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MINISTRY OF HEALTH-ETHIOPIA

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HEALTHIER CITIZENS FOR PROSPEROUS NATION!

**NATIONAL STRATEGIC PLAN
FOR PREVENTION AND CONTROL
OF VIRAL HEPATITIS IN ETHIOPIA, 2021 – 2025**

August 2021

Addis Ababa



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OF VIRAL HEPATITIS IN ETHIOPIA, 2021 – 2025**

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FORWARD

Acute and chronic viral hepatitis make a substantial contribution to the burden of chronic diseases and the premature mortality they cause. Infections with hepatitis B and C viruses cause liver cirrhosis and primary liver cancer. Ethiopia is one of the sub-Saharan African countries where viral hepatitis is endemic. The availability of a vaccine that offers lifelong protection against infection with the hepatitis B virus gives public health an opportunity to prevent a leading cause of cancer and chronic liver disease. The significance of the challenges and opportunities related to viral hepatitis were formally acknowledged in 2010, when the World Health Assembly adopted its first resolution on a comprehensive approach to the prevention and control of viral hepatitis. The Ministry of Health (MOH) considers viral hepatitis prevention and control measures in line with the current drive to strengthen health systems which includes reaching every child with immunization programs that include hepatitis B vaccine, protecting against mother-to-child transmission of viruses, ensuring the safety of blood transfusion services and injection practices.

The MOH recognizes the importance of revising the viral hepatitis national strategic plan as a foundation for building the prevention and control measures that match the local epidemiological profile and health system capacities. This strategic plan is developed as part of the national effort in the prevention and control of viral hepatitis in general and Hepatitis B and Hepatitis C virus infections, in particular. Hence, this strategic plan are intended to scale-up viral hepatitis preventive measures, and standardize screening, diagnosis, treatment and care of patients with viral hepatitis to improve outcomes through reducing morbidity and mortality associated with the disease. The strategic plan will serve as a framework and a quick reference in line with scaling-up of viral hepatitis prevention, diagnosis, treatment and care services considering patient factors and local resource settings.

The MOH urges all program managers, care providers and implementing partners to strictly use this strategic plan as a reference in the program implementation of viral hepatitis prevention and control programs in the country.

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State Minister of Health,
Federal Democratic Republic of Ethiopia

ACKNOWLEDEMENT

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ACRONYMS

anti-HAV	Antibody to Hepatitis A virus
anti-HCV	Antibody to Hepatitis C virus
CBC	Complete Blood Count
CHAI	Clinton Health Access Initiative
CI	Confidence interval
CLD	Chronic Liver Disease
CSO	Civil Society Organization
DAA	Directly Acting Antiviral
DHIS2	District Health Information System 2
DNA	Deoxyribo-Nucleic Acid
DQA	Data Quality Assessment
EFDA	Ethiopia Food and Drug Administration
EGA	Ethiopian Gastroenterology Association
ELISA	Enzyme-Linked Immunosorbent Assay
EPHI	Ethiopian Public Health Institute
EPI	Expanded Program on Immunization
EPSA	Ethiopian Pharmaceutical Supply Agency
EQA	External Quality Assessment
HAV	Hepatitis A Virus
HBsAg	Hepatitis B Virus Surface Antigen
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HDSS	Health and Demographic Surveillance System
HDV	Hepatitis D Virus
HEP	Health Extension Program
HEV	Hepatitis E Virus
HEW	Health Extension Worker
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
HO	Health Officer
IPC	Infection Prevention & Control
MOH	Ministry of Health
M&E	Monitoring & Evaluation
NBTS	National Blood Transfusion Service
NCD	Non-Communicable Disease
NSP	National Strategic Plan
PCR	Polymerase Chain Reaction
PrEP	Pre-Exposure Prophylaxis
PSM	Procurement and Supply Management
PWID	People with Injecting Drug

RHB	Regional Health Bureau
RNA	Ribonucleic acid
SBCC	Social Behavioral Change Communication
SDG	Sustainable Development Goals
SOP	Standard Operating Procedure
STI	Sexually Transmitted Infection
SPA+	Service Provision Assessment Plus
SWOT	Strength Weakness Opportunity & Threat
TB	Tuberculosis
TOT	Training of Trainer
TWG	Technical Working Group
VCT	Voluntary Counseling & Testing
VL	Viral Load
WASH	Water, Sanitation and Hygiene
WHO	World Health Organization

EXECUTIVE SUMMARY

Hepatitis viruses, such as HAV, HBV, HCV, HDV and HEV cause potentially life-threatening inflammation of the liver, which is characterized by acute and chronic forms of liver disease. Despite its high prevalence and highly infectious nature, viral hepatitis infections remain under-diagnosed and under-reported in Ethiopia. Regarding HAV, it is known that there is high prevalence rate and nearly all older children and adults acquired anti-HAV antibody immunity. HEV is also one of the leading causes of major outbreaks of acute viral hepatitis, especially in developing countries.

It was reported that 12% of the hospital admissions and 31% of the mortality in medical wards in Ethiopian hospitals were due to all causes of chronic liver disease (CLD)¹. The national sero-survey conducted by MoH and EPHI in 2017, the prevalence of Hepatitis B surface antigen (HBsAg) was estimated to be 9.4% among the general population aged 15 years and above. There were variations in the prevalence of HBsAg across regions, with the highest prevalence rate being found in the Afar region (28.8%). Overall, there was a minimally higher prevalence in rural areas (9.7% vs 8.35%). The pooled prevalence of anti-hepatitis C virus antibody (anti-HCV) was 3.1% (95%CI: 2.2–4.4).

The viral hepatitis-HIV co-infection and subsequent severe forms of clinical complications could be potentially high. The population based seroprevalence of hepatitis B surface antigen (HBsAg) among HIV positive adults ages 15-64 years in urban Ethiopia is 4.8% (3.6% in women and 7.4% in men)². Unlike HBV, the anti-HCV prevalence in HIV infected individuals was higher (5.5%, 95% CI: 3.8–7.8%, $p = 0.01$) than the prevalence observed in the other subgroup of study population³.

¹ Tsega E. Current views on liver diseases in Ethiopia. *Ethiop Med J.* 1977;15(2):75–82.

² EPHIA 2017-2018. Ethiopia population-based HIV impact assessment

³ Yeshambel Belyhun et al. Hepatitis viruses in Ethiopia: a systematic review and meta-analysis. *BMC Infect Dis.* 2016; 16: 761

Viral hepatitis is generally preventable, treatable and potentially curable. Thus, it is crucial that appropriate intervention measures are put in place. With the latest advances in technology relating to screening and diagnosis of the disease, as well as the availability of effective and relatively affordable treatment, the prevention, treatment and cure of viral hepatitis are now possible.

Ethiopia has recognized the clinical and public health burdens of viral hepatitis and is committed towards combating viral hepatitis by 2030. In working towards achieving this commitment, this national strategic plan has been developed; the second for the country. This national strategic plan document provides a comprehensive strategy, key interventions, program coordination and partnership and monitoring and evaluation of viral hepatitis program in the country. The strategic plan is intended for the use by all stakeholders at various levels, from policy makers to implementers at the service delivery points. The strategic plan also outlines the proposed budget requirements for five years from 2021 to 2025.

The strategic plan defines the vision, goal, objectives and targets in alignment with the national health policy and Health Sector Transformation Plan II that aims achieving the global viral hepatitis elimination targets by 2030.

VISION

To see Ethiopians free from viral hepatitis by halting transmission while those living with hepatitis have access to safe, affordable and effective diagnosis, care and treatment.

GOAL

To promote national response to the elimination of viral hepatitis as a public health threat in Ethiopia through providing access to safe, affordable and effective prevention, diagnosis, treatment and care of the highest possible quality in an equitable manner.

OBJECTIVES

- To create an enabling environment for viral hepatitis through strengthening advocacy, policy discussion, coordination, and leadership.

- To provide effective and affordable promotive and preventive services for viral hepatitis.
- To reduce the morbidity from viral hepatitis through early detection and case management.
- To improve the survival and quality of life among individuals with chronic liver disease.
- To generate and timely utilize data and research for evidence-based decision making.
- To promote partnerships with relevant stakeholders for the prevention, control, diagnosis, treatment and care of viral hepatitis.
- To mobilize resource and maximize efficiencies in allocation and utilization.

STRATEGIC OBJECTIVES

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

Strategic objective 1: Advocacy, communication and social mobilization

Strategic objective 2: Viral hepatitis prevention programs

Strategic objective 3: Access to diagnostic, treatment and care services

Strategic objective 4: Strengthen generation and utilization of strategic information for evidence-based response

Strategic objective 5: Health system strengthening for effective and efficient viral hepatitis program

STRATEGIC TARGETS

Strategic targets are set for 2025 to be in line with the WHO target of combating hepatitis B and C to reach elimination by 2030.

- To diagnose 90% of the population living with viral hepatitis B & C.
- To reduce the number of new cases of viral hepatitis B & C by 90%.
- To reduce mortality due to viral hepatitis B & C by 65%.
- To treat 80% of the population with viral hepatitis B & C in need of treatment.

CHAPTER ONE: BACKGROUND AND EPIDEMIOLOGY OF VIRAL HEPATITIS

INTRODUCTION

Viral hepatitis is an inflammation of the liver, caused by five distinct hepatitis viruses (A, B, C, D, and E). Hepatitis A, C, D and E viruses are RNA viruses while hepatitis B is a DNA virus. While all of these viruses cause liver disease, they vary significantly in terms of epidemiology, natural history, prevention, diagnosis, treatment and health outcomes. The natural history of viral hepatitis is summarized as follow:

1. Hepatitis A virus (HAV) is present in the faeces of infected persons and is most often transmitted through consumption of contaminated water or food. Infections are in many cases mild, with most people making a full recovery and remaining immune from further HAV infections. However, HAV 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.
2. Hepatitis B virus (HBV) is transmitted through exposure to infectious blood, semen, and other body fluids. HBV can be transmitted from infected mothers to infants at the time of birth or from family member to infant in early childhood. Transmission may also occur through transfusions of HBV contaminated blood and blood products, contaminated injections during medical procedures, and through people with injecting drugs (PWID). HBV also poses a risk to healthcare workers who sustain accidental needle stick injuries while caring for HBV infected patients. A safe and effective vaccine is available to prevent HBV.
3. Hepatitis C virus (HCV) is mostly also transmitted through exposure to infectious blood. This may happen through transfusions of HCV contaminated blood and blood products, contaminated injections during medical procedures, and through injection drug use. Sexual transmission is also possible but is much less common. There is no vaccine for HCV.

4. Hepatitis D virus (HDV) infections occur exclusively in persons who are infected with HBV. The dual infection of HDV and HBV can result in a more serious disease and worse outcome. Safe and effective hepatitis B vaccines provide protection from HDV infection.
5. Hepatitis E virus (HEV), like HAV, is transmitted through consumption of contaminated water or food. HEV is a common cause of hepatitis outbreaks in developing countries and is increasingly recognized as an important cause of disease in developed countries. Safe and effective vaccines to prevent HEV infection have been developed but are not widely available.

EPIDEMIOLOGY OF VIRAL HEPATITIS

As indicated in the WHO Global Health Sector Strategy on viral hepatitis 2016–2021 published on June 2016, viral hepatitis is an international public health challenge, comparable to other major communicable diseases, including HIV, tuberculosis and malaria. Despite the significant burden it places on communities across all global regions, hepatitis has been largely ignored as a health and development priority until recently. It will no longer remain hidden, however, with the adoption of the resolution on the 2030 Agenda for Sustainable Development (SDG)– Target 3.3 calls for specific action to combat viral hepatitis.

The viral hepatitis pandemic takes a heavy toll on lives, communities and health systems. Worldwide, approximately 240 million people have chronic hepatitis B virus infection and 130–150 million have chronic hepatitis C virus infection. According to the WHO Global Health Sector Strategy on viral hepatitis 2016–2021, in 2013, viral hepatitis was the seventh highest cause of mortality in the world. It was responsible for an estimated 1.4 million deaths per year globally, mostly from hepatitis-related liver cancer and cirrhosis. Of those deaths, approximately 47% are attributable to hepatitis B virus, 48% to hepatitis C virus and the remainder to hepatitis A virus and hepatitis E virus. Viral hepatitis is also a growing cause of mortality among people living with HIV. About 2.9 million people living with HIV are co-infected with hepatitis C virus and 2.6 million with hepatitis B virus. Unfortunately, most people with chronic viral hepatitis are not aware of their status and do not receive appropriate treatment.

Without an expanded and accelerated response, the number of people living with hepatitis B virus is projected to remain at high level for the next 40–50 years, with a cumulative 20 million deaths occurring between 2015 and 2030. The number of people living with hepatitis C virus is also increasing, despite the existence of an effective cure.

Every year more than 200,000 people in Africa are dying from complications of viral hepatitis B and C-related liver disease, including cirrhosis and liver cancer. Sixty million people in sub-Saharan Africa were living with chronic hepatitis B infection in 2015. More than 4.8 million of them are children under five years old. A further 10 million are infected with hepatitis C, most likely due to unsafe injection practices within health facilities or by communities.

EPIDEMIOLOGY OF VIRAL HEPATITIS IN ETHIOPIA

Since the 1980s, over 30 studies have been conducted in Ethiopia by different groups of investigators to determine the sero-prevalence of various hepatitis viruses in the country. The aim here is not to try and present an exhaustive summary of the entire medical literature but rather to highlight significant trends and observations over time. The studies have focused on hepatitis B and hepatitis C virus infections, mainly due to the involvement of these 2 viruses in causing chronic liver disease, which is a significant public health problem nationally. It was reported that 12% of the hospital admissions and 31% of the mortality in medical wards in Ethiopian hospitals were due to all causes of chronic liver disease (CLD)⁴.

From the systematic review and meta-analysis of hepatitis virus in Ethiopia, the first documented HBsAg prevalence rate was 3.9% in 1968. Then later the magnitude of the peak HBsAg prevalence (10.8%) was available in 1986 and 1989 and then decreased to 6.2% in 2003 and 5.3% in 2007. However, studies conducted in blood donors reported a slightly higher median prevalence of 8.7% than the 6.2% median prevalence rate in the community-based studies. The HBsAg was also reported among various segments of the society such as healthcare professionals (7.3–9.0%), medical waste handlers (6.0–6.3%), outpatient and inpatient department attendants (4.7–7.4%), street dwellers (10.9%), pregnant women (3.0–7.3%), diabetic patients (3.7%), HIV VCT clients (5.7%) and commercial sex workers (6.0%). The HBsAg

⁴ Tsega E. Current views on liver diseases in Ethiopia. *Ethiop Med J.* 1977;15(2):75–82.

prevalence among Ethiopians Jews who immigrated to Israel in different times also showed 6.2 to 19% prevalence rate. Overall, the median HBsAg prevalence in the general population showed 6.3% over the last five decades⁵.

The national sero-survey conducted by MoH and EPHI in 2017, the prevalence of Hepatitis B surface antigen (HBsAg) was estimated to be 9.4% among the general population aged 15 years and above. There were variations in the prevalence of HBsAg across regions, with the highest prevalence rate being found in the Afar region (28.8%). Overall, there was a minimally higher prevalence in rural areas (9.7% vs 8.35%). The pooled prevalence of anti-hepatitis C virus antibody (anti-HCV) was 3.1% (95% CI: 2.2–4.4). Unlike HBV, the anti-HCV prevalence in HIV infected individuals was higher (5.5%, 95% CI: 3.8–7.8%, $p=0.01$) than the prevalence observed in the other subgroup of study population⁶.

More importantly, because of HIV pandemic and possible epidemiological overlap as the result of shared transmission ways and risk factors, viral hepatitis-HIV co-infection and subsequent severe forms of clinical complications could be potentially high in the country. The population based seroprevalence of hepatitis B surface antigen (HBsAg) among HIV positive adults ages 15-64 years in urban Ethiopia is 4.8 (3.6% in women and 7.4% in men ages)⁷.

In summary, the different studies conducted in Ethiopia, mainly on HBV and HCV have produced various seroprevalence estimates. However, arriving to a consensus estimate for each of the hepatitis virus for the country as a whole, remains a significant challenge. This is because the studies have been conducted in different population groups (having increased or lower risk probability), utilized different sample sizes, and most of all, used different laboratory screening methods, some with, and others without, the benefit of confirmatory testing, to arrive at seroprevalence estimations. In addition, the studies have a wide geographical distribution. In

⁵ Yeshambel Belyhun et al. Hepatitis viruses in Ethiopia: a systematic review and meta-analysis. BMC Infect Dis. 2016; 16: 761

⁶ Yeshambel Belyhun et al. Hepatitis viruses in Ethiopia: a systematic review and meta-analysis. BMC Infect Dis. 2016; 16: 761

⁷ EPHIA 2017-2018. Ethiopia population-based HIV impact assessment

light of the above limitations, further population based seroprevalence studies are required to know the real magnitude the problem in the country.

THE CURRENT NATIONAL POLICY AND PROGRAMMATIC RESPONSE

The country follows prevention-first strategy for all health sector and invested a lot on establishing prevention structure in the community, a model of its nature, the health extension program that address the community level prevention services. As viral hepatitis has prevention, treatment and care services, the existing health care facilities are the main service delivery points for primary prevention, case identification through screening and provision of treatment and care for those infected with hepatitis B and hepatitis C viruses.

The prevention of viral hepatitis which is key target has usually been embedded in the context of existing health programs. For example, since 2007, hepatitis B vaccine has been integrated within the childhood EPI program whereas; universal precaution and infection prevention has been implemented at all levels of the health system, using the National Infection Prevention Guideline developed by the MOH. At the same time, the National Blood Bank Service has implemented robust initiatives in 100% screening of blood for HBV and HCV. In addition, compelling efforts are ongoing in awareness creation and promotion of safer sex as part of the overall HIV prevention national effort, that this effort also has relevance for preventing infections due to HBV and HCV.

In line with the World Health Assembly resolutions on viral hepatitis in 2010 and 2014; and the WHO Regional Committee resolutions in 2014, Ethiopia has recognized viral hepatitis as a public health problem. To this effect, the government of Ethiopia has prepared the first five-year national strategic plan for viral hepatitis (2016–2020). Based on the national strategic plan, the national viral hepatitis prevention, diagnosis, care and treatment guidelines developed to standardize and scale-up of the services in public health approach.

To strengthen the leadership and coordination of viral hepatitis program, MoH has moved the national the program from NCD team to HIV team – this restructuring is helpful for efficient program management as well as in alignment of the national practice to the global trend. A focal

person for viral hepatitis program is assigned in MoH and the national viral hepatitis technical working group (TWG) is established and meets regularly.

During the previous national strategic plan period, viral hepatitis interventions including preparation of training materials and M&E tools, capacity building of health workers, quantification and procurement of medicines, standardization of diagnosis, care and treatment services in selected teaching hospitals, advocacy and awareness activities - commemoration of world hepatitis days were implemented. Furthermore, hepatitis B vaccination was provided for more than 450,000 health care providers and students of health science colleges. Piloting of hepatitis B birth dose is initiated aiming the national scale-up in 2022.

However, the overall viral hepatitis program management and services were not strong, and accessibility was limited only to certain tertiary hospitals. The viral hepatitis program SWOT analysis is summarized as below:

Strengths	Weaknesses
<ul style="list-style-type: none"> • Availability of policy documents (National guidelines and strategic plan) • Presence of coordination platform/TWG that includes partners providing technical support • Childhood hepatitis vaccination coverage is high (>90%) • Piloting of birth dose initiated aiming national scale-up • Presence of IPC program that incorporates injection safety and blood safety • Availability of blood safety program • Availability of M&E tools with standard indicators 	<ul style="list-style-type: none"> • Treatment is limited to selected treatment centers (only 13 hospitals); it is not decentralized in public health approach. • No systematic screening for high risk groups (HIV positives, pregnant women and etc.) • Inadequate of trained health care providers due to absence of adequate continuous capacity building activity • Low public awareness of the burden of the disease and treatment • Access to diagnostics (rapid tests, PCR) is very limited; expensive service in private settings • There is no practice of linking those who are positive to treatment at blood donation centers • Gap on establishing social insurance system instead of out of pocket service. • Key/relevant indicators are not incorporated in the DHIS2 (no national data) • Hepatitis surveillance not being done for hepatitis B&C to monitor the trend

Opportunity	Threat
<ul style="list-style-type: none"> • Commitment of Gastroenterologists’ association to support the national program • Availability of antiviral that cure/treat Hepatitis “C”/”B” • Possibility of getting drugs through price negotiation • Presence of global hepatitis elimination strategy by 2030 and inclusion of hepatitis in SDG agenda. 	<ul style="list-style-type: none"> • High cost of the drugs and the diagnostics • Less attention given at global and national levels • Limited donors to support the program

RATIONALE FOR REVISION OF THE 2016 - 2020 VIRAL HEPATITIS NATIONAL STRATEGIC PLAN

Following the global direction on viral hepatitis elimination by 2030 Ethiopia developed its first National strategic plan of hepatitis (2016-2020). During the strategic planning period, some efforts have been initiated and carried out and midterm review conducted in 2018. The feedback gained from the review process was an important element to the improvement of hepatitis program. The national technical working group has been discussing on the importance of revising the national strategic plan considering recent updates and gaps on the current strategic plan. Some of the rationale behind the consensus of revising the strategic plan are:

- Even though the country has a strategic plan (2016-2020), the implementation was not properly done as per the strategic directions... Therefore, this updated strategic document is required for the planning, implementation, monitoring and evaluation of the national viral hepatitis program.
- The ministry of health is currently working on HIV/viral hepatitis program integration and the revision of the viral hepatitis strategic plan will be used as an opportunity for advocacy and resource mobilization. This also helps for meaningful engagement of relevant national and global stakeholders.
- The international and national data used in the strategic plan are outdated; and recent information on the status and efforts towards the response need to be reflected in the revised document.

- There is a need for strategic plan focusing on public health approach including simplified and standardized quality service package, service decentralization through task sharing and task shifting and optimization of viral hepatitis diagnostics and treatment.
- Global direction on strategies to reach key and priority population and strengthening of program management, coordination and alignment of targets towards elimination has to be properly addressed.
- The current NSP lacks M&E framework with precise list of indicator definitions. As the country progresses towards viral hepatitis elimination, strong guidance for well-designed M&E framework is very crucial to monitor the prevention, care and treatment services. Therefore, strategies to guide functional and quality data system should be addressed in order to generate data needed for efficient program impact.

CHAPTER TWO: VISION, GOAL, OBJECTIVES AND TARGETS

This national strategic plan addresses all five hepatitis viruses (hepatitis A, B, C, D and E), with particular focus on hepatitis B and C, owing to the relative public health burden they represent. The strategy defines the vision, goal, objectives and targets in alignment with the national health policy and Health Sector Transformation Plan II that aims achieving the global viral hepatitis elimination targets by 2030.

VISION

To see Ethiopians free from viral hepatitis by halting transmission while those living with hepatitis have access to safe, affordable and effective diagnosis, care and treatment.

GOAL

To promote national response to the elimination of viral hepatitis as a public health threat in Ethiopia through providing access to safe, affordable and effective prevention, diagnosis, treatment and care of the highest possible quality in an equitable manner.

OBJECTIVES

- To strengthen national policies for the prevention, control, diagnosis, treatment and care of viral hepatitis.
- To provide effective and affordable promotive and preventive services for viral hepatitis
- To reduce the morbidity and mortality from viral hepatitis through early detection and case management of hepatitis B and C
- To improve the survival and quality of life among individuals with chronic liver disease.
- To generate and timely utilize national data and research for evidence-based decision making.
- To promote partnerships with relevant stakeholders for the prevention, control, diagnosis, treatment and care of viral hepatitis B and C.
- To mobilize resource and maximize efficiencies in allocation and utilization.

STRATEGIC OBJECTIVES

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

Strategic objective 1: Advocacy, communication and social mobilization

Strategic objective 2: Viral hepatitis prevention programs

Strategic objective 3: Access to diagnostic, treatment and care services

Strategic objective 4: Strengthen generation and utilization of strategic information for evidence-based response

Strategic objective 5: Health system strengthening for effective and efficient viral hepatitis program

STRATEGIC TARGETS

Strategic targets are set for 2025 to be in line with the WHO target of combating hepatitis B and C to reach elimination by 2030.

- To diagnose 90% of the population living with viral hepatitis.
- To reduce the number of new cases of viral hepatitis by 90%.
- To reduce mortality due to viral hepatitis by 65%.
- To treat 80% of the population in need of treatment.

GUIDING PRINCIPLES

The following key principles will guide the strategic plan:

a) Leadership for ownership

- There are already preventive and control initiatives that exist at the national and sub-national levels that are not optimally coordinated and monitored. The plan aims to ensure coordination on multiple fronts and provide oversight to enhance universal access to prevention and control efforts. Guidance is important in developing, adopting and applying new technologies, tools and approaches including research that will lead the country towards viral hepatitis elimination by 2030.

b) Fostering partnership for sustainability

- A strong coalition involving all sectors of society and ensuring that all partners align their support to the national hepatitis response as set out by the government will eventually result to achievement of country key targets on viral hepatitis. A desired partnership aims to further enhance mutual trust and complementarily among stakeholders. The inter-sectoral cooperation where all key stakeholders work together will create sustainable, locally appropriate solutions to limit the burden posed by viral hepatitis on health care systems, society and, most importantly, infected persons and their communities.

c) Access and Equity

- Universal health coverage is the overarching framework to ensure that all people obtain the viral hepatitis services they need without suffering financial hardship when paying for them. Emphasis will be on increasing access to prevention, screening, diagnostic testing, referrals, treatment and support for people infected with viral hepatitis.

d) Integration for efficiency

- This plan aims to integrate hepatitis services into existing health systems and strategies, avoiding stand-alone viral hepatitis programs and strengthening the interface between the health sector and other sectors in the country. For example, the existing HIV prevention interventions has also impact in the prevention of hepatitis transmission.

e) Focused actions for impact

- The viral health national strategic plan has taken into consideration the global guidance, which advocates for a public health approach based on simplified and standardized interventions and services that can readily be taken to scale and bringing them nearer to the population in need. Similarly, the country plan has taken priorities to interventions that can be undertaken based on local epidemiology, contexts, needs and capacities.

STRATEGIC OBJECTIVE 1

ADVOCACY, COMMUNICATION AND SOCIAL MOBILIZATION

Viral hepatitis is recognized as a major public health problem and countries are required to take a strong action towards prevention and control interventions. In Ethiopia, the overall national and sub-national viral hepatitis program is not strong and there is inadequate dedicated funding for

the provision of viral hepatitis services, including prevention, diagnosis, care & treatment, and strategic information system. Because there is no adequate resource, public health institutes are severely challenged in carrying out their important role in responding the impact of viral hepatitis infections.

Advocacy is one of many strategies that aimed at drawing attention to and influencing policy/decision makers on important issues. 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. Based on relevant evidences, an effective advocacy can inform the policy/decision makers and program managers including but not limited to the regulatory bodies, laboratory agencies, procurement agencies and research institutes and facilitates working towards improving the existing policies, regulations and the budgets to strengthen the national viral hepatitis program.

Social mobilization through community engagement and participation is crucial for increasing the public awareness and reducing the stigma and discrimination. Community awareness on viral hepatitis must be achieved through well designed communication strategy to increase the public awareness on the magnitude of the problem and benefits of viral hepatitis prevention, diagnosis and treatment interventions.

To achieve the national viral hepatitis prevention and control objectives and targets, MOH in collaboration with key partners including the CSOs, development partners, private sector, and other relevant stakeholders will implement the following key interventions.

KEY INTERVENTIONS:

- Concerted advocacy efforts to decentralize the viral hepatitis SBCC, prevention, diagnosis, care and treatments services in the principles of public health approach and universal health coverage;
- Gather relevant evidences and publish periodical country fact sheets, news release, media spots and informative videos about viral hepatitis to stimulate the strengthening of preventive and control measures;

- Advocate and incorporate key viral hepatitis SBCC and prevention elements in the health extension program to promote and strengthen viral hepatitis awareness among the community and the general public;
- Integrate key viral hepatitis SBCC elements in the existing national programs such as WASH for hepatitis A & E, immunization for hepatitis B and infection control including injection and blood safety for hepatitis B & C;
- Promote and strengthen viral hepatitis awareness among targeted populations, including those at high risk of infection and/or the serious consequences of viral hepatitis infection, especially hepatitis B and C;
- Promote and strengthen viral hepatitis education and awareness among healthcare professionals and care providers;
- Recognize association of people affected with viral hepatitis and/or CSOs advocating for viral hepatitis and actively involve participating in the national viral hepatitis program planning, implementation and monitoring processes, whenever necessary;
- Support and work together with association of people affected with viral hepatitis and/or CSOs advocating for viral hepatitis in addressing the stigma and discrimination resulting in greater willingness of people to be tested and find out if they are infected;
- Commemorate annual World Hepatitis Day at national and sub-national levels and should be leveraged for nationwide advocacy and awareness raising activities;
- Identify viral hepatitis good-will ambassador (national champion) and conduct periodic national hepatitis awareness campaigns to raise the public awareness and accelerate accessing viral hepatitis services.

STRATEGIC OBJECTIVE 2

VIRAL HEPATITIS PREVENTION PROGRAMS

Viral hepatitis (A, B, C, D and E viruses) mode of transmission differ from one to the other, and the prevention and control strategies need to be tailored accordingly. Viral hepatitis A and E are food and water-borne infections that can result in acute outbreaks in communities with unsafe water and poor sanitation. Infections are in many cases mild, with most people making a full recovery and remaining immune from further infections. However, the infections can also be

severe and life threatening. Hepatitis B virus is transmitted through exposure to infectious blood, semen, and other body fluids. The transmission of hepatitis B virus is significantly higher from infected mothers to infants at the time of birth or from family member to infant in early childhood. The hepatitis B virus infection during early childhood contributes for higher proportion of liver cirrhosis and liver cancer in adults. Hepatitis D virus infections occur exclusively in persons who are infected with hepatitis B virus. The dual infection of hepatitis B & D can result in a more serious disease and worse outcome. Hepatitis C virus is mostly also transmitted through exposure to infectious blood. Sexual transmission is also possible but is much less common.

Countries need to strengthen effective and efficient prevention efforts to achieve the global ending viral hepatitis targets by 2030. A comprehensive approach to the prevention of viral hepatitis includes several strategies. To have greatest impact, effective interventions should be combined and tailored for the specific population, location and setting. These include:

- Safe and effective vaccines are available for hepatitis A, B and E vaccines but only vaccine for hepatitis B virus childhood vaccination programs is widely available in developing countries;
- Prevention of mother-to-child transmission of hepatitis B virus through timely hepatitis B virus birth-dose vaccination;
- Rigorous application of infection prevention and control interventions;
- Harm reduction for people who inject drugs;
- Promoting safer sex and condom use;
- Accessing sanitation and access to safe food and water.

Opportunities exist for ministry of health to collaborate with the existing programs to effectively and efficiently implement the prevention interventions. This can be realized through working in coordination with the national immunization, HIV, WASH and infection prevention and control (including injection and blood safety) programs. To this line, this national strategic plan will indicate key effective and efficient viral hepatitis prevention interventions.

KEY INTERVENTIONS:

1. Infant immunization

- Strengthening of routine immunization services to achieve and sustain at least 90% childhood hepatitis B vaccine third dose coverage (part of pentavalent vaccination) among infants;
- Promote hepatitis B vaccination for high-risk and vulnerable adult population including the health care providers.

2. Prevention of mother-to-child transmission

- Work closely with MOH national immunization program in implementation and monitoring of hepatitis B birth dose piloting exercise;
- Work closely with immunization program to Scale-up the delivery of timely hepatitis B birth dose (within 24 hours of birth) based on the findings of the piloting exercise;
- Integrate and work closely with the national elimination of HIV and congenital syphilis mother-to-child transmission program;
- Pre-Exposure Prophylaxis (PrEP) – Tenofovir (TDF) for eligible pregnant women to prevent mother-to-child transmission of Hepatitis B.

3. Infection prevention and control (injection and blood safety)

The injection and blood safety need to be implemented based on the MOH infection prevention & control reference manual and national strategy for national blood transfusion services. Key interventions include:

- Strengthen and sustain routine infection prevention and control practices in health care settings (public and private), including in laboratories;
- Implement the injection safety policy with the aim of reducing unnecessary injections;
- Provide hepatitis B virus post-exposure prophylaxis to health care workers who have accidental occupational exposure;
- Ensure the availability of safe blood and blood products through universal screening for hepatitis B & C;
- Establish systems of surveillance, hemovigilance and monitoring of the incidence and prevalence of viral hepatitis infections in blood donors and on post-transfusion hepatitis risk;

- Establish and strengthen the linkage mechanism for tested hepatitis B & C positive cases to viral hepatitis care and treatment services.

4. Harm reduction

People with injection drug (PWID) use are those men and women, who, because of using illegal injectable substances are at high risk of acquiring HIV and viral hepatitis infections. The harm reduction programs will be implemented to prevent, and control HIV, viral hepatitis and blood borne diseases among PWID. Harm reduction interventions will be implemented jointly with national HIV program based on the 2021-2025 HIV national strategic plan. The key interventions include:

- Work closely with national HIV program in developing a multi-sectoral approach to address policy issues around establishing a program for people with injecting drug;
- Promote sterile needle and syringe programs through social marketing, non-governmental, civil society organizations and private sector;
- Integrate opioid substitution therapy for in mental health services of government, non-governmental and civil society organizations;
- Integrate HIV, viral hepatitis, other blood borne diseases, STIs and condom promotion services with harm reduction and rehabilitation interventions;
- Design, develop and promote risk reduction communication for PWID;
- Establish and strengthen the linkage mechanism for tested hepatitis B & C positive cases to viral hepatitis care and treatment services.

5. Promote safer sex and condom use

Although sexual transmission of viral hepatitis B and C plays a minor role in most hepatitis epidemics, specific attention should be given to certain populations, particularly heterosexual persons who have with multiple sexual partners. The key interventions include:

- Promote BSCC on safer sex practices, including minimizing the number of sexual partners;
- Promote consistent and correct use of male and female condoms to protect against viral hepatitis B and C, HIV infection, and a range of other sexually transmitted infections.

6. Assuring improved access to safe food and water supply

Poor sanitary and hygienic practices, unsafe water supplies, and poor food hygiene are prevalent in Ethiopia. Assuring access to safe food, drinking water and sanitation systems can dramatically

reduce the transmission and occurrence of acute outbreak of viral hepatitis A and E. The key interventions include:

- Multi-sectoral collaboration of relevant sector offices to work towards improved access to safe food and water supply;
- Advocacy and communication for improved food safety practices through education of the public and enforcement of food safety practices for food handlers;
- Improve proper disposal systems to eliminate sanitary waste;
- Promote SBCC for improved hygienic practices.

STRATEGIC OBJECTIVE 3

ACCESS TO DIAGNOSTIC, TREATMENT AND CARE SERVICES

Early diagnosis of hepatitis infection is critical for effective treatment and care. Even though, there was a global plan to increase the number of people with chronic viral hepatitis who are aware of their status from less than 5% at 2016 to 30% by 2020, there is no clear evidence as to how much was achieved mainly because the yet underdeveloped monitoring and evaluation framework for viral hepatitis programs across countries.

Since the development of the first strategic plan in Ethiopia, efforts have been in place to improve the coverage of diagnosis and testing services. However, due to the limited resources and associated global momentum, the public health approach to scale-up diagnostic and treatment services have been limited for the most part. Efforts to improve public awareness, put reliable diagnostics in place and strengthening of laboratory capacity didn't go well either still because of financial constraints.

During this strategic period, the country intends to seek a major increase in diagnosis of chronic viral hepatitis B and C infection, with 65% of people infected knowing their status by 2025 and 90% by 2030. The strategy is increasing early diagnosis through targeted testing strategies and strengthening laboratory services. Discussed below are selected key area interventions in the diagnosis and treatment of viral hepatitis which would help our 2025 targets.

KEY INTERVENTIONS:

1. Scale-up diagnosis of viral hepatitis and improve linkage to treatment

Currently screening for viral hepatitis is practiced in most hospitals and private facilities, however the service is not adequately standardized and monitored. In the coming five years, MOH will further scale-up diagnostic services in a systematic and coordinated manner across the country through implementing the following activities. The key interventions include:

- Avail viral hepatitis rapid testing in all hospitals and health centers. Whenever resources are constrained the testing should be made available to those who are more likely to get infected or have had chronic infections. The following are lists of population groups prioritized for testing:
 - People who have received medical or dental interventions in settings where infection control practices are substandard
 - Pregnant women
 - Children born to HBV or HCV positive mothers
 - People with injecting drugs
 - People living with HIV
 - Health care workers exposed to biological fluids
 - People who ever received blood or blood products
 - Inmates of correctional facilities
 - Household and sexual contacts of HBsAg positive people
 - Female Sex workers
 - History of multiple sexual partners or STIs
 - Patients undergoing renal dialysis
 - People needing immunosuppressive therapy
- Ensure EPHI to standardize rapid tests, revise algorithms and build the capacity of laboratory technologists/ other health workers;
- Integrate viral hepatitis diagnostics with the existing multi-disease plate forms;
- Build the capacity of EPHI and regional laboratories in order to ensure the quality management system for viral hepatitis;

- Prepare SOP which aims to integrate screening/ diagnosis of viral hepatitis, HIV and STI to take advantage of the fact that these diseases share common social determinants and consequently having a wide overlap of target population;
- Integrate sample transport services already in place for HIV and Tuberculosis to include viral hepatitis tests;
- Ensure timely quantification, procurement and distribution of supplies needed for the diagnosis of viral hepatitis in collaboration with EPSA;
- Establish key linkages between testing and other services to improve referral and access to quality assured treatment and other support services;
- Actively engage private facilities at service delivery and program management.

2. Treatment of viral hepatitis

Effective antiviral agents against viral hepatitis B and C have the potential to dramatically reduce morbidity and mortality, including among people co-infected with HIV. Not all people with chronic hepatitis infection require, or are eligible for, treatment. Individuals need to be assessed for liver disease to determine whether treatment is indicated, and if not eligible for treatment, regularly monitored to determine when treatment should be initiated. Direct-acting antivirals (DAA) for the treatment of chronic hepatitis C virus have cure rates exceeding 95%. Effective treatment is available for chronic hepatitis B virus infection, although lifelong treatment is usually required. WHO guidelines for treatment of chronic viral hepatitis B and C infection promote a public health approach with a move towards simpler and safer oral treatment regimens.

There is no available treatment capable of altering the course of acute hepatitis. Prevention is the most effective approach against the disease. Hospitalization is required for people with fulminant hepatitis and should also be considered for symptomatic pregnant women. Considering these facts, the treatment options discussed here will mainly focus on HBV and HCV.

During this strategic period, the country will strive to achieve 60% treatment rate for both hepatitis B & C among the eligible. Supportive chronic care will be the mainstay for those not eligible. The following activities will be implemented throughout the strategic period with the aim of achieving the treatment target 60% by 2025 and 80% by 2030. The key interventions include:

- Scale-up treatment services for viral hepatitis through public health approach. That means various services of viral hepatitis will be implemented according to the capacity available at each tier of the health system guided by standardized care and treatment guidelines and integrating with and further strengthening referral networks for HIV, TB and STI. Furthermore, capacity of health workforce will be further strengthened through provision of job aids, regular and continues training, supportive supervision and clinical mentoring;
- Define and re-define minimum package of services to be provide at each level of the health system starting from health posts;
- Regularly update viral hepatitis treatment guidelines and treatment protocols, following global updates in the diagnosis and treatment of viral hepatitis B&C;
- Provide quality treatment that ensures standardized care of people with chronic hepatitis infection, including appropriate disease staging, timely treatment initiation, patient and drug toxicity monitoring, management of liver cirrhosis, hepatocellular carcinoma and liver failure;
- Address common comorbidities, including HIV infection and risk factors that may accelerate progression of liver disease, including alcohol use and provide palliative and end-of-life care, including access to adequate analgesia;
- Make sure equitable distribution of DAA to eligible patients is made and work closely with EPSA and regional hubs to perform timely and regular quantification, procurement, distribution of drugs as well as monitor utilization by facilities.

STRATEGIC OBJECTIVE 4

STRENGTHEN GENERATION AND UTILIZATION OF STRATEGIC INFORMATION FOR EVIDENCE-BASED RESPONSE

Information interpreted and used for planning and decision-making to improve the direction of a program. Data are needed to measure the performance, improve program management and increase accountability. The data that constitute strategic information can come from a wide variety of sources, for example, monitoring systems, evaluations, program reviews, surveillance, surveys, researches, vital event registration, human interest story, and computer modeling etc. Computer modeling like SPECTRUM that is being used for HIV estimation and projection are

helpful in the estimation of the country-level disease burden. This tool can be used for viral hepatitis too; to enable the country produces evidence-based and cost effective policies and plan.

Surveillance, surveys, and research are powerful tools and provide a sound foundation for the planning and implementation of evidence-based prevention and treatment approaches. Therefore, availing accurate data enable policy makers and decision makers at all levels to understand the burden of disease caused by viral hepatitis, to prioritize resources, and to tailor different interventions. In order to promote evidence-based decision-making viral hepatitis program the following action needs to be undertaken during the strategic planning period.

KEY INTERVENTIONS

- Increase the understanding of the viral hepatitis epidemic and response in the country through effective data collection, analysis, reporting and use at all levels;
- Prepare a national viral hepatitis epidemiological synthesis using the existing available triangulated data and disseminate at national and regional level;
- **Ensure for timely submission of global report on viral hepatitis;**
- Promote the inclusion of key selected viral hepatitis indicators including biomarkers in the Ethiopian Demographic Health Survey (EDHS);
- Promote and ensure the integrating of viral hepatitis in the existing HIV– SPECTRUM computer modeling for a national viral hepatitis estimation and projection;
- Advocate for the instituting continuous quality improvement tool and dashboard in HIV and hepatitis treatment centers and integrate with HIV data quality activities in the existing DHIS2 system;
- Advocate the establishment of sentinel surveillance for viral hepatitis;
- Promote the integration of viral hepatitis research track at national level with the other similar research tracks including TB and HIV;
- **Ensure the timely development of global hepatitis report and its submission;**
- Promote for producing viral hepatitis and HIV quarterly bulletin.

STRATEGIC OBJECTIVE 5

HEALTH SYSTEM STRENGTHENING FOR EFFECTIVE AND EFFICIENT VIRAL HEPATITIS PROGRAM MANAGEMENT

A comprehensive public health approach is critical in scaling-up and decentralization of viral hepatitis prevention and control services. This will be realized through:

- designing people-centered health services;
- well-functioning laboratories and sample transportation mechanism;
- a secure supply of affordable medicines and diagnostics;
- an appropriately trained health workforce;
- adequate resources for essential services; and
- active involvement of affected communities.

KEY INTERVENTIONS

1. Service delivery

- Scale-up decentralized viral hepatitis prevention and control services in the context of simplified and standardized public health approach;
- Strengthen the integration and linking of viral hepatitis services with other relevant health services (including immunization, HIV, STIs, broader sexual and reproductive health, harm reduction and drug use disorders, IPC, blood safety, WASH, and non-communicable diseases);
- Improve the quality of services by ensuring the implementation of global and national norms and standards, and continuously monitoring and reviewing;
- Ensure continuum of viral hepatitis services at all levels and actively engage the community;
- Strengthen the multi-sectoral collaboration of viral hepatitis services with relevant sector offices (including correctional services, police and justice, social welfare, water and sanitation);
- Define the roles and responsibilities of different levels of the health system in delivering viral hepatitis services, from community-based and primary health services through to tertiary referral centers;

- Actively engage the affected populations in developing policy/strategies, programs and also in addressing viral hepatitis related stigma and discrimination;
- Promote differentiated viral hepatitis service delivery models (in health facility, drop-in centers for sex workers and PWID, prisons, refugee camps, CSOs, etc.).

The minimum service packages for viral hepatitis prevention and control program across the health system is summarized in Annex 1.

2. Human resource capacity building

- Identify opportunities for task-shifting and task-sharing to extend the capacity of the health workforce and community health workers with adequate support;
- Integrating viral hepatitis contents into the training of health workers and defining core competencies relevant to delivering hepatitis services at different levels of the health system;
- Build the capacity of health workers through ongoing TOTs and cascade trainings (both in pre-service and in-service training), mentoring and supervisions;
- Promote community-based and peer-support workers in demand creation, linking people with viral hepatitis to care, supporting treatment adherence;
- Implement occupational health measures that address the risk of viral hepatitis transmission within health care settings and address the needs of health workers living with viral hepatitis.

3. Access to medicines, diagnostics & other commodities

- Advocate and negotiate for price reduction of viral hepatitis medicines with manufactures;
- Strengthen the country's capacity in generating data to forecast the need for viral hepatitis medicines, diagnostics and commodities;
- Strengthen the integration of viral hepatitis medicines, diagnostics and commodities to the broader national procurement and supply management system;
- Assess the quality and performance of commercially available hepatitis diagnostics and issue appropriate recommendations;
- Support regulatory authorities in pre-market assessment and registration of new hepatitis medicines and diagnostics, with post-market surveillance;
- Promote and strengthen the local manufacturing capacity to benefit from reduced prices and guarantee supply.

CHAPTER 3: MONITORING AND EVALUATION

Effective viral hepatitis prevention, care and treatment services require standardized data recording and reporting system. Data recording and reporting is used to systematically monitor and evaluate the progress of patient/s and treatment outcome as well as the overall program performance.

Monitoring and evaluation is done at different levels of the health system where epidemiological and operational indicators of viral hepatitis program are compiled, analyzed, reported and used. The viral hepatitis program indicators are integrated into the HMIS/DHIS2 and all forms and registers are standardized accordingly. Health facilities are the primary sources of data. All required information concerning people living with viral hepatitis should be recorded correctly and completely. All health facilities should have an updated registers and reporting forms and should be used properly.

Monitoring and evaluation is key in helping health facility and program managers in assessing the effectiveness of the interventions and the linkages between services along the cascade of testing, diagnosis, treatment and care of viral hepatitis and associated conditions. Such information is essential for early detection and timely response to the identified bottlenecks and/or gaps of the program. Patient monitoring system is also important to support the follow-up of people living with the disease receiving treatment and ensure retention in care.

In order to strengthen the viral hepatitis national monitoring and evaluation (M&E) system, the following key elements are important:

- Clear goal, objectives and targets of the program: cascading the national viral hepatitis goal, objectives and targets to regions and sub-regional levels is essential in owning the program at different levels.
- A core set of indicators and targets: it is important to identify priority/core indicators and additional indicators that cover program inputs, activities/processes, outputs, outcomes and impact. Also, selection of indicators needs to be through full participation of stakeholders and maintaining relevance and comparability.

- Presence of an M&E focal person: assigning M&E focal person with relevant qualification and experience at national & regional level facilitates the tracking of key indicators, analyzing and reporting of the program implementation.
- A viral hepatitis M&E framework: an overall national level data collection and analysis plan is important. The plan has also to address the data collection and analysis system at different levels.
- A clear plan for data dissemination and use: establishment of an overall national level data dissemination plan is important.

1. DATA REPORTING, DATA FLOW AND QUALITY ASSURANCE

Until all the required global and national viral hepatitis indicators are incorporated in HMIS/DHIS2, data collection and reported will be continued through parallel reporting mechanism. Routine viral hepatitis data are collected and reported on a monthly basis. Facilities aggregate and review their data monthly and report to the woreda (district) office. Woreda (district) health office aggregates the data received from facilities and report to zonal health office; the same true is for zonal health office to regional health bureau and regional health office to MOH.

Emphasis should be given for an improved data quality particularly at the facility level where the entry point for HMIS. Periodic DQA activities should be carried out at different levels. Data analysis and data use at different levels is very important to track the program implementation, planning exercise and decision making.

2. SUPPORTIVE SUPERVISION

Ongoing supportive supervision is an important component for monitoring and evaluation. Supportive supervision is a facilitative approach that promotes communication, mentorship, joint problem-solving practices, and appropriate use of resources. Thus, periodic supportive supervision should be carried out at each level. Monitoring the implementation of recommendations/action points of each round of supportive supervision is crucial in improving the overall quality of the services.

3. SURVEILLANCES AND SURVEYS

Efforts should be made to establish and/or integrate viral hepatitis surveillance system based on the availability of resources. Periodical surveys will be conducted both at a facility and population level in order to understand the epidemiology of viral hepatitis and effectiveness of interventions.

4. RESEARCH AND DEVELOPMENT

MOH in collaboration with EPHI will encourage efforts to generate further evidences that shape and contribute to the national prevention and control of viral hepatitis. Ongoing basic, social and operational researches are important through coordinated manner and aligned with national research ethics.

5. MID-TERM AND END-REVIEWS

Mid-term review of this national strategic plan will take place in mid-2023 while the end-term review will be conducted just before the end-date of the strategy. The mid-term review will assess the results in the achievement of the targets, analyzing the available data to verify the outcome and impact in comparison with baseline values for core indicators. The review will not only assess the effectiveness of the overall national response but will also take into consideration the quality and efficiency of the interventions. If it is necessary, the national strategic plan will be revised based on the findings and recommendations of the review.

CHAPTER 4: COORDINATION MECHANISM AND RESOURCES

1. COORDINATING THE IMPLEMENTATION

The viral hepatitis program will be managed and coordinated at different levels of the health system: The ministry of health, regional health bureaus, zonal health offices and woreda health offices will have different areas of work and responsibilities in the prevention and control of viral hepatitis.

To strengthen the leadership and coordination of viral hepatitis program, MOH and RHBs have moved the viral hepatitis program from NCD team to HIV team – this restructuring is helpful for efficient program management. A focal person for viral hepatitis program is assigned in MOH and RHBs. Furthermore, zonal and woreda health offices will assign their respective viral hepatitis focal person. Ministry of health and regional health bureaus at different levels will be responsible for the coordination of sectors.

A functional viral hepatitis TWG is in place at the national level and the partners like CHAI, EGA, and WHO, are actively engaged in the work of this coordinating structure. The TWG is advising MOH in advocacy, policy development, capacity building and supply chain management. Though the lists are not exhaustive, the key roles and responsibilities of the stakeholders are summarized as below:

Ministry of Health

- Leads and coordinates the viral hepatitis program at different levels for effective and efficient program implementation and for improved quality of services;
- Develop national viral hepatitis strategic plan, guidelines, training materials and tools;
- Capacity building of viral hepatitis program managers and health care workers;
- Facilitate clinical mentorship in improving quality of viral hepatitis services at different levels;
- Monitor and report the implementation of the strategic plan and guidelines (national & global);

- Strengthen the partnership with relevant stakeholders through involving in TWG, operational planning exercises, monitoring and evaluation activities;
- Advocates and negotiate for price reduction of viral hepatitis medicines and diagnostics;
- Mobilize domestic and external resources for viral hepatitis program;
- Strengthen inter-program and multi-sectoral collaboration;
- Ensure data quality and use at different level.

Ethiopian Pharmaceutical and Supply Agency (EPSA)

- Leads and coordinates the viral hepatitis program supply chain management;
- Actively engages in the national viral hepatitis TWG and related national forums;
- Conduct annual viral hepatitis medicines and diagnostics quantification exercises;
- Coordinates the procurement and distribution of the necessary viral hepatitis commodities by integrating into the existing supply chain management system;
- Update the reporting and requisition formats to incorporate commodities needed for viral hepatitis;
- Integrate viral hepatitis in supply chain training manual;

Ethiopian Public Health Institute (EPHI)

- Leads and coordinates the national viral hepatitis laboratory services;
- Actively engages in the national viral hepatitis TWG and related national forums;
- Standardizes the national viral hepatitis B & C testing algorithm;
- Setting up functional diagnostic systems/platforms for viral hepatitis at various levels;
- Leads the development and revision of training manual as well as provision of trainings for laboratory professionals;
- Builds the diagnostic capacities at national, regional and facility levels;
- Promotes integration of viral hepatitis viral load testing into the existing multi-disease diagnostic platforms (GeneXpert, conventional VL machines);
- Strengthen the EQA of viral hepatitis lab tests through integrating into existing quality assurance mechanisms;
- Conduct surveys, surveillance and operational research as needed.

Ethiopian Food and Drug Administration (EFDA)

- Actively engage in national viral hepatitis TWG and related national forums;
- Enlists and approves viral hepatitis medicines and diagnostics in the national drug list as per the recommendation of the national guideline;
- Ensures pre-market assessment and registration of new hepatitis medicines and diagnostics, with post-market surveillance.

Regional Health Bureaus (RHB)

- Lead and coordinate the viral hepatitis program at regional and sub-regional levels for effective and efficient program implementation and for improved quality of services;
- Prepare annual operational plan aligned with the national viral hepatitis plan;
- Cascade the national viral hepatitis strategic plan, guidelines, training materials and tools;
- Cascade the viral hepatitis trainings to program managers and health care workers;
- Facilitate clinical mentorship to improve quality of viral hepatitis services at different levels;
- Monitor and report the implementation of the national strategic plan and guidelines;
- Strengthen the partnership with regional stakeholders through establishing TWG and involve stakeholders in the operational planning exercises, monitoring and evaluation activities;
- Allocate resources for viral hepatitis program;
- Strengthen inter-program and multi-sectoral collaboration;
- Ensure data recording and reporting, data quality, and use at different level.

Civil Society Organization (CSO)

- Advocates to avail accessible and affordable viral hepatitis services;
- Actively engage of affected communities in the national viral hepatitis response;
- Creates awareness and community mobilization for viral hepatitis prevention, diagnosis, treatment and care services;
- Address viral hepatitis related stigma and discrimination;
- Mobilize domestic and international resources.

Development partners

- Engage actively in national viral hepatitis TWG and related national forums;
- Support the country adaptation and revision of national policy documents based on the global updates;
- Provide technical and financial support to the viral hepatitis national response based on country need;
- Enhance local and international resource mobilization and build technical and institutional capacities to sustain effective and efficient national response;
- Ensure the alignment and harmonization of operational plans.

Private health sector

- Engage in national viral hepatitis TWG and related national forums;
- Ensure the provision of viral hepatitis services as per the national guidelines;
- Improve data recording and reporting mechanism as per the national guidance;
- Contribute in the national resource mobilization efforts.

NB: the roles and responsibilities of public health facilities will be reflected in the standard operating procedures, which will be prepared and disseminated.

2. COSTING AND FINANCING

Over the next five years, it is important to promote for sustained domestic commitment to fund the national response to viral hepatitis. The costs for each intervention are estimated as the population in need of the service multiplied by the coverage (the percentage actually using the service) multiplied by the unit costs. The total funding needs for the NSP is \$900,046,797 million for the period of 2021-2025. The annual resources needed for each activity is summarized in the below table and the key inputs and assumptions for the costing of the viral hepatitis national strategic plan are described in Annex 3.

**Financial resource estimates needed for implementation of
2021-2025 viral hepatitis NSP in Ethiopia (in USD)**

Cost Item	Year 1	Year 2	Year 3	Year 4	Year 5	Cumulative
HCWs Training	32,000	85,600	965,600	965,600	965,600	3,014,400
Guidelines and NSP printing	10,000	19,280	36,800	36,800	36,800	139,680
Advocacy/ Communication	9,475	29,000	29,000	29,000	29,000	125,475
Vaccination for HCWs	19,474	21,420	23,563	25,920	28,502	118,879
HBV medicines	477,882	2,477,319	10,262,699	21,234,314	35,658,709	70,110,923
HCV medicines	2,763,845	14,327,664	59,354,683	122,809,402	206,233,396	405,488,989
VL tests for HBV	2,064,808	10,703,883	44,342,582	91,748,211	154,072,448	302,931,933
VL tests for HCV	680,947	3,530,004	14,623,618	30,257,389	50,811,127	99,903,084
Screening test / RDTs both for HBV & HCV	121,136	627,966	260,1450	5,382,600	9,038,981	17,772,133
M & E	63,328	88,458	100,528	88,458	100,528	441,300
Total Cost	6,242,894	31,910,594	132,340,524	272,577,694	456,975,091	900,046,797

ANNEXES

ANNEX 1. Minimum package for viral hepatitis services at each health facility level

Minimum package for viral hepatitis services at each health facility level			
Level/Provider	Prevention	Laboratory	Treatment
Community - HEWs/HEPs	<ul style="list-style-type: none"> - Prevention message - Provide information to the community 	<ul style="list-style-type: none"> - Provide information to the community 	<ul style="list-style-type: none"> - Program adherence support - Provide information to the community
Health Center - General Practitioner - Health officers - Nurse - Laboratory Technician	<ul style="list-style-type: none"> - Prevention message - Vaccination of newborn - Adults vaccination - Pre / Post exposure prophylaxis - Capacity building of HEWs/HEPs 	<ul style="list-style-type: none"> - Rapid tests for screening - Hematology - CBC 	<ul style="list-style-type: none"> - Assess eligibility criteria for HBV and HCV using available capacities - Counselling (adherence, lifestyle) - Initiate HBV treatment for simple cases - Follow up of patients on HBV and HCV treatment - Refer complicated cases to the next level as appropriate
District Hospital - General Practitioner - Health officers - Nurse - Laboratory Technician	<ul style="list-style-type: none"> - Prevention message - Vaccination of newborn - Adults vaccination - Pre/Post exposure prophylaxis - Supervision and clinical mentorship of Health Centers 	<ul style="list-style-type: none"> - Rapid tests for screening - Liver function tests - Renal function tests - Hematology - Capacity building of Lab technicians at health center level (Training, Mentorship) 	<ul style="list-style-type: none"> - Clinical assessment for cirrhosis - Counselling (adherence, lifestyle) - Assess eligibility criteria for HBV and HCV using available capacities - Initiate HBV treatment for intermediary complicated cases - Initiate HCV treatment - Follow up of patients on HBV and HCV treatment - Refer complicated cases to the next level as appropriate - Capacity building of Nurses/HO at Health Center Level (Training, Mentorship)
Referral Hospital/Private hospitals - Specialist - General Practitioner - Nurse - Laboratory Technician - Nutritionist	<ul style="list-style-type: none"> - Prevention message - Vaccination of newborn - Adults vaccination - Pre/Post exposure prophylaxis - Capacity building of medical at District Hospitals & Health centers (Training, Mentorship, Supervision) 	<ul style="list-style-type: none"> - Rapid tests for screening - Liver function tests - Renal function tests - Hematology - ELISA Tests - Viral Load Monitoring - Capacity building of medical at District Hospitals & Health Centers (Training, Mentorship, Supervision) 	<ul style="list-style-type: none"> - Counselling (adherence, lifestyle) - Advanced clinical assessment for cirrhosis - Assess eligibility criteria for HBV and HCV using available capacities - Initiate HBV treatment complicated cases - Initiate HCV treatment - Follow up of patients on HBV and HCV treatment - Provide guidance on HCV and HBV end of treatment - Capacity building of medical at District Hospitals (Training, Mentorship, Supervision)

ANNEX 2. Targets for monitoring of HBV and HCV progress – 2021-2025

S. No.	Service coverage targets	Baseline		Data sources	2021	2022	2023	2024	2025
		Year	Value						
1	Hepatitis B Virus Vaccination: Childhood vaccine coverage (Third Dose)	2020	67%	DHIS2/ EDHS	81%	85%	89%	92%	95%
Numerator: Number of children aged one year, receiving three doses of pentavalent vaccine									
Denominator: Number of surviving infants in a particular year (Census-CSA)									
2	Prevention of Hepatitis B mother-to-child transmission: Hepatitis B virus birth dose vaccination coverage	2020	0 (under piloting)	DHIS2/ EDHS	80%	83%	86%	89%	92%
Numerator: Number of infants receiving HBV birth dose vaccine within 24 hrs. after birth									
Denominator: Expected live births in a particular year									
3	Blood safety: Proportion of donated bloods screened for HBV & HCV with quality assurance	2020	100%	NBTS report	100%	100%	100%	100%	100%
Numerator: Number of donated bloods screened for HBV & HCV with quality assurance									
Denominator: Total number of donated bloods in a particular year									
4	Safe injections: Percentage of injections administered with safety in the health facilities	2020	100%	SPA+/ Survey	100%	100%	100%	100%	100%
Numerator: Number of health facilities providing safe injections									
Denominator: Total number of public and private health facilities in a particular year									
5	Viral Hepatitis B diagnosis coverage	2020	NA	DHIS2	<1%	5%	20%	40%	65%
Numerator: Number of individuals diagnosed positive for HBV									
Denominator: Estimated people living with HBV infection									
6	Viral Hepatitis C diagnosis coverage:	2020	NA	DHIS2	<1%	5%	20%	40%	65%
Numerator: Number of individuals diagnosed positive for HCV									
Denominator: Estimated people living with HCV infection									
7	Viral Hepatitis B treatment coverage	2020	NA	DHIS2	<1%	5%	15%	35%	60%
Numerator: Number of people testing positive for HBV who received treatment									
Denominator: Number of people with positive HBV test and eligible for treatment									
8	Viral Hepatitis C treatment coverage	2020	NA	DHIS2	<1%	5%	15%	35%	60%
Numerator: Number of people testing positive for HCV who received treatment									
Denominator: Number of people with positive HCV testing results									

ANNEX 3. Key inputs and assumptions for the costing of the 2021-2025 viral hepatitis national strategic plan

1. Health care workers training:

- An average of 1,500 ETB would be enough per person per day for per diem, transportation, refreshment, and meeting hall costs. It was also assumed that the conversion rate of 1 USD is 45 ETB.
- The number of trainees include three clinical staff (physician, HO or nurse), 1 laboratory staff and 1 pharmacy staff from each of the health facilities that provide viral hepatitis diagnostic and treatment services. Besides, focal persons from each of the 12 regional health bureaus will be trained every year.
- Training will be provided for staff from 28 hospitals and 95 hospitals (22 referral/specialized hospitals and 73 general hospitals) in Year 1 and Year 2, respectively. In the remaining three years, training will be provided for staff from 1,195 hospitals (22 referral/specialized hospitals, 73 general hospitals and 1,100 primary hospitals) every year. Besides, 12 staff from RHBs will be trained every year considering that there would be attrition or rotation of focal persons.
- The training duration will be three days for clinical and laboratory staff, and two days for pharmacy staff.
- For each of the training participants, an average of two travel days is also considered.

2. Printing of guideline and national strategic plan:

- Both the national viral hepatitis strategic plan and the national viral hepatitis guideline will be printed in 500, 964, 1840, 1840, 1840 in year 1, year 2, year 3, year 4 and year 5, respectively.
- The estimated printing costs per copy for both documents will be 10 USD.

3. Advocacy and communication:

- It was assumed that there will be 60 media spots in each of the years to advocate and promote viral hepatitis services.
- The estimated cost for each of the media spots will be 150 USD. This cost assumption was taken from the current television and radio spots broadcasted on HIV related messages.

- It is also planned to print 95 copies of SBCC materials in year 1 and 4,000 copies of SBCC materials in each of the remaining four years. The estimated printing cost for one copy of SBCC materials is 5 USD.

4. Hepatitis B vaccination of health care workers:

- It was assumed that all health care workers who worked previously or currently in health facilities are vaccinated for HBV. Here, it is assumed that only those newly graduated are eligible for HBV vaccination.
- The number of eligible health care workers in the country for year 1, year 2, year 3, year 4 and year 5 is 3462, 3,808, 4,189, 4,608, and 5,067, respectively.
- Each health care worker will receive three doses of the HBV vaccine.
- The estimated cost of one dose HBV vaccine is 1.50 USD, including 20% margin for procurement and supply management costs and 5% wastage cost.

5. Monitoring and evaluation costs:

- It was assumed that 56 health facilities will be supervised in year 1, and 241 health facilities will be supervised in each of the remaining four years. The estimated cost of supportive supervision per health facility is 138 USD that includes per diem and transportation.
- It was also assumed that viral hepatitis registers with 40 copies in year 1, and 1,207 copies in each of year 3 and year 5 will be printed.
- It was also planned to conduct two review meetings per year, three assessments (baseline, midline, and end line) during the five years, and one planning workshop every year.

6. HBV medicines:

- As per the EPHI survey, the HBV national prevalence was taken to be 9.4%.
- Number of HBV infected people was calculated by multiplying the prevalence and the adult (>15 years) population size, which was projected by the Central Statistics Agency, for each year.
- The number of HBV infected people diagnosed in each of the years was determined based on the targets as indicated in the monitoring and evaluation framework of the national strategic plan.

- Based on the opinions of gastroenterology specialists, 15% of HBV diagnosed people are eligible for antiviral treatment.
- It was also assumed that 90% of this eligible for treatment will be treated using TDF while the remaining 10% will be treated using entecavir as these patients could be either contraindicated to TDF because of renal disease or due to age or failure to TDF treatment.
- The price of 1 pack (30 tablets) of TDF and 1 pack (30 tablets) of entecavir was taken to be 3 USD and 16 USD, respectively, including supply chain management costs or EPSA margins. The reference price was taken from the recent procurement of EPSA.

7. HCV medicines:

- As per systematic review and meta-analysis, the HCV national prevalence was taken to be 3.1%.
- Number of HCV infected people was calculated by multiplying the prevalence and the adult (>15 years) population size, which was projected by the Central Statistics Agency, for each of the years.
- The number of HCV infected people diagnosed in each of the years was determined based on the targets as indicated in the monitoring and evaluation framework of the national strategic plan.
- All of HCV diagnosed people were taken to be eligible for antiviral treatment.
- It was also assumed that 80% of HCV diagnosed people will be treated using combination of SOF 400mg and DCV 60mg tablet while the remaining 20% will be treated using combination of SOF 400mg and VEL100mg FDC tablet. It was assumed that 20% of HCV diagnosed clients have either previous treatment failure with DCV 60mg based regimen or contraindicated to DCV 60mg and hence need SOF 400mg+VEL100mg FDC treatment.
- The price of 1 pack (28 tablets) of SOF 400mg + DCV 60mg tab co-blister tablets and 1 pack (28 tablets) of SOF 400mg+VEL100mg FDC tablet was taken to be 38.75 USD and 75.00 USD, respectively, including supply chain management costs or EPSA margins. The reference price was taken from the recent procurement of EPSA.

8. Viral load tests for both HBV and HCV clients:

- One viral load test will be conducted once in a year for each of the HBV and HCV diagnosed clients.
- The price for one VL test was taken to be 34 USD including supply chain management costs or EPSA margins. The reference price was taken from the recent procurement of EPSA.

9. Screening test / RDTs both for HBV & HCV:

- One RDT test will be conducted once for each of the HBV and HCV diagnosed clients.
- The price for one RDT test was taken to be 1.5 USD including supply chain management costs or EPSA margins. The reference price was taken from the recent procurement of EPSA.

REFERENCE MATERIALS

1. Global health sector strategy on viral hepatitis 2016–2021: Towards ending viral hepatitis, WHO 2016
2. Prevention and control of Viral hepatitis infection Framework for Global action, WHO, 2012
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4. Guidelines for the prevention, care and treatment of person's with chronic Hepatitis B infection March 2015
5. Prevention & control of viral hepatitis infection: A strategy for global action, WHO 2011
6. HIV/AIDS national strategic plan for Ethiopia 2021-2025, FHAPCO 2021
7. Five-year strategic plan for the national blood transfusion service 2015/16-2019/20, MoH
8. National expanded program on immunization - comprehensive multi-year plan, 2021-2025, MoH