VIRAL HEPATITIS IN MONGOLIA: SITUATION AND RESPONSE

2015
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ACKNOWLEDGEMENTS

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The World Health Organization Regional Office for the Western Pacific would like to acknowledge the United States Centers for Disease Control and Prevention (Atlanta) for supporting Geoffrey Beckett, Chief, Prevention Branch, Division of Viral Hepatitis, the National Center for HIV/AIDS, Hepatitis, STD and TB Prevention; and the National Cancer Institute, National Institutes of Health (Bethesda) for supporting Ann Chao, epidemiologist, to join the review team. Narantuya Jadambaa, National Professional Officer, WHO Mongolia Country Office, coordinated all the local meetings and visits, helped with compiling and validating the information, and critical review of the report. We thank Soe Nyunt-U, WHO Representative to Mongolia and Ying-Ru Lo, Coordinator, HIV, Hepatitis and STI, WHO Regional Office for the Western Pacific for the overall guidance.

This report was written by Nick Walsh, Medical Officer Hepatitis, WHO Regional Office for the Western Pacific and Geoffrey Beckett, with Ann Chao contributing the cancer section.
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tr>
<td>ADB</td>
<td>Asian Development Bank</td>
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<tr>
<td>AFP</td>
<td>alpha fetoprotein</td>
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<tr>
<td>aimag</td>
<td>provincial health facility (first-level administrative division)</td>
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<td>ALT</td>
<td>alanine aminotransferase</td>
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<tr>
<td>ANC</td>
<td>antenatal care</td>
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<tr>
<td>anti-HBc</td>
<td>antibody to hepatitis B core antigen</td>
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<td>anti-HCV</td>
<td>antibody to hepatitis C virus</td>
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<td>anti-HDV</td>
<td>antibody to hepatitis D virus</td>
</tr>
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<td>APRI</td>
<td>aspartate aminotransferase-to-platelet ratio index</td>
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<tr>
<td>BD</td>
<td>birth dose</td>
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<tr>
<td>CDA</td>
<td>Center for Disease Analytics, Colorado</td>
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<td>CDC</td>
<td>Centers for Disease Control and Prevention, USA</td>
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<td>ELISA</td>
<td>enzyme-linked immunosorbent assay</td>
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<td>EQAS</td>
<td>external quality assurance system</td>
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<tr>
<td>EWAR</td>
<td>early warning and response</td>
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<tr>
<td>F1–4</td>
<td>METAVIR liver fibrosis stage 1–4</td>
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<td>Gavi</td>
<td>Gavi, The Vaccine Alliance</td>
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<td>GDP</td>
<td>gross domestic product</td>
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<tr>
<td>Global Fund</td>
<td>Global Fund to Fight AIDS, Tuberculosis and Malaria</td>
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<td>HAI</td>
<td>hospital-acquired infection</td>
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<tr>
<td>HAV</td>
<td>hepatitis A virus</td>
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<td>HBCag</td>
<td>hepatitis B core antigen</td>
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<tr>
<td>HBeAg</td>
<td>hepatitis B e antigen</td>
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<tr>
<td>HBsAg</td>
<td>hepatitis B surface antigen</td>
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<tr>
<td>HBV</td>
<td>hepatitis B virus</td>
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<td>HCC</td>
<td>hepatocellular carcinoma</td>
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<td>HCV</td>
<td>hepatitis C virus</td>
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<td>HDV</td>
<td>hepatitis D virus</td>
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<tr>
<td>HepB3</td>
<td>three doses of hepatitis B vaccine</td>
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<td>HEV</td>
<td>hepatitis E virus</td>
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<tr>
<td>HSSMP</td>
<td>Health Sector Strategic Master Plan</td>
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<tr>
<td>ICD</td>
<td>International Statistical Classification of Diseases and Related Health Problems</td>
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<td>Ig</td>
<td>immunoglobulin</td>
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<tr>
<td>INGO</td>
<td>international nongovernmental organization</td>
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<td>LFT</td>
<td>liver function tests</td>
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<tr>
<td>MASLD</td>
<td>Mongolian Association for the Study of Liver Diseases</td>
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<tr>
<td>MSM</td>
<td>men who have sex with men</td>
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<td>NCC</td>
<td>National Cancer Centre</td>
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<td>NCCD</td>
<td>National Center for Communicable Diseases</td>
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<td>NGO</td>
<td>nongovernmental organization</td>
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<td>NHEL</td>
<td>National Hepatitis and Enteroviral Laboratory</td>
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<td>NRL</td>
<td>National Reference Laboratory (Australia)</td>
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<td>OOP</td>
<td>out-of-pocket (costs)</td>
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<tr>
<td>PCR</td>
<td>polymerase chain reaction</td>
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<tr>
<td>PEG-IFN</td>
<td>pegylated interferon</td>
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<td>PWID</td>
<td>people who inject drugs</td>
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<tr>
<td>QA</td>
<td>quality assurance</td>
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<tr>
<td>RBV</td>
<td>ribavirin</td>
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<tr>
<td>SOP</td>
<td>standard operating procedure</td>
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<tr>
<td>soum</td>
<td>district health facility (second-level administrative division)</td>
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<tr>
<td>STI</td>
<td>sexually transmitted infection</td>
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<tr>
<td>SUID</td>
<td>single-use injection device</td>
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<tr>
<td>SVR</td>
<td>sustained virological response</td>
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<tr>
<td>TB</td>
<td>tuberculosis</td>
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<tr>
<td>TNM</td>
<td>tumour–node–metastasis (classification system for malignant tumours)</td>
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<tr>
<td>TTI</td>
<td>transfusion-transmitted infection</td>
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<td>WHO</td>
<td>World Health Organization</td>
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An assessment of the current situation and response to viral hepatitis in Mongolia was carried out in September 2014 and January 2015 by the World Health Organization (WHO) Regional Office for the Western Pacific, Office of the WHO Representative in Mongolia, and the United States Centers for Disease Control and Prevention. The assessment was supported by the Mongolian National Center for Communicable Diseases and the Ministry of Health and Sports. The United States National Cancer Center and the National Institutes of Health carried out the assessment of liver cancer during the September 2014 review. These reviews supported the development of a new national hepatitis strategy in Mongolia.

Mongolia has a large burden of viral hepatitis, especially chronic hepatitis B virus (HBV) and hepatitis C virus (HCV) infections, which are associated with cancer and cirrhosis. Chronic HBV infection is acquired in early childhood in Mongolia, while HCV and hepatitis delta virus (HDV) transmission is healthcare related. Mongolia also has the highest, and increasing, rate of liver cancer and mortality from liver cancer in the world. Cancer is the second most common cause of death in Mongolia and liver cancer is responsible for 44% of all cancers. Chronic hepatitis B and C infections are responsible for 95% of liver cancers in the country.

There have been successes in responding to the epidemic. Mongolia’s National Strategy on Viral Hepatitis Control covered the period from 2010 to 2015 and proposed five objectives, with the overarching aim of reducing the incidence of viral hepatitis to 10 cases per 10,000 by 2015. This goal has now been achieved. The prevalence of hepatitis B surface antigen (HBsAg) among 4–6 year olds has now met the regional goal of <1.0%. In addition, the introduction of vaccination against the hepatitis A virus (HAV) into
routine vaccination schedules has had a substantial impact on reducing the proportion of acute jaundice cases related to HAV infection. HCV and HDV transmission appears to have decreased substantially over the past 20 years as infection control systems have improved.

Given the disease burden, but also the progress made in responding to viral hepatitis, a review was undertaken to assess the current situation and response in Mongolia. The review team visited public and private facilities providing prevention, surveillance, diagnosis, care and treatment services for hepatitis and liver cancer in Ulaanbaatar and Bulgan province. Infection control practices were also reviewed at these services. In addition, a meeting with key stakeholders was held on 12 September 2014, and a consensus meeting to discuss recommendations from the initial review was held on 21 and 22 January 2015. The consensus meeting provided an opportunity to hold a workshop on the content of the new national hepatitis strategy, later to be named the Viral Hepatitis Prevention, Control, and Elimination Programme.

This report presents findings from the assessment and makes 48 recommendations detailed throughout the body of the document and listed in Annex IV. These recommendations were discussed in detail during the review in January 2015 and agreed to at the consensus meeting on 21 and 22 January 2015.

Summary recommendations

This report presents findings from the assessment and makes 48 recommendations detailed throughout the body of the document and listed in Annex IV. These recommendations were discussed in detail during the review in January 2015 and agreed to at the consensus meeting on 21 and 22 January 2015. Key recommendations are as follows:

- It is recommended that the new National Hepatitis Programme align with the Regional Action Plan for Viral Hepatitis in the Western Pacific. This Programme should be costed, including for various testing and treatment options. A comprehensive funding strategy should be developed, incorporating domestic and external funding, so that sustainable action can be ensured.
- Mongolia should adopt the WHO hepatitis guidelines as the Mongolian national guidelines, adapted as appropriate. This includes HBV and HCV screening, care and treatment guidelines.
- Strategies should be developed to increase immunization against hepatitis, and improve disease and treatment literacy among the general public and the affected population.
- Catch-up HBV vaccination is recommended to be extended to at-risk groups other than health-care workers, including those with chronic HCV infection and key populations.
- Alcohol prevention initiatives should be linked with secondary prevention strategies for viral hepatitis in public health messaging.
- The private sector should be brought under the purview of the National
Viral Hepatitis Strategy, particularly for hepatitis diagnostics and treatment, as most chronic hepatitis treatment is provided by the private sector.

• Validated rapid test kits should form the backbone of viral hepatitis testing in Mongolia. Consideration may be given as to how to include both public and private sector laboratories in quality management and external quality assurance procedures.

• There should be a move towards reporting test results for HBV, HCV and HDV by laboratories, with collation at the central level by the NCCD. The national identity number provides a mechanism for de-duplication.

• The number of individuals with advanced liver disease needing prompt antiviral therapy for chronic hepatitis B and C should be estimated to inform treatment planning.

• An HBV and HCV treatment cascade should be developed for Mongolia, inclusive of the private sector, in order to assess screening, care and treatment responses at the population level.

Planning is now under way for the new Viral Hepatitis Prevention, Control, and Elimination Programme.

The WHO Regional Office for the Western Pacific will continue to support the Ministry of Health and Sports in developing the new National Hepatitis Programme and facilitating engagement and alignment with the regional hepatitis response, including the Regional Action Plan for Viral Hepatitis.

The review team concluded that viral hepatitis is recognized as a high-priority health problem, and there is significant political will to address this issue. Immunization programmes have had substantial success to date in addressing perinatal and infant hepatitis B transmission. Mongolia could serve as a model for a successful comprehensive response to viral hepatitis; however, significant investment is required to realize goals within the new Viral Hepatitis Prevention, Control, and Elimination Programme.
1. INTRODUCTION

1.1 Epidemiology

All viral hepatitides are endemic to Mongolia. The epidemiology of viral hepatitis in Mongolia today reflects a number of key inflection points in the incidence of viral hepatitis in Mongolia.

Overview of hepatitis A and E

**Hepatitis A virus (HAV)** Infection: hepatitis A has been endemic in Mongolia since records began. Studies in Mongolia in the 2000s found that 100% of adults and 50% of 5-year-old children were immune (1, 2). HAV was the most common cause of acute jaundice reported until immunization for HAV was introduced among infants in 2012. The lack of chronicity and seroprotection following HAV infection, combined with the introduction of the HAV vaccine, will result in an increasing proportion of the population being immune to HAV infection.

**Hepatitis E virus (HEV)** infection: the seroprevalence of HEV immunoglobulin G (IgG) is high among Mongolian adults above 30 years of age, and is estimated at 12%. Seroprevalence in children is very low (0.8%) (1, 2). Human disease from HEV has not been recorded in Mongolia.

### Table 1. Major adult HBV serosurveys in Mongolia

<table>
<thead>
<tr>
<th>Study/year of data collection</th>
<th>HBsAg prevalence</th>
<th>Estimated absolute number (chronic HBV)</th>
<th>Anti-HDV prevalence in chronic HBV</th>
<th>Study population (M:F)</th>
<th>Tests</th>
<th>Coverage</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dashtseren, 2013 (5)</td>
<td>10.6% N=82</td>
<td>201,387</td>
<td>67% N=82</td>
<td>1158 (599:659)</td>
<td>HBsAg rapid CTK Biotech (San Diego)</td>
<td>4 provinces + Ulaanbaatar</td>
<td>Three-stage cluster sampling Sample included only those ≥20 years</td>
</tr>
<tr>
<td>Baatarkhuu, 2002–2005 (3)</td>
<td>11.8% N=82</td>
<td>41%</td>
<td>1512</td>
<td>12 provinces + Ulaanbaatar</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

M male, F female, HBsAg hepatitis B surface antigen, anti-HDV antibody to hepatitis D virus

Sources: Baatarkhuu et al. 2012 (3); Baatarkhuu et al. 2008 (4); Dashtseren et al. 2014 (5); Dashdorj et al. 2014 (6)
Overview of hepatitis B and C

Two large, population-based seroepidemiological studies of hepatitis B virus (HBV) and hepatitis C virus (HCV) markers have been carried out (3–6) in Mongolia over the past decade (see Table 1). The review team reviewed the methodology of the studies and concluded that both samples could be considered broadly representative of the adult population (with the caveat that the 2013 sample included only four of the 12 provinces, in addition to Ulaanbaatar; however, random clustering was implemented in the selection of subjects at the community level).

Epidemiology of hepatitis B

Hepatitis B is endemic in the adult population of Mongolia. Most cases of chronic HBV are acquired following mother-to-child transmission, or in early childhood. Acute hepatitis B infection acquired after the age of 5 years spontaneously resolves in more than 90% of individuals. However, it is likely that some chronic HBV infections have resulted from health-care-associated transmission among persons who remain susceptible after early childhood.

There have been a number of seroprevalence surveys of HBV infection among children in Mongolia, conducted to assess the effectiveness of the HBV immunization programme. A national community-based, multistage cluster sample survey in 2009–2010 (N = 5894) estimated the seroprevalence of hepatitis B surface antigen (HBsAg) in 4–6-year-old children at 0.53% (7), verifying that Mongolia had achieved the 2012 regional milestone of an HBsAg prevalence of less than 2% among 5-year-old children.

Figure 1. HBsAg prevalence in two national serosurveys of children in Mongolia born between 1995 and 2006

HBsAg prevalence among children decreased most sharply from the early to mid-1990s, and then continued to decrease steadily during the mid–late 1990s. No data are available for 1998–2003 birth cohorts, but the findings suggest that birth cohorts after 2000 have a low probability of perinatal/vertical transmission, while birth cohorts from 1995–2000 have an intermediate prevalence and would require screening in line with adult screening practices.

Sources: Dashtseren et al. 2014 (5); Davaalkham et al. 2007 (8)
**Hepatitis B surface antigen prevalence among adults**

In the most recent serosurvey of adults (≥20 years of age), conducted during 2013 among persons in four aimags and in Ulaanbaatar, the overall prevalence of HBsAg positivity was 10.6% (5). The prevalence was similarly high across age groups ranging from the twenties through the sixties. Prevalence was less among those 60 years and above, as shown in Figure 2.

Among men who have sex with men (MSM), the prevalence of HBsAg has been estimated at 14%, and the prevalence of HBV coinfection among HIV-infected MSM is 8%. However, there are fewer than 200 HIV cases identified in the country.

**Hepatitis B surface antigen prevalence among adolescents**

Two national surveys (2004 and 2009–2010) that assessed the impact of HBV vaccination programmes introduced in the early 1990s have been conducted among children in Mongolia; the surveys utilized stratified random samples of 7–10–year–olds (2004) and 4–6–year–olds (2009–2010), each of which included an assessment of the HBsAg status. The surveys demonstrated that persons born between 1992 and 1994 (currently about 21–23 years old) had an HBsAg prevalence of 9.3%, which is similar to that of older Mongolians; persons born between 1995 and 1997 (currently about 18–20 years old) had an intermediate prevalence of 5.2%; persons born between 2003 and 2006 (currently about 9–12 years old) had a low prevalence of 0.5% (5, 8).

The transition from high to low HBsAg prevalence in Mongolia’s birth cohorts occurred during the late 1990s and early 2000s. It was associated with the increasing effectiveness of the national HBV vaccination programme, illustrated in Figure 1.

![Figure 2. HBsAg prevalence by aimag of residence among Mongolian adults in population serosurvey conducted in 2013](image)

Source: Dashtseren et al. 2014 (5)

**Geographical distribution**

There is geographical variation in the seroprevalence of HBsAg. In general, prevalence is estimated to be higher in rural areas, particularly in the northern provinces, and lower in Ulaanbaatar and the southern provinces. In a study conducted in 2002–2005 (4), the estimated prevalence ranged from 7.3% in Uvurkhangai to 18% in Khuvsgul in the north, bordering Russia. In Ulaanbaatar, the prevalence was estimated to be 9.3%.

Among children born between 1992 and 1997 and tested during the 2004 study (8), HBsAg prevalence was significantly higher among those living in rural
soums (7.7%) than among persons living in urban centres and aimag capitals (3.0%), likely reflecting differential success in vaccination efforts.

Among adults, in a 2013 serosurvey in four aimags and Ulaanbaatar, the prevalence was relatively higher in three of the aimags (Dornogovi, Zavhkan and Uvurkhangai) than in Khentii or in the Ulaanbaatar metropolitan area (5) (Figure 2). There are 21 aimags (provinces) in Mongolia.

Gender
The 2013 serosurvey found a higher prevalence of HBsAg among males (11.8%) than among females (9.7%); the relatively higher prevalence in males is consistent with patterns seen in other countries and regions (5).

Epidemiology of hepatitis C

Hepatitis C infection is also endemic to Mongolia. The major modality of HCV transmission in Mongolia over the past half century has been through parenteral exposure within the formal and informal health sector. The proportion of cases that acquire HCV infection through sexual or vertical transmission is unknown. Injecting drug use is currently very uncommon in Mongolia and does not play a significant role in the transmission of HCV.

The two major seroepidemiological surveys for HBV also included HCV serology, and are the most nationally representative serosurveys carried out in Mongolia to date (4, 6). In addition, a meta-analysis of these two serosurveys was conducted in 2014 (9) Figure 3 (Table 2).

Table 2. Major adult HCV serosurveys in Mongolia

<table>
<thead>
<tr>
<th>Study/year</th>
<th>HCV RNA</th>
<th>HCVAb</th>
<th>Estimated absolute number (chronic HCV)</th>
<th>Study population (Number)</th>
<th>Tests</th>
<th>Coverage</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dashdorj, 2013 (6)</td>
<td>11.1%</td>
<td>113 782</td>
<td>1158 (M:F 599:659)</td>
<td>HBsAg rapid CTK Biotech (San Diego)</td>
<td>4 provinces + Ulaanbaatar</td>
<td>Three-stage cluster sampling</td>
<td>Sample included only persons ≥20 years</td>
</tr>
<tr>
<td>Baatarkhuu, 2002–2005 (4)</td>
<td>11%</td>
<td>15.6%</td>
<td>188 000</td>
<td>1512</td>
<td>12 provinces + Ulaanbaatar</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Ab antibody, M male, F female, HBsAg hepatitis B surface antigen, RNA ribonucleic acid

Sources: Baatarkhuu et al. 2012 (3); Baatarkhuu et al. 2008 (4); Dashtseren et al. 2014 (5); Dashdorj et al. 2014 (6)

Age distribution

Among adults, the prevalence of anti-HCV antibody (Ab) increases with age, with the highest prevalence in both population-based studies seen among persons in birth cohorts from the mid-1950s and earlier (i.e. persons who are currently 60 years and older), and lowest among persons in the birth cohorts from about 1990 onward (i.e. persons who are currently in their mid-twenties and younger).
A nationwide population-based sample of elementary schoolchildren (ages 7–10 years) conducted in 2004 (10) suggests that persons in the birth cohort of approximately 1994–1997 (currently aged 17–20 years) have a very low anti-HCV prevalence (<1%).

**Geographical distribution**

The 2004–2005 serosurvey (4) included sampling from Ulaanbaatar and 12 aimags (sampling frame included 77% of the national population), while the 2013 survey included four aimags and Ulaanbaatar (56% of the population). A total of 12 aimags were included in the sampling frame of one or more surveys, while nine aimags were not included in either survey. Four aimags (Khartti, Dornogovi, Zavhkan and Uvurkhangai) were included in both the surveys. The populations of the eastern and Khangai regions were best represented collectively in both surveys, while populations in the western and central regions were less well represented.

The prevalence in Ulaanbaatar was close to the country mean in both the surveys. The highest anti-HCV prevalence was seen in three rural aimags in 2004–2005; namely, Dormod (18.2%) in the eastern region, and in two Khangai region aimags (Bayankhongor 17.2%, Arkhangai 16.7%). Of the four aimags included in the 2013 survey, Zavkhan (western region) and Uvurkhangai (Khangai region) had a relatively high prevalence.

In 2014, a team from an American Health Consultancy firm (Center for Disease Analysis [CDA], Colorado) worked with both research groups to develop a modelled estimate of HCV prevalence based on a meta-analysis of the two studies, accounting for population distribution changes and ageing among the Mongolian population. The estimated total number of HCV infections (viraemia) from this meta-analysis was 200 000 in 2013. The population prevalence was 6.8%, climbing to more than 20% for those cohorts older than 40 years (9).

**Figure 3.** Prevalence of anti-HCV antibody and HBsAg by age cohort in Mongolia

![Bar chart showing prevalence of anti-HCV antibody and HBsAg by age cohort in Mongolia](chart.png)

Sources: Baatarkhuu et al. 2012 (3); Baatarkhuu et al. 2008 (4); Dashtseren et al. 2014 (5); Dashdorj et al. 2014 (6); Davaalkham et al. 2011 (7)
The CDA analysis estimated that the peak incidence of HCV was in 1970, while the peak prevalence (222,000 individuals) occurred in 1995. The declines were attributed to mortality, given the paucity of HCV treatment in Mongolia. The same model indicated that 3300 new HCV infections occurred in Mongolia during 2013.

The prevalence of anti-HCV in MSM has been estimated at 15%.

Almost all (98%) HCV infections in Mongolia are due to genotype 1b (4).

Hepatitis D, dual and triple hepatitis infection

Hepatitis D infection is highly endemic among individuals with chronic HBV infection in Mongolia. The likely reason is the association between high HBV prevalence, the existence of hepatitis D virus (HDV) in the community and bloodborne virus transmission in health and non-health settings over the past decades. The prevalence of antibody to HDV (anti-HDV) among HBsAg-positive individuals, indicating likely HBV/HDV coinfection, ranged from 41% to 67% among the two major seroepidemiological studies. The National Enterovirus and Hepatitis Laboratory reported that in 2013, 45% of HBsAg-positive samples were also anti-HDV positive, while 30% were HDV IgM positive. HBV/HDV coinfection is associated with more rapid progression of liver disease than is seen in HBV monoinfection. For example, a 2005 study of patients with chronic liver disease reported a prevalence of HDV RNA of 39% among patients with chronic hepatitis, 51% among those with cirrhosis and 80% among those with hepatocellular carcinoma (HCC) (11). These data are consistent with observations of HBV/HDV coinfection in Mongolia.

Triple infection (HBV/HCV/HDV) was identified in 63% of individuals with HCC in the same study, compared with 0% in healthy individuals.

HIV in Mongolia

It should be noted that Mongolia is a country with a low prevalence of HIV. As of April 2014, Mongolia had a cumulative number of 162 identified cases of HIV, with an estimated HIV prevalence of 0.03% in people aged 15–49 years, 99% of which is due to sexual transmission (12). Since 2009, no cases of HIV have been detected in the national blood supply donor screening programme.

1.2 Severity of liver disease in chronic hepatitis

Staging liver disease due to chronic viral hepatitis prioritizes patients with advanced liver disease for treatment, given the limited resources. Few epidemiological data are available for assessing liver disease severity at a population level in Mongolia. The review team identified two data sources (Table 3). Further work is currently being undertaken.

The proportion of those with advanced fibrosis (F3/F4) in the CDA estimate (32%) is lower than the treatment-seeking group in a private clinic (38%) but consistent with the treatment-seeking population skewing towards advanced disease. The CDA model indicates that HCV-related F0–F3 disease has already peaked, while F4 and decompensated liver disease rates are increasing (9).
**Potential treatment burden**

The World Health Organization (WHO) screening, care and treatment guidelines for HBV and HCV infection (13, 14) provide indicative recommendations for commencing antiviral therapy for the treatment of chronic HBV and HCV infection.

For HBV, antiviral therapy is recommended for those with advanced liver disease (F4) and in those in the pre-cirrhosis stage (≤F3) older than 30 years of age with persistently abnormal serum alanine aminotransferase (ALT) levels and high viral load (>20 000 IU/mL). Where viral load measurement is not available, persistently abnormalb ALT is sufficient to indicate treatment.

For HCV, antiviral therapy in resource-limited settings is recommended for viraemic individuals with advanced liver disease (F3/F4) (see Table 4).

**Table 3. Staging of liver fibrosis in patients with viral hepatitis in Mongolia**

<table>
<thead>
<tr>
<th>Fibrosis stage (F)</th>
<th>CDA analysis</th>
<th>Happy Veritas liver clinic</th>
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<tbody>
<tr>
<td></td>
<td>Population-based modelled data</td>
<td>Fibroscan results for 2857 individuals Private hepatitis treatment clinic</td>
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<tr>
<td>F stage</td>
<td>HCV only</td>
<td>All forms of viral hepatitis</td>
</tr>
<tr>
<td>F0</td>
<td>25%</td>
<td>30%</td>
</tr>
<tr>
<td>F1</td>
<td>27%</td>
<td>15%</td>
</tr>
<tr>
<td>F2</td>
<td>16%</td>
<td>12%</td>
</tr>
<tr>
<td>F3</td>
<td>19%</td>
<td>7%</td>
</tr>
<tr>
<td>F4 (cirrhosis)</td>
<td>13%</td>
<td>31%</td>
</tr>
</tbody>
</table>

CDA Center for Disease Analysis, F stage: liver fibrosis stage

Sources: Data from Happy Veritas private clinic, Ulaanbaatar; Hatzakis et al. 2015 (9)

**Table 4. Crude estimates of potential chronic hepatitis treatment burden in Mongolia**

<table>
<thead>
<tr>
<th></th>
<th>Estimated population (N)</th>
<th>% Advanced liver disease</th>
<th>No. with advanced liver disease</th>
<th>No. indicated for treatment</th>
<th>No. indicated for treatment (mid-point)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic HBV</td>
<td>~200 000</td>
<td>13–31%&lt;sup&gt;3&lt;/sup&gt;</td>
<td>26 000–62 000</td>
<td>41 800–71 400&lt;sup&gt;4&lt;/sup&gt;</td>
<td>56 614</td>
</tr>
<tr>
<td>Chronic HCV</td>
<td>~200 000</td>
<td>31–37%&lt;sup&gt;b&lt;/sup&gt;</td>
<td>31 000–74 000</td>
<td>31 000–74 000</td>
<td>52 500</td>
</tr>
</tbody>
</table>

Sources: Data from Happy Veritas private clinic, Ulaanbaatar; Hatzakis et al. 2014 (9)

<sup>1</sup>Data from Happy Veritas private clinic, Ulaanbaatar (Fibroscan results of 2857 viral hepatitis patients) and Hatzakis et al. 2014
<sup>2</sup>Indication is WHO-recommended criteria for treatment initiation.
<sup>3</sup>For HBV disease, F4 (cirrhosis) and >30 years old (as # <30 years assumed to be negligible)
<sup>4</sup>Data from Happy Veritas private clinic. Of 1100 HBsAg-positive patients (clinical dataset), 71.5% had HBV DNA <2000 IU/mL, estimated number with cirrhosis is from column 3.
<sup>b</sup>For HCV liver disease, ≥F3

<sup>b</sup> Three ALT results above the upper limit of normal (men >30 U/L, women >19 U/L) over a 6–12-month period
The treatment burden for HCV infection in Mongolia (mid-point) is 52,500. Given the large number of individuals who need treatment, the cost of treatment and the efficacy of antiviral therapy become key considerations.

1.3 Transmission of hepatitis

In Mongolia, HAV transmission occurs predominantly among young children and is a result of poor sanitation, according to the National Center for Communicable Diseases (NCCD).

HBV transmission resulting in chronic HBV infection is mainly confined to exposure before 5 years of age. Exposure after 5 years of age rarely results in chronic infection, and subsequently HBsAg prevalence is independent of age. Although the route of HDV transmission is similar to that of HCV, only those already infected with chronic HBV are at risk of acquiring HDV coinfection.

The major source for prevalent HCV and HDV infections is likely to be exposure through medical injections and other health care-associated procedures. For example, a cross-sectional survey among 1145 children in four provinces and Ulaanbaatar found that dental manipulation was associated with an odds ratio of 15.4 for HCV infection, while surgery increased the odds by 8.4 (10). Medical injections remain popular in Mongolia. The mean reported by NCCD is 8 injections per person per year; other groups consulted during the review reported up to 12. Until recently, it was common to have a needle and syringe for use in the house or the office. Parenteral medications can be purchased at pharmacies without a prescription. Infection also occurs in traditional settings (acupuncture) and during tattooing, though data are not available (Figure 4).

The proportion of those with advanced fibrosis (F3/4) in the CDA estimate (32%) is lower than the treatment-seeking group in the private clinic (38%) but consistent with the treatment-seeking population skewing towards advanced disease. The CDA model indicates that HCV-related F0–F3 disease has already peaked, while F4 and decompensated liver disease rates are increasing (9).

Figure 4. Registered risk factors for transmission of viral hepatitis 2011–2014

- 17% Surgery
- 18% Injections
- 21% Pregnancy and birth

Source: NCCD 2015
2. FINDINGS AND RECOMMENDATIONS

2.1 Policy, strategy and structures

Viral hepatitis policy and governance

The national viral hepatitis policy in Mongolia has evolved considerably since the legal framework for action on viral hepatitis was created in 1990, when a Ministerial Order first outlined a national strategy to begin addressing viral hepatitis – focusing on the introduction of HBV immunization. Viral hepatitis is included in the Health Sector Strategic Master Plan 2006–2015. The current National Strategy on Viral Hepatitis Control (2010–2015) was approved by Ministerial Order # 119 and had the strategic goal to decrease morbidity due to viral hepatitis to 10 cases per 10,000 population by 2015. This included the following objectives:

- **Strategic objective 1:** To introduce a vaccine against viral hepatitis A in a phase-based manner
- **Strategic objective 2:** To decrease the HBsAg carrier rate to <2% among children under 5 years of age, and reduce HBV and HCV transmission
- **Strategic objective 3:** To strengthen capacity for surveillance, control and laboratory diagnosis of viral hepatitis
- **Strategic objective 4:** To ensure coordination for strategy implementation
- **Strategic objective 5:** To develop a monitoring and evaluation framework for the strategy.

The five-year strategy was costed in 2010 at ~8 billion MNT (~US$ 5.7 million in 2010). The review team assessed the success of the strategy in accordance with the 13 key indicators proposed in Objective 5.

In short, the strategy has been successfully implemented. The NCCD reported that 11 of the 13 objectives had been achieved by 2013, with only antenatal screening for HBsAg (21.4% versus a goal of 60%) and HBV vaccination coverage of healthcare workers (58% versus a goal of 80%) yet to be attained. Nevertheless, there are some important caveats.

Immunization has been at the heart of the Mongolian success in meeting Objectives 1 and 2. Key successes have been the roll-out of two-dose HAV vaccination to infants 1.2 years and 2 years. National HAV vaccine coverage is reported by the NCCD as being 95.9% (2013). The WHO Regional Office for the Western Pacific has verified the HBsAg prevalence among 5-year-old children as 0.53%, achieving not only Objective 2 but also the regional goal of an HBsAg

prevalence of less than 1% by 2017\(^c\). Coverage with three doses of hepatitis B vaccine (HepB3) in 2013 was 97.6%, while coverage with the birth dose (BD) given within 24 hours of birth was 96.9% (15). HBV vaccination coverage among health-care workers has recently improved significantly, with the Ministry of Health and Sports reporting 80% coverage. Importantly, the HBV catch-up vaccination series for health-care workers is a two-dose regimen.

Beyond immunization, work remains to be done on meeting targets for testing, care and treatment. Some progress has been made already: laboratory capacity has been strengthened over the past 5 years, both in central and peripheral health facilities, and treatment has been expanded. Importantly, an external quality assurance scheme (EQAS) has been implemented across Mongolia, with external validation support from the National Reference Laboratory (NRL) in Melbourne, Australia.

Key areas for improvement in testing, care and treatment were identified at the one-day key stakeholders’ meeting at the mid-point of the review. The meeting included an assessment and lessons learned from the implementation of the current National Strategy on Viral Hepatitis Control (2010–2015). Specific concerns focused on logistics around laboratory practice and collation of results rather than national laboratory policies. For screening, care and treatment, specific concerns identified at the meeting and verified by the review team included (i) a lack of capacity for coordinating testing and treatment in the public sector, including reporting, and (ii) a lack of consensus on international standards for the diagnosis and treatment of chronic hepatitis.

Currently, there is no specific national hepatitis steering committee in Mongolia. Implementation of the national strategy is through specific ministerial orders. These orders are generally followed closely by implementers.

The NCCD is the major implementing agency for the National Strategic Plan for Viral Hepatitis. It has significant capacity and a strong relationship with the Ministry of Health and Sports, to which it reports. The NCCD has a hospital (600 beds), reference laboratory, and communicable disease surveillance and response functions. It provides oversight for surveillance, screening, care and treatment for hepatitis to all public health facilities in Mongolia. It has also expanded into a training institution for infectious diseases and epidemiology. As the NCCD manages all communicable diseases, it provides the opportunity for strong links between other key infectious disease responses. Unlike many other countries in the Region, HIV is rare in Mongolia, with only 162 reported cases. Consequently, future hepatitis policy responses are likely to be specific to hepatitis, rather than employing HIV or another communicable disease as a template.

At the time of the review (September 2014), internal discussions had commenced on the need to develop a new national viral hepatitis strategy, later named the National Hepatitis Programme. While it is expected that the key objectives of the previous strategy will be continued, viral hepatitis treatment, in particular HCV treatment, is emerging as a potential key component of action on hepatitis. Indeed, discussions had already begun in September 2014 between the Ministry of Health and Sports and a large pharmaceutical company for access to the new antiviral medication sofosbuvir, as well as scenarios that might see the roll-out of a nationwide HCV treatment programme. An agreement was later reached with two large pharmaceutical companies during 2015.

\(^c\) In 2005, the WHO Regional Committee for the Western Pacific established an interim target of reducing the prevalence of chronic HBV infection to less than 2% among children aged 5 years by 2012, with a future goal of reaching less than 1% prevalence in the Region (Regional Committee resolution WPR/RC56.R8). In October 2013, the Regional Committee resolved to meet the goal of reducing the prevalence of chronic HBV infection to less than 1% in 5-year-old children by 2017.
Health system structure

The structure of the Mongolian health system originated from the Soviet influence and was hierarchical, centralized and funded through general government revenue until 1990. Reorientation and decentralization driven by a more responsive funding system occurred with the adoption of the Health Insurance Law in 1993, which introduced social health insurance as part of a larger social security scheme. Today, over 98% of the population is covered by health insurance. However out-of-pocket (OOP) costs remain high. For example, OOP costs were 41% of per capita health spending in 2010 (16).

The general health system has two levels, in addition to the Ministry of Health and Sports, essentially divided between Ulaanbaatar and the rest of the country (Fig.5). In Ulaanbaatar, there are nine district hospitals and 99 family health clinics.

In provincial areas, there are three regional diagnostic centres, 21 aimag hospitals (one in each province) and 271 soum hospitals, as well as 39 inter-soum hospitals. District hospitals and aimag hospitals report to the NCCD for communicable diseases (Fig.6).

Figure 5  Organizational structure of the Ministry of Health and Sports

![Organizational structure of the Ministry of Health and Sports](image-url)
The specific tasks of the NCCD are: organizing the implementation of the National Programme on Control of Communicable Diseases; providing professional management; improving the prevention, early detection and diagnosis of communicable diseases, as well as treatment standards for infectious diseases; and public information communications. The NCCD has nine epidemiologists with responsibilities that include viral hepatitis. Outside of the NCCD, there are 21 epidemiologists in 21 provinces in charge of communicable diseases in their respective provinces, and a further nine in each of the districts in Ulaanbaatar, all of whom also have responsibility for viral hepatitis.

Public and private health systems

The private health sector has expanded substantially in recent years. For example, by 2010, 1184 of the 1292 hospitals and health facilities in Mongolia were private health facilities (including 519 pharmacies) (16). Attendance at accredited private health facilities is covered by social health insurance. In 2010, private expenditure as a proportion of total health expenditure was 44.9%. Only 7.9% of expenditure in the private sector is covered by health insurance. Total expenditure on health as a proportion of the gross domestic product (GDP) was 5.4% in 2010 (16).
Most outpatient treatment contacts in Mongolia occur in the public sector, and all acute hepatitis cases are treated (by law) in the public sector. Private sector activities are focused mainly on the areas of dentistry, internal medicine, obstetrics and gynaecological care, traditional medicine, and high-tech laboratory services.

Reporting of acute jaundice from the private sector is limited to referral with self-presentation of cases centrally to the NCCD. There is no reporting system for chronic hepatitis.

Parts of the private sector remain functionally outside the regulatory State Inspectorate (infection control) due to limited human resources and the large number of private facilities – dental in particular.

**Workforce**

There are two medical schools in Mongolia, the Health Sciences University of Mongolia and Ulaanbaatar Medical College. Most specialization occurs within the country.

Postgraduate education consists of theoretical and clinical education. Most specialists now obtain postgraduate medical education within Mongolia, though there are fellowships from other countries. There are a number of suppliers of postgraduate education, including the NCCD and major hospitals. There is little coordination between providers. The NCCD is a major supplier of postgraduate medical education for infectious diseases and epidemiology.

Currently, there is no postgraduate medical training in viral hepatitis focused on primary health-care providers, beyond that of the established training programmes in infectious diseases and epidemiology. Medical postgraduate training takes 1–3 years. Graduate doctors need to work in general medicine for two years and only then can they apply for a residency programme. Continuing medical education programmes do exist.

**Governance for viral hepatitis**

The viral hepatitis focal person for the Ministry of Health and Sports, Dr M. Oyunaa, is an employee of the NCCD.

The new National Hepatitis Programme is being developed primarily by the NCCD and Ministry of Health and Sports.

The key players in the viral hepatitis arena in Mongolia are as follows:

- Ministry of Health and Sports
- NCCD
- Mongolian Association for the Study of Liver Diseases (MASLD) and Mongolian Hepatology Society
- WHO
- The National Cancer Center
- The ADB Fifth Project
- nongovernmental organization (NGO), including Onom Foundation and Flagstaff International Relief Effort (FIRE)
Recommendations

1. The upcoming National Viral Hepatitis Strategy should consider the recommendations discussed in this report, and the key stakeholder meeting report.

2. The private sector should be brought under the purview of the National Viral Hepatitis Strategy, particularly for hepatitis diagnostics and treatment, as most chronic hepatitis treatment is provided by the private sector.

3. The National Viral Hepatitis Strategy should align with the Regional Hepatitis Action Plan currently under development. Alignment may facilitate regional and national implementation.

4. Mongolia should adopt the WHO hepatitis guidelines as the Mongolian national guidelines, adapted as appropriate. This includes HBV and HCV screening, care and treatment guidelines.

5. Coordination should be strengthened between providers of postgraduate training in infectious diseases, epidemiology and surveillance.

6. Mechanisms should be explored for increasing integration between infectious disease and hepatology specialists for care and treatment of viral hepatitis.

7. An assessment of training needs related to viral hepatitis should be conducted for primary care clinicians. This could be followed by development and implementation of a training plan.

8. Ministerial orders may provide an authoritative mechanism for policy implementation.

2.2 Strategic information and surveillance

Surveillance for viral hepatitis in Mongolia is limited to reporting of acute jaundice. Reporting began in 1952, and the peak incidence occurred in 1962. Jaundice surveillance is now incorporated into the early warning and response (EWAR) infectious disease monitoring system. Jaundice is probably a proxy for acute hepatitis infection – particularly HAV, HBV and HDV superinfection. The number of patients with acute hepatitis has decreased considerably, from an estimated annual 13,000 cases in 1991 to 3,200 cases in 2013. While there are no historical or modelled data on HAV and HBV (or HDV), the CDA HCV model indicated that peak HCV incidence occurred in 1970. Jaundice is unlikely to be a sensitive marker for acute hepatitis C cases.
Acute and chronic hepatitis

The EWAR system aims to detect events early and respond appropriately. The system began in 2007 in three provinces and has now been rolled out in all the provinces. The EWAR system collects essential clinical and demographic information on persons with infectious disease syndromes. There are six major syndromes, with viral hepatitis covered through the proxy of jaundice. The EWAR system is linked to epidemic response mechanisms at the district and national levels. It operates at all levels of the Mongolian health system. Reporting is aggregated at the lower levels and the number of cases reported to the regional and the central levels (NCCD) without associated information. Reporting is a combination of manual and electronic means.

Acute jaundice cases can be due to any cause, including alcohol use. Retrospective analysis of the etiology of acute hepatitis cases is carried out for those cases presenting to the NCCD.

In comparison, surveillance for tuberculosis (TB) and sexually transmitted infections (STIs) operates within the NCCD rather than the EWAR system. It is a web-based system and funded by the Global Fund to Fight AIDS, tuberculosis and Malaria (Global Fund). It includes case reports, medication expenditure and drug resistance monitoring. Sentinel site reporting is also conducted, but the focus of this system is limited to influenza. There are no sentinel sites for viral hepatitis.

Currently, there is no mechanism to count the number of cases or collate testing to identify acute or newly acquired hepatitis epidemiologically or indeed know how much hepatitis testing is conducted in Mongolia. There is no central registry. The national ID provides a unique identifier, a manipulation of which would allow de-identified de-duplication of cases.
Disease burden markers (e.g. fibrosis scores associated with viraemic individuals) are not sent beyond treatment centres. There is no monitoring of the viral hepatitis cascade outside individual treatment centres in the public or private sectors.

**Deaths**
Deaths are reported to a civil registry. The cause of death is noted on the death certificate. Cancer-related deaths are reported to the National Cancer Registry.

**Chronic cases**
Chronic hepatitis cases are not reported.

**Cancer**

The National Cancer Registry was established in 1971. Its data sources include 21 provincial hospitals, nine district hospitals, 16 other specialized hospitals and centres, the National Pathology Center, the Breast and Cervical Cancer Screening Registry, and hospices. Quarterly information on cancer cases is reported to the National Cancer Center on form AM57. There is a cancer registrar in each district and province who collates this information. Reporting is a combination of manual and electronic (Excel). Line-by-line data are available and aggregation is central, so analysis (e.g. demographics, diagnosis, histological confirmation, etc.) is possible.

Since 2007, the National Cancer Registry office has tried to work with the Mongolian Civil Registry Office on linkage with mortality data. At the national level, the registry has had difficulty in linking cancer incidence data with death information due to lack of access to data. The Registry is now working with the provincial civil registries to match cancer with mortality data on an annual basis. The Registry has already translated the International Classification of Disease (ICD)-10 manual into Cyrillic. They would like to translate the manual for tumour–node–metastasis (TNM) classification of malignant tumours, and have asked for help in contacting the Union for International Cancer Control for permission to translate.

Cancer deaths are reported to the Cancer Registry, as well as the Civil Registry. Back-investigation also occurs to investigate and confirm cancer as a cause of death.

The Strategy for Early Detection of Liver Cancer issued in May 2014 (commenced in 2015) recommends screening people 40–65 years of age for HBV and HCV with rapid tests. Confirmation by enzyme-linked immunosorbent assay (ELISA) will be done at the district level. Those identified with chronic hepatitis will receive alpha-fetoprotein (AFP) and ultrasound tests every 6 months. Data will be collated at the National Cancer Center. Those identified with tumours smaller than 2 cm will be followed every 4 months, which differs from American and European guidelines\(^d\) \((17, 18)\). Patients with lesions larger than 2 cm will be sent to the National Cancer Center. There is an algorithm to indicate the need for biopsy (e.g. AFP level, ultrasound findings).

**Outbreak investigation**

Outbreak investigation does occur for selected infectious diseases as well as hospital-acquired infections (HAI). Single cases of HAI are considered an outbreak and need to be reported within 24 hours to the NCCD. The NCCD is responsible for coordinating outbreak responses, which may include sending a team to the field. In 2009, an HAV outbreak was recorded with a peak incidence of 49 cases.

\(^d\) The American Association for the Study of Liver Diseases (AASLD) and the European Association for Study of the Liver (EASL) guidance on the management of HCC recommends a nodule size of 1 cm as the decision-making point for further investigation of potential HCC lesions, with those <1 cm being followed up every 4 months.
per 10 000. An HAV outbreak was also investigated in 2007 following an increase in hospitalization of HAV cases at the NCCD, with 19% of cases occurring in a household where a previous case had occurred. Most (71%) cases were in children below 10 years (19).

**Unique identifier**

Each Mongolian citizen has an ID number. The sequence of the code is `##IDENTITYNUMBER-DoB-Gendercode`. This number can be used to de-duplicate data, including repeat testing results.

**Research**

To date, there has been limited hepatitis research in Mongolia compared with other countries in northern Asia. The review team concluded that there are currently great opportunities for hepatitis research in a number of domains in Mongolia. These include further understanding of the epidemiology of chronic viral hepatitis B, C and D, particularly in rural areas; the epidemiology of fibrosis and other complications of chronic viral hepatitis; an understanding of the role of alcohol in the epidemiology of liver fibrosis; and the driving factors of the very high rate of HCC in Mongolia. Given the high burden of HDV coinfection with chronic HBV infection in Mongolia, the review team identified this as a particular area requiring further research, as little research has been conducted to date.

As hepatitis screening, care and treatment becomes more widespread in Mongolia, opportunities may arise for operational research/implementation science, although to date these are limited.

**Recommendations**

9. Surveillance for acute jaundice should continue as part of the EWAR system.

10. There should be a move towards test result reporting for HBV, HCV and HDV by laboratories, with collation at the central level by the NCCD. The national identity number provides a mechanism for de-duplication.
   a. The private sector, including laboratories, should be included in this test reporting system.
   b. Aggregation should be done only at the central level to allow analysis.
   c. Reporting should move towards full electronic reporting.

11. Mongolia should adopt the WHO viral hepatitis case definitions for surveillance purposes.

12. In those sites commencing pilot care and treatment initiatives, consideration should be given to implementing pilot viral hepatitis sentinel surveillance sites, where the additional collection of key demographic and clinical information could be carried out in a systematic fashion.

13. A central registry should be developed for viral hepatitis surveillance. This would include HBV, HCV and HDV test results linked to HCC data or the civil death registry, in turn linked by a unique identifier.

14. WHO and key partners should support implementation of the Strategy for the Early Detection of Liver Cancer as a priority. This strategy, and data from it, should be linked to viral hepatitis surveillance in Mongolia.

15. In line with this initiative, given the prevalence of chronic hepatitis and the latency of viral hepatitis-related liver disease, we recommend universal HBsAg and anti-HCV screening for those 40–65 years old in Mongolia. This could be introduced in a phased manner.

16. Consideration should be given to linking the Strategy for the Early Detection of Liver Cancer and the hepatitis test result reporting system by national identity number.
2.3 Prevention

Prevention initiatives for viral hepatitis in Mongolia have focused on (1) the introduction of HBV and HAV vaccination, and (2) reduction in health facility transmission.

Key events resulting in major declines in transmission have been as follows:

- Introduction of HBV vaccination in 1991, increased effectiveness after 1997, optimal effectiveness from 2002 (see also Fig. 7);
  - Coverage of BD <24 hours (2013) 96.9%, HepB3 (2013) 97.6%;
- HBV catch-up vaccination in health-care workers (two-shot course) was mandated by the Ministry of Health and Sports in 2012;
  - Coverage in October 2014 58%, January 2015 80%;
- HAV vaccination introduced in 2012, initially in Ulaanbaatar (now 12 provinces in total) at 1.2 years and 2 years of age;
  - Coverage (2013) 95.9%;
- Disposable syringes introduced in 1995.

Immunization

HBV vaccination was introduced in 1991; however, the effectiveness of HBV programming in Mongolia was suboptimal in the early to mid-1990s. Acute HBV presentations at the NCCD in birth cohorts were substantially reduced only after 1997. HBV vaccine coverage further improved in the 2000s. Mongolia has now been verified as having achieved the 2017, regional goal of less than 1% HBsAg prevalence among 5–year-old children. The current HBsAg prevalence is 0.53%.

In 2012, a Ministerial Order (#432) focused on vaccinating health-care workers. By October 2014, 58% of health-care workers had been vaccinated (increased from 10% in 2011 to 53% in 2013), which increased to 80% by January 2015. This includes medical students entering medical school.

Initial difficulties with the HBV vaccination programme in the early 1990s were overcome in the late 1990s and, since 2002, the Mongolian HBV vaccination programme has been highly successful in markedly reducing mother-to-child and early childhood transmission of HBV infection. Early difficulties included overcoming very low ambient winter temperatures resulting in freezing during vaccine transportation to rural areas and poor coverage. Late administration of the BD, as well as reduced coverage of HepB2 and HepB3 doses were identified as issues in rural areas. Hepatitis B immune globulin is not routinely administered in Mongolia. Recent data suggest that many of these initial difficulties have been overcome.

Introduction of immunization for hepatitis A was the first objective of the National Strategy on Viral Hepatitis Control (2010–2015). The genesis for introduction was endemic hepatitis A resulting in outbreaks, the latest in 2009. In 2012, domestically funded HAV immunization was introduced into infant vaccination.

\[\text{Data from National Center for Communicable Diseases}\]
\[\text{For example, of all the cases of jaundice associated with acute hepatitis B presenting to the NCCD in a retrospective analysis (2009–2013, } N = 508\text{), 91% were born prior to 1998 (within the first 7 years of the introduction of HBV vaccination) and 86% were 15–22 years old.}\]
schedules (at 1.2 and 2 years), which reduced the proportion of acute jaundice cases related to HAV infection. Vaccine coverage was 92.3% in 2012 and 95.9% in 2013. It is plausible that infant vaccination has resulted in a reduced pool of infectious individuals and impacted acute HAV rates at a population level.

The review team consulted widely on the impact of the introduction of hepatitis A immunization. Early data suggest that immunizing infants has impacted on HAV transmission in the general population. This has occurred in other settings and countries with endemic HAV following the introduction of childhood HAV vaccination programmes (21, 22). Seasonal peaks of HAV infection, late in the calendar year, while distinct in 2010 and 2011, were markedly reduced in 2012, and there was no seasonal peak in 2013 (Fig. 8). Anecdotally, the NCCD, Bayanzurkhu District Hospital and Family Clinic #4 in Bayanzurkhu District, Ulaanbaatar all reported reductions in admissions for acute hepatitis A over the previous 2 years.

Hepatitis A vaccination is not part of the Expanded Programme on Immunization but is fully funded through the domestic immunization fund.

Catch-up HBV immunization for health-care workers was mandated by Ministerial Order in 2012. By October 2014, nationwide, 58% of non-immune health-care workers had received a two-dose course of HBV immunization. The review team that visited Bayanzurkhu District Hospital reported that they had immunized 478/546 (87%) service staff (doctors, nurses and other staff). The immunogenicity of a two-dose HBV vaccine course would be estimated to provide more than 75% seroprotection (23). Unlike neonatal HBV immunization, which prevents the development of chronic HBV, catch-up HBV immunization aims to prevent acute HBV acquired through occupational exposure. The review team was unaware of other designated catch-up groups for HBV immunization. Catch-up HAV vaccine is not provided. Seroprotection from HAV is universal in the adult Mongolian population following childhood exposure.

Infection control and injection safety

Prevention beyond immunization has underpinned the Mongolian response since the mid-1990s. Use of single-use sterile needles and syringes commenced only around 1995, though now it is ubiquitous in public health facilities, along with appropriate disposal units. Parallel improvements in the quality of blood products have resulted in 100% of donor units being screened for HBsAg, anti-HCV, anti-HIV and syphilis serology. In 2013, at the National Transfusion Centre, HBV DNA was detected in 0.24% and HCV RNA in 0.04% of donor units.

Nevertheless, transmission from medical injections, dental procedures and invasive surgery remains an issue of concern, particularly outside public health sector facilities and outside regulatory oversight. Occupational exposure to infectious diseases is also common. In 2010, one study in Ulaanbaatar found that 87% (in a study of 354) of health-care workers at all levels of the health system had experienced a sharps injury, and that 42.4% had had at least one exposure resulting in infection. HBV was the most common infection (24).
Summary of the problem

With the implementation in 1995 of a national policy mandating single-use syringes in health-care facilities, the risk of injection-associated transmission of HCV, HBV and HDV in Mongolia is likely to have decreased significantly.

However, assurance of effective procedures for disinfection and sterilization of medical equipment is more challenging, and there are persistent problems associated with reuse of medical instruments and other equipment intended for single use for a number of reasons. These include budgetary constraints, stock-outs, and competing demands on the health-care system; challenges in autoclave maintenance; as well as inadequate numbers of nurses, and insufficient personnel and training to conduct regulatory inspections.

There is particular concern about the potential role of dental clinics, mostly private, in maintaining the transmission of HCV (and potentially HDV), though there are scant data to support or refute this claim. Obstetrics (and gynaecology) services may also play a role, given that the prevalence of anti-HCV is 1.4-fold higher among women than men in Mongolia. These concerns are not unique to Mongolia and other low- and middle-income countries, but the especially high prevalence of viraemia for HBV, HCV and HDV among the population amplifies the risks associated with breaches in safe injection practices and infection control.
There is some limited evidence suggesting that health-care workers have a higher prevalence of bloodborne infections, related in part to a historically high rate of needle-stick injuries; in 2013, the Ministry of Health and Sports initiated a programme for systematic HBV immunization of health-care workers and students in the health professions, which had made great progress by late 2014. Medical waste management and disposal is also an issue; currently, most sharps waste is incinerated and buried in landfills. In response, the Fifth Health Sector Development Project, financed by the Asian Development Bank (ADB) (US$ 38 million loan) has a major component to strengthen hospital hygiene and infection prevention and control in Ulaanbaatar and selected aimag hospitals. The ADB Fifth Health Sector Development Project commenced in late 2014, but is not working with the private sector.

Finally, there is concern about historical beliefs and practices among both consumers and providers of health care, which resulted in very high rates of unnecessary medical injections as well as medically unsupervised injections of over-the-counter antibiotics and vitamins received in the home. The health-care system has also historically promoted hospitalization (over outpatient care) for large numbers of patients, straining resources and increasing the potential for nosocomial exposures.

Status of injection safety

Until 2001

Modelled data suggest that HCV transmission peaked in about 1970 (9). Transfusion of unscreened blood and blood products played a major role; unsafe medical injection practices can also be assumed to have been important to the epidemic transmission of infections due to bloodborne pathogens in Mongolia, from the modernization of the health-care system in the 1920s and until at least 1995. In 1995, the Government adopted a policy mandating the utilization of single-use injection devices (SUIDs) in Mongolian health facilities, and began domestic manufacture of SUIDs. In 2001, a rapid survey of injection practices conducted by the Ministry of Health and Sports supported by WHO, including observations in 20 health facilities, found high levels of awareness of the risks of bloodborne pathogen transmission among health professionals, and that all injections observed were given with freshly opened SUIDs (25, 26). However, other unsafe practices were observed frequently (including the use of large IV infusion bottles as a common diluent for the injection of multiple patients), inadequate availability of puncture-proof disposal boxes, and two-handed recapping of needles by injectors, who reported an average of 2.6 needle-stick injuries per year. Needles and other sharps were incinerated and buried.

Patients reported that they received an average of 13 injections annually (higher than any rate reported for all global regions at that time). Medications commonly prescribed for injection were antibiotics, vitamins and antihypertensives, which would be effective if administered orally in most cases. The authors concluded that injections were overprescribed in Mongolia, and that while the Ministry of Health and Sports was committed to injection safety and SUIDs were pervasively used, other unsafe injection practices were still common and needed to be addressed. Recommendations included promoting the use of oral medications to decrease unnecessary injections, improving risk communication (about injection safety) by physicians, instituting policies to restrict access to injectable medications in the community, and developing comprehensive policies for better medical waste management.
Since 2001, in a five-year follow-up survey by the Ministry of Health and Sports in 2006, the use of puncture-proof sharps disposal boxes had expanded substantially (27). However, overuse of injected medications has been documented and continues to be a concern (28), as has the associated high prevalence of needle-stick and other sharps injuries among health-care workers (29).

During the 2014 review by the WHO Regional Office for the Western Pacific and CDC, team members visited a variety of non-randomly selected facilities in Ulaanbaatar and in Bulgan Province (specialty hospitals, district and soum hospitals, and aimag hospitals). The review team did not observe surgery or other invasive procedures. Puncture-proof needle disposal boxes were widely present in both inpatient and outpatient facilities, and disposable gloves were available in all settings that were visited, and no non-SUIDs were seen stocked in any facility. At Bulgan Aimag hospital, the review team observed the functioning of the new medical waste steam disinfection facility that had been recently established through funding from the ADB Fifth Health Sector Development Project. It was not clear during the visit whether protocols were in place and available for postexposure assessment and management following needle-stick or other sharps injuries.

**Infection control systems**

All hospitals up to the aimag and district levels have designated infection control practitioners and there are guidelines from the Ministry of Health and Sports. Health Minister Regulations (IPC) 186, (Hospital Hygiene) 187 outline steps for infection control in health facilities. However, several studies indicate that infection control is not perceived to be a priority, is poorly resourced and that management of the system is generally weak. Health-care-acquired infections are grossly underreported, in part because of a system that penalizes staff and facilities that report these infections, and also because there is limited laboratory support to help document such infections (30, 31).

The review team observed that infection control systems vary in quality across the health system. For example, at the single soum hospital that the review team visited in 2014, environmental hygiene in procedure rooms and in the delivery room was at a very high level, with a functioning autoclave and a good supply of sterilized sutures and obstetric packs on hand. On the other hand, in general, the technology and equipment necessary for good infection control in surgical and other invasive procedures is frequently inadequate. Health staff from an aimag and a district-level hospital reported to us that autoclave devices are often old, too small for the level of demand, and difficult to maintain and repair, which is consistent with the reports of others (30). Devices intended for single use in surgery (e.g. Bovie tips) are reported to have been reused after efforts to disinfect them chemically. At one facility, surgical staff reported that they had needed to try to clean and reuse endotracheal tubes at one point, because of shortages. Surgical sterilization units in some facilities are located in outbuildings.

Concurring with these observations, the review team heard concerns on a variety of ongoing and widespread deficiencies in the control of autoclaving and other sterilization procedures in dental and acute medical health-care settings from a visiting infection control expert who works with an international nongovernmental organization (INGO) and visits Mongolia annually. These included poor or absent “scrubbing” by surgeons prior to surgery, a shortage of surgical instruments resulting in reuse of single-use instruments, inadequate sterilization procedures,
including the use of non-disinfecting solutions for soaking instruments, poor microbiology capacity in most hospitals, shortage of technicians who can repair autoclaves and other equipment and, generally, an inadequate budget to remedy these many problems. Similar concerns have also been published (32).

**State Health Facility Inspectorate**
The State Health Facility Inspectorate Agency is charged with oversight and enforcement of infection control among health facilities. Previously, the Inspectorate was part of the Ministry of Health and Sports but in 1999 it was placed under the Deputy Prime Minister’s office. Each aimag has a branch of the Inspectorate Agency. In rural areas, it also has oversight of environmental violations. In Ulaanbaatar, there are 1500 health facilities subject to licensing and inspection, including pharmacies, pharmaceutical manufacturers, laboratories, health-care facilities and around 200 private dental practices. There are only 10–12 staff currently, which has resulted in rationing of site visits. For example, while previously dental clinics were inspected annually, inspections now occur based on a “risk assessment”. A major concern of the Inspectorate is that some private practices often have no structure for monitoring and quality assurance. Nevertheless, Inspectorate staff believes that the infection safety situation in dental facilities has improved significantly with improved equipment and an increase in supplies in private facilities.

Inspectors can intervene if minor issues are found on an inspection and return to re-inspect. Facilities in which violations are found are listed on the Agency website. Private citizens can also report to the Inspectorate if they believe that they have acquired an infection from a health facility. If there is a major issue (building standards, human resources), the facility can be closed or license cancelled.

In addition to more human resources, the Inspectorate currently requires support for updating training and regulations. The Inspectorate Agency has a bacteriology laboratory but does not have viral laboratory capacity. Links with existing viral laboratories would be appropriate. Funding of testing remains an ongoing issue.

In the opinion of the Ulaanbaatar Inspectorate, blood product management is much improved, and new infections are most likely occurring in the private sector, including dental and surgical facilities.

**Traditional medicine practice**
A number of procedures in Mongolian traditional medicine (e.g. acupuncture) require high-quality infection control to minimize the risk of HBV and HCV transmission. Although traditional practice has become more integrated with allopathic practice in recent years, it is not clear what sort of training, oversight and resources are given to infection control in these practices (33, 34).

**Key populations**
Key populations with a high viral hepatitis burden in Mongolia include MSM and sex workers. While injecting drug use has been identified in Mongolia, it appears confined to Ulaanbaatar among a very small number of individuals. All experts consulted in-country agreed that the number of people who inject drugs (PWID) is very small, probably less than 100 individuals. There are no harm reduction initiatives for PWID in the country.
**Alcohol**

Alcohol use is a key cofactor in liver disease progression among those with chronic hepatitis infections. Mongolia has a high level of alcohol consumption, particularly among the male population. Around 54% of the population (above 15 years) consumed alcohol in the previous year (66% of men, 44% of women). Of those who drink alcohol, the mean ethanol consumption among men is 21 L/year, while for women it is 6 L. Binge-style drinking is common, with 70% of men reporting that they consumed more than 60 g ethanol in one session within the past month. Eleven per cent of the men who drink fulfil the criteria for alcohol use disorder and 5% for dependence, while for the women the proportions are 2% and 1%, respectively (35). In 2010, Mongolia had the third-highest mortality rate from cirrhosis in the world – a 25% increase from 1990. This was probably due to a combination of a high prevalence of chronic hepatitis coupled with high rates of alcohol consumption (36).

These high levels of consumption occur in a relatively well-legislated policy framework, including a recently revised (2012) National Alcohol Action Plan. Alcohol tax is 40% by volume; there are age (21 years) and time restrictions on sales, and regulation of alcohol advertising.

Currently, there is no public health linkage between alcohol prevention initiatives and viral hepatitis initiatives.

**Hepatocellular carcinoma**

Prevention of HCC in Mongolia falls under the jurisdiction of the National Cancer Center.

There is no system for linking viral hepatitis screening to liver cancer screening. Currently, screening for liver cancer consists of measuring the AFP level and ultrasonography, which is available at the district level. There are four regional diagnostic centres, which have CT scan facilities. Suspected cases are referred to the National Cancer Center for confirmation. Histological examination is not routine, and carried out only if the patient undergoes surgery. Only ~20% of cases have surgery, with partial liver resection being the most common procedure.

**Public awareness and communication**

The NCCD is responsible for public awareness initiatives for hepatitis, and develops materials for health professionals and the public on viral hepatitis awareness.

The current National Strategy (ending in 2015) does not have a communication strategy.

During the review, the team spoke with patients and health-care workers, as well as those working directly in the viral hepatitis arena. Among most of the general public, there is awareness that viral hepatitis exists. However, details on the specifics of the infection or disease, type of virus, the availability of care and treatment options are extremely limited.
Knowledge among health workers at lower levels of the health system was mixed. Viral hepatitis is diagnosed at the primary health-care level, but management (assessment of infection, care and treatment) is done only in specialist facilities centrally (Ulaanbaatar).

Viral hepatitis is incorporated into the medical education curriculum. School-based educational initiatives on viral hepatitis were also reported.

**World Hepatitis Day**

World Hepatitis Day (28 July) is recognized in Mongolia. The NCCD held a press conference. Onom Foundation conducted a testing service in Ulaanbaatar during World Hepatitis Day. They stated that there was substantial demand for testing (by rapid tests for HBsAg and anti-HCV); so much so that they had to continue for four hours more than the planned finishing time.

### Recommendations

17. Strategies should be developed to increase immunization against hepatitis, and improve disease and treatment literacy among the general public and the affected population. Initiatives such as World Hepatitis Day should be utilized more broadly to increase awareness. Consideration should be given to having a specific position within the NCCD on hepatitis education and communication.

18. Consideration should be given to catch-up HBV vaccination consisting of three shots to improve immunogenicity. Given the high prevalence of natural immune protection (antibody to hepatitis B core antigen [HBcAb]) and chronic HBV infection (HBsAg) in health-care workers, the absolute number of health-care workers needing vaccination is likely to be modest, and providing three shots should not drain resources excessively.

19. Catch-up HBV vaccination should be extended to other at-risk groups, including those with chronic HCV infection and key populations.

20. The objectives and outcomes of the Fifth Health Sector Development Project regarding infection control in health-care settings and the management of blood products should align with new National Hepatitis Programme. Lessons learned in implementation of the Fifth Project may be relevant to the new National Hepatitis Programme.

21. Taking into account the Fifth Health Sector Development Project, further assessment of the extent of health sector transmission of viral hepatitis, particularly within the private sector, should be considered. Further resources should be given to the State Health Inspectorate Agency to improve regulatory oversight of infection control.

22. Prevention of hepatitis transmission within the private health sector is a priority for action. Private sector inclusion and participation in viral hepatitis prevention strategies and initiatives are recommended.

23. The State Health Facility Inspectorate Agency should be strengthened. This will require further human and financial resources to enable adequate capacity to meet the demand for infection control oversight of both public and private sector health facilities.

24. Alcohol prevention initiatives should be linked with secondary prevention strategies for viral hepatitis in public health messaging.
2.4 Viral hepatitis treatment cascade

The “cascade” provides an important mechanism to show the effectiveness of public health treatment in programmes at the population level. It captures the full continuum of care from those tested and linked to care. The goal is to reduce loss along the continuum. With the available data, it was not possible to construct a viral hepatitis treatment cascade for Mongolia.

The single most important issue facing the development of a viral hepatitis screening, care and treatment cascade for Mongolia is the parallel nature of the public and private sector responses to chronic viral hepatitis care and treatment. For example, while ~32 individuals have been treated with pegylated interferon/ribavirin (PEG-IFN/RBV) for HCV infection in the public sector (all at the NCCD), several hundreds have been treated in the private sector. Indeed, this phenomenon provides a clear area of difference between the hepatitis response and that of HIV, which is entirely managed in the public health sector in Mongolia and most low- and middle-income countries in the Region.

Testing

Currently, viral hepatitis testing is performed on an ad-hoc basis in public and private health-care facilities. National guidance recommends antenatal testing, though the patient covers the cost. A key indicator for the National Hepatitis Programme was the proportion of pregnant women attending antenatal care (ANC) screened for HBsAg and hepatitis B e antigen (HBeAg) (goal 60%). In 2013, 21.40% were screened for HBsAg. In contrast, it is estimated that 96.9% of pregnant women receiving ANC were tested for syphilis and 94.5% for HIV infection (12). It was reported to the review team that mandatory pre-employment testing is also required for persons in the food industry.

The review team was unable to estimate the number of tests conducted annually or what proportion of individuals have been screened for viral hepatitis; however, it was apparent that a substantial amount of testing occurs in the private sector. The amount of testing in the private sector is illustrated by one clinic the review team visited. Happy Veritas clinic, which specializes in liver disease management (including viral hepatitis treatment), reported that it had tested 29 650 individuals for HBsAg and 28 241 for anti-HCV, and had conducted over 14 000 viral load estimations since 2009. In comparison, the National Hepatitis Reference Laboratory reported having tested 20 000 samples for any viral hepatidity in 2014, and averaging 6–7 viral load estimations a week.

Testing in lower-level public health facilities is limited to rapid tests for HBsAg and anti-HCV. ELISA testing is done in aimag and district hospitals, though a recent review by the NCCD found that only 80% of these facilities had operable ELISA machines. A limited amount of confirmation testing by polymerase chain reaction (PCR) is done in the public sector. PCR testing is restricted to the National Hepatitis Reference Laboratory, the First State Hospital and three private facilities in Ulaanbaatarh.

There is currently no capacity for genotyping of HCV in Mongolia. All treatment facilities, public and private, indicated that genotyping is unnecessary, given that epidemiological studies indicate that 98% of HCV infection in Mongolia is due to genotype 1b. The review team agreed that this was a reasonable approach for the time being.

h Intermed Hospital, Grandmed Hospital, MCA
The high prevalence of HBV/HDV coinfection warrants screening for HDV in individuals who are HBsAg positive. In these individuals, more severe liver disease is expected, so staging is a priority.

Health insurance covers the cost of testing if testing is done as an inpatient, or if a doctor requests the test (i.e. self-presentation for testing is covered by the patient). In the private sector, the OOP cost for rapid tests (e.g. HBsAg, anti-HCV) was 5000 MNT (US$ 2.50), ELISA 15 000 MNT (US$ 7.50) and PCR 70 000–80 000 MNT (US$ 35–40).

Summary of barriers to testing for hepatitis in Mongolia
The review team identified a series of barriers to testing based around recurrent themes:

Testing capacity
Rapid testing for HBsAg and anti-HCV is widely available up to the soum level (testing by ELISA is available up to the aimag hospital level in many places), although it is unclear how many tests have been conducted, or how many persons have tested positive (and had HCV RNA confirmation if anti-HCV positive). No information is systematically collected about demographics, clinical characteristics, or medical disposition and care among persons tested and those testing positive. At the same time, it is anecdotally reported that HCV testing (and perhaps HBV testing as well) is widely requested by patients and/or recommended by health professionals. Because viral hepatitis testing in non-hospitalized persons may be an OOP patient expense (some contradictory reports as to whether patients actually pay part, all or none of the costs in practice), screening may be seen as unaffordable by patients and doctors. In addition, while HCV RNA testing is available at the NCCD for persons who test anti-HCV positive, it is not clear whether routine confirmation of anti-HCV is affordable and accessible, and whether clinicians who test understand the need for the test in this setting.

Stigma
The review team explored stigma and discrimination with patients and health staff in a range of settings as well as a wide variety of individuals working in the hepatitis arena. The review team concluded that hepatitis in Mongolia is associated with minimal, if any, stigma, and that stigma or discrimination is unlikely to be a major factor in patient access to services.

Administrative responsibilities
The EWARS system, including jaundice surveillance, is not within the purview of the NCCD. This may complicate efforts of the NCCD to establish routine or sentinel surveillance.

Logistical issues
Routine reporting of all chronic hepatitis cases will be burdensome as the numbers are large, so a sentinel system may be more practical. It would need to be representative of the geographical and demographic population distribution.

Reporting by the private sector
The private sector has limited responsibility for disease reporting. A meaningful, routine notifiable disease system should include the private sector (which is responsible for an increasing volume of patients receiving specialty care).

Ability to de-duplicate reports
The national ID number system is universally used and can serve to de-duplicate reports.
**Level of priority for health condition**
Viral hepatitis (especially chronic viral hepatitis) is widely viewed by policy-makers, health professionals and the public as a serious problem and a health priority. The National Strategy on Viral Hepatitis Control (2010–2015) includes a surveillance component (Strategic Objective 3).

**Technological limitations**
Web-based reporting of other notifiable conditions (e.g., STI, TB) can be utilized (at least to the aimag level) and limitations to Internet access should not be a problem.

**Case definitions**
Case definitions for acute and chronic hepatitis need to be agreed upon.

**Costs**
A sentinel system, at least initially, may be more cost–effective than universal reporting.

**Understanding rationale and utility**
It may be conceptually challenging for NCCD staff to frame a chronic subclinical condition in a system that is usually used to capture sentinel epidemic-prone acute conditions such as STIs, TB, meningitis and other conditions tracked by the EWAS system.

**Staging liver disease**
Currently, biochemical algorithms (aspartate aminotransferase-to-platelet ratio index [APRI], FIB-4) are not used to stage liver disease in chronic hepatitis infections, and other noninvasive tests (e.g., Fibroscan) are not available in the public sector. At the time of the review, the Ministry of Health and Sports had ordered a number of Fibroscan machines at a substantial cost. Consequently, the diagnosis of advanced liver disease in Mongolia is essentially limited to a clinical diagnosis in the public sector.

One large private clinic in Ulaanbaatar owned a Fibroscan machine and had performed 2857 scans as of September 2014 to assess individuals with chronic infection; however, this accounted for only 26% of viraemic individuals with HBV or HCV.

**Linkage to care and treatment**
Linkages from testing to care are in large part patient dependent and not formalized. For example, testing occurs in peripheral facilities, while treatment is restricted to specialized services (the NCCD). Following a positive test for chronic HBV or HCV infection, patients are given their results and recommended to attend the specialist facility. On referral back to peripheral centres from specialized institutes, the same occurs. This referral mechanism is likely to result in losses to follow-up care.

There are exceptions; for example, following a diagnosis of HBV, HCV or HDV during admission for acute jaundice at the NCCD, there are specific guidelines on the duration and intensity of clinical follow up through the NCCD outpatients’ facility after inpatient discharge.

The review team was unable to estimate how many individuals had been referred for care following a diagnosis of chronic hepatitis; however, considering that the only public provider of therapy for HCV is the NCCD, there is a substantial unmet demand for antiviral therapy. For example, it was noted that each of the eight doctors at the NCCD who can prescribe PEG-IFN/RBV has more than 50 individuals on their waiting list.
Treatment

Treatment of hepatitis in the public sector in Mongolia is limited to symptomatic management of acute hepatitis infection. While acute hepatitis infection is also managed at peripheral health facilities, the major centre providing clinical management is the NCCD, with assessment and care for both acute and chronic viral hepatitis. The NCCD viral hepatitis inpatient treatment facility has 60 beds.

At the NCCD, treatment for acute hepatitis A, C and D is restricted to symptomatic management, though antivirals are used in some cases of acute hepatitis B. Treatment for HBV is limited to lamivudine. In the public sector, tenofovir is available only for HIV (funded by the Global Fund).

Acute hepatitis treatment at the NCCD consists of admission, testing for etiology and then treatment according to the diagnosis. Acute HBV is treated with 2 weeks of lamivudine followed by continuation at the patient’s expense. Ursodeoxycholic acid is used to reduce the bilirubin level. Vitamin K, fresh frozen plasma and platelets are given as indicated. Cirrhosis is treated with albumin (if below 25 U/L), spironolactone and paracentesis as indicated. Proton pump inhibitors and vitamins (IV/IM) are also administered, as well as prophylactic antibiotics (cephazolin).

Recommendations

25. An HBV and HCV treatment cascade should be developed for Mongolia, inclusive of the private sector, in order to assess screening, care and treatment responses at the population level.

26. Priority groups should be identified for testing based on epidemiological likelihood, e.g. health-care workers, MSM, other key populations and those with clinical liver disease. This would include those 40–65 years of age as previously recommended.

27. National hepatitis guidance should provide clinical testing algorithms. Suggested algorithms should include screening for HDV infection in HBsAg-positive individuals, and confirmation of HCV RNA in individuals who are anti-HCV positive.

28. Efforts should be made to increase the proportion of individuals who undergo HCV RNA confirmation after testing HCV Ab positive.

29. It is recommended that simple biochemical algorithms be the primary mechanism for staging liver disease among individuals diagnosed with chronic viral hepatitis (e.g. APRI or FIB-4) to improve accessibility and reduce the costs associated with staging.

30. Linkages from testing to care and treatment should be formalized to reduce loss to follow up in the cascade. Consideration should be given to how the private sector can be incorporated into the testing and care component of the cascade.
The NCCD reported that in 2013, the mean cost of each treatment episode (two-week admission for the management of acute or exacerbation of hepatitis infection) for HBV was 134,631 MNT (~US$ 67), higher than for HCV at 89,481 MNT (~US$ 45), which was in turn higher than that for HAV (27,916 MNT (~US$ 14)). Between 2009 and 2013, the cost of HBV treatment increased at a faster rate than HCV treatment, associated with the cost of antiviral medications, while the costs associated with HAV infection remained relatively stable (see also Table 5).

At the NCCD, 32 individuals had been treated with PEG-IFN/RBV for chronic HCV infection (and four for HBV/HDV coinfection) as of mid-September 2014, with a sustained virological response (SVR) in 52%. As mentioned, demand for treatment is high, with over 300 patients currently on the waiting list. Post-discharge follow up is mandatory for patients admitted with acute hepatitis, with the length of follow up varying by infection. The NCCD has developed a chronic hepatitis management booklet, which is used as a guide for both patient and clinician in this follow-up period.

The majority of treatment for chronic hepatitis B and C in Mongolia occurs in the private sector. For example, the review team visited a large private hepatitis treatment facility in Ulaanbaatar, which reported treating 400 patients annually for HBV and HCV with tenofovir and PEG-IFN/RBV, respectively. Treatment is in line with international hepatitis B treatment guidance with the end-points being sustained normalization of ALT level or sustained loss of HBV DNA. All medication costs, apart from initial admission to commence PEG-IFN/RBV combination therapy (at a nearby inpatient facility for HCV) are borne by the patient. Currently, there is no mechanism to aggregate data from the public and private sectors to establish a viral hepatitis treatment cascade for Mongolia.

### Table 5. Standard costs of selected antiviral medications for chronic HBV and HCV infection in Mongolia (September 2014)

<table>
<thead>
<tr>
<th></th>
<th>Cost per dose (US$)</th>
<th>Annual cost (US$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tenofovir</td>
<td>8</td>
<td>2940</td>
</tr>
<tr>
<td>Entecavir</td>
<td>10</td>
<td>3650</td>
</tr>
<tr>
<td>PEG-IFN (Roche)</td>
<td>220</td>
<td>10,650¹</td>
</tr>
<tr>
<td>Ribavirin</td>
<td>1</td>
<td>336</td>
</tr>
</tbody>
</table>

¹ The duration of follow up is 3–6 months for HAV, 1–2 years following HBV or HCV infection, and lifelong for HDV infection. Follow-up is provided at the outpatient department of the NCCD.

Source: NCCD

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³ 48 weeks of therapy as indicated in genotype 1 HCV infection.
New, highly effective antiviral medications for HCV are now approved in high-income countries. Two major pharmaceutical companies have indicated that Mongolia is among 91 countries globally with potential access to lower-cost HCV medications through tiered pricing initiatives. These oral medicines include sofosbuvir, ledipasvir and daclatasvir, and their combinations. Two hepatitis C medicines are registered since 2015 (sofosbuvir and the combination sofosbuvir-ledispavir).

Finally, the high prevalence of HDV infection among individuals with chronic HBV infection will complicate HBV treatment provision. Prolonged IFN-based therapy (for 1 year or more) remains the only effective treatment for HDV infection (37), although successful clearance of HBV/HDV coinfection with tenofovir monotherapy has been described (38). Only four individuals have received IFN-based therapy for HBV/HDV coinfection so far in Mongolia.

**Recommendations**

31. Priority should be given to increasing access to effective antivirals against HBV with a high barrier to resistance, such as tenofovir and entecavir. The review team recommends that lamivudine not be used for the treatment of HBV infection.

32. Prices of antiviral medications are high in Mongolia compared with other countries in the Region. Priority should be given to reducing the procurement cost and the cost to the consumer for key antiviral medications.

33. The number of individuals with advanced liver disease needing prompt antiviral therapy for chronic hepatitis B and C should be estimated to inform treatment planning. Priority for treatment should also be given to those with viral hepatitis coinfections. It is noted that therapy for HBV/HDV coinfection may prove challenging.

34. Demonstration HBV and HCV treatment initiatives should be undertaken, beginning in centres with a high capacity. The initiative should include screening, care and treatment, and linkages between components of the treatment cascade, as well as pilot key programmatic, monitoring and evaluation mechanisms. The review team recommends that these be undertaken at a selected district (Ulaanbaatar) and aimag (rural area) level.

35. Treatment scale up should be done after thorough evaluation of the demonstration project initiatives.

36. Treatment outcomes should be monitored at the population level, with rigorous programmatic monitoring and evaluation.

**Screening, diagnosis and management of hepatocellular carcinoma**

In 2013, there were 1967 newly diagnosed liver cancer cases and 1578 deaths due to liver cancer. Approximately 11% of cases were diagnosed with histological confirmation, 14% by clinical examination, the remainder by imaging or other methods. Over 80% of all cases were diagnosed in the late stages: 4% in stage I, 14.6% stage II, 48% stage III, and 33.2% in stage IV.

Screening and diagnostic capacity for viral hepatitis-related liver carcinoma is essentially restricted to the National Cancer Center in Ulaanbaatar (Table 6).
Table 7a shows the number of new \( N \) liver cancer cases compared with all cancers diagnosed from 2010 to 2012, the number of cases diagnosed with morphology \( M \), and the proportion of cases diagnosed with morphological verification \( MV\% \). Overall, 45.5\% of all cancer cases were diagnosed with morphological verification; this proportion varied by tumour site (96\% for cervical cancer, 8\% for liver cancer).

Table 7b shows the types of treatment for liver cancer in 2013. Approximately 11\% of cases had surgery and 7\% received chemotherapy. The majority (71\%) of cases received palliative care without other treatment.
### Table 7b. Types of treatment for liver cancer in Mongolia

<table>
<thead>
<tr>
<th>Treatment type</th>
<th>Number of cases</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery</td>
<td>213</td>
<td>10.8</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>135</td>
<td>6.9</td>
</tr>
<tr>
<td>Surgery+chemotherapy</td>
<td>15</td>
<td>0.8</td>
</tr>
<tr>
<td>Palliative surgery</td>
<td>98</td>
<td>5.0</td>
</tr>
<tr>
<td>Other palliative care</td>
<td>1405</td>
<td>71.4</td>
</tr>
<tr>
<td>Hormone therapy</td>
<td>24</td>
<td>1.2</td>
</tr>
<tr>
<td>Refused treatment</td>
<td>77</td>
<td>3.9</td>
</tr>
<tr>
<td>ALL</td>
<td>1967</td>
<td>100</td>
</tr>
</tbody>
</table>

Source: NCC 2014

### Table 8. Survival in patients with hepatocellular carcinoma

<table>
<thead>
<tr>
<th></th>
<th>1 year</th>
<th>3 years</th>
<th>5 years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
<td>95% CI</td>
<td>%</td>
</tr>
<tr>
<td>Liver cancer</td>
<td>22</td>
<td>21.9–22.1</td>
<td>10</td>
</tr>
</tbody>
</table>

Source: NCC 2014

Survival following a diagnosis of HCC is very low (Table 8). The NCC reported (based on 2003 data) that 5-year survival in HCC is 7% (compared to a 5-year survival rate for all cancers of 31%).

The Asian Cancer Centre (Singapore) is conducting a small trial in Mongolia with sorafenib for HCC treatment.

### Transplantation

The majority of liver transplantations for Mongolians have been done outside Mongolia. Liver transplantation (for decompensated cirrhosis) began in Mongolia around 2010. There have been 155 transplantations for Mongolians, though only 14 have been carried out in-country with support from surgeons from the Republic of Korea (beginning 2010).

Medical tourism for liver transplantation occurs to a number of countries. Between January and March 2014, 35 people underwent transplantation in India\(^k\) at a cost of US$ 35 000–40 000 each for the operation. Post-transplant care incurred...
alcohol is a major risk factor for liver cancer in Mongolia. The prevalence of HCV infection is reportedly 4.7%, with a prevalence of 6.2% in women. The prevalence of HBV infection is 12.5%, with a prevalence of 10.6% in women. The country has a high rate of alcohol consumption, with over 30% of adults reporting heavy drinking. The high prevalence of both HCV and HBV infection, along with heavy alcohol consumption, leads to a high rate of liver cancer in Mongolia.

Transplantation in Mongolia is done only at the First State Hospital in Ulaanbaatar, the major public hospital in the country. For the 14 transplantations that have been done in Mongolia, the mean age was 48 years and 70% were women. There have been four deaths, one in the Mongolian cohort. There are 20–30 candidates on the waiting list.

Training and preparation for surgeons, nurses and engineers was done from 2007 to 2009 in the Republic of Korea (Asan Hospital, Seoul). The procedure followed in the country is right-lobe partial liver resection from living donors (usually relatives). Matching (blood group and cross-matching only) is done at the First State Hospital. Donors are also screened for age, health, viruses, liver function and anatomy (magnetic resonance cholangiopancreatography for the biliary tract and vascularization by CT). The cost at the First State Hospital is 75 000 000 MNT (~US$ 37 500), which includes one month of postoperative care. Patients are charged 60 000 000 MNT (~US$ 30 000). Criteria for transplantation are cirrhosis, HCC or biliary atresia; Child–Pugh score 2–3; and decompensated liver failure indicated by ascites, splenomegaly or varices.

All adult transplants (13) have been done in individuals with HBV cirrhosis, three with HDV coinfection and three with HCC. Pretreatment for HBV-related cirrhosis is with tenofovir (300 000 MNT/month – ~US$ 150) or entecavir (500 000 MNT/month – ~US$ 250). Patients with HCV-related cirrhosis have been transplanted in other countries, with recurrence of HCV infection post-transplantation. There have been some attempts to treat post-transplantation recurrence with PEG-IFN/RBV, but complications have been associated with this treatment.

The First State Hospital provides follow-up care for patients who have undergone transplantation, whether locally or overseas. Follow-up transplantation care includes monthly liver function tests (LFT), imaging and tacrolimus trough levels for 1 year, then monthly tacrolimus, LFT and 3-monthly imaging. There are three hepatologists who provide follow-up clinical care. Loss to follow up is high. In total, ~50 patients have been lost to follow up.

Additional costs. Transplants are also done in the Republic of Korea (~US$ 100 000–200 000), Japan, China and some other Asian countries such as Singapore (US$ 250 000) (Fig. 10).

Transplantation in Mongolia is done only at the First State Hospital in Ulaanbaatar, the major public hospital in the country. For the 14 transplantations that have been done in Mongolia, the mean age was 48 years and 70% were women. There have been four deaths, one in the Mongolian cohort. There are 20–30 candidates on the waiting list.

Training and preparation for surgeons, nurses and engineers was done from 2007 to 2009 in the Republic of Korea (Asan Hospital, Seoul). The procedure followed in the country is right-lobe partial liver resection from living donors (usually relatives). Matching (blood group and cross-matching only) is done at the First State Hospital. Donors are also screened for age, health, viruses, liver function and anatomy (magnetic resonance cholangiopancreatography for the biliary tract and vascularization by CT). The cost at the First State Hospital is 75 000 000 MNT (~US$ 37 500), which includes one month of postoperative care. Patients are charged 60 000 000 MNT (~US$ 30 000). Criteria for transplantation are cirrhosis, HCC or biliary atresia; Child–Pugh score 2–3; and decompensated liver failure indicated by ascites, splenomegaly or varices.

All adult transplants (13) have been done in individuals with HBV cirrhosis, three with HDV coinfection and three with HCC. Pretreatment for HBV-related cirrhosis is with tenofovir (300 000 MNT/month – ~US$ 150) or entecavir (500 000 MNT/month – ~US$ 250). Patients with HCV-related cirrhosis have been transplanted in other countries, with recurrence of HCV infection post-transplantation. There have been some attempts to treat post-transplantation recurrence with PEG-IFN/RBV, but complications have been associated with this treatment.

The First State Hospital provides follow-up care for patients who have undergone transplantation, whether locally or overseas. Follow-up transplantation care includes monthly liver function tests (LFT), imaging and tacrolimus trough levels for 1 year, then monthly tacrolimus, LFT and 3-monthly imaging. There are three hepatologists who provide follow-up clinical care. Loss to follow up is high. In total, ~50 patients have been lost to follow up.

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1 Most at Asan Hospital, Seoul
2 Raffles, Beijing

Figure 10. Country of liver transplantation for Mongolians having transplant surgery (N = 155)
2.5 Health systems

Laboratory services

The development of laboratory services for viral hepatitis commenced in 1990 following the initial Ministerial Order outlining action on viral hepatitis (HBV immunization). Laboratory standards, protocols and procedures were developed in 2007. There are current standard operating procedures (SOPs) for laboratories at the different levels of the health system.

The National Strategy on Viral Hepatitis Control 2010–2015 has specific outputs relevant to laboratory services in Objective 2 (Decrease the HBsAg carrier rate to <2% among children under 5 years of age, and reduce HBV and HCV transmission) and Objective 3 (Strengthen capacity for surveillance, control and laboratory diagnosis of viral hepatitis). The NCCD is essentially responsible for implementing all the laboratory components of these objectives, apart from those concerning blood donation (2.8), which is also the responsibility of the National Transfusion Centre.

There are 41 laboratories in Mongolia with the capacity for diagnosing hepatitis (in the public sector) arranged at the three levels of health services (reference laboratory/district hospitals and aimags/family centres and soums). The National Hepatitis and Enteroviral Laboratory (NHEL) was established at the NCCD in 2012 following a US$ 400 000 grant from the Ministry of Health and Sports, and functions as the national reference laboratory. It has developed SOPs for Mongolia based on a number of key external and domestic guidelines, including WHO and CDC guidance on surveillance, diagnosis and treatment, Mongolian laws related to health, hygiene and immunization, as well as Ministerial Orders.

The NHEL provides viral hepatitis, rotavirus and enterovirus testing. Currently, the staff profile is three laboratory doctors, one biologist, three laboratory technicians and one assistant. Equipment includes machines for ELISA, reverse transcriptase (RT)-PCR, and an immunoflocytometer. There is capacity for genotyping for rotavirus, but not for hepatitis viruses. Serology and PCR can be performed on hepatitis A, B, C, D and E viruses. The capacity exceeds the demand. The capacity is 200–300 (non-PCR) tests a day; currently, 60–70 samples are processed in a day. The PCR capacity is 48 samples per run (day). Currently, 6–7 samples are run per week.

External quality assurance for NHEL began in 2010 with the CDC at the Republic of Korea. At the NHEL, the sensitivity and specificity is more than 99.5% for ELISA (HBsAg and anti-HCV) and for HBV DNA and HCV RNA PCR. The RT-PCR system at the NCCD is Cobas E411-ECL, which is fully automated and can run 48 samples concurrently over 5–6 hours, including HBV DNA and HCV RNA at a cost of 95 000–100 000 MNT per test. Costs are covered by health insurance only if the patient is hospitalized.
The NCCD has participated in international EQAS since 2011. The National Transfusion Center joined an international external quality assurance programme in 2005, while other blood banks joined the programme in 2010.

Public sector domestic EQAS commenced in 2011. Technical assistance has been provided by the Australian National Reference Laboratory (Melbourne, Australia), which provided initial and ongoing training, and supported the development of policy documentation. Tests included in EQAS are HIV Ab, HCV Ab and HBsAg, and syphilis antibody. In 2013, there were 46 laboratories participating (21 aimags, five soums, nine district-level health facilities and 11 hospitals in Ulaanbaatar). There are plans to include the private sector in the future.

While EQAS exists, a system to certify and accredit laboratory quality management systems does not. Only 15% of laboratories have a designated quality manager.

In October 2013, the National Reference Laboratory (Australia) provided training to the NCCD and reviewed laboratory standards at the NCCD as well as other institutions in Ulaanbaatar. Key recommendations included the following: (1) use of unique identifier barcodes in samples and worksheets; (2) checking donor samples against the worksheet during testing; (3) having worksheets that contain key information about the test run, key identifying information for the sample, as well as confirmation and authorization information; (4) updating SOPs and making SOPs available at the benchtop; (5) adhering to test manufacturers’ inserts regarding positive and negative control runs and test validation.

The review team visited laboratories at all levels of the health system in Ulaanbaatar and in one rural province. Outside the NCCD, viral hepatitis testing is essentially restricted to rapid tests in the public sector, though PCR and ELISA are also available through the private sector at additional locations. Laboratory services were limited in rural areas. The rapid test kits available were from a range of manufacturers. Reagents for other tests were not always available. It was not clear which test kits had been validated in Mongolia. Laboratory facilities in general were clean, and there was evidence of appropriate waste disposal facilities and hygiene practices within facilities. SOPs were available. A major finding was a lack of systematized data recording and checking. Results were recorded on paper and input into Excel spreadsheets if a computer was available. The review team was not able to assess whether testing algorithms and quality management practices were consistently followed, though this was a concern expressed by senior laboratory personnel at the central level.

Given the high sensitivity and specificity of the new generation of rapid tests for HBsAg and anti-HCV, and logistics in Mongolia, particularly in rural areas and in winter, the review team believed that using rapid test kits for screening for HBsAg and anti-HCV was a valid strategy. A major issue is confirmation of HCV viraemia by HCV RNA testing. While NHEL currently has excess PCR capacity, the cost of PCR is high and transportation of specimens is a challenge.

As noted above, a substantial amount of testing occurs in the private sector, yet the private sector remains outside of quality assurance mechanisms.

* The cost is 170 000 MNT/test (~US$ 90).
**Recommendations**

37. Validated rapid test kits should form the backbone of viral hepatitis testing in Mongolia, with PCR used for estimating HBV viral load in individuals considering HBV antiviral therapy, and to confirm viraemia in HCV infection.

38. The NHEL should develop a list of approved rapid test kits for use in Mongolia.

39. Mechanisms should be developed to ensure appropriate transportation of specimens for PCR confirmation at the NHEL.

40. Laboratory stock-outs of test kits and reagents should be addressed.

41. Consideration should be given to how all laboratories, including private sector laboratories, can be included in quality management and EQAS procedures.

42. Consideration should be given to developing internal quality management systems for TTI testing.

**Pharmaceutical supply management**

Given the very small number of individuals with access to antiviral medications in Mongolia, the review team did not review pharmaceutical supply management services in detail.

Currently, there is one distributor for PEG-IFN/RBV in Mongolia (Sentunari), located in Ulaanbaatar. This distributor is also the supplier of PCR machines (Cobas). In the opinion of the supplier, the small size of the antiviral market is a key impediment in bringing down the high cost of medications.

**Blood safety**

Facilities managing blood products in the country include the National Center for Transfusion Medicine in Ulaanbaatar, and 26 blood banks in the 21 provinces. In addition, blood products are available in 347 soums. The center is responsible for maintaining the safety and supply of blood products, and providing management guidance to hospital blood banks. Provincial blood banks provide blood products to rural areas and provide guidance on the use of blood products for soum-level facilities.

Governance of the blood product sector falls under the Ministry of Health and Sports, which approves the guidelines for the management of blood products and ensures compliance with Mongolian Government policy.

A voluntary, nonremunerative blood donor system was implemented in 1994. The rate of blood donation nationwide is 7.7 units/1000 population, being higher (12/1000) in Ulaanbaatar and lower in rural areas. All (100%) donated blood is screened at all levels of the health sector for anti-HIV (since 1987), HBsAg (since 1996), anti-HCV (since 1997) and syphilis (since 1997). Screening methods differ by level of the health system. At the National Center for Transfusion Medicine, ELISA and PCR are used. At blood banks (in aimags), ELISA and particle agglutination are used, while at health centres (soums), only rapid tests are used.
In 2013, 10.5% of donations tested positive for one of the screened infections, a decrease from 13.6% in 2009. Syphilis prevalence has been increasing over the past 5 years. There have been three cases of HIV identified overall, but known since 2009. PCR testing was introduced in 2012. The serological prevalence of these infections in donated blood over the past 5 years is given in Fig. 11.

**Figure 11. Prevalence of bloodborne pathogens in donated blood in Mongolia, by year**

<table>
<thead>
<tr>
<th>Year</th>
<th>HIV</th>
<th>Syphilis</th>
<th>Hepatitis C</th>
<th>Hepatitis B</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>0.00%</td>
<td>1.60%</td>
<td>5.80%</td>
<td>6.20%</td>
</tr>
<tr>
<td>2010</td>
<td>0.00%</td>
<td>1.60%</td>
<td>5.50%</td>
<td>5.20%</td>
</tr>
<tr>
<td>2011</td>
<td>0.00%</td>
<td>2.60%</td>
<td>3.30%</td>
<td>4.40%</td>
</tr>
<tr>
<td>2012</td>
<td>0.00%</td>
<td>3.00%</td>
<td>2.80%</td>
<td>4.40%</td>
</tr>
<tr>
<td>2013</td>
<td>0.00%</td>
<td>3.10%</td>
<td>3.00%</td>
<td>4.30%</td>
</tr>
</tbody>
</table>

**Nucleic acid testing (NAT) (of blood with negative serology)**

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>0.58%</td>
<td>0.24%</td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>0.07%</td>
<td>0.04%</td>
</tr>
</tbody>
</table>

*Source: National Transfusion Center 2014*
In 2012, under the professional assistance of the National Reference Laboratory of Australia, a national EQAS was started, which focused on serology testing of transfusion-transmitted infections (TTIs) with the cooperation of the NCCD, in 21 aimags and five soums, as well as the nine districts, and 10 national and general hospitals in Ulaanbaatar. In 2012, there were 30 participating laboratories, which increased to 45 by 2014. The panel is twice annual anti-HIV, anti-HCV, HBsAg and antibody to Treponema pallidum.

Funding assistance for EQAS is provided by the Global Fund and WHO. WHO provided financial assistance for the National Center for Transfusion Medicine to screen for HIV, HBV and HCV from 2005 to 2009. Since 2010, the Global Fund has provided funding for blood banks to screen for HIV, HBV, HCV and syphilis.

**Sustainable financing for the response to viral hepatitis**

Funding for the Mongolian health sector is mixed – internal and external, public and private. It is structured around a near-universal health insurance programme. In 2013, 97.7% of the population was covered by compulsory health insurance. In 2013, 89 billion MNT of the expenditure occurred in public hospitals, while 17.1 billion MNT occurred in private facilities (39). Financing for the entire (public and private) health system is shared mainly between the Government (32.3%), social health insurance contributions (22.8%) and OOP payments (41.3%) (16). In 2011, Government expenditure as a proportion of total health expenditure was 85%, while OOP expenditure was 12% (40).

In 2009, 73% of public health sector expenditure was on medical services, including 54% on inpatient services, while 4.5% was on public health and prevention (16). The NCCD budget is funded 90% by Government revenue, 7–8% from social health insurance, and 2–3% from OOP costs.

The Mongolian Government fully finances all of its routine vaccines, with the exception of the pentavalent\(^\circ\), which is financed by both the Government and GAVI, the Vaccine Alliance. The cost of hepatitis A vaccine is covered by the domestic Immunization Fund. In 2011, HAV vaccines consumed a third of the domestic Immunization Fund budget (US$ 1 019 472 of a total budget of US$ 3 152 903). The Fund has the advantage of more flexibility than a typical budget line item. For example, it can receive resources from multiple sources: government, external donors and the private sector. The Fund is overseen by a committee chaired by the Vice Minister of Health with other members from the Ministry of Health and Sports, Ministry of Finance and a number of other State entities, including the NCCD. The oversight committee is tasked with (i) mobilizing and allocating financing to vaccines and injection supplies, (ii) approving annual plans for vaccines and supplies for the “State Stockpile for Infectious Diseases”, and (iii) ensuring the financial sustainability of the Fund (41).

In 2005, the Ministry of Health and Sports in Mongolia initiated the process of developing its Health Sector Strategic Master Plan (HSSMP), and sought to coordinate the disparate inputs from key donors through the HSSMP. Key

\(^\circ\) Diphtheria–tetanus–pertussis (DTP) + hepatitis B + *Haemophilus influenzae* type b
partners in health increased their support to the health sector, and aligned these with HSSMP priorities. The Third, Fourth and Fifth Health Sector Development Projects funded by the ADB (US$ 17.6 million, US$ 18.15 million and US$ 30 million, respectively) focus on the key strategies outlined in the HSSMP: improving the health insurance system, rationalizing hospitals, strengthening primary health care, and improving postgraduate clinical training, drug safety, blood safety and waste management (42). The Fifth Health Sector Development Project began in late 2014. WHO has indicated that it will provide US$ 450 000 of in-kind contributions to the Project.

The actual costs of care to patients vary. In the public sector, testing and treatment of an amount less than ~US$ 30 is free, as is acute communicable disease treatment. Health insurance covers 36 000 MNT (~US$ 18) per person per month on testing expenses. This amount expires each month so accumulation is not possible.

A major financing consideration is how to meet the cost of effective HBV treatment (e.g. tenofovir) and new direct-acting antivirals for HCV in the public sector. For HCV, Mongolia falls under the tiered pricing system of two major pharmaceutical manufacturers. The proposed price of branded sofosbuvir is US$ 900/12 weeks. To achieve a high SVR (cure rates), given that the HBV genotype is 1b, it is likely that sofosbuvir will need to be combined with either ledipasvir, daclatasvir, simeprevir or PEG-IFN/RBV. The estimated cost of treatment per person is therefore difficult to estimate, but likely higher than US$ 1000/person. The review team estimated that the number of individuals requiring HCV treatment due to advanced fibrosis in Mongolia is 31 000–74 000 (mid-point 52 500). The total cost of treating these individuals is therefore likely to be more than US$ 31 million, should coverage be high.

**Recommendations**

43. The new National Hepatitis Programme should be costed, including various testing and treatment options.

44. Price negotiation on drugs will be fundamental to the capacity for an effective response.

45. A comprehensive funding strategy, incorporating domestic and external funding, is recommended to ensure sustainable action for addressing viral hepatitis in Mongolia.

46. There is a need to support research on the epidemiology and clinical management of HBV/HDV coinfection. This should include exploring international collaborative partnerships.

47. Further exploration should be conducted of the role of injecting drug use in hepatitis transmission in Mongolia.

48. Implementation science questions may be considered.
REFERENCES


**ANNEX I: Review team members**

### External team members

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ying-Ru Lo</td>
<td>Coordinator, HIV, Hepatitis and Sexually Transmitted Infections Unit, WHO Regional Office for the Western Pacific</td>
</tr>
<tr>
<td>Nick Walsh</td>
<td>Viral Hepatitis Medical Officer, HIV Hepatitis and Sexually Transmitted Infections Unit, WHO Regional Office for the Western Pacific</td>
</tr>
<tr>
<td>Geoffrey Beckett</td>
<td>Chief, Prevention Branch, Division of Viral Hepatitis, United States Centers for Disease Control and Prevention</td>
</tr>
<tr>
<td>Ann Chao (for cancer only)</td>
<td>Epidemiologist, National Cancer Center, United States National Institutes of Health</td>
</tr>
</tbody>
</table>

### Local team members

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nyunt-U Soe</td>
<td>WHO Representative, WHO Mongolia</td>
</tr>
<tr>
<td>Narantuya Jadambaa</td>
<td>National Programme Officer, HIV, Hepatitis and Sexually Transmitted Infections, WHO Mongolia</td>
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</table>

The review team is indebted to the Mongolian Ministry of Health and Sports and to the NCCD for their strong support during these reviews.
ANNEX II: Overall scope and process of national health sector review

The objectives for the September 2014 review were as follows:

(1) to provide technical support for assessment of the hepatitis surveillance system, laboratory and treatment infrastructure;

(2) to conduct site visits to hospitals and health centres;

(3) to support and participate in the technical discussions on viral hepatitis;

(4) to conduct site assessments in Ulaanbaatar;

(5) to prepare the desk review and write the report; and

(6) to prepare a formal analytical report and outline steps to develop a viral hepatitis action plan.

The terms of reference for the September 2014 review were as follows:

Dr Ying-Ru Lo, Coordinator, HIV, Hepatitis and Sexually Transmitted Infections, WHO Regional Office for the Western Pacific

To lead the assessment of the hepatitis surveillance systems, laboratory and treatment infrastructure to develop a viral hepatitis action plan:

(1) participate in the congenital syphilis workshop in Darkhan-uu province (8 September); and

(2) prepare for the workshop/technical discussions with the Ministry of Health and Sports and partners in Ulaanbaatar (12 September).

Dr Nicholas Walsh, Medical Officer, Hepatitis, Unit (5–20 September, including travel)

(1) to provide technical support for assessing the hepatitis surveillance systems, laboratory and treatment infrastructure to prepare a formal analytical report and outline steps to develop a viral hepatitis action plan;
(2) to conduct site visits in Darkhan-uul province, visiting hospitals and health centres (7–8 September);

(3) to support the preparation of the workshop/technical discussions on viral hepatitis (12 September);

(4) to prepare the desk review and writing of the report of this key stakeholder workshop (13–14 September); and

(5) to conduct site assessments in Ulaanbaatar (15–19 September).

Dr Geoffrey Beckett, Chief, Prevention Branch, Division of Viral Hepatitis, Centers for Disease Control and Prevention (CDC), National Center for HIV/AIDS, Hepatitis, STD and TB Prevention, represented US-CDC in this review.

Dr Ann Chao, epidemiologist at the National Cancer Center, National Institutes of Health (NIH), USA, joined the review to focus on cancer-related issues.

The WHO Mongolia Country Office (CO) also requested technical support from the Divisions of Health Services office to assist in the discussion on universal health coverage and financing in the context of hepatitis treatment. We have consulted the Division of Health Services office to identify the staff who will provide this support. Unfortunately, the timing of the visit did not permit their attendance at the review.

The January 2015 review for Dr Nicholas Walsh, Medical Officer for Viral Hepatitis, to visit Ulaanbaatar took place from 18 to 24 January 2015. The terms of reference for his travel were as follows:

(1) to provide technical assistance on defining major strategic areas of the new National Hepatitis Programme, in line with the global and Regional strategies;

(2) to provide technical assistance in defining short- and long-term targets for the new National Hepatitis Programme;

(3) to provide technical assistance for informing stakeholders on best practices in the control of viral hepatitis; and

(4) to provide technical assistance for finalization of the new National Hepatitis Programme.

Dr Geoffrey Beckett, Chief, Prevention Branch, Division of Viral Hepatitis, Centers for Disease Control and Prevention (CDC), National Center for HIV/AIDS, Hepatitis, STD and TB Prevention, represented the US-CDC in this review.
ANNEX III: Meetings and visits to institutions in Mongolia, 8–19 September 2014 and 19–23 January 2015

**September 2014 mission**

**Mission schedule**

Dr Ying-Ru Lo, Team leader, HIV, Hepatitis and STIs, WHO Regional Office for the Western Pacific, Dr Nick Walsh, Medical officer for Viral Hepatitis, WHO Regional Office for the Western Pacific and Dr Geoffrey Beckett, Chief, Prevention Branch, CDC Division of Viral Hepatitis in Mongolia

8–19 September 2014

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Activity</th>
<th>Responsible person and participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 September</td>
<td></td>
<td>Arrival at the Chingis airport in Ulaanbaatar</td>
<td>J. Narantuya, WHO Country Office (CO)</td>
</tr>
<tr>
<td>8 September</td>
<td>7:00–</td>
<td>Departure to Mandal resort</td>
<td>E. Erdenetungalag, NCCD</td>
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<td></td>
<td></td>
<td></td>
<td>J. Narantuya, WHO CO</td>
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<td>Ying-Ru Lo, Team leader, WHO Regional Office for the Western Pacific</td>
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<tr>
<td></td>
<td>10:00–18:00</td>
<td>Participation in workshop on congenital syphilis</td>
<td>Ying-Ru Lo, Team leader, WHO Regional Office for the Western Pacific</td>
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<td></td>
<td></td>
<td></td>
<td>J. Narantuya, WHO Country Office</td>
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<tr>
<td>9:00–9:30</td>
<td></td>
<td>Meeting with Dr D. Nyamkhuu, General Director of National Center for Communicable Diseases (NCCD)</td>
<td>A. Ambaselmiaa, Head of Infectious Disease Surveillance and Research Department, NCCD</td>
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<td></td>
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<td>M. Oyun, NCCD</td>
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<td>Nick Walsh, WHO Regional Office for the Western Pacific</td>
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<td>Geoffrey Beckett, CDC</td>
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<td>Ann Chao, NIH</td>
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<tr>
<td>Date</td>
<td>Time</td>
<td>Activity</td>
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<tr>
<td>8 September</td>
<td>9:30–11:00</td>
<td>Introduction to surveillance and reporting of viral hepatitis in Mongolia</td>
<td>A. Ambaselmaa, Head of Infectious Disease Surveillance and Research Department, NCCD</td>
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<td>M. Oyun, NCCD</td>
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<td>Nick Walsh, WHO Regional Office for the Western Pacific</td>
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<td>Geoffrey Beckett, CDC</td>
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<td>Ann Chao, NIH</td>
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<tr>
<td>11:00–12:00</td>
<td>Visit to Reference laboratory of NCCD</td>
<td>Altankhuu, Head of Laboratory Department, NCCD</td>
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<td></td>
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<td>Nick Walsh, WHO Regional Office for the Western Pacific</td>
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<td>Geoffrey Beckett, CDC</td>
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<td>Ann Chao, NIH</td>
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<tr>
<td>12:00–13:30</td>
<td>Lunch</td>
<td></td>
<td>M. Tunsag, Director of Medical Services, NCCD</td>
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<td>M. Oyun, NCCD</td>
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<td>M. Sumiya, Quality Manager, NCCD</td>
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<td>B. Saruul, Head of outpatient clinic for viral hepatitis</td>
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<td>Nick Walsh, WHO Regional Office for the Western Pacific</td>
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<td>Geoffrey Beckett, CDC</td>
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<td>Ann Chao, NIH</td>
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<tr>
<td>13:30–15:30</td>
<td>Visit to inpatient department of NCCD</td>
<td>M. Tunsag, Director of Medical Services, NCCD</td>
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<td>M. Oyun, NCCD</td>
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<td>M. Sumiya, Quality Manager, NCCD</td>
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<td>B. Saruul, Head of outpatient clinic for viral hepatitis</td>
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<td>Ann Chao, NIH</td>
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<tr>
<td>15:30–16:30</td>
<td>Interview with hepatitis patients</td>
<td>M. Tunsag, Director of Medical Services, NCCD</td>
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<tr>
<td>9 September</td>
<td>9.00–10:00</td>
<td>Meeting with Dr Soe Nyunt-U, WHO Representative (WR)</td>
<td>J. Narantuya, WHO CO</td>
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<td></td>
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<td></td>
<td>Ying-Ru Lo, WHO Regional Office for the Western Pacific</td>
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<td>Nick Walsh, WHO Regional Office for the Western Pacific</td>
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<td>Geoffrey Beckett, CDC</td>
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<tr>
<td>10:00–11:00</td>
<td>Meeting with Dr Amarsanaa, Vice Minister of Health</td>
<td>S. Evlegsuren, OIC of communicable diseases, MoH</td>
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<td></td>
<td>G. Surenkhand, Deputy Director of NCCD.</td>
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<td>A. Ambaselmaa, Head of Infectious Disease Surveillance and Research Department, NCCD</td>
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<td></td>
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<td></td>
<td>Soe Nyunt-U, WHO Representative</td>
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<td></td>
<td>Ying-Ru Lo, WHO Regional Office for the Western Pacific</td>
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<td>Nick Walsh, WHO Regional Office for the Western Pacific</td>
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<td>Geoffrey Beckett, CDC</td>
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<td>J. Narantuya, WHO CO</td>
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<tr>
<td>Date</td>
<td>Time</td>
<td>Activity</td>
<td>Responsible person and participants</td>
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<tr>
<td>9 September</td>
<td>11:30–12:30</td>
<td>Meeting with Mongolian Association for the Study of Liver Disease</td>
<td>M. Oyun, NCCD</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>O. Baatarkhuu, President of the Association</td>
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<td></td>
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<td></td>
<td>Ying-Ru Lo, WHO Regional Office for the Western Pacific</td>
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<td>Nick Walsh, WHO Regional Office for the Western Pacific</td>
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<td>Geoffrey Beckett, CDC</td>
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<td>J. Narantuya, WHO CO</td>
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<tr>
<td></td>
<td>12:30–14:00</td>
<td>Lunch</td>
<td></td>
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<tr>
<td></td>
<td>14:30–17:00</td>
<td>Meeting with nongovernmental organizations working in the area of hepatitis control</td>
<td>Ying-Ru Lo, WHO Regional Office for the Western Pacific</td>
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<td></td>
<td></td>
<td></td>
<td>Nick Walsh, WHO Regional Office for the Western Pacific</td>
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<td>Geoffrey Beckett, CDC</td>
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<td></td>
<td>J. Narantuya, WHO CO</td>
</tr>
<tr>
<td>10 September</td>
<td>8:30–10:30</td>
<td>Visit to Bayanzurkh district health department</td>
<td>M. Oyun, NCCD</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Ying-Ru Lo, WHO Regional Office for the Western Pacific</td>
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<td></td>
<td>Nick Walsh, WHO Regional Office for the Western Pacific</td>
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<td>Geoffrey Beckett, CDC</td>
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<td>J. Narantuya, WHO CO</td>
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<td></td>
<td></td>
<td></td>
<td>Ann Chao, NIH</td>
</tr>
<tr>
<td></td>
<td>10:30–11:30</td>
<td>Visit to “Eruul urkh” family group practice clinic</td>
<td>M. Oyun, NCCD</td>
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<tr>
<td></td>
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<td>Ying-Ru Lo, WHO Regional Office for the Western Pacific</td>
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<td>Nick Walsh, WHO Regional Office for the Western Pacific</td>
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<td>Geoffrey Beckett, CDC</td>
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<td>J. Narantuya, WHO CO</td>
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<td></td>
<td>Ann Chao, NIH</td>
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<tr>
<td></td>
<td>12:00–13:00</td>
<td>Lunch</td>
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<tr>
<td></td>
<td>14:00–16:00</td>
<td>Visit to the National Cancer Centre (NCC) to review the cancer registry</td>
<td>Ts. Badamsuren, Head of Public Health, Research and Training Department, NCC</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Ying-Ru Lo, WHO Regional Office for the Western Pacific</td>
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<td>Nick Walsh, WHO Regional Office for the Western Pacific</td>
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<td>Geoffrey Beckett, CDC</td>
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<td>J. Narantuya, WHO CO</td>
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<td></td>
<td>Ann Chao, NIH</td>
</tr>
<tr>
<td>Date</td>
<td>Time</td>
<td>Activity</td>
<td>Responsible person and participants</td>
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</tr>
</tbody>
</table>
| 11 September | 8:30–9:30  | Visit to “Interferon alfa” private clinic treating patients with hepatitis | M. Oyun, NCCD  
Ying-Ru Lo, WHO Regional Office for the Western Pacific  
Nick Walsh, WHO Regional Office for the Western Pacific  
Geoffrey Beckett, CDC  
J. Narantuya, WHO CO  
Ann Chao, NIH |
| 11:00–12:00|            | Meeting with ADB                                                         | Ying-Ru Lo, WHO Regional Office for the Western Pacific  
Nick Walsh, WHO Regional Office for the Western Pacific  
Geoffrey Beckett, CDC  
J. Narantuya, WHO CO |
| 14:00–15:00|            | Meeting with Dr. S. Evlegsuren, Officer in charge of infectious diseases   | Ying-Ru Lo, WHO Regional Office for the Western Pacific  
J. Narantuya, WHO CO |
| 12:00–13:00|            | Lunch                                                                    |                                                                                                      |
| 13:00–17:00|            | Preparation for the workshop                                             | Ying-Ru Lo, WHO Regional Office for the Western Pacific  
Nick Walsh, WHO Regional Office for the Western Pacific  
Geoffrey Beckett, CDC  
J. Narantuya, WHO CO |
| 12 September | 12 September | Participation in hepatitis workshop                                      | Ying-Ru Lo, WHO Regional Office for the Western Pacific  
Nick Walsh, WHO Regional Office for the Western Pacific  
Geoffrey Beckett, CDC  
J. Narantuya, WHO CO  
Ann Chao, NIH |
| 23:55      |            | Departure of Ying-Ru Lo                                                 | J. Narantuya, WHO CO |
| 13 September |            | Desk review                                                              | Nick Walsh, WHO Regional Office for the Western Pacific Geoffrey Beckett, CDC |
| 14 September | 9:00       | Departure to Bulgan province                                             | M. Oyun, NCCD  
Nick Walsh, WHO Regional Office for the Western Pacific  
Geoffrey Beckett, CDC  
Ann Chao, NIH |
| 15 September | 8:00–9:00  | Meeting with Director of Bulgan province health department               | M. Oyun, NCCD  
Nick Walsh, WHO Regional Office for the Western Pacific  
Geoffrey Beckett, CDC |
| 12:00–13:00|            | Work at the Bulgan health department                                     | M. Oyun, NCCD  
Nick Walsh, WHO Regional Office for the Western Pacific  
Geoffrey Beckett, CDC |
<p>| 12:00–13:00|            | Lunch                                                                    |                                                                                                      |</p>
<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Activity</th>
<th>Responsible person and participants</th>
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</thead>
<tbody>
<tr>
<td>15 September</td>
<td>13:00–16:00</td>
<td>Work at the Bulgan province hospital</td>
<td>M. Oyun, NCCD Nick Walsh, WHO Regional Office for the Western Pacific Geoffrey Beckett, CDC</td>
</tr>
<tr>
<td>16 September</td>
<td>8:00–12:00</td>
<td>Work at the Bulgan province soum hospital</td>
<td>M. Oyun, NCCD Nick Walsh, WHO Regional Office for the Western Pacific Geoffrey Beckett, CDC</td>
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<tr>
<td></td>
<td>12:00–13:00</td>
<td>Lunch</td>
<td></td>
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<tr>
<td></td>
<td>13:00</td>
<td>Departure to Ulaanbaatar</td>
<td></td>
</tr>
<tr>
<td>17 September</td>
<td>8:30–9:30</td>
<td>Meeting with “Situnari” pharmaceutical company and visit to pharmacy</td>
<td>J. Narantuya, WHO CO Nick Walsh, WHO Regional Office for the Western Pacific Geoffrey Beckett, CDC</td>
</tr>
<tr>
<td></td>
<td>10:30–12:30</td>
<td>Visit to liver transplantation centre at the State Hospital #1</td>
<td>M. Oyun, NCCD Nick Walsh, WHO Regional Office for the Western Pacific Geoffrey Beckett, CDC J. Narantuya, WHO CO</td>
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<tr>
<td></td>
<td>12:30–14:00</td>
<td>Lunch</td>
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<tr>
<td></td>
<td>14:00–15:30</td>
<td>Visit to dental clinic</td>
<td>M. Oyun, NCCD Nick Walsh, WHO Regional Office for the Western Pacific Geoffrey Beckett, CDC J. Narantuya, WHO CO</td>
</tr>
<tr>
<td></td>
<td>16:00–17:00</td>
<td>Meeting with Dr A. Munkhjargal, Fire NGO</td>
<td>J. Narantuya, WHO CO Nick Walsh, WHO Regional Office for the Western Pacific Geoffrey Beckett, CDC</td>
</tr>
<tr>
<td>18 September</td>
<td>9:00–13:00</td>
<td>Preparation for debriefing</td>
<td>Nick Walsh, WHO Regional Office for the Western Pacific Geoff Beckett, CDC</td>
</tr>
<tr>
<td></td>
<td>14:00–15:00</td>
<td>Meeting with Dr Popp [designation?]</td>
<td>Nick Walsh, WHO Regional Office for the Western Pacific Geoff Beckett, CDC</td>
</tr>
<tr>
<td></td>
<td>15:00–16:00</td>
<td>Debriefing with Dr Soe Nyunt-U WHO Representative (WR)</td>
<td>J. Narantuya, WHO CO Nick Walsh, WHO Regional Office for the Western Pacific Geoff Beckett, CDC</td>
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<tr>
<td></td>
<td>16:00–17:30</td>
<td>Debriefing with Ministry of Health and Sports</td>
<td>Nick Walsh, WHO Regional Office for the Western Pacific Geoff Beckett, CDC S. Evlegsuren, OIC of communicable diseases, MoH M. Oyun, NCCD J. Narantuya, WHO</td>
</tr>
<tr>
<td></td>
<td>23:55</td>
<td>Departure of Nick Walsh</td>
<td>WHO Regional Office for the Western Pacific</td>
</tr>
<tr>
<td>19 September</td>
<td></td>
<td>Departure of Geoff Beckett</td>
<td>Corporate hotel</td>
</tr>
</tbody>
</table>
## January 2015 review
### Mission schedule in Mongolia

Dr Nicholas Walsh, Medical Officer for Viral Hepatitis, WHO Regional Office for the Western Pacific and Mr Geoffrey Beckett, Chief, Prevention Branch, CDC Division of Viral Hepatitis in Mongolia

19-23 January 2015

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Activity</th>
<th>Responsible person</th>
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</thead>
<tbody>
<tr>
<td>18 January</td>
<td></td>
<td>Arrival at the Chingis airport in Ulaanbaatar</td>
<td>J. Narantuya, WHO CO</td>
</tr>
<tr>
<td>19 January</td>
<td>8:30–9:30</td>
<td>Briefing with Dr Soe Nyunt-U, WHO Representative (WR)</td>
<td>J. Narantuya, WHO CO</td>
</tr>
<tr>
<td></td>
<td>9:30–10:00</td>
<td>Meeting with Dr D. Atarmaa, Vice Minister of Health</td>
<td>D. Narangerel, OIC of CD, Ministry of Health and Sports G. Surenkhand, Deputy Director of NCCD, A. Ambaselmaa, Head of Infectious Disease Surveillance and Research Department, NCCD</td>
</tr>
<tr>
<td></td>
<td>10:00–12:30</td>
<td>Preparations for hepatitis consultation meeting</td>
<td>M. Oyun, NCCD J. Narantuya, WHO CO Nick Walsh, WHO Regional Office for the Western Pacific Geoffrey Beckett, CDC</td>
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<tr>
<td></td>
<td>12:30–13:30</td>
<td>Lunch</td>
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<tr>
<td></td>
<td>13:30–14:30</td>
<td>Preparations for hepatitis consultation meeting</td>
<td>M. Oyun, NCCD J. Narantuya, WHO CO Nick Walsh, WHO Regional Office for the Western Pacific Geoffrey Beckett, CDC</td>
</tr>
<tr>
<td>20 January</td>
<td>9:30–11:00</td>
<td>Meeting with facilitators for group work during hepatitis consultation meeting</td>
<td>J. Narantuya, WHO CO Nick Walsh, WHO Regional Office for the Western Pacific Geoffrey Beckett, CDC</td>
</tr>
<tr>
<td></td>
<td>11:00–17:00</td>
<td>Preparations for hepatitis consultation meeting</td>
<td>M. Oyun, NCCD J. Narantuya, WHO CO Nick Walsh, WHO Regional Office for the Western Pacific Geoffrey Beckett, CDC</td>
</tr>
<tr>
<td>21–22 January</td>
<td>9:00–17:00</td>
<td>Participation in Consultation meeting on development of the new national hepatitis programme on viral hepatitis prevention and control</td>
<td>Nick Walsh, WHO Regional Office for the Western Pacific Geoffrey Beckett, CDC</td>
</tr>
<tr>
<td>23 January</td>
<td>11:00–13:00</td>
<td>Discussions on preparation for Standing Committee meeting on hepatitis</td>
<td>Discussions on preparation for Standing Committee meeting on hepatitis</td>
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<tr>
<td></td>
<td></td>
<td>Departure</td>
<td>J. Narantuya, WHO CO</td>
</tr>
</tbody>
</table>

Agreed by: P. Oyuntsetseg, Acting Head of Public Health Division, Ministry of Health and Sports
Checked by: D. Narangerel, OIC of CD, Ministry of Health and Sports A. Ambaselmaa, Head of Infectious Disease Surveillance and Research, NCCD
Developed by: A. Oyun, Head of Viral Hepatitis Unit, NCCD
ANNEX IV: Summary of recommendations

Policy

1. The upcoming National Viral Hepatitis Strategy should consider the recommendations discussed in this mission report, and the key stakeholder meeting report.

2. The private sector should be brought under the purview of the National Viral Hepatitis Strategy, particularly for hepatitis diagnostics and treatment, as most chronic hepatitis treatment is provided in the private sector.

3. The National Viral Hepatitis Strategy should align with the Regional Hepatitis Action Plan currently under development. Alignment may facilitate regional and national implementation.

4. Mongolia should adopt the WHO hepatitis guidelines as the Mongolian national guidelines, adapted as appropriate. This includes HBV and HCV screening, care and treatment guidelines.

5. Coordination should be strengthened between providers of postgraduate training in infectious diseases, epidemiology and surveillance.

6. Mechanisms should be explored for increasing integration between infectious disease and hepatology specialists for care and treatment of viral hepatitis.

7. An assessment of training needs related to viral hepatitis should be conducted for primary care clinicians. This could be followed by development and implementation of a training plan.

8. Ministerial orders may provide an authoritative mechanism for policy implementation.

Strategic information

9. Surveillance for acute jaundice should continue as part of the EWAR system.

10. There should be a move towards test result reporting for HBV, HCV and HDV by laboratories, with collation at the central level by the NCCD. The national identity number provides a mechanism for de-duplication.
a. The private sector, including laboratories, should be included in this test reporting system.

b. Aggregation should be done only at the central level to allow analysis.

c. Reporting should move towards full electronic reporting.

11. Mongolia should adopt the WHO viral hepatitis case definitions for surveillance purposes.

12. In those sites commencing pilot care and treatment initiatives, consideration should be given to implementing pilot viral hepatitis sentinel surveillance sites, where the additional collection of key demographic and clinical information could be carried out in a systematic fashion.

13. A central registry should be developed for viral hepatitis surveillance. This would include HBV, HCV and HDV test results linked to HCC data or the civil death registry, in turn linked by a unique identifier.

14. WHO and key partners should support implementation of the Strategy for the Early Detection of Liver Cancer as a priority. This Strategy, and data from it, should be linked to viral hepatitis surveillance in Mongolia.

15. In line with this initiative, given the prevalence of chronic hepatitis and the latency of viral hepatitis-related liver disease, we recommend universal HBsAg and anti-HCV screening for those 40–65 years old in Mongolia. This could be introduced in a phased manner.

16. Consideration should be given to linking the Strategy for the Early Detection of Liver Cancer and hepatitis test result reporting system by national identity number.

Prevention

17. Strategies should be developed to increase immunization against hepatitis, and improve disease and treatment literacy among the general public and the affected population. Initiatives such as World Hepatitis Day should be utilized more broadly to increase awareness. Consideration should be given to having a specific position within the NCCD on hepatitis education and communication.

18. Consideration should be given to catch-up HBV vaccination consisting of three shots to improve immunogenicity. Given the high prevalence of natural immune protection (HBcAb) and chronic HBV infection (HBsAg) in health-care workers, the absolute number of health-care workers needing vaccination is likely to be modest, and providing three shots should not drain resources excessively.

19. Catch-up HBV vaccination should be extended to other at-risk groups, including those with chronic HCV infection and key populations.

20. The objectives and outcomes of the Fifth Health Sector Development Project
regarding infection control in health-care settings and the management of blood products should align with the new National Hepatitis Programme. Lessons learned in implementation of the Fifth Project may be relevant to the new National Hepatitis Programme.

21. Taking into account the Fifth Health Sector Development Project, further assessment of the extent of health sector transmission of viral hepatitis, particularly within the private sector, should be considered. Further resources should be given to the State Health Facility Inspectorate Agency to improve regulatory oversight of infection control.

22. Prevention of hepatitis transmission within the private health sector is a priority for action. Private sector inclusion and participation in viral hepatitis prevention strategies and initiatives are recommended.

23. The State Health Facility Inspectorate Agency should be strengthened. This will require further human and financial resources to enable adequate capacity to meet the demand for infection control oversight of both public and private sector health facilities.

24. Alcohol prevention initiatives should be linked with secondary prevention strategies for viral hepatitis in public health messaging.

**Screening and testing**

25. An HBV and HCV treatment cascade should be developed for Mongolia, inclusive of the private sector, in order to assess screening, care and treatment responses at the population level.

26. Priority groups should be identified for testing based on epidemiological likelihood, e.g. health-care workers, MSM, other key populations and those with clinical liver disease. This would include those 40–65 years of age as previously recommended.

27. National hepatitis guidance should provide clinical testing algorithms. Suggested algorithms should include screening for HDV infection in HBsAg-positive individuals, and confirmation of HCV RNA in individuals who are anti-HCV positive.

28. Efforts should be made to increase the proportion of individuals who undergo HCV RNA confirmation after testing HCV Ab positive.

29. It is recommended that simple biochemical algorithms be the primary mechanism for staging liver disease among individuals diagnosed with chronic viral hepatitis (e.g. APRI or FIB-4) to improve accessibility and reduce the costs associated with staging.

30. Linkages from testing to care and treatment should be formalized to reduce loss to follow up in the cascade. Consideration should be given to how the private sector can be incorporated into the testing and care component of the cascade.
### Treatment

31. Priority should be given to increasing access to effective antivirals against HBV with a high barrier to resistance such as tenofovir and entecavir. The review team recommends that lamivudine not be used for the treatment of HBV infection.

32. Prices of antiviral medications are high in Mongolia compared with other countries in the Region. Priority should be given to reducing the procurement cost and the cost to the consumer for key antiviral medications.

33. The number of individuals with advanced liver disease needing prompt antiviral therapy for chronic hepatitis B and C should be estimated to inform treatment planning. Priority for treatment should also be given to those with viral hepatitis coinfections. It is noted that therapy for HBV/HDV coinfection may prove challenging.

34. Demonstration HBV and HCV treatment initiatives should be undertaken, beginning in centres with a high capacity. The initiative should include screening, care and treatment, and linkages between components of the treatment cascade, as well as pilot key programmatic, monitoring and evaluation mechanisms. The review team recommends that these be undertaken at a selected district (Ulaanbaatar) and aimag (rural area) level.

35. Treatment scale up should be done after thorough evaluation of the demonstration project initiatives.

36. Treatment outcomes should be monitored at the population level, with rigorous programmatic monitoring and evaluation.

### Laboratory

37. Validated rapid test kits should form the backbone of viral hepatitis testing in Mongolia, with PCR used for estimating HBV viral load in individuals considering HBV antiviral therapy, and to confirm viraemia in HCV infection.

38. The NHEL should develop a list of approved rapid test kits for use in Mongolia.

39. Mechanisms should be developed to ensure appropriate transportation of specimens for PCR confirmation at the NHEL.

40. Laboratory stock-outs of test kits and reagents should be addressed.

41. Consideration should be given to how all laboratories, including private sector laboratories, can be included in quality management and EQAS procedures.

42. Consideration should be given to developing internal quality management systems for TTI testing.
**Financing**

43. The new National Hepatitis Programme should be costed, including various testing and treatment options.

44. Price negotiation on drugs will be fundamental to the capacity for an effective response.

45. A comprehensive funding strategy, incorporating domestic and external funding, is recommended to ensure sustainable action for addressing viral hepatitis in Mongolia.

**Research**

46. There is a need to support research on the epidemiology and clinical management of HBV/HDV coinfection. This should include exploring international collaborative partnerships.

47. Further exploration should be conducted of the role of injecting drug use in hepatitis transmission in Mongolia.

48. Implementation science questions may be considered.
ANNEX V: Target indicators for the National Strategy on Viral Hepatitis Control (2010–2015)

The following indicators were developed to gauge the success of the current National Strategy on Viral Hepatitis Control in Mongolia.

<table>
<thead>
<tr>
<th>Specifications</th>
<th>Baseline (2009)</th>
<th>2015 targets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevalence of viral hepatitis, population 10 000</td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>Introduced a vaccine against hepatitis A vaccination</td>
<td>0</td>
<td>60%</td>
</tr>
<tr>
<td>Hepatitis A infection, immunization coverage</td>
<td>0</td>
<td>90%</td>
</tr>
<tr>
<td>Hepatitis A cases per 10 000 persons</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Following the birth of the infant within 24 hours hepatitis B vaccine is given</td>
<td>92%</td>
<td>97%</td>
</tr>
<tr>
<td>HBsAg prevalence among children under 5 years</td>
<td>5%</td>
<td>2%</td>
</tr>
<tr>
<td>Doctors and medical professionals’ HBV immunization coverage</td>
<td>0</td>
<td>80%</td>
</tr>
<tr>
<td>Percentage of pregnant women tested for HBsAg, HBeAg</td>
<td>0</td>
<td>60%</td>
</tr>
<tr>
<td>HCV RNA blood test to determine coverage</td>
<td>0</td>
<td>60%</td>
</tr>
<tr>
<td>Acute hepatitis B, C, D, E virus infection in patients treated with antiviral drugs</td>
<td>0</td>
<td>60%</td>
</tr>
<tr>
<td>Rapid viral hepatitis infection is diagnosed by soum hospitals</td>
<td>0</td>
<td>50%</td>
</tr>
<tr>
<td>Hepatitis infection by ELISA is diagnosed by province and city hospitals</td>
<td>0</td>
<td>60%</td>
</tr>
<tr>
<td>Regional laboratory confirmation of viral hepatitis testing laboratory</td>
<td>20%</td>
<td>80%</td>
</tr>
</tbody>
</table>