

REGIONAL COMMITTEE FOR AFRICA

ORIGINAL: ENGLISH

<u>Sixty-sixth session</u> Addis Ababa, Federal Democratic Republic of Ethiopia, 19–23 August 2016

Agenda item 14

PREVENTION, CARE AND TREATMENT OF VIRAL HEPATITIS IN THE AFRICAN REGION: FRAMEWORK FOR ACTION, 2016–2020

Report of the Secretariat

EXECUTIVE SUMMARY

- 1. Viral hepatitis is a highly endemic disease and a public health problem. It is responsible for an estimated 1.4 million deaths per year globally, mostly from hepatitis-related liver cancer and cirrhosis. Unfortunately, most people with chronic viral hepatitis are not aware of their status and do not receive appropriate treatment.
- 2. The World Health Assembly and the Regional Committee resolutions on viral hepatitis that were adopted in 2010 and 2014 respectively recognized viral hepatitis as a public health problem and the need for governments and populations to take action to prevent, diagnose and treat viral hepatitis. The resolutions call upon WHO to provide the necessary technical support to enable Member States to develop robust national viral hepatitis prevention, diagnosis and treatment strategies.
- 3. Significant barriers, including inadequate data for making decisions and limited coverage of effective prevention interventions, need to be addressed before the goal of eliminating viral hepatitis as a major public health threat can be realized. The lack of simple and effective hepatitis testing strategies and tools; the very limited access to effective treatment and care services; unaffordable hepatitis medicines and diagnostics; and lack of a comprehensive public health approach need to be addressed as well. Various structural barriers increase vulnerability and prevent equitable access to services. Widespread stigma and discrimination hinder access to health services for populations that may be marginalized and who are at higher risk of hepatitis infection.
- 4. The aim of the document, Prevention, Care and Treatment of viral hepatitis in the African Region: Framework for action 2016–2020, is to guide Member States in the African Region to implement the Global Health Sector Strategy on viral hepatitis. The priority actions proposed include developing data systems to understand the burden of the disease, preventing viral hepatitis transmission and countries designing strong hepatitis treatment programmes.
- 5. This framework defines the response to viral hepatitis in the Region for the period 2016–2020 as a contribution to achieving the 2030 agenda for sustainable development by ensuring universal health coverage. Strengthening health systems and prioritizing innovation will be crucial to achieving the targets set in the Regional Strategy. It is proposed that the interventions be carried out in an integrated manner to maximize effectiveness. Furthermore, participation of all stakeholders, including communities, under the leadership of governments, will be essential.
- 6. The Regional Committee examined and adopted this framework.

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INTRODUCTION

- 1. Viral hepatitis is an inflammation of the liver, caused by five distinct hepatitis viruses (A, B, C, D, and E). While hepatitis A and E viruses are spread through the oro-faecal route, hepatitis B and C viruses are transmitted through exposure to blood, sexual intercourse, and from an infected pregnant mother to her unborn child. Although transmitted by blood, hepatitis D can cause infection only in individuals with active hepatitis B infection or in carriers. Viral hepatitis is a highly endemic public health problem in the African Region, comparable to other major communicable diseases, including HIV, tuberculosis and malaria. All five hepatitis viruses can cause acute disease, but the highest numbers of deaths result from liver cancer and cirrhosis which occur after decades of chronic hepatitis B or C infection.
- 2. The World Health Assembly resolutions on viral hepatitis that were adopted in 2010¹ and 2014²; and the Regional Committee resolutions in 2014³ recognized viral hepatitis as a public health problem and the need for governments and populations to take action to prevent, diagnose and treat it. The resolutions call upon WHO to provide the necessary technical support to enable Member States to develop robust national viral hepatitis prevention, diagnosis and treatment strategies with time-bound goals and to examine the feasibility of eliminating hepatitis B and hepatitis C. In recognition of its public health importance, target 3.3 of the 2030 Agenda for Sustainable Development⁵ calls for specific action to combat viral hepatitis.
- 3. The Global Health Sector Strategy (GHSS) 2016–2021 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 a set of priority actions for countries to undertake, which are organized under five strategic directions, namely information for focused action, interventions for impact, delivering for equity, financing for sustainability and innovation for acceleration of the response.
- 4. This framework is aligned with the GHSS on viral hepatitis and it takes into consideration the specific priorities of the African Region. It provides a platform for Member States to implement effective interventions for the viral hepatitis response.

CURRENT SITUATION

5. In 2013, viral hepatitis was the seventh highest cause of mortality in the world. It is responsible for an estimated 1.4 million deaths per year, mostly 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. In the African Region, hepatitis B is highly endemic and probably affects an estimated 5–8% of the population, mainly in West and Central Africa.

Resolution AFR/RC64/R5, Viral Hepatitis: Situation analysis and perspectives in the African Region. In: Sixty-fourth session of the WHO Regional Committee for Africa, Cotonou, Republic of Benin, 3–7 November 2014, Final Report, Brazzaville, Congo, World Health Organization, Regional Office for Africa, 2014 (AFR/RC64/14) pp.9–11.

Resolution A/RES/70/1: Transforming our world: the 2030 Agenda for Sustainable Development; New York; September 2015.

Cooke G.S: Viral hepatitis and the Global Burden of Disease: a need to regroup; Journal of Viral Hepatitis; Volume 20, Issue 9, pages 600–601, September 2013 (Adapted from Global Burden of Disease study).

Schweitzer, Horn et al; Estimations of worldwide prevalence of chronic hepatitis B virus infection: a systematic review of data published between 1965 and 2013; Lancet 2015.

¹ Resolution WHA 63.18: Viral Hepatitis; Geneva, 2010.

² Resolution WHA 67.6: Viral Hepatitis; Geneva, 2014.

⁴ Resolution AFR/RC64/R4, Regional Strategic Plan on Immunization 2014–2020. In: *Sixty-fourth session of the WHO Regional Committee for Africa, Cotonou, Republic of Benin, 3–7 November 2014, Final Report*, Brazzaville, Congo, World Health Organization, Regional Office for Africa, 2014 (AFR/RC64/14) pp.8–9.

- 6. It is estimated that 19 million adults in the Region are chronically infected with hepatitis C. Viral hepatitis is also a growing cause of mortality among people living with HIV. About 2.3 million people living with HIV are coinfected with hepatitis C virus and 2.6 million with hepatitis B virus. Recent outbreaks of hepatitis E virus have been reported in Chad, Senegal, South Sudan and Uganda and high levels of endemicity have been reported in other countries in the African Region
- 7. The hepatitis B virus vaccine is administered in all 47 Member States and coverage of the three-dose childhood vaccination is 77%. However, hepatitis B birth-dose was introduced in few countries with a low regional coverage reported at 11%. In 2015, it was estimated that less than 5% of people with chronic hepatitis infection were aware of their status and less than 1% of those in need accessed effective antiviral therapy.
- 8. In 2015, only Algeria, Mauritania and Senegal had national viral hepatitis action plans and a few additional countries were in the process of developing their plans. Forty countries report testing 100% of all blood donations for all transfusion-transmitted infections, which include hepatitis B and C.

ISSUES AND CHALLENGES

- 9. Some significant barriers need to be addressed before the goal of eliminating viral hepatitis as a major public health threat can be realized. Among these is the lack of action from the majority of countries and the international community as a whole to eliminate viral hepatitis epidemics. Few countries have national viral hepatitis strategies or plans, and even fewer have designated units and budgets within their health ministries to lead, guide and coordinate their hepatitis responses.
- 10. The true public health dimensions and impact of hepatitis epidemics are poorly understood in the Region. National and subnational data are often lacking or inadequate and hepatitis surveillance programmes are weak, making it difficult to plan for focused action and prioritize the allocation of resources.
- 11. Prevention programmes are of limited scope and coverage. Most countries have not introduced the birth dose for vaccination of newborns to prevent perinatal hepatitis B infection. Unsafe blood transfusions have been reported in some settings and there are many unsafe and unregulated practices in the communities and in both private and public health facilities. Implementation of standard precautions for infection control, including unsafe injections is still a challenge in health facilities in the Region and health workers who are at high risk of infection have no access to hepatitis B vaccines. A large proportion of the population in the Region lacks access to clean drinking water and more than 50% have poor sanitation, 11 creating favourable environmental conditions for the easy spread of hepatitis A and E.
- 12. Simple and effective hepatitis testing strategies and tools are lacking, with less than 5% of people with chronic hepatitis infection knowing their status. For this reason, diagnosis often

J. Riou: Hepatitis C virus seroprevalence in adults in Africa: a systematic review and meta-analysis; Journal of Viral Hepatitis; October 2015.

WHO/UNICEF estimate of national immunization coverage 2014, WHO-UNICEF, July 2015.

Philippa C. Matthews: Epidemiology and impact of HIV coinfection with Hepatitis B and Hepatitis C viruses in Sub-Saharan Africa; Journal of Clinical Virology; Volume 61, Issue 1, September 2014, Pages 20–33.

UNICEF and WHO: Progress on Sanitation and Drinking Water – 2015 update and MDG assessment. UNICEF and World Health Organization 2015.

occurs late and appropriate tests to assess liver disease and guide treatment decisions, including when to start treatment, are seldom available.

- 13. Despite availability of treatment for chronic hepatitis B and hepatitis C, it is inaccessible to most patients due to the high prices of medicines. Patients with complications of chronic hepatitis infection, including end-stage cirrhosis and hepatocellular carcinoma, have limited access to basic care, and many of them have turned to traditional medicine. It is also difficult to decentralize the management of viral hepatitis from specialized centres because primary health care workers are not adequately trained and equipped to diagnose and treat patients with chronic hepatitis B and C.
- 14. Structural barriers increase vulnerability and prevent equitable access to services. Discrimination along with widespread stigma continues to hinder access to health services for populations that may be marginalized and who are at higher risk of hepatitis infection.

THE FRAMEWORK FOR ACTION

Vision, Goal, Objectives and targets

- 15. The **vision** is a Region where viral hepatitis transmission is halted and everyone living with viral hepatitis has access to safe, affordable and effective care and treatment.
- 16. The **goal** is to mobilize Member States for effective action to eliminate viral hepatitis as a major public health threat by 2030 in the African Region.
- 17. The **objectives** are:
- (a) To guide the Member States in the African Region to implement the Global Health Sector Strategy on viral hepatitis as a contribution to achieving the 2030 agenda for sustainable development by ensuring universal health coverage.
- (b) To articulate the priority actions required to achieve the global viral hepatitis strategy targets
- 18. The **targets** of the *Prevention, Care and Treatment of viral hepatitis in the African Region: Framework for action 2016-2020* are:

Impact targets by 2020:

- (a) 30% reduction of new cases of chronic viral hepatitis B and C infections
- (b) 10% reduction of viral hepatitis B and C related deaths

Service coverage targets by 2020:

- (a) All 47 countries have developed national action plans for the prevention, care and treatment of viral hepatitis.
- (b) Hepatitis B virus vaccine coverage among infants at 90% region-wide.
- (c) Hepatitis B virus vaccine coverage among health workers at 90% region-wide.
- (d) At least 25 countries have introduced a birth dose of hepatitis B vaccine.
- (e) All countries routinely test all blood donations for transfusion-transmissible infections.
- (f) 50% of injections administered with safe devices in and out of health facilities.
- (g) At least 200 sterile needles and syringes provided per person who injects drugs per year.

- (h) 20% of people with chronic hepatitis infections diagnosed.
- (i) 1 million people will be receiving hepatitis B virus treatment.
- (j) 300 000 people will be receiving hepatitis C virus treatment.

GUIDING PRINCIPLES

- 19. The guiding principles of the Regional Framework are:
- (a) Country ownership to ensure that the national hepatitis response is led, coordinated and owned by the Member States.
- (b) Effective partnerships for multisectoral cooperation involving all sectors of society and ensuring that all partners align their support to the national hepatitis response as set out by governments.
- (c) Universal Health coverage as the overarching framework to ensure that all people obtain the viral hepatitis services they need without suffering financial hardship when paying for them.
- (d) Integration of hepatitis services into health systems and strategies, avoiding stand-alone viral hepatitis programmes and strengthening the interface between the health sector and other sectors.
- (e) 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.
- (f) Intersectoral cooperation where all key stakeholders are encouraged to work together to 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.

PRIORITY INTERVENTIONS AND ACTIONS

Countries should undertake the following actions:

Information for focused action

- 20. Integrate viral hepatitis strategic information activities and indicators within national health information systems and tools. Establish strong surveillance systems, estimate the prevalence of hepatitis B and hepatitis C infection, and where possible, the burden in terms of sequelae (hepatocellular carcinoma and cirrhosis). Countries should monitor access to, uptake and quality of vital hepatitis services, disaggregated by different populations and geographic locations in line with the 10 core indicators proposed by WHO.
- 21. Mainstream the governance of the national hepatitis response into the national health system. Develop a national plan on viral hepatitis with a budget and integrate it into the broader national health plan. Countries should raise national awareness on viral hepatitis, by promoting the national plan, developing behaviour change communication for viral hepatitis, celebrating World Hepatitis Day (28 July), and engaging community and political leaders, advocates and "champions".

Interventions for impact

22. Define a set of essential viral hepatitis interventions and services, relevant to the country context, to be included in the national health benefit package. The benefit package should be

covered in whole, or in part, through public funding so as to minimize out-of-pocket payments, ensure access to services for all who need them, and cover the entire continuum of hepatitis services, including prevention, diagnosis, treatment and care.

- 23. Strengthen national hepatitis B virus vaccination programmes; introduce the hepatitis B virus birth-dose; and offer hepatitis B virus vaccination to people who are at increased risk of acquiring and transmitting the virus. Countries should aim for 100% of blood donations from regular, voluntary, and non-remunerated blood donors; promote the rational use of blood and blood products and ensure reliable screening of blood for viral hepatitis B and C.
- 24. Strengthen and sustain injection, blood and surgical safety and universal precautions in all health care settings; and ensure that people who inject drugs have access to comprehensive harm reduction services that meet their needs. Countries should provide health workers with free vaccination against hepatitis B virus, and provide hepatitis B virus post-exposure prophylaxis as necessary. They should promote safe sex by intensifying condom programming especially for populations most at risk of viral hepatitis B and/or C infection. In addition, ensuring high levels of sanitation and access to safe food and water is essential for preventing and controlling epidemics of hepatitis A virus and hepatitis E virus.
- 25. Integrate viral hepatitis testing into national hepatitis policies and guidelines that define priority populations and locations for testing, testing approaches and strategies, based on WHO guidelines and recommendations. Countries should establish key linkages between testing and other services to improve referral and access to quality-assured treatment and other support services. They should strengthen the national laboratory system to provide quality diagnosis of acute and chronic hepatitis and ensure the reliable supply of WHO pre-qualified diagnostics.
- 26. Prioritize hepatitis treatment by including access to antiviral treatment for people with chronic viral hepatitis B and C infection in their national hepatitis strategy and plan. There should be quality treatment that ensures standardized care of people with chronic hepatitis infection, based on WHO guidelines. This would include appropriate disease staging, timely treatment initiation, patient and drug toxicity monitoring, management of liver cirrhosis, hepatocellular carcinoma and liver failure. Treatment services should 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.
- 27. Strengthen the national procurement and supply management structures and processes to provide quality-assured hepatitis medicines and commodities using the WHO prequalification process. The medicines and commodities include vaccines such as the monovalent hepatitis B vaccine for the birth dose, medicines, diagnostics, condoms, and other hepatitis-related commodities.

Delivering for equity

- 28. Health systems should be strengthened to deliver essential hepatitis services decentralized to different populations and settings. It is essential to reinforce strategic linkages between different levels of the health service delivery system, ensure quality of the services and actively engage communities. The roles and responsibilities of different levels of the health system in delivering hepatitis services need to be defined, from community-based and primary health services through to tertiary referral centres.
- 29. Address critical underlying factors such as poor sanitation, poverty, discrimination, drug dependence and poor mental health in order to make it safe for people to access hepatitis services.

Target hepatitis interventions and services to reach those who are at greatest risk or who are most affected. Involve communities in the planning and delivery of hepatitis services to improve their reach, quality and effectiveness. In addition, policies and practices that condone or encourage stigma and discrimination against people at risk for hepatitis or living with hepatitis, especially in health care settings should be minimized.

30. Train health workers at all levels of care, in both public and private sectors about viral hepatitis risk and infection, and the package of essential hepatitis interventions. Core competencies related to viral hepatitis should be included in pre-service and in-service training for health workers. Community based workers should receive regular training, mentoring and supervision and appropriate compensation for their work.

Financing for sustainability

- 31. Develop a robust viral hepatitis investment case to advocate for adequate allocation of domestic resources and to mobilize external funding support. The investment case should be incorporated into the overall investment case for health to the extent possible. Countries should estimate national hepatitis resource needs and develop a plan for filling any resource gap through raising new funds using innovative financing mechanisms and allocating adequate health resources to hepatitis.
- 32. Provide universal protection against health-related financial risk, covering all populations especially those at high risk of hepatitis infection. Identify opportunities for cost reduction particularly for medicines and diagnostics such as negotiated market guarantees and use of pooled procurement mechanisms. Increasing the efficiency of programmes and services will lead to savings and enable greater coverage of hepatitis services.

Innovation for acceleration

- 33. Define priorities for innovation, facilitate research, document early implementation experiences and lead on operational research. Some of the priority areas include safety-engineered injection equipment, vaccines, rapid diagnostic tests for diagnosing viral hepatitis B and C infection, point-of-care tests for monitoring hepatitis B and hepatitis C viral load, safe and more effective medicines, infection control and new service delivery models based on a public health approach. There should be cooperation between researchers and policy-makers to promote research and ensure that research findings are translated into practice rapidly and on a scale sufficient to have the desired impact.
- 34. The Regional Committee examined and adopted this framework.

ANNEX 1: Global health sector strategy on viral hepatitis, 2016–2021 at a glance

VISION	A world where viral hepatitis transmission is halted and everyone living with viral hepatitis has access to safe, affordable and effective prevention, care and treatment services.	
GOAL	Eliminate viral hepatitis as a major public health threat by 2030	

PRINCIPLES

- 1. Country ownership
- 2. Effective partnerships
- 3. Universal Health coverage as the overarching framework
- 4. Integration of hepatitis services into health systems and strategies,
- 5. A public health approach
- 6. Intersectoral cooperation

STRATEGIC DIRECTIONS

1. Information for focused action

- (a) Understanding the epidemic and the response
- (b) Implementing evidence-based national hepatitis plans

2. Interventions for impact

- (a) Preventing transmission
- (b) Diagnosing hepatitis infection
- (c) Enhancing hepatitis treatment and chronic care

3. **Delivering for equity**

- (a) Adapting viral hepatitis services
- (b) Strengthening human resources for hepatitis
- (c) Ensuring access to good quality and affordable hepatitis vaccines, medicines, diagnostics and other commodities
- (d) Promoting an enabling environment

4. Financing for sustainability

- (a) Increasing investments through innovative financing and new funding approaches
- (b) Addressing financial and other barriers to access and provide financial risk protection
- (c) Reducing prices and costs, and removing inefficiencies

5. Innovation for acceleration

- (a) Optimizing prevention
- (b) Optimizing testing and diagnostics
- (c) Optimizing medicines and treatment regimens
- (d) Optimizing service delivery

ANNEX 2: Regional indicators for monitoring health sector response to viral hepatitis B, C and D

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M&E domai		Indicator and definition	Data Sources
1 Contex and needs	rt Prevalence (epidemiology)	Prevalence of viral hepatitis B or hepatitis C infection Number and percentage of adults and children living or having lived with hepatitis C or hepatitis B HBs Ag serological status or Anti-HCV Ab serological status	Derived from modelling, surveillance, surveys and programme data, or special studies
2 Impac	Incidence (epidemiology)	Cumulated incidence of HBV infection in children 5 years of age	HBs Ag biomarker prevalence survey in children 5 years of age (immunization coverage surveys and administrative vaccination coverage data)
		Incidence of HCV infection	Modelled with inputs from repeated surveys of HCV infection
3 Impact	(epidemiology)	Deaths from hepatocellular carcinoma (HCC), cirrhosis and chronic liver diseases attributable to HBV and HCV infections	 Country cancer registry files National civil registration and vital statistics (CRVS) including mortality registers Hospital-/clinic-based registers monitoring service provision Global databases (aggregated data): WHO mortality databank (liver cancer ICD¹² -10 code C22 only) IARC Cancer Incidence in Five Continents (CI5) databases (liver cancer and HCC data) Global estimated data (modelling) IARC¹³ GLOBOCAN database (liver cancer ICD-10 code C22 only) Prevalence of HBV and HCV infections among patients with HCC, cirrhosis and chronic liver diseases in sentinel sites
4 input	Planning	National action plans Number of countries with national action plans for the prevention, care and treatment of viral hepatitis	Annual reports
5 input	Testing	Infrastructure for HBV and HCV testing	Information for this indicator is derived from programme data. Tests to be used depend on national recommendations based on WHO guidelines.

International Classification of Diseases.
 International Agency for Research on Cancer.

6	output	Testing	Hepatitis B and C testing scale-up Number of adults and children living with hepatitis B and hepatitis C diagnosed	Calculated from programme records: clinical and/or laboratory records of health care facilities. Population surveys, biomarker surveys
7		Blood safety	Number of countries that routinely test all blood donations for transfusion-transmissible infections	Calculated from programme records: clinical and/or laboratory records of health care facilities.
8			Coverage of timely hepatitis B vaccine birth dose (within 24 hours) and other interventions to prevent mother-to-child transmission of HBV) Coverage of third-dose hepatitis B vaccine among infants Percentage of health workers receiving Hepatitis B vaccine	Derived from surveillance, surveys and programme data, modelling and special studies
9		injection safety (Prevention)	Facility-level injection safety Percentage of health care facilities where all therapeutic injections and infusions are given with new, disposable, single-use injection equipment	Health facility survey
10		harm reduction PWID (Prevention)	Needle-syringe distribution Needles-syringes distributed per person who injects drugs. Percentage of PWIDs receiving harm reduction services	N: Programme records, e.g. needle—syringe programme log books. D: Size estimation exercises. Programme records
11		Hygiene and sanitation (prevention)	Water and sanitation coverage Percentage of the population with access to clean water Percentage of the population using improved sanitation facilities	Population-based surveys
12	outcome	Treatment and care	Treatment coverage hepatitis B and hepatitis C Percentage of treatment-eligible persons living with hepatitis B who are on treatment. Percentage of treatment-eligible persons living with hepatitis C who are initiated on treatment.	Programme records (clinical records of health care facilities), modelling estimates for the denominator
13	outcome	Treatment and care	Cure (hepatitis C) or Viral suppression (hepatitis B) Viral suppression for chronic hepatitis B patients treated Cure for chronic hepatitis C patients treated	Programme records, cohort study, patient records, combined with estimates for the population with no viral load data.