Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

22 January 2019

DEPARTMENT MEMORANDUM
No. 2019 - 0062

FOR: **DIRECTORS OF CENTER FOR HEALTH DEVELOPMENT (CHD) CENTRAL LUZON AND NCR; CHIEFS OF DOH HOSPITALS AND DOH-DESIGNATED HIV TREATMENT HUBS IN REGION III AND NCR; PROVINCIAL AND DISTRICT HOSPITAL DIRECTORS, PROVINCIAL GOVERNORS, CITY AND MUNICIPAL MAYORS IN REGION III AND NATIONAL CAPITAL REGION (NCR); AND OTHERS CONCERNED**

SUBJECT: **Integration of Chronic Hepatitis B Management in Selected Health Facilities in the National Capital Region (NCR) and Region III (A Demonstration Project)**

I. RATIONALE

The UN Sustainable Development Goal (SDG) Target 3.3 included the elimination of Viral Hepatitis B and C as one of the goals for 2030. Currently, the estimated Chronic Hepatitis B prevalence in Philippines is 10% (World Health Organization, 2018) Also, there were about 14,082 confirmed Hepatitis B cases in the country from 2013 to 2017 based on data from the Epidemiology Bureau. Of these, 1,184 (8%) and 968 (7%) cases were diagnosed in Region III and the National Capital Region, respectively.

The DOH- Center for Health Development (CHD) in the National Capital Region (NCR) and Central Luzon are initially identified to implement the demonstration project due to proximity of these offices to the Disease Prevention and Control Bureau (DPCB) for monitoring purposes, and the expressed cooperation of the DOH-CHD – National HIV, AIDS and STI Prevention and Control Program (NASPCP) technical officers to participate in this undertaking.

As Hepatitis B treatment is a new strategy of the Department of Health, a comprehensive framework for service delivery for Hepatitis B needs to be developed.

II. OBJECTIVES:

1. Document acceptability of a Viral Hepatitis B Service Delivery and Referral model including packages of services, recording and reporting system and monitoring of cascade of services.

2. Establish baseline information on Cascade of Cure (screening, treatment eligibility, treatment coverage) for Chronic Hepatitis B infection.
3. Evaluate the Hepatitis B Service Delivery and Referral model for planning on sustainability and implementation expansion.

III. SCOPE OF APPLICATION

This guideline is applicable for use in the selected areas of implementation (and its respective Local Government Units) in Region III and NCR. Likewise, this will be applicable for the DOH-CHD Central Luzon and NCR.

IV. GENERAL GUIDELINES:

1. The demonstration project shall be implemented at selected health facilities in the provinces of Bataan and Pampanga in Central Luzon and in the National Capital Region.
2. All clients and/ or patients present in in selected health facilities shall be offered free HBsAg test service.
3. All patients (ages >18 years old) positive with HBsAg screened in selected health facilities shall be referred for clinical assessment and subsequently initiate treatment if with chronic Hepatitis B infection.
4. In this project, **two tiers** of facilities shall be engaged within the service delivery model:

    A. ***Screening, Assessment and Treatment Facilities (SATF):*** These are health facilities capable of performing the following Hepatitis B-related health services:
        1. Hepatitis B screening through the use of a Hepatitis B Surface Antigen (HBsAg) Rapid Diagnostic Testing (RDT).
        2. Initiation of treatment for Hepatitis B patients, excluding those with the following conditions:
            a. Decompensated liver cirrhosis.
            b. Liver Cancer
            c. Immunosuppressed state
            d. Renal impairment
            e. Presence of coinfection
                i. HBV-HIV coinfection
                ii. HBV-HCV coinfection
            f. Uncertain disease progression

            All Chronic Hepatitis B patients with other conditions and/or comorbidities shall be referred to the nearest End-Referral Facility.
        3. Monitoring of patients as stated in the Hepatitis B treatment guidelines
        4. "Walk-in" patients shall also be screened for Hepatitis B, provided that the said patient was not screened prior to visiting the Assessment Facility.

    B. ***End-Referral Facilities (ERF):*** These are hospitals responsible for providing the following health services:
        1. Management of patients with complicated chronic Hepatitis (see *Appendix 1: Interim Guidelines on Chronic Hepatitis B Testing and Treatment*).
        2. These facilities shall also provide Hepatitis B screening services to all "walk-in" patients.

5. A joint evaluation shall be conducted by a Monitoring and Evaluation task Force on the 6th month of the implementation.

V. SPECIFIC GUIDELINES

1. All health facilities in the demonstration project sites shall be categorized into two tiers, based on the facility's capabilities:
   A. **Screening, Assessment and Treatment Facilities (SATF)** – this shall be composed of Rural Health Units (if applicable), Health Centers, Primary HIV care clinics, Social Hygiene Clinics, BEMONC facilities, and Level 1 Hospitals.
   B. **End-Referral Facilities (ERF)** – this shall be composed of Level 2 and Level 3 Hospitals.

2. Concerned LGUs shall adapt the following patient flow as template to their implementation of the demonstration project:
   A. HBsAg screening shall be done preferably in a SATF nearest to the patient's residence. All patients >18 years old shall be offered testing services in the said facilities. ERFs can also do screening services for "walk in" patients, those who will donate blood, pregnant patients as (part of the prenatal work up), or those that are admitted or seen in the Out-Patient Department (OPD) of the ERF that are either suspected to have or previously diagnosed with Hepatitis B. "Walk-in" patients must be given the option to undergo the screening and assessment process in the nearest SATF.
   B. A public health lecture about Viral Hepatitis B shall be performed by a health staff in the SATF and/ or ERF to the patients prior to screening.
   C. Patients who will opt to not undergo the screening shall be given an additional reminder about the risks of having Chronic Hepatitis B.
   D. All patients with a negative HBsAg test result shall be sent home and will be given additional advice on accessing health services for Viral Hepatitis B. They will also be advised to encourage their relatives and neighbors to avail the HBsAg testing services in the SATF.
   E. All patients with a positive HBsAg test result shall immediately be referred to the SATF physician or in the Out-Patient Department of the ERF. The physician shall perform a thorough history-taking and physical examination to the said patients. The patients shall be counselled as well by the physician or a trained nurse afterwards.
   F. All HBsAg positive patients shall also provide laboratory results on AST, ALT and Platelet count done in a DOH-accredited laboratory. The AST and ALT results shall be used as the baseline indication of the patient's liver function. Also, the AST and Platelet test results shall be used to assess the presence or absence of cirrhosis through the AST to Platelet Ratio Index (APRI) Score (See the *Definition of Terms* and *Section II* in Appendix 1 for more details about the APRI Score).
   G. All patients with an APRI score of more than 2 are eligible for treatment, and shall be immediately initiated on a Tenofovir-based regimen. Initiation of treatment shall be done in all SATFs. Patients screened and assessed in ERFs shall be advised to continue their medication in a SATF unless the patient lives nearer the ERF or if it is more practical for the patient to receive medications in the ERF. See *Appendix 1, Section II-2 (General Treatment Guidelines)* for details on treatment.
   H. All patients with an APRI score of less than or equal to 2 shall be referred to the ERF for HBeAg and HBV DNA testing. Patients that are eligible for treatment based on HBV DNA shall be immediately initiated on Tenofovir-based or Entecavir-based regimen in the ERF, whichever is available or applicable to the patient. These patients shall be advised to continue their medication in a SATF

unless the patient lives nearer the ERF or if it is more practical for the patient to receive medications in the ERF. See *Appendix 1, Section II-2 (General Treatment Guidelines)* for details on treatment.

I. All patients with other preexisting conditions, such as Viral Hepatitis C coinfection, HIV coinfection, Liver Cancer, Decompensated cirrhosis, Chronic Kidney Disease, immunosuppression not related to HIV, or undocumented disease progression shall be immediately referred to an ERF for further management.

3. Monitoring and Evaluation
   A. A Monitoring and Evaluation Task Force shall be organized and shall be composed of representatives from the following offices, agencies and organizations:
      1. DOH – Disease Prevention and Control Bureau (DPCB)
      2. DOH – Health Facilities and Services Regulatory Bureau (HFSRB)
      3. DOH – Epidemiology Bureau (EB)
      4. DOH – CHD Representatives
      5. World Health Organization (WHO)
      6. Hepatology Society of the Philippines
      7. Yellow Warriors Society of the Philippines
   B. DOH CHD Central Luzon and NCR shall provide reports on the following indicators:
      1. No. of persons screened for HBsAg
      2. No. of persons positive for HBsAg
      3. No. of persons diagnosed with CHB (Philippine Integrated Disease Surveillance and Response (PIDSR))
      4. No. of treatment eligible CHB patients
      5. No. of treatment eligible CHB patients who were started on treatment
      6. No. of CHB patients who are still on treatment six months after initiation
      7. No. of HBV suppressed (DNA<2,000 copies) patients after 1 – year of treatment, and
      8. No. of CHB patients who developed cirrhosis of Hepatocellular carcinoma after 1-year treatment.

VI. ROLES AND RESPONSIBILITIES

1. **Disease Prevention and Control Bureau (DPCB)** shall:
   A. Organize the Technical Working Group Monitoring and Evaluation Task Force;
   B. Lead the review on the 1-year outcome of the demonstration project;
   C. Augment resources such as RDT and anti-viral drugs in the selected implementation sites;
   D. Give technical assistance in capacity-building activities in the selected implementation sites.

2. **Department of Health – CHD Central Luzon and CHD NCR** shall:
   A. Disseminate these guidelines and other related reference materials to DOH-retained hospitals and other tertiary medical centers; local government units, and regional chapters of the professional medical societies;
   B. Organize trainings on the clinical management of chronic hepatitis B infection in hospitals and other health facilities in coordination with DPCB and medical societies;
   C. Support system of referrals from local government units, private clinics, and various health facilities to designated facilities catering to patients with chronic hepatitis B;

D. Conduct the regular monitoring activities among health care facilities catering to patients with chronic hepatitis B;
E. Collate, analyze and submit reports to DPCB and EB.

3. **DOH- retained hospitals** shall:
   A. Provide treatment and clinical monitoring of chronic Hepatitis B based on the Chronic Hepatitis B treatment guideline;
   B. Provide technical assistance to other health facilities and community-based organizations in need of professional trainings on the clinical management of chronic Hepatitis B infection;
   C. Submit monthly reports to DPCB, EB and DOH-RO.

4. **Epidemiology Bureau (EB)** shall:
   A. Conduct systematic data collection and analysis with NASPCP, DOH-CHD and partners;
   B. Provide technical assistance to enhance and standardize recording of data;
   C. Develop reporting forms and data entry books or spreadsheets;
   D. Analyze and disseminate reliable and timely information on Chronic Hepatitis B treatment done in the implementation sites;
   E. performance indicators.
   F. Develop a centralized repository of data (data dictionary) on Viral Hepatitis.

5. **Civil Society Organizations** are encouraged to:
   A. Assist in the linkage and care of patients with chronic hepatitis B;
   B. Conduct advocacy, patient education and stigma reduction activities to encourage patients to access Hepatitis B testing and treatment.

6. **Local Government Units (LGU)** are encouraged to:
   A. Support DOH-RO in establishing chronic Hepatitis B testing, treatment and care in every district municipality/ city hospital in their locality;
   B. Support their local health personnel to undertake continuous updating on skills and competency building in enhancing and advancing quality service delivery for chronic Hepatitis B;
   C. Ensure functional and efficient referral system among contiguous LGU and regional hospitals for patients with chronic hepatitis B.

7. **World Health Organization and other Bilateral Partners** are encouraged to provide technical support in the initial implementation of Chronic Hepatitis B treatment at selected health facilities in the National Capital Region (NCR) and Region III.

8. **Hepatology Society of the Philippines (HSP)** along with other medical/professional societies shall:
   A. Actively participate in the enhancement and updating of treatment strategies for chronic hepatitis B;
   B. Conduct continuing education activities for health care providers on viral hepatitis.

VII. Financing

1. The **IDPCD** shall allot funds for procurement of hepatitis B antiviral drugs annually based on NASPCP forecasting and recommendation from the involved DOH-CHD.

2. The **DOH-CHD** shall allot funds for capacity building and project monitoring/ evaluation-related activities.

VIII. EFFECTIVITY

This Order shall take effect immediately.

By Authority of the Secretary of Health

MARIA ROSARIO S. VERGEIRE, MD, MPH, CESO IV
OIC – Undersecretary of Health
Public Health Services Team

APPENDIX 1

Republic of the Philippines
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Interim Guidelines on Chronic Hepatitis B Testing and Treatment

I. RATIONALE

The Hepatitis B Virus (HBV) is a partially double-stranded DNA virus belonging to the Hepadnaviridae family. HBV infection has a long incubation period, varying between 1 to 6 months. In 95% of persons infected in adulthood, the infection resolves spontaneously and will not lead to chronic infection. In countries with high Hepatitis B prevalence like the Philippines, the most common mode of transmission is through mother to child at birth (vertical transmission) and transmission via contact with infected body fluids through broken skin in early childhood. Hepatitis B is a vaccine-preventable infection. Hepatitis B vaccination is ideally done by giving a "birth dose" (within 24 hours of birth), followed by the standard 3-dose vaccine regimen. Birth dose followed by at least two doses can effectively prevent vertical transmission of Hepatitis B in around 90% of cases, while a full 3-dose series of regular Hepatitis B vaccine can give 98% to 100% protection in >95% of healthy infants, children and young adults.

Viral hepatitis has a high economic burden. The cost for management and medication of both Hepatitis B and C are not only very expensive, but also very hard to access especially in rural areas. On top of these, patients with viral hepatitis can also lose economic potential due to termination from work, denial of employment for new job applicants, or loss of productivity due to cirrhosis and/ or liver cancer.

An estimated 10% of all adult Filipino population are chronically infected with the Hepatitis B virus (HBV). In the Philippines, chronic Hepatitis B infection (CHB) is the leading cause of cirrhosis and hepatocellular carcinoma (HCC), which develop in up to 30% of patients with CHB. Liver cancer is the fifth most common cancer and the second most frequent cause of cancer-related death globally, with HCC accounting for about 90% of all primary liver cancers.

In 2014, the World Health Assembly (WHA) underscored the need to eliminate Viral Hepatitis (including Hepatitis B) as a public health threat. Also, combating hepatitis has been included in the ratified Sustainable Development Goals, specifically under SDG 3.3. Moreover, the World Health Organization (WHO) defined the elimination of Viral Hepatitis as achieving a 90% decrease in new chronic infections and 65% reduction in deaths. For guidance, the WHO has released the Global Health Sector Strategy on Viral Hepatitis for 2016-2021. This strategy targets to increase diagnosis of those infected by Hepatitis B to 30 percent by 2020, and to give antiviral therapy to 80% of eligible hepatitis B patients by 2030. Antiviral therapy, together with efforts in screening, diagnosis and prevention, should lead to a 65% reduction in mortality from CHB by 2030.

This guideline is developed to ensure the safe and effective use of antiviral therapy in patients with CHB. This is also proof of the Philippine Government's commitment to the WHA

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declaration of eliminating Viral Hepatitis as a public health threat. It is mainly adapted from the *WHO Prevention, Care and Treatment of Persons with Chronic Hepatitis B Infection (2015)* and the *Hepatology Society of the Philippines' Consensus Statements on the Management of Chronic Hepatitis B (2014), and existing liver expert society guidelines (Asian Pacific Association for the Study of the Liver (2015), American Association for the Study of Liver Diseases (2015), and the European Association for the Study of the Liver (2017).* The creation of this treatment guideline was made possible through the collaboration of the Department of Health, the Hepatology Society of the Philippines and the WHO-Western Pacific Region and Country Office. These guidelines shall be updated as new information and data become available.

This copy shall serve as an interim guideline to be used for the Hepatitis B Treatment Demonstration Project in selected sites in Regions III and NCR, and in other future additional sites, if applicable. This shall also serve as an interim reference for the clinical management of Chronic Hepatitis B in the Philippine setting while waiting for the final treatment guideline to be published by the Department of Health.

II. OBJECTIVES

General

This guideline aims to provide all physicians with evidence-based recommendations on the management of patients with CHB in the Philippines.

Specific

1. To provide guidance on the management of patients with CHB.
2. To define the roles and responsibilities of the different stakeholders in the implementation of this guideline.

III. SCOPE AND COVERAGE

This Administrative Order (AO) covers government and private health facilities managing patients with CHB. It sets the minimum requirements for the initiation of and monitoring during antiviral therapy.

I. DEFINITION OF TERMS

1. Natural History of HBV Infection

1. Chronic Hepatitis B infection	Persistence of Hepatitis B surface antigen (HBsAg) for six months or more after acute infection with HBV. **For the purpose of this guideline, in the absence of a recent history of possible exposure in the past 6 months to Hepatitis B, a single positive serological assay for detection of HBsAg warrants the consideration of Chronic Hepatitis B infection.**
2. HBeAg seroconversion	Loss of HBeAg and development of anti-HBe

3. HBsAg seroconversion	Loss of HBsAg and development of anti-HBs
4. Cirrhosis	An advanced stage of liver disease characterized by extensive hepatic fibrosis, nodularity of the liver, alteration of liver architecture and disrupted hepatic circulation
5. Decompensated cirrhosis	Clinical complications of cirrhosis become manifest, including jaundice, ascites, spontaneous bacterial peritonitis, esophageal varices and bleeding, hepatic encephalopathy, sepsis and renal failure
6. Hepatocellular carcinoma (HCC)	Primary cancer of the liver arising in hepatocytes

2. Serological Markers for HBV

1. Hepatitis B surface antigen (HBsAg)	HBV envelope protein and excess coat particles detectable in the blood in acute and chronic hepatitis B infection
2. HBsAg loss	Two (2) consecutive HBsAg levels <0.05 IU/mL at least 1 year apart
3. Hepatitis B e-antigen (HBeAg)	Viral protein found in the high replicative phase of hepatitis B; marker of high levels of replication with wild-type virus. It appears early in the course of Hepatitis B infection.
4. Hepatitis B surface antibody (anti-HBs)	Antibody to HBsAg; develops in response to HBV vaccination and during recovery from acute Hepatitis B, denoting past infection and immunity
5. Anti-HBe	Antibody to HBeAg. Detected in persons with lower levels of HBV replication but also in HBeAg-negative disease (i.e. HBV that does not express HBeAg).

3. Tests for the Assessment and Monitoring of Hepatitis B Infection

1. Alanine aminotransferase (ALT) and aspartate aminotransferase (AST)	Intracellular enzymes which, as they are released after cell injury or death, reflect liver cell injury
2. HBV deoxyribonucleic acid (DNA)	HBV viral genomes that can be detected and quantified in serum. HBV DNA correlates with levels of circulating viral particles. HBV DNA is measured as IU/mL or copies/mL (1 IU/mL ~ 5 copies/mL; values given as copies/mL can be converted to IU/mL by dividing by a factor of 5, i.e. 10000 copies/mL = 2000 IU/mL)
3. AFP (alpha-fetoprotein)	A host cellular protein. High levels can occur in persons with hepatocellular carcinoma (HCC).
4. Persistently abnormal ALT level	In adults: Two ALT determinations above the upper limit of normal at least 3 months apart.

	In children: Three ALT determinations greater than twice the upper limit of normal (to be monitored every 3 months for at least 6 months)

4. Assessment of Liver Fibrosis by Non-Invasive Tests (NIT)

1. Aspartate aminotransferase (AST)-to-platelet ratio index (APRI score)	Simple index for estimating hepatic fibrosis based on a formula derived from AST and platelet concentrations. $APRI\ Score = \left(\frac{AST\ Level/ULN*}{\text{Platelet Count } (10^9/\text{L})}\right) \times 100$ APRI Score can also be derived through the following electronic tools: 1) Online calculator: http://www.hepatitisc.uw.edu/page/clinical-calculators/apri (see Figure 2 for the QR Code) 2) Mobile App: Calculate by QxMD, downloadable via iTunes App Store and Google Play Store (see Figure 3 for the QR Code) **ULN-Upper Limit of Normal*
2. Commercial biomarker test (LiverFast®)	Panel of tests that uses the results of six blood markers to estimate hepatic fibrosis
3. Transient elastography	A technique to measure liver stiffness (as a surrogate for fibrosis) and is based on the propagation of a shear wave through the liver

IV. GENERAL GUIDELINES

1. All Hepatitis B infected persons should be properly assessed for treatment eligibility.
2. Where resources are limited, less costly but reliable alternative diagnostic tests/indices may be utilized to guide the clinician in the decision to initiate treatment, and in monitoring response to treatment and disease progression.
3. Healthcare providers in primary care must be trained to manage Hepatitis B infected persons to ensure early assessment and timely initiation of treatment, especially in resource-limited settings. Opportunities for collaboration with specialists involved in the care of Chronic Hepatitis B patients should be made available.
4. Treatment-eligible chronic Hepatitis B patients should have access to effective and safe antiviral therapy.

   Chronic Hepatitis B patients started on treatment shall be closely monitored for adherence, response to treatment, adverse effects, drug resistance, treatment failure, and liver disease progression.

II. SPECIFIC GUIDELINES

1. Guidelines for Hepatitis B Testing:

A. Target Population
   1. In concurrence to the WHO recommendation, all adult Filipinos should have routine access to and be offered testing services, if linkage to prevention, care and treatment services are both available and accessible to the patients.
   2. In all settings, regardless of whether delivered through facility- or community-based testing, HBsAg serological testing and linkage to care and treatment services must be considered a priority to the following individuals:
      a. Adults and adolescents from populations most affected by HBV infection (i.e. who are either part of a population with high HBV seroprevalence or who have a history of exposure and/or high-risk behaviors for HBV infection):
         i. Men who have sex with men (MSM)
         ii. People who inject drugs (PWIDs)
         iii. People in prisons and other closed settings
         iv. Sex workers
         v. People with HIV
         vi. Overseas Filipino Workers (OFWs)
      b. Adults, adolescents and children with a clinical suspicion of chronic viral Hepatitis B
      c. Sexual partners, children and other family members, and close household contacts of those with HBV infection
      d. Health-care workers: in all settings, it is recommended that HBsAg serological testing be offered and hepatitis B vaccination given to all health-care workers who have not been vaccinated previously (note: to be matched with the guideline from the Occupational Health Office)
      e. Pregnant women: HBsAg serological testing should be routinely offered to all pregnant women in antenatal clinics as part of the prenatal screening, with linkage to prevention, care and treatment services. Couples and partners in antenatal care settings should be offered HBV testing services as well.
   3. In all settings, screening of blood donors should be mandatory with linkage to care, counselling and treatment for those who test positive.

B. Mode of Testing
   1. For the diagnosis of chronic HBV infection in adults, adolescents and children >12 months of age, a serological assay that meets minimum quality, safety and performance is recommended to detect hepatitis B surface antigen (HBsAg).
   2. Laboratory-based immunoassays are preferred in settings where laboratory testing is already available and accessible.
   3. Rapid Diagnostic Tests (RDTs) are preferred in settings where there is limited access to laboratory testing and/or in populations where access to rapid testing would facilitate linkage to care and treatment. Examples of this include Rural Health Units (RHUs), City Health Centers and Antenatal/ Lying in clinics.
   4. A single serological assay for detection of HBsAg is recommended, prior to further evaluation for HBV DNA and staging of liver disease. Confirmation of HBsAg positivity on the same immunoassay with a neutralization step or a second different RDT assay for detection of HBsAg is not required but can be performed whenever there is doubt on the accuracy of the previous test.

C. Quantitative HBV DNA levels and HBeAg status, when available, should be taken at baseline to guide decisions on initiating treatment.
D. Whenever available, HBeAg testing shall be performed following a positive HBsAg serologic test. Afterwards, a quantitative or qualitative Nucleic Acid Test (NAT) for detection of HBV DNA shall be done irrespective of the HBeAg result. This will serve as the preferred system of guidance on who to treat (or not to treat) for Chronic Hepatitis B infection.
E. Whenever HBeAg is not available or accessible, directly following a positive HBsAg serological test, the use of quantitative or qualitative nucleic acid testing (NAT) for detection of HBV DNA can provide guidance on who to treat or not treat.

2. General Treatment Guidelines

A. Diagnosis and Initial Evaluation of Chronic Hepatitis B
   1. In those above 12 years of age, Hepatitis B infection shall be diagnosed using a serologic assay for the Hepatitis B Surface Antigen (HBsAg) either through a Rapid Diagnostic Test, or in the form of a laboratory-based immunoassay *(see Section VI-2, Guidelines for Hepatitis B Testing)*.
   2. In the absence of recent history of possible exposure in the past 6 months to Hepatitis B, a single positive serological assay for detection of HBsAg, warrants the consideration of Chronic Hepatitis B.
   3. Comprehensive patient education and counselling should be provided to all patients who are diagnosed with hepatitis B infection (Table 1).
   4. Following a positive HBsAg test result, the presence of cirrhosis must be assessed based on clinical parameters (i.e., physical exam and laboratory tests) or when available, based on liver biopsy findings or non-invasive testing for fibrosis (NIT).
   5. In resource-limited settings, the aspartate aminotransferase/platelet ratio index (APRI) is the preferred NIT to assess for the presence of cirrhosis (APRI score >2 in adults). Other proprietary NITs may be used where they are available, and cost is not a major constraint. Table 2 shows the cut-off values of these non-invasive tests.
   6. Quantitative HBV DNA levels and HBeAg status, when available, should be taken at baseline to guide decisions on initiating treatment.
   7. For those with risk factors, testing for Hepatitis C Virus (HCV) (Table 3) and Human Immunodeficiency Virus (HIV) (Table 4) is encouraged at baseline. HCV and HIV screening are required for all patients who are to start Hepatitis B antiviral therapy.
   8. For those with risk factors for hepatocellular carcinoma (HCC) (Table 5), screening and surveillance for HCC (e.g. AFP and ultrasound) should be done every 6 months.

B. Criteria for initiation of antiviral therapy in patients with CHB (Figure 1)
   1. Patients diagnosed with Chronic Hepatitis B shall be evaluated for cirrhosis at baseline entry. Cirrhosis can be diagnosed through the presence of any the following:
      a. On history or physical exam: presence of jaundice, coagulopathy, ascites, variceal hemorrhage, hepatic encephalopathy, hepatomegaly, splenomegaly, pruritus, fatigue, spider angiomata, and palmar erythema, or;
      b. APRI score of > 2 or other proprietary non-invasive tests for fibrosis (see Table 2 and Definition of Terms), or;

c. Imaging tests indicating cirrhosis (ultrasound, CT or MRI), when available, or
d. Liver biopsy showing cirrhosis, when available.

2. Adults, adolescents and children with CHB and clinical evidence of compensated or decompensated cirrhosis shall be prioritized and given antiviral therapy, regardless of ALT levels, HBeAg status or HBV DNA levels.
3. Adults with CHB who are **not cirrhotic**, but have **persistently abnormal ALT levels**, together with evidence of significant HBV replication, should be treated with antiviral therapy. The following are the **recommended cut-offs for significant HBV replication based on HBeAg status:**

Table 1. Cut-off Values for Significant HBV Replication Based on HBeAg Status

HBeAg Status	HBV DNA Value
Positive	≥ 20,000 IU/mL
Negative	≥ 2,000 IU/mL

4. **When HBeAg testing is not available:** treatment may be considered for those with persistently abnormal ALT levels and HBV DNA ≥ 20,000 IU/mL.
5. **When HBV DNA testing is not available:** Treatment may be considered based on persistently abnormal ALT levels alone, regardless of HBeAg status, but other common causes of consistently raised ALT such as nonalcoholic fatty liver disease (NAFLD), chronic alcohol abuse, Hepatitis C infection **must be excluded first. Specialist referral is recommended in patients starting antiviral therapy based on this indication.**
6. Continued monitoring is necessary in all persons with CHB. Special attention should be given to those **who do not currently meet the recommended criteria for treatment currently but may require antiviral therapy in the future** to prevent progressive liver disease.

C. Initiating Treatment for Treatment eligible patients

1. In all adults, pregnant women, adolescents and children aged 12 years or older in whom antiviral therapy is indicated, the nucleos(t)ide analogues (NAs) which have a high barrier to drug resistance are recommended: tenofovir disoproxil fumarate (TDF), tenofovir alafenamide (TAF), or entecavir (ETV)). For patients who have been treated with NAs in the past, the recommended NA is TDF or TAF.
2. The dose of antiviral therapy for both adults and children and the dose adjustment for adult patients with renal impairment, are outlined in Tables 6, 7 and 8. Children who require antiviral treatment should be comanaged with a pediatric gastroenterologist or hepatologist.
3. Avoidance of TDF and use of ETV or TAF instead, or dose reduction of TDF (guided by Table 8) is advised in those at risk of renal and bone disease (Table 9).
4. The use of TAF is not recommended in children (<19 years).
5. Nucleos(t)ide analogues with a low barrier to resistance (lamivudine, adefovir telbivudine or clevudine) are associated with high rates of drug resistance and should not be used.

6. Recommended duration of antiviral therapy and criteria for discontinuation of NAs.
    a. Persons with compensated or decompensated cirrhosis-should NOT discontinue treatment and need nucleos(t)ide analogues (NAs) lifelong.
    b. In all other patients, lifelong therapy is likewise recommended because of the high rates of virologic breakthrough after discontinuation
    c. Discontinuation of antiviral therapy may be considered ***exceptionally ONLY*** in those who satisfy ALL of the following criteria:
        i. **No** clinical or diagnostic evidence of cirrhosis **and,**
        ii. Persistently normal ALT level and persistently undetectable HBV DNA level (when testing is feasible). Persistently normal ALT level and persistently undetectable DNA level is defined as normal ALT levels and undetectable DNA levels respectively at 3 determinations taken at 6-month intervals over 2 years **and,**
        iii. Can be followed up carefully long term for reactivation **and,**
        iv. In persons initially HBeAg-positive, HBeAg loss and seroconversion to anti-HBe **and** after completion of at least one additional year of treatment after seroconversion.
    d. Discontinuation of antiviral therapy may also be considered in cases where the patient becomes HBsAg negative, following either antiHBs seroconversion or at least an additional 12 months of treatment following HBsAg loss.
    e. Monitoring in those who discontinue antiviral therapy
        i. Discontinuation of antiviral therapy will require close monitoring for reactivation and should be done under the supervision of a specialist (gastroenterologist/hepatologist for adults and pediatric gastroenterologist/hepatologist for children).
        ii. ALT and HBV DNA (when HBV DNA testing is available) should be monitored monthly for the first 3 months then every 3 months for 1 year, then every 6 months thereafter.
    f. Resumption of prior antiviral therapy should be considered if there are signs of reactivation which include any of the following:
        i. HBsAg or HBeAg becomes positive from negative
        ii. Increasing ALT levels
        iii. HBV DNA becomes detectable again (when HBV DNA testing is available)

D. Monitoring of patients diagnosed with Chronic Hepatitis B

1. Monitoring during antiviral therapy
    a. Persons initiated on antiviral therapy should be seen every 3 months. Adherence and signs of treatment failure should be ***strictly*** monitored regularly and at each visit. More frequent monitoring, and specialist referral shall be done for patients with decompensated cirrhosis.
    b. In persons on antiviral therapy the following should be monitored at least annually:
        i. AST, ALT, and platelet count
        ii. APRI score (calculated from AST and platelet count)
        iii. HBsAg
        iv. HBeAg, anti-HBe and HBV DNA levels (when available)
        v. Signs of treatment failure (i.e., rising ALT or AST levels, rising HBV DNA levels (when available), or development of clinical signs and symptoms of decompensation (i.e., jaundice, ascites, encephalopathy, weight loss)

c. Renal function should be monitored annually. It should be monitored every 6 months in patients at high risk of renal toxicity, including those with CrCL < 50 ml/min. Monitoring of renal function may be through the following:
   i. Serum creatinine and estimated GFR trend (preferred)
   ii. Monitoring for proteinuria and glucosuria (urine dipstick)
   iii. Serum Phosphate
d. Growth monitoring, as well as specialist follow-up by a pediatric gastroenterologist or a pediatrician in children (above 12 years of age) on tenofovir disoproxil fumarate.

E. Monitoring of those not currently on antiviral therapy
   a. In persons who do not yet meet the criteria for antiviral therapy, the following should be monitored at least annually:
      i. ALT, AST and platelet count
      ii. APRI score (calculated from AST and platelet count)
      iii. HBsAg
      iv. HBeAg, anti-HBe and HBV DNA levels (when available)
      v. Noninvasive tests for fibrosis (eg Liver Elastography or proprietary blood tests for fibrosis) to assess for cirrhosis, in those without cirrhosis at baseline (when available).
   b. More frequent monitoring shall be done every 6 months in:
      i. Persons who have intermittently abnormal ALT levels
      ii. HBeAg positive persons who have fluctuating HBV DNA levels between 2000 IU/mL and 20,000 IU/mL (when HBV DNA testing is available)
      iii. HIV and HCV co-infected persons
   c. Screening for Hepatocellular Cancer in high risk HBsAg positive individuals using Liver ultrasound and AFP testing every 6 months for those who have risk factor(s) for HCC (Table 5).

3. Treatment Guidelines for Special Populations
   A. HIV-HBV Coinfection
      1. All HIV-HBV coinfected individuals must be started on appropriate ART regimens regardless of CD4 count.
      2. HIV-HBV-coinfected persons should be simultaneously treated for both HIV and HBV infection, and receive antiretroviral therapy (ART) that is active against both viruses to reduce the risk of resistance. A tenofovir-based regimen is the recommended therapy, which should include tenofovir/lamivudine, or tenofovir/ emtricitabine (provided there is no contraindication to tenofovir), together with a third drug efavirenz, to prevent the selection of HIV-resistant mutants.
   B. Pregnant women
      1. All pregnant women should be screened for Hepatitis B at the first prenatal visit.
      2. Indications to treat Chronic Hepatitis B in adults as already outlined above also apply to pregnant women.
      3. To prevent mother-to-child HBV transmission, the first dose of hepatitis B vaccine should be given to the infant within the first 12-24 hours of life followed by 2-3 doses of the vaccine as prescribed by the DOH EPI schedule.
      4. When it is available, for babies born to HBsAg+ mothers, Hepatitis B Immunoglobulin 0.5 ml should be administered IM as soon as possible after

birth (within 12-24 hours) at the same time but at a different site as the birth dose of the Hepatitis B vaccine.

5. Tenofovir disoproxil fumarate (TDF)is the preferred antiviral if treatment is deemed necessary during pregnancy.
6. Pregnant women considered for antiviral treatment should be co-managed with specialists (hepatologist or gastroenterologist or OB-Infectious Disease specialists).
7. For mothers who do not satisfy criteria for antiviral therapy as outlined in Section VI. B, antivirals may be indicated to decrease the risk of neonatal transmission of Hepatitis B when maternal HBV DNA > 200,000 IU/mL. Short-term treatment with antivirals starting from 28 to 32 weeks of gestation is recommended using TDF for decreasing transmission.
8. For mothers who start TDF in the third trimester, NAs can be stopped at birth, when breastfeeding starts, or 1-3 months after delivery, if there is no contraindication to stopping NAs . Due to the uncertainty in long-term safety for the infants, the risk and benefits of breast-feeding and possible infant exposure to tenofovir must be discussed by the health provider with the mother.
9. Maternal liver disease status may be an indication to continue antivirals after delivery.
10. Pregnant women with Chronic Hepatitis B who remain untreated or discontinue antiviral treatment during pregnancy or early after delivery for any reason, need to be monitored closely for viral flares especially after delivery.
11. Breastfeeding is not contraindicated in mothers who are Hepatitis B positive. TDF may be minimally excreted in breastmilk and are unlikely to cause significant toxicity. The unknown long-term risk of infant exposure to tenofovir must be made known to mothers. If the option of stopping antivirals after birth is taken, close monitoring for flares through ALT monitoring every 1-3 months must be done.
12. Post-vaccination testing with HBsAg and antiHBs of infants of HBsAg positive mothers is recommended 1-2 months after the last dose of the Hepatitis B Vaccine.

C. Patients who are being enrolled in PReP Program

1. All persons starting PReP should be screened for Hepatitis B with HBsAg and anti-HBs.
2. If they are negative for HBsAg and anti-HBs, vaccination for HBV is recommended.
3. Indications to treat Chronic Hepatitis B in adults as already outlined in Section VI.B. also apply to CHB patients starting PReP.
4. If CHB patients starting PReP satisfy criteria for antiviral therapy as outlined in Section VI.B., they should be given antiviral therapy containing TDF and undergo monitoring as outlined in Section VI.D.1.
5. For CHB patients who do not satisfy criteria for antiviral therapy as outlined in Section VI.B. and are started on PReP. A regimen containing TDF must be used for PReP. These patients should be closely followed for adherence.
6. If a CHB patient on PReP decides to stop PReP, the following should be considered:
   a. If they had an indication for antiviral therapy for CHB as outlined in Section VI.B, they need to continue antiviral therapy for CHB with TDF and undergo monitoring as outlined in Section VI.D.1.
   b. If they did not have an indication for antiviral therapy as outlined in Section VI.B, they need to be monitored closely for viral flares especially after discontinuation of PReP. This is done through ALT monitoring every 1-3 months.

7. CHB Patient who are already on antiviral therapy.
    a. These patients should be evaluated according to Section VI.A.
    b. HBV DNA testing within 6 months of clinic visit is mandatory in these patients.
    c. If HBV DNA is not detectable, the patient can be continued on TDF or switched to TAF if they were already of TDF or switched to TDF or TAF if they were on a NA other than TDF or TAF.
    d. These patients should then undergo monitoring as outlined in Section VI.D.1.
    e. If HBV DNA is detectable, referral to a specialist is recommended for co-management.

8. Patients with decompensated cirrhosis
    a. Specialist (Hepatologist or Gastroenterologist) referral should be done.
    b. For patients with signs of hepatic decompensation (encephalopathy, jaundice, coagulopathy), treatment should be initiated promptly with entecavir or TDF.

9. Patients at risk for or with renal impairment
    a. For patients at risk for kidney disease, TAF or ETV are the preferred antivirals. (See Appendix Tables 8 and 9)
    b. All NAs require dose adjustment and should be used with caution in persons with renal impairment or in renal transplant patients. They should be co-managed with a specialist in Hepatitis B and in kidney diseases
    c. Unexpected deterioration of renal function during antiviral therapy may necessitate a change of treatment or further dose adjustment.
    d. All HBsAg-positive persons undergoing renal transplantation should receive prophylactic NA therapy to prevent HBV reactivation.

10. Children
    a. CHB is generally benign and asymptomatic in children (<19 years old) as they are generally in the immune tolerant phase of the infection.
    b. For children with hepatitis B who are assessed to require treatment, refer for specialist consult
    c. Antiviral therapy generally require long-term treatment and there are concerns regarding long- term safety and drug resistance. Hence, a conservative approach is generally indicated unless the child presents with cirrhosis or evidence of severe ongoing liver inflammation on liver biopsy.
    d. Criteria for the initiation of antiviral therapy for HBV in childhood follow the criteria used for adults (Refer to Section VI. B.)
        i. HBeAg positive children with ALT 1-2 times of the upper limit of the normal value (ULN) with HBV DNA> 20,000 IU/ml AND HBeAg negative children with ALT 1-2x of the ULN with HBV DNA > 2,000 IU/mL should have other liver diseases ruled out and preferably have liver biopsy to document moderate to severe necroinflammation prior to starting antivirals.
        ii. Non-invasive tests for fibrosis (i.e., APRI score, commercial biomarker tests, transient elastography) are not recommended for use in children. Currently, the utility of NIT's in the pediatric population, while promising, remain largely investigational.

4. Guidelines on When to Seek Specialist Care

Specialist care is warranted for CHB patients with the following conditions:

A. Decompensated cirrhosis
B. Uncertain progression of disease or with signs of treatment failure
C. Indications for treatment are uncertain
D. Family history of hepatocellular carcinoma
E. HIV or HCV co-infection
F. Renal impairment, on dialysis, or renal transplant patient
G. Current antiviral therapy for CHB with detectable HBV DNA
H. Pregnancy
I. Pediatric patients
J. Patients who will receive chemotherapy or immunosuppressive therapy including steroids
K. Hepatitis B-infected health care workers who need evaluation and clearance prior to performing Exposure Prone Procedures.

Attached in this circular is the algorithm for the demonstration project, from screening to end-referral level.

Table 1. Initial evaluation and counselling of patients with Hepatitis B should include the following:

- History: medical, family history of liver cancer or cirrhosis, liver-related symptoms (i.e., jaundice, abdominal distention, gastrointestinal bleeding, encephalopathy)
- Complete physical examination - jaundice, ascites, hepatomegaly and splenomegaly, encephalopathy, asterixis
- Standard required laboratory tests: ALT, AST, CBC, including platelet count and white cell count;
- Additional tests to assess liver disease: serum albumin and prothrombin time or international normalized ratio (INR),Total bilirubin
- Quantification of serum HBV DNA, HBeAg and anti-HBe, when available
- Non-Invasive Tests for fibrosis – APRI score and/or Transient Elastography (when available) or Liver Fast™ (when available)
- Ultrasonography and alpha-fetoprotein (AFP) for HCC screening
- Baseline renal function[a]: Creatinine, Creatinine clearance (CrCl)/estimated glomerular filtration rate (eGFR) using the Cockcroft–Gault (CG)
- Assessment of baseline risk for renal dysfunction[b]
- Presence of comorbidities including coinfections: HIV, HCV or HDV, impaired glucose tolerance, dyslipidemia, nonalcoholic fatty liver disease, alcoholic liver disease, iron overload and drug/toxin-induced injury
- Assessment of alcohol consumption, counselling regarding abstinence
- Test for anti-HAV IgG. If negative, vaccination is recommended.
- Advise regarding screening of household and family members with HBsAg, and advise regarding contact and transmission precautions

[a]An online calculator is available at http://nephron.com/cgi-bin/CGSI.cgi. For children, the Schwartz or similar formula can be used: http://nephron.com/bedsidepedsnic.cgi.
CG formula: eGFR = (140 – age) x (wt in kg) x 0.85 (if female) / (72xCr in mg%) Estimation of GFR based on these formulas may underestimate the degree of renal dysfunction if muscle mass is lower than the age and sex standards, as is frequently the case in HIV-infected individuals.
[b]Factors associated with a higher risk of renal dysfunction include: decompensated cirrhosis, CrCl <50 mL/min, older age, body mass index (BMI) <18.5 kg/m2 (or body weight <50 kg), poorly controlled hypertension, proteinuria, uncontrolled diabetes, active glomerulonephritis, concomitant use of nephrotoxic drugs or a boosted protease inhibitor (PI) for HIV, and solid organ transplantation.

Table 2. Cut-off values of non-invasive tests for the detection of cirrhosis.

	APRI (high cut-off)	Commercial Biomarker Test (LiverFast®)	Transient Elastography
Cirrhosis (METAVIR F4)	>2.0	>0.75	>12.5 kilopascal (kPa)

Table 3. Persons at risk for acquiring hepatitis C virus (HCV) infection

History of transfusion of blood and/or blood products, and organ transplantation prior to 1995
End stage renal disease patient on maintenance hemodialysis
History of intranasal use or injection of illicit drugs
History of acquiring a tattoo and body piercing in an uncontrolled environment
Incarceration
Unprotected sex with an HCV-infected partner
Unsafe sexual practices
Being born to an HCV-infected mother
Close household contacts of HCV-infected patients
Persistently elevated levels of alanine aminotransferase
History of needle-stick and other sharps injury, or mucosal exposure

Table 4. Risk factors for HIV infection

Multiple sexual partners
Unprotected sex with a person who has multiple sexual partners
History or recent diagnosis with sexually transmitted infections
Men who have sex with men
History of intravenous drug use for recreation purposes
Unprotected sex with an HIV-infected person
Children born to HIV positive mothers

Table 5. Chronic hepatitis B subgroups at risk for hepatocellular carcinoma (HCC) who require surveillance

Asian male Hepatitis B carriers over age 40
Asian female Hepatitis B carriers over age 50
Hepatitis B carrier with a family history of HCC
Cirrhotic hepatitis B carriers, regardless of age and other risk factors
HCV co-infection
Persistent HBV DNA >2,000 IU/mL

Table 6. Recommended first-line antiviral therapy for CHB in adults

Medication	**Dose**
Tenofovir disoproxil fumarate (TDF)	300 mg once daily
Tenofovir alafenamide fumarate (TAF)	25 mg once daily
Entecavir (ETV) (adult with compensated liver disease and lamivudine naive)	0.5 mg once daily
Entecavir (ETV) (adult with decompensated liver disease)	1 mg once daily

Table 7. Recommended drugs for the treatment of CHB and their doses in children

Drug	Dose	
Tenofovir Disoproxil Fumarate (TDF) (in children 12 years of age and older, and weighing at least 35 kg)	300 mg once daily	
Entecavir (in children 2 years of age or older and weighing at least 10 kg)	Recommended once-daily dose (in paper tab) in mg	
	Body weight (kg)	Treatment-naive persons
	10 to 11	0.15
	>11 to 14	0.20
	>14 to 17	0.25
	>17 to 20	0.30
	>20 to 23	0.35
	>23 to 26	0.40
	>26 to 30	0.45
	>30	0.50

Table 8. Recommended dosage in adults with renal impairment

Recommended dose reduction or dosing interval				
Drug	Creatinine clearance, CrCl (mL/min)			
	≥50	30–49	10–29	<10, Haemodialysis or Continuous Ambulatory Peritoneal Dialysis (CAPD)
Tenofovir disoproxil fumarate (TDF)	One 300 mg tablet every 24 hours	One 300 mg tablet every 48 hours	One 300 mg tablet every 72–96 hours	One 300 mg tablet every 7 days. If administered on a dialysis day, administer after the dialysis session
Tenofovir alafenamide fumarate (TAF)	Mild, moderate or severe renal impairment: no dosage adjustment CrCl <15: use not recommended			
Entecavir	0.5 mg once daily	0.5 mg every 48 hours	0.5 mg every 72 hours	0.5 mg every 7 days If administered on a dialysis day, administer after the dialysis session
Entecavir (decompensated liver disease)	1 mg once daily	0.5 mg once daily OR 1 mg every 48 hours	1 mg every 72 hours	1 mg every 7 days If administered on a dialysis day, administer after the dialysis session

Table 9. Indication for selecting Entecavir* or TAF (Tenofovir alafenamide fumarate) over TDF (Tenofovir disoproxil fumarate)†

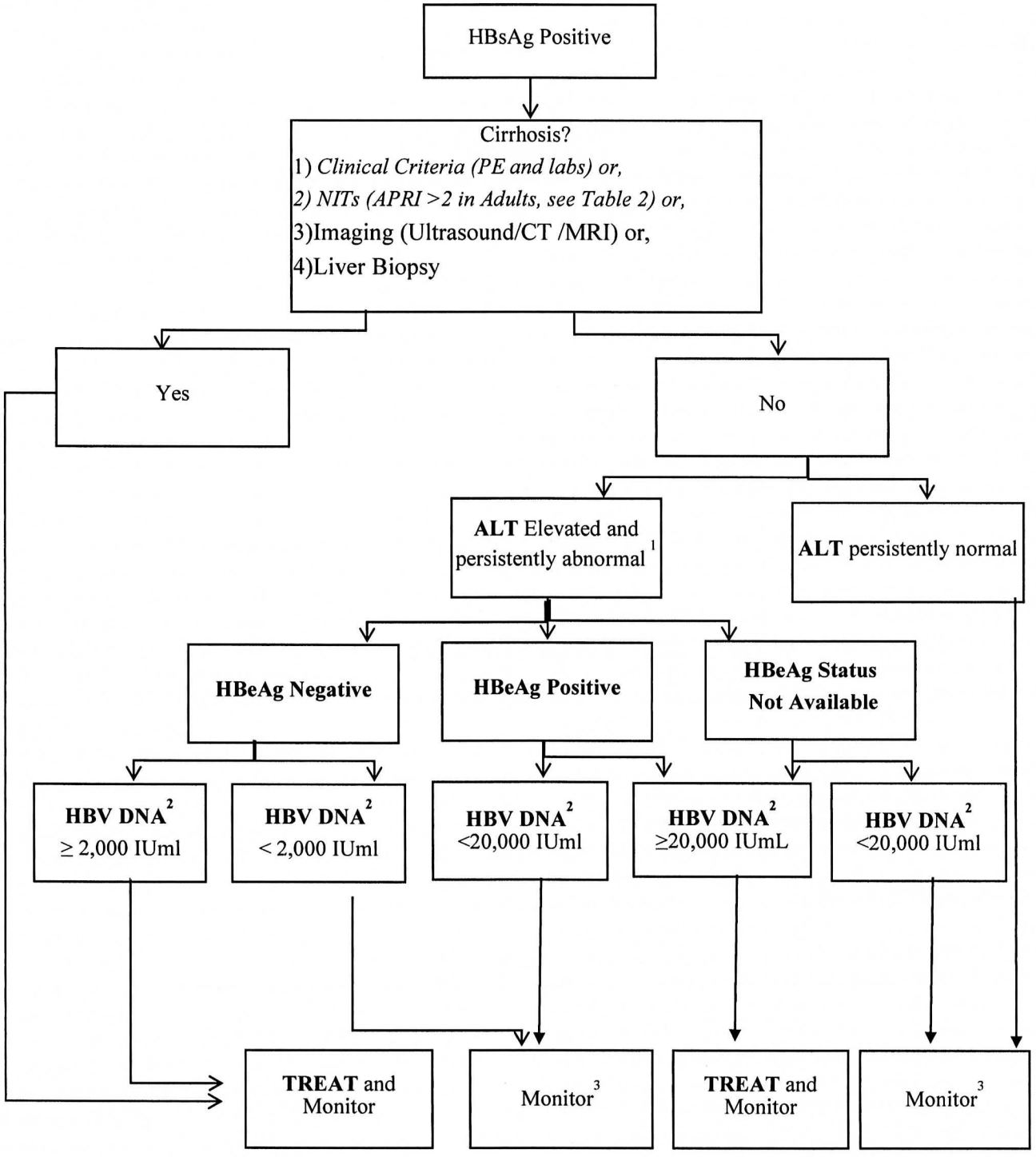
a. Age > 60 years
b. Bone Disease
    a. Chronic Steroid use or use of medications that may worsen bone density
    b. History of fragility fracture
    c. Known osteoporosis
c. Renal Deficiency
    a. eGFR < 60 min/ml/1.73m2
    b. Albuminuria > 30 mg or moderate dipstick proteinuria
    c. Low Phosphate (< 2.5 mg/dl)
    d. Hemodialysis

Source: European Association for the Study of Liver (EASL) 2017 Guidelines

**Entecavir needs to be dose adjusted if CrCl is ≤50 ml/min. No dose adjustment is needed for TAF (aged ≥12 years of age and with body weight ≥35 kg) for CrCl≥15ml/min or in patients with CrCl≤ 15 ml/min receiving hemodialysis.*

†*TAF may be preferred over Entecavir in patients with previous exposure to nucleoside analogues*

Figure 1. Algorithm on the Management of Chronic Hepatitis B infection



[1] *See definition of terms (Section 4, page 2)*

[2] *When HBV DNA testing is not available: Treatment may be considered based on persistently abnormal ALT levels alone, regardless of HBeAg status,* ***but other common causes of consistently raised ALT such as nonalcoholic fatty liver disease (NAFLD), chronic alcohol abuse, HCV infection must be excluded first.***

[3] *Monitor for : 1)HCC every 6 months (especially in those with Cirrhosis and Family history, 2) Monitor for liver disease progression and treatment response in all ;3) Toxicity monitoring in persons with treatment; 4)Signs of treatment failure for those on antiviral treatment – see definition of terms*

Figure 2. APRI Score Online Calculator QR Code

Figure 3. Calculate by QxMD Medical Calculator Mobile App QR Code

List of Abbreviations

AFP	alpha-fetoprotein
ALP	alkaline phosphatase
ALT	alanine aminotransferase
AO	administrative order
APRI	aspartate aminotransferase-to-platelet ratio index
ART	antiretroviral therapy
AST	aspartate aminotransferase
anti-HBe	antibody to Hepatitis B e antigen
anti-HBs	antibody to Hepatitis B surface antigen
CHB	Chronic Hepatitis B
CG	Cockcroft-Gault
CrCl	creatinine clearance
DOH	Department of Health
EPI	Expanded Program on Immunization
ETV	Entecavir
HBeAg	Hepatitis B e-antigen
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B virus
HCC	hepatocellular carcinoma
HCV	Hepatitis C virus
HIV	Human Immunodeficiency Virus
NA	Nucleos(t)ide Analogue
NIT	non-invasive test
TAF	Tenofovir alafenamide fumarate
TDF	Tenofovir disoproxil fumarate
WHO	World Health Organization
WPRO	Western Pacific Regional Office

VIRAL HEPATITIS B SURVEILLANCE

SURVEILLANCE SITE INFORMATION

1

Consult date: _____

Testing facility: _____

Facility address: _____

HBsAg result: ☐ Positive ☐ Negative **Date of test:** _____ *(mm/dd/yyyy)*

Visit type: ☐ First consult at this facility ☐ Follow-up ☐ Inpatient

Philhealth #: _____

Patient Code: _____

DEMOGRAPHIC DATA

2

Name (Full name):

First Name _____ Middle Name _____ Last Name _____ Suffix (Jr., III, etc) _____

Birthdate: *(mm/dd/yyyy)* ___/___/___ **Age:** _____ **Birth order:** _____ **Height:** *(in cm.)* _____ **Weight:** *(in kg.)* _____

Mother's First Name: _____ **Father's First Name:** _____

Sex at birth: ☐ Male ☐ Female **If the client is female, is she currently pregnant?** ☐ Yes ☐ No

Gender Identity: ☐ Male ☐ Female ☐ Transgender Male ☐ Transgender Female ☐ Other: _____

Current Address: City/Municipality: _____ Province: _____ Region: _____

Nationality: ☐ Filipino ☐ Other: _____

HISTORY OF EXPOSURE

3

Number of sex partner/s in the past 12 months: _____

Sexual behavior: ☐ Vaginal sex ☐ Oral sex ☐ Anal receptive ☐ Anal insertive ☐ Other: _____
(check all that apply)

Did the client share needle and syringe with others? ☐ Yes ☐ No

Has the client been accidentally pricked by needles due to nature of work? ☐ Yes ☐ No

Client / Risk Group: ☐ MSM ☐ PWID ☐ Freelance sex worker ☐ Client of FSW
(check all that apply) ☐ Transgender ☐ Female partner of MSM or PWID ☐ Registered sex worker ☐ Other: _____

MEDICAL HISTORY

4

Does the client have a family history of Hepatocellular Carcinoma (HCC)? ☐ Yes ☐ No

Has the client even been tested for HIV? ☐ Yes ☐ No

What was the result? ☐ Positive ☐ Negative ☐ Indeterminate ☐ Was not able to ge the result

Has the client even been tested for Hepatitis C? ☐ Yes ☐ No

What was the result? ☐ Positive ☐ Negative ☐ Was not able to ge the result

CLINICAL ASSESSEMENT

5

Non-invasive tests for detection of cirrhosis: Aminotransferase/Platelet Ratio Index Score _____
Transient Elastography _____

Does the patient have compensated liver cirrhosis? ☐ Yes ☐ No

Does the patient have decompensated liver cirrhosis? ☐ Yes ☐ No

Is the patient eligible for treatment?

☐ Yes, the patient will initiate treatment in this facility

☐ Yes, for initiation of treatment the patient will be referred to:

☐ Rural Health Unit ☐ District Hospital ☐ Regional Hospital ☐ Private Hospital

(Please specify where) _____

☐ No, the patient does not meet the criteria for treatment and was advised to return on: *(mm/dd/yyyy)* _____

TREATMENT

6

Date of enrollment: *(mm/dd/yyyy)* ___/___/___

Regimen: ☐ Tenofovir (TDF) ☐ Other: *(please specify)* _____

Date	# pills missed (past 30 days)	# of pills on hand	# of pills dispensed	Expected date of refill
___/___/___				___/___/___
___/___/___				___/___/___

Date discontinued	Reason (D/C code)	(For code 6 & 7, please specify)
___/___/___		

Discontinuation codes (D/C):

1-Treatment Failure
2-Clinical progression
3-Patient Decision/Request
4-Compliance difficulties
5-Drug Interaction
6-Adverse Event (Specify)
7-Others (Specify)
8-Death

CLINIC PERSONNEL PROVIDING INFORMATION

7

Clinic personnel and signature: _____
Telephone / cellphone number: _____
Email address: _____
Notes: _____

Physician name and signature: _____
Telephone / cellphone number: _____
Email address: _____
Notes: _____

Please send this accomplished form to labbs.doh@gmail.com or to Epidemiology Bureau - Department of Health , 2/F Rm. 209, Building 19, San Lazaro Compound, Rizal Avenue, Sta. Cruz, 1003 Manila
Contact Nos: (02) 495-0513 & (02) 651-7800 loc. 2952

VIRAL HEPATITIS SURVEILLANCE

REFERRAL FORM

*(Kindly notify the Referring Unit using the **return slip** as soon as the patient has been evaluated/enrolled to treatment using the information below.)*

Date of referral: *(mm/dd/yyyy)* _____

Name of the Receiving Unit: _____

Telephone/Cellphone Number: _____ **Email address:** _____

Facility Address: _____

Name of Patient (Full name):

First Name	Middle Name	Last Name	Suffix (Jr., III, etc)

Birthdate: *(mm/dd/yyyy)* _____ **Age:** _____ **Sex at birth:** ☐ Male ☐ Female **Weight:** *(in kg.)* _____

Current Address: City/Municipality: _____ Province: _____

Nationality: ☐ Filipino ☐ Other: _____

Is the client currently pregnant? *(if female only)* ☐ Yes ☐ No

Date of HBsAg test: _____
(mm/dd/yyyy)

Reason/s for Referral: *(check all that apply)*

☐ With HIV co-infection ☐ With renal impairment ☐ Persistent HBV DNA >2,000 IU/mL ☐ Other: _____

☐ With Hepatitis C co-infection ☐ Pregnant ☐ With decompensatated cirrhosis _____

☐ With risk for HCC ☐ Pediatric patient ☐ For initiation of treat _____

Referral Notes:

_____

_____

_____

_____

_____

Name of the Referring Unit: _____

Name of the referring staff:	Designation:	Signature:	Telephone/cellphone number:

Please attach a copy of: 1. Viral Hepatitis B Surveillace Form, 2. Laboratory results (HBsAg result, ALT/AST, Blood Count, etc. if available)

RETURN SLIP

(To be accomplished by the receiving unit. Please return to the referring unit via mail or e-mail.)

Date when the patient was received: *(mm/dd/yyyy)* _____

Name of the Referring Unit: _____

Telephone/Cellphone Number: _____ **Email address:** _____

Facility Address: _____

Action Taken

☐ The patient will be evaluated and enrolled to treatment in this facility

☐ The facility is not capable of providing assessment/treatment to the patient and was referred to:

Name of the facility: _____

Name of the physician: _____ Contact number: _____

☐ The patient was deferred to treatment and was requested to return on *(mm/dd/yyyy)* _____ due to the following reason:

(please specify) _____

Notes:

_____

_____

_____

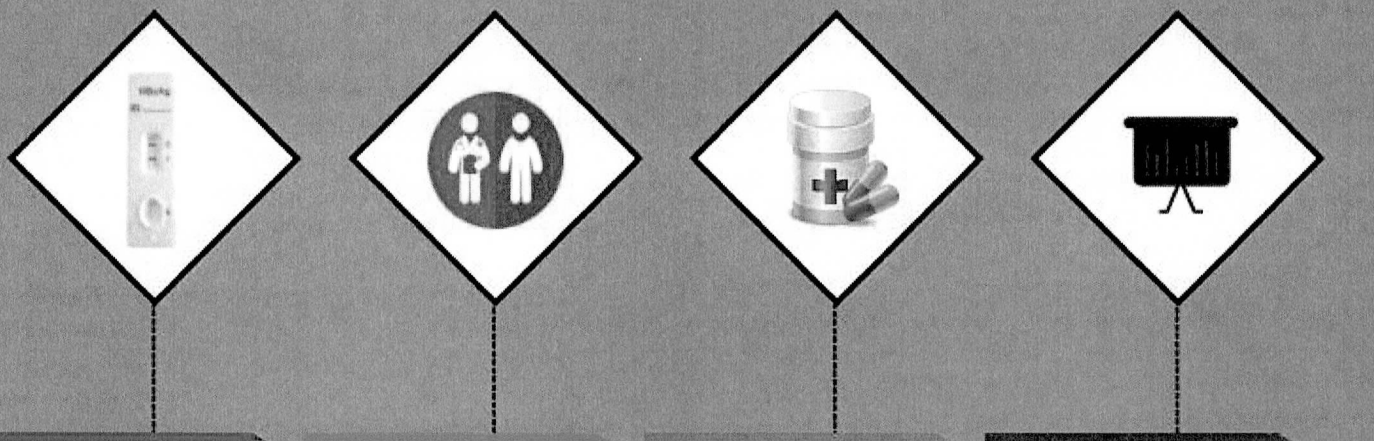
_____

_____

Name of the Receiving Unit: _____

Name of the receiving staff:	Designation:	Signature:	Telephone/cellphone number:

APPENDIX 2: HEPATITIS B MANAGEMENT DEMONSTRATION PROJECT PACKAGE OF SERVICES



Screening

Screening through HBsAg Rapid Diagnostic Tests (RDT)

Plus Generic Public Health Lecture on Viral Hepatitis

Assessment

Assessment of:
1) Cirrhosis
2) HBeAg Status
3) HBV DNA

Plus Counselling

Treatment

Treatment of Eligible Patients and Management of Possible Comorbidities and Coinfection

Monitoring

Monitoring of:
1) HBsAg
2) AST/ ALT
3) Platelet count
4) HBeAg/ anti-HBe
5) HBV DNA
6) Renal Function
7) Growth (12- to 18-year age group)

REPUBLIC OF THE PHILIPPINES · DEPARTMENT OF HEALTH ·

World Health Organization

2006
HEPATOLOGY SOCIETY OF THE PHILIPPINES

Appendix 3: Introduction of Chronic Hepatitis B Management in Selected Health Facilities in the National Capital Region (NCR) and Region III