

WHO Technical Consultation  
on a comprehensive National Hepatitis Programme  
in China  
with a focus on viral hepatitis B and C treatment  
Meeting report

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Convened by:  
WORLD HEALTH ORGANIZATION  
REPRESENTATIVE OFFICE IN CHINA



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## Abbreviations

AEFI	adverse events following immunization
APRI	aminotransferase/platelet ratio index
CEA	cost-effectiveness analysis
HBIG	hepatitis B immune globulin
HBeAg	hepatitis B E antigen
HBsAg	hepatitis B surface antigen
HBV	hepatitis B virus
HCC	hepatocellular carcinoma
HCV	hepatitis C virus
HIV	human immunodeficiency virus
NCAIDS	National Center for AIDS, STD Control and Prevention (China)
NCMS	New Rural Cooperative Medical Scheme
NHFPC	National Health and Family Planning Commission (Ministry of Health, China)
PEG-IFN	pegylated interferon
PMTCT	prevention of mother-to-child transmission
QALY	quality-adjusted life year
SVR	sustained virological response
UE-BMI	Urban Employees Basic Medical Insurance
UN	United Nations
UR-BMI	Urban Residents Basic Medical Insurance
US CDC	United States Centers for Disease Control and Prevention

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WHO	World Health Organization
WPRO	WHO Regional Office for the Western Pacific

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## Executive summary

China has a heavy burden of viral hepatitis. About 93 million people chronically infected with the hepatitis B virus (HBV), including an estimated 20 million in need of long-term treatment to prevent progression to cirrhosis and liver cancer. Out of 7 million people infected with the hepatitis C virus (HCV), 2.5 million need treatment.

China has the highest burden of hepatocellular carcinoma (HCC) and HCC-related deaths in the world, largely caused by viral hepatitis. Of all HCC cases in China, 85% are HBV related and 10% are HCV related. Liver cancer is the second leading cause of death in China in the age group of 35–54 years. Over 11.5 million Chinese will die of liver cancer in the next 20 years if nothing is done. Studies from China show that hepatitis B and C treatment is cost-effective and it is possible to reduce deaths due to chronic hepatitis B-related liver disease including liver cancer by 83% if universal access to hepatitis B screening, long-term monitoring and antiviral treatment for active hepatitis is provided.

In view of the magnitude of the problem of viral hepatitis in China, a technical consultation was held on 21 February 2014 in Beijing with the Chinese government, the Chinese Foundation for Hepatitis Prevention and Control, the Asia and Pacific Alliance to Eliminate Viral Hepatitis, Chinese and international technical experts, the US CDC and WHO to discuss the scientific evidence, current challenges and new opportunities for scaling up hepatitis treatment in China through a public health approach. It also discussed the potential for China adopting a leadership role in the global hepatitis movement to move forward the treatment agenda. The objective of the meeting was to share experiences of, challenges to and new opportunities for the treatment of viral hepatitis B and C in China and internationally as part of a comprehensive viral hepatitis programme.

China has made tremendous progress towards the prevention and control of viral hepatitis. The infant hepatitis B immunization programme has been a huge success; an integrated programme to prevent mother-to-child transmission of viral hepatitis B, syphilis and HIV is being scaled up; and research on treatment for chronic viral hepatitis has increased dramatically in China (second to the United States of America) to address Chinese treatment strategies, and regional and global research gaps. There are clinical treatment guidelines for HBV and HCV. Antiviral drugs for hepatitis are on the list for urban health insurance schemes. Current HCV treatment (injection of pegylated interferon and oral ribavirin) can achieve a cure rate of nearly 70% in China.

However, China faces a number of challenges in addressing hepatitis B treatment. Most infected people do not know their status and treatment coverage is low. Suboptimal antiviral drugs such as lamivudine are widely used, which lead to high rates of resistance. Expensive liver protectors (costing up to RMB 2400 per month) are used along with these drugs. Social health insurance covers a limited proportion of treatment costs, particularly in rural areas. An insufficient number of health providers are trained to ensure adequate treatment and management of chronic disease.

There are opportunities to prevent HCC and liver cirrhosis caused by chronic viral hepatitis in China. Highly effective drugs to treat chronic hepatitis B (tenofovir and entecavir) are registered. A public health hepatitis B treatment programme provides an opportunity for significant price reduction. For example, the price of tenofovir (among the most effective treatments for chronic hepatitis B) has been successfully negotiated at RMB 113 per month for the HIV public health programme. Short-

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term antiviral treatment for hepatitis B can potentially eliminate perinatal transmission from selected mothers with a very high viral load, in addition to vaccination and hepatitis B immune globulin. New, less toxic oral drugs can cure about 90% of persons with hepatitis C within three months of treatment without the need for injection therapy. HCV treatment can prevent transmission (towards elimination of hepatitis C). The ongoing health reform provides an opportunity for the development of a public health programme using health insurance mechanisms.

China has tremendous experience in the clinical management of and research on hepatitis. WHO plans to optimize the contribution of China to the international operational research agenda on hepatitis treatment.

The meeting concluded that China is well positioned to spearhead a global research movement and to phase access to chronic viral hepatitis treatment with a public health approach to ultimately reduce the burden of end stage liver disease and liver cancer. However, there is a clear need to provide China's policy-makers with the evidence that a public health programme for hepatitis treatment is possible and cost-effective. In particular, an investment case using different scenarios for hepatitis B and C treatment to model cost-savings approaches and reduction of deaths due to cirrhosis and hepatocellular carcinoma would support a public health approach embedded in the health reform.

## 1. Background

China has been highly successful in preventing the transmission of hepatitis B virus (HBV) during childbirth and early childhood. However, a whole generation (93 million) of unvaccinated adults are currently chronically infected and more than 20 million people need treatment. About 7 million people are infected with the hepatitis C virus (HCV), of whom 2.5 million are in need of treatment.

China has the highest burden of hepatocellular carcinoma (HCC) and HCC-related deaths in the world, largely caused by viral hepatitis. Viral hepatitis is currently the biggest risk factor for the development of hepatocellular carcinoma (HCC), which ranks as the second-leading cause of cancer-related deaths in men and the third-leading cause of cancer-related deaths in women. Expanding the availability of adequate treatment for viral hepatitis would have an impact on the incidence of HCC and mortality.

China faces several challenges due to the large number of patients and related costs. However, there are concrete new opportunities for the treatment of viral hepatitis. New antiviral drugs have the potential to cure HCV infection with a three-month course of treatment. Nucleotide analogues such as tenofovir could potentially be made available at affordable prices for potent long-term therapy of chronic HBV infection.

The World Health Organization (WHO) has issued a comprehensive strategy for the prevention and control of viral hepatitis, which goes beyond vaccination and includes screening, care and treatment as key elements.

In view of the tremendous burden of viral hepatitis B and C in China, and China's experience in the clinical management of and research on hepatitis, a technical consultation was held on 21 February 2014 in Beijing to discuss the scientific evidence, current challenges and new opportunities for scaling up hepatitis treatment in China through a public health approach. The technical consultation included the participation of the Chinese government, the Chinese Foundation for Hepatitis Prevention and Control, the Asia and Pacific Alliance to Eliminate Viral Hepatitis Chinese and international technical experts, US CDC and WHO.

## 2. Meeting objective

The objective of the meeting was to share experiences of, challenges to and new opportunities for the treatment of viral hepatitis B and C in China and internationally as part of a comprehensive viral hepatitis programme.

The results of this consultation were used to inform a round table discussion on 24 February 2014 with the National Health and Family Planning Commission (NHFPC) and the WHO Regional Director to move forward the viral hepatitis programme beyond immunization.

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### 3. Presentations

#### Session 1: Global viral hepatitis strategy and WHO's role in promoting viral hepatitis treatment (Gottfried Hirschsall)

Globally, the estimated number of annual deaths due to viral hepatitis is similar to that of HIV. In the Asia–Pacific region, the estimated annual number of deaths related to viral hepatitis is much higher than that of tuberculosis or HIV.

In 2010, the World Health Assembly Resolution 63.18 requested Member States to adopt a comprehensive approach to hepatitis prevention and control. WHO committed to developing guidelines and strategies for surveillance, prevention and control of viral hepatitis, supporting the development of scientific research, improving the estimates of global prevalence and disease burden, mobilizing support and strengthening the WHO Safe Injection Global Network.

In 2010–11, WHO developed a global viral hepatitis strategic framework with four components: (1) Partnerships, resource mobilization and communication; (2) Data for policy and action; (3) Prevention of virus transmission, and (4) Screening, care and treatment.

Despite positive trends in the coverage of hepatitis B immunization in the Western Pacific Region, there are major immunization gaps globally. The rapid developments in medicines for treating HBV infection and curing HCV infection provide an opportunity to expand chronic viral hepatitis treatment and massively reduce the disease burden, mortality, and social and economic impact due to these diseases. Yet, treatment is not widely available in low- and middle-income countries. Experiences gained from the HIV programme can be used, particularly for negotiating massive drug price reduction and rapid scaling up.

WHO's activities in viral hepatitis screening and treatment include the development of screening and treatment guidelines (for hepatitis B and C), prequalification of hepatitis medicines and diagnostics, advocacy/negotiation for increased access to medicines and assistance to countries in developing national hepatitis treatment plans.

At the end of 2013, the Executive Board of WHO met to prepare for the World Health Assembly. Member States recognized the lack of action on viral hepatitis treatment. A new resolution on hepatitis was planned for 2014 to accelerate action and develop comprehensive national strategies for hepatitis surveillance, prevention, treatment and control. WHO has initiated some concrete actions: the WHO Viral Hepatitis Programme was moved to the HIV Department in January 2014. The Strategic and Technical Advisory Committee was established in March 2014 as well as a global partner platform. The WHO global HCV screening and treatment guidelines were launched in April 2014. WHO is also engaging with the pharmaceutical sector to negotiate drug access and prices.

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## Session 2: Treatment needs and strategy in China

### Epidemiology of HBV in China, Treatment needs, National strategy for HBV screening and treatment (Li Quanle)

China has reported an increasing number of HBV cases but this is probably due to improvement in the reporting system. Viral hepatitis B is the second most reported communicable disease after hand-foot-and-mouth disease.

China has a comprehensive strategy for the prevention and control of hepatitis B. The national strategy started in the 1980s with the screening of blood donors, surveillance and immunization. In 2008, hepatitis B was included in the national major science and technology operational research projects.

The prevention of HBV transmission during childbirth and early childhood has been a major success in China. HBV vaccine was introduced in 1992, and in 2002, the vaccine was included in the Expanded Programme on Immunization at no cost to parents. A multi-year project supported by the Global Alliance for Vaccines and Immunization accelerated implementation of the timely birth dose vaccination schedule. In the pre-vaccine era, the percentage of chronically infected children below 5 years of age was more than 9%; by 2006, it was less than 1%, thanks to a vaccination coverage of more than 90%. On 22 May 2012, the WHO Regional Office for the Western Pacific (WPRO) Hepatitis B Expert Resource Panel verified that China had reached the WPRO goal of less than 1% prevalence of hepatitis B surface antigen (HBsAg) among 5-year-old children. The China HBV immunization programme has prevented 20 million people from becoming chronic HBsAg carriers between 1992 and 2006.

Catch-up vaccination among children has ensured that most individuals less than 19 years of age are now protected through vaccination. The remaining challenges of the HBV prevention and control programme include the need (i) to scale up the government programme for the integrated prevention of mother-to-child transmission of HBV, syphilis and HIV, and sustain a high coverage of timely birth dose of hepatitis B vaccine in all areas, (2) to develop guidance on vaccination of adults at risk, and (3) to improve surveillance to better distinguish between acute and chronic infections and improve laboratory capacity.

Millions of people were infected in the pre-vaccine era, including many individuals who had been infected prior to vaccination during the catch-up campaign. Based on the latest (2006) population-based serosurvey, China has 93 million HBsAg carriers, including about 20–28 million people in need of HBV treatment. Barriers to accessing treatment are the current high cost of antiviral drugs (estimated annual cost of RMB 49 billion annually (US\$ 8 billion), lack of a national treatment policy and training of health staff, and limited public education and mobilization.

The recent suspicion (December 2013) that adverse events following immunization (AEFIs) were associated with newborn hepatitis B vaccination has resulted in a loss of confidence in the vaccine among parents. It probably caused a 30% reduction in hepatitis B vaccine usage since the AEFIs were publicized by the media.

In the future, China should consider a comprehensive viral hepatitis programme that includes all the components listed above.

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## **Epidemiology of HCV in China, treatment needs, national strategy for HCV screening and treatment (Wu Zunyou)**

The epidemiology of HCV is assessed through HCV case reporting, sentinel surveillance and specific surveys. Increasing trends in HCV case reporting over time are due to improved reporting. The age group 30–44 years has the largest number of reported cases. Xinjiang and Henan provinces are among the top five provinces for the largest numbers of both new and old cases. HCV sentinel surveillance conducted among specific population groups showed that patients on haemodialysis had an infection rate of 5.97% in 2013. HIV sentinel surveillance among populations at risk of HIV included HCV testing. Among high-risk groups for HIV, only people who inject drugs had high infection rates of HCV (38.43% in 2013).

The population-based HBV serosurveys conducted in 1992 and 2006 by the National Immunization Programme to assess the hepatitis B immunization programme also used the remaining blood to test for HCV. In 2013, the prevalence of anti-HCV in the general population was 0.43%. Based on this prevalence, the estimated total number of people infected with HCV is 7 million.

The main challenges to HCV prevention and control are that (i) HCV transmission is not fully under control; (ii) the correct number of HCV-infected persons is not known; (iii) most HCV-infected persons are unaware of their status and are not receiving care; (iv) public awareness about HCV is very low and the disease is stigmatized; and (v) the capacity of health providers to identify and treat HCV infection is inadequate.

In 2008, responsibility for the prevention and control of hepatitis C was assigned to the National Center for AIDS, STD control and prevention (NCAIDS). NCAIDS is developing a national action plan for HCV prevention and control based on an analysis of the epidemic and risk factors for HCV transmission.

The priorities for HCV prevention and control include the prevention of HCV transmission in health-care settings, community awareness and education of health providers, promotion of affordable treatment, and an increase in the number of HCV-infected persons in care.

## **Session 3: A public health approach to viral hepatitis treatment**

### **Achievements and challenges in HBV and HCV treatment in China (Jia Jidong)**

Viral hepatitis B cannot be cured but the development of cirrhosis and HCC can be prevented. China has made some progress in the area of hepatitis B treatment. Mandatory testing for students and employees was banned in 2010. Since 2010, drugs to treat hepatitis B (interferons [IFNs] and nucleoside/nucleotide analogues) have been included in the list of drugs that are reimbursed by insurance. However, these drugs may not be fully covered by the various health insurance schemes. As a result, treatment is available to those with good medical insurance coverage but not for those living in rural areas.

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China has guidelines for the treatment of hepatitis B, which were updated in 2011. Thousands of doctors have been trained. It has also conducted four large-scale randomized control trials (RCTs) on hepatitis B treatment. These are the telbivudine EFFORT study to optimize the efficacy of telbivudine-based treatment (Sun J et al. *Hepatology*. 2013), the pegylated interferon EXCEL study, the lamivudine EXPLORE study and the entecavir DRAGON study.

The LIFT project is based in a group of centres of excellence for hepatitis treatment. This includes selected medical departments of hepatology or infectious diseases. The LIFT project published a standardized approach to the management of liver disease in 2013. The China Registry for patients with hepatitis B is a database, in which, as of 15 January 2014, 24 205 patients have been recorded with 105 502 follow-up times.

The current challenges to the viral hepatitis treatment are the high disease burden, lack of accessibility and affordability of treatment, insufficient reimbursement for rural residents, and inadequate therapy because of the use of non-potent drugs such as lamivudine as first-line therapy.

A survey conducted in 2004 showed that only 19% of patients with chronic hepatitis B received treatment. High cost is a barrier to treatment. A survey conducted in 2006 showed that 76% of patients not receiving treatment complained about the high cost being the reason for not starting treatment. The cost of treatment is very high compared to the income of families.

The economic burden of diseases related to chronic hepatitis B was studied in Beijing and Guangzhou,<sup>1</sup> and showed that direct medical costs increased with the progression of the disease.

A study showed that 33% of patients on first-line therapy had been prescribed lamivudine. Only 13% of patients had been prescribed entecavir.<sup>2</sup>

There are 7.6 million people with anti-HCV antibodies in China, including 2.5 million who are HCV RNA positive and in need of treatment. The major achievements in HCV treatment in China have been the inclusion of pegylated interferon (PEG-IFN) in the reimbursement list for cities only, release of clinical guidelines in 2004 and major national research projects, including HCV cohorts and clinical studies. Optimized therapy with PEG-IFN and ribavirin yields an overall sustained virological response (SVR) of 78.7% in China. The challenges for HCV treatment are the lack of accessibility and affordability of treatment, and insufficient reimbursement for rural residents.

### **US CDC's public health role for hepatitis B and C treatment in the USA (John Ward)**

The US Centers for Disease Control and Prevention (US CDC) works in three areas of public health: (i) assessment (conducting monitoring and investigations), (ii) policy development (gathering and evaluating evidence, setting national priorities to prevent transmission and disease, guiding

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<sup>1</sup> Min Hu, Wen Chen. Assessment of Total Economic Burden of Chronic Hepatitis B(CHB)-Related Diseases in Beijing and Guangzhou, China. *Value in Health*, 2009. Vol 12 Suppl 3.

<sup>2</sup> Sun J, Hou JL.. Management of chronic hepatitis B: experience from China. *J Viral Hepat*. 2010 Mar;17 Suppl 1:10-7.

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prevention programmes and mobilizing partnerships) and (iii) assurance (supporting and evaluating programmes, assessing policy implementation, training the workforce and educating communities).

Because of the success of the hepatitis B vaccination programme, the incidence of acute hepatitis B has fallen but the burden of people living with HBV is sustained by immigration of people from high-burden countries, including Viet Nam and China. The US CDC Division of Viral Hepatitis issued “Recommendations for identification and management of persons with chronic HBV infection” in 2008. Based on economic modelling, it was recommended that populations with a prevalence of 2% or higher should be tested (e.g. those born in Asia, Africa and children born of those from endemic countries with more than 2% prevalence). Free testing is provided for these population groups. The US CDC organizes campaigns in various languages targeted at communities with a high prevalence of HBV.

In the US, 80% of people infected with HCV were born between 1945 and 1965. The number of deaths related to HCV have increased and surpassed the number of deaths from HIV. It is expected that deaths from HCV will continue to increase if nothing is done. Twenty-one of the 50 states are reporting an increase in HCV cases among young persons, reflecting injecting drug use.

The US CDC has issued a first viral hepatitis C action plan. It collected the evidence showing the impact of treatment and a costing committee agreed that testing would be done at no cost. The CDC issued a new algorithm for HCV testing, recommending that a positive antibody test be automatically followed by RNA testing to identify persons with current HCV infection and link them to care. In some specific states, e.g. New York, the law stipulates that any patient admitted to hospital has to be tested for HCV.

The treatment cascade to cure is very poor in the US. Only 50% of HCV-infected people are aware of their status and only 11% are treated. The main mission of the US CDC is to improve this cascade by improving the capacity of the health workforce to test and treat (e.g. through an online course). There are national treatment guidelines for hepatitis C. A large public health education campaign is under way for people born between 1945 and 1965. The US CDC also organizes a national testing day on 19 May.

## **Session 4: Improving access to testing and treatment**

### **What can we learn from HIV (Ying-Ru Lo)**

There has been a global movement to decrease the prices of antiretroviral drugs for HIV, including treatment access campaigns and creation of major funding mechanisms, which shaped market dynamics (e.g. Global Fund to Fight AIDS, Tuberculosis and Malaria, among others). Several countries have issued compulsory licensing for drugs to treat HIV and cancer. A medicine patent pool was created in 2010 by the United Nations (UN) through UNITAID to hold patents of antiretroviral drugs so that they could be manufactured cheaply (voluntary licensing of key antiretroviral patents). These efforts have resulted in a drop in antiretroviral drug prices from more than US\$ 10 000 per person per year in 2000 to less than US\$ 65 in many countries.

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The cost and cost–effectiveness of HIV programmes have been modelled and planning tools developed for decision-makers (investment case). Strong surveillance and patient monitoring systems have been established to understand treatment needs and the efficiency of the response.

Major efforts were made to simplify antiretroviral treatment. The WHO antiretroviral treatment guidelines focus on when to start treatment, what to start with and how to follow up. Point-of-care tests, including rapid tests, have been developed, as well as point-of-care CD4 and viral load machines, and DNA polymerase chain reaction is done on dried blood spots. New simpler antiretroviral drug formulations are now available: fixed-dose once-daily antiretroviral drug combinations to decrease the pill burden and increase adherence.

Service delivery models have been adapted. In generalized HIV epidemics, treatment services have been decentralized to the primary-care level. In HIV epidemics concentrated among key population groups, services have also been integrated with other services (e.g. methadone treatment services for people who inject drugs). Finally, HIV programmes have increased the role of patients and the community in treatment through patient groups and peer counselling/adherence support.

It is possible to have a similar approach to the treatment of viral hepatitis. Shaping drug market dynamics and achieving price reduction is an essential first step.

### **Awareness of viral hepatitis: results of 2011–2013 studies among patients and health-care workers (Duan Zhong Ping)**

In 2011–2013, a series of surveys were conducted among patients with chronic hepatitis B and physicians. The objective of these surveys was to provide evidence for the development of an improved patient education strategy and inform policy-makers about the development of a control strategy.

The 2011 survey among patients with chronic hepatitis B showed that the majority surveyed was suspicious of and pessimistic about antiviral treatment. Only one third of the patients believed that antiviral therapy may help them return to a normal life; 43.4% of patients were most worried about treatment efficacy, and about one third were worried about treatment cost

The 2012 survey among physicians revealed that 98.8% of physicians understood that patients should continue oral antiviral treatment for at least two years but, in actual practice, over half of their patients took treatment for less than two years. Of the physicians surveyed, 88% agreed with the importance of giving antiviral treatment with a high potency and low drug resistance, but in practice, over 70% of patients used antiviral drugs with a low potency and high rate of drug resistance.

The 2013 survey among patients with chronic hepatitis B showed that less than half were willing to be on long-term treatment if the treatment could only control but not eradicate the virus.

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## **Investigation of HBV inpatient costs and treatment accessibility in six hospitals in Shandong province: the health insurance coverage (Yu Baorong)**

China has three health insurance schemes that cover specific groups: rural residents under the New Rural Cooperative Medical Scheme (NCMS), urban employees under the Urban Employees Basic Medical Insurance (UE-BMI) and unemployed urban residents under the Urban Residents Basic Medical Insurance (UR-BMI). Each scheme is different in the way it is financed and operates.

The reimbursement rates vary across the different schemes. For the UE-BMI and the UR-BMI, the drug list is larger and reimbursement rate is higher. Under the NCMS, the list of drugs reimbursed is smaller and the reimbursement rate is lower.

A study was conducted in 2009–10 in six hospitals in Shandong province to investigate the inpatient costs of hepatitis B infection and health insurance coverage. The study found that for each insurance scheme, eligible patients in tertiary hospitals were more likely to get antiviral therapy. In either secondary or tertiary hospitals, eligible patients under the UE-BMI seemed more likely to get antiviral therapy, though the difference was not significant.

The majority of patients eligible for either UE-BMI (60.0%) or NCMS (52.5%) were treated with nucleoside analogues only. Of eligible patients under the rural health scheme, 32.8% were treated with IFN only. PEG-IFN was not widely used.

Four nucleoside analogues and thymosin were prescribed: lamivudine, adefovir dipivoxil, entecavir and telbivudine, and thymosin alpha-1. Lamivudine and adefovir dipivoxil were the cheapest drugs for the treatment of infection with hepatitis B. All five drugs were on the drug list for urban insurance, but only lamivudine was covered by the rural health scheme.

A large number of liver protectors were available. An average of five to six liver protection drugs were prescribed for one hospitalization, independent of insurance type. Liver protectors cost up to RMB 2400 per month.

Patients with employee insurance consumed more health resources and got a better reimbursement rate compared with the other two schemes.

In 2009, the average disposable annual income for urban residents was RMB 17 811 and net annual income for rural residents was RMB 6118.8. The annual income was enough to cover one instance of hospitalization for a person from a rural area, and 1.5 hospitalizations for an urban employee.

In conclusion, drugs covered by the rural health scheme are insufficient. There are huge differences in reimbursement rates between the urban employees scheme (around 70%) and the other two schemes (17–20%).

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## **Session 5: Ensuring affordable quality drugs for effective treatment and elimination of mother-to-child transmission of HBV**

### **Cost and cost-effectiveness in hepatitis B and C treatment (Wei Lai)**

In 2001, it was estimated that the direct medical costs of hepatitis B were nearly RMB 26 billion, accounting for 5% of the total national health expenditure. The direct costs per capita per year increase with disease progression. Of these direct medical costs, 79.6% were used for hospitalizations; such high costs were not needed. The indirect medical costs of hepatitis B were considerable.

For hepatitis C, the average cost of one hospitalization is more than RMB 8000 per patient. These costs include allopathic medication (RMB 8255), laboratory tests (RMB 1574), blood transfusion (RMB 1443) and traditional Chinese medicines (RMB 1038).

The national reimbursement drug list is updated every four years. It should have been updated in 2013. Three types of Category-B drugs were listed in the National Reimbursement Drug List in 2009: IFN alpha for hepatitis C, PEG-IFN alpha-2a and alpha-2b for hepatitis B and C, and nucleoside reverse transcriptase inhibitors (including lamivudine, entecavir and telbivudine) for active hepatitis B. In general, patients have to undergo hospitalization to get higher reimbursement. Outpatients are not well reimbursed.

Reimbursement policies are decentralized. For example, Shanghai has a good reimbursement policy. In Guangzhou, according to a local regulation of the urban basic medical insurance, some specific chronic diseases are selected by the Department of Human Resources and Social Security, Department of Finance and Health Administration, because of their high incidence, impact on quality of life, requirement for long-term outpatient medication and high medical costs. Active chronic hepatitis B was added to the Guangzhou list in October 2010. However, reimbursement policies are deficient in Guangzhou.

High rates of resistance are observed due to the use of suboptimal drugs such as lamivudine. In China, 30% of patients with chronic hepatitis B who are on treatment are prescribed lamivudine. For treatment-naïve patients, the drug resistance rate for lamivudine is 24% at 1 year and 70% at 5 years.

China has conducted an increasing amount of research on the cost and cost-effectiveness of treatment for HBV infection (49 studies in 2013) and HCV treatment (eight studies in 2013). A study showed that the use of entecavir is cost-effective compared with no treatment and compared with lamivudine, telbivudine and adefovir. However, the cost of entecavir is still very high (US\$ 100–120 per month or RMB 600–720 per month).

### **Systematic review of cost-effectiveness analysis of viral hepatitis B and C treatment (Samuel So/Mehlika Toy)**

Cost-effectiveness analysis (CEA) is a method used to evaluate the outcomes and costs of interventions designed to improve health. The purpose of a CEA is to help decision-makers determine how to allocate resources. The quality-adjusted life year (QALY) is a measure of effectiveness – more time spent in good health. The incremental cost-effectiveness ratio is the net

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increase in cost of the intervention compared to standard care/no treatment to gain one QALY. WHO defines the threshold value for intervention cost-effectiveness as 1–3x the gross domestic product per capita of a country. For China, the cost-effectiveness threshold is between US\$ 9083 and US\$ 27 249 (2012 values).

Recent CEA studies for chronic hepatitis B have focused mainly on entecavir and tenofovir monotherapies. Cost-effectiveness studies for HCV have mainly focused on the outcomes of patients with genotype 1 infection treated with dual therapy (PEG-IFN + ribavirin). All studies suggest that treatment versus no treatment is cost-effective. The largest and most impressive gain in QALYs results from the treatment of chronic hepatitis B with or without cirrhosis compared to no treatment. The QALYs for no-treatment scenarios range from 8.80 to 14.00 and treatment with a low-resistance potent drug range from 15.43 to 19.00.

According to a recent study that addresses the clinical impact and cost-effectiveness of managing inactive chronic hepatitis B carriers in Shanghai, monitoring such patients and treating them on activation of disease is cost-effective. In comparison with the current practice in Shanghai, the strategy to monitor and treat was shown to be cost-effective with an incremental cost-effectiveness ratio of US\$ 2996 per QALY gained. The estimated impact of long-term treatment with the low-resistance profile drug reduces deaths caused by chronic hepatitis B by 83%. Achieving substantial population-level health gains depends on identifying more persons with chronic hepatitis B in the population, and increasing rates of treatment, monitoring and treatment adherence. According to estimates, over 11.5 million Chinese will die of liver cancer in the coming 20 years.

### **International scientific evidence and progress towards the elimination of HBV perinatal transmission (John Ward)**

Globally, perinatal transmission accounts for one in five HBV cases. Twenty-one per cent of HBV-related deaths are among people who were infected at birth.

The 2009 WHO recommendations for the prevention of perinatal hepatitis B was based on a systematic review of trials of methods to prevent perinatal HBV transmission.<sup>3</sup> Studies have shown that a birth dose of hepatitis B vaccine significantly decreases perinatal transmission, early vaccination (before 7 days) is most protective and hepatitis B immune globulin (HBIG) and vaccine are superior to vaccine alone but limited by cost, safety concerns and availability. WHO recommends that a dose of hepatitis B vaccine be given as soon as possible after birth (within 24 hours). This is called the timely birth dose.

The protection afforded by the hepatitis B vaccine varies by the hepatitis B e antigen (HBeAg) status of the mother, which is a marker of the HBV viral load. Without vaccination, 5–30% of infants born to HBeAg-negative mothers will become chronically infected. With vaccination, less than 1% of these children will become chronically infected. Without vaccination, 70–90% of infants born to HBeAg-

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<sup>3</sup> Chuanfang Lee et al. Effect of hepatitis B immunization in new born infants of mothers positive for hepatitis B surface antigen: systematic review and metanalysis. *BMJ* 2006; 332:328.

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positive mothers will become chronically infected. With timely vaccination (three doses) and HBIG, 9–15% of these children will become chronically infected.<sup>4,5</sup>

Even with 100% coverage with the hepatitis B vaccine, timely birth dose and HBIG for infants born to HBeAg-positive mothers, it was estimated that China may still have more than 20 000 cases of perinatal transmission. The elimination of perinatal transmission of HBV would require additional interventions for mothers/infants at risk.

Current evidence suggest that antiviral prophylaxis can prevent perinatal HBV transmission.<sup>6,7</sup> The US is currently considering the use of antiviral prophylaxis for pregnant women who are HBeAg-positive or have a high HBV DNA viral load to prevent perinatal transmission, in addition to vaccination and HBIG. A cost–effectiveness analysis has just been completed, showing that it is a highly cost-saving intervention.

Several randomized controlled trials are under way including in China to guide policy development on the use of antiviral prophylaxis. These studies are assessing the efficacy and safety of telbivudine and tenofovir for the prevention of mother-to-child transmission (PMTCT) of HBV.

## Session 6: Simplifying treatment guidelines and model of care

### WHO HCV and HBV treatment guidelines (Stefan Wiktor)

Treatment coverage of HBV and HCV is very low globally. One of the barriers to treatment scale up is the lack of WHO treatment guidelines focusing on low- and middle-income countries. There are major differences in standards of care across countries. Newer antiviral drugs are rapidly being discovered, which are transforming HCV treatment, though the cost of anti-HCV drugs is still very high.

The WHO guidelines have a political dimension. The WHO guidelines development process is based on scientific evidence. For hepatitis C, the WHO treatment guidelines have been launched in April 2014. For hepatitis B treatment, the Guidelines Development Group has been formulated and the questions finalized. The guidelines are expected to be launched in December 2014.

#### *WHO recommendations for HCV screening*

1. It is recommended that HCV antibody testing is offered to individuals who are part of a population with a high HCV prevalence or who have a history of HCV risk exposure/behaviour.
2. It is suggested that RNA testing be performed directly following a positive HCV antibody test to establish the diagnosis of chronic HCV infection in addition to RNA testing as part of treatment evaluation.

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<sup>4</sup> A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States. Part 1: Immunization of Infants, Children and Adolescents. MMWR, December 23, 2005, Vol. 54(RR-16):1-39.

<sup>5</sup> Chang MH. Hepatitis B virus infection. Semin Fetal Neonatal Med. 2007 Jun;12(3):160-7.

<sup>6</sup> Xu H et al. Measures to reduce mother-to-child transmission of Hepatitis B virus in China: a meta-analysis. Dig Dis Sci. 2014 Feb;59(2):242-58.

<sup>7</sup> Celen MK et al. Efficacy and safety of tenofovir disoproxil fumarate in pregnancy for the prevention of vertical transmission of HBV infection. World J Gastroenterol. 2013 Dec 28;19(48):9377-82.

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#### *WHO recommendations for HCV care*

3. An alcohol-intake assessment is recommended for all persons with HCV infection, followed by the offer of a behavioural alcohol reduction intervention for persons with moderate-to-high alcohol intake.
4. In resource-limited settings, it is suggested that APRI (aminotransferase-to-platelet ratio index) or FIB4 be used for the assessment of hepatic fibrosis rather than other non-invasive tests.

#### *WHO recommendations for HCV treatment*

5. All adults and children with chronic HCV infection, including people who inject drugs, should be assessed for antiviral treatment.
6. Pegylated interferon in combination with ribavirin is recommended for the treatment of chronic HCV infection rather than standard non-pegylated interferon with ribavirin.
7. Telaprevir or boceprevir is suggested for genotype 1 chronic hepatitis C infection.
8. Sofosbuvir, given in combination with ribavirin with or without pegylated interferon (depending on the HCV genotype), is recommended in genotypes 1, 2, 3 and 4 HCV infection.\*
9. Simeprevir given in combination with pegylated interferon and ribavirin is recommended for persons with genotype 1 HCV infection.\*

#### *\*Resource use not taken into consideration*

There were a number of additional considerations, e.g. genotyping as an essential eligibility criterion for starting treatment (WHO recommends that treatment should be prioritized for those in F4 stage) and recommendations for special populations (people who inject drugs, HIV-coinfected people), and implementation considerations.

The WHO guidelines should be adapted according to region and research conducted on identifying suitable models of care (service delivery models).

For HBV treatment, the WHO guidelines will try to provide recommendations on who should be screened – at what prevalence is screening cost-effective; how to protect contacts of persons with chronic HBV – screening and vaccination recommendations; who should be treated – treatment eligibility criteria; what medicines to use; when to stop treatment and how to monitor for liver cancer.

### **Review of viral hepatitis treatment research in China which could inform simplification of treatment guidelines and improved HBV PMTCT (Zou Huachun)**

The Burnet Institute, Melbourne, Australia, was commissioned by WHO to provide an overview of China's research efforts in the area of viral hepatitis treatment. One of the objectives of this study

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was to provide an inventory of existing Chinese research efforts to simplify diagnostics and treatment. The Burnet Institute used a combination of key informant interviews and reviews of the Chinese and English literature published in the past five years.

## Key findings

### *Non-invasive method for assessment of liver fibrosis*

In China, available non-invasive methods for the assessment of liver fibrosis are ultrasound-based transient elastography (FibroScan) and the indirect test, APRI. Physicians use FibroScan more often. In 2013, there were 216 FibroScan machines throughout China. Professors Yong-Peng Chen and Jin-Lin Hou from Southern Medical University published a literature review on non-invasive methods for the assessment of liver fibrosis.<sup>8</sup> Professor Ji-Dong Jia is collaborating with Tsinghua University in Beijing to produce FibroTouch, which is similar to Fibroscan.

### *Criteria for starting treatment*

One study from Zhoushan provided evidence for the clinical and economic benefits of early detection of active chronic hepatitis B through monitoring and treatment of eligible patients. It also provided the estimated cost of a screening programme and its cost-effectiveness in combination with the proposed monitoring and treatment strategy as a next research step.<sup>9</sup>

### *Efficacy and safety of new antiviral treatments in Chinese populations*

Johnson & Johnson is currently undertaking a clinical trial on simeprevir (TMC-435) in Chinese patients with chronic hepatitis C infection. Xiamen Amoytop Biotech, in collaboration with Peking University First Hospital, is conducting a phase 3 clinical trial to assess the efficacy and safety of PEG-IFN  $\alpha$ -2b (40 kD, Y-shape) for hepatitis C. New Discovery LLC and Gilead Sciences are conducting a randomized control trial of tenofovir disoproxil among Chinese HBeAg-positive pregnant women with chronic hepatitis B to determine its tolerability and safety during late pregnancy, and its efficacy in reducing the vertical transmission of hepatitis B. Professor G Han, a collaborator in the study above, has also published a paper on the efficacy of telbivudine in the prevention of vertical transmission from HBeAg-positive women with chronic hepatitis B.

### *Cost-effectiveness of pegylated interferon versus interferon*

Professor Lai Wei stated that patients with hepatitis C treated with PEG-IFN combined with ribavirin are more likely to have an SVR to treatment than those treated with standard IFN alone. Multicentre randomized control trials have shown that the use of PEG-IFN combined with ribavirin can result in significantly less recurrence over six months.

### *Effect of antiviral drugs on long-term prognosis in China*

China is part of a current multicentre international clinical trial (Protocol 080), in which 5300 patients with chronic hepatitis B will be followed for six years to study the long-term outcomes associated with entecavir therapy as compared to other antivirals approved for the treatment of chronic HBV infection. This study is led by Professor Jinlin Hou, sponsored by Bristol-Myers Squibb.

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<sup>8</sup> Hep Int. 2013;7(2):356–68 [Pl give refs in full if including them]

<sup>9</sup> Li J. Antivir Antiretrovir. 2013

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The Twelfth Five-Year Plan supports key research in this area. Prognosis for two to three years after antiviral treatment is being studied by teams led by Professor Jinlin Hou, Southern Medical University in Guangzhou and Yimin Mao, Shanghai Renji Hospital.

Professor Wei Lai is currently leading two observational clinical studies: (i) a study (joint programme between the University of Michigan and Peking University) involving more than 1000 HCV-infected patients in Beijing and 1000 HCV-infected patients in Michigan who will be followed for five years up to 2019. This study looks at disease progression in patients on treatment and those not on treatment. (ii) The second is an observational study of HCV-infected patients who are not on treatment. These patients have been followed for 19 years as of now to look for the development of liver fibrosis and HCC.

## **4. Discussion and conclusion**

The evidence presented at the meeting clearly shows that there are opportunities for phased expansion of current efforts into a more comprehensive viral hepatitis programme in China, including a public health treatment programme within the context of the health reform.

An investment case using different drug and service delivery price scenarios for hepatitis B and C treatment and modelling cost-savings approaches would provide policy-makers with the evidence needed to decide to implement a public health programme for the treatment of hepatitis. A public health approach to a treatment programme would also be a major driver for achieving substantial drug price reduction, as demonstrated by the example of tenofovir in the HIV programme.

Preparatory work for expanding current efforts into a more comprehensive public health programme for viral hepatitis is needed through a national consultative process. Essential elements would include (i) the development of an investment case to provide policy-makers with the needed evidence; (ii) piloting of service delivery models; (iii) conducting high-level advocacy among policy-makers and raising awareness among the Chinese Medical Association to promote a public health approach; and (iv) simplification and standardization of treatment guidelines.

The price reduction of antiviral drugs is key to allowing the financing of universal access to viral hepatitis treatment in China. The coordinated efforts of several ministries, such as NHFPC, Human Resources and Social Security Ministry, and Reform and Development Ministry, are needed to negotiate price reduction and develop a financing mechanism to support the programme.

Opportunities will have to be explored to improve the health insurance coverage for chronic hepatitis treatment for all, and/or include these conditions in the current list of 22 catastrophic expenditure conditions for rural health insurance schemes. This would allow a higher reimbursement rate for the most disadvantaged populations.

Implementation research will address some of these outstanding issues, in particular, how to optimize service delivery models and address vulnerable populations (some of which can be reached

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by maximizing links with the HIV programme). This will inform phased expansion of a public health treatment programme for viral hepatitis

## Proposed next steps

The development of a treatment investment case could be used as a basis to inform a country-led multisectoral consultation process to engage high-level political commitment and support for a comprehensive viral hepatitis programme.

A pilot treatment project could be started in selected cities in China (e.g. Beijing and Shanghai) with high capacity for specialized care and sufficient health insurance coverage to shoulder the costs for piloting treatment through a public health approach. Lessons learnt from the pilot projects would inform expansion and scale up of the programme.

During the technical consultation, the following suggestions were put forward for WHO to consider in order to promote a comprehensive viral hepatitis programme in China:

- To set global treatment goals and targets to inform country adaptation;
- To use World Hepatitis Day on 28 July 2014 to promote viral hepatitis treatment for the prevention of liver cancer;
- To launch the global WHO hepatitis B treatment guidelines in China;
- To assist with an economic modelling exercise (investment case);
- To work on drug cost reduction strategies with national counterparts and share examples from other countries.

## Annex 1: Agenda

Time	Topic	Presenter
9:00–9:30	Introduction to the meeting	Nicole Seguy WHO China
9:30–9:50	<b>Global viral hepatitis strategy and WHO's role in promoting viral hepatitis treatment</b>	Gottfried Hirschall WHO HQ
<b>9:50–10:30</b>	<b>Treatment needs and strategy in China</b>	
	Epidemiology of HBV in China, Treatment needs, National strategy for HBV screening & treatment	Li Quanle NHFPC
	Epidemiology of HCV in China, Treatment needs National strategy for HCV screening & treatment	Wu Zunyou CCDC
10:30–10:45	<b>BREAK</b>	
10:45–11:45	<b>A public health approach to viral hepatitis treatment</b>	
	Achievements and Challenges in HBV and HCV Treatment in China	Jia Jidong Beijing Friendship hosp
	US CDC public health role for hepatitis B and C treatment in the US	John Ward US CDC
	Increasing access to hepatitis treatment: What can we learn from HIV	Ying-Ru Lo WPRO
11:45–12:40	<b>LUNCH (box)</b>	
12:40–1:20	<b>Improving access to testing and treatment</b>	
	Awareness on viral hepatitis: result of 2011-2013 studies among patients and health care workers	Duan Zhong Ping You'An hospital
	Investigation of HBV inpatient costs and treatment accessibility in 6 hospitals in Shandong province: the health insurance coverage	Yu Baorong WHO China
1:20–2:20	<b>Ensuring affordable quality drugs for effective treatment and eMTCT</b>	
	Cost and Cost effectiveness in hepatitis B & C treatment	Wei Lai Peking univeristy
	Systematic review of cost effectiveness analysis of Viral Hepatitis B & C Treatment	Samuel So APAVH
	International scientific evidence and progress towards the elimination of HBV perinatal transmission	John Ward US CDC
<b>2:20–3:00</b>	<b>Simplifying Treatment guidelines and model of care</b>	
	WHO HCV and HBV Treatment guidelines	Stefan Wiktor

		WHO HQ
	Review of viral hepatitis treatment research in China that could inform simplification of treatment guidelines and improved HBV PMTCT	Zou Huachun Burnet Institute
3:00–3:15	<b>BREAK</b>	
3:15–5:00	<b>Discussion:</b> Meeting conclusions	

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