ABOUT THE N-HEP
These National Hepatitis Elimination Profiles (N-HEPs) bring together data on each country’s epidemiological burden, status of program delivery, and policy environment. Working with local partners, the profiles break down the essential components of effective public health initiatives and highlight achievements, challenges, and innovations for the 30 countries included. The N-HEPs serve as advocacy tools for catalyzing policy development and resource mobilization in pursuit of the 2030 hepatitis elimination goals.

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8 POLICY ENVIRONMENT FOR THE ELIMINATION OF HEPATITIS
20 NEXT STEPS TOWARD ELIMINATION

AT A GLANCE:

<table>
<thead>
<tr>
<th>National Plan</th>
<th>HBV</th>
<th>YES</th>
<th>HCV</th>
<th>YES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elimination Goal</td>
<td></td>
<td>YES</td>
<td></td>
<td>YES</td>
</tr>
<tr>
<td>HepB Birth Dose Coverage</td>
<td>NO DATA</td>
<td>NO DATA</td>
<td>NO DATA</td>
<td></td>
</tr>
<tr>
<td>Number of needles/syringes per PWID per year</td>
<td>NO DATA</td>
<td>NO DATA</td>
<td>NO DATA</td>
<td></td>
</tr>
</tbody>
</table>

BURDEN OF DISEASE

- Prevalence of HBsAg: 0.28%
- Prevalence of chronic HCV: 0.16-0.35%
- Deaths per 100,000: HBV 5.99, HCV 29.61

OVERVIEW OF POLICY ENVIRONMENT

- Insurance claims and health checkups from all hospitals and clinics in Japan are recorded into a national database.
- Japan also has a patient survey on HBV and HCV diagnosis every three years conducted by the Ministry of Health, Labor and Welfare.

NOTABLE ACHIEVEMENT:
There are little to no barriers to prescribing HCV medicines.

KEY CHALLENGE:
The screening systems were set up for particular groups of the population (i.e., blood donors, residents aged ≥40 years, pregnant women, etc) so others are less likely to receive hepatitis screening before 40 years.

KEY NEXT STEPS:
- Reduce barriers to HBV and HCV referral and treatment.
The first national plan for addressing viral hepatitis, “Basic Act on Hepatitis Measures”, was established in 2009 (Act No.97 of the year 2009). Following in 2011, the “Basic Guidelines for Promotion of Control Measures for Hepatitis” was issued by the government, comprising 9 principles of measurement, in order to promote prevention of hepatitis B and C and was updated in 2016.
THE HEALTH BURDEN OF VIRAL HEPATITIS

**Prevalence**

- **0.28%** Prevalence of chronic HBV (HBsAg+), 2017
  - Based on worker health screenings
- **0.16-0.35%** Prevalence of anti-HCV, 2011-2017
  - Based on blood donors and worker health screenings

**Number of persons living with chronic HBV infection, 2020**

- **1.00-1.07M**

**Persons living with chronic HCV infection, 2020**

- **0.47-0.84M**

**Incidence**

- **4.01** Rate of HBV infections per 100,000, 2015-2019
  - Estimated from incidence rate in blood donors
- **0.4 (0.27-0.57)** Rate of new HCV infections per 100,000, 2008-2013
  - Estimated from incidence rate in blood donors

**Mortality**

- **353** HBV-related deaths, 2020
  - Based on national death certificate data
- **0.3 Deaths per 100,000, 2020**
  - Based on national death certificate data
- **1,686** HCV-related deaths, 2020
  - Based on national death certificate data
- **1.4 Deaths per 100,000, 2020**
  - Based on national death certificate data

HCC-related mortality peaked at 27.5 persons/100 000 population in 2002, and thereafter started to decline gradually after the number of national countermeasures.
## PROGRESS TOWARDS 2020 WHO ELIMINATION GOALS

### PREVENTION OF NEW INFECTIONS AND MORTALITY

<table>
<thead>
<tr>
<th>Hepatitis Type</th>
<th>Percentage Change in New Infections</th>
<th>Percentage Change in Deaths, 2015-2020</th>
<th>WHO 2020 Target</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HBV</strong></td>
<td></td>
<td></td>
<td>30%</td>
</tr>
<tr>
<td><strong>HCV</strong></td>
<td></td>
<td></td>
<td>50%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hepatitis Type</th>
<th>Prevalence of HBsAg in Children &lt; 5 years (%)</th>
<th>SDG 2020 Target</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HBV</strong></td>
<td>Based on sero-survey, 2010</td>
<td>1%</td>
</tr>
<tr>
<td><strong>HCV</strong></td>
<td>Modelled, 2019</td>
<td>1%</td>
</tr>
</tbody>
</table>

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*Data as of 2020, based on sero-survey and modelled estimates.*

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*SDG = Sustainable Development Goal*
**ACCESS TO RECOMMENDED VACCINATION**

- **NO DATA**
  - Hepatitis B vaccination coverage for newborns
    - WHO 2020 Target 50%
    - Coverage: 92%
    - WHO 2020 Target 90%

  - HepB 3 dose vaccine coverage for infants (%), 2020
    - 92%

**ACCESS TO RECOMMENDED TESTING**

- **NO DATA**
  - Proportion of persons living with HBV diagnosed (%), 2015
    - 56–62%
    - WHO 2020 Target 30%

  - Proportion of persons living with HCV diagnosed (%), 2015
    - 74–82%
    - WHO 2020 Target 30%

**HBV**

- Proportion of diagnosed HBV persons receiving appropriate treatment
- 0

For persons who inject drugs (PWID), number of sterile needles per year

- WHO 2020 Target 200
OVERVIEW

HEALTH BURDEN

PROGRESS

POLICY ENVIRONMENT

NEXT STEPS

ACCESS TO RECOMMENDED TESTING

Number of persons screened for HBsAg, 2012-2017

2012: 1,106,116
2013: 1,165,637
2014: 1,201,633
2015: 1,206,910
2016: 1,013,403
2017: 967,172

Number of persons screened for HCV, 2012-2018

2012: 1,097,664
2013: 1,151,063
2014: 1,191,633
2015: 1,196,077
2016: 1,003,032
2017: 956,093
2018: 1,250,000
ACCESS TO RECOMMENDED TREATMENT

23.2-29.6%
Proportion of diagnosed HBV persons receiving appropriate treatment (%), 2015

331,780
Number of treatments for HBV, 2016-2021

Number of persons treated for HCV, 2018-2020
## POLICY ENVIRONMENT FOR THE ELIMINATION OF HEPATITIS

### STRATEGIC INFORMATION

<table>
<thead>
<tr>
<th>Status</th>
<th>Notes</th>
</tr>
</thead>
</table>
| Routine official reports to monitor HBV and HCV | 4,22,14
| Mortality         | Adopted                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Incidence         | Adopted                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Prevalence        | Partially Adopted                                                                                                                                                                                                                                                                                                                                                                                                                                                       |

The National Institute on Infectious Diseases (NIID) is required to release reports on acute HBV and HCV based on the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (the Infectious Diseases Control Law).

Large-scale seroprevalence studies have been undertaken since 2007 using two large databases obtained from screening of first-time blood donors by Japan Blood Cross and from hepatitis examinations among residents aged 40 years and over by the health promotion project. No estimates have been made since 2012.

<table>
<thead>
<tr>
<th>Status</th>
<th>Notes</th>
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<tbody>
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</tbody>
</table>

| Estimates of HBV and/or HCV economic burden | 13,30 | Adopted |

Insurance claims and health checkups from all hospitals and clinics in Japan are recorded into the NDB, which contains demographics, diagnosis, medical practice, and drug prescription information of all patients. Japan also has a patient survey on diagnosis of HBV and HCV every three years conducted by Ministry of Health, Labor and Welfare of Japan. Additionally, the local and regional governments have their own system for follow-up of the patients linked with core hospital and/or institution.

<table>
<thead>
<tr>
<th>Status</th>
<th>Notes</th>
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<tbody>
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</tbody>
</table>

| Monitoring of HBV and HCV diagnosis and treatment | 27,31 | Adopted |

Insurance claims and health checkups from all hospitals and clinics in Japan are recorded into the NDB, which contains demographics, diagnosis, medical practice, and drug prescription information of all patients. Japan also has a patient survey on diagnosis of HBV and HCV every three years conducted by Ministry of Health, Labor and Welfare of Japan. Additionally, the local and regional governments have their own system for follow-up of the patients linked with core hospital and/or institution.
**OVERVIEW**

**HEALTH BURDEN**

**PROGRESS**

**POLICY ENVIRONMENT**

**NEXT STEPS**

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**ACHIEVEMENTS**

Since the introduction of anti-HCV screening system to all blood donors in 1990, a nationwide epidemiological study on HCV infection has been conducted in routine intervals

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Japan has conducted an economic evaluation for treatment of viral hepatitis with antivirals

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**INNOVATIONS**

“The Hepatitis Information Centre in NCGM” was established in November 2008 - to support information sharing between hospitals, the medical personnel training and the provision of up-to-date information about hepatitis

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**LEARN MORE ABOUT STRATEGIC INFORMATION:**

- The Hepatitis Information Centre in NCGM was established in November 2008 to support information sharing between hospitals, the medical personnel training, and the provision of up-to-date information about hepatitis.
PREVENTION OF MOTHER TO CHILDREN TRANSMISSION

Universal policy for hepatitis B vaccination of newborns 14,17

Status: Partially Adopted

Notes: In 2016, HBV prevention shifted from targeted vaccination of infants of HBV-infected mothers to universal vaccination of all infants (not birth dose), and “targeted” birth dose vaccine for babies born to HBsAg-positive mothers.

Recommendations for:

- **HBV** testing of pregnant women 14
  - Status: Adopted

- **HCV** testing of pregnant women 1
  - Status: Adopted

LEARN MORE ABOUT JAPAN'S WORK IN **PREVENTION OF MOTHER TO CHILD TRANSMISSION**:

**ACHIEVEMENTS**

Since January 1986, hepatitis B vaccination with HBIG to babies born to HBV carrier mother have been available free of charge. Since April 1995, health insurance covers this as well.

In 2015, prevention guidelines were modified so that all children born to pregnant women positive for HBsAg, irrespective of their HBeAg status, were given HBIG and HepB vaccine at birth simultaneously, followed by another two doses of HepB vaccine at 1 month and 6 months of age.
### ACCESS AND REGISTRATION OF MEDICINES AND TESTS

<table>
<thead>
<tr>
<th>Status</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Registration of originator DAA</strong>s</td>
<td>Adopted</td>
</tr>
</tbody>
</table>

Eligible for generic DAA

Not Eligible

Registration of generic DAA

Not Applicable

Licensed point-of-care PCR testing to detect HBV and HCV

Not Adopted

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**LEARN MORE ABOUT JAPAN’S WORK IN ACCESS AND REGISTRATION OF MEDICINES AND TESTS:**

**ACHIEVEMENTS**

Globally, Japan is one of a few countries providing nearly unrestricted access to DAA therapies

**INNOVATIONS**

A rapid diagnostic test for hepatitis B core-related antigen (HBcrAg-RDT) has been recently developed in Japan with promising results to identify HBV-infected people with high viremia. Studies to evaluate its performance are ongoing in several African/Asian countries with limited access to HBV DNA PCR, and the HBcrAg-RDT will be commercialized soon in 2023.
<table>
<thead>
<tr>
<th>Testing recommendations for:</th>
<th>Status</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HBV:</strong> Risk-based ¹</td>
<td>Adopted</td>
<td>Japan has two HBV and HCV screening pathways: One is for those over 40 years through the “Project of Health Promotion Service” and the other is for all residents irrespective of age via the “Project of screening for specific infectious diseases by respective prefectures” for persons with national health insurance</td>
</tr>
<tr>
<td><strong>HCV:</strong> Risk-based ²³</td>
<td>Adopted</td>
<td></td>
</tr>
<tr>
<td><strong>HBV:</strong> Universal ¹</td>
<td>Adopted</td>
<td></td>
</tr>
<tr>
<td><strong>HCV:</strong> Universal ¹</td>
<td>Adopted</td>
<td></td>
</tr>
<tr>
<td>No patient co-pays for HBsAg and anti-HCV testing ⁷⁴</td>
<td>Adopted</td>
<td>Health insurance/Government funded screening &gt; 40 years</td>
</tr>
</tbody>
</table>
LEARN MORE ABOUT JAPAN’S WORK IN TESTING TO DIAGNOSE HBV AND HCV INFECTION:

ROADBLOCKS

Although all persons are recommended for screening, the screening systems were set up for particular groups of the population (blood donors, residents aged ≥40 years, pregnant women, and hospitalized patients recommended by doctors with sound reasons). The remaining population are less likely to receive hepatitis screening before the age of 40 years.

The government does not subsidize screening of general workers for viral hepatitis, and the coverage of screening is at the discretion of each health insurance union and company. Local governments do not conduct hepatitis screening in conjunction with workplace health check-ups, and hepatitis virus testing system is not sufficiently widespread in the workplace. Some workplaces lack medical staff, including staff to obtain informed consent for testing, manage the test results, and refer employees found to be positive for treatment.

ACHIEVEMENTS

The government recently mandated by law that viral hepatitis screening should be carefully performed during mandatory health examinations.

The Ministry of Health, Labour and Welfare (MHLW) of Japan introduced the initial 5-year project (2002-2006) for the national screening of HBV and HCV among all residents at and over 40 years old.

The government covers the cost for screening of hepatitis virus to all residents at the nearest health center and also provides the medical expenses for the first detail examination if positive result after screening.
### ACCESS TO HBV AND HCV TREATMENT

<table>
<thead>
<tr>
<th>Status</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Developed</td>
<td>Current guidelines recommend for individuals to begin treatment in institutions that specialize in hepatitis treatment</td>
</tr>
<tr>
<td>Not Adopted</td>
<td>The out-of-pocket monthly maximum for HBV or HCV treatment is 20,000 Yen for households making more than 235,000 yen per year and 10,000 yen or less for households making less than that</td>
</tr>
<tr>
<td>Partially Adopted</td>
<td>Intensive follow-up is required</td>
</tr>
<tr>
<td>Adopted</td>
<td></td>
</tr>
</tbody>
</table>

**HBV: National treatment guidelines**

**HBV: Simplified care:**
- Simplified treatment and monitoring algorithm for primary care providers

**HBV: Simplified care:**
- No patient co-pays for treatment

**HCV: National treatment guidelines**

**HCV: Simplified care algorithm:**
- Less than 2 clinic visits during treatment

**HCV: Simplified care algorithm:**
- Non-specialists can prescribe treatment

**HCV: Simplified care:**
- No patient co-pays for treatment
<table>
<thead>
<tr>
<th>No fibrosis restrictions</th>
<th>Adopted</th>
</tr>
</thead>
<tbody>
<tr>
<td>No sobriety restrictions</td>
<td>Adopted</td>
</tr>
<tr>
<td>No genotyping</td>
<td>Adopted</td>
</tr>
</tbody>
</table>
LEARN MORE ABOUT JAPAN’S WORK IN ACCESS TO HBV AND HCV TREATMENT:

ACHIEVEMENTS

In 2007, the Ministry of Health, Labor and Welfare issued the “Notice on the Establishment of Liver Disease Care Systems” (Notice No. 0419001 issued by the Director of the Health Service Bureau, MHLW) which initiated the construction of liver disease care systems nationwide, starting with regional core centers and specialized institutions. Currently, at least one regional core center is designated in each prefecture, with a total of 71 institutions nationwide, all of which have established liver disease consultation and support centers to provide support to patients and their families. Specialized institutions are selected by the Council for Promotion of Hepatitis Measures in each prefecture and are required to i) make a diagnosis and determine a treatment strategy, as recommended by specialists; ii) appropriately implement antiviral therapy; and iii) identify groups at high risk of liver cancer and perform early diagnosis. Over 3,000 specialized medical institutions have been designated nationwide.

The government provides subsidies to cover antiviral therapy expenses for all persons.

There are little to no barriers to prescribing antiviral drugs or direct-acting antiviral drugs (DAAs) to patients with hepatitis C for patients with health insurance.

In March 2017, the Ministry of Health, Labor and Welfare issued the “Notice on the Establishment of Liver Disease Care Systems and Support Systems for Liver Disease Patients” (Notice No. 0331-8 issued by the Director of the Health Service Bureau, MHLW; hereafter referred to as the “new notice”). The new notice, while maintaining the previous basic policies, set out the following new basic approaches: i) setting of goals and milestones; ii) establishment of a system to ensure the smooth linkage of hepatitis screening, examination, treatment, and follow-up; iii) realization of patient-centered liver disease care; iv) improvement of and elimination of disparities in liver disease care; and v) provision of consultation and appropriate support for hepatitis patients.

ROADBLOCKS

For eligibility of using such the insurance coverage program, the patients have to submit an application to the prefecture office with a recommendation from a designated hepatologist or gastroenterologist.

INNOVATIONS

The national program has established hepatitis medical care coordinators (HMCC), who are specialized personnel expected to support patients and their families in every aspect of the cascade of care. Through the end of March 2019, 16,546 HMCCs were certified in Japan.

In the Severe Disease Prevention Project, which started in April 2014, the prefectural government or other authority, after obtaining the consent of the individual, confirms the status of visits to medical institutions and medical treatment by sending a survey sheet once a year and, if the individual has not yet visited a hospital, recommends that the individual visits a specialist and receives medical consultation by telephone or other means.
## HEALTH EQUITY AND ADDRESSING DISPARITIES

<table>
<thead>
<tr>
<th>National strategy addresses populations most affected (^7)</th>
<th>Partially Adopted</th>
</tr>
</thead>
<tbody>
<tr>
<td>National anti-discrimination laws against persons living with hepatitis B and/or C (^7,^{14})</td>
<td>Adopted</td>
</tr>
<tr>
<td>National policy for adult hepatitis B vaccination (^4,^{32})</td>
<td>Adopted</td>
</tr>
<tr>
<td></td>
<td>High risk populations are recommended to receive HepB vaccine and can access it for free, including healthcare workers</td>
</tr>
</tbody>
</table>

### National policy for:

<table>
<thead>
<tr>
<th>Harm reduction for persons who inject drugs (PWID) (^2,^{25})</th>
<th>Not Developed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syringe exchange in federal prisons (^2,^{25})</td>
<td>Not Adopted</td>
</tr>
</tbody>
</table>

| At least one needle-syringe exchange program (NSP) operational \(^2,^{25}\) | Not Adopted |

| Decriminalization of drug use \(^6,^{25}\) | Not Adopted |

In 2017, courts in Japan began to show moderation in sentencing people who use drugs. In addition, there have been increasing incidences where Japanese courts have shown moderation, moving from harsh sentencing towards community rehabilitation.
LEARN MORE ABOUT JAPAN’S WORK IN HEALTH EQUITY AND ADDRESSING DISPARITIES:

**ROADBLOCKS**

Despite recommendations, routine measures to screen healthcare workers are not universally in place.

Despite recommendations, high-risk groups are not routinely vaccinated for HBV.

Funding for harm reduction work in Japan is negligible, and the Japan Advocacy Network for Drug Policy (JANDP) only receives minimal funding from the Open Society Foundations for its advocacy activities.

Though antiretroviral therapy is available free of charge for some and low cost for others, individuals are hesitant to inform practitioners that they inject drugs as there is the high risk of being reported to police.

**INNOVATIONS**

The “Shitte kan-en” project was launched by the Ministry of Health and Labor Workforce to leverage popular Japanese athletes, actors and singers as delegates for building public awareness around hepatitis to target early detection and treatment by highlighting the importance of testing.

**ACHIEVEMENTS**

The Japan Advocacy Network for Drug Policy (JANDP) is a multidisciplinary collective working to increase and strengthen the debate on drug policy alternatives in Japan. JANDP gained membership of the New York Non-Governmental Organisation Committee on Drugs and is currently being considered for affiliation with the Vienna Non-Governmental Organisation Committee on Narcotic Drugs.
## FINANCING

<table>
<thead>
<tr>
<th>Status</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Public budget line for HBV and HCV testing and treatment</strong>&lt;sup&gt;1&lt;/sup&gt;</td>
<td><strong>Adopted</strong></td>
</tr>
</tbody>
</table>
NEXT STEPS TOWARD ELIMINATION

Increase awareness of viral hepatitis by increasing education on transmission and importance of testing.

Collaborate with employers to establish a hepatitis workplace program, so that individuals with hepatitis can continue working while receiving treatment for hepatitis.

Expand hepatitis C screening and improve strategies to link patients to care.

Establish effective processes to identify high-risk sub-populations.

Reduce barriers to referral and treatment.

Establish survey on the burden of HBV and HCV among persons who inject drugs to inform investments in harm reduction.
SOURCES


13. The Institute for New Era Strategy (2020). Japan should accelerate measures to achieve WHO 2030 hepatitis C elimination targets as it will provide significant clinical and economic benefits. https://www.globalhep.org/sites/default/files/content/news/files/2020-11-Japan%20should%20accelerate%20measures%20to%20achieve%20WHO%202030%20hepatitis%20C%20elimination%20targets%20as%20it%20will%20provide%20significant%20clinical%20and%20economic%20benefits.pdf


34. Communication with Prof. Yasu Tanaka-Kumadai


WORKING TOGETHER,
WE WILL ACHIEVE ELIMINATION.

This National Hepatitis Elimination Profile (N-HEP) was developed by the Coalition for Global Hepatitis Elimination. Funding for this N-HEP was provided by Gilead Sciences. The Coalition for Global Hepatitis Elimination retained final control over the content.

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