

# The public health challenge of chronic viral hepatitis: An urgent need for screening

## Introducing the HEPscreen Toolkit

By Abby Falla, Irene Veldhuijzen and Jan Hendrik Richardus on behalf of the HEPscreen consortium

### Abby Falla

PhD Researcher at the Department of Public Health, Erasmus MC in Rotterdam

### Dr. Irene Veldhuijzen

Epidemiologist working at the Municipal Public Health Service in Rotterdam

### Prof. Dr. Jan Hendrik Richardus

Professor of infectious diseases and public health at Erasmus MC and PI of the HEPscreen project

E-mail: am.falla@rotterdam.nl

## The HEPscreen consortium partners:

### Hamburg University of Applied Science, Germany

Prof. Dr. Ralf Reintjes,  
Dr. Amena Ahmad

### University of Florence, Italy

Prof. Dr. Paolo Bonnani,  
Dr. Miriam Levi, Dr. Angela Bechini

### Queen Mary University of London, the UK

Prof. Dr. Graham Foster, Dr. Jan Kunkel

### NHS Grampian in Scotland, the UK

Dr. Maria K. Rossi

### Public Health Agency of Barcelona, Spain

Dr. Joan Cayla, Dr. Manuel Fernandez,  
Dr. Sandra Manzanares

### National Institute for Public Health and the Environment, the Netherlands

Dr. Susan Hahné

### National Center for Epidemiology, Hungary

Dr. Ágnes Csohán

### The Hepatitis C Trust, the UK

Charles Gore



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## Summary

Hepatitis B and C are stealthy viruses that, if left untreated, silently attack the liver and can cause serious liver disease including cancer decades later. Most viral hepatitis in Europe remains undiagnosed, a scenario evocatively described as a 'ticking time bomb' of liver disease-related ill-health and death. Without screening and treatment, mortality from viral hepatitis associated liver disease in Europe is predicted to increase and peak around 2030. The HEPscreen Toolkit has been developed through research including pilot studies and aims to motivate and enable others to respond to this public health challenge through the implementation of effective screening.

## Global policy context

The urgency and scale of action required on viral hepatitis is recognised in a number of high profile global policy documents, frameworks and guidelines. Spring 2014

was an especially important time as the first World Health Organization (WHO) guidelines dealing with hepatitis C screening and treatment were published in April<sup>(1)</sup>. In May, the World Health Assembly passed a resolution to improve the prevention, diagnosis and treatment of viral hepatitis as well as ensure equitable access among vulnerable groups including migrants<sup>(2)</sup>. These build on the WHO's Framework for Global Action on Viral Hepatitis (2012), which outlined the need for a comprehensive approach to viral hepatitis on a global scale including obtaining data for evidence-based policy, raising awareness, creating partnerships, and prevention, diagnosis, care and treatment.

## European policy interest

Action on screening for viral hepatitis at the European level contributes to two areas of the EU policy agenda. The infectious nature of viral hepatitis and the role of migration in contributing to the burden of disease place

the issue within the domain of cross-border health threats. The disproportionate impact on marginalised populations and therefore on health inequalities links to the principles of human rights, dignity and solidarity on which the EU was built. The European Centre for Disease Prevention and Control (ECDC), an EU agency with an infectious disease surveillance and coordination mandate, established a viral hepatitis network to improve data quality, bring stakeholders together, share good practices and support Member States to tackle the issue in their populations. A high level meeting in June 2014, under the auspices of the Greek EU Presidency and involving key stakeholders including the ECDC, examined national approaches, debated new developments and identified public policies that facilitate and improve access to treatment for hepatitis B (HBV) and C (HCV), especially in countries where austerity programmes are in place. Concluding outcomes are for health care systems to develop urgent responses to this smouldering public health crisis.

## The EU Health Programme-funded HEPscreen project

HEPscreen comprised ten partners in six countries – the UK, Germany, the Netherlands, Hungary, Italy and Spain. The central aim of our project was to assess, describe and communicate good practices in screening among migrant communities for hepatitis B and C. A key area of inquiry concerned the epidemiological evidence for the burden of hepatitis B and C among migrants in Europe. Building on this, we reviewed cost-effectiveness and whether the benefits of screening outweigh the harms. Another line of inquiry focused on recommended (i.e. guidelines) and current practices in screening, counselling, referral and treatment. Another key task was the collation and appraisal of translated information materials for people offered testing.

Finally, four pilot investigations using both innovative and well-known approaches to screening were conducted in Grampian (Scotland), London (England), Central Hungary including Budapest (Hungary) and Barcelona (Spain). These research and practice questions were

especially interesting given the three models of health system organisation found in our participant countries: Beveridge-style in the UK, Spain and Italy; Bismarkian in Germany and the Netherlands; and a transitional Semashko-Bismarkian model in Hungary. These six countries also differ in regards to their history and experience of migration. Italy and Spain experienced much more rapid and recent migration than the UK, Germany and the Netherlands, for whom migration dating back to the 1950s has been common. Migration to Hungary is also a recent phenomenon and remains less common compared to northern European nations. In this article, we summarise the key findings, recom-

### Box 1: Key HEPscreen findings and recommendations

- 1.** Screening needs to be scaled up. The small scale, time limited examples we identified are not sufficient to adequately address the public health challenge of chronic viral hepatitis. Guidelines and policy recommendations are urgently needed as a first step.
- 2.** There are pragmatic yet systematic responses that are relatively simple to implement. Routine (but voluntary) registration of country of birth by primary care, as part of a medical history, for example. This can improve access to screening for viral hepatitis-related liver disease among people from endemic areas.
- 3.** Clear referral pathways need to be central in the design of screening interventions. Highly complex and at times ineffective patient pathways, along with the complex nature of viral hepatitis, compound other health service-related and patient-side barriers facing migrant groups. Effective linkage to specialist care, including antiviral treatment, is crucial to maximise the possible health impact of screening.

mendations and practical tools developed during our three year study.

## Viral hepatitis in Europe - successful preventive measures

Public health primary prevention measures including antenatal HBV screening, HBV vaccination, sterile medical/dental procedures, a safe blood supply and harm reduction activities among people who inject drugs (PWID) have successfully halted much transmission of hepatitis B and C across Europe. However, variable speed of adoption over time has resulted in distinct geographical variations in prevalence across Europe; prevalence in the general population varies from 0.1% to 5.6% for chronic hepatitis B infection and from 0.4% to 5.2% for chronic hepatitis C<sup>(3)</sup>. The burden of disease is generally low in the north western countries and higher in the south eastern region of Europe. However, as primary prevention measures do little for those who are already infected, there remains a large undiagnosed burden of chronic viral hepatitis.

## Viral hepatitis in Europe - the impact of migration

Over centuries an exporter of people, it is only in the last half century that Europe became a receiver of people. Migration has major impacts on physical, mental and social dimensions of health, and presents new public health challenges for receiving societies. Indeed, most chronic viral hepatitis infections in Europe are among people born in hepatitis B or C endemic countries. In an epidemiological analysis, we found that even though migrants make up a minority (~4 – 15%) of the population in the six HEPscreen study countries, the top five most affected migrant communities (defined by country of origin) account for between ~10 - 45% of the burden of chronic hepatitis B in these countries. In endemic countries, HBV is most commonly transmitted from mother to child during pregnancy or in early childhood. Unsterile medical, shaving or dental equipment are most common exposure risks in areas where hepatitis C is common. However, as a large proportion

of HCV in Europe is also found among PWID, infection is often associated with illicit drug use. This has stigmatised infection and overshadowed the health needs of people from endemic countries.

## Current action on screening for chronic viral hepatitis in Europe

Outside Europe, national guidelines from Canada, the US and Australia recognise the need for screening among people from endemic countries. We investigated availability of guidelines within Europe via a literature search and an extensive survey among expert clinicians and public health professionals. We also investigated current practices for screening among risk populations, including migrants from endemic areas. In the six HEPscreen European countries, we identified one guideline, from the UK, about screening among people from endemic areas<sup>(4)</sup>. Our assessment of current practices mirror this: other than antenatal HBV and HBV/HCV blood donor screening, there is no other systematic HBV/HCV screening for in the six study countries. We did identify some good practice examples of screening among people from endemic countries, mostly from the UK or the Netherlands, but these examples remain time-limited, small-scale and scarce.

## The four main ways of screening

One objective of the project was to identify and synthesise the fragmented knowledge of effective ways of screening among migrant communities. As part of the HEPscreen Toolkit, we compiled a repository of the good practice examples we identified. There are four main ways of screening (Box 2). Each method has ethical, epidemiological, evaluative and economic implications. GPs, community nurses and sexual health clinics are often in a well-trusted position to raise awareness and offer testing opportunistically to their patients with country of origin-related risk factors. Combining with an existing infectious disease screening programme, such as tuberculosis (TB), builds on existing infrastructure, including staff trained in such issues. Each model varies in the scope and means to raise awareness in

the community and to provide information to people offered testing. For example, public awareness information and education sessions and materials are a key part of community outreach screening models.

## Restricted access to treatment among vulnerable groups

Legal and other barriers to health care, such as socio-economic vulnerability and insecure housing or employment conditions, are suggested as partial explanations for the lack of screening among migrants. Previous studies also found lower preventative health care usage<sup>(5)</sup> and poorer health outcomes from viral hepatitis among migrant groups<sup>(6)</sup>. We were interested to find out whether there are formal treatment restrictions in place in the six countries for vulnerable risk groups such as asylum seekers, undocumented migrants, people without health insurance and PWID. Results from a survey of over 60 gastroenterology or infectious disease specialists involved in the direct clinical care of chronic viral hepatitis patients show a distinct lack of consensus among professionals in the same country about which patients are entitled to which sort of care. This discordance was especially surprising given that the health care system or policy context often defines access to treatment for these specific groups. Our results suggest that health care entitlement guidance is unclear, unavailable or unknown to medical professionals most involved in treating patients. A lack of consensus may also either be an important explanation of, or in fact caused by, the limited existence of screening programmes that target these higher risk populations. Significant restrictions in treatment for undocumented migrants and people without health insurance were reported by the majority in the UK, Germany, the Netherlands, Hungary and Spain; only in Italy did the majority report there to be no or few restrictions. Our results suggest that risk groups such as undocumented migrants, people without health insurance coverage and asylum seekers are rarely screened for viral hepatitis and if found to be chronically infected, do not reliably reach secondary care.

### Box 2: The four main implementation models of screening

1. **Outreach-based combining educational/awareness raising with testing either in the community or in a closed/fixed setting** like a workplace or institution.
2. Offering **opportunistic HBV/HCV testing as part of other health care encounters in primary care** such as GPs, public health services or sexual health clinics.
3. **Extending existing screening initiatives already targeting migrants such as TB screening** to include viral hepatitis.
4. **Invitation-based models using municipal population or patient registries** as a means to increase access to screening among individuals born in countries of medium/high viral hepatitis endemicity.

## Access to antiviral treatment for hepatitis B/C in Europe

The centralised approval system for pharmaceutical innovations for viral diseases in Europe, the European Medicines Agency (EMA), appraises applications for grant approval for single marketing authorisation in all EU countries. Decisions on pricing and reimbursement are generally made at the national level however, and differences between Member States in availability, uptake and use of new medication, especially for HCV, have been suggested<sup>(7)</sup>. Using the same survey described above, we found that first generation protease inhibitors for HCV, boceprevir and telaprevir, are either significantly or completely restricted for use Italy, Spain and Hungary despite European-level approval. Epidemiological, health system, clinical and economic factors offer some explanations for this finding. Since our sur-

vey in 2012, three new HCV drugs have been approved for use in Europe, with future antiviral development expected. But with expected costs in excess of €60,000 per patient, differences in approval and subsequent use of these expensive options are likely to emerge across Europe.

## Health information in a linguistically and culturally diverse Europe

Providing accurate, appropriate and understandable information to people from endemic countries is a means to raise awareness, improve the acceptability of screening, secure informed choice, normalise testing and alleviate feelings of stigma, shame and fear. To enable health professionals across Europe to provide this in a written format to people offered testing, HEPscreen has developed a tool to create multi-lingual leaflets. The culturally appropriate and simple to understand content is available in 40 languages, from which any combination of two can then be selected to generate a health information leaflet. It has been particularly written for with people with limited health literacy or people from cultures where norms and values about unsafe sex and illicit drug use heighten stigma when viral hepatitis is explicitly associated with these routes of transmission.

## The Toolkit - practical support for implementation

The HEPscreen Toolkit builds on the increasing recognition of the need for systematic action on viral hepatitis. Epidemiological HEPscreen tools can assist public health planners and other professionals to estimate the burden among people from endemic countries, as well as to understand which communities are most at risk of viral hepatitis-related liver disease. Focusing screening on higher risk groups increases the chance of finding positive cases and makes more effective use of scarce health care resources. Knowledge of which communities are most affected can add to local community expertise and be used to tailor approaches to specific cultural, linguistic, and social norms and values. To complement this, culturally appropriate, understand-

### Box 3: Key aspects of the HEPscreen Toolkit

1. Videos and animations about the public health challenge of chronic viral hepatitis
2. Epidemiological tools to assess the burden of chronic viral hepatitis among migrants
3. How to...guides, case studies and videos about the different ways of screening
4. A repository of good practice screening projects
5. A tool to create multi-lingual leaflets for people offered hepatitis B/C screening - with over 40 languages available
6. Tools to support primary care to offer testing to their patients from endemic areas, including a pre-test discussion checklist
7. Good practice recommendations for post-test counselling and linkage to specialist care

able pre-test information leaflets are available in over 40 languages. A pre-test discussion checklist, compiled through a literature review and survey can aid health professionals offering testing to discuss viral hepatitis with culturally and linguistically diverse populations. Practical guides and case studies of the different ways of screening can help to design evidence-based screening programmes. An indicator set and guide to evaluation can help to monitor screening programmes after implementation. These are a few examples of how aspects of the HEPscreen Toolkit can raise awareness, improve knowledge and motivate action to tackle the smouldering public health crisis of viral hepatitis in Europe. As Da Vinci once said: "Knowing is not enough; we must apply. Being willing is not enough; we must do."

## Scientific consensus – time for action

The Global Burden of Disease study (2010) ranked viral hepatitis 9th in the list of causes of mortality, with a larger disease burden in Europe than HIV and TB<sup>(8)</sup>. Studies also show that screening in populations with an expected prevalence of 2% or higher is likely to be cost-effective<sup>(9)</sup>. Yet, viral hepatitis receives much less public health, policy or political attention in comparison to HIV. The complex epidemiology and natural history, insufficient advocacy in the field, the global economic crisis and the immense pressure on health care expend-

iture are important explanations<sup>(10)</sup>. The current climate of economic austerity, rumbling xenophobia and an increasing demand for health care resources is not ideal to advocate for resource allocation to the secondary prevention of a condition mostly limited to some of the most marginalised and vulnerable members of society. But in the midst of this noisy, highly politicised debate it is our responsibility as public health professionals to articulate the case for evidence-based disease prevention and health promotion.

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