with food- and waterborne transmission and typically resolve without long-term pathology. HBV, HCV and HDV are bloodborne infections with a high risk of transmission through unsafe injections and other medical practices, sexual contact and sharing equipment for injecting drug use (IDU). 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 they lead progressively to liver cirrhosis and cancer.

Fig. 1. Estimated mortality from viral hepatitis in the WHO European Region, 2013



HAV: hepatitis A virus; HBV: hepatitis B virus; HCC: hepatocellular carcinoma; HCV: hepatitis C virus; HEV: hepatitis E virus.
Source: Naghavi et al. (1).

HAV infections remain a challenge for many countries; tens of thousands of cases occur 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 falling since the 1990s, with most countries having a low-endemicity profile. However, incidence, transmission source and risk groups vary widely between countries, with those in eastern Europe and central Asia most affected.

The epidemiology of hepatitis B in the WHO European Region is diverse, indicated by hepatitis B surface antigen (HBsAg) prevalence that ranges from extremely low (< 0.1%) in northern Europe to high (> 10%) in countries in central Asia (3). Despite a decrease in incidence since 2000 and the positive impact of vaccination on seroprevalence in younger age groups, many Member States in eastern and southern parts of the Region still face a heavy burden due to chronic HBV infection in older age cohorts. In most countries of western and northern Europe, the majority of cases are now registered as imported (4), and the burden is considerably higher among immigrants from countries with high prevalence (5). 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.

The epidemiology of hepatitis C in the WHO European Region varies substantially, ranging 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 (3). The burden of chronic hepatitis C is disproportionately high among PWID and MSM in HIV-infected populations. 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 Area (EU/EEA) countries (6). In several Member States transmission due to unsafe procedures inside and outside health care settings continues to play an important role.

HDV infection occurs either as coinfection (with HBV) or as superinfection 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 (7). HDV infection accelerates progression of liver disease and is increasingly difficult to treat.

HEV infection often is asymptomatic and usually is limited to acute hepatitis. Until recently the majority of cases were considered to be associated with travel to endemic regions. However, recent studies show that in the last few 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 of the European Region (8). Certain population groups, such as transplant patients receiving immunosuppressive treatment, are also more vulnerable to hepatitis E infection resulting from blood transfusion.

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

The epidemiology and burden of viral hepatitis across the Region are 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



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southern and eastern Europe and central Asia. In addition to this geographical variability, specific populations can be more affected by, or at higher risk of, viral hepatitis infection.¹

In some Member States progress has been made in 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, have still 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 information on disease burden, including viral hepatitis-related liver cirrhosis and cancer, is scarce, and challenges persist in ensuring high-quality, validated diagnostic assays. This results in poor epidemiological baselines and undermines specific and targeted response efforts.

¹ Populations most affected and at risk: each country should define the specific populations within their borders that are most affected by viral hepatitis epidemics, and its particular response should be based on the epidemiological and social context. Such populations may differ according to local contexts but could include: (a) people who have been exposed to hepatitis viruses through unsafe blood supplies and unsafe medical injections and procedures; (b) transgender people and MSM; (c) sex workers; (d) prisoners; (e) PWID; and (f) 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 (TB); and HIV and viral hepatitis (9).

A total of 47 Member States in the WHO European Region (87%) have successfully implemented universal childhood HBV immunization programmes. The majority of these have achieved at least 90% coverage with three doses of HBV vaccine. However, the six remaining Member States, with very low HBV endemicity as of 2016, did not implement universal vaccination, instead relying on selective immunization of people at high risk of HBV infection, including health care workers. However, in most countries HBV vaccination coverage still remains low among high-risk populations, such as prisoners, MSM and sex workers.

All Member States have implemented 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 of pregnant women and the extent to which post-exposure prophylaxis of newborns is timely and complete.

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

Infection prevention and control in health care settings, including blood and injection safety, have improved significantly in the European 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



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some countries, nonmedical settings such as cosmetic and tattoo facilities have been associated with poor infection control due to inadequate disinfection and sterilization practices, thereby increasing the risk of transmission of bloodborne hepatitis viruses.

The incidence and prevalence of viral hepatitis among certain most affected and at-risk populations, particularly PWID and prisoners, remain high in many countries, and access to prevention and harm reduction services varies widely across the Region. In some countries, legal barriers and discriminatory environments and challenges hamper effective viral hepatitis and HIV prevention measures, such as needle and syringe programmes and opioid substitution therapy (OST) among PWID. In other countries, 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 immigrants, refugees and asylum seekers to the WHO European Region poses health challenges for the displaced individuals and their host communities. Migrant populations often lack access to health care, their vaccination status may be uncertain, and the prevalence and incidence of infection among them may go underreported or unreported. Many western European countries have experienced a rise in chronic HBV infections due to migrants moving from high- or intermediate-endemicity areas to low-endemicity areas. Strategies and interventions tailored for these migrant populations need to be prioritized (5).

The burden of comorbidities and coinfections for chronic hepatitis patients is high. Alcoholic liver disease remains the main cause of liver cirrhosis in many countries of the Region and its comorbidity with chronic viral hepatitis is not uncommon. The burden of HCV–HIV coinfection is particularly high 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, while chronic HBV infection can be effectively controlled through suppression of viral replication. As a result, there has been 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.

The Action plan for the health sector response to viral hepatitis

Purpose

This Action plan provides the framework for a comprehensive health sector response to viral hepatitis; it comprises evidence-informed national planning based on local contexts and needs, awareness-raising, prevention of transmission, diagnosis, and care and treatment, with special attention to the populations most affected and at risk of infection by hepatitis viruses. Recognizing variations in viral hepatitis epidemiology and the availability of resources across the countries of the European Region, the Action plan is intended to guide Member States in developing country-specific strategies and plans, aligned with national priorities, policies and legislation, to prevent and control viral hepatitis. 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 framework of the Action plan is built on three organizing principles: 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. The plan should take a whole-of-society approach, ensuring respect for human rights, gender equality and equity; and it proposes 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 sexually transmitted infections (STIs), held in Copenhagen, Denmark, in June 2015.

The Action plan adapts the Global Health Sector Strategy on Viral Hepatitis, 2016–2021 (9), endorsed by the Sixty-ninth World Health Assembly in resolution WHA69.22, to the epidemiological, social and political contexts of the countries of the WHO European Region. It is also aligned with the 2030 Agenda for Sustainable Development; Health 2020: a European policy framework and strategy for the 21st century (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 WHO European Region (14).

This Action plan has been developed through a participatory process across the European Region, 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.



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 of the Action plan is the elimination of viral hepatitis as a public health threat in the European Region by 2030.² This is to be achieved by:

- reduction the transmission of hepatitis viruses;
- reduction the 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 set for 2018 (Annex 1). These will guide Member States in setting national targets in accordance with their local context and will be used to monitor the implementation of the Action plan.

Seven regional targets, to be met by 2020, are essential in order to achieve the ambitious goal of hepatitis elimination. The first five targets relate to prevention, while the sixth and seventh relate to testing and treatment:

- 95% coverage with three doses of HBV vaccine in countries that implement universal childhood vaccination;
- 90% coverage with interventions to prevent mother-to-child transmission of HBV (hepatitis B birth-dose vaccination or other approaches);
- 100% of blood donations screened using quality-assured methods;
- 50% of injections administered with safety-engineered injection devices;³ integrated into broader infection prevention and control;
- at least 200 sterile injection equipment kits distributed per person per year for PWID, as part of a comprehensive package of harm reduction services;⁴

2 Elimination of viral hepatitis as a public health threat has been defined as a 90% reduction in the number of new chronic hepatitis B and C infections and a 65% reduction in the number of deaths by 2030, with milestones for 2020 set as 30% and 10% reductions respectively (9). Each Member State, however, will need to define specific national targets with respect to mortality and incidence for 2020 and beyond, based on local epidemiological context and best available baseline data.

3 Safety-engineered injection devices are syringes (or other injection devices) that have been engineered so that they cannot be reused and do not lead to accidental needlestick injuries among health workers (15).

4 A comprehensive package of evidence-based interventions to reduce harm associated with IDU 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* (16). Since bloodborne transmission is common to HIV and hepatitis viruses, interventions effective in preventing HIV among PWID also help to prevent HCV and HBV transmission.

- 50% of people living with chronic HBV and HCV infections to be diagnosed and aware of their condition; and
- 75% treatment coverage of people who are eligible for treatment and diagnosed with HBV and HCV infections.

Guided by the 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; they 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.

Strategic directions and priority actions

To achieve the 2020 and 2030 targets and goals, action is required in five strategic directions. These aim to maximize the synergies between viral hepatitis and other settings within national health systems and to align the health sector response with other relevant regional and global health and development strategies, plans and targets. They are intended to provide countries with guidance on how to prioritize viral hepatitis and broader health investments on the basis of national epidemiological context and needs and by means of recommended priority health sector policies, interventions and approaches.

The five strategic directions are:

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

Aligned 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 set for 2018 (Annex 1). These will guide Member States in setting national targets in accordance with their local context.

Strategic direction 1: Information for focused action

Develop strong strategic information systems to understand viral hepatitis epidemics and focus responses to them

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



Data for informed decisions

Robust national hepatitis strategic information systems can generate timely and high-quality data about epidemics and the interventions in place to respond to them. Such systems provide the basis for a comprehensive situation analysis and are essential to inform programme decision-making and structure services according to need 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 responses to viral hepatitis are essential to inform more strategic investment in hepatitis services and to maximize 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”.

Rigorous application of ethical standards in gathering and using data is important to avoid compromising the confidentiality and safety of individuals and communities. Greater community and stakeholder involvement in collection and analysis of data has the potential to improve the quality and use of information.

2018 Milestones	2020 Targets
<p>Harmonized surveillance objectives and case definitions to be aligned with current WHO technical considerations and adopted.</p> <p>National disease burden to be estimated and investment case developed.</p>	<p>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 do effective real-time tracking of the viral hepatitis diagnosis, treatment and care cascade, including in specific vulnerable populations.</p>

Priority actions for Member States include:

- to assess and strengthen current viral hepatitis and related communicable disease data sources and surveillance system;
- to adapt WHO-compatible case definitions for viral hepatitis surveillance and to ensure that the viral hepatitis surveillance system serves its main purposes;⁵
- to develop national estimates of the disease burden of chronic viral hepatitis (including incidence, prevalence and mortality for the general population, vulnerable groups and key populations);
- to link and integrate viral hepatitis strategic information systems with broader health information systems, including those focusing on coinfections and other comorbidities (particularly HIV, TB and STIs), and to expand cross-border sharing of information to ensure service continuity for refugees, migrants and other mobile populations;
- to 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;

5 The viral hepatitis surveillance system should be able to (a) detect outbreaks, monitor trends in incidence and identify risk factors for new infections; (b) estimate the prevalence of chronic infections and monitor trends in the general population and in sentinel groups; and (c) estimate the burden of sequelae of chronic hepatitis, including cirrhosis and hepatocellular carcinoma (HCC) (17).

- to develop a country-specific investment case for action on viral hepatitis;
- to achieve stakeholder consensus on data.

WHO and partners will provide:

- assistance to Member States in implementing and adapting WHO technical guidance on viral hepatitis surveillance (17);
- methodological and technical assistance in improving surveillance systems, conducting serosurveys 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;
- close collaboration with the European Centre for Disease Prevention and Control (ECDC), the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and other regional agencies to optimize 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. Such processes should allow 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. They should facilitate advocacy of political commitment to sustained financing and national ownership.

2018 Milestones

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

Priority actions for Member States include:

- to establish a national governance structure and coordinating mechanism to oversee the national hepatitis response, integrated with the national health programme;
- to develop a national action plan for viral hepatitis by bringing together relevant sectors, with a budget and timeframe for achieving targets and milestones;
- to 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, multisectoral national plans as a cost-effective and cost-saving means of responding to viral hepatitis; and technical assistance in national planning, using the WHO national planning manual (18).

A national viral hepatitis communication and awareness strategy as an integral part of the national action plan

Lack of awareness about viral hepatitis and the stigma associated with chronic viral hepatitis B and C often lead to widespread discrimination and prevent people who live with chronic hepatitis from being diagnosed and seeking care. Targeting undiagnosed patients will require a reduction of this stigma in combination with effective case-finding, testing, and increased public and professional awareness. Systematic methods to monitor knowledge, attitudes and health-seeking behaviours with respect to HBV and HCV should also be developed to enable authorities to effectively address this public health concern.

2018 Milestones	2020 Targets
World Hepatitis Day to be marked in all Member States.	National viral hepatitis communication and awareness strategies to be adopted in a majority of Member States.



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Priority actions for Member States include:

- to educate and train health professionals, decision-makers, the media and the public to create awareness, increase knowledge, and improve attitudes and practices that assist in viral hepatitis prevention;
- to address stigma and discrimination through comprehensive awareness and communication strategies;
- to reduce language and cultural barriers currently existing in populations that limit access to prevention and treatment services;
- to devise specific awareness campaigns and anonymous free viral hepatitis testing programmes, which cover the general population but also target groups that are specifically at risk according to the epidemiological situation of a given country.

WHO and partners will provide:

- communication guidance to support Member States, including an annual World Hepatitis Day toolkit and information package for use in countries, available in a range of languages;
- assistance in encouraging patient and affected population groups to actively participate in regional guidance development and in promoting cooperation of the civil society and government sectors in viral hepatitis prevention and control;
- examples of targeted awareness campaigns suitable for different settings and risk groups.

Strategic direction 2: Interventions for impact

People should receive all the hepatitis services they need

Each country should define a set 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 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, delivered through integrated services in which a public health approach is adopted and which are managed 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 to prevent mother-to-child transmission; prevention of health care-associated transmission; and high-intensity prevention of transmission associated with IDU. 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 vaccination coverage of infants, with three doses of hepatitis B vaccine, 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 for the entire next generation before risk behaviour starts, without

discriminating between country of birth or sexual preference. Improvement of hepatitis B vaccination coverage should be considered in the context of strengthening 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; they should be seen in the context of comprehensive viral hepatitis prevention, which includes improvement of hygiene, sanitation and outbreak control.

2018 Milestones	2020 Targets
<p>90% coverage with three doses of HBV vaccine in countries that implement universal childhood vaccination.</p> <p>National guidelines on HAV and HBV vaccination for high-risk groups to be developed and implemented.</p>	<p>95% coverage with three doses of HBV vaccine in countries that implement universal childhood vaccination.</p> <p>≤0.5% HBsAg prevalence in vaccinated cohorts.</p> <p>80% of health care workers to be vaccinated against HBV.</p>

Priority actions for Member States include:

- to consider, on the basis of scientific advice provided by national immunization advisory bodies, introduction of universal childhood hepatitis B vaccination in countries that do not implement it;
- to improve HBV vaccination coverage by monitoring public perceptions, knowledge and attitudes, and by developing tailored and innovative strategies to create demand for vaccination among all population groups, as outlined in the European Vaccine Action Plan 2015–2020 (12);
- to consider, in light of local epidemiology, catch-up vaccination strategies targeted at older age groups as a supplement to universal childhood vaccination;
- to define country-specific risk groups according to local context and to develop a national policy on vaccination of high-risk individuals against hepatitis B (health care workers, who are at high risk of hepatitis B infection and can occasionally transmit it to patients, should be prioritized in all countries);
- to define the local HAV disease burden by using data from viral hepatitis surveillance or population-based serosurveys, and to develop adequate HAV vaccination strategies (Member States with 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 2015–2020 (12), WHO and partners will provide:

- support to Member States in setting up evidence-based policies on HBV and HAV vaccination;
- guidance and tools to generate and maintain demand for immunization services and to address vaccine hesitancy;
- advocacy and guidance on how to reach high-risk populations in accordance with resolution 140730 of the 64th 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 newborn, is a major concern for hepatitis B transmission since 70–90% of newborns infected perinatally become chronic carriers and are therefore at high risk of morbidity and mortality from cirrhosis and liver cancer during later phases of their lives.

Maintaining control of hepatitis B in the population requires effective control of perinatal transmission, alongside achieving high levels of immunity in children through universal immunization.

There are two basic strategies adopted in the WHO European 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 of birth. The second is to screen all pregnant women for HBsAg prenatally and then to provide post-exposure prophylaxis to 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.

2018 Milestones	2020 Targets
85% coverage with timely HBV birth dose vaccination for countries that implement universal newborn vaccination.	90% coverage with timely HBV birth dose vaccination for countries that implement universal newborn vaccination.
85% coverage with screening in pregnant women and 90% coverage with post-exposure prophylaxis in infants born to infected mothers for countries that implement screening of pregnant women and post-exposure prophylaxis of newborns.	90% coverage with screening in pregnant women and 95% coverage with post-exposure prophylaxis in infants born to infected mothers for countries that implement screening of pregnant women and post-exposure prophylaxis of newborns.

Priority actions for Member States include:

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

WHO and partners will provide advocacy and technical support in defining national strategies to prevent perinatal HBV transmission and establishing effective systems to monitor and evaluate coverage of 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 transfusion of contaminated blood and blood products is extremely high, and – despite considerable success in improving blood safety in the European Region – it still occurs because screening in blood transfusion services is either lacking or of poor quality. Ensuring 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 to be obtained from regular, voluntary and non-remunerated blood donors.

2018 Milestones	2020 Targets
All countries to have effective haemovigilance systems in place and all donations to be tested at least with serological methods for HBV and HCV infection.	All donated blood to be screened with nucleic acid testing methods for HBV and HCV. All donated blood to come from non-remunerated donors.

Priority actions for Member States include:

- to harmonize national legislative acts with the WHO global strategic plan for safe blood transfusion (19);
- to develop nationally coordinated transfusion and transplantation services with full authority and responsibility to ensure safe blood supplies are integrated into the national health system;
- to standardize donor selection and blood testing processes;
- to strengthen the quality-control system for blood production and testing.

WHO and partners will provide:

- guidance on managing safe blood and tissue supplies and on strengthening linkages between blood transfusion and transplantation services and viral hepatitis services;
- assistance in promoting development and use of blood and blood product substitutes.

Injection safety and infection prevention and control (IPC) inside and outside health care settings

2018 Milestones	2020 Targets
Safe injection policies and IPC rules to prevent transmission of bloodborne infections in the health sector (including in prisons) to be in place and implemented. National disinfection and sterilization protocols for non-health care settings (cosmetic and tattoo facilities) to be developed and implemented.	50% of injections to be administered with safety-engineered devices inside and outside health care facilities, integrated into broader infection prevention and control

Priority actions for Member States include:

- to establish or strengthen a national infection prevention and control regulating authority, covering medical and nonmedical settings, including prisons;

- to regularly revise and update, according to the latest available evidence, national sterilization and disinfection guidelines in health care settings (including health care settings in prisons), specifically covering injection safety, endoscopic procedures, dental and oral health, haemodialysis and other potential sources of exposure to bloodborne infections;
- to improve understanding, at all levels of the health care system, including auxiliary and cleaning personnel, of viral hepatitis and other bloodborne infection transmission risks and infection control principles;
- to develop or strengthen national sterilization and disinfection guidelines in nonmedical settings (e.g. tattooing and piercing facilities) and to ensure effective monitoring and control mechanisms are in place;
- to develop, where appropriate and based on the latest scientific evidence, national guidance on post-exposure prophylaxis of parenteral hepatitis viruses;
- to reduce unnecessary injections inside and outside health care facilities;
- to implement measures to promote universal use of safety-engineered devices (e.g. reuse-prevention and needlestick 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 (15); IPC inside and outside health care services; and IPC 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 of implementation of safe injection practices, including introduction of non-reusable injection devices and WHO universal precautions and infection control guidelines (20).



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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, as a result of insufficient awareness and widespread unsafe injection practices such as sharing injection equipment. A package of harm reduction services for PWID can be highly effective in preventing transmission and acquisition of viral hepatitis A, B and C, as well as HIV and other bloodborne 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, so harm reduction services should be up-scaled and include provision of all injecting paraphernalia, including mixing containers and solutions.

2018 Milestones	2020 Targets
<p>Policies to be developed and implemented in support of a comprehensive package for infection prevention and harm reduction among PWID, including: needle and syringe programmes (NSPs); OST and other evidence-based drug dependence treatments; targeted information, education and communication (IEC) for PWID; and HAV and HBV vaccination.</p>	<p>A comprehensive package of harm reduction services for all PWID, including:⁶</p> <ul style="list-style-type: none"> • at least 200 syringes distributed per PWID per year; • at least 40% of opioid-dependent PWID to receive OST; • HBV and HAV vaccination. <p>90% of PWID to receive targeted IEC provided by NSPs, drug treatment service sites (including OST) and other services targeting PWID.</p>

Priority actions for Member States include:

- to implement a comprehensive, interdisciplinary infection-prevention and harm reduction programme based on the WHO package of interventions (16), with integrated services for PWID, including treatment for HCV infection and effective measures to prevent reinfection, as well as harm reduction interventions;
- to implement measures aimed at preventing initiation of drug use, including promotion of healthy lifestyles;
- to 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 appropriate;
- to make effective drug treatment, including OST, available to opioid-dependent individuals, ensuring equivalence of services in prisons; and to make safe injection sites accessible where appropriate;
- to assess, and address accordingly, the risk of transmission associated with new injection drug practices (such as injection of amphetamines and other stimulant drugs, and image- and performance-enhancing drugs) and other types of drug consumption (such as “snorting”);

6 A comprehensive package of evidence-based interventions to reduce harms associated with IDU 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 (16). Since bloodborne transmission is common to HIV and hepatitis viruses, interventions effective in preventing HIV among PWID also help to prevent HCV and HBV transmission. However, because HCV is more virulent than HIV, higher levels of intervention coverage may be necessary to achieve comparable reductions in incidence.

The WHO, UNAIDS, UNODC guidance suggests a target of 200 syringes distributed per PWID per year on the basis of studies in developed-country settings and mathematical modelling investigating levels of syringe distribution and its impact on HIV transmission. The distribution levels required for 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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- to implement an interdisciplinary approach and integration of services for PWID, including testing and treatment for viral hepatitis, HIV and TB infection, drug-dependence treatment and mental health;
- to consider routine testing for HBV and HCV infections not only as individual benefit for linkage-to-care but also as testing-for-prevention approach among PWID.

WHO and partners will provide:

- promotion and updating of policies and guidance on evidence-based prevention and management of viral hepatitis and other bloodborne infections for PWID, including people who use cocaine (including intranasal consumption practices) and amphetamine-type stimulants;
- advocacy and technical support to mobilize commitment and resources for recommended harm reduction interventions;
- assistance in creating a stakeholder network to ensure 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 MSM who indulge in high-risk behaviour, but also heterosexual individuals with multiple sexual partners. In low-endemicity countries, sexual contact constitutes one of the main transmission routes for HBV infection among individuals 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 in reducing sexual transmission of viral hepatitis is hard to measure in most settings, therefore reduction of other STI infections will serve as an indicator of success in reducing sexual transmission of hepatitis.

2018 Milestones	2020 Targets
90% of countries to provide STI services or links to such services in all primary, HIV, drugs, reproductive and perinatal care services.	Access for all individuals to a full range of services relevant to STIs, including HIV, HBV and HCV, access to condoms, testing and counselling.

Priority actions for Member States include:

- to guarantee provision of comprehensive and evidence-based sexual and reproductive health, including health promotion, education, prevention, diagnosis and management of STIs for all;
- to ensure dedicated services for those who may have difficulty accessing sexual and reproductive health services, including adolescents and the elderly, migrants and asylum seekers, people living with HIV, MSM and transgender people, PWID, incarcerated people, and people engaged in sex work;
- to develop and implement strategies to strengthen sexual partner management, ensuring patient confidentiality and linkage to counselling and treatment of partners;
- to develop and implement targeted awareness campaigns for specific populations at risk of STIs 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, paying 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 multinational 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 resistance 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 mainly to 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.

Priority actions for Member States include:

- to ensure collaboration and information-sharing between the health, environment, food safety and agriculture sectors;
- to develop and implement policies and regulations on food safety that address the safety of food in a whole-food-chain approach including primary production, the food industry and food-handlers;
- to develop and promote recommendations and raise awareness among the general public of food safety and water safety, including the importance of applying the WHO five keys to safer food (21) and the WHO five keys to growing safer fruits and vegetables (22);
- to ensure uptake, in policy and practice, of the guidance given in the WHO water safety plans⁷ and sanitation safety planning,⁸ including in high-risk settings and camps for internally displaced persons and refugees;
- to establish and/or maintain effective surveillance, outbreak response and reporting systems for HAV and HEV infections.

WHO and partners will provide:

- guidance on scale-up of risk-assessment and management approaches (i.e. WSPs and SSP) in water supply and sanitation;
- updated guidance on food safety-related issues;
- 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 those 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 that these shortcomings are remedied, by means of effective testing approaches, quality-assured diagnostics, and linking the results of testing to treatment and care services.

2018 Milestones	2020 Targets
High-quality viral hepatitis testing and diagnosis services to be available and accessible to all.	50% of all people with chronic HBV, HCV and HDV to be diagnosed.
All countries to have national HBV and HCV testing policies, aligned with WHO guidelines.	75% of the estimated number of patients at late stage of viral hepatitis-related liver disease (cirrhosis or HCC) to be diagnosed.
All countries to have estimated the diagnosis rate and the proportion of patients diagnosed at late stage of viral hepatitis-related liver disease (cirrhosis or HCC).	
All health care workers to know their viral hepatitis B and C serostatus.	

⁷ 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 (23).

⁸ Sanitation safety planning (SSP) is a step-by-step risk-based approach to assist in the implementation of the WHO guidelines for safe use of wastewater, greywater and excreta (24).

Priority actions for Member States include:

- to develop and roll out national viral hepatitis testing and diagnostic guidelines in accordance with WHO guidance and to devise local policies that identify and target high-risk groups and high-risk behaviours;
- to offer hepatitis testing to all clients at drugs services, on an opt-out basis, as part of a yearly health check-up;
- to test all prisoners on entry into prison for viral hepatitis, on an opt-out basis;
- to strengthen the national laboratory system to provide high-quality diagnosis of acute and chronic hepatitis;
- to ensure availability and access to good-quality and affordable diagnostics and testing, including diversified testing approaches (e.g. outreach programme, self-testing);
- to ensure confidentiality of test results and sharing of test results in order to avoid stigma and promote linkages to recommended care and treatment;
- to ensure continuous education of health care professionals, including general practitioners and noncommunicable 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 coinfecting with HIV. Direct-acting antivirals for treatment of chronic HCV have cure rates exceeding 95%, with pan-genotypic regimens becoming available. Effective treatment is available for chronic hepatitis B.

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 an 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 Milestones	2020 Targets
<p>National hepatitis treatment and care guidelines and protocols to be established and updated in line with WHO guidelines.</p> <p>Baseline estimation of people who need to receive treatment for chronic HBV, HCV and HDV infection to be obtained, preferably by liver disease stage.</p>	<p>Treatment for chronic HBV, HCV and HDV infection, in line with international standards, to be available and affordable for all.</p> <p>90% of patients diagnosed with chronic HBV, HCV and HDV infections to be linked to care and adequately monitored.</p> <p>75% of patients diagnosed with chronic HBV and HDV infection, and eligible for treatment, to begin treatment; and among those on long-term treatment for HBV, 90% to obtain viral suppression.</p> <p>75% of eligible patients diagnosed with chronic HCV infection to receive effective treatment and at least 90% of them to be cured.⁹</p>

Priority actions for Member States include:

- to establish and regularly update national hepatitis treatment and care protocols, in line with WHO guidelines, using a public health approach;
- to include HBV and HCV (and HDV) medicines in the national essential medicines list or any positive list of reimbursed medicines;
- to provide good-quality treatment that ensures standardized care of people with chronic viral hepatitis, including disease staging, patient and drug toxicity monitoring, and management of late-stage liver disease;
- to address common comorbidities and coinfections that may accelerate progression of liver disease or increase the risk of reinfection with HCV, including alcohol and substance use;
- to ensure post-treatment/post-cure monitoring of patients at risk of HCC;
- to make use of patient registry data to identify gaps in care quality and individuals who become reinfected and are in need of prevention interventions and re-entry into care.

WHO and partners will provide:

- regularly updated and disseminated consolidated guidelines on prevention, diagnosis and treatment of chronic viral hepatitis;
- technical support to countries in updating and optimizing their treatment protocols and plans for chronic viral hepatitis;
- advocacy for adequate investment to expand chronic hepatitis treatment;
- advocacy for a public health approach and continuity of chronic hepatitis care and treatment.

⁹ All patients with chronic HCV infection are eligible for treatment; however, in resource-constrained settings, treatment prioritization might be needed.

Strategic direction 3: Delivering for equity

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

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, community-based and of 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 epidemiological situation and socioeconomic and political context. For this reason, it is necessary to identify populations most affected by viral hepatitis and the essential set of interventions, services, medicines and commodities that is most appropriate to the country context and national legislation.



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Priority actions for Member States include:

- to define the populations and locations that are most affected and require intensified support, prioritizing them in the hepatitis response on the basis of the best epidemiological evidence from available sources of strategic information, while minimizing the risk of stigmatization;
- to support the involvement of civil society in the national response to viral hepatitis by creating a platform for civil society and by building community capacity to deliver community-based viral hepatitis services;
- to provide patient-oriented and integrated services – in particular, to consider integrating services for PWID and making treatment of infections (HIV, TB, viral hepatitis) available at harm reduction and drug treatment/ OST facilities;
- to regularly undertake “hepatitis cascade” analysis for different populations and settings, in order 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.



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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 organizations 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. These workers should receive regular training, mentoring and supervision, as well as appropriate compensation for their work.

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

Priority actions for Member States include:

- to ensure that the national health workforce strategy and educational curriculum sufficiently address the needs of hepatitis services;
- to identify opportunities for task-shifting and task-sharing – for example, involving general practitioners in viral hepatitis care and treatment;
- to involve community-based organizations and peer-support workers in providing viral hepatitis services, particularly in the context of vulnerable populations (such as PWID, the Roma population and migrants);
- to educate and raise awareness among health care workers on viral hepatitis-related issues, in order to reduce the stigma and discrimination against people affected by viral hepatitis and also to improve occupational health and safety of health workers.

WHO and partners will provide guidance and technical assistance in capacity-building and educating and training a competent workforce that can effectively deliver viral hepatitis services.

Ensuring access to good-quality and affordable vaccines, medicines and diagnostics

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

Priority actions for Member States include:

- to 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;
- to ensure a strong focus on procurement and price negotiations, assessing the feasibility of joint procurement of medicines and diagnostics and/or joint negotiations, transparency in drug-pricing and sharing information with Member States, as well as other mechanisms directed towards influencing the price of medicines (e.g. benefiting from voluntary licensing agreements where applicable, or using flexibilities allowed by the Agreement on Trade-Related Aspects of Intellectual Property Rights where necessary).



WHO and partners will provide:

- advocacy for comprehensive strategies to reduce prices for viral hepatitis medicines and diagnostics;
- guidance on viral hepatitis product selection by national programmes, based on WHO guidelines, a public health approach and transparency;
- technical assistance in assessing possible ways to improve access to diagnostics and treatment.

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. Removing other barriers may require reform or repeal of certain laws, regulations and policies.

Priority actions for Member States include:

- to use public health evidence to shape laws that affect people's health and to inform actions (including legal regulation of drug use) in all relevant sectors that will enable an effective hepatitis response;

- to ensure that legal and regulatory frameworks uphold human rights for populations affected by and at risk of hepatitis virus infections, and to facilitate involvement of civil society at all levels of the viral hepatitis response;
- to address gender inequalities, including gender-based discrimination of MSM and transgender people; and age-based inequality (including lack of paediatric viral hepatitis services and age restriction on chronic HCV treatment) by integrating evidence-based interventions into national hepatitis plans and strategies.

WHO and partners will provide:

- advocacy for a public health approach and a 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 criminalization;
- facilitation of partnerships and encouragement for Member States in creating an enabling environment for accessible, equitable and affordable viral hepatitis services through multisectoral collaboration and the engagement of civil society, including patient organizations.

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 for cost-saving approaches that allow people to 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 to move towards the global goal of eliminating viral hepatitis as a public health threat by 2030. Member States of the WHO European Region are diverse in terms of political and socioeconomic context, and the organization of their health systems varies. Some priority actions (e.g. joint procurement procedure) may be more relevant for the Region's EU/EEA Member States; other actions will apply specifically to lower-middle-income countries from the eastern part of the Region.

Increasing investments including through innovative funding approaches and other means

Priority actions for Member States include:

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

WHO and partners will provide:

- support for countries in developing investment cases;
- facilitation of best-practice sharing among Member States;
- advocacy for sustained financing and national ownership by building political commitment.

Reducing prices and costs, and removing inefficiencies

Priority actions for Member States include:

- to monitor the efficiency of interventions, health expenditures and cost-effectiveness of services, taking into account the direct and indirect costs of the disease burden;
- to strengthen coordination between viral hepatitis services and relevant health interventions and programmes (including HIV, STIs, TB, cancer prevention, blood and tissue safety, alcohol and drug use disorders, and mental health), thereby improving people-centred care, optimizing use of resources, and exploring mechanisms to ensure best prices for medicines and diagnostics;
- to assess possible price-reduction strategies, including differential pricing initiatives, price controls, joint negotiation, managed entry agreements, voluntary licensing, and use of the flexibilities allowed by the Agreement on Trade-Related Aspects of Intellectual Property Rights;
- to reallocate funds to remove inefficiencies.

WHO and partners will provide:

- assistance in assessing and monitoring health service costs, and cost-effectiveness of services;
- advocacy for a public health approach and a universal health coverage framework;
- promotion of information-sharing on prices of medicines and diagnostics (e.g. by use of online tools);
- guidance on use of appropriate price-reduction strategies;
- economic experts to support a finance reallocation process.

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 across the entire continuum of prevention, diagnosis, treatment and care services. They need to be backed up with operational research and collaboration between researchers and policy-makers to ensure that research findings are translated into policy 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.

Priority actions for Member States include:

- to prioritize viral hepatitis as a research area and provide public funding for targeted projects, increasing transparency and promoting a public health approach;
- to incentivize alternative research and development models to prevent private sector-driven research bias;
- to disseminate research findings quickly and efficiently;
- to introduce and integrate innovations in care and treatment, while removing those that are outdated and no longer qualify as best practice;
- to ensure that operational research (e.g. on feasibility and effectiveness of service integration) and other studies are included in the development of viral hepatitis policies.

WHO and partners will provide:

- Advocacy for innovative evidence-based and effective interventions; this should include 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 support of the WHO collaborating centres, in introducing/implementing innovative technologies, such as new treatment regimens, telemedicine and services provision models.



Implementation

Member States will be supported by the WHO Regional Office for Europe and partners in developing 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 on populations most affected and at risk.

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 between disease-specific and cross-cutting programmes are established and strengthened.

In addition to working with the health ministries of Member States, the Regional Office will work closely with all 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.

Monitoring and evaluation

In 2016 WHO published a monitoring and evaluation framework for HBV and HCV with 10 core (global) indicators (25). 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 WHO/UNICEF Joint Reporting Form on Immunization (26) and the joint UNAIDS/WHO/UNICEF Global AIDS Response Progress Reporting (27), while diagnosis data are collected through the annual WHO European Communicable Diseases Reporting Form and the ECDC Hepatitis B and C surveillance in Europe.

To date, no regionally or globally coordinated reporting mechanism on the health sector response to viral hepatitis has been implemented, but it is likely that such a mechanism will be established, alongside existing relevant reporting mechanisms, to support monitoring of the Global Health Sector Strategy implementation. In the meantime, WHO will support countries in building 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.

Implementation of this Action plan, and progress at regional and global levels in moving towards the targets set in the plan and the Global Health Sector Strategy will be regularly reviewed and assessed; this will be achieved through the WHO Global hepatitis report and reports to the Regional Committee for Europe at its 69th and 72nd sessions, in 2019 and 2022 respectively.



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Annex 1. Summary of proposed milestones and targets

2018 MILESTONES	2020 TARGETS
SURVEILLANCE AND DATA	
<p>Harmonized surveillance objectives and case definitions to be aligned with current WHO technical considerations and adopted.</p> <p>National disease burden to be estimated and investment case developed.</p>	<p>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 do effective real-time tracking of the viral hepatitis diagnosis, treatment and care cascade, including in specific vulnerable populations.</p>
EVIDENCE-BASED POLICY	
<p>A costed and funded national hepatitis plan with clear targets, or a viral hepatitis response plan, to be integrated into a broader health strategy or action plan.</p>	<p>---</p>
AWARENESS	
<p>World Hepatitis Day to be marked in all Member States.</p>	<p>National viral hepatitis communication and awareness strategies to be adopted in a majority of Member States.</p>
IMMUNIZATION	
<p>90% coverage with three doses of HBV vaccine in countries that implement universal childhood vaccination.</p> <p>National guidelines on HAV and HBV vaccination for high-risk groups to be developed and implemented.</p>	<p>95% coverage with three doses of HBV vaccine in countries that implement universal childhood vaccination.</p> <p>≤0.5% HBsAg prevalence in vaccinated cohorts.</p> <p>80% of health care workers to be vaccinated against HBV.</p>

2018 MILESTONES	2020 TARGETS
PREVENTION OF MOTHER-TO-CHILD TRANSMISSION OF HBV	
<p>85% coverage with timely HBV birth dose vaccination for countries that implement universal newborn vaccination.</p> <p>85% coverage with screening in pregnant women and 90% coverage with post-exposure prophylaxis in infants born to infected mothers for countries that implement screening of pregnant women and post-exposure prophylaxis of newborns.</p>	<p>90% coverage with timely HBV birth dose vaccination for countries that implement universal newborn vaccination.</p> <p>90% coverage with screening in pregnant women and 95% coverage with post-exposure prophylaxis in infants born to infected mothers for countries that implement screening of pregnant women and post-exposure prophylaxis of newborns.</p>
BLOOD SAFETY	
<p>All countries to have effective haemovigilance systems in place and all donations to be tested at least with serological methods for HBV and HCV infection.</p>	<p>All donated blood to be screened with nucleic acid testing methods for HBV and HCV.</p> <p>All donated blood to come from non-remunerated donors.</p>
IPC IN HEALTH CARE SETTINGS AND BEYOND	
<p>Safe injection policies and IPC rules to prevent transmission of bloodborne infections in the health sector (including in prisons) to be in place and implemented.</p> <p>National disinfection and sterilization protocols for non-health care settings (cosmetic and tattoo facilities) to be developed and implemented.</p>	<p>50% of injections to be administered with safety-engineered devices inside and outside health care facilities, integrated into broader IPC.</p>
PREVENTION AMONG PWID	
<p>Policies to be developed and implemented in support of a comprehensive package for infection prevention and harm reduction among PWID, including: needle and syringe programmes (NSPs); OST and other evidence-based drug dependence treatments; targeted IEC for PWID; and HAV and HBV vaccination.</p>	<p>A comprehensive package of harm reduction services for all PWID, including:¹</p> <ul style="list-style-type: none"> • at least 200 syringes distributed per PWID per year; • at least 40% of opioid-dependent PWID to receive OST; • HBV and HAV vaccination. <p>90% of PWID to receive targeted IEC provided by NSPs, drug treatment service sites (including OST) and other services targeting PWID.</p>

1 A comprehensive package of evidence-based interventions to reduce harms associated with IDU 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 (16). Since bloodborne transmission is common to HIV and hepatitis viruses, interventions effective in preventing HIV among PWID also help to prevent HCV and HBV transmission. However, because HCV is more virulent than HIV, higher levels of intervention coverage may be necessary to achieve comparable reductions in incidence. The WHO, UNAIDS, UNODC guidance suggests a target of 200 syringes distributed per PWID per year on the basis of studies in developed-country settings and mathematical modelling investigating levels of syringe distribution and its impact on HIV transmission. The distribution levels required for 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.

2018 MILESTONES	2020 TARGETS
PREVENTION OF SEXUAL TRANSMISSION	
90% of countries to provide STI services or links to such services in all primary, HIV, drugs, reproductive and perinatal care services.	Access for all individuals to a full range of services relevant to STIs, including HIV, HBV and HCV, access to condoms, testing and counselling.
DIAGNOSING HEPATITIS VIRUS INFECTIONS	
<p>High-quality viral hepatitis testing and diagnosis services to be available and accessible to all.</p> <p>All countries to have national HBV and HCV testing policies, aligned with WHO guidelines.</p> <p>All countries to have estimated the diagnosis rate and the proportion of patients diagnosed at late stage of viral hepatitis-related liver disease (cirrhosis or HCC).</p> <p>All health care workers to know their viral hepatitis B and C serostatus.</p>	<p>50% of all people with chronic HBV, HCV and HDV to be diagnosed.</p> <p>75% of the estimated number of patients at late stage of viral hepatitis-related liver disease (cirrhosis or HCC) to be diagnosed.</p>
ENHANCING CHRONIC HEPATITIS CARE AND TREATMENT	
<p>National hepatitis treatment and care guidelines and protocols to be established and updated in line with WHO guidelines.</p> <p>Baseline estimation of people who need to receive treatment for chronic HBV, HCV and HDV infection to be obtained, preferably by liver disease stage.</p>	<p>Treatment for chronic HBV, HCV and HDV infection, in line with international standards, to be available and affordable for all.</p> <p>90% of patients diagnosed with chronic HBV, HCV and HDV infections to be linked to care and adequately monitored.</p> <p>75% of patients diagnosed with chronic HBV and HDV infection, who are eligible for treatment, to begin treatment; and among those on long-term treatment for HBV, 90% to obtain viral suppression.</p> <p>75% of eligible patients diagnosed with chronic HCV infection to receive effective treatment and at least 90% of them to be cured.²</p>

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² All patients with chronic HCV infection are eligible for treatment; however, in resource-constrained settings, treatment prioritization might be needed.

Annex 2. Resolution EUR/RC66/R10 of the 66th session of the Regional Committee for Europe



Regional Committee for Europe

66th session

Copenhagen, Denmark, 12–15 September 2016

EUR/RC66/R10

14 September 2016
160771
ORIGINAL: ENGLISH

Resolution

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

The Regional Committee,

Having considered the Action plan for the health sector response to viral hepatitis in the WHO European Region;¹

Recognizing the importance of tackling viral hepatitis within the framework of Health 2020 – the European policy framework,² adopted in resolution EUR/RC62/R4 in 2012, to improve health and well-being in the Region and to reduce health inequalities;

Noting Transforming our world: the 2030 Agenda for Sustainable Development,³ and the Sustainable Development Goals (SDGs), in particular SDG target 3.3 (AIDS, tuberculosis, malaria, neglected tropical diseases, hepatitis, water-borne diseases and other communicable diseases) of SDG3 (Ensure healthy lives and promote well-being for all at all ages) specifically calling for combatting viral hepatitis;

1 Document EUR/RC66/10.

2 Document EUR/RC62/9.

3 United Nations General Assembly resolution A/RES/70/1.

Recalling resolutions WHA63.18 in 2010 and WHA67.6 in 2014 on viral hepatitis and resolution WHA69.22 in 2016 adopting the Global health sector strategies on HIV, viral hepatitis and sexually transmitted infections, for the period 2016–2021, which requests Member States to strengthen national prevention and control programmes for viral hepatitis adapted to national priorities, legislation and specific contexts and also calls for improved public awareness;

Reaffirming resolution EUR/RC64/R5 adopting the European Vaccine Action Plan 2015–2020⁴ in 2014 with its goal 3 to control hepatitis B infection through immunization, and resolution EUR/RC62/R5 endorsing the European Action Plan for Strengthening Public Health Capacities and Services⁵ in 2012;

Acknowledging the concurrent development of the Action plan for the prevention and control of noncommunicable diseases in the WHO European Region, the Action plan for sexual and reproductive health: towards achieving the 2030 Agenda for Sustainable Development in Europe – leaving no one behind, the Strategy on women's health and well-being in the WHO European Region and the Action plan for the health sector response to HIV in the WHO European Region;⁶

Concerned that viral hepatitis, with increasing chronic viral hepatitis-related liver diseases, is a serious public health burden in the European Region that has not been addressed adequately;

Acknowledging that the challenges in developing quality-assured, laboratory-supported surveillance systems for viral hepatitis lead to low rates of detection and that the high cost of diagnostics and medicines for treatment of hepatitis B and C infection hampers equal access to services across the Region;

Concerned that viral hepatitis disproportionately affects specific at-risk populations who experience barriers to accessing health services, that access to comprehensive prevention and harm reduction services for people who inject drugs is limited in some countries, and that challenges persist in the prevention of health-care associated infections in several Member States;

Understanding that this resolution does not replace any existing Regional Committee resolutions;

1. ADOPTS the Action plan for the health sector response to viral hepatitis in the WHO European Region, with its goal and targets;
2. URGES Member States:⁷
 - (a) to align, as appropriate, their national viral hepatitis strategies and action plans with the Action plan for the health sector response to viral hepatitis in the WHO European Region, ensuring political commitment and resources required to combat the viral hepatitis epidemics;
 - (b) to strengthen public health systems for comprehensive viral hepatitis prevention and control interventions with a particular focus on: strengthening strategic information, including laboratory-supported surveillance; providing universal childhood hepatitis B immunization and increasing the rate of hepatitis B vaccination; and scaling up testing and treatment through sustained and affordable systems for diagnostics and treatment of hepatitis B and C;

4 Document EUR/RC64/15 Rev.1.

5 Document EUR/RC62/12 Rev.1.

6 Documents EUR/RC66/11, EUR/RC66/13, EUR/RC66/14 and EUR/RC66/9.

7 And, where applicable, regional economic integration organizations.

- (c) to ensure that prevention, treatment and care programmes target individuals most affected by viral hepatitis and at higher risk of transmission, based on the local epidemiological context;
- (d) to address regulations and policies as well as discriminatory environment that prevent access to comprehensive prevention, treatment and care of viral hepatitis;

3. REQUESTS the Regional Director:

- (a) to support the implementation of the Action plan for the health sector response to viral hepatitis in the WHO European Region by providing leadership, strategic direction and technical guidance to Member States;
- (b) to provide technical support for developing and implementing national action plans for viral hepatitis and support for further development of surveillance systems that will be able to evaluate the burden of and monitor the response to viral hepatitis in Member States;
- (c) to facilitate partnerships with international, regional and national organizations, agencies and all relevant stakeholders in advocating for and scaling up response to viral hepatitis;
- (d) to identify and facilitate the exchange of best practices and experiences among Member States⁸ and to produce evidence-informed tools for an effective response to viral hepatitis;
- (e) to monitor and report progress to the 69th and 72nd sessions of the Regional Committee in 2019 and 2022, respectively, on the implementation of the Action plan for the health sector response to viral hepatitis in the WHO European Region.

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⁸ And, where applicable, regional economic integration organizations.

The WHO Regional Office for Europe

The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

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