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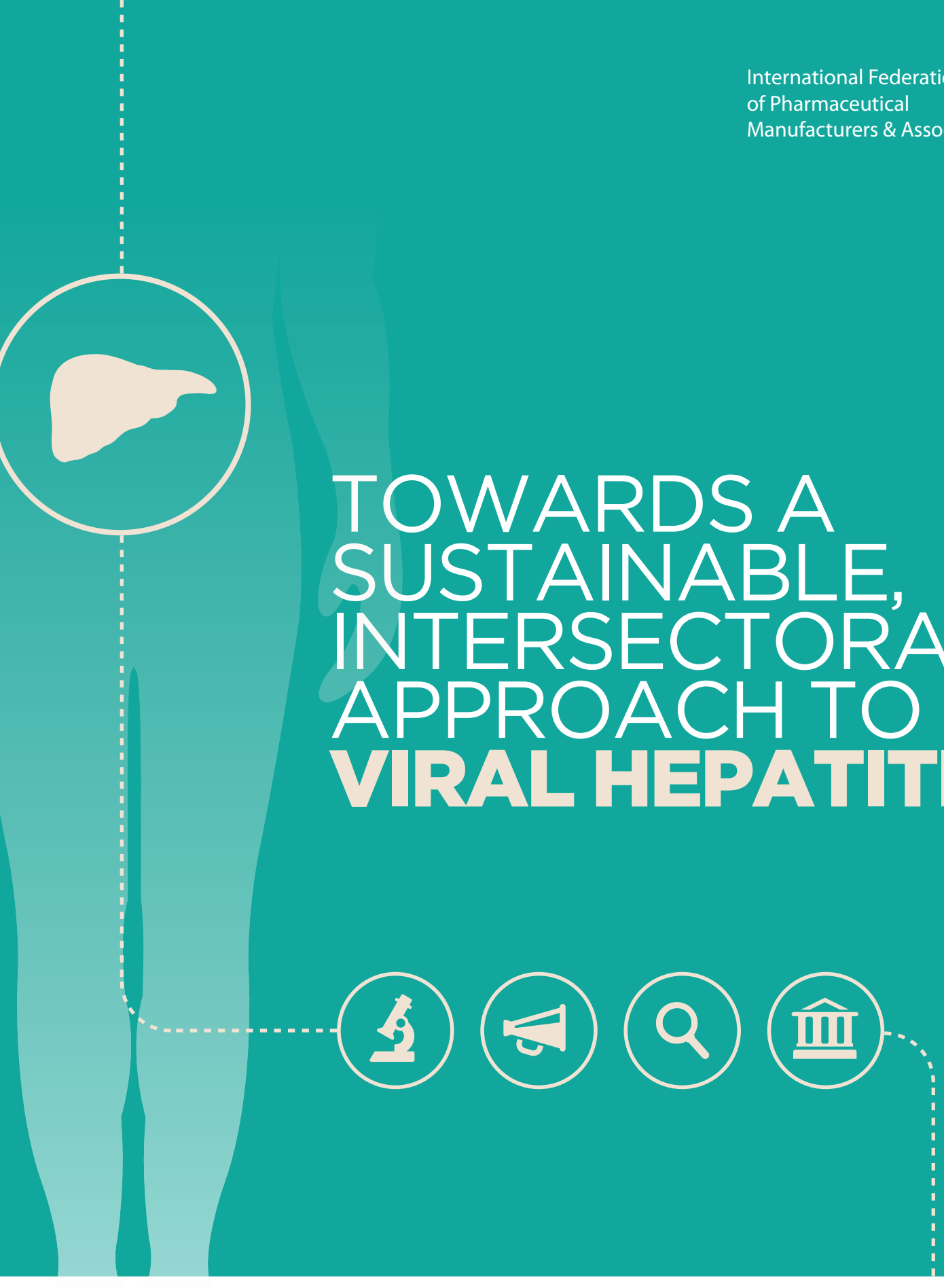

TOWARDS A SUSTAINABLE, INTERSECTORAL APPROACH TO **VIRAL HEPATITIS**

MAY 2014

IFPMA

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EXECUTIVE SUMMARY

Viral hepatitis is a significant public health problem, with **one in every 12 people** worldwide chronically infected[5] and **1.6 million deaths** per year.

In the past years, improvements in screening practices have enabled healthcare providers to identify increased cases of advanced liver diseases in chronically infected patients. Due to the large number of people unaware that they are chronically infected with hepatitis B (HBV) and hepatitis C (HCV) the identification of new advanced liver diseases will continue to increase as people progress in their disease and more screening is undertaken. This will be coupled with an increased burden on healthcare systems and society.[6]

Viral hepatitis causes 75% of the world's primary liver cancer, which is now the **2nd most common cause of cancer death** worldwide.[8]

The WHO has called on governments to invest sufficient resources to help reduce the burden of viral hepatitis in their respective countries, however the **policy response so far has been inadequate**, with only one third of countries having a national plan in place for viral hepatitis.

The **research-based biopharmaceutical industry** has invested years of research and development into finding solutions to the growing burden posed by viral hepatitis. Vaccination against HBV is available in 177 countries worldwide, and has led to 90% decrease in mortality from HBV-related complications, including liver cancer, in vaccinated children.[15]

Advances in treatment for HBV have transformed it into a treatable condition. And most recently, the introduction of newer drugs for HCV – the direct acting antivirals (DAAs) – have increased cure rates for patients with HCV from 50 to over 90%.

Yet **significant limitations to support access** exist across the world – due to combination of inadequate funding, stigma surrounding the condition, limited understanding of the disease by physicians and patients themselves, and lack of comprehensive models of care that provide linkages between screening and care.

Addressing these multiple challenges requires a **holistic and intersectoral approach**, in which all key stakeholders – including the biopharmaceutical industry – are encouraged to work together to create sustainable, locally-appropriate solutions to limit the burden posed by viral hepatitis on health care systems, society and, most importantly, people infected and their communities. It is only through taking such an intersectoral approach that **a sustainable response to viral hepatitis** may be found, and significant steps towards its effective eradication, as a public health concern, may be envisaged.

VIRAL HEPATITIS – KEY FACTS AND FIGURES

	HBV	HCV
How many people are chronically infected?	350 – 400 million[1]	180 million[1]
What proportion of the world population is chronically infected?	5%[1]	2%[1]
How many people die each year of viral hepatitis?	600,000[2]	350,000 – 500,000[3]
What proportion of infected cases progress to chronic infection?	The risk varies by age: 80-90% if infected at birth but 5% if infected as an adult[2]	55-85%[3]
How infectious is the virus?	50-100 times more infectious than HIV	10 times more infectious than HIV
What are the main routes of transmission?	Mother-to-child, intravenous drug use, sexual contact, household contact with infected person	Exposure to infected blood (intravenous drug use, needle stick injuries,...). More rarely: mother-to-child, sexual contact.
Which regions are most affected?	75% cases are in Asia. High prevalence in SubSaharan Africa, Amazon, Southern parts of Central and Eastern Europe, but worldwide presence[2;4]	Most affected regions are: Central and East Asia and North Africa but worldwide presence.[3;4]
Is a vaccine available?	Yes	No
Is treatment available?	Up to 95% of cases of HBV are treatable, but cure is not yet possible.	With current treatments, at least 90% of cases are curable.
How many patients receive treatment?	5-10% in Asia, 20% in Europe, fewer in poorer countries.	2-3% in high income countries, fewer in poorer countries.

I. WHAT IS VIRAL HEPATITIS?

Viral hepatitis: the 'silent epidemic' that kills 1.6 million people every year

"Although the burden of disease is very high, the problem has not been addressed in a serious way for many reasons, including the relatively recent discovery of the causative viruses, the mostly silent or benign nature of the disease in its early stages, and the insidious way in which it causes chronic liver disease. Decades-long delay between infection and the expression of chronic liver disease or liver cancer made it difficult to link these diseases to earlier HBV or HCV infections. All these factors have resulted in 'the silent epidemic' we are experiencing today."

(WHO Prevention and control of viral hepatitis infection: a framework for global action, 2012)

WHAT IS VIRAL HEPATITIS?

Viral hepatitis is an inflammation of the liver caused by one of the five hepatitis viruses (A, B, C, D or E). Hepatitis A and E are water-borne, and usually self-limiting diseases. Hepatitis B, C, and D are typically transmitted through blood but can also be transmitted through other bodily fluids (eg. through sexual contact).

The main public health burden comes from HBV and HCV. With both these conditions, disease progression may take place very slowly over several years without any obvious symptoms, so that many people remain unaware of their infection until serious complications emerge. These include cirrhosis, hepatocellular carcinoma (HCC), the major form of liver cancer, and premature death.

Table 1: HBV and HCV – key facts and figures

	HBV	HCV
Number of people chronically infected	350 – 400 million[1]	180 million[1]
% of world population chronically infected	5%[1]	2%[1]
Number of deaths per year	600,000[2]	350,000 – 500,000[3]
% infected cases that progress to chronic infection	The risk varies by age: 80-90% if infected at birth but 5% if infected as an adult[2]	55-85%[3]
Infectiousness	50-100 times more infectious than HIV	10 times more infectious than HIV
Main routes of transmission	Mother-to-child, intravenous drug use, sexual contact, household contact with infected person	Exposure to infected blood (intravenous drug use, needle stick injuries,...). More rarely: mother-to-child, sexual contact.
Global distribution	75% cases are in Asia. High prevalence in SubSaharan Africa, Amazon, Southern parts of Central and Eastern Europe, but worldwide presence[2;4]	Most affected regions are: Central and East Asia and North Africa but worldwide presence.[3;4]
Number of cases of HCC caused by the virus:	10-15% in Europe, 20% in North America, 70% in Asia and Africa (Japan is an exception: 10-20%).	60-70% in Europe, 50-60% in North America, 20% in Asia and Africa (Japan is an exception: 70%).

ONE IN EVERY TWELVE PEOPLE INFECTED

One in every 12 people worldwide is infected with viral hepatitis[5] , and 1.6 million people die from the complications of viral hepatitis every year. Most of this burden falls on lower-resourced countries, where lack of availability of appropriate screening, diagnosis, and specialist

care result in many patients not receiving timely diagnosis and treatment. Even in higher-income countries, where public health prevention measures have helped control the rise of new infections, the number of people chronically infected with HBV and HCV is increasing, as is the number of cases of advanced liver disease, liver cancer and related healthcare costs.[6]

- In Asia Pacific, three times more people die of viral hepatitis than HIV/AIDS and nine times more than malaria.[7]
- More people die of HCV in Europe and North American than of HIV/AIDS.

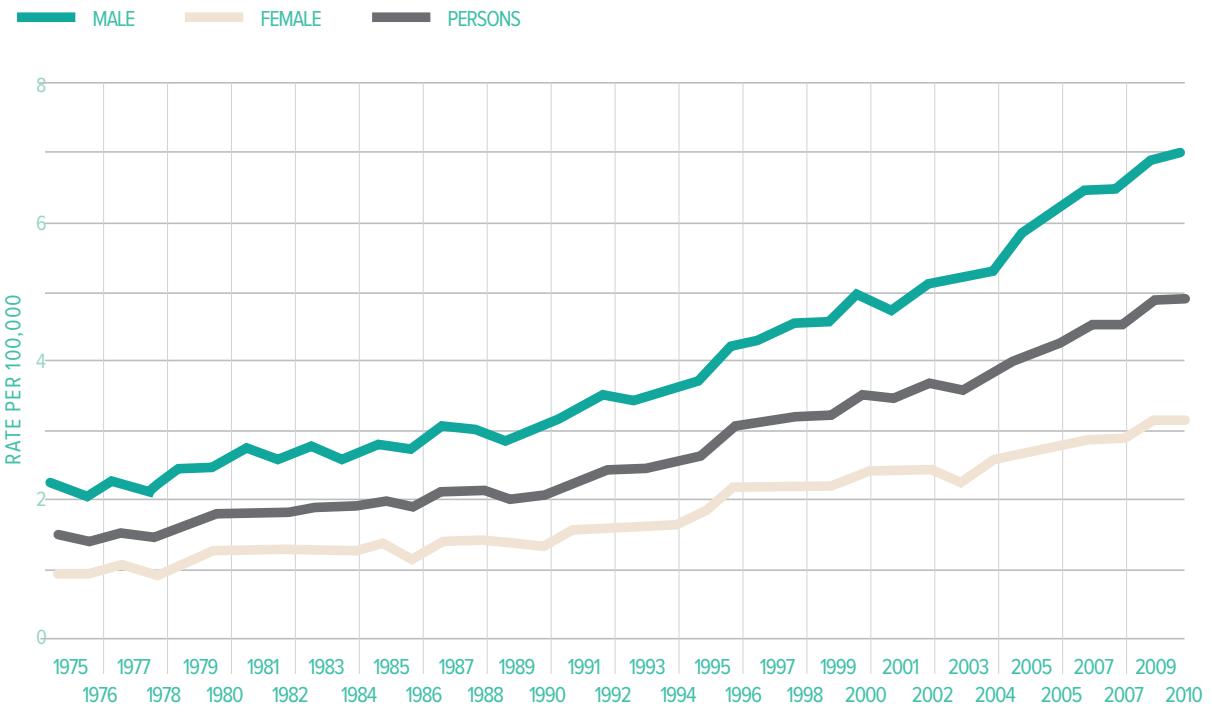
THREE-QUARTERS OF LIVER CANCER CASES WORLDWIDE

Viral hepatitis causes 75% of the world's primary liver cancer, which is now the 2nd most common cause of cancer death worldwide.[8] In many countries, the incidence of liver disease is expected to increase three-fold by 2017,[9] and mortality from liver cancer is increasing steadily.

A HUGE COST TO SOCIETY

This significant public health burden translates into considerable economic costs linked to viral hepatitis, in terms of direct medical costs but also lost productivity[10] and premature death due to advanced liver disease and liver cancer. **Improving the detection and early treatment of patients is therefore needed to help avoid the development of these serious complications.**

FIGURE 1: Increase in age-standardised mortality rates from liver cancer in the UK, 1971-2011



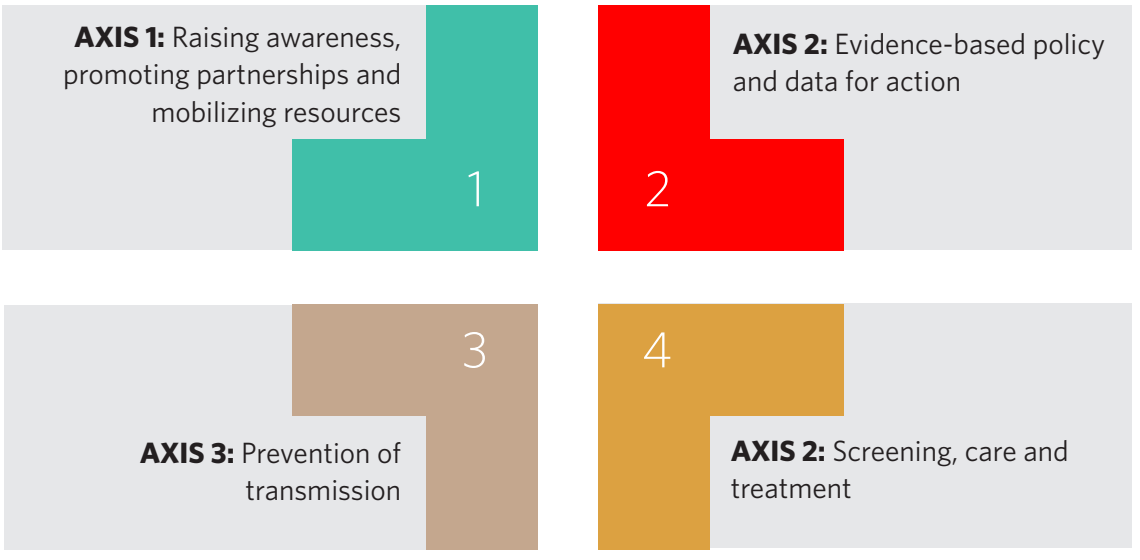
II. MANAGEMENT OF VIRAL HEPATITIS: WHAT CAN BE DONE?

THE NEED FOR A HOLISTIC APPROACH

Developing an effective, global response to viral hepatitis is complex, for a number of reasons. First, there is significant variability in the epidemiology of HBV and HCV by region, in terms of genotype distribution (particularly for HCV), risk groups most affected and prevalence rates. Secondly, due to its 'silent' nature, **screening** is vital to ensure that infected individuals seek early diagnosis and treatment and that they do not infect others unknowingly. Thirdly, **targeted prevention measures** are needed to prevent multiple routes of transmission of infection, including blood bank safety, safe injection practices in medical settings, needle exchange programmes for people who inject drugs (PWIDs). And finally, resources must be in place to ensure **appropriate access** to vaccines, diagnosis, testing, and treatment to reduce the burden posed by the condition and offer the best outcomes possible to patients.

To meet these objectives, the WHO has recommended a **holistic approach** to the management of viral hepatitis, as is illustrated in the four axes of its 2012 framework for global action on viral hepatitis.[11]

FIGURE 2: The four axes of the WHO global framework on viral hepatitis[11]



MANAGEMENT OPTIONS FOR VIRAL HEPATITIS: THE ROLE OF INNOVATION

The past few decades have seen considerable advances in the prevention and treatment of viral hepatitis, so that today, HBV is 95% preventable, 95% of cases are treatable, and at least 90% of cases of HCV can be cured. Key innovations in the field of viral hepatitis include:

An effective and safe vaccine against HBV:

A safe and effective vaccine against HBV has existed for several years and the WHO has recommended universal HBV vaccination of all children and adolescents as well as vaccination of high risk groups since 1991. Today, 177 countries have implemented national vaccination programmes against HBV, leading to decrease in the incidence and mortality due to HBV infection as well as a decrease in chronic liver disease and liver cancer in children.[12,13] Vaccination has been shown to be effective against all known HBV genotypes,[14] and once immunised, no booster is required (ie. immunogenicity is long-lasting). Also, due to the virological association between the HBV and D viruses, HBV vaccination has led to a parallel decline in incidence of hepatitis D.[13]

There is currently no effective vaccine against HCV, although research efforts continue in this domain.

Antiviral therapy for HBV:

There are two therapy options for HBV: nucleot(s)ides, which act by suppressing the viral load, and pegylated interferon, which stimulates the immune system.[16-18] Sustained virological response has been observed with both of these treatment options in approximately 30-40% of HBV patients, leading to significant reductions in the risk of progression to cirrhosis, liver cancer and eventual death.[19;20] Because oral treatments for HBV medicines must be taken for several years, and sometimes for life, adherence to treatment and the development of resistance to the medicines is an important issue. However, some of the newer drugs available have been shown to have a high threshold for resistance, making them more suitable for long-term therapy.[21] Research is also ongoing into combination of treatments that may offer a cure for HBV and also allow for a reduced duration of treatment.

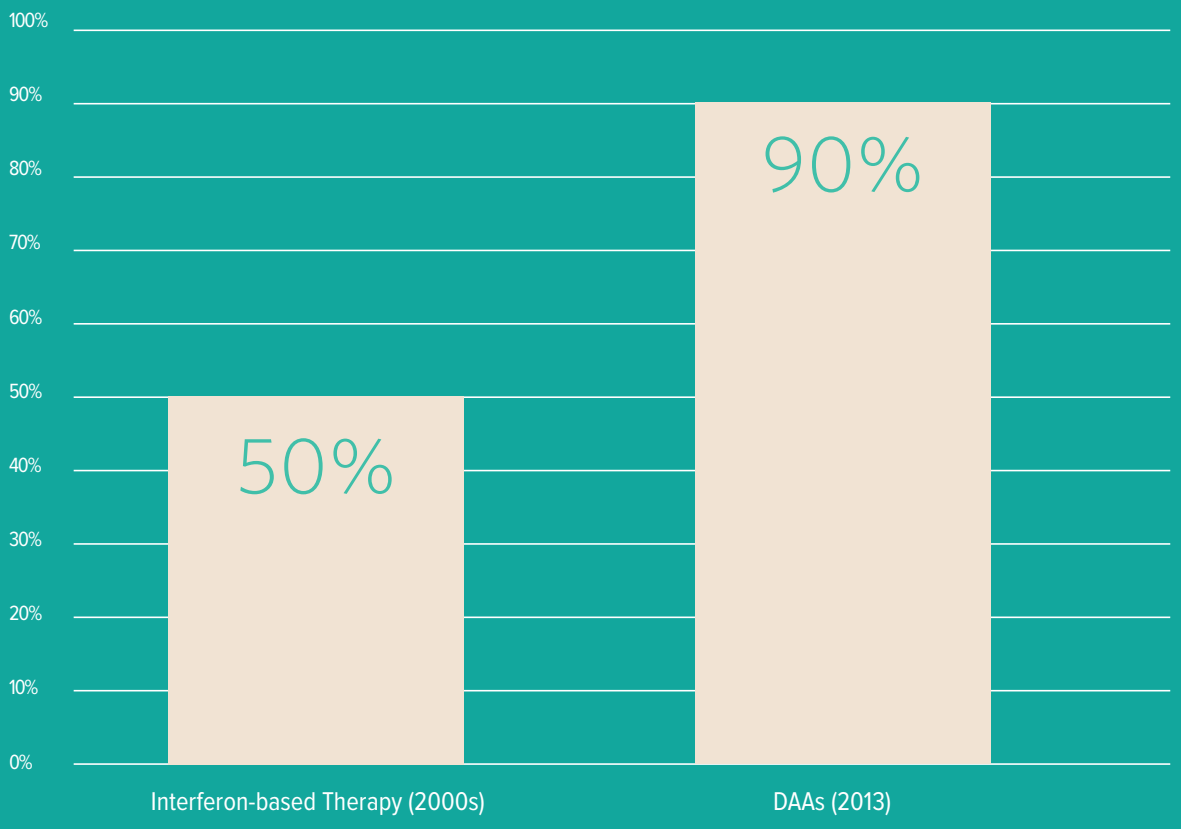
Direct Acting Antivirals (DAAs) for HCV:

The introduction of direct-acting antiviral (DAA) agents for the treatment of HCV in recent years has revolutioned outcomes for patients (see Figure 3). Prior to their introduction, standard treatment was interferon, an injectable treatment which is given for 48 weeks, is associated with debilitating, flu-like side effects and is only able to cure about 50% of patients.

The first generation of DAAs, introduced a few years ago, was effective against genotype 1 only, however the newer generation of DAAs, the first of which was introduced in 2013, may be effective against other genotypes as well, thereby offering the **potential for cure to over 90% of HCV patients** around the world. The 2014 WHO guidelines on HCV recommend use of the newest DAAs on the basis of their high cure rates and lower toxicity for patients.[22]

Universal vaccination of infants was implemented for the first time in Chinese Taipei in 1984. There, vaccination has led to a 90% decrease in mortality from HBV-related complications, a 90% decrease in HCC mortality and a 80% reduction of HCC incidence.

FIGURE 3: The evolution of cure rates for HCV



There are **over 20 investigational DAAs currently in phase II or III trials:** These have shown promising results in terms of offering high cure rates, lower toxicity and shorter duration of treatment.[23;24] Ongoing research efforts are also focused on identifying regimens that may be effective in treating patients who have typically not responded well to treatment, including patients with certain genotypes, those with cirrhosis, co-infected with HIV, and post-liver transplantation patients.[25]

III. TOWARDS THE EFFECTIVE MANAGEMENT OF VIRAL HEPATITIS: CHALLENGES IN IMPLEMENTATION

In 2010, the WHO first raised the alarm on the rising toll of viral hepatitis, and the World Health Assembly Resolution WHA63.18 was introduced, calling on governments to commit appropriate resources and health system infrastructure to reduce the burden of viral hepatitis in their respective countries.

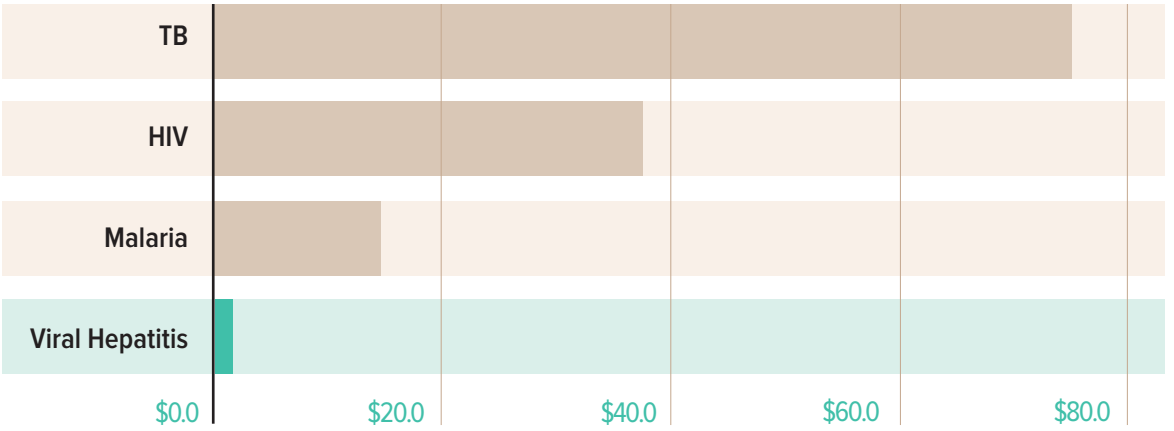
Current challenges include:

- **Only one third of countries have a national plan** in place to tackle viral hepatitis.[26]
- **Relative funding for research and programmes** on viral hepatitis is low in international organisations compared to HIV/AIDS (see Figure 4).
- Viral hepatitis is **absent from the Millennium Development Goals**
- Viral hepatitis is **excluded from the Global Fund on HIV/AIDS, Malaria and Tuberculosis**.

Poor prioritisation at the policy level is reflected in widespread gaps in access to hepatitis prevention, screening and treatment in many countries. For example:

- Approximately **30% of children around the world remain unvaccinated against HBV**, and efforts to overcome economic and logistic barriers to implementation of vaccination programmes are needed, particularly in poorer-resourced countries.
- **Nosocomial spread of viral hepatitis**, particularly in dialysis units, remains a significant problem in many countries[14] – calling for greater investment in prevention measures in health care settings.
- **Testing for HCV and HBV is only available in about 30% of all countries**.[26] In Europe for example, only France and Scotland have government-led screening programmes against HCV, whilst other

FIGURE 4: Estimated budget allocation by the WHO towards viral hepatitis and other conditions



countries such as the Netherlands have targeted specific regions or risk groups.[13;27] Greater availability of screening programmes for HBV and HCV is urgently needed.[13;28-30]

- **Treatment rates** for HBV and HCV remain very low: It is estimated that **4-10%** of patients in Asia, and **20%** of patients in the United States and Europe receive treatment for HBV.[28] Figures for HCV are even lower: only **2-3%** of HCV patients receive treatment in high-income countries, and figures for low and middle income countries are still even lower. Greater access to treatment should be a priority in all countries.

It is important to recognise that **limitations in access to prevention and care are not caused by lack of funding alone**, and that many other factors contribute to inadequate management of viral hepatitis. These include:

- ***Low awareness*** among the general public and those at risk of HBV and HCV***:* 65% of those infected with HBV and 75% of those infected with HCV are unaware of their condition prior to diagnosis;**
- ***Stigma*:** Viral hepatitis is still associated with a high degree of stigma, partly because of the high prevalence of disease among people who inject (or formerly injected) drugs. Stigma may partly explain, for example, why uptake of screening, even when it is available, is so low and why many patients who test positive for HBV or HCV do not seek treatment;
- ***Insufficient physician understanding*** of the natural history of HBV and HCV, and limited knowledge of available treatment options: Physicians may also fear poor adherence due to toxicity of former treatments;
- ***Inadequate linkages between screening and care,*** particularly in primary care, so that

patients who test positive are often not referred to appropriate treatment and care;

- ***Lack of reliable epidemiological and economic data,*** and lack of harmonisation on data collection standards,[31] which makes it difficult to convey the scale of the problem to policymakers and encourage investment into appropriate care delivery;
- ***Access barriers for marginalised populations:*** Prisoners, PWIDs and sex workers may face many barriers to accessing prevention and care for HBV or HCV, and often have a difficult relationship with health care providers. For example, some healthcare professionals may be reluctant to treat PWIDs on the basis that they run a high risk of re-infection and poor adherence. This practice goes contrary to mounting evidence that the treatment of PWIDs is effective and may elicit a '**treatment as prevention**' response, allowing for reduced transmission among PWIDs who are successfully cured of the virus.[22;32]
- ***Treatment barriers for people co-infected with HIV:*** Co-infected individuals are at greater risk of liver disease progression, liver cancer and death, and are therefore among those in greatest need of treatment and care.[33;34]

IV. ADDRESSING THE CHALLENGES: THE NEED FOR AN INTERSECTORAL APPROACH

In light of the challenges posed by viral hepatitis, the WHO has recommended that an **intersectoral, multi-pronged** response is needed to address the mounting toll of viral hepatitis worldwide.[11;22] This must **involve all stakeholders**, including the private sector, to implement sustainable and comprehensive solutions that take into account the resources available in each particular country and engage all local stakeholders in achieving desired goals.

Besides the development of innovative vaccines and treatments, the biopharmaceutical industry has a track record of working with local actors to ensure that these technologies are delivered safely and appropriately over time.

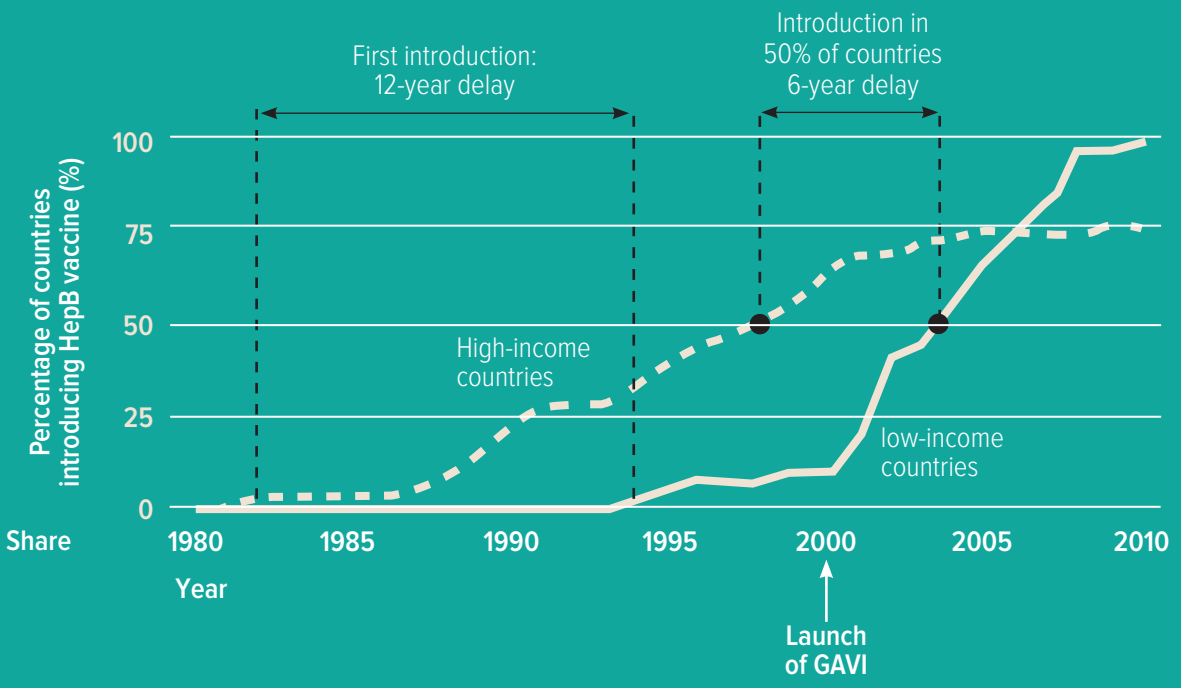
What follows are a few promising examples of intersectoral efforts, in which industry has played an essential role, which illustrate the potential of such initiatives and hopefully provide inspiration for future development.

1. THE GLOBAL VACCINE ALLIANCE (GAVI): PROVIDING ACCESS TO HBV VACCINES IN POORLY-RESOURCES COUNTRIES

GAVI – the Global Alliance for Vaccines Initiative – has been supporting the introduction of vaccination against HBV since 2000. GAVI is a global, intersectoral collaboration, and includes a number of industry partners, whose role is to invest in the development of new vaccines and in enhanced global vaccine manufacturing capacity. This includes helping to provide facilities in developing countries, educating healthcare providers and developing technologies to facilitate vaccine distribution.

GAVI's mobilization of a multi-sector response has allowed for an acceleration of vaccination against HBV in poor-resourced countries which achieved higher HBV vaccination rates as compared to high-income countries. Between 2000-2011, 296 million children were immunised against HBV thanks to GAVI support, representing a 3-fold increase in HBV coverage.

Hepatitis B vaccine introduction in high and low-income countries



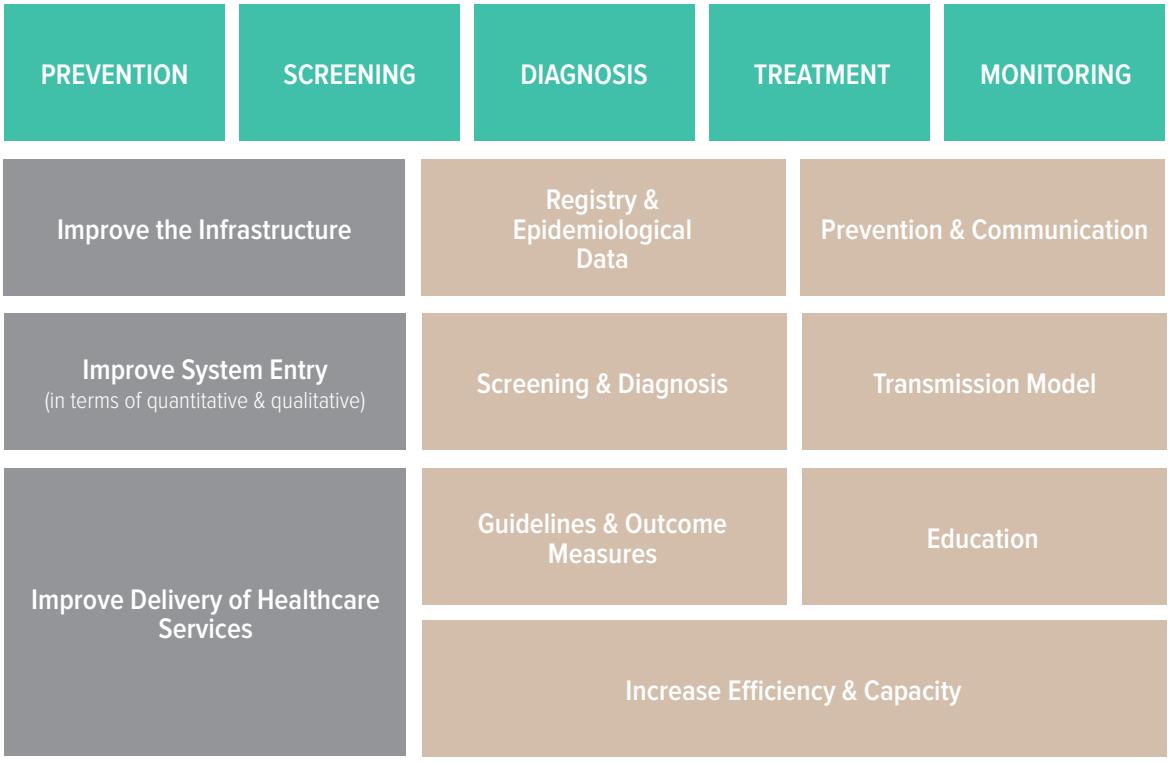
See more at: http://www.gavialliance.org/support/nvs/hepb/#sthash.10KJwvxR.dpuf

2. BUILDING LOCAL COALITIONS TO FIGHT HEPATITIS - "TOGETHER AGAINST HEPATITIS" IN ROMANIA

Romania has the highest prevalence of HCV in Europe (3.23%) and only 1% of patients receive treatment for their disease. In 2013, the 'Together Against Hepatitis' Coalition was initiated with the goal to make Romania a world leader in best-in-class HCV management and health research by 2020. The coalition is led by the Ministry of Health and is supported by several biopharmaceutical companies, including Janssen, Bristol-Myers Squibb, AbbVie and Merck Sharp and Dohme (MSD).

The programme aims to provide up to 50,000 HCV patients with best-in-class treatment every year by 2020 and to create an innovative, efficient and sustainable model of care for HCV, which may be replicated in other countries. The creation of this programme (illustrated below) was inspired from the national anti-HIV programme, and key components include: systematic data collection systems to monitor progress and public health impact, improved logistics, infrastructure and delivery of all HCV components of care and expanded funding sources for treatment and care through the creation of innovative payment mechanisms.

Key items - Operational model



For more information: www.impreunaimpotrivahepatitei.ro

3. TECHNOLOGY TRANSFERS TO BUILD LOCAL CAPACITY FOR MANUFACTURING OF HBV VACCINES IN CHINA

In the 1980s, there were more than 120 million people living with HBV in China and an estimated 10 percent of China's 20 million newborns were infected every year. In September 1989, MSD signed a Technology Transfer Agreement with the Chinese government, providing China with the technology to produce the world's most advanced genetically engineered recombinant Hepatitis B vaccine. During the technology transfer, MSD brought Chinese scientists and technicians to America for training, and helped China establish vaccine production plants in Beijing and Shenzhen. This technology and equipment are still benefiting the Chinese people. The recombinant vaccine has made a huge impact on public health in China.

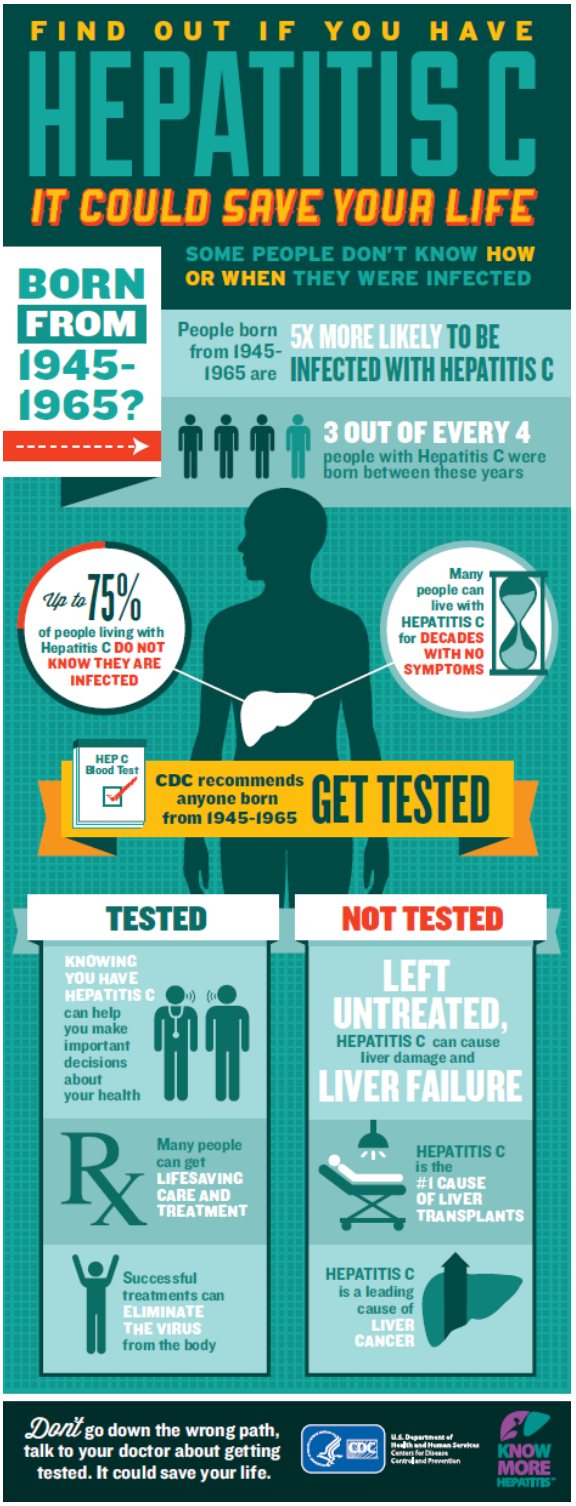
Figures from the Chinese Center for Disease Control and Prevention suggest that the programme has prevented more than 30 million infections in the past two decades and the vaccine is administered to approximately 93 percent of infants annually, reducing the proportion of infections amongst infants under 5 from 10.1 percent in 1987 to 0.96 percent in 2006. Between 1992 and 2010, the number of carriers in China fell by about 80 million; the number of children positive for antibodies (HBsAg) has fallen by about 19 million.

4. TARGETING SCREENING TOWARDS THE MOST RELEVANT POPULATIONS – THE KNOW MORE HEPATITIS CAMPAIGN IN THE UNITED STATES

In 2011, the Centres for Disease Control (CDC) in the United States set up the KNOw More Hepatitis campaign to encourage people born between 1945-1965 to get tested for HCV, on the basis that focusing screening effects on this target group offers the greatest promise of delivering a significant return on investment in terms of reduction of disease burden.[29;35] In order to implement the campaign, the CDC set up the CDC Foundation to allow the private sector to partner and provide funding for CDC research and prevention activities through the Viral Hepatitis Action Coalition.

The campaign has been a huge success and today, both the Centre for Disease Control and the US Preventive Services Task Force recommend that all adults born between 1945-1965 be tested once for HCV in the United States.[18;36] These recommendations stem from a series of public consultations, community engagement programmes and expert reports suggesting that HCV now kills more Americans than HIV/AIDS.

An example of a poster used for the campaign is shown on the right.



5. TARGETED APPROACHES FOR HIGH-RISK GROUPS, PARTICULARLY PWIDS: THE SCOTTISH NATIONAL PLAN FOR HCV

The Scottish National Plan for HCV was launched in 2006 by Public Health Scotland and has been heralded as leading example around the world of a comprehensive programme to tackle HCV which engages all local stakeholders to achieve its goals. As part of the National Plan, a number of major research projects looking at optimising ways to treat PWIDs in Scotland have been funded jointly by the Scottish government and a number of biopharmaceutical companies.

The programme established comprehensive managed care networks which encompassed prevention, screening and care, and allowed to engage 'difficult to reach' groups of patients, such as prisoners and PWIDs. It included a peer-to-peer education programme and a 'Break the Cycle' programme aimed at helping practitioners working with PWIDs support current users in trying to break the cycle of addition and prevent others from moving to injecting drugs.

The programme also had very clear goals and resulted in a doubling of people receiving treatment and a 5-fold increase in the number of prisoners treated.[37] It also secured national procurement of antiviral drugs at reduced prices. It has also provided compelling evidence to support the need to offer treatment to PWIDs. For example,

using Scottish data, a model was developed suggesting that treating 10 per 1000 PWIDs annually could result in a 13% decrease in HCV prevalence over a 10-year period.

For more information: http://www.healthscotland.com/drugs/hepatitis%20C.aspx

6. DELIVERING COMPREHENSIVE MODELS OF CARE FOR PEOPLE WITH HEPATITIS – THE DELIVERING HOPE PROGRAMME IN ASIA

Asia is home to 75% of cases of HBV and suffers a disproportionate burden of HCV, with China alone having more cases of HCV than Europe and the Americas combined. The Bristol-Myers Squibb Foundation's "Delivering HOPE" is a far-reaching programme focused on HBV and HCV in China and India, working with local governments, civil society, businesses, patients and professionals to build sustainable solutions for the prevention, treatment and management of viral hepatitis in the region.

The starting point for all projects is community involvement, and programmes are targeted to the particular needs of the communities of patients involved. For example, a comprehensive programme of care was developed in a rural township of Taiwan to ensure that patients who had tested positive for HBV or HCV in local screening programmes were offered lifelong surveillance and high-quality care through the establishment of specialist clinics at the local level. These patients usually would have had to travel up to 30km to reach the nearest hospital. Other activities include targeted health education, prevention and control programmes focused on particular risk groups and communities, precautionary measures to limit nosocomial spread of HBV and HCV in hemodialysis units and other health care settings and professional training programmes, including nurses, doctors working in rural communities, and community leaders.

For more information: http://www.bms.com/documents/foundation/Delivering-Hope-Backgrounder.pdf

7. IMPROVING ACCESS TO HEPATITIS IN POORER COUNTRIES – THE EXAMPLE OF EGYPT

Egypt has the highest prevalence rates of HCV in the world and the Egyptian government created the National Committee for Control of Viral Hepatitis to bring together national as well as international experts from across different sectors to try to improve the prevention and care for patients infected with HCV in Egypt. A number of manufacturers of HCV treatments have worked with the National Committee to try to expand screening and treatment capacity and to ensure that large numbers of patients infected with HCV in Egypt have access to therapies at affordable prices, including through the introduction of differential pricing strategies.

V. CONCLUSION

A CALL FOR ACTION: AN INTERSECTORAL APPROACH TO VIRAL HEPATITIS

Since the WHO first raised the alarm on viral hepatitis in 2010, there have been remarkable developments in prevention, testing and treatment options available to patients with HBV and HCV. The policy response to viral hepatitis, however, has lagged behind – as is illustrated by the fact that only one-third of countries have a national plan for hepatitis.

With liver cancer now the second most common cause of cancer death worldwide and 1.6 million people dying from viral hepatitis every year, it is time for governments and policymakers around the world to adopt a comprehensive policy response towards viral hepatitis.

This policy response should meet several objectives:

- It should address viral hepatitis in all its complexity, in terms of its multiple routes of transmission, groups at risk, and geographic diversity.
- It should be holistic and cover all facets of prevention, screening, diagnosis and care.
- It should address the many challenges which have hampered an appropriate response to viral hepatitis so far, including widespread stigma and poor understanding of the disease by policymakers, the general public and health professionals.
- It should be sustainable, and ensure that countries have the necessary health care infrastructure, policies and programmes in place to be able to deliver the most effective prevention and care to patients over the next several years.
- It should incentivise the continued development of prevention, screening and treatment advances and encourage their access within broad, comprehensive care networks.

The research-based biopharmaceutical industry has invested years of research and development into viral hepatitis, and is committed to continue investing in the delivery of better and safer technologies that may prevent and improve the outcomes of people infected with HCV and HBV around the world. As a major stakeholder in the fight against viral hepatitis, this sector urges governments and the international community to open a broader dialogue on viral hepatitis. Together we can create innovative inter-sectoral collaborations that will help shift the landscape towards the effective management of viral hepatitis around the world.

HEPATITIS C

DEFINITION

Hepatitis C is a liver disease caused by the hepatitis C virus (HCV), the virus can cause both acute and Chronic hepatitis infection, ranging in severity to a mild illness lasting a few weeks to chronic liver diseases, liver cancer and in some cases death.

GLOBAL HEALTH BURDEN

Viral hepatitis is found worldwide. However, there is a higher prevalence in North Africa and Eastern & Central Asia.

3 to 4 million new cases each year.

350 000 to 500 000 people die each year from Hepatitis C.

180 million infected worldwide.

THE SILENT EPIDEMIC: EVOLUTION OF THE DISEASE

Due to the large number of people unaware that they are chronically infected with HCV the identification of new advanced liver diseases will continue to increase as people progress in their disease and more screening is undertaken.

Infection

80% of people do not exhibit any symptoms following initial infection.

Chronic Disease

60-85% of people infected with HCV will develop chronic infection.

Cirrhosis

15-30% of people with chronic HCV infection will develop Cirrhosis

0 — 5 YEARS — 10 YEARS — 20 YEARS

PATH TO HCV MANAGEMENT

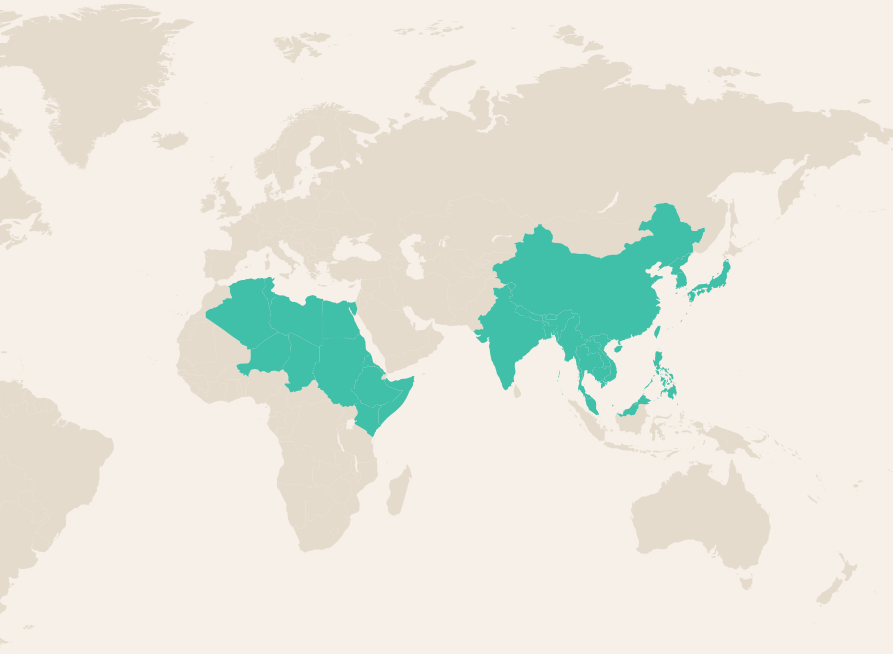
SUPPORT RESEARCH & DEVELOPMENT

There are currently **20 candidate products** in the pipeline.

INCREASE AWARENESS AND PREVENTION

3 out of 4 persons are unaware they are infected with HCV.

IFPMA



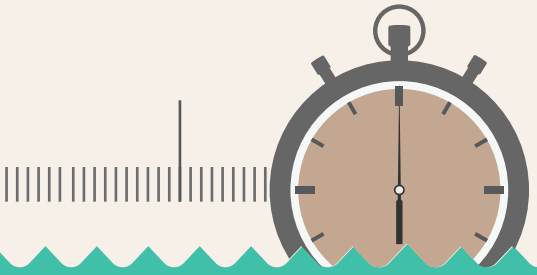
MAIN ROUTES OF TRANSMISSION

- Unsafe Injections
- Inadequate Sterilization of Medical Equipment
- Blood Transfusion
- Sexual Transmission

1

Liver Cancer

HCV is the **n°1** cause of Liver Cancer.



TREATMENT INNOVATION

60 to 90%

of HCV infections can be cured. New treatments offer better cure rates, reduced treatment duration and fewer side effects.

FROM SCREENING TO CARE

Too often, patients who test positive are not referred to appropriate treatment and care.

Only 3-5%

of patients receive treatments even in high income countries.

IMPROVE SCREENING AVAILABILITY

Only 1 in 3 countries provides testing accessible to all.

DEVELOP POLICIES & ALLOCATE RESOURCES

Only 1 in 3 countries has a national strategy to combat HCV.

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