Hepatitis B

Revealing a silent killer

A Workshop at the

European Parliament

hosted by Thomas Ulmer, MEP
and Holger Krahmer, MEP

Workshop panelists:

This report is based on the contents of a workshop held in the European Parliament on 25 April, 2006.
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1. Introduction

When people speak of infectious disease, their immediate thought is of HIV/AIDS. If hepatitis is mentioned, most people think of Hepatitis C or possibly of the risk of contracting hepatitis A from food or water whilst travelling abroad. For most people, hepatitis B is most likely to be an afterthought.

Understanding and awareness of the threat posed by the hepatitis B virus is low. Most people would not know how to recognise the symptoms. Most professionals would not be able to describe the evolution of disease or know what course of treatment to recommend. And finally, most policymakers do not appreciate the public health threat that it represents.

Yet hepatitis B represents a significant public health problem in Europe and around the world.

- **2 billion people worldwide** have been in contact with Hepatitis B.
- Of these, **350 million** have chronic hepatitis B virus infection. This is 5% of the global population.
- In Europe, **14 million people** live with chronic hepatitis B.
- Hepatitis B is **100 times more infectious** than HIV.
- Hepatitis B is **as common as Hepatitis C.**
- **80% of all liver cancer** in the world is caused by hepatitis B.
- The hepatitis B virus is the **most common carcinogen** after tobacco in man.
- **Safe and effective vaccination exists,** however it is unevenly implemented across the world and across Europe.
- **Less than 4% of patients** diagnosed with chronic hepatitis B receive treatment.

On 25 April, 2006, a group of Members of the European Parliament (MEPs), national policymakers, hepatologists, public health specialists and patient representatives gathered together to propose a way forward to address hepatitis B in European policy.

This report draws from discussions held at this workshop. Its aims are to:

- **Create an understanding** of the high prevalence and infectiousness of Hepatitis B.
- **Raise awareness** of the importance of Hepatitis B as a 'silent killer' in Europe.
- **Create a sense of urgency** to position Hepatitis B alongside Hepatitis C and HIV on the policy agenda at EU and national level.
- **Encourage the sharing** of best practices between EU member states.
- **Advance the development of EU guidelines** to increase standards for prevention, diagnosis and treatment of Hepatitis B.

Tackling Hepatitis B will require true partnership across different sectors, policy spheres, geographies and academic disciplines. There is a real opportunity for us to work together in a concerted fashion to build a comprehensive European programme to limit the burden posed by Hepatitis B on our societies and our populations. We hope that this report will serve as a helpful starting point to achieve this goal.

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2. The Issues

A poorly understood disease

What is hepatitis B?

Hepatitis B is a viral disease that can lead to cirrhosis (liver damage), liver failure and liver cancer. The hepatitis B virus (HBV) is one of many viruses (the others being A, C, D and E) that can cause hepatitis.

Signs and symptoms

Symptoms of acute hepatitis B are difficult to identify as they are not specific to hepatitis. They include loss of appetite, tiredness, vomiting, fever, joint pain, nausea, abdominal pain and jaundice. **Even at the chronic stage of infection, many people are unaware of symptoms. Symptoms are absent in up to 40% of cases.**

Diagnosis and treatment

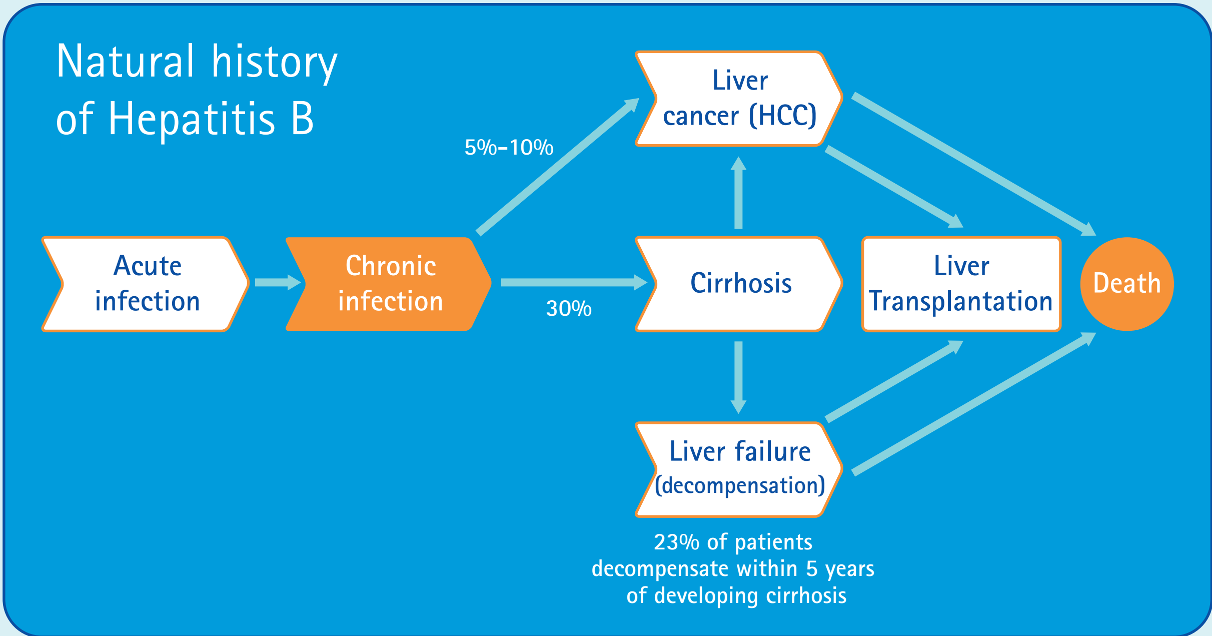
Identification of the hepatitis B virus is done by various tests, where one looks for hepatitis B markers.

Treatment of chronic hepatitis B consists mainly of antiviral drugs, which may limit progression of the disease. **If not treated in the early stages, liver damage may be too advanced to benefit from treatment and cancer may have already occurred.** The only solution in the case of end-stage liver disease or small-size liver cancer is often liver transplantation. Viral hepatitis B and C are the leading cause of liver transplants in the industrialised world.

Natural history of hepatitis B

Hepatitis B starts by being an acute disease that can develop into a chronic condition.

- 95% of adults infected by the hepatitis B virus will get rid of the virus from their bodies after a few months – they have had acute hepatitis B.
- 5% of those infected will not be able to get rid of the virus and will develop chronic hepatitis B.
- In contrast, children, particularly newborns, have a much higher risk of developing chronic disease.
- If left untreated, 30% of those with chronic hepatitis B will develop cirrhosis.
- **Nearly half of people whose chronic infection develops into cirrhosis will die from liver failure or cancer.**



(Torresi J & Locamini S. Gastroenterology 2000:118 (Suppl 1): S83-103; Fattovich G, et al. Hepatology 1995;21:77-82)

A neglected public health threat

High prevalence and mortality

Five percent of the world's population is chronically infected with the hepatitis B virus. Epidemiology of the disease varies significantly from one region to another and is impacted upon by population movement and migration.

Liver cancer is the 5th most prevalent cancer in the world. And **80% of cases of liver cancer are caused by the hepatitis B virus. Hepatitis B is thus the most common carcinogen after tobacco in man.**

Epidemiological data are scarce on hepatitis B. The table below presents the best available data on the incidence, prevalence and mortality associated with HBV.

Hepatitis B	Worldwide	Europe
Prevalence/incidence	~ 2 billion with past/present infection	1 million new infections/yr
Chronic HBV infection	350-400 million	14 million*
Deaths	0.5-1.2 million/year	24,000-36,000/yr
Ranked cause of death	10th worldwide	n/a

* in the European Union. Other data for Europe are for entire European continent.

Source: Lavanchy 2004; Conjeevaram et al. 2003; Van Damme et al, 1995.

100 times more infectious than HIV

The hepatitis B virus replicates at much higher levels than HIV or the hepatitis C virus (HCV) and is present in most body fluids from infected individuals. As a result, **hepatitis B is 100 times more infectious than HIV and 10 times more infectious than Hepatitis C. It is also more prevalent than both HIV and Hepatitis C.** Yet it is not on the public health agenda.

Comparing the numbers: Hepatitis B, Hepatitis C and HIV

	Hepatitis B	Hepatitis C	HIV
Number of people infected worldwide	350 million	170 million	50 million
New cases per year worldwide	10-30 million	2-4 million	3-6 million
Infectiousness	100 times more than HIV	10 times more than HIV	100 times less than hepatitis B

Hepatitis B is 100 times more infectious than HIV. It is the most common carcinogen after tobacco in man and causes 80% of cases of liver cancer.

How does one get infected?

Hepatitis B virus is transmitted by contact with the blood or body fluids of an infected person. Unlike hepatitis A or E, it is not spread by contaminated food or water, nor can it be spread casually in the environment.

The main routes of transmission are:

- *Sexual transmission:* through protected or unprotected sex with an infected person (transmission by body fluids can occur even in case of sexual protection)
- *Contaminated needles or sharp instruments:* of particular risk for health workers, IV drug users, and those receiving injections or transfusions where blood has not been screened for hepatitis
- *Mother-to-infant:* infected mothers may transmit Hepatitis B through blood to their babies during the first year of life
- *Child-to-child:* through contact within the household

The first two causes currently are the most frequent in Europe, whereas mother-to-infant transmission is extremely frequent in Asia and child-to-child transmission is very frequent in Africa.

Hepatitis B is preventable

Safe and effective vaccines against Hepatitis B have existed since 1982. **Vaccination is more than 95% effective at preventing acute and chronic infections from developing. However, it cannot cure chronic hepatitis from occurring in those already infected.**

In 1991, the World Health Organization recommended to add the Hepatitis B vaccine to childhood immunisation schedules, and 116 countries have done so.

A Taiwanese study showed that vaccination against hepatitis B was associated with a reduction in deaths from liver cancer (HCC) in children. **Thus in many ways, Hepatitis B vaccine is the very first vaccine that prevents a major cancer.**

3. The challenges

Low awareness

The first fundamental challenge facing hepatitis B is low awareness. Hepatitis B is not on the political agenda. Awareness is low amongst the general public, public health authorities, and treating physicians. In each of these groups, ignorance carries particular risks:

Low awareness amongst **individuals**:

- Puts individuals at risk of contracting hepatitis B
- Stops those at risk from getting tested
- Stops those at risk from getting vaccinated
- Stops those with chronic hepatitis B from taking it seriously

Low awareness amongst **public health authorities**:

- Increases the amount of disease transmission
- Prevents adequate surveillance
- Allows for lack of rigour for infection control, eg. in blood banks
- Prevents adequate action to tackle this disease now

And because of **low awareness** among professionals:

- Patients do not get suitable treatment early on in the course of disease
- Those at risk of developing chronic hepatitis B do not get regular monitoring.

Whoever the risk groups are and whatever the mode of transmission may be, chronic hepatitis B is a serious condition that must be taken seriously. **Blaming those who get infected is always unjustified and must not be used to excuse inaction.**

Stigma

Low awareness is also compounded by stigma against people affected by hepatitis B. Attitudes are reminiscent of those reserved for HIV-positive people when the AIDS/HIV outbreak began in the 1980s. There is a sense that this is a disease 'of others'. We blame people for bringing the infection onto themselves through promiscuous behaviour, unprotected sex, illegal immigration or i.v. drug use.

Hepatitis B, of course, can affect anyone. It is, for example, the greatest infectious occupational health risk for health workers.

Underdiagnosed and undertreated

Hepatitis B is both underdiagnosed and undertreated. Why?

- Up to 40% of those infected with chronic hepatitis B do not have any symptoms.
- Even if they do have symptoms, many people may not be aware that these could be due to hepatitis B.
- Fear of social stigma may make people reluctant to seek medical help.
- Fear of discrimination (eg. through employment) may hold people back from being diagnosed.
- Many of the people at greatest risk of contracting chronic hepatitis B belong to vulnerable groups (eg. immigrants and i.v. drug users) that may not have access to health care.

Limited treatment options

Less than 4% of patients diagnosed with chronic hepatitis B receive treatment. Why?

- **Hepatitis B is a silent disease:** The virus can quietly and continuously attack the liver over a period of several years without being detected. Many individuals will not have any noticeable symptoms and will only get diagnosed once the disease has progressed.
- **Awareness of treatment options for hepatitis B is low** amongst health professionals.
- **Access to existing treatments**, particularly newer and more expensive treatments, is often limited for budget reasons.
- There is **lack of agreement on standards of best practice** for hepatitis B across Europe.

Early treatment is important: it can help slow the progression of liver disease in those chronically infected. Yet access to existing treatments is severely limited in many European countries.

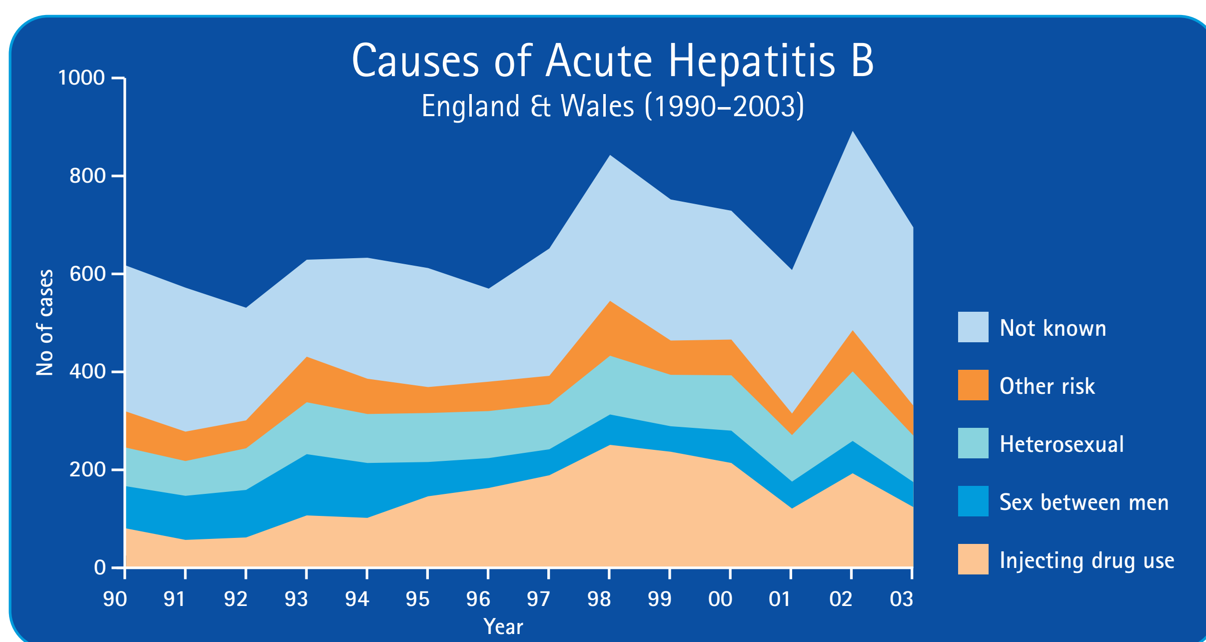
A poor evidence base

Actions and policies on hepatitis B are limited by lack of available data on the disease, its prevalence and mortality, and changing epidemiology of the hepatitis B virus. There is also a dearth of data on the clinical effectiveness and cost-effectiveness of available treatments, limiting their uptake in practice.

In Europe, much of the epidemiological data on hepatitis B is more than 10 years old. Also, little is known about how issues like immigration are changing the pattern of hepatitis B across Europe.

The figure below illustrates the changing face of Hepatitis B. It is striking to note that most of the causes of infection are unknown.

Changing causes of transmission for Hepatitis B (UK data)



Source: Health Protection Agency, UK

Targeting at risk groups

Certain groups are at greater risk of contracting chronic hepatitis B. For each of these groups, a targeted approach is needed to gather information on the burden and presentation of hepatitis B, help reduce the risk of chronic disease, ensure access to appropriate treatment for those affected and limit transmission from infected persons.

At risk: children

95% of newborns infected by HBV-carrying mothers run the risk of developing chronic hepatitis B as their immature immune systems cannot cope with the virus. This risk is substantially lower if infection occurs at a later age: 3 out of 10 of those infected between the ages of 1-5 years will develop chronic disease and less than 1 out of 20 of those infected after the age of 5.

Another group at risk consists of internationally adopted children, who often come from areas of high or moderate HBV prevalence and are thus high carriers of HBV.

Children of infected mothers and internationally-adopted children are at particularly high risk of developing chronic hepatitis B. Targeted screening and regular monitoring of these children is critical to contain the risk of disease.

At risk: immigrants

There is an inflow of at least 1 million immigrants each year into the EU, with an increasing diversification of the origin of immigrants (International Committee on Migration). Though prevalence rates vary by country of origin, prevalence of HBV infection in immigrants from South-east Asia, sub-Saharan Africa and East Europe has been found to be higher than in the native population in several European countries.

The national prevalence of HBV is in some countries being augmented due to the influx of HBV carriers. For example, data from Denmark and the Netherlands suggest that up to 80-90% of the total HBV prevalence is attributable to immigration (Gjorup et al, 2003; Kretzschmar et al, 2002).

At risk: Health care workers

Each year 304,000 health care workers in Europe are exposed to at least one percutaneous injury with a sharp object contaminated with HBV. The probability of acquiring bloodborne infection is 18-30% depending on type of exposure, infectivity of the patient etc (Pruss-Ustun et al 2005). **Yet awareness of this risk and safety measures to prevent infection are not applied uniformly across European Union member states.**

4. Priority solutions

A clear EU mandate

All data point to the need for a concerted action to limit the risk and burden of Hepatitis B. National initiatives are not enough, as **hepatitis B is a disease that knows no borders.** As a major cause of cancer and a highly infectious and prevalent infectious disease, hepatitis B clearly falls within the EU remit of public health.

The EU has a clear role to play to bring hepatitis B onto the policy agenda. The EU may create avenues for research, harmonise surveillance and set standards for prevention and care of chronic hepatitis B across Europe.

Hepatitis B is the second most common carcinogen in Europe. The EU should replicate the tremendous efforts it has made to fight tobacco and target resources to fight hepatitis B.

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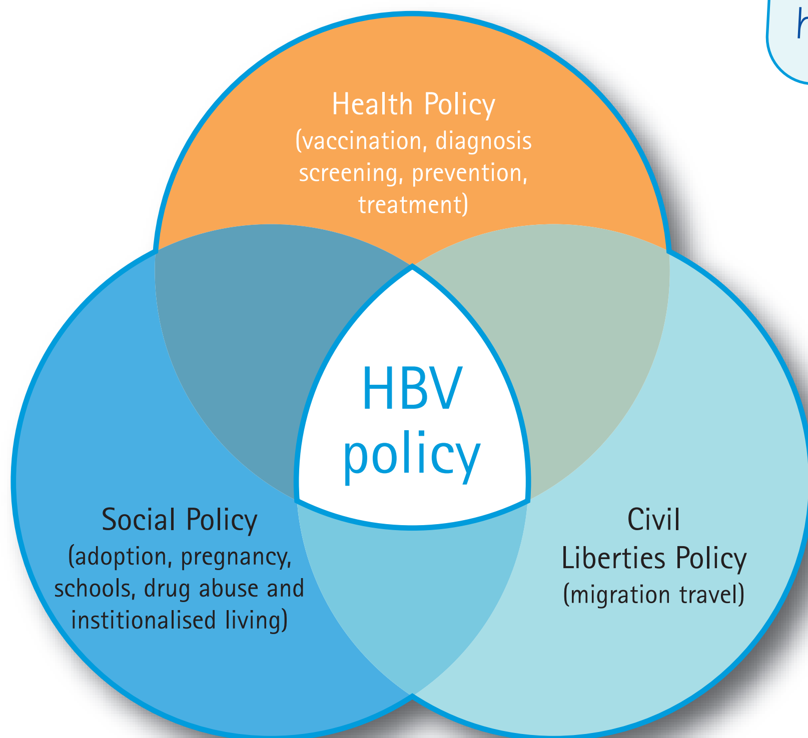
A joined-up policy on hepatitis B

Addressing Hepatitis B within Europe is not just a matter of health – it requires a holistic approach and a concerted action that spans social policy, immigration and educational policy, and civil liberties policy. **To address all the inherent complexity in the way hepatitis B affects our societies, a joined-up approach to policy is needed.** This is illustrated below.



Access to appropriate information on hepatitis B is urgently needed. Information will help individuals make informed choices about prevention and treatment and help them self-manage their own health (lifestyle, diet, exercise etc) to minimise the impact of disease.

More information to patients about risks, prevention and treatment options

Ignorance of how hepatitis B manifests itself is probably the main barrier to good care and management for people infected with hepatitis B.

- **Education about hepatitis B** should start early, possibly in schools. School nurses should be aware of the condition and its risks.
- **Public health campaigns and media communications** may help raise awareness of the general patient population.
- **Information leaflets** should be made available at GP offices, public health and STD clinics, in hospitals and blood donation centres.
- And finally, specific communication campaigns are needed to **reach at risk, vulnerable groups** who may be excluded from the regular health care system, namely i.v. drug users and immigrant communities.

Fostering communication about hepatitis B

Fostering communication between patients, professionals and policymakers has been a key success factor in reducing ignorance and stigma for other conditions such as depression and schizophrenia. A similar communication platform on hepatitis B needs to be created between patient advocates, professionals, public health authorities and the media.

The European Liver Patients Association (ELPA) plays a key role in raising awareness of hepatitis. This and other advocacy groups need to be involved in policy development and recognised as a tremendous resource for patients, professionals and policymakers.

We need to talk about hepatitis B. Only open communication will help 'normalise' hepatitis B and help reduce stigma towards those affected by it.

The European Association for the Study of the Liver (EASL) aims to promote liver research and improve the treatment of liver disease around the world. The association plays an important role in raising awareness of liver disease and acts as a network linking hepatologists around the world.

Weblink: www.easl.ch

Sharing best practice

One of the best ways to dispel ignorance about hepatitis B and to reduce divergence in treatment approaches is by sharing best practices amongst professionals. The European Commission is fostering the idea of sharing best practice in the area of health. This is clearly needed in the field of viral hepatitis care.

The European Association for the Study of the Liver (EASL) was created as a forum to foster exchange amongst hepatologists on liver disease, including hepatitis B. Initiatives such as these require dedicated funding and support at a European level.

Better surveillance systems and data

Surveillance of Hepatitis B is patchy across Europe. A surveillance system on Hepatitis B, which gathered data from 26 countries, used to exist, called EuroHepNet. However funding for this initiative (which came from the European Commission) stopped in August 2005.

With the establishment of the European Centre for Disease Control, there is a real opportunity to consolidate and standardise surveillance systems across Europe and improve the quality of epidemiological data available on Hepatitis B.

Solid, reliable epidemiological data on hepatitis B is urgently needed across Europe to allow policies and actions to focus efforts where they are most needed and to keep up to date with the changes in disease patterns and geographic distribution.

There is a currently a lack of scientific consensus on effectiveness data on preventive measures and treatments for Hepatitis B which is a huge impediment to establishing best practice for the prevention and management of hepatitis B.

A stronger research base

Research is severely lacking on all aspects of Hepatitis B. We need to develop specific research programmes in order to:

- Reassess prevalence and incidence figures, particularly in light of migration patterns and possible mutations in the virus.
- Gain further insights into mechanisms of treatment failure and viral resistance.
- Develop a better understanding of what works in terms of preventative approaches to Hepatitis B.
- Determine what works to raise awareness of the public and develop effective communications strategies that will reach at-risk groups.

Improving vaccination across Europe

European countries have implemented different vaccination policies. In some countries, vaccination is mandatory in some parts of the population, such as newborns and at-risk populations. In others, it is recommended but voluntary.

In addition, targeted vaccination programmes are particularly important to reduce the risk of disease in infants whose mothers are infected with HBV.

Improving access to care and improving management of disease

Dedicated resources are needed to ensure that Hepatitis B is appropriately managed in the community and that patients are receiving the best care possible. This includes **removing barriers to access to effective treatments,** ensuring appropriate training of physicians and clinical personnel, and establishing standard protocols for care of people with chronic hepatitis B.

Particular care must also be given to ensure access to care to vulnerable groups at risk of Hepatitis B.

Targeted programs for immigrants

A targeted program of vaccination, testing and monitoring should be introduced to halt the possible transmission of the disease in immigrant populations.

Any vaccination program that is compulsory needs to respect individual civil rights. Also, it is critical that they aim to engage and empower immigrants being vaccinated to help raise awareness of hepatitis B and help them manage their risk and eventual disease within their families.

'Our will is not to stigmatise immigrants but to give them access to vaccines. Access to treatment for immigrant populations is a huge issue of equity, also relevant for i.v. drug users and all vulnerable groups.' (workshop participant)

'Vaccination is a huge issue in terms of solidarity. You cannot have a European policy of eradication if some countries do not vaccinate. Thus, clearly, there is a need for a common protocol for vaccination across the EU'. (workshop participant)

A recommended approach for immigrants has proposed that:

- All immigrants from countries with high or intermediate prevalence of HBV should be screened for Hepatitis B markers.
- All HBV-negative individuals from families where at least one member has positive HBV markers should be vaccinated.
- All newly arrived children should be tested at the time of arrival for markers of Hepatitis B and retested again 6 months later.
- Children with no evidence of recent or past HBV infection should be vaccinated
- Children positive for HBV markers should undergo additional testing.

Source: Miller 2005

Targeted approaches for health care workers

As has been discussed previously, infection with HBV is the major infectious occupational health risk for health care workers – greater than HIV or Hepatitis C. Targeted programmes are therefore needed within all health care settings to protect health care workers from the risk of contracting HBV.

Suggested approaches include:

- Educational programs and training of health care workers
- Reporting an occupational exposure
- Compulsory HBV vaccination (responders, non-responders)
- Management of occupational exposures (immediate treatment of the exposure site, risk assessment, management of exposures to HBV, follow-up)

Source: Puro et al, 2005

A first important step has been taken by the European Parliament in 2006 with the issuing of a report on the protection of health care workers from bloodbourne infections cause by needlestick injuries. In this report, the Parliament requests the European Commission to undertake detailed measures to protect healthcare workers from bloodbourne infections. This example demonstrates that the European Union institutions can greatly contribute to the prevention of hepatitis B.

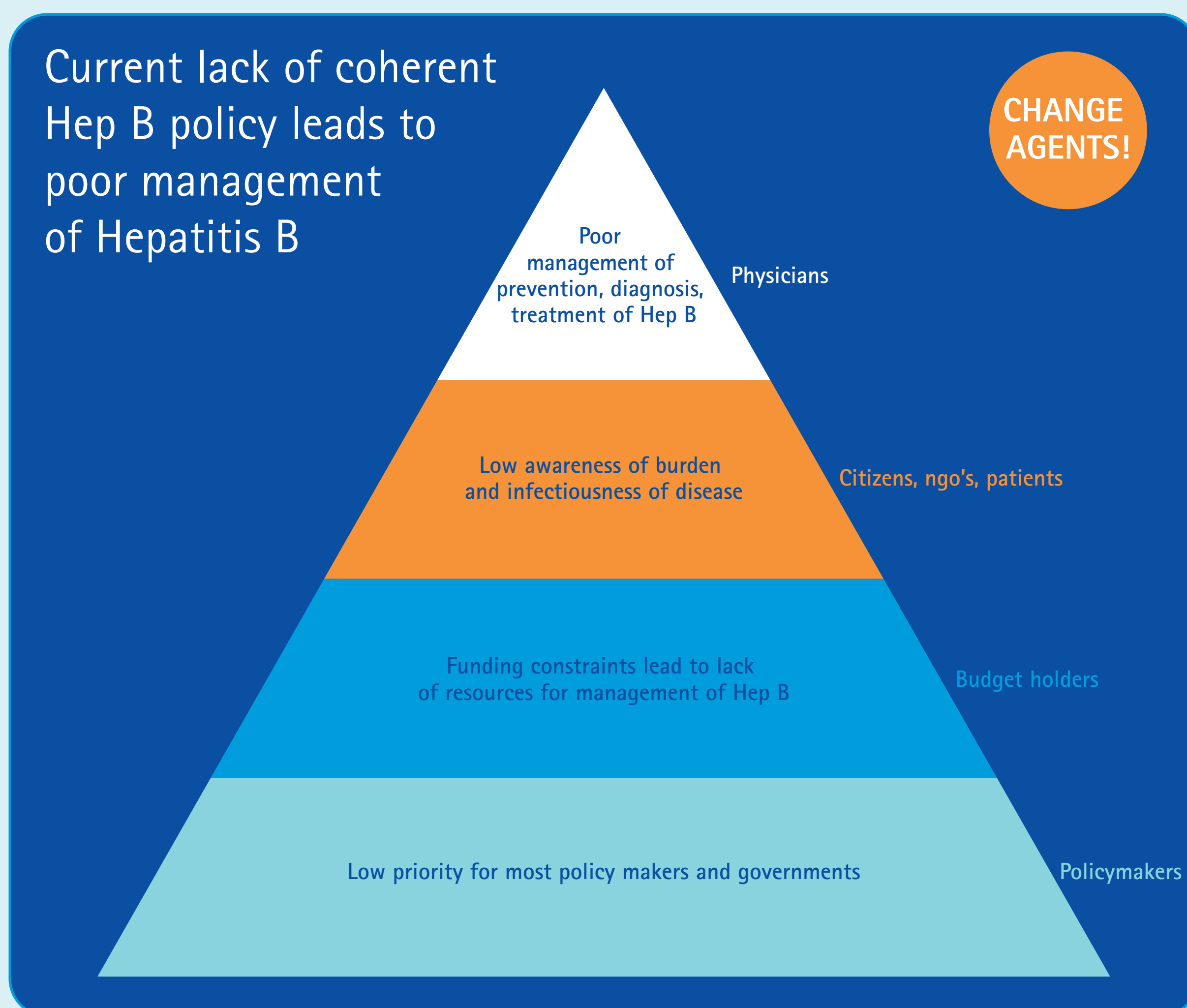
5. Conclusions

Hepatitis B is a neglected public health threat. It is 100 times more infectious than HIV and more prevalent than both Hepatitis C and HIV around the world. 14 million Europeans have chronic hepatitis B and nearly a quarter of these will die of liver failure or liver cancer. Hepatitis B is the second major carcinogen after tobacco in man, as it is responsible for 80% of liver cancer.

Hepatitis B is preventable: vaccination is more than 95% effective and since 1991 the WHO has recommended universal vaccination of children. Treatment may help slow the progression of disease. Targeted measures combining vaccination, testing and monitoring may help limit the spread of disease amongst those most of risk.

There is an urgent need to act now. Awareness of hepatitis B is low and management of the disease is inadequate. There is a lack of solid data upon which to build policies. The policy landscape is barren when it comes to hepatitis B. It is not accorded the same position as hepatitis C on the policy agenda.

Multiple barriers are working together against the development of a coherent European policy on hepatitis B. It is only when each of these barriers is removed and all relevant players enact their parts that we can hope for policies to be developed, implemented and successful.



6. Calls to Action

'Infectious diseases, such as HIV/AIDS and Hepatitis C, have enjoyed the appropriate political focus in European policy; however Hepatitis B is currently not high on the European agenda and deserves similar awareness and support for new treatment options.' (Thomas Ulmer, MEP)

As mentioned above, different players must act together to fight hepatitis B in Europe.

European policymakers:

- Europe must take the lead in putting Hepatitis B on the political and policy agenda.
- The European Commission should develop a **holistic strategy** to improve the prevention, control and clinical management of Hepatitis B. This strategy should be developed in consultation with patients, professionals and public health experts.
- In the spirit of **'health in all policies'**, the European Commission should ensure that the causes and impact of Hepatitis B are reflected in all relevant policy areas.
- The Commission should lead to develop best practice guidelines for **Hepatitis B prevention, treatment and monitoring.**
- These guidelines should provide clear direction to ensure that people identified via screening programs as infected with Hepatitis B get **access to clinical evaluation and management,** including recommending existing treatments when appropriate.
- The European Commission should recommend and fund **targeted programmes** aimed at halting transmission of hepatitis B amongst **immigrant communities and other vulnerable groups.**
- The European Commission should help support the creation of a forum for exchange and sharing of best practices on addressing hepatitis B. This forum could be housed within the Commission or within an existing organisation, such as the European Association for Studies of the Liver (EASL).
- The Commission should call for dedicated research on all aspects of hepatitis B within its research funds (European Social Fund, structural funds and others).

National governments:

- Member States should implement programs to support the objectives of a new EU strategy on hepatitis B.
- National governments should set up joined-up policy frameworks that mirror the EU recognition that 'health is in all policies', and include consideration of the impact of hepatitis B on employment, education, migration, family and other social policy arenas.
- They should integrate Hepatitis B prevention and control into existing national public health programs and couple these with information campaigns about prevention and treatment options.
- They should ensure that vaccination programs are aligned with the WHO recommendations and monitor adherence.
- National Ministries and Departments of Health should support training programs for health care professionals regarding the prevention, detection and clinical management of Hepatitis B.
- Governments should allow for sufficient resourcing and funding of care, services and treatment for hepatitis B to allow best practice guidelines to be implemented.

Patient advocacy groups

- Patient advocacy groups must be consulted and involved at all levels of policy-making to ensure that healthcare is patient-centred.
- They must continue to help raise awareness of the importance of hepatitis B and help find a platform for hepatitis B alongside hepatitis C.
- They should work with policymakers, the media and professionals to ensure that appropriate messages related to hepatitis B are communicated and that misconceptions about hepatitis B are overturned.
- They should continue to provide information and support to people infected with HBV and encourage them to take control of their conditions and seek appropriate care.

The European Centre for Disease Control

- The European Centre for Disease Control should make surveillance of hepatitis B across Europe one of its immediate priorities and conduct a feasibility study to see how an extensive surveillance network might best be implemented.
- Following the lead of the US Center for Disease Control, the ECDC should use collected data to help raise awareness and inform European audiences about hepatitis B via its website.

Health care professionals:

- Health care professionals should acquaint themselves with the natural history and epidemiology of Hepatitis B.
- They should learn to recognise the 'hidden' symptoms of hepatitis B and offer their patients early treatment to halt progression of hepatitis B disease.

Health care workers:

- Health care workers should ensure that they are fully protected against the risk of infection from hepatitis B and that appropriate safety measures are put into place within their work settings. They should enjoy the similar type of protection through adequate 'health and safety at work measures' that other professional groups enjoy through existing EU legislation.

Public/private partnerships

- Public/private partnerships have a clear role to help fund research and implement pilot initiatives at community level that may help improve the prevention and management of hepatitis B, particularly amongst vulnerable groups.

Local communities:

- Local communities must educate themselves about hepatitis B and understand its impact on all aspects of society (employment, immigration, adoption, healthcare).
- Local community leaders, particularly of immigrant communities from high-prevalence countries, must take an active role in raising awareness and reducing stigma of hepatitis B and encourage individuals to take responsibility for appropriate risk containment.

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