



Myanmar National Strategic Plan On Viral Hepatitis 2016-2020

**National Hepatitis Control Program
Department of Public Health
Ministry of Health and Sports
July 2017**



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Foreword

Viral hepatitis, caused by hepatitis viruses A, B, C, D or E, is recognised as a global public health concern. It is estimated that approximately 240 million people are chronically infected with hepatitis B virus (HBV) and 130-150 million with hepatitis C virus (HCV) globally.¹ An estimated 1.4 million deaths per year from acute infection and hepatitis-related liver cancer and cirrhosis are comparable to that of HIV and tuberculosis. Of those deaths, approximately 47% are attributable to HBV, 48% to HCV, and the remainder to hepatitis A virus (HAV) and hepatitis E virus (HEV). Viral hepatitis is also the growing cause of mortality among people living with HIV.² Co-infection with HCV was seen in about 5-15% of people living with HIV and with HBV in 5-20% of all people living with HIV. Viral hepatitis is more prevalent in Asia than other regions. From the survey done among the general population in 2015 in Myanmar, the prevalence of hepatitis B was 6.5% and hepatitis C was 2.7%.³

The 67th World Health Assembly in May 2014 approved a resolution to improve the prevention, diagnosis and treatment of viral hepatitis. In November 2014, Myanmar initiated the establishment of a National Hepatitis Control Program (NHCP) following the resolution set up by the World Health Organization (WHO). This National Strategic Plan (NSP) was finalised after several consultative meetings and workshops with professionals from the Ministry of Health and Sports, hepatologists, clinicians, public health professionals from other affiliated programs such as the National AIDS Program, and relevant stakeholders. At the 69th World Health Assembly, adopted the global health sector

¹ World Health Organization, 2016. *Global health sector strategy on viral hepatitis 2016-2021*.

² World Health Organization, 2016. *Global health sector strategy on viral hepatitis 2016-2021*.

³ Department of Medical Research, 2015. National prevalence survey on hepatitis B and C in Myanmar.

strategy on viral hepatitis (2016-2021) with a vision of a world in which viral hepatitis transmission is halted and everyone living with viral hepatitis has access to safe, affordable, and effective care and treatment. The global goal is to eliminate viral hepatitis as a public threat by 2030, with targets to reduce the incidence of chronic hepatitis infection from the current 6-10 million cases to 0.9 million and the annual deaths from chronic hepatitis from 1.4 million to less than 0.5 million by 2030.⁴ In April 2016, Regional Action Plan for Hepatitis in the South-East Asia Region was approved by Member States. Myanmar is taking a public health approach to the treatment and care of viral hepatitis, treating not only mono-infected patients but also those co-infected with HIV, in line with the WHO's strategic directions and the National Clinical Treatment Guidelines. Myanmar's approach to elimination of viral hepatitis is bounded by the following four strategic directions:

Strategic direction 1: Prevention of transmission of viral hepatitis

Strategic direction 2: Diagnosis, clinical care and treatment

Strategic direction 3: Workforce development

Strategic direction 4: Surveillance, research and strategic information.

These strategic directions will be implemented through a series of activities, undertaken by professionals from the Ministry of Health and Sports, civil societies, communities, INGOs and other relevant stakeholders.

Elimination can only be achieved through collaboration, coordination and cooperation among all stakeholders. I hope that the vision will become a reality through this joint effort. I wish to thank all those involved, including the Clinton Health Access Initiative (CHAI), WHO and other implementing partners in

⁴ World Health Organization, 2016. *Global health sector strategy on viral hepatitis 2016-2021*.

Myanmar for their support in creating the National Hepatitis Control Program, the National Strategic Plan, and the Operational Plan as well as the devoted professionals of the Departments of Public Health and Medical Services.

MH
6.6.17

Dr. Myint Htwe
Union Minister
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Acknowledgement

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National Hepatitis Control Program
Department of Public Health
Ministry of Health and Sports, Myanmar
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Abbreviations

ALT	Alanine aminotransferase
APRI	Aminotransferase/Platelet Ratio Index
ART	Antiretroviral Therapy
AST	Aspartate aminotransferase
CBO	Community Based Organization
CBP	Complete Blood Picture
CDC	Center for Disease Control (US)
CDCP	Communicable Diseases Control Program
CEU	Central Epidemiology Unit
CSO	Civil Society Organization
CME	Continuous Medical Education
CSW	Commercial Sex Worker
CTC	Controlled Temperature Chain
DAA	Direct-Acting Antiviral (drug)
DMR	Department of Medical Research
DOPH	Department of Public Health
EASL	European Association for the Study of the Liver
ELISA	Enzyme-Linked Immunosorbent Assay
EPI	Expanded Program on Immunization
FBP	Full Blood Picture
GAVI	The Global Alliance for Vaccines and Immunizations
HAV	Hepatitis A Virus
HBeAg	Hepatitis B envelope Antigen
HBsAg	Hepatitis B surface Antigen

HBV	Hepatitis B Virus
HCC	Hepato Cellular Carcinoma
HCV	Hepatitis C Virus
HCV-Ab	Hepatitis C Virus Antibodies
HepB3	3 Doses of Hepatitis B Vaccine
HepB-BD	Hepatitis B vaccine - Birth Dose
HEV	Hepatitis E Virus
HLP	Health Literacy Promotion Unit
HR	Human Resource
HRH	Human Resource for Health
IBBS	Integrated Biological Behavioral Surveillance
ICT	Immuno Chromatographic Test
IFN	Interferon
LFT	Liver Function Test
LMIS	Logistics Management Information System
MMA	Myanmar Medical Association
MCH	Maternal and Child Health
MHSCC	Myanmar Health Sector Coordinating Committee
MLF	Myanmar Liver Foundation
MMT	Methadone Maintenance Therapy
MOHS	Ministry of Health and Sports
MSM	Men who have Sex with Men
NAP	National AIDS Program
NAT	Nucleic Acid Testing
NDACP	National Drug Abuse Control Program
NGO	Non-Governmental Organization

NHCP	National Hepatitis Control Program
NHL	National Health Laboratory
NNRTI	Non-nucleoside Reverse Transcriptase Inhibitor
NRTI	Nucleoside Reverse Transcriptase Inhibitor
NS5B	Non-structural protein 5B (of HCV)
NSP	National Strategic Plan
NTP	National TB Program
OCC	Out of Cold Chain
OOP	Out-of-Pocket
OST	Opioid Substitution Therapy
PCR	Polymerase Chain Reaction
PEG-IFN	Pegylated Interferon
PHL	Public Health Laboratory
PI	Protease Inhibitor
PLHIV	People Living with HIV
PMCT	Prevention of Mother to Child Transmission
PPP int \$	Purchasing Power Parity international dollar
PSE	Population Size Estimation
PWID	People Who Inject Drugs
PWUD	People Who Use Drugs
QC	Quality Control
RBV	Ribavirin
RDT	Rapid Diagnostic Test
RMNCH	Reproductive, Maternal, Newborn & Child Health
RNA	Ribonucleic Acid
SOP	Standard Operating Procedure

SVR	Sustained Virological Response
TWG	Technical Working Group
UHC	Universal Health Coverage
UN	United Nations
VL	Viral Load
WHA	World Health Assembly
WHO	World Health Organization
YGH	Yangon General Hospital

Table of Contents

Content	Page No
Part I	Myanmar National Control Strategy for Viral Hepatitis 2016-2020
1.	Introduction 15
2.	Purpose, Vision, Goal, Objectives and Principles 29
3.	Strategies and Priority Actions 34
Part II	Strategic Directions And Priority Interventions
4.	Strategic Direction 1: Prevention of Transmission of Viral Hepatitis B and C 39
5.	Strategic Direction 2: Diagnosis, Clinical Care and Treatment 53
6.	Strategic Direction 3: Workforce Development 59
7.	Strategic Direction 4: Surveillance, Research and Strategic Information 62
8.	Conclusion 65
9.	References 67
Annexes	Annex 1: Proposed Research Agenda 71
	Annex 2: Country Profile 75
Figures	Figure 1: The prevalence of hepatitis B antigen and hepatitis C antibodies among general population in 18 selected townships
	Figure 2: Burden of hepatitis by population
	Figure 3: The three dimensions of Universal Health Coverage
	Figure 4: National Strategic Framework
	Figure 5: Estimated cost of each strategic direction under the National Strategic Plan 2016-2020

PART I

Myanmar National Control Strategy for Viral Hepatitis

(2016-2020)

1. Introduction

The five hepatitis viruses have different epidemiological profiles, and their impact, duration, and transmission route also vary. The most common transmission routes contributing to the spread of hepatitis are exposure to infected blood via blood transfusion or unsafe injection practices, consumption of contaminated food and drinking water, and transmission from mother to child during pregnancy and delivery. Also, unsafe injection practices, including the use of unsterile needles and syringes, serve as a major pathway for the spread of hepatitis B and C, and reducing transmission of both diseases requires addressing these practices.

Due to its largely asymptomatic nature, viral hepatitis is a silent epidemic; most people are unaware of their infection. Untreated chronic hepatitis B and C infection can result in liver cirrhosis and liver cancer. In 2013, viral hepatitis was the seventh highest cause of mortality globally. It is responsible for an estimated 1.4 million deaths per year from acute infection and hepatitis-related liver cancer and cirrhosis - a toll comparable to that of HIV and tuberculosis.⁵ Of those deaths, approximately 47% are attributable to hepatitis B virus, 48 % to hepatitis C virus, and the remainder attributed to hepatitis A virus and hepatitis E virus. Viral hepatitis is also a growing cause of mortality among people living with HIV (PLHIV). Globally, about 2.9 million PLHIV are co-infected with hepatitis C virus (HCV) and 2.6 million with hepatitis B virus (HBV).⁶ This population is at three times greater risk of progression to cirrhosis or liver cancer and has a 10-fold greater risk of liver-related mortality than mono-infected patients. Hepatitis related diseases have become the leading non-AIDS cause of morbidity and mortality among HIV-infected individuals. Prevention and control of hepatitis can, therefore, make a significant contribution to saving lives by

⁵ Institute for Health Metrics and Evaluation, 2016. Global burden of disease and WHO/UNAIDS estimates.

⁶ World Health Organization, 2015e. Implementation of the global strategy for prevention and control of sexually transmitted infections: 2006-2015.

preventing cancer, thereby reducing the burden of non-communicable diseases.

The global public health response to viral hepatitis recognises that surveillance and control are vital to ensuring that testing, care, and treatment are available to all people who need these services in every country around the world. As there is an effective vaccine for hepatitis B, immunization has been a central strategy for most countries to reduce the burden of hepatitis B. There is no vaccine available to prevent the spread of hepatitis C, but screening of blood products and use of sterile needles and syringes have contributed to lowering hepatitis C transmission in many countries.

However, the mere existence of effective tools and strategies for prevention and treatment is not enough to halt viral hepatitis as with other major public health challenges. A major stumbling block has been the low awareness of viral hepatitis, both in the general population and among key populations. Since knowledge of the various risks and transmission routes is central to preventing the spread of hepatitis, increasing awareness is another critical component of the global public health response.

Increasing awareness is also a key to making hepatitis a larger part of the local, national and regional health agenda. Gaps can be seen between policy and practice; as even in countries with evidence-informed hepatitis policies, there is inadequate implementation of protocols for prevention, treatment, and control. This situation indicates a need for improvement in response to viral hepatitis at all levels.

Viral hepatitis is a global health problem for which no country, rich or poor, is spared. This problem takes a multitude of forms, with factors such as the type of hepatitis, the most common transmission pathways, and the most effective strategies for diagnosis and treatment across and within countries. Thus, Myanmar has adopted the WHO global hepatitis strategy mentioned below into prevention and control strategies that are tailored to specific conditions at the national and sub-national levels.

The World Health Assembly (WHA) adopted resolution WHA 63.18 in 2010 and WHA 67.6 in 2014 in recognition of viral hepatitis as a global public health priority. The resolution emphasised the need for governments and populations to take action to prevent, diagnose, and treat viral hepatitis, and called upon the World Health Organization (WHO) to develop and implement a comprehensive global strategy to support these efforts. The WHO has crafted guidance for the WHA's 194 Member States Manual for the Development and Assessment of National Viral Hepatitis Plans and drafted the Global Health Sector Strategy on Viral Hepatitis in 2016, which addresses the following strategic directions:

- Strategic Direction 1: Information for focused action (know your epidemic and response)
- Strategic Direction 2: Interventions for Impact (covering the range of services needed)
- Strategic Direction 3: Delivering for equity (covering the populations in need of services)
- Strategic Direction 4: Financing for sustainability (covering the financial costs of the services)
- Strategic Direction 5: Innovation for acceleration (looking towards the future)

The 2010 resolution adopted by the World Health Assembly designated the 28th of July as World Hepatitis Day, envisioning this as an opportunity for member states to promote awareness about viral hepatitis. The first official World Hepatitis Day was in 2011. WHO encourages governments, international organizations and civil society groups around the world to observe World Hepatitis Day with activities that call attention to the disease burden imposed by viral hepatitis and also to the

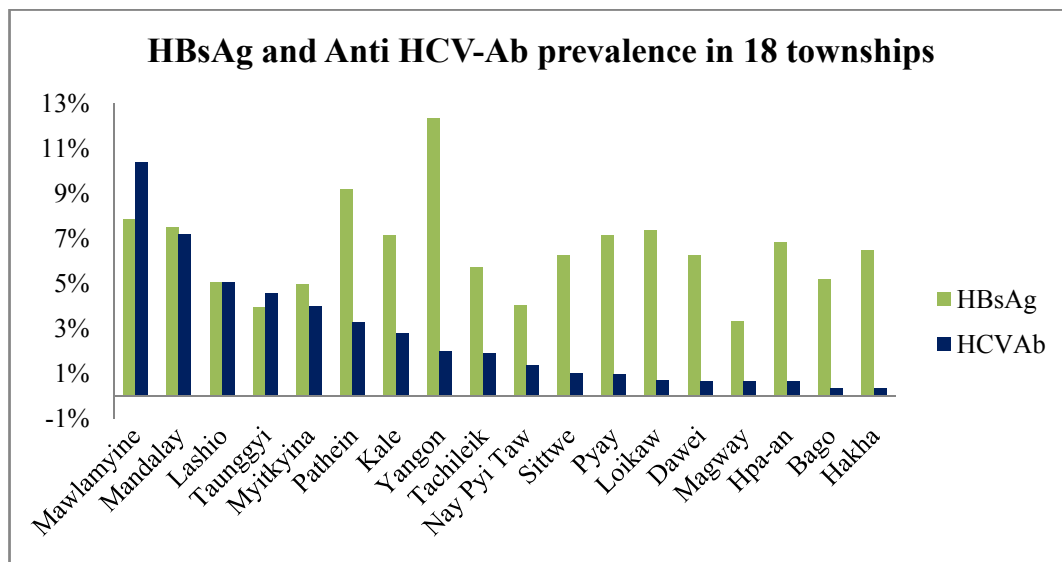
prevention and control measures that need to be implemented. The periodic evaluation for implementation of the WHO strategy requires an initial baseline survey of how all member states are responding to viral hepatitis. In mid-2012, WHO and the World Hepatitis Alliance conducted such a survey, asking member states to provide information relating to the five axes of the WHO strategy. It is anticipated that follow-up surveys, some utilizing the same questionnaire and others addressing specific issues in greater detail, will be carried out every one to two years to monitor overall progress in the implementation of the WHO hepatitis prevention and control strategy.

1.1. Epidemiology of viral hepatitis

The national prevalence survey for hepatitis B and C was conducted by the Department of Medical Research (DMR) and the Department of Public Health (DOPH) from May to November of 2015 in 18 study sites covering all States and Regions. Key preliminary results from the prevalence survey showed that the disease burden for hepatitis B and C in the general population was 6.51% and 2.65%, respectively. The highest occurrence of hepatitis B Surface Antigen (HBsAg) positivity was found in Yangon (12.29%), Patheingyi (9.15%), and Mawlamyine (7.84%). The highest occurrence of anti-HCV positivity was found in Mawlamyine (10.34%), Mandalay (7.17%) and Lashio (5.03%) respectively.⁷ Depending on the age group, hepatitis B was found to be more prevalent in the young adults (20-39 years) and hepatitis C in the older age group of 40-59 years. The risk factors associated with transmission of hepatitis B were male gender, history of liver disease or hepatitis and history of household contacts. For hepatitis C transmission, the risk factors were male gender, age > 50 years, history of blood transfusion, dental treatment, surgery and history of liver disease or hepatitis.

⁷ Department of Medical Research, 2015. National hepatitis B and C prevalence survey 2015.

Figure 1: The prevalence of hepatitis B surface antigen and hepatitis C antibodies among general population in 18 selected townships



Data source: Department of Medical Research, 2015. National hepatitis B and C prevalence survey 2015.

In the 2014 IBBS/PSE study, among intravenous drug users in Myanmar, one of the sub-populations, mono-infection was as high as 47.7% for anti HCV-Ab and 7.3% for HBsAg. The highest occurrence of anti HCV-Ab positivity was found at 84.4%, 83.9% and 73.9% in Yangon, Lashio (Shan-North) and Bhamaw (Kachin), respectively. The prevalence of HIV/HBV co-infection was found to be 2.2%, HIV/HCV co-infection was 20.1%, and HIV/HBV/HCV combined co-infection was 20.7%.⁸

Overall, in selected 154 blood screening sites country-wide, the prevalence of anti HCV-Ab positivity was found to be 0.5% out of 379,088 blood donors. At the State/Regional level, the highest anti HCV-Ab positivity rate was seen in

⁸ Department of Health, 2014b. *Myanmar integrated biological and behavioral surveillance survey and population size estimates among people who inject drugs.*

Kachin state at 1.28% among 11,174 blood donors, and the lowest rate of 0.11% was found in Magway region among 18,889 blood donors.⁹ Several studies from 1998 to 2013 also provide further insights into the burden of disease among different sub-populations and geographies across the country.

⁹ Ministry of Health, 2015a. Annual report of the National Blood Centre.

Figure 2: Burden of Hepatitis by Population

Prevalence	Population	Prevalence rate
Mono-infection of HBV		
	**General Population (2015)	6.51%
	**Adult Males	8.95%
	**Adult Females	5.47%
	*PWID	7.3%
	§Among blood donors (2015)	2.3%
Mono-infection of HCV		
	**General population (2015)	2.65%
	**Adult males	3.51%
	**Adult females	2.29%
	§Among blood donors (2015)	0.5%
	*PWID (2014)	47.7%
	*PWID (Yangon) (2014)	84.4%
	*PWID (Lashio) (2014)	83.9%
	*PWID (Bhamaw) (2014)	73.9%
Co-infection of HBV & HCV		
	^ PWID (2007)	6.7%
	^ PWID (Myitkyina) (2007)	9.5%
	^ PWID (Moegaung) (2007)	8.5%

Data source: * Department of Health, 2014b. *IBBS study among PWID 2014*; ** Department of Medical Research, 2015, National hepatitis B and C prevalence survey 2015; § Ministry of Health - Myanmar, 2015a. Annual report of the National Blood Centre; ^ Aung-Thu, et al., 2008. *Myanmar Health Sciences Research Journal*, 20 (3).

1.2. Current services for viral hepatitis

Prevention and control of communicable diseases is the priority task of the Ministry of Health and Sports (MOHS) to achieve its objectives of enabling every citizen to attain full life expectancy and enjoy the longevity of life that is free from disease. The task is undertaken by the Communicable Diseases Control Program (CDCP) to reduce morbidity and mortality from communicable diseases to halt them from becoming a public health concern and to mitigate subsequent social and economic problems. Among the communicable diseases, viral hepatitis, both water-borne and blood borne are of major concern to the country. For hospital services, there are five liver specialty units in the following facilities: Yangon Specialist Hospital, North Okkalapa General Hospital, Mandalay General Hospital, Nay Pyi Taw General Hospital (1000 beds) and Defense Services General Hospital (1000 beds). Liver research was started in the Clinical Research Division at the Department of Medical Research (DMR) in 1972, and the Liver Research Unit at Yangon General Hospital (YGH) was established in 1973. The Experimental Medicine Research Division was established in the early 1980s, which has since carried out research on liver diseases and vaccines.

Hepatitis B vaccine research was started in collaboration with the Centre for Disease Control, Atlanta (CDC) and the Pasteur Institute in the early 1980s and later with universities in Japan. Plasma-derived HBV vaccine development started in 1991 according to WHO safety criteria and was certified by the New York Blood Centre.

Development of recombinant hepatitis B vaccine plant under the DMR was completed in 2003 and production was started in 2004. The Quality Control (QC) and vaccine safety trial started in 2005 and completed in 2006. In the clinical trial, the recombinant vaccine was found to be safe and 100% immunogenic in newborns and adults. The plant was transferred to the Ministry of Industry (1) in

2006-2007. Other commercial vaccines are imported and are available in the private sector. Hepatitis B vaccine, as per the national immunisation schedule, is currently provided in the pentavalent vaccine (DPT-Hib-HepB) at age 2, 4 and six months; in three doses. Additionally, during hospital deliveries, monovalent HepB vaccine is administered to babies as the birth dose (within 24 hours).

In the public sector, both HBV and HCV screening through Rapid Diagnostic Test (RDT) kits is available in all laboratories for screening of blood safety. Enzyme-Linked Immunosorbent Assay (ELISA) is available but not used routinely for HBV and HCV diagnosis in the reference laboratories, and it is also not feasible in the state, region and township laboratories due to the requirement of 24 hour- electricity for test kits storage. Viral load (VL) machines and human resources (HR) for HIV and HCV confirmatory testing are available, but limited tests are conducted routinely at the National Health Laboratory (NHL), the National Blood Center, and the Mandalay Public Health Laboratory (PHL) due to the limitation of reagents. Liver Function Test (LFT) is available in tertiary hospitals, states and regional hospitals and some district hospitals. Laboratory facilities for tests for differential genotyping of viral hepatitis, assessment of the stage of disease, and those needed for care of patients with viral hepatitis and its consequences are limited. Even though there is limited availability of tools, such as fibro scan for the staging of liver disease, basic biochemistry tests to obtain Aminotransferase/Platelet Ratio Index (APRI) scores for the staging of fibrosis can be done at the township level, and ultrasonography is available up to District hospitals in Myanmar. Hepatitis B and Hepatitis C screening tests can be done at both National Laboratories and some private facilities; they are compulsory and free for blood donors but are not free of charge for everyone.

There are two main organizations concerned with liver diseases in the country: 1) The Gastro-Intestinal and Liver Society of Myanmar Medical

Association (MMA), the leading professional society which was formed 18 years ago, comprising mainly of clinical specialists such as hepatologists, gastroenterologists, surgeons, microbiologists, and physicians and 2) The Liver Foundation, a non-governmental organization founded on 12th December 2012, comprising mainly of physicians, researchers, business entities, celebrities, media, technicians and the general public.

The Gastro-Intestinal and Liver Society of MMA developed Viral Hepatitis Clinical Management Guidelines in 2013 and 2014. The Liver Foundation of Myanmar has been undertaking notable efforts to raise awareness among policymakers and the general public through conducting public talks, regular broadcasting on radios, occasional telecastson viral hepatitis; public screening for hepatitis B and C, hepatitis B vaccination (with limited resources) and counselling for seropositive cases.

Access to treatment for HBV and HCV infections is often limited to those who can afford out-of-pocket (OOP) payment in the private sector locally or overseas. Currently, there is no treatment facility in the public sector due to lack of drugs. The lack of drugs and the need for OOP payments often lead to treatment interruption or lack of treatment.

There was no previous National Strategic Plan (NSP) that focuses solely on the prevention and control of viral hepatitis. However, hepatitis prevention and control measures had been integrated with other disease control programs such as the National AIDS Program (NAP) and the National Tuberculosis Program (NTP). They include components for raising awareness, vaccination, general disease prevention, and prevention of transmission via injecting drug use, prevention of transmission in health-care settings, and treatment and care.

1.3. Government Leadership

The Department of Public Health (DOPH) has been designated for coordinating and carrying out viral hepatitis-related activities since 2014. The National Hepatitis Control Program (NHCP) is under the Central Epidemiological Unit (CEU) of the Department of Public Health, Ministry of Health and Sports. However, the operational nature of the program is expected to transverse over other related departments under the Ministry such as the Department of Medical Services (laboratory services and treatment), Department of Medical Research, and Department of Food and Drug Administration.

The government is undertaking viral hepatitis prevention and control activities that include targeting the following populations: health-care workers (including health-care waste handlers), people who inject drugs, migrants, prisoners, people living with HIV, pregnant mothers, children under one year of age(Routine Immunization), and low-income populations.

The Department of Public Health is responsible for awareness-raising for viral hepatitis. World Hepatitis Day events have been carried out since 2009, though not nationwide yet. In 2016, World Hepatitis Day events were held at the University of Nursing in Yangon, which included lectures and seminars by a panel of liver specialists with a focus on viral hepatitis prevention and control. There was active participation from representatives from various health sectors and communities. The government has funded other viral hepatitis public awareness campaigns since January 2011. The government also collaborates with the following in-country civil society groups to develop and implement its viral hepatitis prevention and control program: MMA, Myanmar Liver Foundation (MLF), Myanmar Health Assistant Association, Myanmar Nurses and Midwives' Association, Myanmar Maternal and Child Welfare Association, and Myanmar Red Cross Society.

The Ministry has developed a specific national strategy and policy for infection control and national guidelines for hospital infection control. This includes universal precaution to prevent hepatitis B and hepatitis C infection in health-care settings. Although there is a policy, a gap remains in implementation of infection control practices. The national policy on injection safety in health-care settings recommends single-use syringes for therapeutic injections. Single-use or auto-disable syringes, needles, and cannulas are available in all health-care facilities. However, there is no specific immunisation policy for health care providers and high-risk populations. There is also a national infection control policy for all blood banks. All donated blood units (including family donations) and blood products are screened nationwide for hepatitis B and hepatitis C. The government has guidelines that address food and water safety. Hospital infection control guideline was recently completed and disseminated.

In addition to the national policy, the Clinical Guidelines for Management of Viral Hepatitis have been finalised. To disseminate the simplified guidelines to health professionals, there are ongoing training efforts through the pre-service educational curriculum, on-the-job training, postgraduate training, and continuing medical education activities. The guidelines also include recommendations for cases with HIV co-infection.

For prevention of mother to child transmission, Myanmar has the national policy for hepatitis B which includes birth dose hepatitis B vaccination. Although that is limited to hospital deliveries, pentavalent vaccination was initiated in routine immunization program in 2013. Due to intermittent supply for birth dose vaccination since 2010, only 20-25% of hospital deliveries were covered.¹⁰ However, there is no national policy on hepatitis A vaccination.

¹⁰ Department of Health, 2014a. Myanmar EPI program data.

Myanmar is now ready for comprehensive prevention and control of viral hepatitis. The country is building a strong public-health program, with the help of international organizations, and is actively taking steps to address the health problems of its population. Myanmar has adopted the strategic directions for Universal Health Coverage (UHC), and action plans have already been initiated.

With overwhelming support from The Global Alliance for Vaccines and Immunizations (GAVI), policymakers, public health professionals, and medical practitioners in the country are aware that hepatitis B and C virus infection needs attention, and are interested in its prevention and control. However, awareness about viral hepatitis among the general population is limited, with little information available on the burden of hepatitis virus infection, diseases caused as a consequence of these infections, the routes of transmission of these infections, and their impact on mortality, quality-of-life and socio-economic aspects in the country.

There is only limited data available for developing evidence-based policy and action, and there is no routine surveillance for viral hepatitis. There are standard case definitions for hepatitis. Deaths, including from hepatitis, are reported to a central registry. Less than 5% of hepatitis cases are reported as “undifferentiated” or “unclassified” hepatitis. Liver cancer cases and cases with HIV/hepatitis co-infection are registered in specific responsible departments and units.

Acute viral hepatitis (A and E) outbreaks are reported to the government and are further investigated; the data are compiled and analyzed but not published. There is adequate laboratory capacity nationally to support investigation of viral hepatitis outbreaks and other surveillance activities.

1.4. National Consultative Workshops and development of strategies for NSP of Viral Hepatitis

The first national consultative workshop on the development of the National Hepatitis Control Program (NHCP) was conducted on 17th November 2014. This workshop served to develop the roadmap for the NHCP.

As part of the roadmap, the national workshop for developing treatment guidelines and the framework for the National Strategic Plan (NSP) was conducted on the 21st - 22nd of May 2015 and simplified clinical guidelines for screening, diagnosis, and treatment of management of hepatitis B was revised, and a simplified hepatitis C treatment guideline was also developed.

On 25th June 2015, the third consultative meeting was held in Nay Pyi Taw with the responsible national authorities, professionals and administrative personnel, WHO, INGOs, and civil societies;, and the National Simplified Guidelines for Diagnostic and Treatment of viral hepatitis and the framework for the NSP for Hepatitis were finalised. The Technical Working Groups (TWG) for the four strategic directions were also identified.

The fourth consultative meeting on the development of the NSP for hepatitis was conducted on the 15th - 16th September 2015, during which participants developed the draft NSP for viral hepatitis and introduced the Five-Year Action Plan of viral hepatitis. TWG meetings for each strategic direction were held in June and July 2016 to revise the draft and finalise the National Strategy and Operational Plan. The Operational Plan was developed with the activities which were costed out for each relevant year with the inputs from TWG and core group members.

2. Purpose, Vision, Goal, Objectives and Principles

2.1. Purpose

Given the high prevalence and ongoing transmission of viral hepatitis, it is imperative to reduce morbidity and mortality and to raise awareness among policymakers and the public for comprehensive interventions in collaboration with all stakeholders.

2.2. Vision

Free from viral hepatitis by stopping transmission, while those living with hepatitis have access to safe, affordable, and effective care and treatment.

2.3. Goal

To work within a health systems framework and use an effective public health approach within the premises of UHC to reduce:

- the incidence of HBV
- the incidence of HCV
- mother-to-child transmission of HBV
- mortality due to viral hepatitis
- the burden of disease attributed by chronic hepatitis, and
- the socio-economic impact of viral hepatitis on the individual, community, and national level.

To accomplish these goals, Myanmar will take an integrated health systems approach, including scaling-up successful interventions and developing new approaches while mobilising much-needed resources. The program will follow the framework for action to address the remaining challenges in hepatitis prevention and control.

2.4. Objectives

- To reduce hepatitis transmission through curative, preventive interventions and promotion of community awareness
- To ensure access to safe and effective care and treatment equitably according to severity of the disease
- To strengthen surveillance by detection of viral hepatitis transmission, morbidity, and mortality

2.5. Principles

The NSP is developed in line with the following key principles:

Equity - Viral hepatitis prevalence is higher among some groups where there is typically poor access to health care, such as People Who Inject Drugs (PWID), Men who have Sex with Men (MSM), sex workers, people in detainment, and also those with low socioeconomic status. Co-infection rates with HIV and TB are typically higher in these groups as well. When there is accessibility to treatment, there should be equity in which everyone with the infection will be treated. That said, in a resource-limited country, where there will initially be insufficient drugs to treat all, criteria need to be in place to prioritise treatment for people where it will be most effective in preventing mortality and transmission. When more resources become available, all those who are infected, regardless of sexuality, gender, drug usage, or social status, will be equally treated.

Universal Health Coverage (UHC) - The overall goal of the strategy is to work within a health system framework and use an effective public health approach within the premises of the UHC. This would include expanding the range of services provided, covering the populations in need of services and reducing the direct costs of the services.

Public Health Approach - The strategy is based on the public health approach. To ensure quality services for prevention, health promotion, and continuum of care for viral hepatitis, a plan of scaling-up access to the entire population is essential.

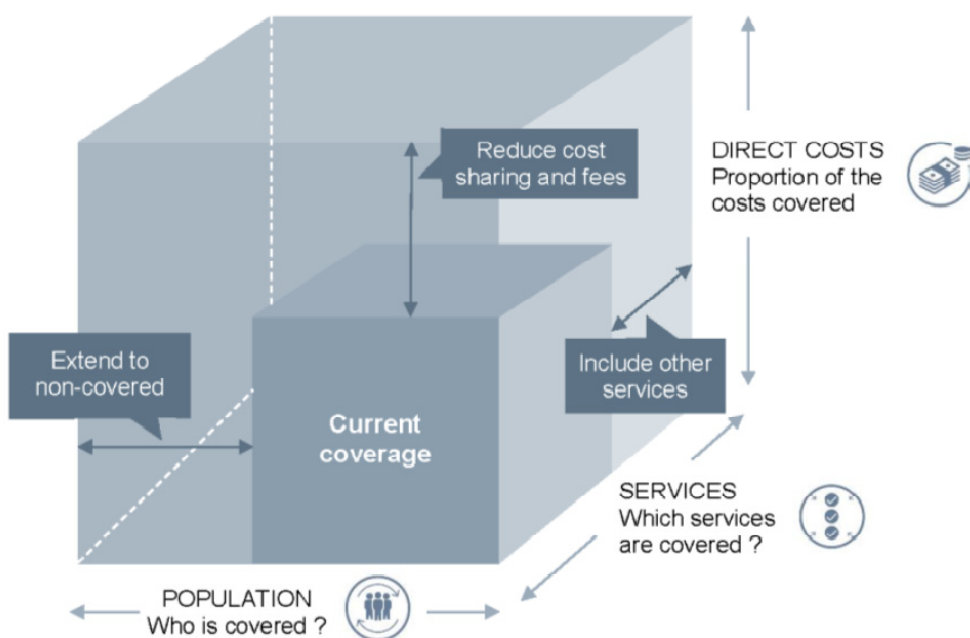
Evidence-Based Policy and Program Planning - The national response to viral hepatitis should be built on the principle of formulating policy and program planning based on high-quality research and surveillance, monitoring and evaluation. A strong and updated evidence base is essential to address new challenges and evaluate the effectiveness of current interventions. This will help to formulate policies which will be effectively tailored to a country context with limited available resources.

Partnership and community engagement - In a resource-limited country like Myanmar, the elimination of viral hepatitis needs collaborative involvement of relevant departments within the Ministry of Health and Sports (Department of Public Health, Department of Medical Services, Department of Medical Research, Department of Human Resources for Health, Department of Food and Drug Administration), and also between Ministries (Ministry of Education, Ministry of Social Welfare, Ministry of Home Affairs, and City Development Committees). To achieve its goal and plans for NHCP, partnership among the following actors is important: the Government, UN organizations, international and national NGOs, CBOs, self-help groups, professional associations, national and international entities, researchers, policy developers, and the private sector.

Integration - For optimization of service delivery, integration of NHCP with other established services/programs (e.g. NAP, NTP, National Drug Abuse Control Program (NDACP), Expanded Program on Immunization (EPI), Maternal and Child Health (MCH)) is crucial. Some areas of integration to consider for NHCP include:

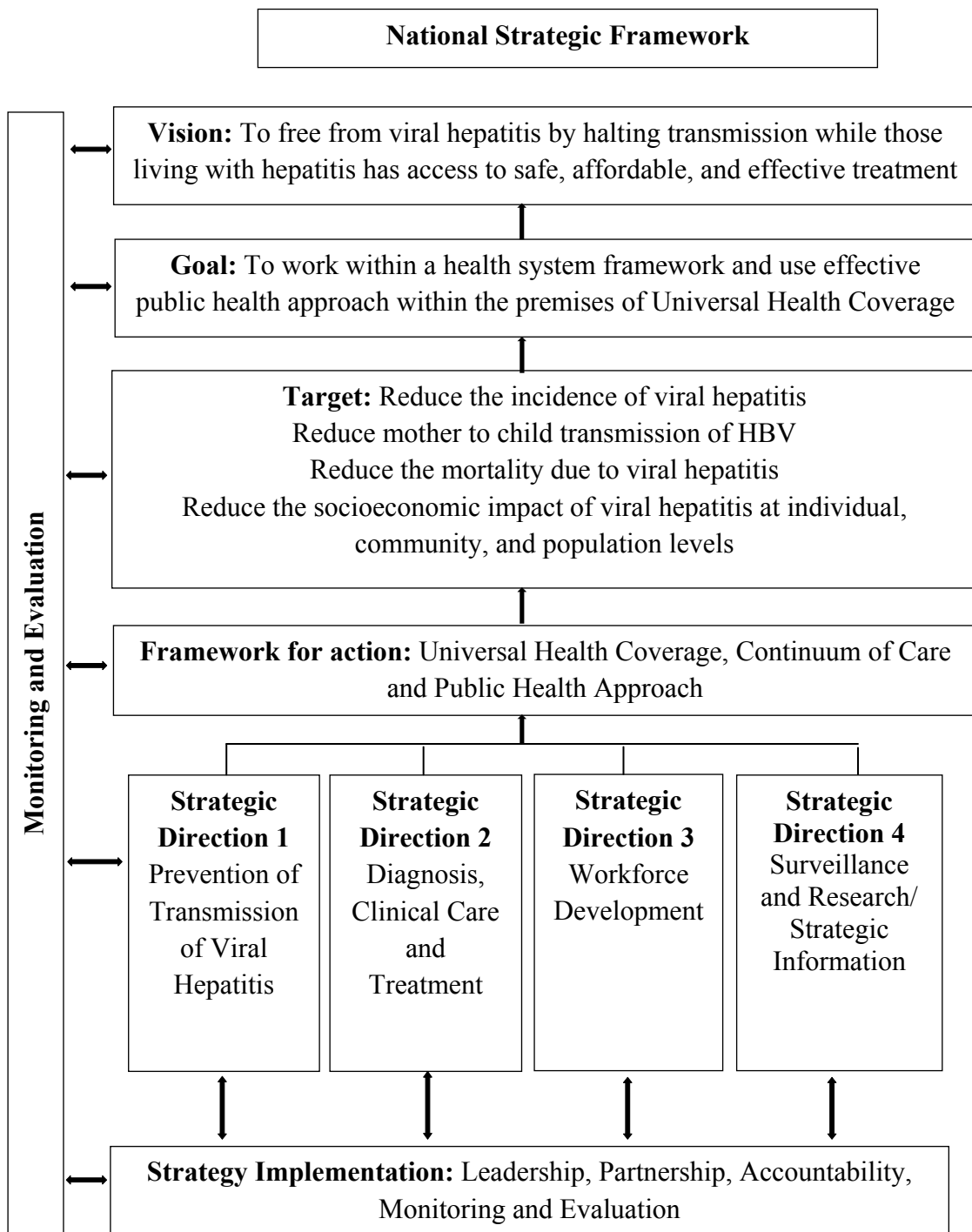
- Logistics Information Management System (LMIS) to strengthen procurement of hepatitis medications and diagnostics,
- EPI for delivering immunization
- Harm Reduction Program for service delivery to PWID and
- Linkage to NAP for treatment and care services through efficient referral systems

Figure 3: The three dimensions of Universal Health Coverage



Source: World Health Organization 2016. *Global health Sector Strategy on Viral Hepatitis 2016-2021*. p. 18.

Figure 4: National Strategic Framework



3. Strategies and Priority Actions

Strategies and priority actions and interventions under each strategic direction are based on available epidemiological data in line with the Global Health Sector Strategy for Viral Hepatitis and tailored to country context. The National Strategic Plan was costed, and the activities were included in the development of the Operational Plan. To achieve these objectives, the national strategic framework has four directions as:

- Strategic Direction 1: Prevention of Transmission of Viral Hepatitis
- Strategic Direction 2: Diagnosis, Clinical Care,& Treatment
- Strategic Direction 3: Workforce Development
- Strategic Direction 4: Surveillance, Research, and Strategic Information

Summary of Strategic Directions and Priority Actions

Strategic Direction 1 Prevention of Transmission of Viral Hepatitis	Strategic Direction 2 Diagnosis, Clinical Care and Treatment	Strategic Direction 3 Workforce Development	Strategic Direction 4 Surveillance and Research/ Strategic Information
1. Advocacy Education, communication for public awareness	1. Create systems and tools to enhance access to diagnosis, treatment and care	1. Collaborate with professional, medical, and other organisations to build a workforce capable of providing viral hepatitis prevention, care and treatment	1. Establish a national monitoring and evaluation system for comprehensive prevention and care of viral hepatitis interventions and activities
2. Prevention of mother to child transmission and Hep B birth dose	2. Identify persons infected with viral hepatitis early in the course of their disease and improve access to quality treatment and care	2. Build capacity of a workforce capable of providing viral hepatitis prevention, care, and treatment for Hepatitis	2. Establish a national hepatitis surveillance system
3. Achieve Hepatitis B vaccination for high risk populations and vulnerable adults		3. Strengthen enabling environment for health care workers to prevent viral hepatitis transmission	3. Strengthen research agenda for evidence-based documentation and planning
4. Infection control precautions & safe injection practices in health care setting			
5. Harm reduction program for the people who inject drugs (PWID) and People who use drugs (PWUD)			
6. Implementation of blood safety strategies			
7. Ensuring access to safe food and water			
8. Promoting safer sex through condom program			
9. Prevention and control measures for acute viral hepatitis outbreaks (A and E)			

PART II

Strategic Directions and Priority Interventions

1. Strategic Direction 1: Prevention of Transmission of Viral Hepatitis

Background

In Myanmar, the five hepatitis viruses are prevalent, and given the differences in geographic distribution, transmission routes and treatment, tailored prevention and control strategies are required. A successful prevention campaign against viral hepatitis will encompass a broad swath of policies, including infection control in hospitals and other medical and paramedical settings, a full coverage rate of childhood vaccination against HBV, and a strategy to control infection in high-risk groups such as health care workers, sanitation workers and PWIDs. An extensive public information campaign is also called for, as a significant proportion of HCV and especially HBV infections are community-acquired.

Opportunities exist for the Ministry of Health and Sports, Myanmar to collaborate with existing programs to efficiently and effectively implement the NSP for viral hepatitis. In 2015, the Department of Medical Research conducted a prevalence study on hepatitis B and C in the general population, and it has provided the country with baseline data for evidence-based preventive interventions tailored to the Myanmar epidemiological context. There is also an opportunity to collaborate with the MCH Program for screening of pregnant mothers and to include birth dose vaccination through the EPI program, which already has trained and experienced basic health staff.

For the management of viral hepatitis and HIV co-infection, screening and treatment in collaboration with the well-established NAP serve as an important opportunity. Also, partnership with the NDACP for provision of HBV vaccination and HCV treatment for people who inject drugs (PWID) and people who use drugs (PWUD) as part of harm reduction interventions is another potential area of work. Screening for hepatitis B and C has been conducted among PWID and PWUD as a part of the harm reduction package; however, more receptiveness and

effective coordination among different programs are critical for leveraging existing resources. Moreover, intra-ministerial coordination is also required to address viral hepatitis.

Standard Operational Procedures (SOPs) exist regarding the infection control in health care settings (dental and surgical procedures) and blood safety strategies on handling blood and blood products and for transportation of the samples. However, the SOPs should be reinforced and functionalised. Presently, mechanisms for data collection and reporting, coverage of preventive interventions and measures, and systematic referral network for diagnosis, treatment, and follow-up are not in place. To carry out the interventions on prevention and awareness activities, domestic and international funding sources must be identified.

Objectives

- To increase community awareness of viral hepatitis and preventive measures
- To reduce transmission of viral hepatitis in key targeted population
- To improve coverage of harm reduction programs inclusive of viral hepatitis

Interventions

1. Advocacy, Education and Communication for public awareness
2. Prevention of mother-to-child transmission of hepatitis B and hepatitis B birth dose
3. Hepatitis B vaccination for high-risk populations and vulnerable adults.
4. Infection control precautions and safe injection practices in healthcare settings
5. Harm reduction program for PWID and PWUD
6. Implementation of blood safety strategies
7. Access to safe food and water
8. Prevention and control measures for acute viral hepatitis outbreaks
9. Promotion of safe sex through condom program

1.1. Advocacy, Education, Communication for Public Awareness

To achieve national viral hepatitis prevention and control targets, the MOHS in collaboration with key partners must prioritise advocacy for leadership and commitment of politicians, policy/decision makers, the private sector, national and international donor organizations, and other relevant stakeholders.

Communication strategies will target national, state, regional, district, and township levels, as well as the private sector, donors, and implementing agencies. Advocacy measures and messages will clearly demonstrate the disease burden,

economic impact, pros and cons of action and inaction, and the overall impact of viral hepatitis on development.

Health care providers at all levels must be able to recognise the diversity of patients at increased risk for viral hepatitis, including pregnant women due to high risk of mother to child transmission of viral hepatitis, specifically hepatitis B. In addition, they must be aware of the updated guidelines on management and treatment of viral hepatitis, various cofactors that can hasten the progression of liver disease (e.g. obesity, alcohol use), monitoring of patients for signs of disease progression, and when to refer patients for specialty care.

Community engagement and participation is crucial for scaling up awareness and reducing stigma and discrimination. Community awareness on viral hepatitis must be achieved through active efforts designed to educate communities about the burden of viral hepatitis, infection control, and injection and blood safety in the country and respective localities. Moreover, an effective health education strategy which has emphasis on the benefits of viral hepatitis prevention, screening and care, liver wellness, alcohol reduction interventions, and food and water safety for Hepatitis A and E, is essential to increase public awareness. World Hepatitis Day should be held on the 28th of July annually and should be leveraged for nationwide advocacy and awareness raising activities.

1.2. Prevention of mother-to-child transmission of Hepatitis B and Hepatitis B birth dose

In 1992, WHO recommended that countries introduce hepatitis B vaccine into their national immunization schedules to prevent HBV-related disease and death. Hepatitis B vaccination is the most effective way to prevent HBV infection and is also one of the safest and most effective vaccines available to prevent liver cancer. It is considered as one of the top ten “best buys” in the field of non-communicable diseases.

Mother to child transmission of HBV occurs primarily at birth through infected blood. The risk of transmission from infected mother to her newborn is up to 90%. In 2009, the WHO emphasised prevention of mother-to-child HBV transmission by recommending that all countries, even those with low HBV prevalence, introduce universal hepatitis B birth dose (HepB-BD) vaccination.

Based on available evidence of high endemicity of chronic hepatitis B, expansion of HepB-BD in the national immunization schedule is a matter of priority. Birth dose vaccination was initiated in Myanmar in 2010, but due to the intermittent supply for birth dose vaccination, only 20-25% of hospital deliveries were covered.¹¹ There needs to be an increase in the coverage of HepB-BD vaccination as part of the national programs both for EPI and prevention of hepatitis.

Immunization-based strategies for prevention of HBV include:

(a) Provision of HepB-BD vaccination within 24 hours: Almost 90% of children with perinatally acquired infections will remain chronically infected. The baby of an HBsAg-positive mother has a 70% to 90% risk of infection if the mother is HBeAg-positive, and a 5% to 20% risk if she is HBeAg-negative. Post-exposure prophylaxis with HepB-BD vaccine immediately after birth dramatically reduces the risk of infection. In addition to the birth dose, it is advisable to give Hepatitis B immunoglobulin for those infants born of highly infectious HBeAg positive mothers.

HepB-BD administered within 24 hours, provides higher protection (70% to 95%) than if it is given after one week (50% to 57%). However, there are still protection benefits, reduced proportionately, if given within up to seven days after birth; this is particularly relevant for births outside health facilities.

¹¹ Department of Health, 2014a. Myanmar EPI program data.

In consideration of the public health approach, birth dose vaccination is to be implemented in a phased manner, with the primary focus on institutional deliveries, gradually scaling up to the community level to improve coverage and accessibility to infants born at home. Assessment of evaluation of the uptake after an appropriate time should be conducted to inform the scale-up plans.

- In Phase I, birth dose will be made available to infants born in General hospitals and Teaching hospitals in large cities by using multi-dose vials
- In Phase II, birth dose will be made available to infants born in District/ Township hospitals and health centres by using single dose, pre-filled injection devices
- In Phase III, birth dose will be made available to infants born at home by Midwives and Trained Birth Attendants at post-partum visit soon after birth

To successfully reduce mother to child transmission of hepatitis B, other technical considerations should be made to achieve community coverage of HepB-BD. NHCP can be used as a platform to:

- Ensure integration of birth dose vaccination into the cold chain network which includes availability of cold chain equipment to accommodate HepB-BD
- Consider providing birth dose vaccination Out of Cold Chain (OCC) or Controlled Temperature Chain (CTC) when available to achieve community-level coverage

(b) Achieving high level of three doses of Hepatitis B vaccination known as HepB3 coverage (Pentavalent Vaccine) among infants less than one year through routine immunization program: Based on estimated burden of disease, modelling suggests that a minimum HepB3 coverage (Pentavalent Vaccine) of 90% is

needed to reduce chronic infection rate to <1% among children. The HepB-BD must be followed by 2 to 3 subsequent doses to complete protection against perinatal infection to protect infants. Once high coverage of HepB3 is achieved, catch-up vaccination in younger children may also be considered.

Coordination and integration between the MCH Program and the Prevention of Mother to Child Transmission (PMCT) Program for screening of mothers during antenatal care to identify those with the risk of transmission to the baby, as well as provision of HepB-BD within the Expanded Program for Immunization (EPI) is needed to ensure that both HBV-infected mothers and infants receive the services needed to prevent hepatitis B transmission. The existing Adverse Effects Following Immunization surveillance system will need to be strengthened to include HepB-BD vaccination to monitor for any adverse events.

1.3. Achieve hepatitis B vaccination for high-risk populations and vulnerable adults

Hepatitis A and hepatitis B vaccines are safe and effective. The hepatitis B vaccine provides immunity for more than 20 years, and there is no need for boosters in immunologically potent persons as long as a full course has been adequately administered according to the recommended timelines.

Determining the duration of vaccine-induced immunity is particularly important for persons vaccinated as an infant and for the minority of healthy people and certain populations (e.g., the elderly and those with co-morbidities such as diabetes, chronic renal failure, HIV, and obesity) who respond poorly or are nonresponsive to the vaccine.

The cost of the vaccine is a barrier to hepatitis B vaccination among adults. It is essential to increase availability of and access to hepatitis B vaccines for adults, including those in priority/vulnerable populations.

Priority populations for vaccination outreach include:

- Health care providers
- Migrant population (internally and internationally)
- Institutionalised population
- People living with HIV & AIDS
- Patients with chronic liver disease due to the causes other than HBV
- Patients with chronic renal disease and patients on renal dialysis
- People who inject drugs & people who use drugs
- Men having sex with men
- Commercial sex workers

The EPI program is already providing HBV vaccination to infants and is planning a catch-up program to vaccinate the cohort who missed the birth dose between 2012 and 2013. Mobilization of Civil Society Organizations (CSOs) for provision of hepatitis B vaccination through preventive service packages in the community is encouraged.

1.4. Infection control and injection safety precautions and practices in health care settings

Infection control is one of the main priority areas in health care services of MOHS. Hepatitis B and C virus can be transmitted through infected blood, blood products and body secretions during surgical procedures, dental procedures, through the use of unsterilised syringes and equipment, blood transfusion, and other minor invasive procedures.

Infection control measures should include standard hygiene protocols as well as transmission-based precautions such as

- Hand washing (hand hygiene)
- Aseptic procedures

- Use of personal protective equipment when handling blood, body substances, excretions, and secretions
- Appropriate handling of patient care equipment and soiled linen
- Prevention of needle stick/sharp injuries
- Appropriate handling of sharps, and waste segregation, management and disposal
- Environmental cleaning and spill management

Injection-associated transmission of blood borne pathogens can be prevented through the development and implementation of a strategy to reduce injection overuse and promote injection safety. This strategy includes the use of a sterile, single-use, disposable needles and syringes for each injection given and prevention of contamination of injection equipment and medication. Use of single-dose vials is preferred over multiple-dose vials, especially when medications are to be administered to multiple patients. In healthcare settings, safe administration of all types of injections should be secured through the following activities:

- Conduct an initial assessment
- Secure government commitment and support for safe and appropriate use of injections
- Establish a national injection safety coalition, coordinated by MOHS
- Develop a national policy and plan
- Develop a systematic strategy for behaviour change among patients and health-care workers to decrease injection overuse and achieve injection safety
- Ensure the continuous availability of injection equipment and infection control supplies
- Set up a waste management system for safe disposal of sharps

Centralised standard infection controls, along with injection safety precautions and policies, should be implemented and practised by all health care service providers at both public and private institutions. The MOHS should train all health care workers for strict adherence to adopt standard procedures and

protocols. Hygiene practices in healthcare settings should also be monitored and evaluated to assess the need for improvement and reinforcement.

1.5. Harm reduction program for people who inject drugs (PWID) and people who use drugs (PWUD)

Harm reduction is a public health and human-rights-based approach that is critical to reducing the spread of blood-borne viruses such as HIV, hepatitis B and C, and other drug-related health and social harms among people who inject drugs (PWID). Harm reduction policies and practices are cost-effective, pragmatic, comprehensive, and evidence-informed.

Currently, there is no data on the number of drug users in the country. Injection drug users (males only) are estimated to be about 83,000.¹² People who inject drugs have been one of the key target populations of the NAP, and harm reduction interventions have been included in the National Strategic Plan of the NAP. These interventions need to be scaled up to maximise the impact. Also, many issues surrounding hepatitis B and C among PWID remain largely unaddressed, and it is critical to raise the profile and importance of prevention, vaccination, diagnosis, and treatment for viral hepatitis in this population.

To harness synergy between harm reduction and hepatitis prevention activities, the hepatitis program should:

(a) Optimise service delivery

- Provide needle-syringe program services at facility-based Drop-in Centres, mobile sites (out-reach), and through pharmacy-based distribution and peer-based outreach using a variety of program service delivery models. Regarding geographical location, the service delivery models should be feasible and convenient to all clients, and be tailored to reach

¹² National AIDS Program, 2014. Population Size Estimation.

subpopulations (e.g. women injecting drugs, new starter of PWID, PWID in prisons.)

- A comprehensive package of interventions in a one-stop service model, especially with HIV and Methadone Maintenance Therapy (MMT) programs, should be endorsed widely for prevention, treatment, and care of HBV and HCV among PWID. A comprehensive harm reduction program consists of ten interventions:
 1. Needle and syringe exchange programs
 2. Opioid substitution therapy (OST) and other drug dependence treatment
 3. HIV testing and counselling
 4. Antiretroviral therapy (ART)
 5. Prevention and treatment of sexually transmitted infections
 6. Condom programs for PWID and their sexual partners
 7. Targeted information, education, and communication
 8. Prevention, vaccination, diagnosis, and treatment for viral hepatitis
 9. Prevention, diagnosis, and treatment of tuberculosis
 10. Overdose treatment
- Provide community-based harm reduction activities with a referral system.

(b) Strengthen harm reduction networks

- Promote strong one-stop service delivery related to antiretroviral therapy, sexually transmitted diseases, tuberculosis, and overdose prevention.
- Collaborate with local pharmacies and local networks to provide no-cost NSP services in rural and underserved areas.

- Strong linkage needs between NAP and HBV/HCV control activities with harm reduction activities through regular coordination and collaboration meetings and information sharing.

(c) Educate, train, and evaluate

- Provide clients with information about distribution and disposal venues.
- Provide ongoing training and support to peer workers, and voluntary workers.
- Conduct community education, including schools to help increase support and maintain uninterrupted operation of programs.
- Conduct ongoing needs and feasibility studies for program models that are not offered and publish findings.

1.6. Implementation of blood safety strategies

One of the main modes of transmission for viral hepatitis B and C is by transfusion of contaminated blood and blood products. However, transmission is preventable by screening all blood and blood products in all transfusion services to ensure safe blood and blood products are available and accessible to the masses. Screening of blood products for hepatitis B and C should be incorporated into haemovigilance and monitoring activities. Improving blood safety is a vital public health duty to strive towards availability of quality and safe blood and blood products donated by regular, voluntary, and non-remunerated blood donors.

To implement blood safety and testing strategies in health care settings, the following activities must occur:

- Test all donated blood for hepatitis B and C.
- Prevent unnecessary blood transfusions by establishing policies and practices that promote rational use of blood and blood products.
- Strengthen national blood screening policies and strategies. Blood safety protocols and guidelines should include a reliable supply of quality-assured screening assays.

- Implement QC measures for laboratory testing for HBV and HCV.
- Strengthen and sustain routine infection control practices in health care and other settings.

1.7. Ensuring access to safe food and water

Hepatitis A and E viruses can be transmitted through the fecal-oral route. Poor sanitary and hygienic practices, unsafe water supplies, and poor food hygiene are prevalent in Myanmar, and are common modes of transmission, and contribute to the occurrence of outbreaks. Hepatitis A and E infections are usually not associated with chronicity such as cirrhosis and hepatocellular carcinoma, however, these acute infection can lead to severe complications in those who are alcoholics or certain populations such as pregnant women and can lead to the development of acute fulminant hepatitis followed by liver failure and eventually death.

There is a need for the following to improve access to safe food and water:

- Inter-sectoral collaboration with the water and sanitation department to ensure access to safe drinking water.
- Advocacy and communication for improved food safety practices through education of the public and enforcement of food safety practices for food handlers.
- Improved access to safe sanitation facilities and public education for safe disposal of human faeces and prevention from contamination of natural source of water.

1.8. Promotion of safer sex through condom program

Hepatitis B and C can be transmitted through sexual contact. Though the contribution of heterosexual sex to the overall burden of infection is small, some populations (e.g. men who have sex with men and heterosexual persons with

multiple sex partners) are at increased risk of these infections. Safe sex practices in these high-risk groups (e.g. the use of barrier methods and reduction in the number of partners) can reduce transmission of hepatitis viruses and several other pathogens (e.g. HIV and sexually-transmitted infections). In this regard, the NHP has to ensure sustainability of condom programs and communicate for consistent condom use especially among key populations.

Most preventative activities, which can prevent various forms of viral hepatitis, have already been undertaken as parts of other programs, such as HIV and sexually-transmitted diseases, food-borne illnesses, health promotion activities, and environmental health, though not specifically designed for prevention of viral hepatitis.

1.9. Prevention and control measures of Acute Viral Hepatitis outbreaks

The most common viral hepatitis outbreaks are due to viral hepatitis A and viral hepatitis E. The CEU is responsible for acute outbreak investigation and response. Hepatitis A virus (HAV) is usually transmitted by the fecal-oral route, either through person-to-person contact or through ingestion of contaminated food or water. Certain sex practices can also spread HAV. In many cases, infections are mild, and with most people recover fully and remain immune from further HAV infections. However, HAV and Hepatitis E Virus (HEV) infections can also be severe and life threatening. Most people in areas of the world with poor sanitation have been infected with this virus. Safe and effective vaccines are available to prevent HAV infection.

The evidence of faecal contamination of drinking water supplies has been associated with the outbreaks. Shedding of virus from enteric excretion into the environment from infected patients is one of the common modes of transmission of HAV and HEV. Therefore, prevention is the most effective approach against

outbreaks to have access to clean water and sanitation is the most effective approach to prevent outbreaks. The following approaches are to be considered:

- The environmental health unit and the city development committee should be coordinated.
- SOPs for outbreak response should be updated.
- The surveillance reporting system should be strengthened.
- Investigation and diagnosis of viral hepatitis should be expedited.
- Logistics and HR should be effectively mobilised.
- Vaccination of HAV at outbreak areas should be considered.

2. Strategic Direction 2: Diagnosis, Clinical Care & Treatment

The main goal of this strategic objective is to develop and maintain services to provide the highest quality of viral hepatitis diagnosis, care, and treatment. The Myanmar NHCP has adopted a service delivery model based on the public health approach of providing access to diagnosis, treatment, and care for viral hepatitis down to the township level. The NHCP will liaise with other programs to identify service delivery points for diagnosis, treatment, and care and to develop appropriate referral pathways for linkage between diagnosis and treatment. Significant attrition occurs between testing and referral to treatment at a health-care facility; as such, it is important to identify the appropriate referral pathways to improve linkage to treatment for those testing positive for viral hepatitis.

Additionally, developing mechanisms and systems to facilitate the implementation such as procurement and access to diagnostics and drugs, logistics and information management tools, the National Simplified Clinical Guideline, training model of health staffs for hepatitis prevention, care, and management are to be designed to reflect public health approach of obtaining expanded access to quality prevention, treatment, and care of viral hepatitis services. The facility

readiness for providing diagnosis and treatment is to be assessed based on availability of diagnostics and drugs, human resource capacity, and readily available systems for program implementation and reporting to ensure the quality of the services.

Objectives:

- To increase the number of people who know their HBV or HCV status
- To increase the number of eligible HBV and HCV patients on treatment
- To decrease mortality associated with HBV and HCV

Interventions:

1. Create systems and tools to enhance access to diagnosis, treatment, and care
2. Identify those infected with viral hepatitis early in the course of their disease and improve access to quality treatment and care

2.1. Create systems and tools to enhance access to laboratory diagnosis, treatment, and care

To enhance delivery of quality services for hepatitis diagnosis, treatment, and care, there needs to be systems and tools, which would serve as basic platforms on which the program is to operate. Within the existing health facility establishment, the mechanism for a standardised referral system for viral hepatitis B and C between testing/screening sites and treatment centres is to be formed. Furthermore, the available services should be mapped out to make use of the limited resources better. To sustain uninterrupted supplies of diagnostics and drug commodities, which is one of the important areas for delivery of effective treatment and care management, suitable quantification and forecasting tools should be used to determine the need of supplies for program implementation. The LMIS of NHCP should be integrated into an existing system in the country.

Health care providers should be trained by the hepatologists and the clinicians to improve attitude and skills to increase uptake of treatment and improve patient outcomes. An effective monitoring system should be established and operationalised for data collection and reporting among health facilities and integrated into existing Health Management Information System. A quality assurance mechanism and QC Guidelines should be designed for optimal testing of HBV and HCV.

The program should track the continuum of viral hepatitis services and the retention cascade. However, currently, there are limited systems and capacity of testing for confirmed diagnosis, treatment, and care in the public or private health sector in the country. Further surveillance and analysis that describe the continuum of care in various settings can illuminate health disparities among priority populations and guide resource allocation, program planning, and implementation.

2.2. Identify persons infected with viral hepatitis early in the course of their disease and improve access to quality treatment and care

Effective treatment of viral hepatitis requires timely screening and diagnosis. The majority of individuals, PWID, and those chronically infected with hepatitis B or C are unaware of their infections. Increasing the proportion of people, who are aware of their viral hepatitis infection, is a major goal of this strategic plan. Testing for HBV and HCV is a prerequisite for entry into care and treatment programs. Entry points for screening should be integrated into the National AIDS Program, the National Drug Abuse Control Program, the Reproductive, Maternal, Newborn and Child Health (RMNCH) Program, NGOs, and PLHIV network. Viral hepatitis B and C testing and diagnosis, referral to care, initiation of treatment, and achievement of viral suppression or cure represent a

continuum of care that can be used to evaluate and improve efforts to comprehensively address these endemic health problems.

Testing and diagnosis form a part of the continuum of care of hepatitis services. In Myanmar, laboratory diagnosis for viral hepatitis has not been strong other than screening for blood safety. Patients admitted to the hospitals with signs, and symptoms of liver pathology should be screened for hepatitis B and hepatitis C. The screening test should be advised to pregnant women, institutionalised populations, and population at risk, apart from blood donors for further management.

Screening of viral hepatitis by RDTs and basic biochemical tests needed for staging of the liver using APRI score is available at the township level. However, there is no mechanism to confirm positive cases for HBV and HCV in the public sector by Viral Load (VL) testing. VL testing and genotyping in private laboratories are expensive and not usually accessible by all patients. It is essential to establish VL testing facilities in the public sector and train laboratory staff to be able to enhance diagnosis and monitoring. The possibility of harnessing into the existing VL platforms from other programs such as NAP and NTP should be considered to fully utilise the existing capacity and reduce the extra expense of setting up a parallel system. Also, diagnostic platforms procured for the NHCP should be chosen carefully in consideration of the future plan of scale-up and decentralisation.

Establishment of the VL testing facilities should be in a phased manner, in line with the treatment implementation and strategic placement for accessibility of services.

- Phase I - National Health Laboratory, Public Health Laboratory, and 5 Specialist Hospitals
- Phase II - General Hospitals, Teaching Hospitals, States & Regional Hospitals
- Phase III - District and Township Hospitals

The National Simplified Treatment Guidelines for Hepatitis B and C in line with international guidelines were developed with the inclusion of pre-treatment care, on-treatment care, and post-treatment care. The purpose of the National Simplified Clinical Guidelines is to provide information on prevention, screening, diagnosis, treatment, and care of hepatitis C to physicians, general practitioners, and all health care providers in Myanmar so that access to curative services can descend to the township level with referral to the liver specialist for consultancy when appropriate. Treatment at INGO and NGO clinics may be done after prior approval from MOHS and should be in line with the National Simplified Clinical Guidelines.

Treatment of viral hepatitis C is to take place in a phased manner:

- Phase I - 5 Specialist Hospitals
- Phase II - States & Regional General Hospitals, Teaching Hospitals
- Phase III - District and Township Hospitals

Monitoring along the cascade of care includes the followings:

Pre-treatment Care

- Initial clinical assessment
- Counseling
- Laboratory testing
- Health education
- Psychosocial support

Treatment and On-treatment care

- Clinical monitoring
- Laboratory monitoring
- Adherence support

- Managing adverse effects such as toxicity
- Psychosocial support

Post-treatment care

- Adherence to counselling and support
- Clinical monitoring
- Laboratory testing
- Management of complication
- Health education
- Psychosocial support

A continuous sustainable supply of drugs and diagnostics is the most crucial for the program to be able to expand in its public health approach in delivering diagnostic and treatment services. This necessitates the NHCP to liaise with various suppliers locally and internationally to procure quality-assured drugs and diagnostics commodities at the best possible prices. Innovative sources for funding to procure diagnostics and drugs commodities should be explored to ensure sustainable funding to provide uninterrupted supplies. The Department of Food and Drug Administration (FDA) is responsible and will facilitate in accessing quality generic drugs and control of over-the-counter drugs to prevent occurrence of drug resistance and to improve patients' health outcomes.

Early diagnosis and improvements along the entire continuum of care can lead to reductions in the incidence of cirrhosis, liver cancer, and as well as improved quality of life, survival, and productivity for persons who are infected.

3. Strategic Direction 3: Workforce Development

The Viral Hepatitis Plan of Action is a multifaceted, comprehensive approach to preventing viral hepatitis and improving the lives of a huge number of infected persons. The country is well-endowed in human resources, to the point where there may be an excessive number of physicians compared to bed capacity. In public facilities, there are 56, 748 beds in 1, 056 facilities.¹³ According to the MOHS annual report in 2014, there are 63, 084 physicians in the country, and 31, 542 of them work for the MOHS.¹⁴ An insufficient number of these doctors, however, are trained in the management of patients with viral hepatitis.

The NHCP is obliged to build up the capacity and readiness of the health system for prevention, screening, diagnosis, and provision of quality care and treatment for infected persons leveraging the optimum skills-mix of the health workforce. Health care providers will be educated and trained to prevent transmission and provide treatment of viral hepatitis and to ensure reducing the disparities in provision of services for educating communities.

Objective:

- To build and strengthen the capacity of health workforce in prevention, diagnosis, treatment, and care

Interventions:

1. Collaborate with professional, medical, and other organisations to build a workforce capable of providing viral hepatitis prevention, care, and treatment
2. Build capacity for viral hepatitis prevention, care, and treatment
3. Strengthen an enabling environment for health care workers to prevent hepatitis transmission

¹³ Ministry of Health - Myanmar, 2012. *Annual hospital statistics report*.

¹⁴ Ministry of Health - Myanmar, 2014. *Health in Myanmar*.

3.1. Collaborate with professional, medical, and other organisations to build a workforce capable of providing viral hepatitis prevention, care, and treatment

Development of a workforce capable of providing viral hepatitis prevention, treatment, and care, requires participation of many stakeholders, including the NHCP, medical professionals from public and private sectors, people living with hepatitis, INGOs, NGOs, and CBOs. Training activities should be collaborative and leverage existing capacity building activities within other program areas. To achieve this, the National Human Resource Policy should include collaborative skill training.

In addition to collaboration among national programs, the work and expertise of professional associations, international partners, and other non-state actors should be strategically leveraged in order to build upon already existing and on-going skill development efforts. The DOPH and the Department of Medical Services should lead training to streamline training capacity for implementing partners involved in care and treatment of hepatitis. By engaging in effective partnerships, workforce development efforts will be scaled up more comprehensively and efficiently. Lastly, there should be a continuous effort to identify partners for additional technical and financial assistance so as to increase the resources available.

3.2. Building capacity for hepatitis prevention, care and treatment

To build the capacity of the viral hepatitis workforce, some training interventions/activities are required. Comprehensive training programs focused on the entire cascade of prevention, treatment, and care must be developed and disseminated throughout the healthcare system. In addition to training programs focused on diagnostics and treatment, healthcare workers must be equipped with the knowledge of best practices in injection safety and infection control measures

in order to prevent ongoing transmission. There must also be training programs available to those responsible for managing supporting systems, such as surveillance, monitoring, and evaluation, etc. Also, the capacity building of the workforce must be structured as part of an ongoing program, which includes Continuous Medical Education (CME) and mentoring programs for all.

Lastly, to effectively manage the growing viral hepatitis workforce, a human resource database must be developed to track the HR plan and monitor retention and turnover within the system. The human resource database will have the ability to track various training programs and will be able to map the placement of various healthcare professionals and therefore upgrade the capacity of various facilities to treat viral hepatitis.

3.3. Strengthen an enabling environment for health care workers to prevent hepatitis transmission

Initial training of healthcare workers is a critical aspect of workforce development, but for the workforce development to be sustainable, there must be CME programs focused on viral hepatitis infection control. While this is critical in all disease areas, it is a high priority for the NHCP's treatment and care landscape as it has been evolving rapidly and will continue to do so in the coming years.

The government is responsible for creating a safe and enabling environment for health care workers to prevent hepatitis transmission. The healthcare workers should be vaccinated while providing care, and infection control and universal precaution procedure should be reinforced and practised.

4. Strategic Direction 4: Surveillance, Research and Strategic Information

The monitoring and evaluation system is crucial to strengthen the national hepatitis response to viral hepatitis B and C and to enhance the availability of quality data to formulate evidence-based interventions to improve program implementations further.

The surveillance of viral hepatitis should encompass three main components which include: 1) the acute form of hepatitis, such as Hepatitis A, and E - infections often reported as hepatitis outbreaks, 2) the chronic form of hepatitis; HBV and HCV and 3) complications from chronic hepatitis, such as cirrhosis, hepatocellular carcinoma and chronic liver diseases. Out of the five known forms of viral hepatitis, hepatitis B and C virus infections pose the largest disease burden. Hence these infections form the focus of this surveillance strategy. Surveillance of chronic HBV and HCV may be used to evaluate the outcome of prevention and treatment activities such as immunization, infection control, safe injection and blood safety, harm reduction and programs for testing and treatment of HBV and HCV infection.

In Myanmar, many gaps exist in understanding the burden of viral hepatitis and the interventions needed to combat these infections. Even though a seroprevalence survey of hepatitis B and C among general population was conducted in 2015, there is a need to determine the prevalence of hepatitis B and C in children, the incidence of acute hepatitis, and establish a baseline prevalence of the complications (cirrhosis, hepatocellular carcinoma and chronic liver disease) attributable to HBV and HCV. The practical and good research questions formulated for identifying the gaps and solutions will lead to an evidence-based research linking to the decision making for quality care and management.

Objectives:

- To obtain evidence for advocacy and planning
- To understand the epidemic and the required response

Interventions:

1. Establish a national monitoring and evaluation system for the cascade of services
2. Establish a national surveillance system for program and disease monitoring of viral hepatitis
3. Strengthen research agenda for evidence-based documentation and planning

4.1. Establish a national monitoring and evaluation system for the cascade of services

A national monitoring and evaluation operational plan for hepatitis should be developed with involvement of all stakeholders, and use a multidisciplinary approach. For this to happen, a monitoring and evaluation system, consisting of data collection tools, reporting and recording systems, and sets of indicators, has to be established. Indicators will follow a clear cascade approach along the continuum of care for delivery of hepatitis services. Monitoring and evaluation of the viral hepatitis program builds upon other existing programs as information for viral hepatitis could be collected from different sources including immunization/EPI, National AIDS Program, Harm Reduction Program, National Drug Abuse Control Program, National Blood Transfusion Safety, and others. Therefore, some of the indicators should be streamlined and consistent with those of NAP and EPI.

There needs to be a strong coordination with hepatitis service providers and stakeholders to harmonise monitoring and evaluation procedures across all settings. Monitoring the program will allow documentation of the processes,

practices, and periodic results to see if the program is on track to achieve its goals. Evaluations should appraise data and information which can then be used as a basis for effective decision-making and efficient formulation of strategic information for programmatic improvement. Monitoring and evaluation should also include a logistics management system to track laboratory equipment, medicines and vaccines to identify best practices and to ensure an adequate supply of commodities. To achieve these objectives, securing a sustainable funding source is vital.

4.2. Establish a national surveillance system for program and disease monitoring of viral hepatitis

Surveillance for viral hepatitis is needed to direct and evaluate prevention and control interventions in the hepatitis cascade of care. There is a need to establish a national hepatitis surveillance system for hepatitis B and C infection. Based on the data collected from the surveillance system, the epidemiology of hepatitis B and C in the general population can be used to monitor trends in specific groups. Surveillance for acute hepatitis can be used to detect outbreaks, monitor trends of incidence, and identify risk factors for new infections.

4.3. Strengthen research agenda for evidence-based documentation and planning

There must be strong research capacity to implement evidence-based interventions. Partners should be identified for collaboration on research at both the national and international levels. Identification of funding is also important to carry out research. A research agenda should be developed, and the findings of the research should be disseminated for further implementation. Operational research is encouraged to assess different service delivery models and opportunities for improving coverage.

With the purpose of innovation for acceleration of the viral hepatitis agenda, new innovative approaches in diagnostics such as point of care tests, VL testing with dried blood samples, use of vaccines in Controlled Temperature Chain, pathogen reduction technology for blood safety, etc. should be explored.

5. Conclusion

Based on the four strategic directions of the Myanmar National Strategy for the Control of Viral Hepatitis, a five-year action plan shall be developed, and implementation will be started within the framework of the National Health Plan (NHP) 2017-2021. Access to quality services equitably and affordably is the overarching principle of the country's Universal Health Coverage approach. The action plan should also be confined to the principles of strengthening the integrated health system and reaching underprivileged populations.

For the NHCP to achieve success, there needs to be capacity building in all respective fields - clinical care, laboratory, research, surveillance, procurement and storage, and M&E. This requires strong collaboration with all relevant stakeholders on a regular basis to efficiently carry out an operational plan, make use of limited resources, and avoid duplication of work. Data collection and reporting should be harmonised across both public and private sectors as obtaining quality data is pivotal to effective implementation. Securing funding and resources is an integral part for the long-term sustainability of the program to achieve set targets and goals.

**Figure 5: Estimated cost of each strategic direction under the
National Strategic Plan
2016- 2020**

No	Strategic Direction	2017	2018	2019	2020
	Governance, Leadership and Coordination		17,400	17,400	17,400
Strategic Direction 1:	Prevention of Transmission of Viral Hepatitis B and C	244,900	218,942	304,627	304,627
Strategic Direction 2:	Diagnosis, Clinical Care & Treatment	5,338,304	19,184,857	31,684,232	38,226,149
Strategic Direction 3:	Workforce Development	40,500	66,750	57,950	48,150
Strategic Direction 4:	Surveillance, Research and Strategic Information	204,815	203,101	206,660	210,219
Total		5,828,519	19,691,050	32,270,869	38,806,545

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Annex 1: Proposed Research Agenda

Developing Research Agenda

- Create multidisciplinary research task force
- Conduct systematic review of available research/publications
- Identify gaps in research
- Increase capacity of MOHS to conduct research agenda on viral hepatitis, considering Ethics Review Committee and disseminate results

Proposed Research Agenda Regarding Health Systems Research

1. Determine incidence and prevalence in general population and specific groups
2. Determine incidence and prevalence of hepatitis B and C in advanced disease (cirrhosis and HCC, etc.)
3. Evaluate infection-control practices, behaviors, and attitude about HCV infection in different settings and groups.
4. Conduct qualitative research with Health Care Provider's to identify barriers (e.g. nurse/patient ratio, work overflow, and lack of knowledge) to adhere to recommended practices and preventive measures (e.g. HBV vaccination).
5. Conduct epidemiologic studies on needle sticks, endoscopy, laparoscopy, cardiac catheterizations, obstetrical procedures and other known risk factors of healthcare-associated viral hepatitis.
6. Evaluate purchasing practices of healthcare facilities to understand the patterns of use that contribute to poor compliance.
7. Evaluate reuse of single-use items.
8. Conduct a cost-effectiveness evaluation of several strategies to implement infection- control programs in different settings.

Proposed Research Agenda Regarding Blood Safety:

1. Determine the prevalence and incidence of HBV and HCV infection in the donor population and in transfused patients.
2. Identify risk factors for viral hepatitis infection among blood donors.
3. Research blood donor profiles, motivations, and deterrents.
4. Identify the most efficient interventions to recruit and retain uninfected blood donors.
5. Analyze patient outcomes following transfusion of blood products (e.g. adverse reactions and transfusion-transmitted infections).
6. Examine the effects of transfusion on the HCV-associated disease process.
7. Conduct cost-effectiveness studies on introducing nucleic acid testing in Myanmar.

Proposed Research Agenda Regarding Vaccination:

1. Identify the most effective HBV vaccine strategies among Health Care Providers.
2. Research non-responders to HBV vaccination.
3. Estimate HBV vaccination coverage in infants, children, and persons in high-risk populations.
4. Conduct cost-effectiveness studies on HAV vaccination.
5. Research need for a booster dose of HBV vaccine in Myanmar
6. Measure the HBV vaccinated population in the country
7. Calculate the HBV vaccine efficacy.

Proposed Research Agenda Regarding Care and Treatment:

1. Prioritise populations in need of viral hepatitis treatment through examination of cost- effectiveness data, markers of treatment response, and other variables.

2. Validate new methods for viral hepatitis screening and monitoring (e.g. point-of-care tests and markers of disease severity).
3. Comparative study on HCV core antigen and Viral Load
4. Estimate treatment response rates in “real-life” conditions, and identify factors associated with treatment response.
5. Estimate rates of relapse and re-infection following HCV treatment.
6. Determine the prevalence of genotypes of hepatitis C virus that would help in treatment
7. Identify safe and effective drugs or treatment regimens for persons with chronic viral hepatitis, whether naïve or former relapsers or non-responders.
8. Conduct a cost-effectiveness analysis of treatment strategies, including use of newly available antiviral therapies.
9. Conduct research access to care and treatment for infected populations.

Proposed Research Agenda Regarding Information, Education, and Communication:

1. Conduct modelling studies to identify the most powerful Information, Education, and Communication (IEC) interventions to decrease viral hepatitis transmission.
2. Conduct studies (e.g. KAP/focus groups) to determine a baseline for Health Care Provider’s beliefs, knowledge, and practices regarding hepatitis.
3. Identify indicators that can be measured repeatedly (e.g., during Demographic Health Surveys) to monitor behavioral changes (e.g. number of injections in the past year, proportion of re-use of injecting material).
4. Conduct studies to better understand the magnitude of stigma against people with viral hepatitis.

5. Conduct studies on school-aged children and school teachers to determine gaps in knowledge about viral hepatitis.
6. Conduct studies to understand youth (15-25 years of age) awareness of viral hepatitis.
7. Administer a survey to informal healthcare providers to better understand factors contributing to unsafe injections.
8. Research why the general population prefers injections over oral medications.

Annex 2: Country Profile

Population (in millions)*	51.49
Country classification (2014)	Low income
Gross income per capita (PPP int \$) (2014)	NA
Total health expenditure as % of GDP** (2014)	2.3%
Per capita total health expenditure (PPP int\$) (2013)	\$ 37
Per capita government health expenditure***	7268.5 MMK
Life expectancy at birth (in years) ****	66.8
Human Development Index (Human Development Report 2014)	0.524
Median age (in years)*****	27.1
Total fertility rate per women****	2.29
Sources:	
* Census Report, 2014	
** Global Health Observatory, 2013	
*** Health in Myanmar 2014	
**** Census, 2014	

