Hepatitis B Policy Workshop

Monday, 29 March 2010
Beijing

The Forgotten Disease?

Workshop Report

This report summarises presentations, discussions and recommendations made by participants at a Hepatitis B Policy Workshop in Beijing on 29 March 2010.

The Hepatitis B Policy Workshop was organised under the auspices of the ACT-HBV (Advancing the Clinical Treatment of Hepatitis B Virus) initiative, Asia Pacific chapter.

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Executive Summary

- Over 2 billion people globally have been exposed to hepatitis B and an estimated 350-400 million people have chronic hepatitis B infection. Hepatitis B is a leading cause of death worldwide with most of these deaths occurring in the Asia Pacific region.
- Despite effective vaccination and an increasing range of treatment options for hepatitis B the burden of hepatitis B on the health system will continue to increase unless effective public policy interventions are implemented.
- Clinicians in the Asia Pacific region cannot solve this problem alone. In partnership with other stakeholders they *can* provide expertise and leadership in advocating for public policy change in the region – a key premise of the Hepatitis B Policy Workshop in Beijing.
- The central focus of the workshop was to identify a broad range of public policy issues that impede the optimum diagnosis, monitoring, treatment and care of people with hepatitis B in Asia Pacific, in particular:
  a) specific policy reforms needed to reduce the burden of chronic hepatitis B;
  b) achievements, best practice and processes being undertaken in some countries to generate future policy reform;
  c) tools and resources needed to enable engagement with a broad range of stakeholders with a similar goal of reducing the burden of hepatitis B.
- Minimal coordinated advocacy work has been undertaken in Asia Pacific to bring together the other cross-cutting policy areas - social, economic and health – affecting hepatitis B. Although many challenges are country-specific, there are a number of issues that are common across all countries:
  - low patient and public understanding of the disease and its implications
  - differing opinions among medical experts on the best clinical management regime
  - lack of effective prevalence and surveillance data in many countries
  - lack of policy coordination across different areas of government
  - no identification of common advocacy messages or coordination of advocacy activity amongst stakeholders within specific countries or across the region
  - competing priorities for policy makers / short term focus of governments
- Access to treatment across the region was seen as sub-optimal, with reimbursement policies in some countries being seen to perversely influence prescribing behaviour.
- Adoption of the first viral hepatitis resolution (EB126.R16) by the World Health Organisation (WHO) on 21 May 2010 was seen as an important opportunity to enable hepatitis B advocates across the Asia Pacific region to engage with policy makers to highlight individual country commitments to implementation.
- Asia Pacific does not have a single, cohesive advocacy group dedicated to achieving policy change in the area of viral hepatitis. While workshop participants focussed on hepatitis B, it was recognised that there are many areas of commonality across the viral hepatitis spectrum and that greater impact could be achieved by conducting activities under a 'viral hepatitis' banner.

Recommendations

1. Establish a single, independent, multidisciplinary body called the "Coalition to Eradicate Viral Hepatitis in Asia Pacific" (CEVHAP).
2. Establish an Interim Working Group to develop Terms of Reference for the new group, and prepare for an inaugural meeting mid October 2010
3. Develop an Action Plan to:
   i. Incorporate policy issues and objectives into the Asian Pacific Association for the Study of the Liver (APASL) program for 2011
   ii. Identify and engage with other stakeholder groups seeking to reduce the burden of hepatitis B in the region to ensure alignment on common issues
   iii. Develop strategies to leverage the WHO resolution on Viral Hepatitis within individual countries in the Asia Pacific region
   iv. Determine funding opportunities and resource avenues to develop a sustainable public policy response across the Asia Pacific region in response to hepatitis B.

1. Introduction

1.1 Context

The hepatitis B virus (HBV) was identified 40 years ago yet its impact remains a global public health challenge. It is now estimated that at least 350 million people[1] worldwide are chronically infected with hepatitis B and that between 500,000 and 700,000 people die annually as a result. **The Asia Pacific region accounts for seventy-five percent of all chronic hepatitis B (CHB) infections in the world.**

Asia Pacific is not the only region in the world to identify a severe lack of policy coordination and focus in relation to hepatitis B and viral hepatitis generally. In the past 20 years or so, most countries in Asia Pacific have implemented national hepatitis B vaccination programs which in the long term will achieve a significant reduction in prevalence and, perhaps, eventual eradication. However, in addition to at-risk individuals who are unable to access vaccination programmes, there remains a very large number of adults, already chronically infected, for whom vaccination is too late.

Despite significant advances in implementation of vaccination programs and clinical treatments in hepatitis B, there is an alarmingly high and increasing incidence of liver cirrhosis, liver failure and liver cancer associated with CHB infection. In short, **while great strides have been made in science in terms of vaccination, diagnosis, monitoring and treatment, the formulation and implementation of corresponding public health policies by governments to reduce the burden of hepatitis B have not kept pace with these advances.**

The medical community cannot solve these problems alone but its members *can* act as leaders and catalysts for change in partnership with other key stakeholders. We are now, for the first time in decades, seeing some signs of positive action as exemplified in the recent WHO Resolution on Viral Hepatitis (EB126.R16), the result of sustained advocacy from clinicians and medical experts in partnership with other stakeholders: from civil society, patient groups, the health industry and policymakers.

There are compelling reasons why there is an urgent need for concerted action in Asia Pacific:

- **Hepatitis B causes 80% of all liver cancers around the world**
- **Less than 4% of people, who are diagnosed with chronic hepatitis B, receive clinical treatment**
- **Hepatitis B virus is 100 times more infectious than HIV**
- **Around 350million people worldwide are living with chronic hepatitis B virus – around 75% live in Asia Pacific**
- **There have been little or no public policy developments as a result of the increasing burden of hepatitis B across the region**

1.2 Workshop Objectives

On 29 March 2010, directly after the Asian Pacific Association for the Study of the Liver (APASL) Conference in Beijing, a group of 30 clinicians and others working in the area of hepatitis B came together to develop practical strategies in Asia Pacific that will reduce the burden of a disease in this region. **The central focus of the workshop was to identify a broad range of public policy issues that impede the optimum diagnosis, monitoring, treatment and care of people with hepatitis B in the Asia Pacific region.**

While a number of interested parties were unable to attend, they nonetheless expressed their commitment and support to the meeting objectives. Organisers also acknowledged that, due to time and budget constraints, it was not possible to include representatives from all countries in Asia Pacific, but a commitment was made to ensure that actions and deliberations flowing from the meeting would be openly available and communicated to interested parties from other countries in the region. Participants attending came from: China, Korea, Japan, Australia, Taiwan, Singapore, Hong Kong, Europe and the USA.

In developing the workshop agenda, organisers sought to bring to the forum various policy and research initiatives being carried out in Europe, Australia and the USA, in addition to presenting an assessment of achievements and current activities in Asia Pacific (see *Attachment 1* for Workshop Agenda).

[1] World Health Organization. Viral hepatitis: Report by the Secretariat - http://apps.who.int/gb/ebwha/pdf_files/EB126/B126_15-en.pdf (accessed 25 May 2010)

In addition to a background briefing paper prior to the meeting, a policy position paper developed by a group of medical experts from Vietnam and the USA was distributed to workshop participants. (*Attachment 2*).

In working to key objectives, workshop participants were asked to identify:

1. **Specific policy reforms needed to reduce the burden of hepatitis B in their respective countries;**
2. **Achievements, best practice and process to generate future policy reform;**
3. **Tools and resources needed – those currently available as well as those still needed - to enable engagement with the broad range of stakeholders needed to bring about hepatitis B policy reform.**

2. Presentations and Discussion

2.1 Advocacy Efforts to Date

Advocacy groups and individuals have been working for several years to raise awareness of the impact of hepatitis B among policy makers in Europe, the USA and a number of individual Asia Pacific countries, with the aim of securing comprehensive national policy strategies and funding to improve national responses and reduce the burden of the infection. Progress has been slow and although many challenges are specific to individual countries, there are common challenges across all countries in the region.

Great advantage and strength can be gained by identifying areas of common purpose and working collaboratively to achieve global outcomes that can also influence policies locally. Several presentations to the policy workshop discussed the challenges involved in engaging with public policy in relation to hepatitis B. These presentations are summarised below.

2.1.1 EUROPE – EASL – Heiner Wedemeyer, Director General, EASL

1. The European Association for the Study of the Liver (EASL) was established more than 40 years ago and has individual members from more than 100 countries.
2. Viral hepatitis is its primary area of expertise and **EASL has recently incorporated identification of policy issues and advocating for them into the Association's agenda. The organisation** has a central office in Geneva, providing continuity and focus, a great step forward, particularly when working with multiple government and non-government stakeholders.
3. The body has its own governing board and journal which, in addition to its core scientific content, provides a useful tool for policy advocacy.
4. EASL actively supported the development of the WHO resolution (EB126.R16) on viral hepatitis and welcomed its adoption on 21 May 2010.
5. Following policy workshops in the European Union (EU) Parliament, and subsequent activities at a national level in Europe, **on 14-15 October 2010 a Hepatitis B and C Summit Conference[2] will be held in Brussels.** The Conference will involve multiple stakeholders: clinicians, patient groups, bureaucrats, politicians. Five deliverables have been identified by the Summit Steering Committee:
    1. Awareness and Prevention
    2. Enhancing Surveillance for HBV and HCV by the European Centre for Disease Control (ECDC)
    3. Screening/case findings for HBV/HCV and Related Diseases where co-infection is common
    4. Universal Access to Early Treatment in line with Evidence-Based Guidelines
    5. Expansion of research resources under the 7th and 8th Research Framework Programmes of the EU

2.1.2 EUROPE - WORLD HEPATITIS ALLIANCE: Charles Gore, President, World Health Alliance (WHA)

- The World Hepatitis Alliance is a non-governmental organisation that represents approximately 280 hepatitis B and C patient groups from around the world. In working to its mission to **"halt the death toll and improve the lives of people living with viral hepatitis B & C" by "working with governments to eradicate the diseases",** the WHA supported the need to have the World Health Organisation (WHO) designate viral hepatitis as a serious global health issue.
- In Europe, WHA has also worked hard to garner support for the WHO resolution on Viral Hepatitis, adopted at the Sixty-third World Health Assembly on Friday, 21 May 2010.

[2] http://hepsummit2010.org

- Upon adoption of the resolution, WHA members in individual countries have committed to the following actions:
  - Compare what a Government says it's doing in the policy report and what it's really doing
  - Campaign to make it close the gap
  - Compare what countries say they are doing and use that as a lever
  - Compare what a country has signed up to in the resolution to what is really happening
  - Campaign to make it put the resolution into action
  - Use the policy report and the resolution to get it to sign up to the WHA "12 Asks"
  - Monitor the implementation of the "12 Asks"
  - Use the World Health Alliance to apply international pressure
  - Use the WHO Director General's requirement to report back in 2012 as a lever
- Another activity recently undertaken by WHA as part of its strategy to increase WHO commitment and action in relation to viral hepatitis is an **online survey of 138 countries**[3], commissioned by WHO, to ascertain the current status of their policies in relation to viral hepatitis, and what they most need by way of assistance. Responses were received from 108 countries. The survey **revealed that 60%-70% of countries needed assistance with: surveillance, goal setting, evaluating interventions and increasing awareness.**
- To support its lobbying efforts with consistent, clear messages, WHA developed a set of 12 "asks", derived from the fact that 1 in 12 people worldwide are living with hepatitis B or C:
  1. Public recognition of chronic viral hepatitis as an urgent public health issue
  2. The appointment of an individual to lead Government strategy nationally
  3. The development of a patient pathway for screening, diagnosis, referral and treatment
  4. Clear, quantifiable targets for reducing incidence and prevalence
  5. Clear, quantifiable targets for reducing mortality
  6. Clear, quantifiable targets for screening
  7. Effective surveillance and publication of national incidence and prevalence statistics
  8. Commitment to examine cases of best practice internationally
  9. Commitment to work with patient groups in policy design and implementation
  10. Provision of free and anonymous (or confidential) testing
  11. A public awareness campaign that alerts people to the issue and is committed to reducing stigma
  12. Commitment to an on-going national vaccination programme

2.1.3 AUSTRALIA: Jack Wallace, La Trobe University, Melbourne

- At a national level, the Australian health system has developed national strategies for HIV since 1989, and hepatitis C since 1999, in order to coordinate activity to prevent new infections, and to reduce the burden of infection on individuals and the community.
- The strategies reflect government commitment to each health issue and use a partnership approach between government, clinicians, researchers, and importantly the communities most affected by the viruses, recognising that **each partner has a unique and important place in responding to the infection.**
- The strategies look at the social context in which people with blood borne viruses live and identify interventions to address these issues. These social issues include discrimination, access to health services, and emotional and practical support needs for people with the virus.
- Consistent with many other locations hepatitis B has previously been included in health strategies, but only as a vaccination issue.

[3] Full Report available at: http://www.worldhepatitisalliance.org/en/Policy/2010PolicyReport.aspx

- To support advocacy arguments for the development of a National Health Strategy in Hepatitis B, social policy research was conducted to identify the needs of people with hepatitis B. The "*National Hepatitis B Needs Assessment*"[4] study was able, through qualitative research, to **expand and personalise the experience of being infected with hepatitis B outside the clinical setting to provide data which is more accessible for many public health policy makers**.
- Australia has now developed its first National Hepatitis B Strategy with the following priority action areas:
  - Building partnerships and strengthening community action
  - Preventing hepatitis B transmission
  - Testing, diagnosis and screening
  - Clinical management of people with chronic hepatitis B
  - Developing health maintenance, care and support for people with hepatitis B
  - Research and surveillance
  - Priority actions in research and surveillance
  - Workforce and organisational development

2.1.4 U.S.A.: Professor Tim Block, Drexel University College of Medicine Mrs. Joan Block, Hepatitis B Foundation USA, Philadelphia

- The Hepatitis B Foundation is a national research and disease advocacy organization committed to finding a cure and improving the lives of those affected worldwide through research, education and patient advocacy. For the past 20 years it has been a leading authority and its website offers comprehensive information about hepatitis B for patients and providers alike, as well as information about prevention, management and treatment.[5]
- To address the low numbers of hepatitis B infected people who receive clinical treatment in the USA, the Foundation advocates for better surveillance of chronic infections to obtain accurate numbers of those living with hepatitis B as well as raising awareness among providers and the public to ensure that more people get tested for hepatitis B.
- The overall goal of the Foundation is to eliminate hepatitis B by advocating for the following: improved vaccination rates among infants, children and adults; better compliance with existing CDC guidelines that call for testing of all pregnant women for hepatitis B infections and administering the birth dose of hepatitis B vaccine to newborns at risk; increased screening rates among at-risk populations; and more federal investment in hepatitis B research and public health issues.
- In the effort to advocate for increased funding from the US Government, the Foundation recognized that the lack of authoritative data was a primary obstacle to presenting the case to key policy makers. This became a primary area of focus in the national advocacy strategy of the Foundation and its many partners. **By working together, all parties succeeded in securing approval from the Institute of Medicine (IOM) of the National Academies to conduct a comprehensive review of the current prevention and control activities of hepatitis B and hepatitis C in the USA.** The final report included 22 recommendations on specific ways to reduce the burden of new infections and death from chronic infections.
- Importantly, many stakeholders were involved in the effort to gain the IOM support for the first-ever report on chronic hepatitis and liver cancer in the USA **:** advocacy groups, Congressional champions, the private sector and Federal health agencies.
- The final IOM report "Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C" [6] was released on January 10, 2010 and was the result of a comprehensive literature review and two public hearings conducted by a 14-member expert panel over an 18 month period. The IOM report is an authoritative report which finds that, **because these diseases are not recognized as serious health problems, they do not receive sufficient resources to provide appropriate prevention, control and surveillance.** As the study provides an evidence-based rationale for increased funding for hepatitis B and C and liver cancer, it can be used by advocacy groups as a powerful, independent blueprint for addressing the problem of chronic viral hepatitis when speaking with key policy makers in the USA.

[4] http://www.ashm.org.au/images/publications/guidelines/07hepbneedsassess_000.pdf
[5] www.hepb.org
[6] http://www.iom.edu/Reports/2010/Hepatitis-and-Liver-Cancer-A-National-Strategy-for-Prevention-and-Control-of-Hepatitis-B-and-C.aspx

2.1.5 ASIA PACIFIC

A. Cost-effectiveness Analysis - Assoc Professor Seng Gee Lim, National University Hospital, Singapore

The challenges and complexities associated with the use of cost effectiveness analyses (CEA) to determine treatment access and, where available, reimbursement levels were presented in an overview of recent achievements and developments in Asia Pacific.

The overview included a summary of recent work of the cost-effectiveness working group at APASL which aimed "to agree on a consensus model for CEA which uses commonly agreed variables, transitions and assumptions". Key objectives of the group's work were:

- To review current assumptions on natural history of chronic HBV infection
- To determine appropriate treatment endpoints and long-term efficacy of different treatment regimens
- To develop Markov models for cost-effectiveness in different settings

In terms of the difficulties relating to the use of CEA in policy development, it was noted that, **due to the limited understanding of CEA and pharmacoeconomics among stakeholders and the lack of coherent and consistent messages, wide confusion reigns.** As a result, policy makers will often dismiss complex arguments or, conversely, call for more evidence when presented only with broad requests.

It is necessary to ensure that arguments and policy proposals are underpinned by the intellectual rigour of CEA and scientific evidence, while at the same time developing key advocacy messages that are clear, consistent and persuasive. While marshalling these arguments however, a particular challenge for Asia Pacific (as opposed to a single nation or say, the EU) is the lack of a central body through which to effect policy reform.

Other challenges identified in the AP region were:

- Due to low income levels of patients and varying levels (partial, or non-existent) reimbursement in many countries, most physicians in Asia Pacific must also take into account a patient's financial circumstances when prescribing. In this way, **reimbursement policy can have a significant influence on treatment practices.**
- A further difficulty for Asia Pacific lies in the fact that much of the CEA data available is based on USA thresholds which are vastly different to the GDP levels of many countries in this region. Ultimately, governments must formulate health expenditure policies based on how much a particular society is prepared to pay. In this context, the generally accepted current value of US$50,000/ QALY in the US or £30,000/ LYG in the UK is not realistic for countries like Vietnam, Philippines, China etc.
- An alternative suggestion for the assessment of cost-effective thresholds has been suggested by the WHO which has put forward criteria based on GDP levels:
  - < 1 x GDP/capita : very cost-effective
  - 1-3 x GDP/capita : cost-effective
  - > 2 x GDP/capita : not cost-effective

B. Achievements and Challenges in Hepatitis B Management and Control Asia Pacific Country Overviews were presented by: China - Prof Jia Ji-Dong Korea - Prof Han Japan - Prof Yokosuka Taiwan - Prof Kao Hong Kong - Prof Yuen

- Many countries in Asia, led by Taiwan, have successfully implemented universal hepatitis B vaccination programs, although in a number of countries implementation of the program remains patchy.
- While developing policies to increase access to vaccination programs is an important area of focus for many governments, **there remains a vast population of people with hepatitis B, born prior to the availability of vaccination, who are in need of diagnosis and management plus a significant number of people who have, and continue to miss out on vaccination.**
- If real progress is to be made to reduce the current high levels of mortality and morbidity resulting from hepatitis B infection **government policies must be developed that are specific to Asia Pacific and that span the full spectrum of patient needs - social, economic and clinical.**

- Difficulty in achieving consensus on management and control across Asia Pacific was identified as a key challenge. While it makes sense to aim for consistency and alignment with guidelines in Europe and the USA, economic, cultural and social issues specific to developing countries in Asia Pacific need to be acknowledged and addressed.
- Cost and low affordability of clinical treatment are often identified as barriers, especially in developing countries. It is instructive to look to the way HIV was positioned as a global issue with the ultimate mobilisation of governments and civil society to provide free or low-cost drugs to patients.
- Cost-effectiveness is complex and confusing, with data largely based on studies outside Asia Pacific. **It is important to have data specific and relevant to the region and to distil key advocacy and policy recommendations from the data that resonate with politicians and policy makers.**
- Policies on diagnosis and treatment and public funding support vary from country to country. A range of restrictions in level or length of reimbursement coverage has had the perverse effect of sub-optimal prescribing behaviour. In Korea, for example, restrictions on length of reimbursement coverage, has forced treatment with older, cheaper therapies. This and similar policies in other countries is responsible for the development of multi-drug resistance.

2.2 Priorities for Asia Pacific

Workshop attendees were asked to identify the top 3 key issues in the Asia Pacific region that, if addressed, would have the greatest impact in their country.

Acknowledging that the priorities chosen are reflective of a group comprised largely of clinicians, overwhelmingly, the key issues were judged to be:

1. **Low patient and public understanding of the disease and its implications**
2. **Lack of coordination amongst all stakeholders to develop a specific policy platform for hepatitis B**
3. **Differing opinions among experts on best management regime**

Other challenges deemed of high importance were:

a) **Short term focus of governments** and low awareness of disease implications amongst politicians and policy makers
b) **Lack of social policy research and surveillance data** to support the case for policy change
c) **Patient affordability** / hepatitis competes with other diseases for public funding

3 First WHO Resolution on Viral Hepatitis Welcomed

3.1 Viral Hepatitis designated a global health problem

The first comprehensive resolution on Viral Hepatitis (EB126.R16) was adopted at the Sixty-third meeting of the World Health Assembly in Geneva on Friday, 21 May 2010. Adoption of the resolution is reflected in the following statement on the WHO website[7]:

> **The delegates at the World Health Assembly adopted resolutions on a variety of global health issues**
>
> 21 MAY 2010 | GENEVA -- The Sixty-third World Health Assembly, which brought together Health Ministers and senior health officials from the World Health Organization (WHO) Member States, concluded business and closed Friday evening...

> **Viral hepatitis**
>
> **Member States accepted the report to the World Health Assembly and adopted a resolution including a World Hepatitis Day on 28 July. Viral hepatitis (i.e. hepatitis A, B, C, D and E) —a combination of diseases that are estimated to kill over 1 million people each year and an estimated 1 in 12 persons are currently infected and have to face a life with liver disease if unrecognized. This endorsement by Member States calls for WHO to develop a comprehensive approach to the prevention and control of these diseases.**

The report and resolution clearly recognise viral hepatitis as a global public health problem (see *Attachment 3*). The statement sets out the many reasons why the disease, particularly hepatitis B and C, requires an integrated, global approach. These include: high prevalence, poor prevention and control procedures, lack of affordable treatments; suboptimal vaccination coverage; high rates of morbidity; and globally, 78% of primary liver cancer cases attributable to viral hepatitis.

The resolution designates 28 July as World Hepatitis Day and urges all Member States to adopt a range of measures to address current deficiencies such as: increased awareness; improved surveillance; protection of health workers; implementation of prevention, control and disease management strategies, improved blood safety; improved vaccination coverage and increased access to appropriate diagnosis and treatment programmes.

Importantly, the resolution also requests the Director-General to report back to the Sixty-fifth World Health Assembly (in 2012) on the implementation of this resolution.

3.2 Opportunities and Challenges in Asia Pacific

The increased focus and commitment by WHO member countries to reduce the burden of viral hepatitis provides great opportunities to leverage issues relating to hepatitis B in Asia Pacific. While recognising and welcoming this as an extremely valuable and necessary step forward, workshop participants expressed concern about the very low base they are working from, in terms of viral hepatitis advocacy in Asia Pacific.

Despite Asia Pacific having the highest number of people with chronic hepatitis B, many workshop participants pointed to the low priority currently given to hepatitis B by WHO, exemplified by the relatively weak resourcing and administrative support allocated to regional offices. This makes it difficult to identify and engage individuals who could make a difference. For these reasons, and **with so many countries in the developing world refusing to allocate any meaningful resource to a disease that is not listed as a public health priority, the importance of the WHO resolution on viral hepatitis in Asia Pacific is significant.**

While recognising the challenges within the region, workshop participants agreed that the resolution provides a strong platform and leverage point for hepatitis advocates in the Asia Pacific region, enabling representations to governments at all levels – bureaucratic and political – to advocate for implementation of the requirements of the resolution in their countries.

[7] http://www.who.int/mediacentre/news/releases/2010/wha_closes_20100521/en/index.html

For example, advocates* in Asia Pacific can work with their counterparts in Europe and the USA to:

a) Highlight to policy makers the need to increase public awareness of the disease and its implications
b) Increase participation and representation of stakeholder groups in Asia Pacific
c) Develop a strategy and action plan for leveraging the requirements of the WHO resolution within member countries in Asia Pacific including a proposal for broader focus and discussion at APASL 2011
d) Work towards closer alignment of the various viral hepatitis management regimes across geographies

* *It is acknowledged that there are a number of issues relating to organised advocacy in Asia Pacific and further discussions will be needed amongst this group both in relation to the WHO Resolution and to agree on future group structure, strategies and work program.*

4 Emerging Themes

4.1 A Silent and Forgotten Disease

- Despite being regarded by many as an "old disease", hepatitis B has a very low priority in most national health policies around the world. **Only now**, as a result of continuing scientific developments and a concerted advocacy effort by multiple stakeholders, **is viral hepatitis starting to be recognised globally as a significant economic & social burden**.
- Reasons for the lack of attention to viral hepatitis are multi-pronged and include: the historical lack of clinical solutions; competition with other major diseases for public funding; a successful prevention intervention; overriding attention to existing prevalence and risk, low public awareness coupled with low appreciation of disease implications if left untreated, and social stigma.
- **The many issues impeding adequate attention to hepatitis are complex and multifarious and demand a multifaceted advocacy response which cuts across a number of policy areas and affects a number of different interest groups.** Careful prioritisation is required to ensure focus and cohesion in the development of advocacy strategies.

4.2 Low Public Awareness a Major Concern

- Overwhelmingly, **the greatest priority is the need to dramatically increase the level of public understanding of viral hepatitis**. In one small study in Korea among patients presenting with advanced liver disease, less than 50% were aware of their status – even among those who were aware they were infected with hepatitis B few sought medical guidance until they became ill. In a study from Taiwan, of 3 million people with hepatitis B, only 30% were aware of their status.
- **Low awareness levels about hepatitis B is not restricted to the general public. There is a need to educate general practitioners, health workers and policy makers.**
- A poor understanding of the disease and the lack of urgency in terms of diagnosis, management and treatment means that large populations of people with viral hepatitis do not seek medical attention or receive treatment. **While the high cost of therapy and lack of affordability was identified in China as a major factor behind low treatment rates (<20%), countries with universal reimbursement such as Korea and Australia also report relatively low treatment rates, suggesting that cost alone is not the only reason for low treatment access.**

4.3 Stakeholder Engagement Essential

The need to engage all stakeholders including governments, patients, medical experts, private enterprise, civil society and healthcare providers in the development of consistent and cohesive messages was stressed throughout the workshop. Greater traction with policy makers will be achieved by all advocacy groups presenting consistent and cohesive arguments, data and requests, across all regions.

In this regard, major challenges in Asia Pacific were identified in relation to a lack of patient support groups and a lack of a single, identifiable group dedicated to building an advocacy agenda in the region (this is not only an issue for Asia Pacific but was also identified as a challenge for Europe).

While the priority for the group attending the policy workshop - and the major priority for Asia Pacific - is hepatitis B, it was agreed that greater impact could be gained by aligning with the recent WHO resolution to encompass advocacy and collaborative effort under the "viral hepatitis" banner.

4.4 A Need to Coordinate Advocacy Efforts Across Asia Pacific

- To date, **much has been achieved by individual clinicians and liver associations in their respective countries to improve access, reimbursement and treatment guidelines.** While Australia has recently endorsed its first National Hepatitis B Strategy, in many Asia Pacific countries the high prevalence rate, diversity of cultures, poorly resourced health systems and low GDP profiles of many, add to the challenges in developing a cohesive advocacy strategy in individual countries, making a pan-regional approach even more challenging. Even with the development of a nationally coordinated strategic response to hepatitis B in Australia, this response has not received any funding for its implementation.
- **Minimal advocacy work has been undertaken in Asia Pacific to bring together the other cross-cutting policy areas - social, economic and health** - that if properly coordinated, can have a significant impact on arresting disease transmission and progression as well as improving access to diagnosis, management and where necessary, treatment. In addition to medical experts, such work requires input and resourcing from multiple stakeholders.

4.5 Organising for the Future

Notwithstanding the challenges identified during presentations and discussion, all participants agreed that to effectively reduce the burden of hepatitis B in the Asia Pacific region, public policy responses within individual countries - and the region as a whole - needed to be substantially improved.

With ACT-HBV funding having ceased, there was strong support for this group to transition to a new organisational structure. While continuing to support the ACT-HBV objective of advancing clinical treatment of hepatitis B, the new organisation, CEVHAP, will embed these issues in a broader health and social context to address a range of other issues affecting people living with the disease.

The importance of a long term strategic and sustainable approach to developing effective public policy, and the need to establish continuity for the group was identified as an important factor in building a specific, dynamic group to undertake viral hepatitis advocacy in Asia Pacific. As membership of this group, in addition to clinicians and medical experts, would also include a broad range of expertise including patient representatives, public health experts and social researchers, it was not felt appropriate for the group to be auspiced by APASL but that the group would work very closely with APASL in particular, as well as EASL, AASLD[8], WHA and WHO and other important stakeholder groups.

[8] American Association for the Study of Liver Diseases

5 Recommendations

Recommendation 1

Establish a single, independent, multidisciplinary body, called the "Coalition to Eradicate Viral Hepatitis in Asia Pacific", appropriately structured to enable continuity of effort and focus on policy reform.

It is proposed that the **Coalition to Eradicate Viral Hepatitis in Asia Pacific (CEVHAP)** have the following mission:

> **To reduce the significant social and economic burden of viral hepatitis in the Asia Pacific region by working with governments and other stakeholders to achieve health policy reform and greater public awareness.**

5.1.1 Structure

The proposed structure would include an Executive Committee and general membership. This would allow the organisation the capacity to respond to issues that arise in an effective manner, but also provide leadership through representation from a broader range of members.

Executive Committee:

A total of 12 positions will comprise the Executive:

- 1 - Rotating Chair (medical expert)
- 2 - Joint Secretary (medical expert)
- 3 – Joint Secretary (medical expert)
- 4 – Current President of the Asian Pacific Association for the Study of the Liver (APASL)
- 5 – A representative from the World Health Organisation
- 6 – A representative from the World Hepatitis Alliance
- 7, 8, 9 – Three medical experts rotated from countries. These should be annually rotated with initial selection guided by: countries not already represented on Executive; and countries with highest viral hepatitis prevalence
- 10, 11, 12 - Three non-medical representatives, selected based on area of expertise e.g. patient advocacy, policy, social research, health economics, communications etc.

General Membership:

While it is intended that CEVHAP use the model developed by ACT-HBV primarily as a group of clinicians and medical experts, with expertise and interest in viral hepatitis, membership will also be invited on an ad hoc basis from experts who have a particular interest or expertise to offer.

Working Groups:

As CEVHAP membership and participation is voluntary and non-remunerated, to minimise workload as much as possible, it is recommended that responsibility for the development and execution of work plans, while driven by the Executive, will be apportioned across the entire membership.

5.1.2 Funding

At this stage, no funding source has been identified to support this group but preliminary discussions have been encouraging, having identified several potential funding streams. These will be followed up in due course. As the organisation's ability to pursue a meaningful work program will depend upon the extent to which funding can be raised, this will be an early priority.

5.1.3 Meeting Frequency

Feedback from participants following the Workshop favoured a face-to-face meeting at least annually, initially associated with the APASL annual meeting conferences, with teleconferences and working group meetings as required.

5.1.4 Next Meeting

The next opportunity for an inaugural meeting of CEVHAP will be either before or after the HBV Molecular Biology Meeting to be held in Taipei between 9-13 October 2010. Dependent upon funding, it is proposed that a meeting be convened around this time to elect the Executive Committee, agree strategies and develop work plans.

Recommendation 2

Establish an Interim Working Group to:

i. Develop draft Terms of Reference for the future operation of **CEVHAP**
ii. Secure seed funding for an inaugural **CEVHAP** Meeting
iii. Develop the Agenda and preparatory materials for **CEVHAP's** first meeting
iv. Oversee logistical arrangements for **CEVHAP's** first Meeting

Recommendation 3

Develop an Action Plan with a targeted focus on a limited number of key goals in the short to medium term:

i. Incorporate policy issues and objectives into the APASL program for 2011
ii. Identify and engage with other stakeholder groups seeking to reduce the burden of hepatitis B in the region to ensure alignment on common issues
iii. Develop strategies to leverage the WHO resolution on viral hepatitis within individual countries in the Asia Pacific region
iv. Determine funding opportunities and resource avenues to develop a sustainable public policy response across the Asia Pacific region in response to hepatitis B.

ATTACHMENT 1

Hepatitis B Policy Workshop
Monday, 29 March 2010, Beijing
AGENDA

Time	Topic	Speaker
Venue: Olympic Room 6, Third Floor		
0830- 0840 **(10 mins)**	**Welcome & Introduction** • Policy defined - Different countries, different issues but clinicians recognize policy reform is needed in all - What role can the clinician play in AP Policy reform? - How best to generate greater political awareness and generate a call to action • Agenda Outline: Achievements and Work Needed	**Prof S Locarnini** Co-Chairman
0840 – 0900 **(20mins)**	**Keynote Address – Building our Political Capital from Past Success** • The story of universal vaccination in Taiwan - Early challenges and how they were overcome • Is Vaccination alone enough – what more does Taiwan need to do (eg high prevalence in >20yo) • "Towards Eradication" in the long term – can we achieve it?	**Prof DS Chen** Co-Chairman
0900 - 0920 **(20mins)**	**Case Study: European Parliament – The Snowball Effect** • Identifying the Need • Building the Case • Garnering Stakeholder Support • Securing Political Will • Summit Conference Plan – 2010	**Dr Heiner Wedemeyer** Hannover Medical School
0920 – 0940 **(20 mins)**	**A Global Policy for Hepatitis B**: • The WHO Resolution - How it was achieved • Leveraging the Resolution in member countries • Securing global implementation	**Mr Charles Gore** World Hepatitis Alliance
0940 – 1000 **(20mins)**	**Case Study: Australia – From Advocacy to Policy Strategy** • Identify the Need (Needs Assessment) • Build the Case • Stakeholder Engagement (Who received our message?) • Securing Political Will (How was this achieved?)	**Mr Jack Wallace** Latrobe University, Aust
1000 – 1020 **(20mins)**	**Case Study: USA – A National Strategy for Prevention and Control of Hepatitis B&C** • Recent IOM Report & Recommendations • History behind the study • Involvement of HB Foundation and other stakeholders • Securing Political Will – What Now?	**Prof Tim Block** **Mrs Joan Block**, **BSN, RN** Hepatitis B Foundation USA

1020 – 1045 (25mins)	**Morning Tea + Group Photograph**	
SPECIFIC COUNTRY ISSUES		
1045 – 1200 (15 mins ea)	• What Govts are doing well; what still needs to be done? • The ideal state - What I would like my country's policy landscape to look like in 5 years?	**1. Korea (Prof Han)** **2. China (Prof Jia)** **3. Taiwan (Prof Kao)** **4. Hong Kong (Prof Yuen)** **5. Japan (Prof Yokosukao) Korea (Prof Han)**
1200 - 1230 (30mins)	**PANEL DISCUSSION**	
1230 - 1245	**PRIORITISATION EXERCISE:** What are the top 3 issues that, if addressed effectively, would have the greatest impact on the natural history of Hepatitis B in your country ?	**ALL**
Venue: Café Marco, First Floor		
1245 - 1400 (Address - 30mins + 10min Qs)	**Luncheon Address– What do Politicians Want to Hear?.... What do they <u>Need</u> to hear?**	**Hon Dr Michael Wooldridge** F/up questions led by Co-Chairs
Venue: Olympic Room 6, Third Floor		
1400 -1430 (30 mins)	• **Developments in cost-effectiveness for Hepatitis B in the AP region** - The Hepatitis Story in Asia Pacific - What have we learnt about communicating data to governments and payers ie economic and pharmacoeconomic? - What more do we need to have to build the case for policy-makers?	**Prof SG Lim**
1430 – 1615	• **GROUP BRAINSTORMING – They Way Forward** 1. What would good hepatitis B policy look like in my country? Do we have this policy? (you could be harsh and ask if not, why not) 2. Do we have the data to feed into this policy? What are the key messages? 3. Who are the key people we need to influence to get this policy developed in our country and the A/P 4. Who are the allies that we need at a country/regional level who can support developing a policy	**ALL** **Led by Chairs:** **Prof DS Chen** **Prof S Locarnini**
Tea, Coffee & Beverages to be available in room		
1615 – 1630	**Wrap Up & Closing Remarks**	**Prof D S Chen** **Prof S Locarnini**

ATTACHMENT 2

A Plan for Action for Liver Diseases in Viet Nam

Hue, Viet Nam

March 23, 2010

Prevention, Detection, and Control of Viral Hepatitis and Other Liver Diseases in Viet Nam

Executive Summary

A. Background and Urgent Needs

Chronic viral hepatitis affects over 500 million people worldwide, with 15-30% of people who are infected eventually dying of liver disease such as cirrhosis or liver cancer. Studies have shown that there is a very high prevalence of liver disease in Viet Nam, much of which results from chronic infection with hepatitis viruses, especially hepatitis B, as well as high consumption of alcohol among men. As a result, liver cancer is the fastest growing cancer in Vietnam, both in terms of incidence and death rates. In fact, a recent nationwide study found that liver cancer is the most common cause of cancer death in Viet Nam.

One large study has predicted an enormous liver disease burden in Viet Nam over the next fifteen years from chronic hepatitis B (CHB) alone. Viet Nam has one of the highest

rates of hepatitis B virus (HBV) infection in the world, with an estimated 10 to 15 million people thought to be chronically infected. This means that at least one in eight people in this country are living with this disease. HBV is responsible for almost 80% of all hepatocellular carcinoma (HCC, the most common type of liver cancer), both in Viet Nam and worldwide. By the year 2025, it is estimated that CHB will result in 58,650 patients with cirrhosis, 25,000 patients with HCC, and 40,000 deaths in Viet Nam. Adding the additional factors of chronic hepatitis C (CHC), alcoholic liver disease, and fatty liver disease, all of which affect substantial numbers of people in Viet Nam, could make the ultimate costs to both individuals and society quite staggering.

Unfortunately, liver disease has not yet been critically considered by either the Vietnamese people or their health professionals as a major health risk. Moreover, there is substantial confusion among health professionals as to what can and should be done to provide prevention, early detection, and treatment for liver disease. Factors that contribute to the lack of education on liver disease in Viet Nam include cultural misconceptions, misdirected knowledge, misinformation and mythology about the disease, disaffected attitude, poor financial support, inadequate access to care and, in particular, a lack of formal and professional educational programs about hepatitis B directed to the Vietnamese population and to health care professionals, including nurses, physicians, public health professionals, and pharmacists.

There needs to be a particular emphasis on widespread education about HBV. There is too much misinformation about hepatitis B in some groups, and a complete lack of knowledge about it in others. Proper education for both the public and health care workers could dramatically limit the spread of HBV. It will be important to teach the public about the ways in which HBV is spread: when blood, semen, or other body fluids

infected with the virus enter the body of a person who is not infected. Thus, people need to be taught that in addition to infection at birth (when the virus is passed from an infected mother to her baby) people can become infected during sex with an infected partner, through exposure to blood via re-use of needles or sharp instruments (for example, as when used for tattoos or in traditional medicine practices), through sharing items such as razors or toothbrushes with an infected person, through direct contact with the blood or open sores of an infected person, and among drug users, through sharing needles, syringes, or other drug-injection equipment previously used by an HBV-infected person.

Medical personnel nationwide need to be taught that transmission in the medical setting can occur when patients are exposed to HBV-contaminated blood via re-use of needles, syringes, or improperly sterilized medical equipment. Since prevention approaches have been generally under-emphasized in medical education, there is a clear need to ensure that all of Viet Nam's medical schools provide up-to-date information as part of their curriculum, while also teaching this in CME (Continuing Medical Education) programs.

On the policy standpoint, one of the greatest challenges is extending the success in childhood vaccination to the adult population. Therefore, policies, standards of care, guidelines and regulations need to promote that not only young children but also older children and adults be vaccinated for the disease.

It is both timely and extremely urgent to create a scientifically based project that addresses this fast-growing problem among the Vietnamese population. A comprehensive approach should combine updated public health methods (including

health education, health economics, health administration, epidemiology, health information, biostatistics, health systems, health planning, and health policy) with a state-of-the science medical approach that includes screening, immunization, detection, and treatment. With the looming threat of a rapidly growing liver disease burden in Viet Nam, this program needs to be strategically planned and effectively implemented as soon as possible.

B. Project Scope of Work

The project will include the design and implementation of a comprehensive health promotion program to educate the Vietnamese public, to train health professionals, and to provide screening, vaccination, and treatment services to the Vietnamese population. Integration with current health systems in Viet Nam will be an essential part of this program development. In order to achieve the goal of culturally sensitive and competent health systems, our proposed five year project includes the ten major tasks discussed below.

Task 1: Education of the Vietnamese Population.

This program will apply three major communication channels, including person-to-person, group education, and mass media. Structured interviews, surveys, and focus groups will identify the best educational intervention strategies, the most efficient messages, the most cost-effective messengers, and the most effective materials. The strategies will be selected and applied depending on the educational targets, including patients, the public, health professionals, and health policy makers. The strategies used will depend on the targets' educational levels. We will test and use a variety of

resources for educational messages. For example, celebrity endorsement, dramatic interaction, documentary, or factual presentation formats might be selected for video spots. The actual approaches for each medium will be assessed by focus groups in order to review and decide on the most effective presentation approaches to communicate with the targeted audience.

The commune health centers in Viet Nam could be an extremely valuable resource for providing education on HBV infection and CHB, as well as carrying out screening and vaccination and providing treatment, where indicated. Because these commune health centers already have information flowing to and from the academic and hospital community, the Ministry of Health, the Provincial Health Bureaus, and the District Health Divisions, a national mandate to improve HBV education, screening, vaccination, and treatment could efficiently reach the local commune level. According to a 2005 report on the human resources for healthcare in Viet Nam, almost all of the 10,769 communes have a health center where commune health workers provide both primary health care and most preventive health care activities. In addition, the District Health Divisions already have teams that provide education and assistance in specific areas (such as Hygiene and Epidemiological). Thus, these health workers at both the commune and district levels could be an invaluable resource for this project when properly educated about screening, vaccination, and treatment.

Where necessary, additional health educators can be selected and trained in health education on liver disease, so that they can perform person-to-person health education activities in such settings as policy makers' offices, health centers, physicians' offices, pharmacies, and hair salons, as well as group education sessions at gathering points such as waiting rooms in hospitals, churches, temples, senior centers, community

centers, schools, universities, music performance, health fairs, and food markets. In addition, the mass media can promote awareness via articles in Vietnamese or English language newspapers and magazines, posters, pamphlets, flyers, and television or radio talk shows.

Task 2: Training of Health Providers.

This program will include both regular classroom educational seminars and online CME courses. With the collaboration of expert consultants, we will design and conduct CME seminars to update and improve the knowledge base of medical professionals regarding liver disease. While the classroom setting continues to be a popular format for CME, research indicates that it results in a significantly lower level of behavior change than the computer-based CME approach, often referred to as internet or e-learning CME. Because time available to physicians for CME is so limited, the approach must be flexible, permitting physician learners to re-review the materials as frequently as desired. Online CME courses will consist of a series of e-learning modules for health professionals focusing on screening, vaccination, and treatment of HBV, screening and treatment of HCV, and the prevention, early detection and case management of liver cancer. The internet CME courses will be available to all health professionals nationwide, including physicians, public health professionals, pharmacists, and nurses.

Task 3: Data Collection and Analysis.

We will create a comprehensive nationwide hepatitis B and C surveillance system. There will be targeted active surveillance to collect and monitor data on incidence and prevalence of hepatitis B and C virus infection, as well as capturing data on other liver

diseases such as alcoholic liver disease and non-alcoholic fatty liver disease. As part of this, the program will include conducting scientific samples of the population, using the medical records of hospitals and health centers, to collect and analyze data on the incidence and prevalence of all of these liver diseases.

Task 4: Immunization, Screening and Vaccination.

Screening for hepatitis B will be performed at the Commune Health Centers and at the gathering points indicated in Task 1. After the screening, recommendations will be made to individuals with negative results who are not immune to do the vaccination series either at the Commune Health Center or at the office of their primary care physician. Three vaccination shots are required within a six-month period. Patients with test results that show that they have chronic infection with HBV will be referred to the Commune Health Centers, to primary care physicians, or to physician specialists for treatment.

Task 5: Treatment of CHB and CHC.

Although there is no current cure for CHB, it can be effectively treated in a way that leads to durable viral suppression and reversal of liver disease through use of long-term oral antiviral drugs, a growing number of which are available, some in inexpensive generic versions, as well as use of short-term injectable antivirals, when needed. Effective treatment can reduce liver damage and substantially decrease the risk of progression to cirrhosis, liver cancer, death, or the need for liver transplantation. A specific action plan for the initiation of liver transplantation is outlined in a separate document. CHC is treatable and in some cases curable with the combination of

interferon and ribavirin. However, with the most common types of HCV that are found in Viet Nam, the likelihood of effective treatment (what is called a “sustained virological response”) is less likely. In addition, the standard recommended therapy, the combination of pegylated interferon with oral ribavirin, continued for 24-48 weeks, is expensive. It is also the cause of potentially serious side effects in a few percent of patients which can lessen patients’ willingness to complete the treatment series. Educational programs and materials will be developed to help ensure that up-to-date information on treating CHB and CHC is available to Commune Health Centers, primary care physicians, and physician specialists so an appropriate treatment program can be recommended to patients who are screened and found to have chronic infection with one or both viruses.

Task 6: Alcoholic Liver Disease and Fatty Liver Disease.

Alcoholic liver disease (ALD) is another major contributor to the overall burden of liver disease in Viet Nam. Mortality from alcoholic liver disease is closely tied to per capita alcohol consumption which recent studies have shown is quite high among Vietnamese men. Complete abstinence from alcohol is the most effective treatment for ALD although a message of moderation would be a key step to decrease unhealthy consumption of alcohol. With less advanced disease, abstinence may allow reversal of liver damage. With more advanced disease, abstinence may at least help prevent disease progression. Without abstinence from alcohol, the majority of people with ALD will eventually develop cirrhosis. When ALD is apparent, it is appropriate for healthcare workers to refer patients to counseling and alcohol support groups, where available. ALD in combination with CHB, CHC and/or fatty liver is an even more serious disease.

In addition, non-alcoholic fatty liver disease is rapidly emerging as a serious liver disease in all developing countries. Counseling about healthy eating will be one key to decrease the weight trajectory that we see in all countries that can contribute to the development of fatty liver. In addition, it will be important to educate both the public and health professionals about the need to address other risk factors for the development of fatty liver, including type 2 diabetes, heart disease, exposure to pesticides, and malnutrition. Educational materials on alcoholic liver disease and non-alcoholic fatty liver disease and resources available for addressing them will be developed as part of this project.

Task 7: Liver Cancer Toolbox .

We will develop, test and evaluate an educational toolbox of medical intervention and educational materials to inform and educate the Vietnamese public and their health care providers about the relationship between HBV and liver cancer. The toolbox will incorporate Vietnamese culture and medical ethics, particularly Hai Thuong Lan Ong's Ethics for Vietnamese Health Professionals. We will use a variety of assessment tools to determine the most effective intervention strategies and the best educational messages.

Task 8: Training of Health Educators.

We will include as part of our project approaches to improving the knowledge, awareness, attitude and behavior of health educators related to the high risk of HBV and HCV, and the need for screening for both viruses, vaccination against HBV, and treatment for CHB and CHC. We will select, train and manage educators and

messengers who can plan and perform effective intervention tasks, either in community health centers or in outreach activities. The goal will be to increase screening, testing and, for HBV, vaccination rates, followed by treatment of CHB and/or CHC, where appropriate, ultimately leading to reduction of illness and death rates from these infections. As more fully discussed in the section on Task 1, the health educators that are part of the current health system will play an important role in carrying out this task.

In addition, where needed, additional health educators may be selected among health professionals (such as nurses, pharmacists, physicians, public health educators, and social workers) as well as non-health professionals such as musicians, singers, teachers, hair stylists, and others who come in contact with the public. Health educators will be tested for qualification and performance and then will be trained in health education, counseling, health behavior, and cultural adaptation. Assessment of existing educational materials and development and testing of new materials will be performed to select materials that can be effectively used within the constraints of the Vietnamese language, behavior, and culture. Website material delivery will be applied to satisfy on-demand printing and the quick download of digital audio-visual and preformatted educational tools.

Task 9: Cost and Health Care Quality.

As part of this project, we will work to design and promote methods which can manage costs while maintaining quality. Quality must be controlled using quality assurance and quality improvement methods including practice guidelines, criteria, Joint Commission standards, and indicators. Cost must be considered and justified by analyses showing cost/benefit, cost effectiveness, and cost to buy one Quality-Adjusted Life Year (QALY).

Based on such assessments, decisions can be made about which approaches are the worst and the best values.

Task 10: Project and Performance Evaluation.

An evaluation expert team will perform process evaluation for each of the tasks above, as well as outcome evaluation for the entire project. Both qualitative information and quantitative data will be collected, analyzed, and reported by the evaluators for adjustment under formative evaluation and for final report under a formal/summative evaluation. Convenient samples of patients in commune health centers, selected clinics, and selected pharmacies who have been screened or vaccinated for hepatitis B will be statistically analyzed for effectiveness. Samples of people at the gathering points will be selected for pre-post knowledge, attitude, and practice changes. Evaluation forms at health education training meetings and health professionals training sessions will be analyzed to assess training effectiveness and trainers' performance. Evaluation reports will be submitted during and after the project life to indicate the achievement of project goals and objectives.

CONCLUSION

The combined results of an integrated approach to liver disease in Viet Nam may significantly help to turn the tide against this disease, preventing HBV and HCV infection of the uninfected, providing effective education, prevention and treatment of all the causes of liver disease, to the greatest extent possible, substantially lowering the risk of HCC, liver failure, and cirrhosis and decreasing the need for liver transplantation, thus generally improving the lives of affected individuals while greatly reducing the associated healthcare burden.

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126th Session **EB126.R16**

Agenda item 4.12 **23 January 2010**

Viral hepatitis

The Executive Board,

Having considered the report on viral hepatitis,[1]

RECOMMENDS to the Sixty-third World Health Assembly the adoption of the following resolution:

The Sixty-third World Health Assembly,

Having considered the report on viral hepatitis;

Taking into account the fact that some 2000 million people have been infected by hepatitis B virus and that about 350 million people live with a chronic form of the disease;

Considering that hepatitis C is still not preventable by vaccination and around 80% of hepatitis C virus infections become a chronic infection;

Considering the seriousness of viral hepatitis as a global public health problem and the need for advocacy to both governments and populations for action on health promotion, disease prevention, diagnosis and treatment;

Expressing concern at the lack of progress in the prevention and control of viral hepatitis in developing countries, in particular in the sub-Saharan African region, due to the lack of access to affordable treatments as well as an integrated approach to the management of the disease;

Considering the need for a global approach to all forms of viral hepatitis – with a special focus on viral hepatitis B and C, which have the higher rates of morbidity;

Recalling that one route of transmission of hepatitis B and C viruses is parenteral and that the Health Assembly in resolution WHA28.72 on utilization and supply of human blood and blood products recommended the development of national public services for blood donation and in resolution WHA58.13 agreed to the establishment of an annual World Blood Donor Day, and that in both resolutions the Health Assembly recognize the need for safe blood to be available to blood recipients;

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[1] Document EB126/15.

Reaffirming resolution WHA45.17 on immunization and vaccine quality which urged Member States to include hepatitis B vaccines in national immunization programmes;

Considering the need to reduce the liver cancer mortality rates and that viral hepatitides are responsible for 78% of cases of primary liver cancer;

Considering the collaborative linkages between prevention and control measures for viral hepatitis and those for infectious diseases like HIV and other related sexually transmitted and blood-borne infections;

Recognizing the need to reduce incidence to prevent and control viral hepatitis, to increase access to correct diagnosis and to provide appropriate treatment programmes in all regions,

1. RESOLVES that 28 July shall be designated as World Hepatitis Day in order to provide an opportunity for education and greater understanding of viral hepatitis as a global public health problem, and to stimulate the strengthening of preventive and control measures of this disease in Member States;

2. URGES Member States:

(1) to implement and/or improve epidemiological surveillance systems in order to generate reliable information for guiding prevention and control measures;

(2) to support or enable an integrated and cost-effective approach to the prevention, control and management of viral hepatitis considering the linkages with associated coinfection such as HIV through multisectoral collaboration among health and educational institutions, nongovernmental organizations and civil society, including measures that strengthen safety and quality and the regulation of blood systems;

(3) to incorporate in their specific contexts the policies, strategies and tools recommended by WHO in order to define and implement preventive actions, diagnostic measures and the provision of assistance to the population affected by viral hepatitis;

(4) to strengthen national health systems to effectively address prevention and control of viral hepatitis through the provision of health promotion and national surveillance, including tools for prevention, diagnosis and treatment for viral hepatitis, vaccination, information, communication and injection safety;

(5) to provide vaccination strategies, infection-control measures, and means for injection safety for health-care workers;

(6) to use national and international resources, either human or financial, to provide technical support to strengthen health systems in order to adequately provide local populations with the most cost-effective and affordable interventions that suit the needs of local epidemiological situations;

(7) to consider, as necessary, national legislative mechanisms for the use of the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights in order to promote access to specific pharmaceutical products;[1]

(8) to consider, whenever necessary, using existing administrative and legal means in order to promote access to preventive, diagnostic and treatment technologies against viral hepatitis;

(9) to develop and implement monitoring and evaluation tools related to preventive, diagnostic and treatment activities;

(10) to promote the celebration of 28 July each year, or on such other day or days as individual Member States may decide, as World Hepatitis Day;

3. REQUESTS the Director-General:

(1) to establish in collaboration with Member States the necessary guidelines, time-bound goals, strategies and tools for the prevention and control of viral hepatitis;

(2) to provide the necessary support to the development of scientific research related to the prevention, diagnosis and treatment of viral hepatitis;

(3) to improve the assessment of economic impact and estimate the burden of viral hepatitis in the world;

(4) to support, as appropriate, resource-constrained Member States in conducting events to mark World Hepatitis Day;

(5) to invite international organizations and financial institutions to give support to strengthen capacity in developing countries for increasing the use of reliable diagnostic and treatment methods suitable to local epidemiological situations and health systems;

(6) to encourage international organizations and financial institutions to assign resources for the prevention and control of viral hepatitis, providing technical support to countries in an equitable, most efficient and suitable manner;

[1] The WTO General Council in its Decision of 30 August 2003 (i.e. on Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health decided that "'pharmaceutical product' means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included.".

(7) to collaborate with other organizations in the United Nations system, partners, international organizations and other relevant stakeholders in enhancing access to affordable treatments in developing countries;

(8) to report to the Sixty-fifth World Health Assembly, through the Executive Board, on the implementation of this resolution.

Thirteenth meeting, 23 January 2010
EB126/SR/13

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ATTACHMENT 4

World Health Organization

EXECUTIVE BOARD
126th Session
Provisional agenda item 4.12

EB126/15
12 November 2009

Viral hepatitis

Report by the Secretariat

THE DISEASES AND BURDEN

1. The group of viruses (hepatitis A, B, C, D and E) that cause acute and/or chronic infection and inflammation of the liver gives rise to a major public health problem globally. Hepatitis B and C viruses are major causes of severe illness and death. The global burden of disease due to acute hepatitis B and C and to cancer and cirrhosis of the liver is high (about 2.7% of all deaths) and is forecast to become a higher ranked cause of death over the next two decades. An estimated 57% of cases of liver cirrhosis and 78% of cases of primary liver cancer result from hepatitis B or C virus infection. About 2000 million people have been infected with hepatitis B virus worldwide, of whom more than 350 million are chronically infected, and between 500 000 and 700 000 people die annually as a result of hepatitis B virus infection. Some 130–170 million people are chronically infected with hepatitis C virus, and more than 350 000 people are estimated to die from hepatitis C-related liver diseases each year.

2. Because hepatitis A, B, C, D and E viruses differ in their global distribution and routes of transmission, prevention strategies need to be tailored. Hepatitis B virus infection early in life is associated with the highest risk of chronic infection, and people with chronic infection risk progression to cirrhosis of the liver and primary liver cancer. About 90% of infants infected with hepatitis B virus around the time of birth, 30% of children infected in early childhood and 6% of those infected after five years of age will develop chronic hepatitis B virus infection. The likelihood of progression to chronic infection is the same whether infection is symptomatic or asymptomatic. People with chronic hepatitis B virus infection have a 15% to 25% risk of dying prematurely from hepatitis B virus-related cirrhosis and liver cancer. People with chronic hepatitis C virus infection are also at high risk for developing cirrhosis and liver cancer. Both superinfection by, and coinfection with, hepatitis D virus in hepatitis B virus-infected patients result in worse outcomes than infection with hepatitis B virus alone; these include a higher rate of liver failure in acute infections and a greater likelihood of developing liver cancer in chronic infections.

3. Exposure to blood through injections with nonsterile equipment or transfusion of contaminated blood products is a common and preventable cause of hepatitis B and C virus infections. Unsafe injection practices are estimated to be responsible for 21 million new hepatitis B virus infections and two million new hepatitis C virus infections a year. A significant proportion of the blood supply is either not screened for hepatitis B or C virus or not screened properly. The probability of transmission of hepatitis B and C viruses through transfusion of unsafe blood can be as high as about 70% and 92%, respectively, depending on the volume transfused and the concentration of virus. In many countries,

injecting drug use represents the highest risk for hepatitis C virus infection, with prevalence rates in people reporting this behaviour ranging between 30% and 60%.

4. It is estimated that about 1.4 million new hepatitis A virus infections occur globally each year. Infection is usually by the fecal-oral route either through person-to-person contact or ingestion of contaminated food or water. Paradoxically, as water and sanitation systems improve in developing countries, infections occur later in life, when the risk for severe disease from hepatitis A is greatest. This shifting epidemiology is responsible for increased numbers of cases in some countries and the emergence of community-wide outbreaks of hepatitis A.

5. Hepatitis E virus infection occurs both sporadically and in large epidemics, causing significant morbidity and mortality, especially deaths in pregnant women. It is estimated that one third of the world's population has been infected with hepatitis E virus. However, the true burden of hepatitis E is unknown.

6. Foodborne and waterborne transmission of hepatitis A and E viruses is common; indeed, hepatitis A virus is one of the most frequent causes of foodborne infections. Outbreaks of hepatitis A and E affecting up to more than 100 000 people and causing significant morbidity, mortality and disruption of trade and tourism have been documented. Foodborne contamination may be the result of infected food handlers unknowingly contaminating food. Hepatitis A and E viruses persist in the environment and can resist food-production processes routinely used to inactivate and/or control bacterial pathogens.

7. Hepatitis B virus/HIV and hepatitis C virus/HIV coinfections are an increasing problem in countries with concentrated HIV epidemics and among injecting drug users. For those coinfected persons who are being treated with antiviral medicines, underlying viral hepatitis is becoming a major cause of death.

PREVIOUS HEALTH ASSEMBLY ACTION AND SECRETARIAT ACTIVITIES

8. The Health Assembly has considered specific aspects of hepatitis prevention in past resolutions. First, in 1992, in resolution WHA45.17 on immunization and vaccine quality it urged Member States to integrate cost-effective new vaccines, such as hepatitis B vaccine, into national immunization programmes in countries where it is feasible. The Secretariat acted on this resolution by recommending that all countries integrate hepatitis B vaccine into national immunization programmes by 1997. Support from the GAVI Alliance for the introduction of hepatitis B vaccine has resulted in great increases in vaccination coverage in the past decade. As of 2007, more than 88% of Member States have introduced hepatitis B vaccine; overall coverage with three doses of vaccine was 65%, and globally 27% of newborn infants received the birth dose of hepatitis B vaccine. Secondly, in 2005, in resolution WHA58.22 on cancer prevention and control the Health Assembly called for including reduction in hepatitis B virus infection among the outcome objectives of national cancer control programmes; implementation of this resolution and its monitoring are still in progress. Thirdly, as part of the Global plan of action on workers' health 2008–2017, endorsed by the Health Assembly in 2007 in resolution WHA60.26, the Secretariat's activities would include working with Member States for immunization of health-care workers against hepatitis B. Little progress has been made in the short time since the resolution endorsing the plan was adopted. In addition, the Health Assembly has

considered several hepatitis prevention issues relating to immunization,[1] safe blood supply,[2] food safety[3] and safe injections.[4]

9. In 1998 the WHO-cosponsored Conference Regarding Disease Elimination and Eradication as Public Health Strategies (Atlanta, Georgia, United States of America, 23–25 February 1998) concluded that hepatitis B is "a primary candidate for elimination or eradication". In 1999, WHO joined UNICEF and UNFPA to recommend the exclusive use of auto-disable syringes for all immunization injections by the year 2003.[5] Much progress has been made with the support of the GAVI Alliance for the procurement of non-reusable syringes for immunization. WHO has issued position papers on hepatitis B vaccines (2009)[6] and hepatitis A vaccine (2000).[7] In 2005, the Western Pacific Region set a goal of reducing chronic hepatitis B virus infection rates to less than 2% among five-year-old children by 2012. In 2008, WHO with FAO convened an expert meeting on viruses in foods in order to provide scientific advice in support of risk-management activities. Recently, the European Region has developed clinical protocols for the management of hepatitis B virus/HIV coinfection, hepatitis C virus/HIV coinfection, and prevention of hepatitis A, B and C virus infections in people living with HIV. In November 2008, WHO's Strategic Advisory Group of Experts on immunization recommended that "all regions and associated countries develop goals for hepatitis B control appropriate to their epidemiologic situations". The Regional Committee for the Eastern Mediterranean adopted a resolution (EM/RC56/R.5) for hepatitis B and C control and set a target for reduction of the prevalence of chronic hepatitis B to less than 1% among children below five years of age by 2015 at its fifty-sixth session (Cairo, 3–6 October 2009). Several countries have established national goals for the elimination of transmission of hepatitis B virus.

OPPORTUNITIES FOR PREVENTION AND CONTROL

10. Coordinating programmes for the prevention and control of hepatitis with other related programmes will contribute to the strengthening of health systems in all countries. To date, prevention and control efforts have been successful but fragmented. WHO does not have a comprehensive strategy for viral hepatitis. Thus, the time is right to create new opportunities for prevention, including establishing goals and strategies for disease control, increasing education and promoting screening and treatment of the 500 million or so people already infected with hepatitis B and C viruses. The impact of these efforts on mortality and morbidity will be significant because of the tremendous burden of disease.

[1] Resolutions WHA44.33 on World Summit on Children: follow-up action, WHA53.12 on Global Alliance for Vaccines and Immunization, and WHA61.15 on Global immunization strategy.

[2] Resolutions WHA28.72 on utilization and supply of human blood and blood products and WHA58.13 on blood safety: proposal to establish World Blood Donor Day.

[3] Resolutions WHA53.15 on food safety, WHA56.23 on joint FAO/WHO evaluation of the work of the Codex Alimentarius Commission, and WHA58.32 on infant and young child nutrition.

[4] Resolution WHA55.18 on quality of care: patient safety.

[5] Document WHO/V&B/99.25.

[6] *Weekly Epidemiological Record*, 2009; **84**:405-419.

[7] *Weekly Epidemiological Record*, 2000; **75**:38-44.

11. Progress has been made in preventing hepatitis B virus infection through immunization of infants. Despite this, coverage with hepatitis B vaccine has not yet reached the goal set by the Global Immunization Vision and Strategy 2006–2015 of 90% national vaccination coverage by 2010 and lags behind global coverage levels for vaccination against diphtheria, tetanus and pertussis. Vaccination of infants at birth, a safe and effective means of preventing perinatal infections that are associated with the worst health outcomes, remains low and is an important element in strengthening health systems as part of efforts to provide services to mother and child around the time of pregnancy. Health-care workers are still not being vaccinated against hepatitis B in most developing countries and vaccination coverage levels are not monitored. Elimination of hepatitis B virus transmission is feasible for future generations, but vaccines are too late to protect those 350 million who already have chronic hepatitis B virus infections.

12. Many new and effective treatments that can significantly delay progression of liver disease, prevent the onset of liver cancer, and reduce deaths are available for the more than 500 million people living with hepatitis B and C virus infection. The challenge remains to ensure that these people have timely access to testing, care and effective treatments, especially in resource-limited settings.

13. Demand for hepatitis A vaccine is increasing in large parts of the world that are experiencing an increase in symptomatic cases and more frequent epidemics because of changing epidemiology. Effective candidate vaccines for hepatitis E prevention exist. Some progress has been shown in developing candidate vaccines against hepatitis C. Further development and increased access to these vaccines for those who would benefit most should be a high priority.

14. Because unsafe health-care practices remain common in many parts of the world, all countries need to make concerted efforts to implement strategies to prevent hepatitis in health-care settings based on safe blood supply and safe injections. Safe injections cause no harm to the recipient, do not expose the provider to any avoidable risk and do not result in any dangerous waste. The primary means of preventing transmission of hepatitis viruses in blood donations is the collection of blood from voluntary, unpaid blood donors who are at low risk of infection. The second means of prevention in blood product transmission is quality-assured screening of all donated blood for hepatitis B and C virus markers. The third strategy is the rational use of blood in order to minimize unnecessary transfusions. Implementation of these strategies needs strengthening. Safe injection devices that are not reusable and have features to prevent needlestick injuries need to be used universally, and the training of all health-care providers on best injection practices, including proper sharps waste management, should be strengthened.

15. WHO is in a position to provide coordinated global support and leadership in the development of a comprehensive approach to prevention and control of viral hepatitis. Elements of this approach apply across the health system.

To prevent the transmission of hepatitis virus through safe and effective public health strategies:

(a) Immunization against hepatitis B virus infections

(i) protecting all persons against infection with hepatitis B virus through full immunization as early in life as possible, beginning with the first dose of hepatitis B vaccine within 24 hours of birth as part of routine maternal and child health services;

(ii) increasing coverage of hepatitis B vaccination among health-care workers, travellers and other most at-risk persons and ensuring access to post-exposure prophylaxis for blood-borne pathogens;

(iii) setting and achieving national goals for hepatitis B control appropriate to the epidemiologic situation.

(b) Safe health care to prevent transmission of hepatitis B and C viruses and other blood-borne pathogens

(i) ensuring safe blood supplies by: recruiting only voluntary, unpaid blood donors; introducing effective blood donor selection and screening of all donated blood for markers of hepatitis B and C virus infection with highly sensitive and specific assays and following basic standardized procedures; and training clinicians and nurses in safe clinical transfusion practices;

(ii) ensuring that all injections are safe through sustainable procurement of sufficient quantities of appropriate syringes, training in safe injection practices and ensuring that sharps waste is properly managed and that wider infection-control practices (in the hospital and in community health-care settings) are followed;

(iii) increasing awareness among communities and health-care workers of the opportunities to prevent viral hepatitis.

(c) Immunization and provision of safe food and water in order to prevent hepatitis A

(i) guiding implementation of hepatitis A vaccination to prevent hepatitis A in countries with shifting epidemiology;

(ii) improving food safety by preparing and introducing international guidelines for the management of viruses and toxins in foods.

To identify and treat those people most at risk for hepatitis virus-related disease with safe and effective therapies:

(d) Identification and treatment of chronic hepatitis B and C in order to prevent progression to cirrhosis and liver cancer

(i) developing evidence and policy basis for screening and treatment of viral hepatitis;

(ii) formulating guidelines for treatment of chronic viral hepatitis, especially taking into consideration needs of resource-constrained settings;

(iii) expanding care and treatment services for people chronically infected with hepatitis viruses.

To integrate proven public health strategies for preventing viral hepatitis across the health system:

(e) Integration of interventions for the prevention, treatment and care of hepatitis B and C virus infections (including access to sterile needles and syringes, hepatitis B vaccination and

antiviral treatment) into existing services for those at risk for HIV infection and sexually transmitted infections and those who inject drugs, and into national cancer control programmes. These services and programmes can provide good entry points for both infected and most-at-risk people, and coordination can promote synergies.

To innovate by developing new vaccines and technologies for use in viral hepatitis prevention:

(f) Prioritization of new preventive strategies including development of vaccines for hepatitis C and E virus infection and technologies for vaccination, screening and health care in order to prevent chronic liver disease and liver cancer.

ACTION BY THE EXECUTIVE BOARD

16. The Executive Board is invited to take note of the report and provide further strategic guidance.

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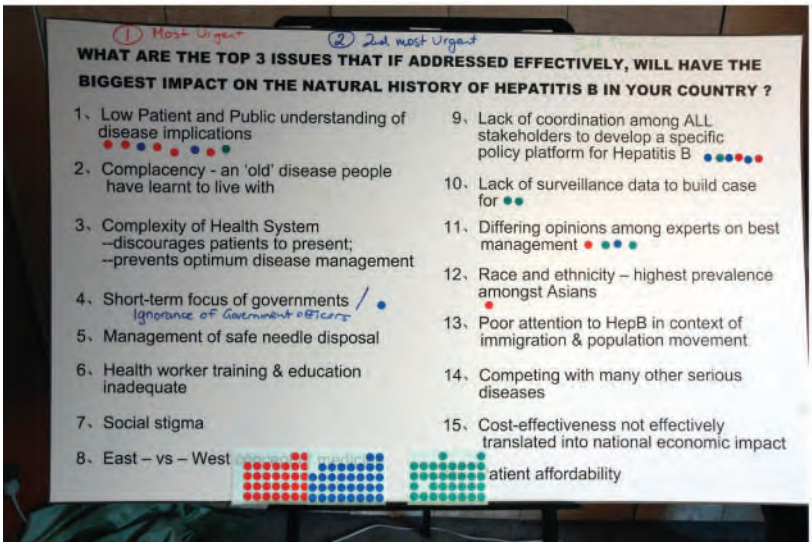
The problem of cost effectiveness in Asia


WHAT ARE THE TOP 3 ISSUES THAT IF ADDRESSED EFFECTIVELY, WILL HAVE THE BIGGEST IMPACT ON THE NATURAL HISTORY OF HEPATITIS B IN YOUR COUNTRY ?
1、Low Patient and Public understanding of disease implications
2、Complacency - an 'old' disease people have learnt to live with
3、Complexity of Health System
--discourages patients to present;
--prevents optimum disease management


① Most Urgent
② 2nd most Urgent
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1、Low Patient and Public understanding of disease implications
2、Complacency - an 'old' disease people have learnt to live with
3、Complexity of Health System
--discourages patients to present;
--prevents optimum disease management
4、Short-term focus of governments / Ignorance of Government officers
5、Management of safe needle disposal
6、Health worker training & education inadequate
7、Social stigma
8、East – vs – West
9、Lack of coordination among ALL stakeholders to develop a specific policy platform for Hepatitis B
10、Lack of surveillance data to build case for
11、Differing opinions among experts on best management
12、Race and ethnicity – highest prevalence amongst Asians
13、Poor attention to HepB in context of immigration & population movement
14、Competing with many other serious diseases
15、Cost-effectiveness not effectively translated into national economic impact
atient affordability