



Viral Hepatitis Prevention Board

**Elimination of viral hepatitis in Hungary:
Lessons learnt and the way forward**

BUDAPEST, HUNGARY
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Objectives

- Provide an overview of the current viral hepatitis situation in Hungary: surveillance systems, epidemiology, screening, disease burden, prevention and the cascade of care
- Discuss achievements and challenges in the prevention of viral hepatitis, the possible implementation of new prevention strategies in Hungary
- Discuss the development and implementation of a national hepatitis plan
- Assess the needs to achieve the goal of eliminating viral hepatitis as a major public health threat by 2030 as set out in the WHO Global Strategy on Viral Hepatitis, 2016-2021, and the WHO Regional Office for Europe's action plan for viral hepatitis, building on commitments to the United Nations' 2030 Agenda for Sustainable Development and its Goals
- Discuss successes, issues and barriers to overcome, and the way forward

International context

- UN's 2030 Agenda for Sustainable Development; target 3.3 in Goal 3 (on good health and well-being) specifies "combat hepatitis"
- WHO's global health sector strategy on viral hepatitis, 2016-2021 (which calls for the elimination of viral hepatitis as a public health threat by 2030), and the related WHO Regional Office for Europe's action plan: elimination of viral hepatitis as a public health threat by 2030 – WHO has published a progress report on the plan's implementation. WHO is working on a new system to monitor the cascade of screening and linkage to care and will issue a compendium of good practices in the hepatitis response by the end of 2019. Also WHO has issued numerous documents on several aspects of viral hepatitis prevention and control.
- VHPB – more than 27 years of activity in Europe, with tangible results, including contributing to changing national policies, encouraging development and implementation of national plans and strategies, fostering networking and provision of information
- EASL's activities and publications, including strategies for treatment of viral hepatitis such as simplification of treatment of hepatitis C, micro-elimination strategy, position statements and establishment of a foundation
- The UN's Global Commission on Drug Policy has for several years advocated decriminalization of drug use and has multiple resources

- Viral hepatitis – heavy disease burden globally, with widely unrecognized imbalance of both morbidity and mortality of viral hepatitis compared with those of HIV, malaria and tuberculosis (WHO report 2017) and in allocation of funds; globally 20% of people living with HCV have been diagnosed and only 7% treated, although cost of treatment is a declining barrier
- Diverse and dynamic epidemics in Europe, good data collected by ECDC
- Lessons to be learnt from other countries (e.g. Italy, Bulgaria, and Poland; Hungary's neighbour Slovenia provided a comprehensive model with plans to attain the elimination target before 2030)

Hungary – health system and financing

The presentations in the meeting showed a great deal of activity and enthusiasm for work towards elimination of viral hepatitis in Hungary set against a sometimes difficult political and social background; progress is being made but more needs to be done.

Health system and financing

- The former Ministry of Health has been subsumed into a new “superministry” (Ministry of Human Capacities), losing its individual voice in cabinet. The Ministry is responsible for several major institutions such as the National Public Health Centre, the National Centre for Epidemiology and the National Health Insurance Fund which are actively engaged in work on viral hepatitis.
- A National Hepatitis Therapeutic Committee decides and authorizes treatments (e.g. for hepatitis C). A National Hepatitis Committee was established at the end of 2018.
- Health care is based on a solidarity-based insurance system, financed through the single-payer national health insurance fund, under a 1997 law. Expenditure on health as a percentage of GDP has declined, from 7.5% in 2012 to 6.6% in 2018, but average remuneration for general practices has risen slightly
- Contracts for services are made with healthcare providers with different types of financing (e.g. general practitioners are eligible for capitation fees, fixed costs and other fees such as for night duty)
- There is both a small private sector and limited role of civil society for work on viral hepatitis; the Hungarian Association of Infectious Liver Patients (VIMOR) has been active since 2003, and offers screening events, awareness-raising (including use of media) and capitalizes on major events such as World Hepatitis Day and festivals
- The repeated restructuring of the system over the past years is not finished – the Government has approved a plan for the harmonized development of the health system through better horizontal collaboration and reinforced vertical teamwork. Restructuring of the financing is in progress, with salaries of nurses being raised substantially and raises planned for doctors, whose salaries are low, while investment overall in the system is insufficient and some low-threshold services covering viral hepatitis have been cut.

Health system and financing (continued)

- A new programme of funding for GP practices has been introduced through the “Three Generations for Health” project, as part of the reform of primary care and aiming to improve prevention and treatment of diseases or activities with high epidemiological impact (e.g. cancer, childhood obesity, smoking and lack of exercise)
- A hepatitis B vaccination programme was introduced in 1984; the current programme is not a universal infant vaccination programme, but targets adolescents (at 13 years of age) and at-risk people; vaccine is purchased centrally
- The perceived focus of work on viral hepatitis is predominantly on HCV; 34 centres are allowed to diagnose and treat HCV, with reporting to an accredited centre for treatment and follow-up
- An electronic hepatitis registry for hepatitis C patients has existed since 2006 and been web-based since 2011; it offers multiple functions including reminders: the registry is considered to be a valuable resource
- There is no budget limit for HCV treatment; DAAs are available and costs are reimbursable, with treatment being free of charge to patients. (In cases of failure of DAA treatment, Pharma bears the cost.)
- Negotiations to reduce treatment costs could open opportunities for savings to be directed to expanded testing and treatment
- Few harm-reduction programmes exist; drug use is criminalized; society is generally conservative and traditionally-minded

Screening

- Screening generally, whether in general practitioners' practices or elsewhere, is a key element in any approach towards elimination; much work is already being undertaken, but no organized screening for HCV is done by general practitioners; such action is restricted to highly motivated doctors in areas where high-risk patients abound
- The National Public Health Centre coordinates screening programmes for HBV, HCV and HIV with NGOs, and also conducts bio-behavioural surveys; surveillance was brought into line with EU requirement in 2013. Data are collected through a professional information system for collation digitally and reporting to ECDC
- Regulations have been changed so that since 2019 all HCWs will have been screened for HCV by mid-2020; screening will be mandatory for healthcare professionals starting work after June 2020, with rescreening required every 5-10 years subsequently (depending on risk exposure)
- The State budget for screening is being increased by 50% between 2019 and 2020 to the equivalent of €1.85 million
- Based on experiences in Italy, the UK and the USA, a proposal is being made to introduce screening of HBV and HCV in accident and emergency units in order to detect new and existing infection with point-of-care tests
- Since 1983 all blood products screened for HBV and since 1992 for HCV; there is a universal mandatory programme for screening pregnant women for HBsAg with passive and active treatment of infants of HBsAg-positive mothers and treatment of highly infectious mothers, and follow-up of infants at 15 months of age
- HCV core antigen testing could replace RNA testing and confirmation; it was reported that a point-of-care test costing about US\$ 2 was under development

Epidemiology

Hungary has a strong tradition of good reporting of communicable diseases; notification is mandatory for viral hepatitis; reporting is done by doctors; the National Public Health Centre collates data. The quality of data needs validation. Given the criminalization of drug use and the stigmatization of risk behaviours, such as men having sex with men and commercial sex work, it is rare and potentially dangerous for patients to report such risk factors for infection.

HAV

- With most of the population now being susceptible to HAV infection cyclical patterns of outbreaks are seen, as expected; the most recent outbreak was in 2013-2014, apparently originating in MSM but spreading both heterosexually through bisexual men more widely into the general population and through poor food hygiene
- Hepatitis A is not covered by the national immunization programme, but vaccine is used in outbreaks

HBV

- By 2015 some 7500 people had been diagnosed with HBV with only 35 cases of acute disease were seen in 2018 (91% in >30-year olds). HBV vaccination coverage said to be very high (but no data on coverage were presented) and to have resulted in a substantial drop in incidence of acute cases (to an estimated 0.2/100,000 in 2019). No cases seen in dialysis patients and few in HCWs; 23 cases seen in PWIDs, but the trend is decreasing. Predominant genotypes are A and D (but genotypes are not routinely tested for).
- Screening of pregnant women for HBsAg is mandatory (but no performance data were presented). One study in 2018 found that a low percentage had been vaccinated against HBV (43%)

Epidemiology (continued)

HCV

- Acute cases: very few seen (12 cases in 2018, 0.1/100,000), even in HCWs and PWIDs, and no outbreaks seen in children or MSM; there were questions about adequacy of surveillance. Overall prevalence is still low, estimated at 0.4% in 2019; genotype 1b predominates although GT3 incidence is increasing.
- An estimated 50,000-70,000 people are infected with HCV in Hungary, most said to have been infected before 1993 through contaminated blood products or other health interventions; most are considered to be HCV RNA positive. Most infected people remain undiagnosed and few have access to testing or treatment.
- District VIII in Budapest had a particularly high rate; it is home to a large Asian population as well as CSWs and PWIDs. The rate of HCV RNA positivity in prisoners is 10% nationally with a figure of 16% reported in one (see below). Another study in 2018-2019 found a 10% seropositivity rate for anti-HCV antibodies and 7% positivity for HCV RNA.
- Concrete steps have been taken towards elimination – some 140,000 people have been screened so far, including HCWs – but still many infected people remain undiagnosed
- Patients with cirrhosis treated with antiviral agents who attain a sustained viral response need thorough monitoring after therapy for onset of malignant disease.

HEV

- Diagnostic competence has improved and tools have become increasingly available since 2004; the epidemiological pattern was stable until 2014 but since then there has been an upturn with some 250 cases recorded in 2018; possibly this reflects greater awareness; identification of the sources of the cases would be prudent.

Epidemiology in groups at risk

PWIDs

- Among the estimated 40,000 people who have injected drugs at some time in their life, about 10,000 are thought to be infected with HCV and an upward shift in HBV and HCV prevalence was seen in 2014. A study of PWIDs in detoxification programmes found 3% positive for HBsAg and 25% positive for HCV. HCV prevalence is typically higher than 50% in PWIDs without access to harm-reduction.
- Low-threshold services, the main setting for HCV testing, exist but receive little funding; fewer PWIDs attended services after 2015 for a variety of possible reasons (e.g. capacity problems of services, more purchases of syringes in pharmacies, new patterns of drug use with less injecting and more restrictive application of laws) – also, harm-reduction programmes in Budapest was closed or forced to curtail some services.
- Low uptake of screening (HCV, HIV) was seen in 2018 – a serious concern.
- Main barriers to treatment identified by WHO at system and provider levels and the criminalization of drug use are seen in Hungary, as elsewhere.
- Routine testing and data collection will improve the precision of seroprevalence estimates and guide programme development.

Roma

- A classical hard-to-reach community: one study found a 15% HCV seropositivity rate, but most had been vaccinated against HBV.

Incarcerated people/prisoners

- The rate of infection with HCV is comparable to the global figure of 13% and the European average of 18-23%; about 25,000 people pass through prisons a year and the data from testing, although not representative, could illuminate the cascade of care.

Prevention and control

- The Ministry of Human Capacities responded rapidly to an appeal from hepatitis experts and established a National Hepatitis Committee for the elimination of hepatitis at the end of 2018; it is composed of hepatology experts who act in a voluntary capacity.
- A national strategy is being drafted that will propose a step-by-step approach and encompass prevention and control activities and care programmes for all risk groups, including MSM and HIV-infected people.
- A law in 1999 stipulated that employers must ensure that workers at risk of HBV were vaccinated as a condition of employment. Screening of all HCWs will be completed in 2020 (see above).
- HBV vaccination is recommended for people with risk behaviours (including MSM and CSWs) and for chronic HCV carriers. In 1999 a school-based vaccination programme was introduced, and in 2010 the age for vaccination was lowered from 14 years to 13 years. Coverage is reported to be >99%.
- HBV vaccination is having a major impact, but targeting adolescents is not in line with WHO's clear recommendation of universal infant immunization (adopted by the World Health Assembly), already being implemented in 188 countries by 2017. Adolescent immunization leaves children susceptible to HBV infection. Universal infant immunization is one of the indicators used to measure compliance with WHO's elimination guidelines. Infant immunization with a hexavalent vaccine might be cheaper than adolescent immunization.
- Only one NGO, in Budapest, currently offers needle-exchange services for PWIDs and HCV and HIV testing.

Challenges

- In Hungary, the seemingly-endless restructuring, sometimes regarded as excessive, impedes work and progress, leading consequently to difficulty in sustaining political commitment.
- Low salaries for healthcare workers have led to demoralization and loss of skilled workers through emigration (a considerable brain drain among young professionals) and an increased burden on remaining healthcare professionals.
- The feasibility of getting greater commitment and engagement of general practitioners in work of viral hepatitis is cast into doubt by the fact that each has on average 1500 registered patients; the difficulties in strengthening the role of family doctors were described – for instance, the use of questionnaires is beset by the need to thoroughly evaluate such tools before use.
- The efficient functioning of a national database on acute and chronic cases, including work to check the consistency of the data, will need active collaboration of clinicians and support from the Ministry of Human Capacities.
- Hepatitis A – consideration needs to be given to the fact that increasingly the population is susceptible to HAV infection and to vaccination.

Challenges (continued)

- HBV vaccination
 - sustainability – keep up or increase coverage rates
 - how to cope with non-responders
 - how long does vaccine-induced protection last
 - how best to prevent perinatal HBV infection
 - how to cope with vaccine issues and increase vaccine confidence
 - use of hexavalent vaccine
 - how to change to a universal infant immunization programme
- Criminalization of drug use impedes access to care and prevention, and routine testing is not available for PWIDs; a recent stricter policy on drug use may have adversely affected the dynamics of HCV infections in PWIDs. Guidance from the UN's Global Commission on Drug Policy is either unknown or not accepted.
- MSM and CSWs are underserved populations; the experiences of other countries in outreach could provide useful lessons
- Linkage to care not optimal, with need for presentation to doctors and proof of valid health insurance

Conclusions and recommendations

- The National Hepatitis Committee should broaden its remit to cover funding and financing, and has an opportunity to bring together information from different groups. It is recommended that the National Hepatitis Committee expand its composition to include representatives of civil society and experts in areas such as prevention, health economics, education, sociology and communications. It is also encouraged to join the global community of practice for hepatitis elimination in order to share experiences and identify collaborators who can help efforts to scale up testing and treatment. Also, the committee could consider recommending cost-effectiveness studies of various options for screening and treatment and liaise with the Coalition for Global Hepatitis Elimination, which is developing guidance and tools in that area.
- Health insurance should be extended to the whole population.

Surveillance and screening

- It was recommended that a special budget be dedicated to screening for HBV and HCV generally.
- Reporting of acute cases of viral hepatitis by laboratories or clinicians is mandatory but not so for chronic hepatitis. The recommendation is to make reporting of chronic cases of viral hepatitis also mandatory. Reporting is incomplete because private laboratories and physicians do not always submit data; this problem needs to be rectified.
- In the present legal environment, screening on the basis of risk factors is a sensitive issue. The importance of screening different populations was underlined: testing should be designed for diagnosis only. The following groups should be screened: PWIDs, MSM, Roma and other hard-to-reach communities, patients attending STI clinics, homeless, and patients attending emergency departments. About 500,000 people need to be screened annually if the WHO goal is to be met.

Conclusions and recommendations (continued)

- There is no connection between the clinical registry and national surveillance data (HepReg) – there are many data but no capacity for differentiation; screening programme data are necessary to determine the denominator of cases and should be linked to other databases.
- No link exists between screening programmes in prisons and the HepReg registry, but it is possible for healthcare workers; a government-supported programme to screen all HCWs for HCV started in 2019.
- Public and professional awareness needs to be raised, both for advocacy and challenging the Government. Awareness-raising could be an intervention in itself. Examples were the work of VIMOR and the engagement of the media.
- Consideration needs to be given to validation of data and issues of monitoring and evaluation. It was also emphasized that not only is this important for viral hepatitis but for a transmissible disease programme at national level (e.g. HIV).
- Consideration should be given to conducting a seroprevalence study for HAV/HBV/HCV in the general population in order to inform policy and prevention.
- For linking infected subjects identified by screening to care it was recommended that action be taken to create, re-establish or strengthen low-threshold services for PWIDs. One solution would be the use of mobile teams for outreach. They should comprise multidisciplinary teams including doctors, nurses, social workers and other relevant professionals. Examples of successful application of this model exist in Europe.

Conclusions and recommendations (continued)

Prevention and control

- Careful consideration should be given to changing the HBV vaccination policy from adolescent vaccination to universal infant vaccination. The latter because it is better logistically and is cost-effective, but the change will take time (to adapt legislation and for new processes such as tendering); also the issue of infection and transmission in infants needs to be addressed.
- It was recommended that free and anonymous testing for HBV and HCV be introduced into existing services and location providing HIV testing.
- It was also recommended to create, re-establish or strengthen low-threshold services, in particular NSPs in most affected areas (nationally and in Budapest).
- Consideration should be given to the introduction of opt-out testing upon prison entry, annual routine provider-initiated testing at drug services and provide the relevant budget (so not only diagnostic testing should be made available).
- The law should be changed to decriminalize PWIDs and other stigmatized groups such as MSM and CSWs.
- Besides the recommended introduction of a universal infant immunization against HBV, HBV vaccination coverage should be extended.
- A HAV vaccination programme was recommended for certain populations.

Conclusions and recommendations (continued)

Treatment

- Participants highlighted the following positive aspects: there is a sufficient budget for treating an unlimited number of cases of hepatitis B and for 5000 HCV-infected patients a year; treatment is universally available – there is no restriction depending on stage of fibrosis; treatment is initiated immediately following diagnosis – there is no waiting list; and that treatment is free (with social insurance paying).
- It was recommended that given the widespread availability of DAAs the need for a national therapeutic committee to decide on eligibility for treatment be reviewed.
- The viral hepatitis registry should be further developed – at present SVR rates are recorded but no information is provided on routes of transmission or risk factors (admittedly a sensitive area in view of existing legislation).

Participants recognized the continuing need to undertake the following actions:

- If the WHO goals are to be met 3000 people need to be treated but only 1400 are currently being treated; the figure needs to be increased. National insurance coverage should be extended to everybody in the country – that ensures the basis for testing and treatment.
- The group also recommended that pangenotypic treatments be made available – they are not available at present - for those who failed first treatment with DAAs. About 200 patients are still on waiting list after failure. They are also more convenient and eliminated the need for genotype testing.

All the above elements and recommendations should be reflected in the national strategic plan.