

**Elimination of viral hepatitis in the Balkan countries:
lessons learnt and the way forward**

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Background

The Viral Hepatitis Prevention Board has previously organized country meetings in South-East Europe but mainly looking at individual countries: Bulgaria (2011)¹, Albania and western Balkans (2016)² and Romania (2018)³. A separate meeting (2021) looked at the impact of COVID-19 on immunization programmes, including those for hepatitis B.⁴ This present meeting, opened by the Minister of Health of North Macedonia, looked at the viral hepatitis situation in nine countries: Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Kosovo, Montenegro, North Macedonia, Serbia and Slovenia. Of these, three are members of the European Union.

In the past decade, the World Health Organization (WHO) has issued strategies for the prevention and control of viral hepatitis, starting with the global health sector strategy for 2016-2021,⁵ with milestones set for 2018 and 2020, and the European Union's health programme has launched several projects and actions. In May 2022, the Seventy-fifth World Health Assembly endorsed WHO's Global Health Sector Strategies on HIV, Viral Hepatitis and Sexually Transmitted Infections, 2022-2030, with their elimination goals for 2030.⁶ Shortly afterwards, the WHO Regional Committee for Europe, at which the nine South-eastern European countries were represented, adopted a regional action plan that includes the ending the epidemic of viral hepatitis.⁷ In both cases targets for elimination of viral hepatitis for 2030 were set and adopted.

Countries in the Balkan region have made diverse but generally relatively good progress over recent years, with one rapidly approaching the goal of elimination of hepatitis C. However, the efforts towards overall elimination of viral hepatitis have been slow in the majority of countries, with uneven progress. In most of the countries public interest in health care policies and viral hepatitis has been low, undermining the garnering of support in general populations.

In 2019, COVID-19 upturned normal life. The disease and social disruption that followed derailed immunization programmes (including those for hepatitis B but also other routine vaccination programmes), interrupted harm-reduction programmes for those at risk, and hindered testing, screening and treatment (from access to finance).⁴ COVID-19 also undermined secondary prevention, with Montenegro and Serbia performing no liver transplants during the pandemic, and expensive advanced care being postponed or cancelled. On the other hand, it did lead to innovations in testing and surveillance systems, adaptations and some radical changes of policy, including some for people with viral hepatitis or with behaviours that put them at risk such as people who inject drugs (PWID) and men who have sex with men (MSM). The current economic and social problems coming on top of COVID-19 also undermine campaigns to improve health education, health literacy and health promotion as well as funding.

Meeting

The objectives of the meeting were to:

- provide an overview of the current viral hepatitis situation in the countries: surveillance systems, epidemiology, screening, burden, prevention, treatment and the cascade of care;
- discuss achievements and challenges in the prevention and control of viral hepatitis, the possible implementation of new prevention strategies, control measures and monitoring system in the countries;
- discuss the development and implementation of national hepatitis plans, including putting prevention and control of viral hepatitis on national public health agendas;
- assess what is needed to achieve the goal of eliminating viral hepatitis as a major public health threat by 2030 as set out in WHO's renewed global strategy and the WHO Regional Office for Europe's action plan, building on the commitments made to the United Nations Sustainable Development Goals; and
- discuss successes, issues, barriers to overcome and the way forward.^a

European strategies and action plans

WHO's regional plan for Europe contains multiple country actions, with focus on most at-risk populations, with milestones for 2025 on the way to the 2030 goals.⁷ Each country is expected to produce and implement a comprehensive national plan so as to be able to define progress on the cascade of care and other targets, and to assist in bulk negotiations. The WHO Regional Office for Europe offers to help in negotiations with industry (not only pharmaceutical firms but laboratory equipment and diagnostics companies as well), but to do so it needs a national plan that is costed and contains details.

Furthermore, WHO has issued several publications such as interim guidance on viral hepatitis elimination (2021), updated guidelines (including self-testing for HCV), and HCV policy briefs (June 2022), for instance on treatment of adolescents and children and simplified service delivery and diagnostics.⁸ WHO stands ready to facilitate exchanges of best practices between Balkan countries. Through its Regional Office for Europe and its collaborating centres it offers technical assistance in exploiting the lessons from COVID-19, such as service delivery.

Health systems

Each country was asked to complete a questionnaire about basic elements of its health systems and epidemiological situation. Tables 1–3 summarize some of the responses.

Some, but not all, countries have a national plan or strategy for prevention and control of viral hepatitis. Such a plan is fundamental if they are to meet their commitment to the elimination goals for 2030 and, for any negotiations with the pharmaceutical and diagnostic testing industry, a costed plan with numbers will be vital.

Several countries reported slightly lower life expectancies than the European average, indicating that they need to make further efforts to improve suboptimal health care systems. Non-EU member countries have some way to go to eliminate poverty and reduce socioeconomic inequalities. Some of the nine countries have predominantly young populations whereas others are ageing, with shrinking populations.

The proportions of gross domestic product or gross national income spent per capita on health are generally low, both as a percentage (around 3–5% but up to 7–9% in Bulgaria, Serbia and Slovenia)

^aIt is intended to make available the detailed information presented during the meeting through the VHPB or its website (<https://www.vhpb.org/vhpb-meetings>).

and in cash terms (ranging from several hundred euros only up to several thousands of euros^b per capita).

Overall, the general organization of the public health system related to viral hepatitis does not differ widely between the nine countries, with compulsory health insurance and mixes of public and private services that on the whole work well together (except in the area of reporting). Funding of the systems, including reimbursement of treatment and diagnostic costs, is generally based on national health insurance funds (although in one country such a fund has been established but is not yet fully functional). A comprehensive review of reimbursement of costs and restrictions on diagnostics and treatment of HBV and HCV showed that, with the exception of Slovenia, the Balkan countries are disadvantaged compared with their richer western European neighbours, with lower access to antiviral agents and more restrictions on their use.

In most of the nine countries, the health systems are hierarchical and top-down, with some complex and convoluted structures and pathways. In Bosnia and Herzegovina, for instance, health care coverage and insurance are mandatory but the government does not pay for insurance; the Federation has 13 different subsystems of health care insurance, with 10 cantonal and one federal system, whereas the Republika Srpska has a more centralized system. Neither contributes to ideal health care.⁹ Kosovo reported a long and complex path for obtaining treatment for viral hepatitis, available only in the capital. In some other countries services are also restricted to the capital cities. Centralized systems may work and be more cost effective for small countries, but current organizational thinking tends to favour decentralization, bringing services appropriately to the periphery, which approach was encouraged at the meeting. Other national examples of health systems range from assemblies with excellent interdisciplinary coordination to silo-type approaches.

Albania has a national plan which includes Roma and pregnant women and has established screening policies for migrants. It also has mandatory reporting of acute viral hepatitis, cases of HBsAg positivity and anti-HCV testing results by both public and private services through a digitalized surveillance system.

Bulgaria has a compulsory health insurance system, but many young people (an estimated 15%) are not insured. At district level, public health policy is organized by regional health inspectorates. Its surveillance system is consistent with European Union standards, and in 2019 hepatitis E was added to the list of notifiable diseases. National surveillance of viral hepatitis includes national centres for public health analysis, and the legal framework for surveillance, prevention and control includes screening of pregnant women for anti-HCV antibodies and monitoring of children and over-18-year-olds with chronic viral hepatitis. As in Albania, screening policies for migrants have been set and funded.

Kosovo is densely populated and about half its two million people are under the age of 25 years. With 3.5% of the gross domestic product spent on health and 8.5% on social protection, its poverty rate at 23% makes it one of the poorest countries in Europe. Its primary health care system contributes little to the prevention and control of viral hepatitis. Testing for HBsAg and anti-HCV antibodies on prescription or referral is free in the public health services but costs in private laboratories are not reimbursed. Nucleic acid testing, genotyping and determination of drug resistance are available only in private laboratories. The national health insurance fund is not fully functional. Elastography is available without charge. Chronic infection can be treated, in only one clinic in the capital, with tenofovir disoproxil fumarate for all cases of chronic hepatitis B (so far 440 patients) and sofosbuvir/velpatasvir for chronic hepatitis C (direct-acting antiviral agents (DAAs) have been available since September 2019 and 157 patients treated, half not reimbursed).

Montenegro, a small country with about 620,000 people, has mandatory reporting of cases (acute and chronic) by physicians and laboratories (HBsAg and anti-HCV) but no registry of viral hepatitis

^b Or national equivalents.

cases. It faces a difficult situation with the arrival of displaced people from the Russian Federation where infection rates with hepatitis viruses is high.

In North Macedonia vaccination against hepatitis B has been mandatory since 2004 and there is a catch-up programme. A protocol for the treatment of patients with acute viral hepatitis based on evidence-based medicine was last updated in 2015, but that for treatment of chronic viral hepatitis has not been updated since 2004. All donated blood is screened (including for HBV and HCV). Haemodialysis patients are tested and offered hepatitis B vaccination. Screening for viral hepatitis is not mandatory for pregnant women (although most are screened), prisoners or other marginalized groups of subjects, but NGOs conduct anonymous screening including testing of PWID in needle-exchange programmes. Any doctor can order tests for viral hepatitis and patients can even request a laboratory test without a referral. PCR tests, at two centres, are free but are charged for by private laboratories. No national register of patients with chronic hepatitis exists but the University Clinic for Infectious Diseases in Skopje keeps an in-house register (with more than 14,000 patients recorded). The country is trying to cope with a large influx of families from Ukraine, where rates of viral hepatitis infection are higher than in the host country.

In **Serbia**, a health care law sets out procedures, including collecting data and interventions. Responsibility for surveillance runs through regional institutes of public health in partnership with health care facilities, the private sector and the health ministry. Reporting is mandatory by doctors and microbiology laboratories. The data are held in a database for both communicable and non-communicable diseases.

In all the countries, reporting of acute viral hepatitis is mandatory and, in some, of chronic hepatitis as well. All have well-established viral hepatitis B vaccination programmes.

Access to universal health care is limited in some of the countries and lack of insurance also hinders access to diagnosis, linkage to care and up-to-date treatment. Little information was provided on access to health care for migrants and hard-to-reach populations other than PWID in some cases, even though an electronic personal health record system that registers health data on newly arriving migrants is being implemented in eight European countries including Bulgaria, Croatia, Serbia and Slovenia.¹⁰

Exchanges of information and experience do occur between viral hepatitis professionals at various levels as well as among the countries, but not in any systematic manner. There is a regional health cooperation initiative of governments of South-eastern European countries^c with its secretariat in Skopje, North Macedonia, and a regional development centre on communicable disease surveillance in Tirana, Albania, that has facilitated mutual cooperation and regional collaboration for certain diseases, but there was little evidence on specific collaboration for viral hepatitis even though it was accepted as a priority disease for the region.

Patient associations (see below) and nongovernmental organizations (NGOs) have a role in health systems but they often have little power, insecure funding and an uncertain position in the hierarchy of health systems.

Patient organizations

The role of patient associations is to inform, strengthen awareness, prevent, support and promote screening. Informing and educating means determining how to respond to all enquiries, and determining by whom and by what means. During the COVID-19 pandemic, the appointment of spokespersons led to them being identified as part of the government and consequently, their authority was undermined. Patients need authoritative and trustworthy information, access to preventive programmes and measures, support, and screening. The task is not as easy as in other

^c South-Eastern Europe Health Network (<http://seeh.org>) (accessed 10 January 2023).

regions in Europe. Members of the organizations are often volunteers – professionals and members of the public and often not fully supported.

One such body, the Hepar Centar Bitola, in North Macedonia, has been active successfully through networking, teamwork and lobbying in order to bring together health stakeholders. It launched the First National Declaration on Liver Cancer in the country in 2021 and has been active in the preparations for a Centre for Liver Diseases scheduled to be opened in the University Clinic for Gastroenterology in Skopje in 2023.

The European Liver Patients' Association (ELPA), whose slogan is "Together we are stronger", is active at the highest levels of the European Union and other influential bodies. Its lobbying efforts following patients' dissatisfaction with their comments being ignored caused the European Medical Association to change its forms for the reporting of adverse reactions to medicines. ELPA's eight working groups train patients to be experts in specific fields of liver disease. ELPA is involved in 10 medical research projects, and works in several other research projects, with partners including the European Centre for Disease Prevention and Control (ECDC) and WHO Regional Office for Europe.

The Croatian Association "Hepatos" is a humanitarian, nongovernmental and non-political organization founded in 2000 whose primary goal is to provide support to people with hepatitis.¹¹ It was the first NGO to work on hepatitis in the region and introduced a mobile information and help centre that enables linkage to care as well as support. Its work is featured in ACHIEVE's compendium. It continued to be active during COVID-19 and organized several meetings. Other organizations in the region have followed in its steps.

In some countries in the region patient organizations either do not exist or, if they do, are very weak.

Epidemiology

European Union and European Economic Area

ECDC presented an overview of epidemiology and the burden of disease in the 30 countries that make up this region, in which altogether 3.6 million people are estimated to have been living with chronic hepatitis B in 2016 and for chronic hepatitis C the figure for 2022 is 2.4 million. The total of six million is a significant population. The burden of disease varies widely across countries and population groups. Case burdens of HCV ranged from less than 300 in Iceland to more than 600,000 in Italy (respectively 870 and 10,200 per million). The true picture is obscured by a lack of data and the various changes over time: from the impact of different prevention and control measures, including curative HCV treatment, to the impact of migration from high-endemicity countries. Only a limited number of countries consistently report data to ECDC and there are questions about the validity of the data. The same issues apply to data collected by WHO Regional Office for Europe.

In order to meet WHO's 2030 elimination target the 2015 estimated mortality for EU/EEA countries and the UK of 64,000 deaths from hepatitis B and C will have to be lowered to around 22,000 a year. The latest data for the EU/EEA indicate that this target will not be met and deaths from hepatocellular carcinoma are still increasing.

Prevention activities are hampered by a lack of knowledge about transmission routes and their variation between countries and areas. However, the implementation of hepatitis B vaccination programmes across the EU/EEA region has had a major impact as seen through the continued downward trend in notifications of acute hepatitis B, a proxy measure for incidence. The vaccines are available in all countries within well-established programmes even if there are differences in vaccine procurement, with UNICEF supplying vaccines to some of the countries.

Data from the EMCDDA on HCV prevalence trends over time in young/new injectors, which are also used as proxies for incidence, indicate no significant downward trends.

WHO and ECDC are ready and willing to continue to provide technical assistance to countries to help to optimize the collection of data, improve surveillance, and support the effective implementation of prevention and control programmes.

Balkan countries – burden of disease and control

The picture painted was diverse, heterogeneous and complex. Data submitted by the individual countries were incomplete, including a lack of baseline figures; sometimes reported data were old and from small and not necessarily representative samples. Moreover, the data presented were not always collected in a uniform standard method: they were derived from national health systems and various different bodies within countries. Incidence and prevalence data were not always presented per capita. For these reasons, interpretation of data should be approached with caution. It should be added that the mass of data presented contained much valuable information and reflected the results of much-dedicated work and effort.

Gaps, such as infection rates in health care workers and migrants, were evident. Pre-COVID-19, data on birth doses of hepatitis B vaccine showed high rates (about 95%) in Albania, Bulgaria, North Macedonia and Serbia, with no data being presented by the other countries. The monitoring of the cause of death from viral hepatitis and hepatocellular carcinoma requires attention, especially as data on the attributable fractions of the latter due to hepatitis B and C are hard to assign.¹² A breakdown of deaths by country revealed that for HBV mortality figures in most of the countries in the region the rates are steady or declining. For HCV trends are increasing for all the countries examined.

EU members are expected to report data to ECDC. A few countries report to WHO using the database of the Regional Office for Europe, most of the countries that are reporting use the Joint Reporting Form. The practice of reporting in various Balkan countries, however, is not homogenous and requires attention; ideally it could be improved through the electronic submission of digitalized data.

All the countries appear to be undergoing the epidemiological transition for **hepatitis A**, with most of the populations aged over about 40 years now susceptible to infection. Periodic outbreaks are observed, with several in MSM,¹³ but routine vaccination is not practiced.^d

Evidence of autochthonous **hepatitis E virus** (genotype 3) infection is increasingly being seen, with relatively high rates in exposed populations such as veterinarians, hunters and people who are in contact with pigs and wild boar. Hepatitis E viral RNA has also been detected in surface waters in Slovenia and particularly Serbia (17%) although not detected in sewage.¹⁴

Albania

Surveillance for viral hepatitis has been digitalized; it is disease specific and both syndrome-based and laboratory-based. Several prevalence studies showing high rates are some 10 or more years old and those in the general population are almost too old to explain the current situation. Screening for HBV and HCV now focuses on several risk groups such as pregnant women, PWID, sexually transmitted infections clinic patients, MSM, health care workers and migrants; NGOs in collaboration with Public Health Institute undertake screening of female commercial sex workers (CSWs) and PWID. The more recent data confirm high infection rates in Roma (9.8% HBsAg positive in 2015) and for anti-HCV antibodies (11.6% for prisoners and 44.3% for PWID in 2019), and a decrease of hepatitis B is evident in the young population. Several DAAs are available. Needle-exchange and methadone programmes are available.

Bosnia and Herzegovina

^d WHO published a position paper on hepatitis A vaccines a couple of weeks before the meeting (Weekly Epidemiological Record, 2022, 97(40):493-512, <https://apps.who.int/iris/handle/10665/363396>, accessed 1 November 2022).

For Bosnia and Herzegovina the current situation is unclear. WHO estimates a prevalence of 1.5% for HCV, possibly 40,000 people infected, but this may be an overestimate. The quality of data and reporting is a major issue, with no data available on the general population. No case of HBV or HCV infection has been reported in prisoners or health care workers. Trends in HCV infections differ in the two halves of the country, falling to about 22 in the federal part and rising to 49 in Republika Srpska, with females dominating, in 2021.

Bulgaria

Bulgaria has seen a dramatic decline in viral hepatitis since 1982 and now most cases are seen in men. Hepatitis A is still seen in five-year epidemic waves but their intensity is declining. Hepatitis B vaccination has also dramatically reduced both infections and deaths from HBV and HDV. The vaccination rate dipped below 90% during COVID-19 but is now recovering. Most cases of hepatitis B are seen in hospitalized men aged 25-40 years old, some unvaccinated. Rates of HCV infection have also declined with only 25 cases in 2021. HCV genotypes are mostly 1a, 1b and 3a (predominating in PWID) but other types are also seen. Serological studies before 2011 of the general population indicated rates of 3.9% for HBV and 1.3% for HCV and higher rates in PWID, prisoners and the Roma community. A health economic study showed that the cost of liver cirrhosis due to HCV (about 300 patients), with a high mortality rate of 6.9%, amounted to €2340 per patient. In 2020–2021, as in Croatia, the number of patients treated for HCV infection declined owing to the COVID-19 pandemic, which reduced screening capacity, impeded access to health care and led to a shift of medical personnel to care for patients with COVID-19.¹⁵ Hepatitis E has been added to the list of notifiable diseases.

Croatia

An effective surveillance system reports from primary health care levels through field epidemiological units to a national institute. A low prevalence of HCV is seen in the general population and blood donors but rates of 37% or higher were seen in PWID in 2021, in whom most newly diagnosed cases are found.¹⁶ Studies are lacking in the general population and several risk categories, including health care workers. Among an estimated 20,000 people infected with HCV, about a third have been diagnosed and of those about 80% have been treated. Four DAAs are available.

High rates of HAV antibodies are found in MSM, and HEV antibodies have been detected in veterinarians, hunters and recipients of liver transplants.

Kosovo

Following the first assessment of viral hepatitis in Kosovo by WHO in 2019, the country is seeing a rise in infections with HCV, with particularly high rates in haemodialysis patients.¹⁷ Surveillance covers six regions and is syndrome-based. Some 13% of the general population is positive for HBsAg and 5% for anti-HCV. Lower rates are found in blood donors and transfusion-associated infections have been reduced substantially. Haemodialysis patients still face risks of infections with HBV and HCV but data are lacking for health care workers, only 9% of whom are known to be vaccinated against hepatitis B.

Vaccination against hepatitis B dropped during COVID-19 to 87% from 95%. There is no routine vaccination against hepatitis A.

Montenegro

No serological surveys for HBV or HCV infections have been undertaken, although bio-behavioural surveys among risk groups have been done as part of HIV surveillance. Low rates of HBV and HCV are estimated (for 2019) but data are lacking on pregnant women and health care workers. Among risk groups, data for 2021 show a prevalence of 2.4% and 3.2% for HBsAg in prisoners and female CSWs, respectively, and for anti-HCV of 17.2% in female CSWs, 20.2% in prisoners and 62.8% in PWID. Testing

is free of charge for all individuals covered by national health insurance, as is treatment (funded by the State); in 2022 so far, 30 hepatitis C patients and about 60 hepatitis B patients have been treated. Treatments are available, including tenofovir and sofosbuvir combinations. It is considered that diagnosis and treatment are sufficient for the burden of disease. No needle-exchange programme is available.

North Macedonia

Few data are available. In 2021, 1.4/100,000 of the general population carried HBsAg as did 0.68% of first-time blood donors. Reported data showed declining trends in acute and chronic cases to low levels. Care for patients with viral hepatitis is based on two centres, both in the capital, with genotyping of HCV and both quantitative and qualitative PCR for HBV and HCV. Treatment for hepatitis C is with sofosbuvir/ledipasvir and glecaprevir/pibrentasvir (with costs of the pangenotypic therapy for chronic disease covered by the State) and for hepatitis B lamivudine (the cost of which is covered by the State) and TDF (cost limits its availability to about 15% of patients). By the time of the meeting, more than 500 people have been treated for hepatitis B and more than 700 for hepatitis C (259 with DAAs) at the University Clinic for Infectious Diseases in Skopje.

Serbia

Data for 2020 indicated that the prevalence in blood donors is 0.8% for HBsAg and 0.03% for anti-HCV antibodies. Some 0.4% of pregnant women carry HBsAg, and 0.2% anti-HCV. Hepatitis B mostly affects MSM and PWID (3.2% and 1.5%) whereas anti-HCV antibodies are most commonly seen in PWID (11.9% of 937 people). Low rates of infection with HBV and HCV (0.5% and 0.3% respectively) have been reported in health care workers. Several DAAs are included in the national essential medicines list or subsidized by the Government, among them TDF and TAF. So far, some 2000 chronic hepatitis B patients and 5500 hepatitis C patients have been treated. No restrictions apply to the treatment of hepatitis B.

Slovenia

Low rates of HBsAg positivity are seen: an estimated 0.8% in the general population in 2019 (annually reported cases of both acute and chronic cases fell in 2016–2020), 0.004% in first-time blood donors, but 0.25% in MSM in 2019–2022. No mother-to-child-transmission of HBV has been detected since 1996. Data in pregnant women are being gathered but are lacking for prisoners and health care workers.

More attention has been paid to HCV than HBV as it is curable. HCV RNA is detected in about 0.01% of the general population (2022), has not been detected in any blood donor in 2018–2020, but was reported in 2022 at higher rates in former and recent PWID (5% and 13%, respectively). Other recent data appear to be lacking. By 2020 sharp declines in annually reported cases of both acute and chronic HCV had been reported.

Screening for HBV or HCV is not recommended for migrants except in the case of refugees from Ukraine in view of the “considerable public health problem” posed in that country by HBV, HCV and HIV.¹⁸ All DAAs have always been available for treatment. The cascade of care for 2020 showed good progress with 82% of the estimated number of patients diagnosed and 65% treated, although that left an estimated 1100 people not yet diagnosed or cured, among them around 800 former or current drug users.

HEV RNA or antibodies were detected in studies of blood donors in 2019 (0.06% and 7.6%, respectively).

Lessons learned, best practices and future challenges

The Balkan countries noted several achievements, from Slovenia's long-term successes towards HCV elimination to the development of national plans and strategies in some other countries for elimination of viral hepatitis. Even though some countries still have not prepared or approved national strategies for elimination of viral hepatitis, all the Balkan countries at the meeting have been active in taking even small steps to prevent and control hepatitis B and C within their resources.

Decentralization may be more appropriate for some aspects of the health system, including service delivery, but major discussions are necessary before wide-ranging changes can be made.

Many notable steps have been taken. Some countries have programmes or best practices for testing and treating prisoners, operating mobile clinics, testing and prevention in the community, integrating services in the community, needle-exchange programmes, using telemedicine for linking to care, and investing in collaboration between clinicians, physicians and epidemiologists (and maybe NGOs). WHO's compendium of good practices¹⁹ contains examples from Croatia and Slovenia.

Several examples from Croatia illustrated best practices, including the Mobile InfoHelp Centre (described the best and the most complete system of linkage to care in the Balkan region) and CheckPoint Centre Zagreb (which offers testing and education in the community, following ECDC's guidelines²⁰). Needle-and-syringe-exchange programmes have been established since 1996. Operated by NGOs at the local level they continue to be funded by national and local authorities. A screening and treatment programme, developed by the Ministry of Justice with a NGO HUHIV, was launched in three prisons in 2021.

In Slovenia, the national management of HCV infection represents an example of good practice, starting already in 1997 with the setting up of a national strategy and integration of the continuum of services into routine health care activities. The National Viral Hepatitis Expert Board decided in 2017 to accelerate progress by implementing several microelimination strategies focusing on subpopulations where HCV infection is most prevalent including haemophiliacs and patients receiving haemodialysis or organ transplants and people with HIV and HCV coinfection. PWID on opioid substitution treatment are the next target for HCV elimination; however, those not on such treatment represent the most difficult-to-discover subpopulation.

Opportunities exist to build on lessons, such as those for self-testing and differentiated service delivery, learned from HIV and COVID-19, as well as ways of improving outreach.

Future challenges for *health systems* include: sustaining commitment and political will; completing and implementing national strategies and plans; coordinating activities at local and national levels; raising awareness and educating decision-makers, health professionals and the general population (by means such as identifying medical and other specialists who are not visibly part of the government, for example through programmes such as ELPA's to create expert patients for advocacy); increasing systematic collaboration and maintaining communication between viral hepatitis professionals and greater regional collaboration on the whole, especially in areas such as negotiating prices for medicines and diagnostics (with acceptance of offers of support from WHO and ECDC); and monitoring and evaluation, with regular review of the performance and achievements of the various health systems and their impacts.

Challenges for *prevention* include: countering vaccine hesitancy; ensuring access to prevention, care and support services for all who need them; preventing viral hepatitis and liver disease in migrants; and reducing stigmatization and discrimination.

Challenges for *treatment and care* include: maximizing the number of patients in treatment, especially for hepatitis C given that it is curable, and making antiviral agents as affordable, available and accessible as possible; and bringing the cascade of care into line with expected targets.

Needs and output of breakout groups during the meeting

Participants broke out into three *working groups* to have an in-depth discussion on surveillance and epidemiology, prevention and treatment. Based on these discussions and the overall discussions during the meeting, the following needs were identified:

Surveillance and epidemiology

Urgent needs highlighted were:

- better baseline data and data on the burden of disease, including information from qualitative behavioural surveys with seroprevalence surveys in general and key populations; costs need not be high and opportunities should be investigated for piggy-backing other surveys, such as web-based applications and serosurveys during COVID-19;
- a standardized method to collect and measure prevalence and incidence at the national level, such as nationwide serosurveys with a common methodology. Balkan countries should unite to generate acceptable data and to coordinate the collection of data on incidence and prevalence, and national or federal governments and partners should support such a commitment;
- improved surveillance of hepatitis B and C, including cases of chronic disease, with better and digital reporting, standard case definitions, more detailed case information and more complete clinical and epidemiological information, and extended to birth cohorts and immunocompromised subjects or patients about to receive immunomodulatory treatment or chemotherapy;
- promotion of participatory surveillance by using NGOs or other patient organization sources and their integration into the national system;
- upgraded reporting, including digital systems, with the creation of databases and registries, with data on infections in health care settings, pregnant women (especially viral load and antiviral treatment in the third trimester of pregnancy), coinfections, and for acute cases the transmission routes, and collection of data from private entities. (The principal stakeholders are national public health institutes, under the aegis of the health ministry. WHO can provide technical support with most of these needs.)
- integration of data from different sources (in particular, national screening registries of patients, treatment registries or data systems that collect sufficient information to allow monitoring of the cascade of care routinely; other potential sources include transfusion medicine records and the data collected by NGOs and service providers); the data should be interoperable, used and shared; all those activities need dedicated personnel for collection and management as well as digitalization, even though they were recognized as imposing an extra financial burden. (The principal stakeholders are public health physicians and clinicians, under the aegis of the health ministry.)
- capacity raising and provision of human resources, with training and professional exchanges to make the profession of public health attractive again. (The responsible bodies are public health institutes and health ministries.)

Prevention

In addition to solid baseline data being vital for robust prevention programmes, several other needs were identified and recommendations made:

- coordination and support of NGOs, the main providers of preventive services except immunization and opioid agonist treatment;
- more physicians should be in place to coordinate work to prevent and control viral hepatitis, with more formal bodies or structures to create strategic documents;

- standardized infection prevention and control practices should be formulated or, where they exist, implemented, especially in private facilities and by providers of manicures, dentistry and other registered (health) facilities, with reinforced inspections;
- increased screening and diagnosis by mobilizing more resources and exploring more support from partners;
- screening, vaccination against hepatitis B where appropriate, and monitoring of health care workers together with formulation of policies and funding mechanisms (with time, an increasing proportion of health care workers, medical students and nurses will have been immunized in childhood);
- agreements on how to collect data on blood safety and which tests to use;
- restoration after COVID-19 and/or expansion of harm-reduction activities;
- increased and maintained birth dose coverage rates of hepatitis B vaccination, and ensuring high vaccination rates after COVID-19;
- vaccination of main risk groups, especially PWID, against hepatitis B and monitoring of such programmes;
- greater availability or provision of needle-exchange programmes, with an associated review of policies, ending of restrictions on access, and work on funding from both private and public sources;
- programmes for hard-to-reach subjects and groups, including Roma, migrants and displaced persons, and people in the prison system.

Underlying all these proposed actions lies the thorny issue of funding. NGOs need support, at a sustainable level. Programmes, let alone their proposed expansions, need to be guaranteed with continued support which in turn relies on political commitment and strong public advocacy.

[Treatment: recommendations based on epidemiology and disease burden data, increasing access to treatment, coverage of the most affected groups](#)

Ensuring early access to linkage to care and treatment is vital for all cases of viral hepatitis. Another general need is securing and maintaining funding so treatment can be offered free of charge to patients.

Recommendations and identified needs specifically *for hepatitis B* included the following:

- resolution of issues of centralized or decentralized approaches and definition of professional responsibilities at various levels;
- setting up or updating of national guidelines or at least adopting or adapting according to the national needs the existing international guidelines (for example, the Clinical Practice Guidelines of the European Association for the Study of the Liver (EASL)) on treatment and care, with education of doctors in both the public and private sectors about those guidelines;
- identification of those patients who need immediate treatment and those who are not eligible for treatment, with definition by public health systems of who should treat and care for hepatitis B patients and at which levels;
- simplified processes for prescribing treatment and referring patients;
- broadening of access to treatment in order to reach the most affected groups: pregnant women, MSM, PWID and migrants;
- expansion of financial coverage of hepatitis B treatment by health insurance funds;
- greater availability of free PCR testing for HBV DNA, with consideration of testing for HDV infection in cases where HBsAg is detected;
- exploration of mechanisms by which all countries can ensure availability of all relevant medicines when needed for treatment and gradually increase the coverage with treatment of all patients in need.

Recommendations and identified needs specifically *for hepatitis C* treatment and control included the following:

- treatment should take a pangenotypic approach;
- simplification of the whole diagnostic process and evaluation of patients for treatment, with a reduced bureaucratic burden on patients;
- setting up or updating of guidelines or at least adopting or adapting according to the national needs the existing international guidelines (EASL's Clinical Practice Guidelines providing a good basis);
- evaluation of treatment, with appropriate collection and collation of data on treatment regimens and outcomes;
- increasing access to treatment, for example through expanding diagnostic capacity (with provision of PCR diagnostic capacity in countries lacking access), linking with reference laboratories and optimizing collaboration between the State system and private laboratories with appropriate quality control;
- expanding the range and volume of medicines available with reimbursement of costs;
- resolution of funding issues, for instance through health insurance funds, with engagement of several stakeholders, including clinicians, public health practitioners, policy-makers and patients;
- negotiations with the pharmaceutical industry to lower the price of medicines and diagnostics, for which a costed strategic plan with numbers of patients is vital; such comprehensive national plans will help in determining progress towards improving the cascade of care and elimination targets and will increase the chance for the partnership with the pharmaceutical industry;
- exploration of mechanisms by which all countries can ensure availability of all relevant medicines when needed for treatment and gradually increase the coverage with treatment of all patients in need;
- scaling up examples of microelimination programmes for the most affected groups;
- facilitation of the treatment of PWID, for instance by removing the criterion of abstinence from drug use, introducing regular testing for reinfection and removing barriers to access;
- rethinking of old policies on treating people in prisons, including finding funds for testing and treatment, and introducing screening, diagnosis, and subsequent treatment on entry to prison.

Next steps

Immediate action is needed:

- to ensure passing the 2025 milestones on the way towards elimination of viral hepatitis as a public health problem, especially as indications seem to be that vaccination rates – not just birth doses of hepatitis B vaccine, but completed courses of three doses – are showing signs of falling below recommended levels;
- to expand hepatitis B vaccination programmes to key population groups;
- to raise and maintain hepatitis B vaccination rates and to initiate or firmly establish the screening of pregnant women for HBsAg;
- to complete national strategies and plans for meeting the 2030 targets, including costed plans containing numbers and solid baseline data;
- to generate and share strategic information on equity across the continuum of care;
- to improve management of information about viral hepatitis with consolidation to provide solid data;
- to raise the number of patients experiencing each step of the continuum of testing, care and treatment.

Other next steps include:

- reviewing lessons learned from elimination pilot countries (for instance, Georgia);

- preparing and implementing regional action plans;
- disseminate and implement updated guidelines ; and
- drawing lessons from HIV (such as “hit early and hit hard”) in the region.

Numerous willing potential partners, from the World Hepatitis Alliance to ECDC and WHO and its collaborating centres, exist whose expertise and support could be drawn upon. At the same time, finding people able and willing to take on leadership roles and to provide the drive and motivation for continued and sustained work and advocacy remains a challenge but the current regional collaborative approach of South-Eastern Europe Health Network could be explored.

Useful resources

The recently launched updated version of its compendium of good practices *Stories to inspire*, by ACHIEVE (the Associations collaborating on Hepatitis to immunize and eliminate the Viruses in Europe) shows how regional, national and local initiatives are helping to achieve the elimination of viral hepatitis. It is available online²¹ as is WHO’s compendium of good practices in the response to viral hepatitis in the European Region²¹.

WHO has also published a series of documents on viral hepatitis. These include Interim guidance for country validation of viral hepatitis elimination²² and policy briefs, one with updated recommendations on simplified service delivery and diagnostics for hepatitis C infection²³ and another with updated recommendations on treatment of adolescents and children with chronic HCV infection.²⁴

Table 1. Basic demographic and health information

<i>Country</i>	<i>Area (km²)</i>	<i>Population</i>	<i>% of GDP spent on health</i>	<i>Cash spent per capita</i>	<i>Life expectancy (yr)</i>	<i>National plan or strategy to eliminated viral hepatitis</i>
Albania	28,748	2,829,741 (2021)	5.23	US\$ 727	79 (M), 81 (F)	Drafted but not yet officially approved by health ministry apart from the plan on vaccination
Bosnia and Herzegovina^e (Republika Srpska)	51,129	1,128,309 (est. 2021)	5.5	€353	76.2	No
Bosnia and Herzegovina		2,219,220 (2021)	8.1	US\$554	77.4	No
Bulgaria	110,994	6,838,937 (2021)	8.1	€ 1,311 (2021)	73,6	National programme for 2021-2025 adopted in 2021
Croatia	56,594	3,871,833 (2021)	7	€1392	77.8	National plan written but not yet adopted
Kosovo	10,887	1,850,000	3.24	US\$ 162	68.6 (M), 73.7 (F)	No
Montenegro	13,812	617,683	10.9	€744	75.9	No
North Macedonia	25,713	1,836,713 (residents 2022)	7.1	€443	76.1	Need for newly-written plan acknowledged (consensus dd. 2004)
Serbia	88,361	6,834,326 (estimated 2021)	9	€456	73.5 (M), 78.4 (F) (2018)	No; awaiting new Government's action
Slovenia	20,273	2,106,215 (2022)	7.9	€2277	77.6 (M), 83.7 (F) (2021)	National strategy for HCV for 25 years

^e United Nations projection for 2022 for B&H 77.78 years excluding any impact due to COVID-19.

Table 2. Main prevention and control activities and challenges for viral hepatitis management

<i>Country</i>	<i>National guidelines</i>	<i>Vaccination</i>	<i>Hepatitis B vaccination coverage*</i>	<i>Screening</i>	<i>Laboratory capacities</i>	<i>Surveillance</i>	<i>Main challenges</i>
Albania	Mother-to-child screening for infectious diseases	Universal, mandatory and catch up and risk groups Plans for hepatitis A and B to be revised	97.5% (2021)	Risk groups (PWID, MSM, female CSWs) by NGOs for HBV markers, but not the prison population	Centralized	Reporting of chronic hepatitis is not mandatory; lack of funds for seroprevalence studies; private sector is reporting through “participatory” surveillance (NGOs)	Transition from paper to web-based surveillance system Decentralize cascade of treatment
Bosnia and Herzegovina (Republika Srbska)		Hepatitis B: mandatory universal and risk groups	90% (2021)				Data collection and quality
Bosnia and Herzegovina		Hepatitis B: mandatory universal and risk groups					
Bulgaria		Hepatitis B: universal; public awareness campaigns about value of hepatitis A and B vaccinations	89% (2021) (HepB3)		Capacity of National Reference Laboratory being strengthened	Surveillance and registration of viral hepatitis (B, C and E) a priority of national programme	Reaching people in prisons, CSWs, and the Roma community and preventing spread of hep A, B and C; reducing stigmatization and discrimination;

							coordination at national and local levels
Croatia		Hepatitis B: universal, catch up and risk group Hepatitis A: risk groups	90% (2021)	Pregnant women (since 1999) HBsAg; people in prisons (with treatment); integrated community testing for HIV and HCV (following ECDC guidance)			Education of primary care physicians; screening in risk populations and linkage to care; monitoring impact
Kosovo		Universal, risk group	HepB3 87% (2021) (92% in 2020)				With about 5000 PWID and DAAs available, more work needed on vaccination, prevention of PTCT testing and treatment
Montenegro	Good clinical practice for treatment of hepatitis C (2019), EASL	Universal, risk group	51% (2021) (HepB3) Very few health care workers vaccinated			Reporting system insufficient; under-reporting from the private sector. Screening recommended for all risk groups	Simplified testing and linkage to care a priority; decentralization vital; harm reduction programmes run by NGOs – uncertain sustainability; no

							biobehavioural studies
North Macedonia	National (2004); EASL 2017	Universal, catch up, and risk groups (including medical workers)	79% (2021)	Mandatory (HBV and HCV) for blood donors and in vitro fertilization; recommended for PWID and other groups		Screening for birth cohorts and risk groups (including some of the prison population) but not migrants	Specialized centre for liver disease due to be opened in 2023 in capital; Screening should be extended to CSWs, MSM, prisoners and transgender populations
Serbia	Special working group formed 2021; action plan submitted for adoption	Universal, catch up, and risk groups	89% (2021), Full dose in newborns 99% (2021)	Emphasis on screening for HCV infection (with links to care and treatment)		Screening recommended for all risk groups (or some migrants and incarcerated people)	Need for cross-sectoral cooperation. An estimated 50,000 people with HCV infection need treatment; more testing and more treatment proposed
Slovenia	National strategy and clinical guidelines for management of viral hepatitis B (since 2000) and hepatitis C (since 1997) with updates in accordance to the EASL's Clinical Practice Guidelines; special guidelines for: management of HCV in	Universal +, risk groups for hepatitis B; risk groups for hepatitis A	86.4% (2021) (79.9% 2020)	Recommended for most risk groups	Dispersed for screening, centralized for PCR testing for HBV and HCV DNA	Regular national monitoring of HBV and HCV treated patients since 1997 by the National Viral Hepatitis Expert Board	Need to increase third dose of hepatitis B vaccine for children

	PWID (2007), management of HBV in patients with chronic kidney disease (2021), prevention of HBV reactivation in patients on immunosuppressive treatment (2008), management of viral hepatitis during COVID-19 pandemic (March 2020).						
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*Data from: [Hepatitis B vaccination coverage \(who.int\)](https://www.who.int)

Table 3. Data dashboard showing modelled and survey values for national prevalence of chronic infection and deaths from HBV and HCV

Country*	Prevalence				Hepatitis-related deaths			
	Modelled		Survey/surveillance		Modelled		Survey/surveillance	
	HBV (HBsAg+)	HCV (RNA/ cAg+)	HBV	HCV	HBV Number (rate per 10 ⁵)	HCV Number (rate per 10 ⁵)	HBV	HCV
Albania (2019)	0.7%	1.01%	-	-	123 (4.5)	145 (5.32)	-	-
Bosnia and Herzegovina (2019)	0.64%	1.22%	-	-	210 (6.4)	262 (7.9)	-	-
Bulgaria (2019)	2.43%	1.15%	-	1.1% (anti-HCV, 2014)	635 (9.2)	651 (9.4)	-	-
Croatia	1.17%	0.97%	HBsAg+ 0.8% (2011)	0.9% (anti-HCV, 2011)	263 (6.2)	271 (6.4)	-	-
Kosovo	4.17% (2013)	-	-	-	-	-	-	-
Montenegro	0.62%	0.98%	-	-	22 (3.5)	25 (4)	-	-
North Macedonia	0.81% (Institute for Public Health: 2-4%)	1% (Institute for Public Health: 1.5-1.8%)	-	-	124 (5.8)	139 (6.5)	-	-
Serbia	0.76%	1.11% (1.13% estimated, government figures***)	-	-	406 (4.6)	575 (6.6)	-	-
Slovenia	0.84%	1.28% (0.01% estimate in 2022**)	-	-	147 (7.1)	169 (8.1)	-	-

*Data for 2019 except where indicated.

Source: Coalition for Global Hepatitis Elimination (<https://www.globalhep.org/>); for further information see <https://www.globalhep.org/country-data-dashboards>. ** Matičič M. *** Rakič V.

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