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

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

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

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

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

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

The Action plan has been developed through a Region-wide participatory process, and was finalized after consideration by and guidance from the Twenty-third Standing Committee for the Regional Committee for Europe.

This document provides a summary of the Action plan and is submitted with an accompanying resolution for consideration by the 66th session of the Regional Committee. The full Action plan is available as a background document.

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Introduction

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

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

3. The epidemiology and burden of viral hepatitis across the Region is diverse, with very low prevalence of chronic hepatitis B and C among the general population in northern Europe and high prevalence in many countries in southern and eastern Europe and central Asia. In addition to this geographical variability, specific populations can be more affected by, or be at higher risk of, viral hepatitis infection.[1]

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

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

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[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 the response should be based on the epidemiological and social context. These could differ according to different local contexts but may include: (a) people who have been exposed to viral hepatitis through unsafe blood supplies and unsafe medical injections and procedures; (b) transgender people and men who have sex with men; (c) sex workers; (d) prisoners; (e) people who inject drugs; (f) mobile populations and people affected by conflict and civil unrest. People who will require specific attention include those with coinfections such as: hepatitis B and C combined; viral hepatitis and tuberculosis; and HIV and viral hepatitis *(3)*.

6. A total of 47 Member States in the European Region (87%) have successfully implemented universal childhood HBV immunization programmes. The majority of them have achieved 90% or higher coverage with three doses of HBV vaccine. However, six remaining Member States with very low HBV endemicity do not implement universal vaccination, thereby relying on selective immunization of people who are at high risk for HBV infection.

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

8. Infection prevention and control in health care settings, including blood and injection safety, have improved significantly in the Region over recent decades. Nosocomial transmission of viral hepatitis, however, continues to play an important role in some Member States, particularly in eastern Europe and central Asia. In some countries, non-medical settings such as cosmetic and tattoo facilities have been associated with poor infection control owing to inadequate disinfection and sterilization practices thereby increasing the risk of transmission of blood-borne hepatitis viruses.

9. The incidence and prevalence of viral hepatitis among certain most affected and at risk populations,[1] particularly people who inject drugs and prisoners, remain high in many countries, and access to prevention and harm reduction services varies widely across the Region.

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

Purpose

11. This Action plan provides the framework for a comprehensive health sector response to viral hepatitis, including evidence-informed national planning based on local contexts and needs, awareness raising, prevention of transmission, diagnosis, care and treatment of viral hepatitis, with special attention to the populations most affected and at risk of viral hepatitis infection.[1] Recognizing variations in viral hepatitis epidemiology and availability of resources across the countries in the European Region, the Action plan is intended to guide Member States in developing country-specific national viral hepatitis prevention and control strategies and plans. While the Action plan addresses all five hepatitis viruses, its major focus is on HBV and HCV, given the high public health burden they represent in the Region.

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

Development

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

14. This Action plan adapts the Global Health Sector Strategy on Viral Hepatitis 2016–2021 *(3),* endorsed by the Sixty-ninth World Health Assembly in resolution WHA69.22, to the epidemiological, social and political contexts of the countries of the European Region. It also aligns with the 2030 Agenda for Sustainable Development and Health 2020, the European policy framework for health and well-being *(4),* the European Vaccine Action Plan 2015–2020 *(5);* the Action plan for sexual and reproductive health: towards achieving the 2030 Agenda for Sustainable Development in Europe – leaving no one behind *(6)* and the Action plan for the health sector response to HIV in the Region *(7).*

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

16. This working document provides a summary of the Action plan's vision, goal and targets, strategic directions, priority actions and a monitoring and evaluation framework. The full Action plan for the health sector response to viral hepatitis in the WHO European Region, which provides a more detailed description of its epidemiology, the regional context and a detailed list of recommended actions, is available as a background document.

Vision, goals and targets

17. The vision of the Action Plan for 2030 is a European Region in which the transmission of new hepatitis infections is halted, testing is accessible, and people living with chronic hepatitis have access to care and to affordable and effective treatment *(3).*

18. The goal for the Action plan is the elimination of viral hepatitis as a public health threat in the European Region by 2030 through the reduction of transmission, morbidity and mortality due to viral hepatitis and its complications,[2] and by ensuring equitable access to comprehensive prevention, and recommended testing, care and treatment services for all.

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

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

- 95% coverage with three-dose HBV vaccine for infants, in countries that implement universal 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]
- at least 200 sterile injection equipment kits distributed per person per year for people who inject drugs, as part of comprehensive package of harm reduction services;[4]
- 50% of people living with chronic HBV and HCV infections are diagnosed and aware of their condition; and
- 75% treatment coverage of people diagnosed with HBV and HCV infections who are eligible for treatment.

21. Guided by the regional goals and targets, Member States should develop national goals and targets for 2020 and beyond. Such goals and targets should take into consideration the local context of each Member State, should be based on the best available data, and monitored through a set of measurable indicators. The targets should apply to everyone, with a particular focus on those populations most affected and most at risk of transmission.[1]

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

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

[4] A comprehensive package of evidence-based interventions to reduce harm associated with injecting drug use is outlined in the WHO, UNAIDS, UNODC technical guide for countries on setting targets for universal access to HIV prevention, treatment and care for injecting drug users. Since blood-borne transmission is common to HIV and hepatitis viruses, interventions effective in preventing HIV among people who inject drugs also help to prevent HCV/HBV transmission *(8)*.

Strategic directions and priority actions

22. To achieve the 2020 and 2030 targets and goals, action is required in five strategic directions. These actions 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.

23. The five strategic directions are:

- **information for focused action** (know your epidemic and response – the "who" and the "where");
- **interventions for impact** (defining an essential package of interventions – the "what");
- **delivering for equity** (identifying the best approaches for delivering services, ensuring 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).

24. This working document presents an overview of priority actions considered critical for Member States and for WHO and partners to achieve the proposed targets.

Strategic direction 1: information for focused action

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

25. Strategic direction 1 focuses on the need to generate and use quality strategic information about viral hepatitis epidemics and country responses to those epidemics as a basis for focused national strategic planning, urgent and accelerated programme implementation and advocacy to garner political commitment.

1.1 Data for informed decisions

26. Robust national hepatitis strategic information systems that generate timely and good quality data about epidemics and interventions in place to respond to them provide the basis for a comprehensive situation analysis and are critical to inform programme decision-making and to structure services according to needs and available resources, with the aim of achieving the greatest possible impact.

27. Priority actions for Member States include:

- assessing and strengthening available data sources for viral hepatitis and surveillance system, adapting WHO-compatible case definitions and ensuring that the viral hepatitis surveillance system serves its main purposes;[5]
- integrating viral hepatitis strategic information systems and indicators within national broader health information systems, including for outbreak surveillance, and monitoring and evaluation of the national hepatitis response; and
- developing national estimates of the disease burden of chronic viral hepatitis (including incidence, prevalence and mortality for the general population, vulnerable groups and key populations).

28. WHO, with partners, will provide methodological and technical assistance for improving surveillance systems and conducting sero-surveys and modelling exercises, and will support Member States with data analysis and interpretation. The Regional Office will collaborate closely with relevant partners, particularly the European Union and its institutions (the European Centre for Disease Prevention and Control (ECDC) and European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)) to optimize data collection, harmonize case definitions, improve data analysis and avoid duplication in reporting.

1.2 Evidence-based national planning

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

30. Priority actions recommended for Member States include:

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

[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 *(9)*.

- developing a viral hepatitis communication and awareness strategy as an integrated component of the national action plan, including specific awareness-raising campaigns, and interventions addressing stigma and discrimination against people affected by viral hepatitis.

31. WHO, with partners, will continue to provide technical assistance to Member States in developing and assessing national plans. It will also support the development of communication tools and provide guidance to Member States, including necessary tools to mark annual World Hepatitis Day, with an information package and examples of targeted awareness campaigns for different settings and populations.

Strategic direction 2: interventions for impact

People should receive all the hepatitis services they need

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

Prevention

33. There are three major areas of action required to prevent viral hepatitis transmission, which are essential to achieve the ambitious goal of elimination. These are: hepatitis B immunization; prevention of health care-associated transmission; and high-intensity prevention of transmission associated with injection drug use. Additional areas of action include preventing the sexual transmission of viral hepatitis and ensuring food and water safety.

2.1 Prevention: immunization, including prevention of mother-to-child transmission of HBV

34. Member States should improve HBV vaccination coverage by monitoring public perceptions, knowledge and attitudes, and developing tailored and innovative strategies to create demand for vaccination among all population groups. The countries that do not implement universal HBV childhood vaccination should consider its introduction based on scientific advice provided by national immunization advisory bodies. In addition to universal immunization, countries should develop policies to immunize people at high risk of HBV infection,[1] based on the local context.

35. Member States should establish systems to assess coverage of interventions aimed to prevent the perinatal transmission of HBV, including screening of pregnant women for HBV and post exposure prophylaxis of newborns. Efforts should be made to achieve high screening coverage among pregnant women from ethnic minorities, immigrants, undocumented migrants and marginalized groups. The countries that implement

universal newborn immunization should establish monitoring of timeliness of HBV vaccine birth dose to ensure that all children are vaccinated within 24 hours after birth.

36. Member States that have intermediate incidence of hepatitis A should consider integrating HAV vaccination into their national immunization programmes, based on considerations of cost-effectiveness. Countries with low and very low endemicity should provide targeted vaccination of high risk groups.

37. In line with the European Vaccine Action Plan, WHO will support countries in making evidence-based policies on HBV and HAV vaccination, provide guidance and tools to generate and maintain demand for immunization services and address vaccine hesitancy, and provide support in establishment of effective systems to monitor coverage for interventions aimed to prevent perinatal transmission of HBV.

2.2 Prevention: blood and injection safety (in and out of health care settings)

38. Priority actions recommended for Member States include establishing and regularly updating safe injection policies and instituting comprehensive infection prevention and control practices for preventing the transmission of blood-borne infections in health care settings and in prisons (in collaboration with other sectors, where relevant), including the introduction of safety-engineered injection devices. Member States should also develop, update, and implement national disinfection and sterilization protocols for non-health care settings, such as cosmetic and tattooing facilities.

39. Member States should develop a nationally coordinated transfusion and transplantation service to standardize donor selection and testing procedures for blood, tissue and solid organs, and to strengthen the quality control system for blood production and testing.

40. WHO will promote and disseminate guidance on standard precautions and effective disinfection and sterilization methods, safe injection practices and alternatives to injections *(10)*, infection prevention and control inside and outside health care services, and for specific procedures, including endoscopy, cosmetic and tattooing procedures. WHO will also provide updated guidance to countries on the management of safe blood and tissue supplies and the strengthening of linkages between blood transfusion and transplantation services and viral hepatitis services.

2.3 Prevention of HBV and HCV transmission associated with injecting drug use

41. Priority actions recommended for Member States include implementing a comprehensive, interdisciplinary infection prevention and harm reduction programme based on the WHO package of interventions *(11)*, with integrated services for people who inject drugs, including treatment for HCV infection and effective measures to prevent re-infection, as well as harm reduction interventions.

42. WHO will support Member States by updating and disseminating policies and guidance on evidence-based prevention and management of blood-borne infections for people who inject drugs, advocate for political commitment and resources, and provide technical support for effective harm reduction interventions.

2.4 Prevention of sexual transmission of viral hepatitis and other sexually transmitted infections (STIs)

43. Member States should ensure access to a full range of integrated services relevant to sexual and reproductive health, including health promotion, education, and the prevention, diagnosis and management of STIs.

44. WHO will support Member States by disseminating guidance on STI diagnosis and management in various epidemiological contexts, promoting a life-course approach and expanding access to good quality sexual and reproductive health services, and supporting national capacity building for integrated service delivery with special attention to vulnerable populations, adolescents and women.

2.5 Prevention: ensuring food and water safety

45. Member States should ensure collaboration and information sharing between the health, environment, food safety and agriculture sectors, to develop and implement policies and regulations on food safety, and to ensure uptake of Water Safety Plans (WSPs)[6] and Sanitation Safety Planning (SSP)[7] in policy and practice, including in high-risk settings and camps for internally displaced persons and refugees.

46. WHO, with partners, will continue to promote and provide guidance on water supply and sanitation risk assessment and management (WSPs and SSP) and on food safety-related issues.

Testing and treatment

2.6 Testing: diagnosing hepatitis virus infections

47. Member States should substantially increase testing and diagnosis rates for viral hepatitis by developing and implementing national viral hepatitis testing guidelines. These must be in line with the latest WHO guidance and based on local epidemiological contexts, ensuring availability and access to good quality and affordable diagnostics and testing, and delivered under the principles of universal health coverage, using a public health approach, and integrated service delivery, and addressing common comorbidities and coinfections. This may require the diversification of testing approaches, such as outreach programmes and self-testing.

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[6] WSPs require a risk assessment encompassing all steps in water supply from catchment to consumer, followed by implementation and monitoring of risk management control measures (http://www.who.int/water_sanitation_health/dwq/WSP/en/).

[7] SSP is a step-by-step risk-based approach to assist in the implementation of the 2006 WHO Manual for safe use and disposal of wastewater, greywater and excreta (http://www.who.int/water_sanitation_health/publications/ssp-manual/en/).

48. Member States should ensure continuous education of health care professionals, including general practitioners and noncommunicable disease specialists, on viral hepatitis testing and diagnostics-related issues.

49. WHO will regularly update and distribute guidance on viral hepatitis testing approaches including models of integrated, people-centred service delivery and community-based viral hepatitis testing services. The Regional Office, with partners, will support Member States in capacity building and quality assurance of laboratory practices to help adopt and implement WHO policies and guidelines on viral hepatitis diagnostics, testing approaches and strategies.

2.7 Enhancing chronic hepatitis care and treatment

50. Member States should substantially increase access to affordable, sustainable viral hepatitis treatment and care by establishing and regularly updating national hepatitis treatment and care guidelines. These must be in line with WHO guidelines on providing quality treatment that ensures standardized care for people with chronic viral hepatitis. The service delivery model should promote equity and human rights, universal health coverage and a public health approach.

51. Member States should consider measures to address common comorbidities and coinfections that may accelerate the progression of liver disease or increase the risk of reinfection with HCV, while implementing integrated service delivery approaches.

52. Supporting actions by WHO and partners will include: advocating for adequate investment to scale up chronic hepatitis treatment; developing and regularly updating and disseminating consolidated guidelines for the prevention, diagnosis and treatment of chronic viral hepatitis; and providing technical support to countries in updating and optimizing their treatment protocols and plans for chronic viral hepatitis management.

Strategic direction 3: delivering for equity

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

53. Strategic direction 3 responds to the need for an enabling environment and optimization of service delivery using a public health approach under a model of universal health coverage. Interventions to address viral hepatitis and the health and community-based systems that provide them should respect the principles of equity and human rights. The continuum of hepatitis services should be people-centred, integrated, accessible, equitable and community-based and of sufficiently high quality to ensure that no one is left behind.

54. Member States should take the following priority actions:

- use epidemiological evidence from available information sources to identify the populations and locations most affected and requiring special attention, and to prioritize them in the national hepatitis response while minimizing the risk of stigmatization;
- ensure that national health workforce strategies and educational curricula adequately address the needs of hepatitis services, identify opportunities for task-

shifting and task-sharing, and involve civil society, patient groups and community-based organizations and peer-support workers in providing viral hepatitis services;

- ensure that legal and regulatory frameworks respect human rights for populations affected by and at risk of hepatitis virus infections and facilitate involvement of civil society at all levels of viral hepatitis response; and
- address inequities, including gender- and age-based discrimination, by integrating evidence-based interventions into national hepatitis plans and strategies.

55. WHO, and partners, will take the following actions:

- provide updated guidance on the essential viral hepatitis services, differentiated care and service delivery models, especially for those populations most affected and at risk for viral hepatitis infection;[1]
- provide policy and technical guidance aimed at building a competent workforce that can effectively deliver viral hepatitis services; and
- facilitate partnerships and encourage Members States to create an enabling environment for accessible, equitable and affordable viral hepatitis services through multisectoral collaboration and the engagements of civil society, including patient organizations.

Strategic direction 4: financing for sustainability

People should receive the hepatitis services they need without experiencing financial hardship

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

57. Member States should develop a viral hepatitis investment case to advocate for adequate allocation of domestic resources, monitor the efficiency of interventions, health expenditures and cost-effectiveness of services, taking into account direct and indirect costs of burden of disease, and use innovative approaches in service delivery to maximise the cost efficiency of the response.

58. Member States should strengthen coordination between viral hepatitis services and relevant health interventions and programmes, including HIV, STI and cancer prevention, blood and tissue safety, alcohol and drug use disorders and mental health thereby improving people-centred care, optimize the use of resources and explore mechanisms to assure best prices for medicines and diagnostics.

59. WHO, with partners, will assist in developing investment cases, facilitating the sharing of best practices among Member States, advocating for political commitment for sustained financing, and provide guidance on the use of price reduction strategies.

Strategic direction 5: innovation for acceleration – the future

New technologies and approaches will be required to progress towards the elimination of viral hepatitis epidemics

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

61. 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.

62. WHO will support Member States in convening partners and promoting and shaping global and regional research agendas. WHO will also monitor the development of new vaccines, medicines, diagnostics, other commodities and service delivery approaches across the Region, and, where appropriate, suggest their integration into WHO guidelines.

Implementation: partnerships, monitoring and evaluation

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

64. In addition to working with the ministries of health in 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

65. In 2016 WHO published a monitoring and evaluation framework for HBV and HCV with 10 core (global) indicators *(12)*. 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 *(13)*, the

Global AIDS Response Progress Reporting (GARPR) *(14)*, while diagnosis data are collected through the annual WHO European Communicable Diseases Reporting Form and the ECDC Hepatitis B and C Surveillance in Europe. No regionally or globally coordinated reporting mechanism on the health sector response to viral hepatitis has been implemented so far, but this is likely to be established as an integral process with existing relevant reporting mechanisms to support monitoring of the Global Health Sector Strategy implementation. In the meantime, WHO will support countries 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 the regional and global levels.

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

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Annex. Proposed targets and milestones

2018 MILESTONES	2020 TARGETS
SURVEILLANCE AND DATA	
• Harmonized surveillance objectives and case definitions aligned with current WHO technical considerations and adopted • National disease burden estimate and investment case	• Member States to have a national hepatitis infection surveillance programme (strategic information framework) that can detect outbreaks in a timely manner, assess trends in incidence, inform disease burden estimates and effectively track "in real time" the viral hepatitis diagnosis, treatment and care cascade, including in specific vulnerable populations
EVIDENCE-BASED POLICY	
• A costed and funded national hepatitis plan with clear targets or a viral hepatitis response plan integrated into a broader health strategy or action plan	
AWARENESS	
• World Hepatitis Day marked in all Member States	• National viral hepatitis communication and awareness strategy adopted in a majority of Member States
IMMUNIZATION	
• 90% coverage with three doses of HBV vaccine in countries that implement universal childhood vaccination • National guidelines on risk group HAV and HBV vaccination developed and implemented	• 95% coverage with three doses of HBV vaccine in countries that implement universal childhood vaccination • ⩽0.5% HBsAg prevalence in vaccinated cohorts • 80% of health care workers vaccinated against HBV
PREVENTION OF MOTHER-TO-CHILD TRANSMISSION OF HBV	
For countries that implement universal newborn vaccination: • 85% coverage with timely HBV birth dose vaccination For countries that implement screening of pregnant women and post-exposure prophylaxis of newborns: • 85% coverage with screening in pregnant women and 90% coverage with post-exposure prophylaxis in infants born to infected mothers	For countries that implement universal newborn vaccination: • 90% coverage with timely HBV birth dose vaccination 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
BLOOD SAFETY	
• All countries have effective haemovigilance systems in place and all donations are tested at least with serological methods for HBV and HCV infection	• All donated blood tested with NAT-screening methods for HBV and HCV • All donated blood from non-remunerated donors
INFECTION PREVENTION AND CONTROL IN HEALTH CARE SETTINGS AND BEYOND	
• Safe injection policies and IPC rules for preventing transmission of blood-borne infections in health sector (including in prisons) in place and implemented • National disinfection and sterilization protocols for non-health care settings (aesthetic cosmetology and tattoo facilities) developed and implemented	• 50% of injections administered with safety-engineered devices in and out of health care facilities
PREVENTION AMONG PEOPLE WHO INJECT DRUGS	

• Policies developed and implemented to support a comprehensive package for infection prevention and harm reduction among people who inject drugs including: needle and syringe programmes (NSPs); opioid substitution therapy (OST) and other evidence-based drug dependence treatment targeted information, education and communication (IEC) for people who inject drugs and HAV and HBV vaccination	• A comprehensive package of harm reduction services to all persons who inject drugs, including:
	  – At least 200 syringes distributed per PWID per year*
	  – At least 40% of opioid dependent PWID receive opioid substitution therapy
	  – HBV and HAV vaccination
	• 90% of PWID receiving targeted IEC provided by NSPs, drug treatment service sites (including OST) and other services targeting PWID

2018 MILESTONES	2020 TARGETS
PREVENTION OF SEXUAL TRANSMISSION	
• 90% of countries 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 and HBV and HCV, and access to condoms, testing and counselling
DIAGNOSING HEPATITIS VIRUS INFECTIONS	
• High quality viral hepatitis testing and diagnosis services are available and accessible for all • All countries have national HBV and HCV testing policies, aligned with WHO guidelines • All countries have estimated the diagnosis rate and the proportion of patients diagnosed at late stage of viral hepatitis-related liver disease (cirrhosis or HCC) • All health care workers know their viral hepatitis B and C sero-status	• 50% of all persons with chronic HBV, HCV and HDV diagnosed • 75% of estimated number of patients at late stage of viral hepatitis-related liver disease (cirrhosis or HCC) diagnosed
ENHANCING CHRONIC HEPATITIS CARE AND TREATMENT	
• National hepatitis treatment and care updates, in line with WHO guidelines established and regularly updated • Baseline estimation of people who need to receive treatment for chronic HBV, HCV and HDV infection obtained, preferably by liver disease stage	• Treatment for chronic HBV, HCV and HDV infection, in line with international standards, is available and affordable for all • 90% of diagnosed patients with chronic HBV, HCV and HDV infections are linked to care and adequately monitored • 75% of the diagnosed patients with chronic HBV and HDV infection, who are eligible for treatment, begin treatment and among those on long-term treatment for HBV, 90% obtain viral suppression • 75% of the diagnosed eligible patients with chronic HCV infection receive effective treatment and at least 90% of them are cured

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

* A comprehensive package of evidence-based interventions to reduce harms associated with injecting drug use is outlined in the WHO, UNAIDS, UNODC technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users. Since blood-borne transmission is common to HIV and hepatitis viruses, interventions effective in preventing HIV among people who inject drugs help to prevent HCV/HBV transmission. Because HCV is more virulent than HIV, however, higher levels of intervention coverage may be necessary to achieve comparable reductions in incidence. The WHO, UNAIDS, UNODC guidance suggests a target of 200 syringes distributed per PWID per year based upon studies in developed-country settings and mathematical modelling investigating the levels of syringe distribution and its impact on HIV transmission. Levels required for the prevention of HCV are likely to be much higher. The 40% OST target is based on levels of coverage achieved in countries with well-established OST programmes.

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