## CONTENTS

<table>
<thead>
<tr>
<th>Page</th>
<th>Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Introduction</td>
</tr>
<tr>
<td>6</td>
<td>Executive summary</td>
</tr>
<tr>
<td>8</td>
<td>Glasgow declaration on viral hepatitis</td>
</tr>
<tr>
<td>10</td>
<td>The need for a global response</td>
</tr>
<tr>
<td>14</td>
<td>The need for comprehensive programming: evidence for action</td>
</tr>
<tr>
<td>14</td>
<td>Best practice in the prevention of hepatitis B</td>
</tr>
<tr>
<td>15</td>
<td>Best practice in the prevention of hepatitis C</td>
</tr>
<tr>
<td>16</td>
<td>Best practice in the treatment of hepatitis B and C</td>
</tr>
<tr>
<td>18</td>
<td>Best practice in HBV and HCV case finding</td>
</tr>
<tr>
<td>22</td>
<td>Countries move towards national programmes: early examples</td>
</tr>
<tr>
<td>26</td>
<td>Steps towards development of national viral hepatitis plans</td>
</tr>
<tr>
<td>26</td>
<td>The role of the community in catalysing and developing national plans</td>
</tr>
<tr>
<td>27</td>
<td>Simulation exercise</td>
</tr>
<tr>
<td>30</td>
<td>Parallel sessions on key national planning themes</td>
</tr>
<tr>
<td>30</td>
<td>Treatment and access to drugs</td>
</tr>
<tr>
<td>32</td>
<td>Strategic information for planning</td>
</tr>
<tr>
<td>34</td>
<td>Prevention</td>
</tr>
<tr>
<td>36</td>
<td>Service delivery</td>
</tr>
<tr>
<td>38</td>
<td>Universal health coverage, costing and prioritisation</td>
</tr>
<tr>
<td>40</td>
<td>Governance, ownership and partnership</td>
</tr>
<tr>
<td>42</td>
<td>Steps towards a global investment case</td>
</tr>
<tr>
<td>42</td>
<td>Cost-modelling of comprehensive global viral hepatitis prevention and treatment activities</td>
</tr>
<tr>
<td>44</td>
<td>Potential funding mechanisms for national programmes</td>
</tr>
<tr>
<td>46</td>
<td>Potential mechanisms for reducing drug costs</td>
</tr>
<tr>
<td>48</td>
<td>The global hepatitis community calls for access to life-saving hepatitis drugs</td>
</tr>
<tr>
<td>49</td>
<td>Operational research</td>
</tr>
<tr>
<td>52</td>
<td>Impact</td>
</tr>
</tbody>
</table>
• The World Hepatitis Summit was convened to build on the World Health Assembly 67.6 resolution, which asked WHO Member States to develop and implement national viral hepatitis strategies, as well as calling on WHO to examine the feasibility of eliminating hepatitis B and C with a view to setting global targets and develop a monitoring mechanism.

• The Summit sought to build momentum towards development of comprehensive national plans within the framework of WHO 2016-2021 viral hepatitis strategy.

• The Summit offered an opportunity to forge relationships between civil society and governments for development of national planning and strengthening of the community voice in the viral hepatitis response.

• The Summit also offered an opportunity to share key learning from early country scale up activities and from other disease areas.

• The World Health Organization launched a national programme planning toolkit at the Summit, providing an opportunity to reflect on its key themes and participate in a scenario-based national planning exercise.

INTRODUCTION
EXECUTIVE SUMMARY

- Approximately 1.4 million people die as a result of viral hepatitis annually. Viral hepatitis is now ranked seventh among the leading causes of death worldwide and represents a growing burden for health systems in lower- and middle-income countries. Inaction today will result in higher future costs as the number of people infected with hepatitis B or C grows, and more people develop liver disease.
- Global momentum is building towards greater investment in viral hepatitis control. The recent development of drugs which can cure the vast majority of hepatitis C infections has offered the hope of eliminating hepatitis C. The 2014 World Health Assembly requested the World Health Organization to review the feasibility of, and strategies for, elimination of hepatitis B and C with a view to setting global targets. The 2015 Sustainable Development Goals set a goal `to combat hepatitis`, giving greater prominence to viral hepatitis as a public health issue for development.
- The World Health Organization has proposed global targets for viral hepatitis control of a 30% reduction in new infections of hepatitis B and C by 2020, and a 90% reduction by 2030. A mortality target of a 10% reduction in deaths due to hepatitis B and C by 2020, and a 65% reduction by 2030, has also been proposed. These targets must be achieved through dramatic increases in coverage of key prevention interventions, diagnosis and treatment.
- Comprehensive national plans developed through consultation between governments, health sectors and civil society will be needed in order to scale up services, mobilise funding and catalyse national commitment. Early examples of country planning show the potential for rapid movement towards scale up when price reductions facilitate the expansion of treatment. Examples from Egypt, Georgia, The Gambia and Uganda demonstrate that national governments are ready to act when effective treatment is available and affordable.
- Modelling shows that financing to achieve these global targets would need to grow to approximately $11 billion a year in 2025 before beginning to decline as the effects of prevention and treatment scale up gradually reduce the burden of disease. Lower-income countries will need donor support in order to achieve scale up of prevention and treatment. Middle-income countries which do not have access to generic products for treatment of HCV under current voluntary licensing agreements will need to secure much lower drug prices to achieve scale up of treatment.
- Mechanisms are being explored to reduce the cost of HCV treatment for middle-income and lower-income countries.
- Community organisations of people with viral hepatitis and their advocates have an important role to play in mobilising political support for a public health response, advocating for affordable treatment and the most effective evidence-based prevention measures. Community organisations are key partners in development of a national viral hepatitis plan, delivering an improved understanding of the needs of people with viral hepatitis and the design of effective prevention, treatment and care. Community organisations play a central role in challenging the stigma associated with viral hepatitis. Stigma was identified by delegates as a major obstacle to prevention, diagnosis and treatment and to the prioritisation of viral hepatitis as a public health issue.
- Operational and public health research will play a critical role in identifying the most effective and cost-effective forms of service delivery and treatment. Greater investment will be needed in research in order to maximise the effectiveness of investments in scale up of prevention and treatment.
- The Glasgow Declaration is a call endorsed by delegates at the World Hepatitis Summit for governments to develop comprehensive national plans and programmes in partnership with all stakeholders. We urge all who read this report to disseminate the Glasgow Declaration and work at national level to achieve its aims.
GLASGOW DECLARATION ON VIRAL HEPATITIS

Because there are 400 million people living with hepatitis B or hepatitis C infection with no country/region unaffected,

Because there is a lack of global awareness and most persons with hepatitis remain undiagnosed,

Because 1.4 million people die every year from complications of viral hepatitis yet most of these deaths can be prevented,

Because there are highly effective measures to prevent new hepatitis B and C infections and highly effective treatments that can suppress hepatitis B virus replication and cure hepatitis C infection,

Because universal access to prevention, diagnosis, care and treatment is a human right and promoting access to and affordability of these services is the responsibility of all stakeholders,

The participants of the inaugural World Hepatitis Summit believe it is possible and essential to set as a goal the elimination of both hepatitis B and C as public health concerns. We therefore call upon governments in all jurisdictions to develop and implement comprehensive, funded national hepatitis plans and programmes in partnership with all stakeholders and in line with the World Health Assembly Resolution 67.6 and, in collaboration with the World Health Organization, to define and agree on realistic yet aspirational global targets for prevention, testing, diagnosis, care and treatment.

#ELIMINATEHEP

186 tweets to hashtag at launch of Glasgow Declaration on 4 September 2015

“World Hepatitis Summit: A voice to deal with elimination of hepatitis as a threat in the world”
THE NEED FOR A GLOBAL RESPONSE

Key messages from presentations by: Dr Graham Cooke, Clinical Senior Lecturer in Infectious Diseases, Imperial College London; Professor Ji-Dong Jia, Professor of Medicine/Director, Liver Research Center/Medical Director, Liver Transplant Program, Beijing Friendship Hospital, Capital Medical University; Dr Gottfried Hirschl, Director, HIV/AIDS Department and Global Hepatitis Programme, World Health Organization.

In 2013 approximately 1.4 million people died worldwide as a consequence of viral hepatitis. The 2013 Global Burden of Disease study showed that viral hepatitis was ranked seventh among the leading causes of death worldwide, compared to tenth in 1990. Disability-adjusted life years lost due to liver cancer attributable to hepatitis B have risen by 4.8% since 2005, and due to hepatitis C by 35.1% since 2005. A similar pattern holds true for cirrhosis.1 The gap between higher- and upper-middle income and lower-and-middle income countries in morbidity and mortality attributable to viral hepatitis has narrowed since 1990.

Viral hepatitis kills more than 1.4 million people a year, yet there is a remarkable lack of global awareness and action to combat the disease.

Global prevalence of hepatitis B is estimated to range from 0.81% in the Americas to 5.26% in the Western Pacific region and 8.83% in the African region, according to systematic review of data published between 1965 and 2013. Approximately 248 million people were estimated to be HBsAg positive worldwide in 2010.2 Improvements in national coverage of infant hepatitis B immunization between 1990 and 2013 are correlated with declines in HBsAg prevalence in several countries in Asia and Africa including China, India, Egypt, Mozambique and Tanzania. In China prevalence of HBsAg in children aged 1-4 was 0.96% in 2006, compared to prevalence of 8.57% in adults aged 15-59.3

The World Health Organization estimates that 130-150 million people have chronic hepatitis C infection worldwide, and around 500,000 people die each year from liver disease caused by HCV. Hepatitis C is concentrated in specific populations (people who inject drugs, people who received blood products prior to the introduction of screening) and in certain regions, notably Africa and Central and East Asia. The highest prevalence of HCV is found in North America, the Middle East, Central Asia, China and Mongolia (>3.5%) and the greatest numerical burden of chronic infection in the Western Pacific region

(62 million).4 Prevalence rises sharply with age in settings where infection is attributable to receipt of unscreened blood products or inadequate infection control. Today’s hepatitis C epidemic represents the historical legacy of inadequate screening and infection control, lack of health system capacity, a growth in injecting drug use and a lack of harm reduction services for people who inject drugs.

In recognition of the global burden of disease and the ongoing transmission of viral hepatitis, the 2014 World Health Assembly requested the World Health Organization to review the feasibility of, and strategies for, elimination of hepatitis B and C with a view to setting global targets. As part of its Global Health Sector Strategy on viral hepatitis, for consideration by the 2016 World Health Assembly, the World Health Organization has proposed the following targets:

- A 30% reduction in new infections of hepatitis B and C by 2020, and a 90% reduction by 2030
- A 10% reduction in deaths due to hepatitis B and C by 2020, and a 65% reduction by 2030

Highly effective prevention and treatment interventions now exist for viral hepatitis, offering the opportunity to make substantial progress towards elimination of viral hepatitis transmission. Achievement of the proposed targets will be facilitated through:

- Increasing childhood hepatitis B vaccine coverage from 81% to 90% by 2020, and increase coverage of birth-dose hepatitis B vaccine (or other interventions to prevent mother to child transmission of hepatitis B) from 38% today to 50% in 2020 and 90% in 2030
- Increasing the proportion of injections carried out safely worldwide from 5% today to 50% in 2020 and 90% in 2030
- Increasing the coverage of needles and syringes supplied to people who inject drugs from an average of 20 per person per year today to 200 per person per year in 2020 and 300 per person per year in 2030
- Treating 5 million people with hepatitis B by 2020 and provide treatment for 80% by 2030
- Treating 3 million with hepatitis C by 2020 and provide treatment for 80% by 2030

THE NEED FOR COMPREHENSIVE PROGRAMMING: EVIDENCE FOR ACTION

Key messages from presentations by: Professor Yen-Husan Ni, Professor of Paediatrics, National Taiwan University College of Medicine (hepatitis B prevention); Professor Sharon Hutchinson, Professor of Epidemiology and Population Health, Glasgow Caledonian University (hepatitis C prevention); Professor Massimo Cambi, Chairman, Department of Medicine and Organ Transplantation/Head, Division of Gastroenterology and Hepatology, Fondazione Ospedali Maggiore, University of Milan (treatment); Dr John Ward, Director, Division of Viral Hepatitis, Centers for Disease Control and Prevention (case finding).

In order to achieve elimination of viral hepatitis transmission, comprehensive national programmes of prevention, screening, diagnosis and treatment will need to be developed. Several presentations summarised the current evidence supporting a range of highly effective interventions.

BEST PRACTICE IN THE PREVENTION OF HEPATITIS B

Hepatitis B transmission can be eliminated through screening of pregnant women and prevention of perinatal transmission, universal infant vaccination, adoption of preventive measures to prevent bloodborne transmission, and treatment of chronically infected people. Universal infant vaccination against hepatitis B has proved highly successful in the prevention of hepatitis B. Taiwan was the first country to launch a universal infant vaccination programme in 1984, achieving 97% coverage by 2014. Subsequent prevalence surveys have shown a decline in HBsAg prevalence in children and young adults under 30, from 9.8% in 1984 to 0.6% in 2014. Similar magnitudes of decline in prevalence have been observed in a wide range of countries after the implementation of universal infant vaccination. Rates of hepatocellular carcinoma in children have declined by approximately 70% in Taiwanese children born after 1984.

WHO recommends that all infants receive HBV vaccine as soon as possible after birth, preferably within 24 hours. The birth dose should be followed by 2 or 3 doses of HBV vaccine to complete the course. In 2013, 93 Member States had introduced the birth dose, 183 Member States vaccinated infants against hepatitis B as part of their EPI, and 81% of children received the hepatitis B vaccine. By 2011 60% of countries had achieved immunization coverage of 90% or greater. Vaccination is also recommended for groups at high risk of HBV infection: people who inject drugs, sexual partners of people with chronic HBV infection, haemodialysis and frequent transfusion recipients, and people with multiple sex partners.

Best practice in the prevention of hepatitis C

Along with the re-use of injecting equipment to inject drugs, infected blood products or invasive medical procedures in health care settings account for the vast majority of hepatitis C transmission worldwide. In 2012 25 countries were still unable to screen all donated blood, and only 60% of countries had achieved 100% voluntary blood donation. Unsafe injections were estimated to account for 315,000 new HCV infections in 2010, compared to 1.9 million in 2000. The World Health Organization has recommended that countries should implement entirely voluntary blood donation systems and quality-assured testing of all donated blood, together with infection control measures that include safe cleaning of all equipment, safe disposal of sharps and waste, and a transition to the use of new safety-engineered injection devices with re-use prevention and sharps (needle) injury prevention.

Worldwide approximately 60% of people who inject drugs are infected with HCV, with especially high prevalence (>60%) in Pakistan, China, Thailand, Indonesia, Russian Federation, Ukraine, Vietnam, Brazil, North America and Western Europe. Needle and syringe provision and opioid substitution therapy have each been associated with a reduced risk of HCV transmission, while provision of injecting paraphernalia, safe injection rooms and education, information and counselling have been associated with reductions in injecting risk behaviours. High coverage of needle and syringe provision and opioid substitution therapy has been associated with an 80% reduction in the odds of HCV acquisition when compared to low coverage of needle and syringe provision alone. Nevertheless coverage of these key interventions remains extremely low outside Western Europe and Australasia. Prisons represent a high-risk setting for HCV transmission but few countries have yet implemented a World Health Organization recommendation to provide needle and syringes programmes in prisons.

Increasing the uptake of treatment using direct-acting antivirals has the potential to reduce HCV transmission among people who inject drugs substantially, even at relatively modest levels of coverage. Modelling of three HCV epidemic settings suggests that where prevalence is lower (30%), achieving coverage of 40 treatments per 1000 PWIDS has the potential to eliminate HCV transmission among people who inject drugs within a decade. At higher levels of HCV prevalence, correspondingly higher levels of treatment coverage would be needed to achieve a similar effect, and the greatest impact is likely to be achieved where coverage of needle and syringe programmes, opioid substitution treatment and direct-acting antiviral treatment are simultaneously increased.

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References:
**Best Practice in Treatment of Hepatitis B and C**

Highly effective treatment is now available for both hepatitis B and hepatitis C. In the case of hepatitis B, a strong correlation between higher levels of HBV DNA and increased liver-related mortality provides the rationale for suppressive antiviral treatment to reduce the risk of progression of liver disease in those with high levels of replicating virus. Antiviral treatment with tenofovir or entecavir results in viral suppression in >95% of treatment-naïve and nucleoside-experienced patients, and a large study in 43190 patients in Taiwan has shown that nucleoside side-effect reduced the five-year risk of developing liver cancer by 69%. Although suppressive antiviral treatment results in HBsAg clearance in <20% of Caucasian patients who are HBeAg positive at baseline, and <1% of other patient groups, treatment results in ALT normalisation in approximately 85% of patients.

Direct-acting antiviral treatment for hepatitis C is now curative in the vast majority of previously untreated and treatment-experienced patients, including those with compensated cirrhosis. Outcomes are also improving in harder-to-treat patient groups, including those with decompensated cirrhosis, pre-transplant patients and post-transplant patients with recurrent HCV.

EASL recommendations for HCV therapy 2015

**Interferon-free regimens**

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<thead>
<tr>
<th>Regimen</th>
<th>Genotypes</th>
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<tr>
<td>Sofosbuvir / ribavirin</td>
<td>2, 3</td>
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<tr>
<td>Sofosbuvir / ledipasvir +/- ribavirin</td>
<td>1, 4, 5, 6</td>
</tr>
<tr>
<td>Ombitasvir/Paritaprevir/Ritonavir + Dasabuvir (+/- RBV)</td>
<td>1</td>
</tr>
<tr>
<td>Sofosbuvir + Simeprevir (+/- RBV)</td>
<td>1, 4</td>
</tr>
<tr>
<td>Sofosbuvir + Daclatasvir (+/- RBV)</td>
<td>All</td>
</tr>
<tr>
<td>Ombitasvir/Paritaprevir/Ritonavir (+/- RBV)</td>
<td>4</td>
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**Interferon-based regimens**

<table>
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<tr>
<th>Regimen</th>
<th>Genotypes</th>
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<tbody>
<tr>
<td>PegIFNa + RBV + sofosbuvir</td>
<td>All</td>
</tr>
<tr>
<td>PegIFNa + RBV + simeprevir</td>
<td>1, 4</td>
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Pan-genotypic regimens for hepatitis C have been advocated as a means of scaling up treatment in lower- and middle-income countries, due to their suitability for use without the need for genotyping prior to treatment. Pan-genotypic regimens would also be advantageous from a public health perspective in settings where national epidemics encompass a wide distribution of genotypes rather than a predominance of genotype 1 (as in Western Europe, North America and Australasia). However, there will be a continuing need for regimens suitable for patients with special needs in all epidemic settings, including those with previous experience of direct-acting antivirals, those with decompensated cirrhosis and treatment-experienced patients with genotype 3 infection.

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**Best practice in HBV and HCV case finding**

Case finding plays multiple roles in a comprehensive response to viral hepatitis. Identification of chronically infected persons permits treatment for the prevention of disease and mortality, as well as preventing transmission. Case finding is also an essential element in public health surveillance and programme monitoring.

Case finding supports primary prevention of HBV infection by allowing antiviral prophylaxis or HBIG to be provided in addition to infant vaccination. Case finding also permits the vaccination of household contacts. Case finding can also enhance the impact of harm reduction by permitting focused behaviour change interventions in people who inject drugs, and enhanced infection control measures in haemodialysis settings.

Case finding supports secondary prevention of disease through counselling on hazards such as alcohol, and through linkage to care and treatment, permitting staging of liver disease and therapy to suppress virus replication or cure hepatitis C. **Timely diagnosis and treatment of hepatitis B has been shown** to significantly reduce the risk of developing liver cancer, with the greatest reduction in risk in those with viral loads > 20,000 IU/mL, and the greatest benefit observed in those who received treatment with nucleoside or nucleotide analogues. 

**Lack of knowledge of HCV status is a huge barrier to a successful public health response to viral hepatitis. Rates of diagnosis remain low in most countries.** Modelling of the potential impact of enhanced case finding and direct-acting antiviral treatment in six western European states has shown that enhanced case finding in addition to provision of direct-acting antivirals compared to pegylated interferon and ribavirin alone had the potential to increase the uptake of treatment by 50% in France, 150% in Italy and 246% in the United Kingdom.

National case finding policies will vary according to local epidemiology and population cost-effectiveness. In the United States, for example, national policies recommend hepatitis B testing for persons born in African or Asian countries with HBV prevalence of 2% or over, men who have sex with men and people who inject drugs. HBV testing has been shown to be cost-effective at an HBV prevalence of 2% and above in the United States. The United States Centers for Disease Control has adopted a one-time birth cohort screening policy for hepatitis C (those born 1945-1965), as well as recommending testing for people who inject drugs and people who received blood transfusions prior to 1992. Birth cohort screening has been shown to be cost-effective in the United States.

Quality of testing will be critical to ensure that screening achieves its goals. HBsAg is recommended for identification of chronic hepatitis B infection. In higher-income settings HCV antibody and confirmatory PCR testing are usually recommended for confirmation of chronic infection, but up to 50% of people who test positive for HCV antibody do not receive a confirmatory PCR test in the United States. On grounds of efficiency and cost a single test to diagnose chronic hepatitis C would be preferable. Preliminary evidence shows that hepatitis C core antigen testing demonstrated a sensitivity of 100% and specificity of 94.3% in 551 blood donors and people who inject drugs, implying that it may be suitable as a single diagnostic test for hepatitis C.

Monitoring of case finding and linkage to care will also form an essential element of national programmes. Monitoring both changes in testing volume following changes in policy, and tracking linkage to care from receipt of test results through referral to attendance for care, will be critical for identifying opportunities for improvement in health systems and priorities for future investments.

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COUNTRIES MOVE TOWARDS NATIONAL PROGRAMMES: EARLY EXAMPLES

Key messages from presentations by: Dr David Sergeenko, Minister of Labour, Health and Social Affairs, Georgia; Professor Imam Waked, National Liver Institute, Egypt; Hon. Omar Sey, Minister of Health and Social Welfare, The Gambia; Dr Amandua Jacinto, Commissioner Clinical Services, Ministry of Health, Uganda.

Georgia, one of several states in Eastern Europe with a high prevalence of hepatitis C (6.7%), has embarked on an ambitious programme designed to eliminate hepatitis C, in partnership with the US Centers for Disease Control and Prevention (CDC) and Gilead Sciences, the manufacturer of sofosbuvir (Sovaldi) and sofosbuvir/ledipasvir (Harvoni). Georgia’s programme is intended, in part, to demonstrate that elimination – the ending of transmission resulting in the disappearance of disease over several decades – is a feasible proposition even for middle-income countries with limited health systems. By negotiating a substantial price reduction in the cost of treatment from Gilead Sciences, and with advice and training on programme design and monitoring, Georgia aims to treat 5000 people with advanced liver damage and to screen 70,000 people for hepatitis C in 2015 alone, with an increase in volume in subsequent years, Dr David Sergeenko, Georgian Minister of Labour, Health and Social Affairs told the summit. Georgia’s 2016-2020 Hepatitis C Elimination Strategy and Action Plan aims to diagnose 95% of people with HCV by 2020, link 95% of diagnosed people to care, treat 95% of those linked to care and achieve cure in 95% of treated people. This would result in 81% of all people with hepatitis C being cured by 2020.

Egypt, the country with the highest prevalence of hepatitis C in the world, has treated 100,000 people in the past year as a result of negotiated price reductions in the costs of sofosbuvir and pegylated interferon. Two hundred thousand people registered online for evaluation for free treatment within three days of the launch of a government website earlier this year, and 1.1 million had registered by July 2015, but Egypt will prioritise for treatment those with the most advanced liver disease – 350,000 people over the next three years. Despite the advanced disease stage of people treated so far, cure rates are very high: approximately 85% of those with cirrhosis have been cured, reported Professor Imam Waked of the National Liver Institute, Cairo.

The Gambia, a West African country with approximately 80,000 live births per year, achieved 98% coverage of birth-dose hepatitis B vaccination, and 96% coverage of the pentavalent vaccine that is supported by GAVI in the 73 poorest countries of the world. The Gambia follows a four-dose hepatitis B schedule comprising the birth dose and three doses of pentavalent vaccine at monthly intervals from 2 months of age. The Gambia began its vaccination programme in 1990. A cross-sectional study conducted in the Three Rivers Region in 2007-2008 found that in children born since 1990 HBsAg prevalence was 0.41%, compared to an estimated prevalence of 10% in under-15 year olds prior to the introduction of vaccination.

Uganda has a high prevalence of chronic hepatitis B (approximately 10%) with an especially high concentration of infections in northern regions of the country. Testing shows a high prevalence of HBV among blood donors in several northern districts (4.2%-5.7%), although national efforts to improve selection of blood donors have resulted in a decline in prevalence among donors since 2007. Uganda has developed a National Plan for the Control of Hepatitis, supported by The Public Health (Declaration of Hepatitis B as a Formidable Epidemic Disease) Order, 2014, and mandatory vaccination of health care workers against HBV. Uganda’s Parliament has allocated $2.8 million for hepatitis B prevention and treatment in 2015/16. A four-year national vaccination programme was launched by President Museveni on World Hepatitis Day 2015, beginning in northern Uganda. The vaccination programme includes integrated testing for HBV, HIV, syphilis and malaria, and will prioritise health workers, students, the armed forces and high-risk populations before the general population. Antiviral treatment will be offered through two hospitals to 350 eligible patients, taking advantage of the low price of generic tenofovir ($7 per month) as first-line treatment.
STEPS TOWARDS DEVELOPMENT OF NATIONAL VIRAL HEPATITIS PLANS

Having a comprehensive national viral hepatitis treatment and prevention plan is critical if progress is to be made towards decreasing the burden of viral hepatitis. The WHO’s National Planning Toolkit can support governments in developing such plans and delegates had the opportunity to attend a selection of parallel sessions that focused on key national planning themes.


The purpose of this manual is to provide guidance to public health professionals tasked with managing a response to viral hepatitis. As every country’s needs are different with respect to its epidemiology and the current level of response, people would use this manual in different ways. This manual is intended:

- to help think more comprehensively about the hepatitis response in a country;
- to provide a step-by-step approach to setting up a national hepatitis plan and/or programme;
- to propose a governance structure that can be adapted according to needs; and
- to propose the outline of a national hepatitis plan.


THE ROLE OF THE COMMUNITY IN CATALYSING AND DEVELOPING NATIONAL PLANS

Delegates identified community involvement as key both to catalysing national plans and to their development. The Summit provided opportunities for community organisations representing people with viral hepatitis to engage in dialogue with national decision makers through the simulation exercise and workshop sessions, and for decision makers to learn more about the perspectives and experiences of community organisations and people living with viral hepatitis.

“Most amazing gathering of hepatitis patients, advocates from around the world, personal healing and professionally reassuring to be part of this global movement.”

“First opportunity to network with all the major players. It has opened my eyes to global issues, I can now see the importance of all working together to achieve goal of elimination. I want to be a part of a global movement.”

SIMULATION EXERCISE

The Summit included a simulation exercise in which delegates played the roles of public health experts, clinicians, health officials and advocates called to develop a national response to viral hepatitis under time pressure from a Minister of Health confronted by sudden media interest in viral hepatitis. Delegate teams were also tasked with identifying priority actions to achieve a specific target for prevention, treatment or diagnosis of viral hepatitis C.

Delegates commented:

“(The) simulation to me looked like a scenario of my country. The work helped in aggregating the steps that we are developing for hepatitis strategy.”

“(I am) able to relate it to my country’s health situation regarding viral hepatitis; it is always best to hold hands and handle things together.”

Many people emphasized that the main lesson learnt from the exercise was the importance of bringing all parties around the table to agree on a common mode of action. The importance of different types of expertise and of consensus building were repeatedly emphasized.
Parallel sessions on key national planning themes: main points arising from presentations and discussions

Treatment and access to drugs

- Delegates stressed the importance of access to good-quality hepatitis C drugs and the importance of WHO prequalification. Not only are donors unwilling to support treatment with products that have not been prequalified, but patients are concerned about generic drug quality.
- There is widespread concern regarding the slowness of registration procedures at country level and the need for accelerated review. Governments should take the initiative regarding registration where companies have not been proactive in filing for registration. Countries have an opportunity to speed up the registration of prequalified products by joining the WHO Collaborative Registration Procedure, which enables the sharing of product evaluation and manufacturer inspection data between the WHO Prequalification of Medicines Programme and National Regulatory Agencies.
- Concerns were also expressed regarding the lack of transparency over where patent applications have been filed. The lack of transparency impedes consideration of generic drugs.
- International price transparency is needed in all regions in order to give national programmes leverage in negotiations regarding price; transparency is too often restricted by confidentiality clauses in agreements.
- Lack of knowledge regarding the scope of voluntary licensing agreements is constraining national programmes from taking advantage of lower prices to scale up treatment. There is a need for regular circulation of information on the scope of these agreements and on prequalification of new products.
- There was a consensus among delegates that DAAs are unaffordable at current prices and that profits are coming before lives. Countries would welcome greater advice and information on the range of instruments that can be used to attain affordable drugs (i.e. TRIPS flexibilities, production of generic drugs, compulsory licenses, direct negotiation with pharma). The choice of instrument will depend on country circumstances.
- Consideration of the use of TRIPS flexibilities gives countries leverage in pricing negotiations, as in the case of Brazil.
- Differences of income within countries mean that even if products are judged to be affordable, people on low incomes may still be excluded from benefit by high prices, co-payments etc.
- Generic competition has the potential to reduce drug costs considerably below current agreements negotiated with national programmes by Gilead. Based on an estimation of the chemical processes, active pharmaceutical ingredient and manufacturing costs, research published in 2015 estimates that currently available 12 and 24-week regimens could be made available at prices ranging from $267-$444 per treatment course.
- The cost of treatment is also influenced by the cost of monitoring and genotyping, which might comprise up to half the total cost of the treatment package even when generic prices fall to less than $250 per treatment course.
Strategic information for planning

- Lack of data underpins lack of action on viral hepatitis. Strategic information helps us to understand the epidemic and monitor how it changes as a result of interventions.
- Strategic information informs programme improvement, assures quality and maximal return on resources invested and helps to identify bottlenecks and opportunities.
- Surveillance data enable policy-makers to identify modes of transmission, risk populations, and burden of disease, and to tailor policies to meet local needs.
- Viral surveillance systems remain weak in many countries. A preliminary 2012 survey for the WHO Global Hepatitis Programme found 55 countries had surveillance systems for hepatitis B and 51 for hepatitis C. Lack of surveillance data weakens the policy case for hepatitis control by depriving us of data on prevalence, incidence, disease burden and treatment outcomes.
- The 2014 World Health Assembly urged member states to develop epidemiological surveillance systems for viral hepatitis to support decision-making on evidence-based policy. The WHA requested that WHO develop a system for regular monitoring and reporting on the progress in viral hepatitis prevention, diagnosis and treatment, in consultation with member states. Delegates highlighted the need for donor investment in surveillance systems.
- WHO is working to finalise ‘Guidance on Indicators for Viral Hepatitis B, C, D’ and ‘Guidance on Viral Hepatitis Surveillance for Low- and Middle-Income Countries’, and to develop ‘Strategic Information Framework’ and ‘Consolidated Strategic Information Guidance’ for viral hepatitis.
- Delegates discussed potential innovative ways of capturing performance data, such as use of laboratory serology and cancer registries, as well as use of indirect measures already captured through HIV programmes (e.g. receipt of OST or antiretroviral therapy to measure the impact of needle and syringe programs in settings where injecting drug use is criminalised or highly stigmatised). Delegates stressed the need for national-level access to reliable, inexpensive and quick diagnostic tests as an important element of improved surveillance.
- Delegates asked for clarification on how treatment eligibility will be determined as part of the proposed global treatment target, and who will be responsible for defining eligibility.
PREVENTION

- High coverage of the birth-dose of the HBV vaccine has been achieved in the Western Pacific region through the successful implementation of targets and policies (particularly in China), and has been reflected by reduced levels of HBV infection among children.
- Safety concerns with regard to the vaccine persist in some countries, particularly where adverse events have occurred (which are often not caused by the vaccine itself). An appropriate and timely response is crucial in order to preempt any negative impact on vaccine uptake.
- Given the high coverage of the birth-dose vaccine in the Western Pacific region, other interventions – such as screening all mothers – may be considered.
- Hepatitis B virus (HBV) and hepatitis C virus (HCV) infection are a significant issue among people who inject drugs (PWID); harm reduction interventions to prevent these infections among PWID are now underpinned by a strong evidence base.
- Countries are at different stages in the implementation of harm reduction (HR) programmes; nevertheless, even in countries with well-established programmes, HR can be under threat as a result of changing governments.
- Healthcare related injections are an important risk factor for transmission of viral hepatitis in many countries.
- There are many economic and psychosocial barriers to changing risky healthcare injection behaviours, this is notably difficult in the unregulated private healthcare sector.
- Multi-stakeholder engagement and formation of comprehensive structural and behavioural interventions is necessary to inhibit forward transmission.
- Impact of interventions must be measured and evaluated to remove shaky estimates and provide key evidence.
**SERVICE DELIVERY**

- What can we learn from HIV scale up? 15 million people are now receiving antiretrovirals. A combination of reductions in drug costs, donor mobilisation, target setting, operational research and careful monitoring have been important in achieving extraordinary progress from a very low baseline in 2000.

- A simplified and standardised public health approach to prevention, treatment and care has struck a balance between implementing the best-proven standard of care and what is feasible to implement on a large scale in resource-limited settings.

- Simplification of treatment and task shifting from physicians to other cadres in the health sector has enabled the expansion of treatment and decentralisation of care. Integration of treatment at one site has contributed to accessibility and retention in care. This is already happening with HIV and hepatitis: of 58 focus countries, 41% are already offering integrated HIV and hepatitis services.

- The delivery of targeted screening of high risk groups (e.g. health care workers, students, armed forces, prisoners, STI clinic attendees, sex workers, men who have sex with men, travellers) was highlighted by several presenters. This approach enables vaccination of those found to be negative, harm reduction advice to be given, and treatment to be offered to those found to be infected.

- To maximise the cost-effectiveness of services and to ensure a patient-centred approach, hepatitis programmes can be incorporated into those which are already established (e.g. HIV, sexually transmitted infections (STI) or tuberculosis). Integration of services, such as HIV and STI clinics, offers the opportunity for health education and harm reduction among high risk groups.

- To improve service delivery, care should be provided at local level thereby improving uptake and treatment adherence and avoiding loss to follow-up. In Kenya, services are delivered at multiple levels (e.g. community, health centres, secondary and tertiary care).

- Programme planning has required modelling of impact and prioritisation of interventions. National epidemiological data to attract government commitment. Many countries lack the necessary surveillance and data collection systems to quantify the burden of disease. Resources must be put in place to meet these challenges and to progress the hepatitis agenda.

- A strong monitoring and evaluation framework (the Global AIDS Response Progress Report) has been supported by the implementation of a standardised patient monitoring and surveillance system.

- Delegates agreed on the importance of simplifying the diagnostic pathway for hepatitis C, both for entry into care and for confirmation of cure. Hepatitis C core antigen testing has the potential to replace molecular diagnostics, simplifying the laboratory requirements for hepatitis C management. Similarly routine liver function tests could be used to stage liver disease.

- A pangenotypic regimen with no serious drug interactions and minimal assessment and monitoring requirements would greatly simplify treatment for hepatitis C.

- Very rapid scale up of hepatitis C treatment is possible. Egypt has been able to provide treatment for 130,000 people since September 2014, by negotiating the lowest drug costs worldwide and expanding clinics providing treatment from 26 to 36 clinics, open six days a week, with staff working in three shifts each day.
Universal health coverage, costing and prioritisation

- National prioritisation of HCV interventions will depend on the burden of late stage illness and local rates of transmission.
- Priority setting as part of a drive to achieve universal health coverage will ask: which population groups should be covered first, where should coverage of existing services be increased, and how can out of pocket payments be reduced for people using existing services?
- Strategic planning will develop a timescale for implementation with clear goals, rather than seeking to do everything at once. Planning will consider the existing strength of the health system, available resources and the investments needed to improve skills and capacity, in order to deliver new interventions or medicines.
- Decision makers can use the OneHealth tool for strategic planning to quantify the impact of their national plans on population health and the cost of national plans.
- When considering the cost of new medicines it is useful to ask at what price they would become as cost-effective as existing alternatives and as cost-effective as other interventions which might be displaced by prioritisation of treatment.

- In Brazil access to HCV treatment has emerged within the context of a constitutional right to health care. Brazil has sought to gradually expand access to treatment, prioritising advanced liver disease.
- At the current pace of access to treatment, where price and funding are constraints, elimination of HCV from the population is unachievable in the mid- to long-term – for example Brazil estimates that it would take 100 years to eliminate HCV at the current pace of access to treatment.
In Australia ministerial “buy-in” was key to the development of strategies. A partnership approach to STIs and blood-borne virus was taken in Australia. Partners included the Australian government; territory governments; non-state actors including patient groups and community-based organizations; and research organizations. Coordination of all partners ensures activities are delivered, that is, implementation is shared between all partners. Targets provided goals for all stakeholders and actors – this is critical to good governance.

In Pakistan politics were important in the beginning. Prime Ministerial involvement from the beginning of planning was critical. Challenges in Pakistan include the large population and the devolution of the government and hepatitis programme leading to a decentralized situation. Serosurveys in Pakistan and Indonesia were critical for informing national responses. In Indonesia a Ministerial Regulation on Hepatitis Control Program in Indonesia led to the development of a hepatitis strategy. Dialogue with government has led to an increase in the budget, however, work needs to continue to ensure efficiency, such as negotiating the lowering of drug and diagnostic prices. The importance of partnerships was emphasized, particularly the need for synergies and dialogue between all stakeholders especially in the face of limited resources.

In Mongolia the Onom Foundation presents a success story of civil society involvement and the importance of civil society in jump-starting responses. Governance requires a National Strategy to be developed with clearly defined targets. Policy dialogue, stakeholder involvement and partnership are key enablers for the implementation of strategies. There needs to be a clear division of roles and responsibility between all stakeholders. A major challenge for governance is communicating to decision makers that the investment now will be cost saving in the future. An Implementation and Evaluation Plan and a Surveillance and Monitoring Plan will be important for ongoing success.
**Steps Towards a Global Investment Case**

The development of a global investment case for viral hepatitis control will support the development of national programmes by mobilising funding for comprehensive programmes. Several presentations at the meeting discussed critical elements that will contribute to the development of an investment case:

- Projected costings for viral hepatitis control activities that will contribute to the proposed WHO elimination targets, 2016-2030
- Potential mechanisms for funding viral hepatitis programming from donor and domestic resources
- Potential mechanisms for reducing drug costs through voluntary licensing and generic production, permitting greater affordability of treatment

**Cost-modelling of Comprehensive Global Viral Hepatitis Prevention and Treatment Activities**

Stefan Wiktor of the WHO Hepatitis Programme presented preliminary results of modelling carried out by WHO with in collaboration with modellers at Imperial College, London.

The model was designed to produce estimates of how much funding would be needed to achieve the proposed WHO targets for viral hepatitis control. The model assumes that it will be possible to provide treatment for hepatitis C at $200 per course of treatment in lower-income countries, $500 per course in middle-income countries and $10,000 per course in higher-income countries. Hepatitis B treatment will cost $80 a year (tenofovir will become available in generic form for higher-income countries from 2017 after its patent expires). The financing projections assume that hepatitis C treatment scale up will begin to grow from 2018 and reach an interim WHO target of 3 million treated by 2020, with drug prices sharply reduced by 2020.

Stefan Wiktor warned that the estimates would be critically dependent on the pricing of generic versions of direct-acting antivirals for hepatitis C and antiviral drugs for hepatitis B, and the speed at which these prices decline as a result of competition and growth in market volume.

Funding of harm reduction interventions such as needle and syringe exchange and opioid substitution therapy will be the biggest budget item in the period leading up to 2020, as WHO seeks to expand coverage of needle and syringe programmes in order to rapidly reduce transmission of hepatitis C.

According to the preliminary model, the cost of viral hepatitis control in lower- and middle-income countries would rise from $2 billion in 2016 and $8 billion in 2020, to just over $11 billion in 2025. Thereafter total costs would decline, to $9 billion in 2030 as harm reduction and hepatitis B treatment costs begin to decline.

Prevention and treatment of viral hepatitis will become affordable if treatment costs decline, but it will be important for health systems to identify ways in which costs can be shared with existing programmes within the health system, such as HIV for harm reduction and for treatment of coinfected people, and the immunisation programme for hepatitis B vaccination. A simplified treatment package that can be delivered with less monitoring and a standardised treatment regimen would also reduce costs. Based on an investment-case analysis conducted for China, this public health approach to treatment would prove cost saving in China for both hepatitis B and hepatitis C by preventing progression of liver disease, and might also eliminate spending on ineffective forms of treatment.

Opening the conference, Dr Gottfried Hirschl, head of the department of HIV/AIDS and Hepatitis at the World Health Organization reminded policy makers that spending on viral hepatitis was not discretionary. Action will be cheaper than inaction in the long run, he told delegates, because prevention and treatment will avert the future costs of untreated viral hepatitis, arising in the forms of management of chronic liver disease, hospitalisation, liver transplantation and liver cancer. Investing in viral hepatitis prevention and treatment will pave the way for elimination of two infectious diseases that otherwise will continue to place a growing burden on health systems.
How hepatitis treatment can be made affordable - especially for lower-income and middle-income countries - was one of the big questions of the World Hepatitis Summit. Daniel Lavanchy of the Viral Hepatitis Prevention Board reported on a recent stakeholder meeting which reviewed potential mechanisms for funding hepatitis treatment. The meeting identified potential opportunities for mobilising new funding in several areas:

- Directing existing pools of donor funding to support viral hepatitis programming, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, GAVI Alliance and UNITAID
- Create new funding pools within existing funds such as Global Fund to Fight AIDS, Tuberculosis and Malaria specifically dedicated to hepatitis, leveraging the experience of these existing funds in developing and managing large-scale public health programmes in partnership with governments.
- Create a specific funding body for viral hepatitis
- Develop new financing mechanisms such as discounting for large scale purchasers of drugs, social impact bonds, commodity or activity-specific taxes, development of national health insurance systems and insurers.

<table>
<thead>
<tr>
<th>Potential funding mechanism</th>
<th>Pros</th>
<th>Cons</th>
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<tbody>
<tr>
<td>Redirect existing funding pools</td>
<td>Extends existing programmes</td>
<td>Has the potential to harm existing programmes</td>
</tr>
<tr>
<td>Create new funding pools within existing frameworks</td>
<td>Profits from existing expertise and structures</td>
<td>Existing institutions already heavily committed</td>
</tr>
<tr>
<td>Hepatitis-specific new fund</td>
<td>Dedicated funding for hepatitis</td>
<td>Finding the appropriate structure and governance may be time-consuming</td>
</tr>
<tr>
<td>Develop new funding mechanisms</td>
<td>May have the potential to mobilise new types of funders such as pension funds, or new streams of finance</td>
<td>Largely unproven</td>
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Although some are attracted by the idea of a specific donor funding pool for hepatitis, one of the big problems of reproducing a model that has succeeded in expanding treatment of HIV, tuberculosis and malaria in developing countries is that a large proportion of the burden of viral hepatitis is in countries that no longer qualify for development assistance, such as China, India, Brazil and Russia. The costs of treatment will need to be met from domestic resources, emphasising the importance of improving universal health coverage and insurance systems.

Regardless of how treatment is financed, mechanisms to reduce drug prices in middle-income countries will play a critical part in making treatment affordable for governments and insurance funds. Besides voluntary licensing, discounts for large-scale payers might enable some countries to scale up treatment – as long as the political will exists. Innovative methods of finance are also being examined, such as social impact bonds, in which a portion of the health care costs saved by preventing disease are returned to investors as a reward for putting up the money to pay for a treatment programme.

The Viral Hepatitis Prevention Board stakeholder meeting concluded that mobilisation of funding will depend on:

- Better definition of the burden of disease and socio-economic costs, together with analysis of data and trends; improved quality of data
- Formulation of policies and strategies for prevention and control of viral hepatitis at national level where none exist
- Generation of commitment and political will through continued advocacy, and identification of strong leadership
- Definition of objectives and priority setting
- Identification of a broad base of potential partners in an alliance or coalition to advance and coordinate activities on prevention and control of viral hepatitis at an international level
- Identification and establishment of a base for the work described.
- Creation of new partnerships and commitments, with building a business case based on priorities and partners’ interests
- Research into identifying the success factors of projects, programmes and financing mechanisms
- Identification of best practices and demonstration projects for further development
Greg Perry, Executive Director of the Medicines Patent Pool, told delegates at a consultation satellite meeting during the World Hepatitis Summit that the organisation was considering how it could act to speed up and expand access to direct-acting antivirals for lower- and middle-income countries, where around 85% of people with hepatitis C are estimated to live.

The Medicines Patent Pool was established with the support of UNITAID, the international drug and diagnostics purchase fund for HIV, tuberculosis and malaria, to negotiate voluntary licensing agreements with pharmaceutical companies that would allow widespread access to low-cost antiretroviral drugs for HIV treatment. The Medicines Patent Pool was also designed as a mechanism to overcome barriers to the development of fixed-dose drug combinations of products from more than one manufacturer, for efficient delivery of treatment in lower- and middle-income countries.

Since its launch in 2010, the Medicines Patent Pool has negotiated voluntary licensing agreements with all the major pharmaceutical companies that allow some or all of their antiretroviral products to be copied by generic manufacturers for sale at greatly reduced prices in lower- and middle-income countries.

Some of the most important drugs used in HIV treatment are now covered by Medicines Patent Pool agreements, although the geographical scope of the agreements varies between products.

Now the Medicines Patent Pool is weighing whether it can make a similar difference in the field of viral hepatitis, where access to new antiviral drugs is very limited outside higher-income countries.

The Medicines Patent Pool’s first priority is to negotiate voluntary licensing agreements that would allow the development of pan-genotypic combinations of direct-acting antivirals. Pan-genotypic drug combinations should be equally active against all genotypes of hepatitis C. Although many advocates argue that pan-genotypic combinations are needed in order to simplify treatment by dispensing with the need for genotype testing, a greater advantage to a pan-genotypic combination would be efficacy against all the genotypes present in lower- and middle-income countries, allowing a larger proportion of the population with hepatitis C infection to benefit from lower-cost treatment. Whereas genotype 1 predominates in the high-value markets of Europe and North America, the mixture of genotypes is far more varied in Asia and Africa. Whereas all direct-acting antiviral combinations are active against genotype 1, some are much less potent when used to treat genotype 3. Having one regimen that suits all patients would vastly simplify treatment by removing the need for a mosaic of national guidelines to cater for local variations in the genotype mix, and would overcome delays in registration of multiple products needed to treat different genotypes.

Approximately 85% of people with hepatitis C live in lower-income or middle-income countries, Homi Hazavi of the Center for Disease Analysis said, but a major challenge facing all efforts to reduce the price of hepatitis C treatment lies in the fact that a large number of these people live in countries such as China, Brazil and Russia which may not be covered by voluntary licensing deals. A review by the Center for Disease Analysis suggests that 23 to 29% of people with hepatitis C live in upper middle-income countries, and 43 to 49% in lower middle-income countries.

The only existing voluntary licensing arrangements for hepatitis C cover Gilead’s products Sovaldi (sofosbuvir) and Harvoni (sofosbuvir/ledipasvir). Voluntary licensing to 11 Indian generic manufacturers allows those companies to market versions of the Gilead products in 101 lower- and lower middle-income countries, and to combine the agents with other products not owned by Gilead. Strict anti-diversion measures designed to prevent the drugs being sold in markets not covered by the licence have also been agreed, but these terms have been strongly criticised by Médecins sans Frontières for their potential to harm patient confidentiality and autonomy. Advocates would like to see less onerous terms and greater coverage of middle-income countries in future licenses.
THE GLOBAL HEPATITIS COMMUNITY CALLS FOR ACCESS TO LIFE-SAVING HEPATITIS DRUGS

The World Hepatitis Alliance has been examining the issue of access to treatment for some time and believed that the Summit was the perfect opportunity to launch a call for more vigorous efforts from government and pharmaceutical companies as it is only forum where pharma representatives, policy-makers and patients from across the globe are brought together. During the Summit the letter was signed by over 175 organisations and individuals from 56 countries, representing WHA members, patient organisations, activists and public health specialists, as well as even some government and World Health Organization representatives.

More people die each year from hepatitis B and C than from HIV/AIDS, TB or malaria. The single most important reason for this is that they do not have access to life-saving drugs for hepatitis B and hepatitis C. This is a scandal. It is unacceptable.

The undersigned on behalf of the 400 million people living with hepatitis B and C call for the following immediate actions:

1. National governments should take all necessary steps to remove the stigma and discrimination that prevents people coming forward for testing, since the vast majority of those with hepatitis B and C remain undiagnosed.
2. National governments should take all necessary steps to put in place adequate infrastructure and to reduce the price of diagnostics sufficiently so that they can afford to screen their at-risk populations and ensure that those testing positive can progress from diagnosis to treatment.
3. National governments should take all necessary steps to remove barriers to, and speed up the process of, national registration of anti-viral hepatitis B and C drugs, including the relaxation of requirements for specific national drug trials where good evidence of efficacy and safety already exists.
4. National governments should take all necessary steps to reduce the price of the best anti-viral drugs for hepatitis B and C to the extent that they can afford to massively scale up national treatment programmes but equally so that those forced to pay for the drugs themselves can also afford them. These measures should be decided according to whatever delivers the quickest affordable access to those in need, whether that is the use of TRIPS flexibilities, patent opposition, use of generics or negotiation with pharmaceutical companies.
5. Pharmaceutical companies should take all necessary steps to ensure their drugs are affordable in all countries, whether high, middle or low income. These steps should include:
   - Pricing the drugs so that, as a bare minimum, the best combinations for the optimum treatment duration are always cost-effective in every market based on accepted per capita GDP determinants of cost-effectiveness
   - Making the Intellectual Property of the best drugs available to the Medicines Patent Pool in as many countries as possible
6. Pharmaceutical companies should not:
   - Put in place anti-diversion policies that infringe the confidentiality or human rights of people living with hepatitis B or C
   - Use a dominant market position to prevent people getting access to the best combination of drugs at affordable prices

OPERATIONAL RESEARCH

Operational and public health research forms an essential element of the scale up of viral hepatitis control. Professor Philippa Easterbrook outlined priority areas for operational research:

- Improve quality of testing technologies, algorithms, and services and evaluate their impact
- Develop and evaluate models of service delivery for hepatitis testing, care and treatment
- Evaluate treatment strategies

Selected key research funding agencies were surveyed, including US National Institutes of Health, US Centers for Disease Control, UK Medical Research Council, French Anrs, Wellcome Trust. The main observations were that funding available is a fraction of that of HIV, has not increased significantly over time, and that funding for HCV is around two to three times that of HBV. Basic science accounts for a significant proportion especially in the case of NIH, and there is little funding of implementation research and large scale up projects.

MORE INFORMATION

To access presentations, videos and photos from the World Hepatitis Summit, visit: www.worldhepatitissummit.com.
**WORLD HEPATITIS SUMMIT IMPACT**

- **506 DELEGATES**
- **46 GOVERNMENTS IN ATTENDANCE**
- **84 COUNTRIES REPRESENTED**

**PRESS**
- **102 ARTICLES IN GLOBAL MEDIA**
- **22 COUNTRIES REACHED**
- **5 MILLION AUDIENCE REACH**

**SOCIAL MEDIA**
- **45,468,474 IMPRESSIONS**
- **5,569 TWEETS TO #HEPATITIS2015**
- **1,738 PARTICIPANTS**
- **AVERAGE 50 TWEETS PER HOUR**

**MOST BENEFICIAL SESSIONS**
1. Simulation exercise
2. State of the Art
3. Treatment and access to drugs

*as ranked by delegates in post-Summit evaluation survey*