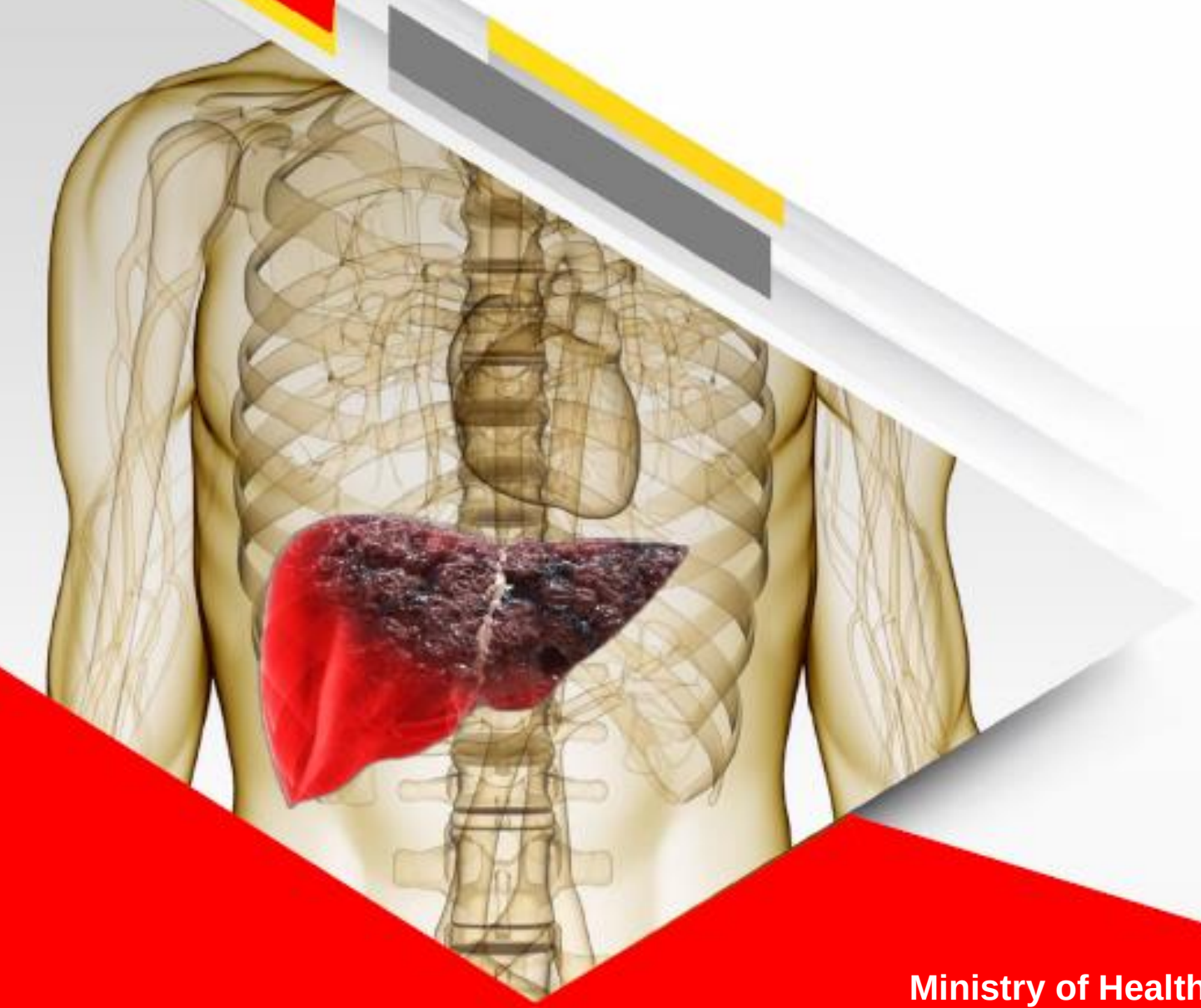
NATIONAL STRATEGIC PLAN FOR HEPATITIS B AND C 2019 - 2023



Ministry of Health
Malaysia
2019

NATIONAL STRATEGIC PLAN FOR HEPATITIS B AND C MALAYSIA 2019 - 2023

Prepared by

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Acronyms and Abbreviations

CME	Continuous Medical Education
DALY	Disability-Adjusted Life Year
DCD	Disease Control Division
EPI	Expanded Programme for Immunisation
FHDD	Family Health Development Division
IEC	information, education, and communication
HBV	hepatitis B virus
HBsAg	hepatitis B surface antigen
HCC	hepatocellular carcinoma
HCV	hepatitis C virus
HCWs	healthcare workers
MAA	Malaysia Medical Association
MDD	Medical Development Division
MINDEF	Ministry of Defense
MOE	Ministry of Education
MOH	Ministry of Health
MOHA	Ministry of Home Affairs
NADA	National Anti-Drug Agency
NGO	non-governmental organisation
NIOSH	National Institute of Occupational Safety and Health
NSEP	needle and syringe exchange programme
NSP	National Strategic Plan
NSPHBC	National Strategic Plan for Hepatitis B and C
POCT	point-of-care testing
PWID	people who inject drugs
UKK	Corporate Communication Unit (*Unit Komunikasi Korporat*)

Foreword

First of all, I would like to congratulate the Ministry of Health's Disease Control Division and Gastroenterology & Hepatology Services, as well as relevant stakeholders, for their hard work and commitment in documenting and publishing the National Strategic Plan for Hepatitis B and C (NSPHBC).

Viral hepatitis remains as one of the public health concerns in the country. It is estimated that in 1998 one million people were chronically infected with hepatitis B virus (HBV)[1] while in 2009; 453,700 were infected with hepatitis C virus (HCV)[2] . Hence, it is crucial that appropriate measures are taken to reduce the burden of disease related to viral hepatitis. With the current technology in expediting screening and diagnosis of the disease, as well as the availability of effective and affordable treatment, it is not impossible to prevent and treat viral hepatitis and even cure viral hepatitis in context of HCV infection.

The NSPHBC is a documentation of a structured and comprehensive strategy and plan of action for the planning, implementation, monitoring and evaluation of viral hepatitis prevention, testing, treatment and care programmes in the country. This is in line with the country's commitment towards combating viral hepatitis. The NSPHBC will be a guidance to all relevant stakeholders, from top management to implementers, in our effort to combat viral hepatitis.

I believe and am confident that with the commitment from all stakeholders, including the private sector, relevant government agencies and non-governmental organisations (NGO), our goal towards eliminating viral hepatitis especially hepatitis B and C will become reality.

(Datuk Dr Noor Hisham Abdullah)
Director General of Health

EXECUTIVE SUMMARY

The burden of viral hepatitis in the country has been increasing. It is estimated that 1.1%[3] and 2.5%[2] of the population in the country were infected with hepatitis B virus and hepatitis C virus in 2017 and 2009, respectively. Furthermore, a high disease burden also means more cases of complications resulting from viral hepatitis infection, such as liver cirrhosis and hepatocellular carcinoma. Viral hepatitis is generally preventable, treatable and potentially curable. Thus, it is crucial that appropriate intervention measures are put in place. With the latest advances in technology relating to screening and diagnosis of the disease, as well as the availability of effective and affordable treatment, the prevention, treatment and cure of viral hepatitis are now possible

Malaysia has committed towards combating viral hepatitis by 2030. In working towards achieving this commitment, a national strategic plan has been developed; the first for the country. This National Strategic Plan for Hepatitis B and C (NSPHBC) documents a structured and comprehensive strategy and plan of action for the planning, implementation, monitoring and evaluation of viral hepatitis programmes and activities in the country. The NSPHBC is intended for the use by all stakeholders at various levels, from policy makers to implementers.

The objectives of this NSPHBC are:

- To establish and strengthen national policies for the prevention, control, diagnosis, treatment and care of viral hepatitis B and C.
- To prevent the transmission of viral hepatitis B and C.
- To reduce the morbidity and mortality of viral hepatitis through early detection and effective case management.
- To improve the survival and quality of life among individuals with chronic liver disease.
- To promote partnerships with relevant stakeholders for the prevention, control, diagnosis, treatment and care of viral hepatitis B and C.

This NSPHBC outlines five key strategic areas:

Strategy 1	:	Advocacy, communication and social mobilisation
Strategy 2	:	Quality and coverage of prevention programmes
Strategy 3	:	Access to diagnostic, treatment and care services
Strategy 4	:	Quality strategic information, monitoring and evaluation, and research
Strategy 5	:	Capacity building and enhancement

The targets to be achieved by 2030 are;

- To diagnose 90% of the population living with viral hepatitis.
- To reduce the number of new cases of viral hepatitis by 90%.
- To reduce mortality due to viral hepatitis by 65%.
- To treat 90% of the population in need of treatment.

The action plan outlined to guide the implementation of activities to address the key strategies and to achieve the targets set mainly focus on the following:

a) Promoting the awareness of viral hepatitis among healthcare providers, the general population and high-risk groups;
b) Strengthening the professional training for viral hepatitis management;
c) Establishing a national-level steering group for the strategic planning and governance of viral hepatitis management;
d) Upscaling the screening for viral hepatitis, especially in high-risk groups and antenatal mothers;
e) Strengthening the current system for blood and blood product screening;
f) Sustaining the coverage for HBV vaccination;
g) Improving and upscaling the existing harm reduction programmes;
h) Expanding the coverage, ensuring the sustainability and improving the patient adherence for hepatitis B and C treatment;

i) Strengthening the current notification system, developing a centralised monitoring system or patient registry, establishing a domestic laboratory network and encouraging research activities for viral hepatitis;

j) Strengthening the collaboration with non-governmental organisations via knowledge sharing.

The NSPHBC also outlines the proposed budget requirements for five years from 2019 to 2023. A midterm review and a second evaluation are to be carried out, in 2021 and 2023 respectively.

CHAPTER 1: INTRODUCTION

1.1 BACKGROUND

Globally, viral hepatitis is responsible for 1.45 million[4] deaths every year – higher than the 1.3 million deaths caused by HIV/AIDS and 1.4 million deaths caused by tuberculosis[5]. Viral hepatitis is the seventh most common cause of mortality[4], and of all the viral hepatitis-related deaths, approximately 48% are attributable to HBV and HCV[4], respectively. HBV and HCV infections share the same transmission routes, particularly unsafe injection practices, sexual transmission and mother-child transmission. It is estimated that 39% of the global mortality related to hepatitis occurred in the Western Pacific Region[6]. The complications of chronic hepatitis B and C infections – cirrhosis (end-stage liver fibrosis) and liver cancer – are responsible for 94% of the deaths associated with hepatitis infections in the region[6].

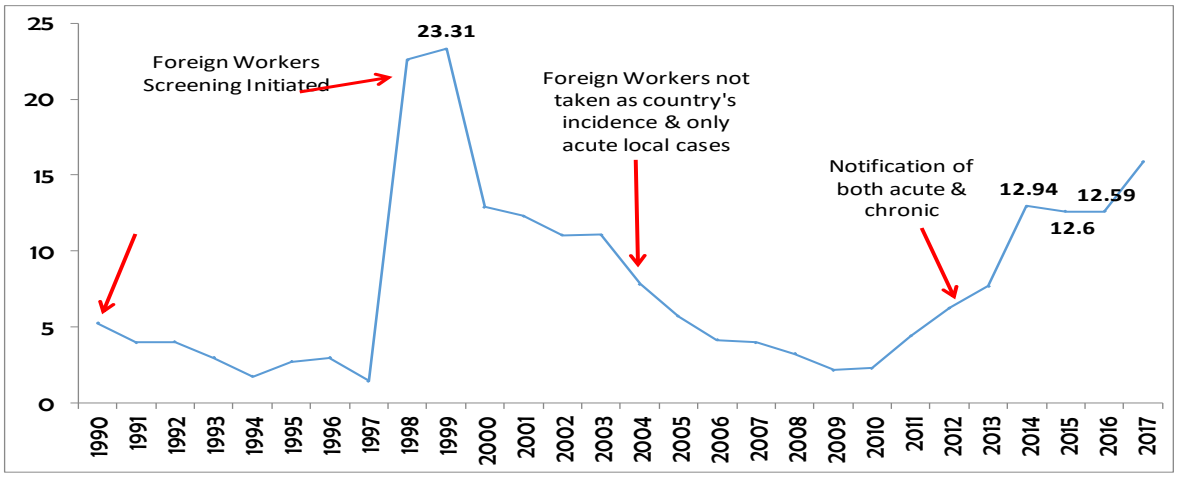
In Malaysia, viral hepatitis, most commonly hepatitis A, B and C poses a public health concern. In 2010, the notification of viral hepatitis was made mandatory under the First Schedule of Control and Prevention of Communicable Disease Act 1988[7]. Liver diseases, including both cirrhosis and liver cancer, were also reported to be the sixth most common cause of deaths in Malaysia between 2013 and 2015. In 2010, the notification of viral hepatitis was made mandatory under the First Schedule of Control and Prevention of Communicable Disease Act 1988.

1.1.1 HEPATITIS B IN MALAYSIA

The incidence rate of hepatitis B has since increased from 2.26 per 100,000 in 2010[8] to 12.65 per 100,000 population in 2015[9].

Up till 2017, 35,861 cases of hepatitis B had been notified to the Ministry of Health (MOH)[10]. The incidence rate of hepatitis B was reported to have increased from 2.26 per 100,000 in 2010[8] to 12.65 per 100,000 population in 2015[9] (**Figure 1**). Most of the hepatitis B patients were born in the pre-vaccination era, with approximately 45% to 50% of them aged between 20 to 40 years. Males outnumbered females with a ratio of 3:1. More than 50% of them were Malay. Most of hepatitis B patients also had a history of intravenous drug use[10].

Figure 1: Notification rate (per 100,000 population) of hepatitis B in Malaysia, 1990 – 2017

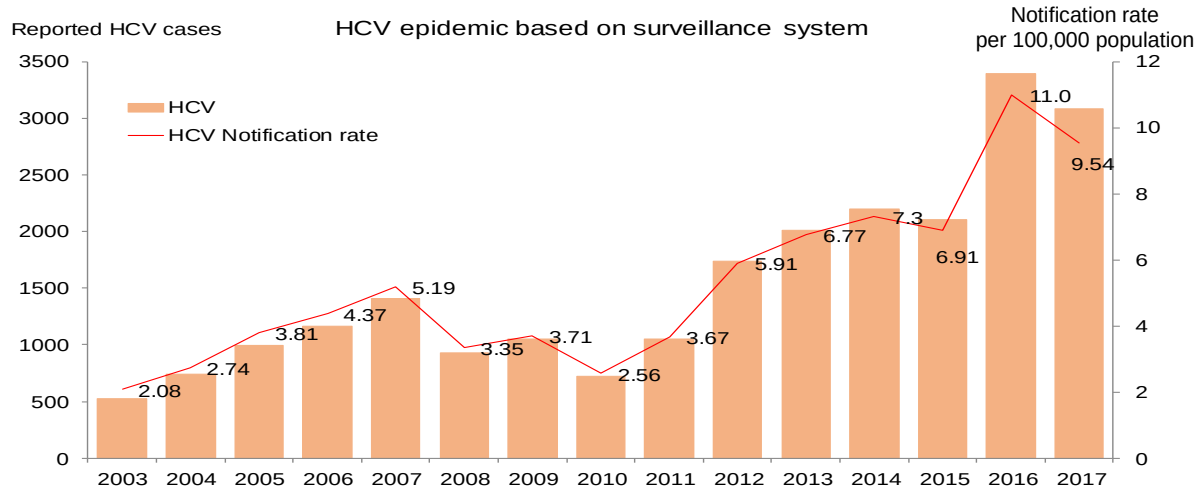


Source: Ministry of Health[11]

1.1.2 HEPATITIS C IN MALAYSIA

A total of 23,112 hepatitis C cases had been notified to the MOH between 2003 and 2017[10]. The notification rate peaked in 2016 at 11.0 per 100,000, and slightly reduced to 9.54 per 100,000 in the following year (Figure 2)[11]. It was also reported that the incidence of hepatitis C had increased from 2.56 per 100,000 in 2010[8] to 6.91 per 100,000 population in 2015[9]. Similar in males and females, slightly more than 50% of the patients were aged between 26 and 45 years. More than 80% of the patients were of Malay ethnicity. Most patients (72%) were diagnosed with hepatitis C at hospitals when seeking treatment for symptoms, while less than 30% of the patients were diagnosed at health clinics[10].

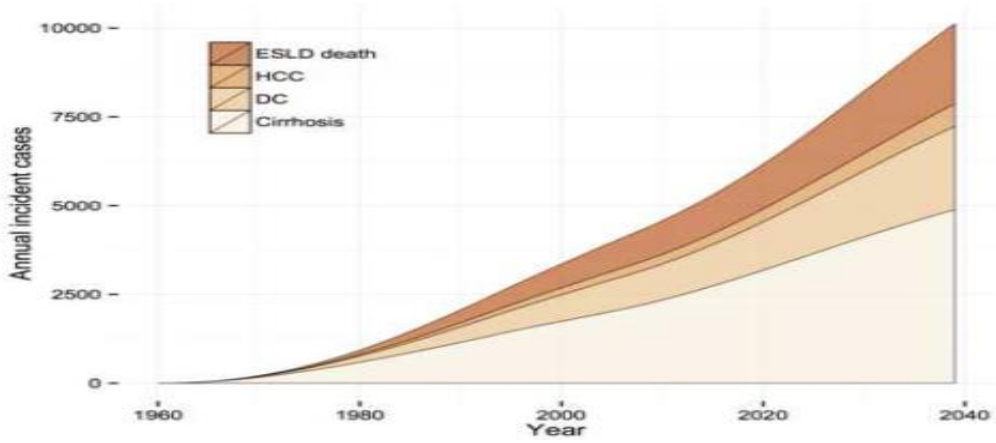
Figure 2: Number of cases and notification rate (per 100,000 population) of hepatitis C in Malaysia, 2003 – 2017



Source: Ministry of Health[11]

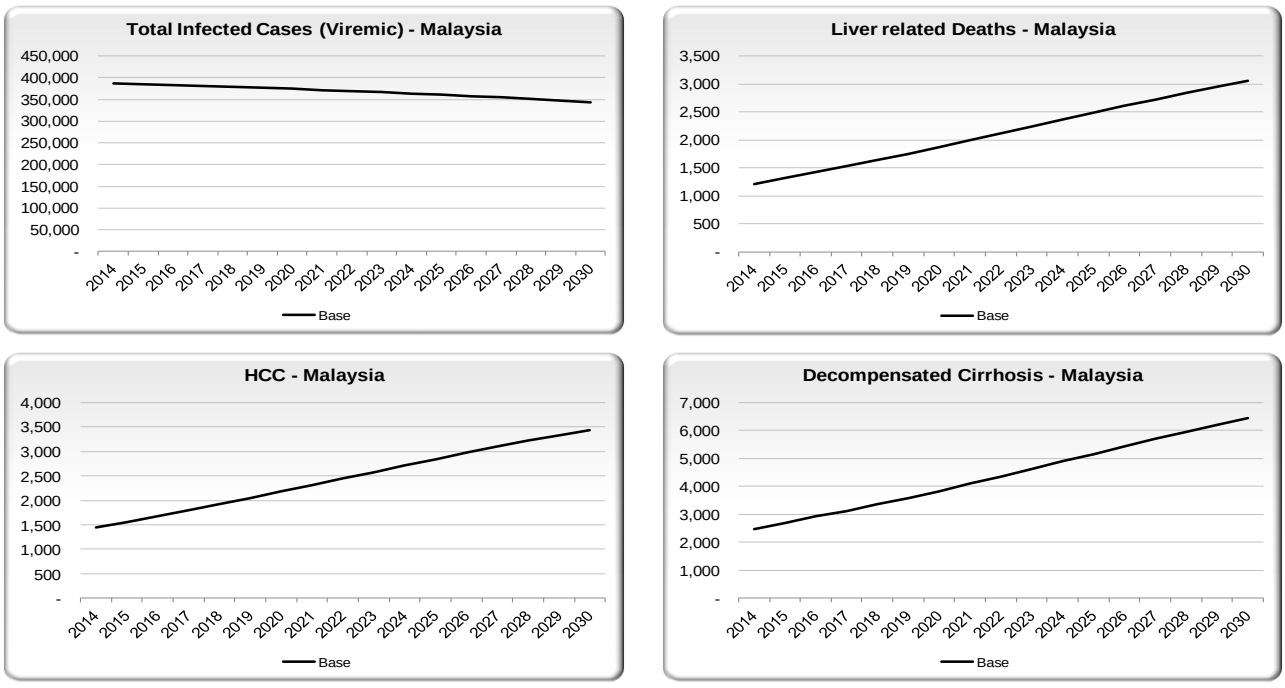
A 2014 modelling study by McDonald et al. estimated that in 2009, 2.5% of the adult population in Malaysia were anti-HCV positive (95% CrI: 2.2-3.0%), of whom 59% (95% CrI: 50-68%) acquired their infection through injecting drugs[12]. The burden of liver disease due to viral hepatitis was also projected to continue to rise, as shown in the Figure 4.

Figure 3: Projection of current and future disease burden of hepatitis C infection in Malaysia.



Source: McDonald et al

Figure 4: Projections of hepatitis C infection and its complication, Malaysia, 2014 - 2030.



Source: Razavie at al,

Without a coordinated response to the hepatitis epidemic, the burden of viral hepatitis in the country will likely to continue to increase. Based on modelled projections, it is anticipated that the number of chronic hepatitis C will continue to rise to reach 523,500 in 2039 if preventive, control, treatment and care measures are not enhanced. The disease burden is predicted to increase to 94,900 DALYs/year of which 47% is from premature mortality. At the same time, it is anticipated that 2,002 (95% CrI: 1,340–3,040) patients with hepatitis C will progress to decompensated cirrhosis while 540 (95% CrI: 251–1030) will develop hepatocellular carcinoma (HCC) in 2039. These complications will incur greater costs for treatment and care[13].

1.2 THE CURRENT NATIONAL POLICY AND PROGRAMMATIC RESPONSE

1.2.1 SCREENING AND TESTING

Hepatitis B and hepatitis C screening have been mainly performed at hospitals and at central and regional laboratories (except for the screening performed for blood donors and foreign workers). With the availability rapid diagnostic tools as well as viral load machines for point-of-care testing (POCT), decentralization of screening for viral hepatitis is possible in the future. Currently, apart from those with signs and symptoms, the following high-risk groups are the main target of screening:

i. Blood Donors

All blood donations are screened for HBV and HCV. The screening for hepatitis B surface antigen (HBsAg) among blood donors was started in 1974, while anti-HCV screening was started in 1992 at the Blood Services Centre of the Hospital Kuala Lumpur[14], which was then expanded nationwide in 1994. In 2016, Hepatitis B surface antigen (HbsAg) and hepatitis C antibody (anti-HCV) were detected in 0.13% and 0.04% of the blood donors[10].

ii. Healthcare workers (HCWs)

The Occupational Health Unit in the MOH reported an incidence rate of 4.7 needlestick injuries per 1,000 HCWs in 2005[15]. HCWs with needlestick injuries have been screened for both HBV and HCV and treated accordingly. A guideline was also developed to ensure standardised treatment and post-exposure management for these cases.

iii. People who inject drugs (PWID) participating in harm reduction programmes

PWID receiving methadone maintenance treatment (MMT) have been screened for HBV and HCV. In 2017, the percentage of HBV- and HCV-infected PWID receiving MMT was reported to be 2.9% and 18.6%, respectively[10]. PWID who were enrolled in the needle- and syringe-exchange programme (NSEP) are also advised to receive not only HIV screening but also HBV and HCV screening as of 2017.

iv. Foreign workers

HBV screening was first introduced in the Foreign Workers' Medical Examination (FONEMA) in 1998. Foreign workers with a reactive HBsAg test result are not to be allowed to work in the country. In 2017, 0.3% of foreign workers were found to have a reactive HBsAg test result[10].

With the availability rapid diagnostic tools as well as viral load machines for point-of-care testing (POCT), decentralization of screening for viral hepatitis is possible in the future.

1.2.2 VIRAL HEPATITIS SURVEILLANCE AND NOTIFICATION

Viral hepatitis is a notifiable disease under the Prevention and Control of Infectious Diseases Act 1988 (Act 342)[7]. An online notification system known as e- Notification has long been used to gather information about all types of acute and chronic viral hepatitis, including hepatitis B and C. However, the current notification system does not capture the risk factors of infections, treatment outcomes, disease progression and survival.

1.2.3 PREVENTION

i. Hepatitis B vaccination

The hepatitis B vaccination program for infants was introduced in 1989. The three doses vaccination are, respectively, given at birth (within 24 hours of birth), one month and six months of age. A seroprevalence study showed that the prevalence of HbsAg in children born after the implementation of the program was lower than those born before the implementation of the program (0.3% versus 1.7-1.8%)[16].

Hepatitis B vaccination has also been given to HCWs, who actively manage patients or their clinical specimens, since 1989[2].

ii. Harm reduction programmes

The MMT and the NSEP were launched by the MOH in 2005/2006 in partnership with non-governmental organisations (NGOs) and private health practitioners. They are mainly funded by the Malaysian government, with technical assistance provided by WHO, UNAIDS and UNODC. The proportion of anti-HCV positive MMT patients had decreased from 52.8% in 2006 and to 18.6% in 2017[10]. In 2015, the distribution of 58 needles and syringes per person was recorded[10].

1.2.4 TREATMENT, TESTING AND CARE

Treatment and clinical monitoring are mainly performed by gastroenterologists and hepatologists in hospitals. Patients are required to undergo an assessment prior to and during the therapy. Confirmatory testing and monitoring such as anti-HBV and HBeAg tests, HCV RNA and genotyping have been conducted by hospital-based laboratories or other designated regional laboratories.

The availability of direct acting antiviral (DAA) drugs, specifically sofosbuvir at an affordable price in Malaysia since September 2017 has provided hope in curing more HCV infection cases in the near future. A drug combination of sofosbuvir and ravidasvir has been shown to be safe and effective with an extremely high cure rate of 97%[17].

1.2.5 HEALTH EDUCATION

Since 2008, MOH has been encouraging the screening for hepatitis B and C in the general public and vaccination for those found to be HBsAg negative. The public education about viral hepatitis was further strengthened with the introduction of World Hepatitis Day, which has been celebrated on 28 July each year since 2011. Health education materials for viral hepatitis are also made available at www.myhealth.gov.my. Nevertheless, to date, the awareness of viral hepatitis is still limited in Malaysia.

1.3 RATIONALE

The Government of Malaysia is concerned by the increasing trend of viral hepatitis in the country. It is crucial that Malaysia has its National Strategic Plan (NSP) for viral hepatitis, to align the country's efforts to combat viral hepatitis by 2030 with its commitment towards the Sustainable Development Goal (SDG), *(Item 3.3: By 2030,*

end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases).

The National Strategic Plan for Hepatitis B and C (NSPHBC), which is the first for the country, is to be used as a guide for programme implementers and stakeholders. It outlines the strategies and plan of actions, as well as the overall financial requirements. This structured plan also optimises the existing programme on viral hepatitis and resources, working in smart partnership and implementing cost-sharing models with relevant stakeholders.

1.4 DEVELOPING THE NATIONAL STRATEGIC PLAN FOR HEPATITIS B AND C 2019 - 2023

The national strategic plan for viral hepatitis cover the period of 2019 – 2023.

A technical working group of experts from various backgrounds, government and non-government, was involved in the developing the NSPHBC. The process was initiated since mid-2014, through a series of meetings, consultations and workshops. These were convened i) to discuss, identify and recommend priority issues in combating viral hepatitis; ii) to identify challenges, gaps and needs for capacity building and financial inputs; and iii) to discuss and recommend indicators for the monitoring and evaluation of the plan for the period of 2019 - 2023.

An action plan was developed to facilitate the implementation at all levels. The costing and budgeting for the implementation of the action plan was conducted on 17th – 20th January 2017 and reviewed on 8th – 12th August 2018 to ensure that the costs of the proposed interventions and activities in the NSPHBC were properly estimated.

The NSPHBC was endorsed on 22nd July 2019 and this document can be accessed online through the MOH website.

CHAPTER 2: NATIONAL STRATEGIC PLAN FOR HEPATITIS B AND C 2019 – 2023

2.1 VISION

To prevent and control hepatitis B and C, towards their elimination.

2.2 MISSION

To decrease the transmission of viral hepatitis, limit the complications and to reduce the socioeconomic impact of viral hepatitis in Malaysia.

2.3 OBJECTIVES

2.3.1 To establish and strengthen national policies for the prevention, control, diagnosis, treatment and care of viral hepatitis.

2.3.2 To prevent the transmission of viral hepatitis.

2.3.3 To reduce the morbidity and mortality of viral hepatitis through early detection and case management.

2.3.4 To improve the survival and quality of life among individuals with chronic liver disease.

2.3.5 To promote partnerships with relevant stakeholders for the prevention, control, diagnosis, treatment and care of viral hepatitis B and C.

2.4 STRATEGIC TARGETS

While this NSPHBC document and the accompanying action plan are for the time frame 2019-2023, the overall strategic targets are set for 2030, to be in line with the WHO target of combating hepatitis B and C to reach elimination by 2030[18].

The targets of NSPHBC to be achieved by 2030 are;

2.4.1 To diagnose 90% of the population living with viral hepatitis.

2.4.2 To reduce the number of new cases of viral hepatitis by 90%.

2.4.3 To reduce mortality due to viral hepatitis by 65%.

2.4.4 To treat 90% of the population in need of treatment.

2.5 STRATEGIES

There are five main strategies to be undertaken under this plan, namely:

Strategy 1 : Advocacy, communication and social mobilisation

Strategy 2 : Quality and coverage of prevention programmes

Strategy 3 : Access to diagnostic, treatment and care services

Strategy 4 : Quality strategic information, monitoring and evaluation, and research

Strategy 5 : Capacity building and enhancement

2.5.1 STRATEGY 1: ADVOCACY, COMMUNICATION AND SOCIAL MOBILISATION

The National Strategic Plan for Hepatitis B and C (NSPHBC) will focus on empowering healthcare providers and communities on viral hepatitis, thus decreasing their ignorance about the matter. To increase public and healthcare provider awareness, education and training campaigns on viral hepatitis will be conducted, including building awareness among public health policy and decision makers. In order to achieve success in responding to viral hepatitis, communities, healthcare providers and policymakers must be aware of the extent of the hepatitis epidemic in the country and within various communities, and its health consequences, including related liver disease.

Key activities:

i. Promote and strengthen viral hepatitis education and awareness among healthcare professionals and providers.

ii. Promote and strengthen viral hepatitis awareness among the community and the general public.

iii. Promote and strengthen viral hepatitis awareness among targeted populations, including those at high risk of infection and/or the serious consequences of viral hepatitis infection, especially hepatitis B and C.

iv. Address stigma and discrimination in the awareness and communications strategy. Awareness building should be appropriate to the targeted population and avoid reinforcing stigma and discrimination.

v. Affected groups or those at risk of infection should be recognised and invited to actively participate in viral hepatitis management development processes, whenever necessary.

vi. Integrate viral hepatitis prevention and treatment into healthcare professionals' training curricula to promote the development of a hepatitis literate workforce.

vii. Recognise and carry out hepatitis-related activities on World Hepatitis Day and beyond.

2.5.2 STRATEGY 2: QUALITY AND COVERAGE OF PREVENTION PROGRAMMES

The NSPHBC will focus on the effort to curb viral hepatitis transmission by improving the quality and coverage of prevention activities. The strategy will address three primary prevention efforts namely screening, vaccination and harm reduction.

a) Strategy 2.1: Strengthening screening for viral hepatitis

Individual or targeted populations, who are at high risk for viral hepatitis infection specifically HBV and HCV must be screened. In Malaysia, these include people who inject drugs (PWID), prisoners (during incarceration and post-release), sub-populations among non-Malaysian citizens, and men who have sex with men (MSM), among others. The availability of highly performance and rapid diagnostic kits such as those for HCV at a reasonable cost must be considered for better screening coverage.

Key activities:

i. Promote and strengthen viral hepatitis screening for individuals/groups who are at high risk of infection.

ii. Establish HBsAg screening of pregnant women at their initial prenatal visit.

iii. Expand viral hepatitis screening to primary healthcare with the availability of POCT tools/rapid diagnostic kits.

iv. Ensure safe blood supply by strengthening national blood/blood product screening for HBV and HCV.

v. Support the implementation of the WHO Global Strategic Plan (2008 – 2015) for Universal Access to safe blood transfusion.

b) Strategy 2.2: Hepatitis B prevention through vaccination

The NSPHBC will strengthen and improve hepatitis B immunisation services.

Key activities:

i. Vaccination of infants

a) Strengthening of routine immunisation services to achieve and sustain at least 95% coverage with three doses of hepatitis B vaccine by one year of age in each birth cohort at the national level, and at least 85% coverage in each district. Focus efforts on poor performing districts and high prevalence groups, identified through improved data collection, mapping and regular analysis of subnational/district-level surveillance data.

b) Delivery of a timely birth dose (within 24 hours of birth), with a target of reaching at least 95% of births at the national level and at least 85% coverage in each district.

c) Coordination with the maternal and child health programme to improve access to immunisation including vaccination coverage to include births outside of health facilities.
- 'Reaching every district' (RED) strategy.
- Novel strategies to increase birth dose coverage, including:
  - Promoting the appropriate use of controlled temperature chain (CTC) for hepatitis B vaccine to increase birth dose coverage with home deliveries.
  - Work closely with PMTCT initiatives in HIV and STIs programme.

ii. Immunisation of high-risk population groups including HCWs and frequent recipients of blood/ plasma transfusions.

iii. Management of vaccine supply and quality.

a. Elimination of vaccine stock-outs at the national and district levels through improved training in vaccine management.

b. Prevention of vaccine freezing through improved training in temperature monitoring.

c. Promotion of the use of controlled temperature chain for the delivery of hepatitis B birth dose vaccine.

c) Strategy 2.3: Improving quality and coverage of harm reduction programmes

This strategy goes in line with strategy 2.1 of the National Strategic Plan on Ending AIDS 2016-2030. The harm reduction programmes will be intensified to prevent and control viral hepatitis infection as well as HIV among PWID.

Key activities:

i. Sustaining and scaling up the harm reduction programme, which consist of NSEP and methadone therapy.

ii. Intensify targeted behaviour change initiatives for male and female PWID, emphasising on risk reduction and safer sexual behaviours. Develop innovative approaches to attract women who use drugs or are partners of people who use drugs to address sexual transmission and sexual health.

iii. Review and revise as appropriate the package of services offered to programme beneficiaries, to include hepatitis screening, sexual and reproductive health services, opioid substitution therapy and community-based TB.

2.5.3 STRATEGY 3: ACCESS TO DIAGNOSTIC, TREATMENT AND CARE SERVICES

The NSPHBC will strengthen and improve access to diagnostic, treatment and care of viral hepatitis.

Key activities:

i. Improve coverage and early access to and quality of viral hepatitis testing, care and treatment.

ii. Integration of viral hepatitis management (testing, treatment and care) at primary healthcare centres.

iii. Improve adherence to treatment and detection of treatment failure.

iv. Develop guidelines on testing, treatment and care.

v. Aim for the elimination of mother-to-child transmission of hepatitis B through the universal screening, and if necessary, treatment, of antenatal mothers. This will be initially implemented as a pilot programme in selected states, and upon review, rolled out nationwide.

2.5.4 STRATEGY 4: QUALITY STRATEGIC INFORMATION, MONITORING AND EVALUATION, AND RESEARCH

The NSPHBC will focus in improving the availability of research and surveillance data, and analysis of monitoring and evaluation of viral hepatitis programme to guide and determine policy and programme frameworks for prevention, treatment, care and support.

Key activities:

i. Develop a monitoring and evaluation framework that complements the strategies and targets of this NSPHCB, including indicators and baseline assessment.

ii. Strengthen viral hepatitis case notification to the District Health Office or into e-Notification system.

iii. Increase the completeness of viral hepatitis cases investigation, including all appropriate public health and epidemiologic active case-finding and cases follow-up.

iv. Develop a viral hepatitis registry, which include the epidemiology, testing, treatment and outcome monitoring components.

v. Produce and disseminate viral hepatitis epidemiological reports to healthcare providers, policy-makers and other interested parties.

vi. Review case definition for viral hepatitis and adapt WHO viral hepatitis surveillance guidelines to make it comparable between countries.

vii. Develop a domestic laboratory network for viral hepatitis, linked to a regional laboratory network.

viii. Adopt standardised testing algorithms for viral hepatitis surveillance, blood safety and diagnosis.

ix. Promote and support research and partnerships in viral hepatitis in order to move towards evidence-based response.

2.5.5 STRATEGY 5: CAPACITY BUILDING AND ENHANCEMENT

The NSPHBC will focus on improving the knowledge and skills of healthcare providers in the prevention and control as well as testing, treatment and care of viral hepatitis.

Key activities:

i. Ensure adequate number and training of HCWs to manage viral hepatitis.

ii. Strengthen the capacity of staff in viral hepatitis management (prevention, testing, treatment and care).

iii. Improve knowledge of non-government organisations on viral hepatitis to ensure adequate and correct dissemination of information on viral hepatitis to the community.

iv. Encourage task-shifting and the decentralisation of service provision through the empowerment of, and collaboration and strategic partnership with NGOs, the community and related industries.

CHAPTER 3: COORDINATION, IMPLEMENTATION AND RESOURCES

3.1. COORDINATION AND IMPLEMENTATION

It is necessary to ensure that the implementation of the National Strategic Plan for Hepatitis B and C (NSPHBC) is structured and managed accordingly to facilitate the participation and involvement of relevant stakeholders from the government, civil society, the private sector and development partners, and to achieve the intended results from the many interventions.

The prevention component of viral hepatitis will be coordinated by the Disease Control Division, specifically Vaccine Preventable Diseases & Food Water Borne Diseases Sector (VPD/FWBD) and HIV/AIDS/Hepatitis C Sector. Diagnostic, treatment and care components of viral hepatitis will be coordinated by the Gastroenterology and Hepatology Services and Pathology Services. The HIV/STI/Hepatitis C Sector will act as the NSPHBC secretariat.

3.2. RESOURCES

Over the next five years, it will be important to advocate for sustained domestic commitment to fund the national response to viral hepatitis. Resource allocations will need to be aligned to the priority areas and programmes identified in the National Strategic Plan for Hepatitis B and C (NSPHBC) and National Action Plan on Viral Hepatitis.

The respective programme/division/sector/stakeholder is responsible in ensuring planned activities can be implemented within the existing current budget. Should there is a need for additional budget, programme/division/sector is responsible to submit a financial budget proposal to the Finance Division for approval.

The responsible programme/division/sector will need to track the variety and amount of resources allocated to the NSPHBC in which will provide crucial information on whether the existing allocation of funding is aligned with agreed national priorities.

3.2.1 FINANCING VIRAL HEPATITIS RESPONSES

Information on the expenditures of past programmes/activities were collected by reviewing the financial reports for each activities.

Table 1: Approximate Total Expenditure (RM) of Viral Hepatitis B and C Programme, Malaysia 2015-2017

Year	HCV		HBV		Total Viral Hepatitis	
	Prevention	Treatment and Care	Prevention	Treatment and Care	Prevention	Treatment and Care
2015	36,075,010.73	7,003,983.03	5,265,084.21	13,345,443.64	41,340,094.93	20,349,426.67
2016	37,052,003.89	4,749,746.01	4,449,974.53	18,503,194.77	41,501,978.42	23,252,940.77
2017	25,712,062.69	5,626,569.75	4,382,244.42	14,787,494.85	30,094,307.11	20,414,064.60

3.2.2 ESTIMATING THE RESOURCES NEEDED

The resources required to achieve the NSPHBC coverage and impact goals need to be calculated from estimates of the numbers of people receiving each services and the costs per person. Service estimates are based on the population in need of the service or programme and the coverage level to be achieved. Coverage is assumed to increase from the baseline levels to the planned targets by 2023. The unit costs for these services are based on existing interventions currently being implemented by agencies and organisations.

Table 2: Proposed Annual Resource Need for Viral Hepatitis B and C, Malaysia 2019 – 2023

Year	Prevention (RM)	Diagnostic, Treatment & Care (RM)	Total (RM)
2019	4,555,000.00	22,710,000.00	**27,265,000.00**
2020	4,830,000.00	30,787,500.00	**35,617,500.00**
2021	6,639,720.00	52,972,320.00	**59,612,040.00**
2022	6,969,000.00	67,970,368.00	**74,939,368.00**
2023	6,869,000.00	87,869,228.00	**94,738,228.00**
Total	**29,862,720.00**	**262,309,416.00**	**292,172,136.00**

An estimated RM 292,172,136.00 is needed for the implementation of NSPHBC for the five-year period from 2019 - 2023 The annual resources needed for each activity is as in Annex 2, based on the action plan outlined in Annex 1.

CHAPTER 4: MONITORING AND EVALUATION

The implementation of the National Strategic Plan for Hepatitis B and C (NSPHBC) will be monitored and evaluated through the national viral hepatitis monitoring and evaluation framework, which is coordinated by the HIV/STI/Hepatitis C Sector.

Information gathered from national monitoring and evaluation of viral hepatitis programme will be used to:

a) Ensure viral hepatitis prevention programmes achieve high levels of accountability and efficiency.

b) Inform and help determine whether programme up scaling or expansion is required.

c) Allow corrective or remedial actions to be taken.

d) Provide information and data, which is beneficial for the implementation of the programme, and serve as input for the design of future programmes.

e) For the purpose of reporting on international commitments.

Expected results and targets will be monitored and evaluated periodically.

4.1 INDICATORS AND TARGETS

To monitor the NSPHBC, the indicators for measuring programme coverage targets have been selected to get consistent and accurate information on programme performance and outcomes, which ensure access to high quality prevention, treatment, care and support services. The indicators are as listed in Annex 3.

4.2 MONITORING AND EVALUATION PROCESS

Monitoring and evaluation will utilise a process that is able to capture and evaluate various levels of programme implementation from measures of input, activities, output and impact. All stakeholders involved in the response to viral hepatitis in Malaysia are contributors to the various indicators and are equally responsible to ensure that they are regularly monitored.

The respective programme/division/sector is given the responsibility to monitor and evaluate the viral hepatitis framework.

4.3 PROGRESS MONITORING

Progress monitoring and evaluation are conducted at both state and national levels involving all relevant stakeholders. The intention of the performance reviews will be to evaluate progress based on coverage, effectiveness, relevance and sustainability of the programmes. The state level viral hepatitis programme review will be conducted every six months with the respective State Officers and the State Health Department taking the lead.

The NSPHBC secretariat will coordinate the progress monitoring at the national level. The viral hepatitis programme performance will be presented and reviewed by a proposed National Steering Committee on Viral Hepatitis chaired by the Director-General of Health Malaysia.

4.4 MID TERM REVIEWS AND IMPACT EVALUATION

An interim evaluation will take place in 2021, together with the midterm review. It will recommend corrective action and adjustments to the NSPHBC if necessary. The second evaluation will take place in 2023. These evaluations will assess the results in the achievement of targets, analysing the available data to verify outcome and impact in comparison with baseline values for core indicators. These evaluations will not only assess effectiveness of individual programmes and of the overall national response, but will take into consideration the quality and efficiency of programmes and interventions.

4.5 RESEARCH ON VIRAL HEPATITIS

Monitoring and evaluation of the NSPHBC will also require data collected through research, including regular surveys. Research complements monitoring and evaluation by building a knowledge base which will guide the national response. Thematic research will be conducted to better understand underlying causes, dynamics and impacts of the epidemic, such as epidemiological trends, new and emerging areas of concern and a better understanding of vulnerability and long-term consequences of the epidemic.

ANNEXES

Annex 1

NATIONAL ACTION PLAN FOR NSP HEPATITIS B AND C 2019 – 2023

No.	Key Activities	Key Stakeholders	Programmatic Target	Remarks
Strategy 1 : Advocacy, Communication And Social Mobilisation				
i.	Promote and strengthen viral hepatitis education and awareness among healthcare professionals and providers.	• Ministry of Health (MOH) • Ministry of Education (MoE) • Ministry of Defence (MINDEF) • Ministry of Home Affairs (MoHA) - prison/NADA • Private sector (Malaysian Primary Care Network/MMA/Association of Private Hospitals)	• Continuous Medical Education (CME) at all levels • Course on viral hepatitis – at least once in services	CME and course/training are ongoing activities at state and district level

No.	Key Activities	Key Stakeholders	Programmatic Target	Remarks
ii.	Promote and strengthen viral hepatitis awareness among general population	• MOH (HECC, DCD, FHDD, UKK, MDD) • Ministry of Communication & Multimedia (KKMM) • NGO • Pharmaceutical companies • Private sector	• Conventional (radio/TV/paper/IEC material) • Media social (facebook, instagram, twitter, dll)	Last IEC material : 2016 as part of immunization programme
iii.	Promote and strengthen viral hepatitis awareness among targeted populations, including those at high risk for infection and / or the serious consequences of viral hepatitis infection especially hepatitis B and C. a) Health education and promotion on viral hepatitis during outreach activities for targeted / high risk population (PWID, MSM, FSW, TG – integration of harm reduction programme)	• MOH • Malaysia AIDS Council (MAC) NGO – Pengasih, PEMADAM • MoHA	• Outreach activities • Referral for hepatitis screening	Ongoing programme (harm reduction) Ongoing budget : RM 7million /year for harm reduction / HIV prevention Last : Training on Hep C for outreach worker : RM150,000
	b) Health education and promotion on viral hepatitis during antenatal visit (pregnant mothers)	• MH • MoE • MINDEF • Private sector	Health talk and antenatal counselling	Ongoing antenatal activities

No.	Key Activities	Key Stakeholders	Programmatic Target	Remarks
	c) Health education and promotion on viral hepatitis for incarcerated population (prisoner, inmate in rehabilitation center, NADA)	MoHA (prison/ NADA)	• Incorporate Hepatitis information during health examination. • Health talk session (at least once / year)	Health information and education on HIV & TB was given during health examination. (to include Hep during the session)
iv.	Integrate viral hepatitis prevention and treatment into health professional training curricula to promote the development of a hepatitis literate workforce.	• MOH • MoE • MINDEF • Private sector (including universities and colleges)	Health professional training curricula	Hepatitis is part of medical & paramedical course Eg. Medical nursing 3 (GIT)
v.	Recognize and carry out hepatitis activities on World Hepatitis Day (WHD)	• MOH • KKMM • NGO • Pharmaceutical companies • Private sector	Annual event	• Since 2010 • 2016 – 2017 : • media campaign on immunisation • world hep day in small scale (banner, exhibition) • 2017 – Hosp Selayang marathon on World Hepatitis Day • TV/Radio talk : free

No.	Key Activities	Key Stakeholders	Programmatic Target	Remarks
vi.	To assess awareness on hepatitis	• MOH • NGO	• Pre & post evaluation on hepatitis awareness (public / HC provider / high risk population) • Integrate knowledge assessment on viral hepatitis among PWID in IBBS	No evaluation
vii.	To assess awareness on hepatitis among public (mass study KAP)	• Institut Penyelidikan Tingkahlaku (IPTK) • HECC • DCD	• KAP study in 2022 and KIV every 5 years	
viii.	Establish national-level Steering Group (or its equivalent) responsible for setting the high-level strategic direction, funding, oversight and governance of the national plan and programme.	• MOH • Academia • Private sector • NGO	• To establish in 2019/2020	
Strategy 2 : Quality and coverage of prevention programmes				
A)	**Strategy 2.1 : Strengthening Screening for Viral Hepatitis**			
i.	Promote and strengthen viral hepatitis B screening for individual / group who are at high risk of infection a) To develop policy and guideline on hepatitis B screening	• MOH • MMA • MoHA • NGO	To develop national policy and guidelines by 2020 • National Policy on Hep B Screening for all high risk	• Currently, Hep B screening are done for high risk group HCW (Govt)

No.	Key Activities	Key Stakeholders	Programmatic Target	Remarks
			employees and individuals • National Policy for Universal HBsAg Screening for Antenatal mothers at initial prenatal visit. • Guidelines Of National Policy on Hep B Screening for all high risk employees and individuals • Guidelines for Universal HBsAg Screening for Antenatal mothers at initial prenatal visit. • Guideline of PMTCT of Hep B	• To date there is no national policy on Hep B screening for all high risk employees and individuals. • Currently, there is policy on Hep B and C screening for high risk population (PWID) in harm reduction Programmes.
	b) PMTCT of Hepatitis B – to expand and implement Hep B screening among antenatal mothers • Strengthening PMTCT Hep B in Sabah • Pilot PMTCT Hepatitis B at 4 states initiated in 2019 (Pahang, Kelantan, Pahang, Kedah)	• MOH • MoE • MINDEF • MMA	• Programme Targets : - antenatal hep B screening : ≥ 95% - Birth dose Hep B vaccination coverage : ≥ 95% - 3rd-dose Hep B vaccination coverage : ≥ 95% • Impact Target : Prevalence of HBsAg among children : ≤ 0.1% • To expand to all state by 2021	Currently only Sabah does antenatal screening. 1. %antenatal mothers screened 2. % seropositive (HBsAg) among antenatal mothers 3. (KIV) % antenatal mothers treated 4. % MTCT HBV

No.	Key Activities	Key Stakeholders	Programmatic Target	Remarks
ii.	Promote and strengthen viral hepatitis C screening for individual / group who are at high risk of infection	• MOH • NGO/CSO • MoHA (NADA, Prison Department)	Target for HCV screening; **Year** — **Target** • 2019 — 15,000 • 2020 — 20,000 • 2021 — 25,000 • 2022 — 35,000 • 2023 — 45,000	• Screening for HCV are been carried out at hospital setting
iii.	To make the availability of POCT tools/rapid diagnostic kits in primary health care facilities	• MOH (DCD, IMR, NPHL) • MDA	Percentage of healthcare facilities that are able to offer screening using POCT • 50% of health facilities by 2023 • 100% of health facilities by 2030	• RDT HCV and HBV are currently available in the market. • Two (2) RDT HCV are certified by IMR • Majority RDT are still awaiting registration by MDA
iv.	Ensure safe blood supply by strengthening national blood / blood product screening for HBV and HCV. a) Strengthening national blood / blood product screening for HBV and HCV by using NAT.	• MOH - National Blood Centres (NBC)	100% of donors blood screened by using NAT By 2023 2020/2021 (upon approval from MOH)	• Currently PDN already ensures safe blood supply by implementing serology and NAT testing. • However NAT testing still not implemented in Terengganu, Penang, Perak, Sabah and Sarawak. • Currently the NAT service cover only 60%.

No.	Key Activities	Key Stakeholders	Programmatic Target	Remarks
	b) Consolidation of the 13 screening centres (Transfusion Microbiology Laboratory-TML) into 4 screening centres in order the increase good quality management system and reduce the cost of manpower and other requirements.	• MOH (NBC)	Four (4) screening centres proposed : i. TML, NBC ii. TML in one of the Northern Region. iii. TML in Sabah iv. TML in Sarawak	• Maintaining 13 screening centres will more expensive in terms of manpower needed, and difficult to monitor the standard of quality each screening centres. • Currently: NEQAP HBV and HCV • Participants: 40 hospitals and screening centres • Cost for 2 cycles/year : RM19K (not including transportation cost) • Transportations cost (via courier service): RM3000-RM4000/cycle
	c) Strengthen the TML Makmal Rujukan Kebangsaan (MRK) in PDN. MRK act as a National Reference Laboratory (NRL) for screening centres (blood / blood product)	• MOH (NBC)	Strengthen MRK act as a National Reference Laboratory (NRL) for screening centres	MRK lab function are: a) To do confirmatory testing on screening Reactive donations or donors. b) To evaluate and select assays systems and equipment for blood donor screening and confirmatory testing c) As an organisation of External Quality Assessment Scheme for Transfusion Microbiology

No.	Key Activities	Key Stakeholders	Programmatic Target	Remarks
				Lab/ screening centres: • As for now, TML NBC will do the NEQAP for Hep B and Hep C (participants- 40 hospitals including 13 screening centres). • TML NBC and other institutions can provide the samples, but NBC will maintain as EQA provider for HBV and HCV for screening centres only (and in the future, HIV and Syphilis) and other institutions might cover the rest of microbiology
iii.	Support the implementation of the WHO Global Strategic Plan (2008 – 2015) for Universal Access to safe blood transfusion.	• MOH (NBC)	Continuous Implementation	MOH already implement WHO Global Strategic Plan (2008 – 2015) for Universal Access to safe blood transfusion.
B)	**Strategy 2.2 : Hepatitis B Prevention Through Vaccination**			
i.	Strengthening of immunization services to achieve and sustain at least 95% national coverage.	• MOH (FHDD, DCD) • MOH (all health clinic and hospital) • Private health facilities	Coverage of 3 doses of Hep B vaccination : • 2020 : ≥95% • 2030 : ≥95%	Coverage in 2015 : 98.6% Hep B immunization coverage for dose two and three are more than 95% for the past 5 years.

No.	Key Activities	Key Stakeholders	Programmatic Target	Remarks
ii.	Strengthen the implementation of Hep B timely birth dose (within 24 hours of birth) • Strengthening the coordination with maternal and child health programme to improve access to immunization including vaccination to births outside of health facilities. • Education material for mother - importance of Hospital delivery - importance of timely birth dose vaccine - importance of treatment of babies with HBIG - (babies of mothers with positive HBsAg)	• MOH (FHDD, DCD, MDD) • MOH (all health clinics and hospitals) • MOH (District Health Office) • Private health facilities	• National Coverage of timely birth dose hep B vaccine (within 24 hours of birth): - 2020 : ≥95% - 2030 : ≥95% • District coverage of timely birth dose hep B vaccine (within 24 hours of birth): - 2020 : ≥85% - 2030 : ≥85%	• Coverage (Includes all those vaccination within and beyond 24 Hrs) - 2015 : “86.5%” - 2017 : “88.2%” • Monitoring of current practices from hospitals showed problems in data collection. • Data had been manually collected so there are some quality issues in regards of this matter. • Currently, new-borns delivered at home are brought to healthcare facilities for vaccination.
iii.	Provision of free immunization to all non-citizen children less than 2 years of age. (implementation is subjected to financial approval)	MOH - DCD - FHDD - Treasury Division	• To propose to Treasury MOH by 2019 • Target : - 2020 : ≥50% Non-Citizen less than 2 years immunised - 2023 : ≥95% Non-Citizen less than 2 years immunised	Since the introduction of Fee Act (2015), non – citizen have to pay for immunization services – RM 80. Proposal paper was been submitted to the post cabinet in Nov 2018 (for all vaccine including HB)

No.	Key Activities	Key Stakeholders	Programmatic Target	Remarks
iv.	Development of integrated shared database (on immunisation) among public and private healthcare facilities (implementation is subject to financial approval)	MOH - DCD - FHDD - MDD - Health Informatics Centre	Percentage of states implementing both a Birth Registry and an Immunisation Registry - 50% by 2020 - 100% by 2023	• This is to address the issue of mobile population and to trace the defaulters for immunization and improve the immunization coverage with a realistic denominator. • Currently, few states already implement online - Birth Registry (Sarawak, Sabah, N.Sembilan & P.Pinang)) and - Immunization Registry (Sarawak, N.Sembilan & P.Pinang)
v.	Hep B Immunization for blood donor	NBC	Continue as donor privilege	Free Hep B vaccination (3 doses) given to donors who donated 2-5 times - Donor privilege
vi.	Hepatitis B immunisation among HCWs Advocating for national policies requiring free and universal hepatitis B vaccination for HCWs – Govt to cover HCWs in government healthcare facilities meanwhile private healthcare facilities to cover their HCWs	• Government • Private health facilities	100% HCW received hepatitis B immunisation by 2023	• Immunization Hep B among high risk Govt HCW – ongoing programme • However – private : nil

No.	Key Activities	Key Stakeholders	Programmatic Target	Remarks
viii.	Management of vaccine supply and quality • Elimination of vaccine stock-outs at the national and district levels through improved training in vaccine management. • Prevention of vaccine freezing through improved training in temperature monitoring. • Promotion of use of controlled temperature chain for delivery of hepatitis B birth dose. • To implement regular audits of cold chain management procedure in all the designated healthcare facilities.	• MOH - DCD - FHDD - Pharmaceutical Services Programme • MOH (all health clinic and hospital) • MOH (District Health Office) • Private health facilities	• For facilities to keep the required minimum stock • Target : ≥ 80% number of facilities audited by 2023	• Currently, there is no comprehensive training on vaccine management. • Family Health Dev.Division (FHDD) had been conducting training on COLD Management on estimated cost of RM 10 000. • Pharmaceutical Services to coordinate training on vaccine management. • Currently, minimum stock required are kept as per *Garis Panduan Pengurusan Stor Farmasi* in Hospitals and *Klinik Kesihatan* MOH.

No.	Key Activities	Key Stakeholders	Programmatic Target	Remarks
C)	**Strategy 2.3 : Improving Quality And Coverage Of Harm Reduction**			
i.	Sustaining and scaling up the harm reduction programme, which consist of needle and syringe exchange (NSEP) and opiate substitution therapy (OST). a) Increase OST center at healthcare facilities	• MOH • MoE • MAC • Other NGO	No. of health clinic providing OST Target: • Min 45% of health clinics provide OST by 2020; • 55% by 2025; • 65% by 2030 (~20 clinics/year)	• 2015 : 37.8% (359/949) health clinic provide OST services • 2017 : 41.9% (398/949) health clinic provide OST services • RM 1.5 million for methadone
	b) Strengthen and sustain OST services at the existing center	• MOH • MoE • MoHA (NADA, Prison Department) • MAC • Other NGO	• Sustain OST services at the existing center (in 2015)	• In 2015 : 482 facilities provide OST services (55 hospitals, 359 health clinic, 24 GP-MOH collaboration, 24 NADA, 18 prison and UMCAS) • In 2017 : 520 facilities provide OST services (53 hospitals, 398 health clinic, 22 GP-MOH collaboration with MOH, 24 NADA, 22 prison and UMCAS)

No.	Key Activities	Key Stakeholders	Programmatic Target	Remarks
	c) Increase OST/HTC/ARV uptake of methadone patient	• MOH • MoE • MoHA (NADA, Prison Department) • MAC • Other NGO		2015 : 3,710 new methadone patient registered at govt facilities
	d) Increase active NSEP registered client by: • *Stress on the need of regular NSEP service to client* • *Establish 'to increase rate of active clients' as indicator that need to be achieved* • *Conduct activities/event to attract back client into NSEP once every quarter (4 times a year)*	• MAC • Other NGO • MOH	Min 35% active NSEP client by 2020; 40% by 2025 and 50% by 2030	Less than 30% registered NSEP clients were active in 2014 & 2015.
	e) Ensure adequate needles and syringes provided to NSEP Client	• MAC • Other NGO • MOH	No. of needles distributed per person : • 2020 : 200 needles distributed/PWID • 2030 : 300 needles distributed/PWID	• 2015 : 58.1 N&S distributed /PWID • 2017 (GAM 2018) : 19 / PWID pop or 282 / active PWID
ii.	Provide accurate information on HIV and co-infection (Hep/TB), SRH, OST, testing, ARV treatment and condom usage to NSEP's clients	• MAC • Other NGO • MOH	Frequency of session with NSEP client : at least 3 sessions per client per year	-

No.	Key Activities	Key Stakeholders	Programmatic Target	Remarks
iii.	Increase number of referral to testing and treatment (OST/ARV/SRH/Hep/TB)	• MAC • Other NGO • MOH	• Min 30% of active NSEP client (opiate users) referred to OST services per year • At least 60% of active NSEP client referred to Hep screening per year	• Outreach worker is to advise and refer NSEP client for VCT (HIV). • 2015 - Referral NSEP for VCT: 13%. However no available data on NSEP client referred for hepatitis screening
Strategy 3: Improving Access To Diagnostic, Treatment And Care				
i.	Improve coverage and access to viral hepatitis testing, care and treatment. a) Scale up HBV and HCV screening and diagnosis among population at risk (HIV, PWID, prisoners, drug rehabilitation centers, hemodialysis patients, needlestick injury among HCWs, transplant patients, and contacts of PLHBV & PLHCV) and blood donors	• MOH (Hospital – incl. Nephro, NBC, Health clinics, KPAS) • MINDEF • MoE (PPUM, PPUKM, HUSM, PPUITM) • MoHA • Private hospitals	• % PLHBV diagnosed • % PLHCV diagnosed • Number of person screened for HBsAG • Number of person screened for HCV	Based on notified cases from e-notis Note: Need to have practical estimates of PLHBV and PLHCV as denominator (Currently we don't have an estimate for PLHBV)

No.	Key Activities	Key Stakeholders	Programmatic Target	Remarks
	b) Scaling up treatment coverage at Hospitals	• MOH (Hospital – incl. Nephro, National Blood Centre, Health Clinics, KPAS) • MINDEF • MoE (PPUM, PPUKM, HUSM, PPUITM) • MoHA • Private hospitals	• Number of hospitals treating HBV and HCV • Number of HCV infection treated • Number of HBV infection treated	
iii.	Improve adherence to treatment and determine treatment success rate (SVR) • Provision of adherence counselling – training to healthcare providers treating Hepatitis • Differentiated service delivery for PWID through engagement with NGO/CSO	• MOH • NGO/CSO	• SVR (HCV) : 90% (2020) & 95% (2030)	Baseline NA
ii.	Integration of viral hepatitis management (testing, treatment and care) at primary healthcare • Develop training module for Care & Treatment of Hepatitis C at Primary Care • Training of FMS	• MOH - FHDD and FMS Services - Gastroenterology / Hepatology Services	• Number FMS/HCW trained (as in strategy 5) • Development of module for Care & Treatment of Hepatitis C at Primary Care	
ii.	Ensure adequate and continuous supply of drugs (to ensure no stock-out)	• MOH - Pharmaceutical Services Programme - Gastroenterology / Hepatology Services - DCD	•	

No.	Key Activities	Key Stakeholders	Programmatic Target	Remarks
iii.	Introduction of DAA drugs into the national drug formulary	• MOH - Pharmaceutical Services Programme - NPRA	• Continuous update of the national drug formulary, with periodical review	
iv.	Introduction of procurement mechanisms by individual hospitals, in addition to the current mechanism of centrally pooled procurement.	• MOH - Pharmaceutical Services Programme - Gastroenterology / Hepatology Services	• Review of procurement mechanism, to achieve further de-centralisation	
v.	Strengthen quality of Hepatitis testing services • Ensuring quality system is implemented in all testing laboratories • Trained & competent manpower • Subscription to EQA programme or having inter-laboratory comparison • Efficient inventory and procurement system (to ensure no stock-out)	• MOH	achieve ≥80% of overall performance	

No.	Key Activities	Key Stakeholders	Programmatic Target	Remarks
	EMTCT pilot programme • Pilot implementation in four states (Pahang, Kedah, Kelantan and Terengganu) Assessment of the operational and epidemiological findings of the pilot programmes.	• MOH - State health departments (JKN Pahang, Kedah, Kelantan and Terengganu) - MCH - Primary care - Gastroenterology / Hepatology Services	• State-wide coverage of screening of antenatal mothers, and antenatal mothers who are screened positive for hepatitis B and in need of treatment are provided treatment. • Operational and epidemiological research.	
Strategy 4 : Quality Strategic Information, Monitoring and Evaluation, and Research				
i.	Develop a monitoring and evaluation framework for the NSPHCB	• MOH	An M&E framework that complements the NSPHCB that includes the following: • Goals • Quantifiable targets for mid-term and end of term • Specific activities/programme implementation • Indicators • Baseline assessment of indicators Mid-term review of M&E indicators • Mid-term updates of indicator values End of NSPHCB evaluation	

No.	Key Activities	Key Stakeholders	Programmatic Target	Remarks
			report • End of term update of indicator values • Assessment report of NSPHCB	
ii.	Strengthening viral hepatitis case notification to the nearest District Health Office or into e-Notification System. • Monthly return from all laboratories (notified positive cases) to State Health Department - Strategic patient information system that links to e-notification system • Review case definition for viral hepatitis and adapt WHO viral hepatitis surveillance guidelines	• MOH - DCD (HIV/STI/Hep C Sector & VPD /FWBD Sector) - District Health Office (Health inspectors) - State Health Department - (Deputy State Health Director in Public Health, State Epid Officer)	Review case definition for viral hepatitis by February 2019	
iii.	Strengthen viral hepatitis cases investigation, including all appropriate public health and epidemiologic active case-finding and cases follow-up. • Develop standard case investigation format for HCV and HBV	• MOH - DCD (HIV/STI/Hep C Sector & VPD /FWBD Sector) - District Health Office (Health inspectors) - State Health Department - (Deputy State Health Director in Public Health, State Epid	Development of standardised case investigation form	HCV case investigation format has been finalised and to be used starting in 2019. HBV - No standardised investigation form

No.	Key Activities	Key Stakeholders	Programmatic Target	Remarks
		Officer)		
iv.	Develop centralised patient monitoring system / viral hepatitis registry, which include the epidemiology, testing, treatment and outcome components. (A centralised patient monitoring system yields the necessary information on enrolment to care / treatment / patient outcome)	• MOH - Gastroenterology / Hepatology Services - DCD	• % patient on treatment • % patient achieving SVR • Number of deaths attributable	Registry is currently being developed by Gastroenterology / Hepatology Services
v.	Develop domestic laboratory network for viral hepatitis, linked a to regional laboratory network • Appointment of IMR as national reference laboratory for Hepatitis as well as for EQA diagnostic	• MOH - IMR - Hospital laboratories (HOD) - NBC	• All hospital labs standardised EQA by 2020. • Letter of appointment to IMR - To be national reference laboratory for Hepatitis - for EQA diagnostic	PDN is the EQA provider for Hep B/C blood screening laboratories.
vi.	Promote and support research and partnerships in viral hepatitis • Engage external consultant for capacity building • Modelling for estimated population of PLHBV and PLHCV • Cost-effectiveness study for treatment	• MOH - DCD (HIV/STI/Hep C Sector & VPD /FWBD Sector - CRC - IKU - IHSR	• Engage consultant for capacity building / modelling study by 2020 / 2021 • Practical population estimate ready by 2023	

No.	Key Activities	Key Stakeholders	Programmatic Target	Remarks
vi.	To determine prevalence of HCV and HBV among key population • Incorporate HCV and HBV screening test in Integrated BioBehavioural Study	• MOH - DCD (HIV/STI/Hep C Sector & VPD /FWBD Sector	• Incorporate HCV and HBV among key population in IBBS 2020	Currently IBBS capture prevalence of HIV among key population
Strategy 5 : Capacity Building and Enhancement				
i.	Ensure adequate number and training of HCWs to manage viral hepatitis	• MOH • MoE • MINDEF • Private sector	• CME – yearly (once) • Symposium – yearly (once) • Training – two sessions / state / yr : RM 10,000 x 15 = RM 150,000 / yr • No. HCW been trained : at least 50% trained by 2020	•
ii.	Strengthen capacity of staff in viral hepatitis management (prevention, testing, treatment and care).	MOH		
	a) Training on hepatitis and initiation of hepatitis C treatment at primary healthcare (training for FMS)	MOH	Training of FMS • 2019 – at least 25% FMS • 2020 – at least 50% FMS • 2021 – at least 75% FMS • 2022 – at least 100% FMS	• Modul Hep C Tx for FMS already available • No. of FMS as of June 2018 : 408 • HCV treatment at PHC by FMS piloted at two (2) health clinic (KK Bandar Alor Setar dan KK Sg. Petani) in 2019

No.	Key Activities	Key Stakeholders	Programmatic Target	Remarks
	b) Review man power requirement annually at all level (*dasar baru/jawatan*)	MOH	Man power requirement – to review from time to time • Request for additional staffing (if necessary / critical)	
iii.	Improve knowledge of non-government organisation on viral hepatitis to ensure adequate and correct dissemination of information on viral hepatitis to the community.	• MOH • NGO	Symposium – yearly (once) Training – yearly (once)	Training on hepatitis by MAC in 2017 for outreach worker : One session RM 150,000

Annex 2

PROPOSED ANNUAL RESOURCE NEED FOR NSPHBC

Year	Prevention			Diagnostic, Treatment & Care		
	HCV	HBV	Total (RM)	HCV	HBV	Total (RM)
2019	225,000.00	4,330,000.00	**4,555,000.00**	22,710,000.00	0.00	**22,710,000.00**
2020	500,000.00	4,330,000.00	**4,830,000.00**	28,387,500.00	2,400,000.00	**30,787,500.00**
2021	575,000.00	6,064,720.00	**6,639,720.00**	39,742,500.00	13,229,820.00	**52,972,320.00**
2022	675,000.00	6,294,000.00	**6,969,000.00**	51,097,500.00	16,872,868.00	**67,970,368.00**
2023	575,000.00	6,294,000.00	**6,869,000.00**	67,730,000.00	20,139,228.00	**87,869,228.00**
TOTAL (2019 - 2023)	**2,550,000.00**	**27,312,720.00**	**29,862,720.00**	**209,667,500.00**	**52,641,916.00**	**262,309,416.00**

Annex 3

INDICATORS FOR MONITORING OF NATIONAL STRATEGIC PLAN FOR HEPATITIS B AND C

Level	Areas	Indicators
Service coverage	Prevention	1. Three-dose hepatitis B vaccine for infants (coverage %)
		2. Prevention of mother-to-child transmission of HBV: hepatitis B birth dose vaccination or other approaches (coverage %)
		3a. Blood safety: donations screened with quality assurance (coverage %)
		3b. Injection safety: use of engineered devices (coverage %)
		4. Harm reduction (sterile syringe/needle set distributed per person per year for PWIDs
	Testing and treatment	5a. Diagnosis of HBV and HCV (coverage %)
		5b. Treatment of HBV and HCV (coverage %)
Impact leading to elimination	Incidence	Incidence of chronic HBV and HCV infections
	Mortality	Mortality from chronic HBV and HCV infections

Annex 4

GLOBAL SERVICE COVERAGE TARGETS THAT WOULD ELIMINATE HBV AND HCV AS PUBLIC HEALTH THREATS, 2015–2030

Level	Areas	Indicators	Baseline 2015	2020 target	2030 target
Service coverage	**Prevention**	1. Three-dose hepatitis B vaccine for infants (coverage %)	**82%**	90%	90%
		2. Prevention of mother-to-child transmission of HBV: hepatitis B birth dose vaccination or other approaches (coverage %)	**38%**	50%	90%
		3a. Blood safety: donations screened with quality assurance (coverage %)	**89%**	95%	100%
		3b. Injection safety: use of engineered devices (coverage %)[1]	**5%**	50%	90%
		4. Harm reduction (sterile syringe/needle set distributed per person per year for PWIDs[2]	**20**	200	300
	Testing and treatment	5a. Diagnosis of HBV and HCV (coverage %)	**<5%**	30%	90%
		5b. Treatment of HBV and HCV (coverage %)	**<1%**	5 million (HBV) 3 million (HCV)	80% eligible treated
Impact leading to elimination	**Incidence**	Incidence of chronic HBV and HCV infections	**6–10 million**	-30%	-90%
	Mortality	Mortality from chronic HBV and HCV infections	**1.46 million**	-10%	-65%

[1] While the service coverage target is about output (Adoption of re-use prevention injection devices), the C.5 indicator focuses on outcome (provision of safe injections)
[2] PWIDs : Persons who inject drugs

Annex 5

BASELINE ESTIMATE OF THE 10 CORE INDICATORS FOR VIRAL HEPATITIS, MALAYSIA, 2018 (2017 DATA)

Indicators	Estimate			Data quality level	Comments, including Source of information
	General	HBV	HCV		
C.1 Prevalence of infections	Blood donors	0.09%(2017)	0.03%(2017)	2&3	National blood transfusion services
	Population	1.1% (N=328,000)	2.5% (N=453,700)		Modelled estimates
C.2 Capacity for testing	Serology	58	58	2	Reports from MOH. Excludes some private labs
	NAT	6	6		
C.3 Hepatitis B vaccine coverage	Third dose	99.4% (2016)			National survey
	Birth dose	100%* (2016)		1	National survey
C.4 NSP/PWIDs	19 /PWID			1	Global AIDS Monitoring 2018 (report 2017 progress)
C.5 Safe healthcare injections	98.8%			3	Western pacific regional estimate
C.6. Proportion diagnosed		10.5% (N=34419)	6.1%(N=23258)	3	Notifiable disease reporting
C.7 Treatment coverage / initiation		22.4%(N=7709)	1.4%(N=331)	2	* No tx/dx*100
C.8 Treatment effectiveness	Sentinel	76.6%	95.4%	2	
C.9 Incidence of infections		0.3% (2009, ages 9-10)*	2.51 per 100,000 (2014 blood donor seroconversion)	1/3	
C.10 Mortality infections		2,500	600		Source: 2015 WHO Global Health Estimates adjusted for IARC2 and Malaysian data.[4]

[a] http://whohbsagdashboard.com
[a] http://polarisobservatory.org/
[a] Timely birth dose means administered within 24 hours of birth. Indicator 3b refers to timely birth dose and other interventions to prevent mother to child transmission of HBV.
[a] Does not specify if timely or not
[a] Needle and syringe provision
[a] PWID : Person who inject drugs
[a] 2018 updated PSE for PWID (80,000 vs 140,000 previously, the value becomes 40 NS/PWID)
[a] certified in 2011 (WHO) as fulfilling the target of <1% among children at least 5 yrs old.

Annex 6

HEPATITIS C: SCREENING AND TREATMENT TARGET 2019 – 2030

Year	Target	
	Screening	Treatment
2019	15,000	2,000
2020	20,000	2,500
2021	25,000	3,500
2022	35,000	4,500
2023	45,000	6,000
2024	55,000	8,000
2025	65,000	10,000
2026	75,000	11,500
2027	85,000	13,000
2028	95,000	14,500
2029	100,000	16,000
2030	105,000	17,500

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