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PLAN OF ACTION FOR THE PREVENTION AND CONTROL OF VIRAL HEPATITIS: FINAL REPORT

Background

1. The purpose of this document is to report to the Governing Bodies of the Pan American Health Organization (PAHO) the results of the implementation of the Plan of Action for the Prevention and Control of Viral Hepatitis (Document CD54/13, Rev. 1 [2015]) (1), which covers the period 2016-2019. The Plan of Action is aligned with the vision, goals, and strategic directions of the WHO Global Health Sector Strategy for Viral Hepatitis 2016-2021 (2), adopted by the World Health Assembly (WHA) in May 2016, which calls for the elimination of viral hepatitis as a public health threat by 2030 (defined as a 65% reduction¹ in mortality and a 90% reduction² in incidence of hepatitis B and C) and reflects the inclusion of viral hepatitis (VH) in Goal 3 of Sustainable Development Goals.

2. The objective of the Plan of Action was to strengthen national and regional public health responses with respect to the prevention, treatment, and control of viral hepatitis and reductions in VH-related morbidity, disability, and mortality in Member States. To achieve these objectives, five strategic lines of action were proposed to Member States, namely: promoting an integrated comprehensive response; fostering equitable access to preventive care; fostering equitable access to clinical care; strengthening strategic information; and strengthening laboratory capacity to support diagnosis, surveillance, and a safe blood supply.

3. In 2019, PAHO's updated estimates of hepatitis prevalence in the Americas indicate that 3.9 million people in the Region are living with hepatitis B (HBV) and another 5.9 million with hepatitis C (HCV), while approximately 108,000 people died from viral hepatitis and sequelae in 2017 (3). Around 96% of the mortality from viral hepatitis is a

¹ Baseline year is 2015.

² Ibid.

result of chronic hepatitis B and C infection leading to cirrhosis and primary liver cancer, or hepatocellular carcinoma (HCC). In fact, approximately 78% of HCC worldwide is a result of chronic hepatitis B or C infection (2). New direct-acting antivirals (DAAs) for HCV can cure this infection in 95% of cases in first-line treatment, and up to 99.9% of cases in second-line regimens.

Analysis of the Progress Achieved

4. The Plan of Action achieved its goal. Since its approval, the Region has seen substantial and consistent progress against hepatitis and, critically, viral hepatitis is now on national public health agendas in the Americas. National responses to viral hepatitis have been expanding at an accelerating rate. The number of countries with national action plans has more than doubled and the number of countries and territories with the stated goal of eliminating viral hepatitis as a public health problem by 2030 continues to rise. Nevertheless, the strength of national responses continues to be markedly heterogeneous across the Region.

5. Key successes in the Region include achieving the goal that 23 countries (up from 10 in 2015) have established national action plans for hepatitis, either within existing or new national action plans on HIV, or as designated hepatitis-specific plans. In addition, 10 countries have the stated goal of eliminating hepatitis as a public health problem by 2030 and at least 19 countries have the stated goal of eliminating mother-to-child HBV transmission. A substantial number of countries has adopted guidelines for hepatitis testing, hepatitis B treatment (19 countries), and hepatitis C treatment (16 countries) aligned with WHO recommendations; strategic information for hepatitis has been standardized; and the Global Hepatitis Reporting System was launched in 2018.

6. Regarding preventive interventions, all 52 countries and territories in the Region have introduced hepatitis B vaccination in their routine infant immunization schedules. In line with the targets of the Regional Immunization Action Plan (RIAP) 2016-20 (4), important progress has also been made on introducing the universal hepatitis B birth dose, from 18 countries in 2013 to 31 countries in 2019. The Pan American Sanitary Bureau (PASB) estimates that at least 13 countries have now reached the 0.1% HBsAg³ prevalence goal in 5-year-olds. This low prevalence can be attributed to the early and widespread use of hepatitis B vaccine by these countries over the past two decades. A methodology and process for validation of these achievements is currently being developed.

7. During the period of the action plan, PASB has supported the collection of baseline data reports in 16 countries, the investment case for hepatitis B or C in three countries, the inclusion of WHO-recommended hepatitis B and C antivirals in the Regional Revolving Fund for Strategic Public Health Supplies, and the publication of specific tools including support for the elimination of mother-to-child transmission of hepatitis through the

³ HBsAg – hepatitis B surface antigen.

Elimination of Mother-to-Child Transmission of HIV, Syphilis, Hepatitis B, and Chagas Disease (EMTCT-Plus) initiative (5).

8. This is a summary of the ultimate impact of the Plan of Action at the end of 2019:

Strategic Line of Action 1: Promoting an integrated comprehensive response

9. The Plan of Action has contributed to include viral hepatitis into national health agendas, allowing national planning and commitment to respond to the viral hepatitis. It was also important to secure the substantial gains achieved previously on prevention through immunization and blood safety programs. Despite these achievements, HBV and HCV testing and treatment in the Region is expanding in a limited number of countries. In Latin America and the Caribbean, only a very small percentage of individuals living with chronic HBV or HCV have ever been diagnosed and treated. Hence the Region as a whole still has a long way to go towards the 2030 elimination goals.

Objective 1.1: Promote integration of viral hepatitis prevention, surveillance, diagnosis, care, and control interventions and services within the health sector and implement them in a concerted and effective manner with relevant partners and stakeholders	
Indicator, baseline, and target	Status
<p>1.1.1 Number of countries that have a structured and budgeted national strategy or plan related to prevention, treatment, and control of viral hepatitis</p> <p>Baseline: 10 in 2015 (9) Target: 20</p>	<p>By the end of 2019, 13 additional countries, for a total of 23, had developed national hepatitis strategies or plans that go beyond immunization (10). This indicator is critical to supporting national action. Indicator exceeded target.</p>
Objective 1.2: Promote the development and implementation of coordinated public health policies and interventions with the aim of eliminating hepatitis B and hepatitis C in PAHO Member States by 2030	
Indicator, baseline, and target	Status
<p>1.2.1 Number of countries with goals of elimination of hepatitis B and hepatitis C as public health problems</p> <p>Baseline: 0 in 2015 (8) Target: 6</p>	<p>In addition to all countries and territories being committed to the Global Health Sector Strategy to eliminate viral hepatitis as a public health threat by 2030, 10 countries have viral hepatitis elimination as a stated goal (10). Indicator exceeded target.</p>
<p>1.2.2 Number of countries with goals of elimination of mother-to-child transmission of hepatitis B</p> <p>Baseline: 1 in 2012 (11) Target: 5</p>	<p>19 countries and territories have mother-to-child elimination of HBV as a stated goal (10). Indicator exceeded target.</p>

Objective 1.3: Implement information and communication activities and campaigns at the regional, subregional, national, and local levels to raise awareness of the existence, severity, and routes of transmission of viral hepatitis and measures to prevent and control the disease	
Indicator, baseline, and target	Status
<p>1.3.1 Number of countries that commemorate World Hepatitis Day through awareness campaigns or major thematic events</p> <p>Baseline: 10 in 2015 (9) Target: 20</p>	<p>World Hepatitis Day is well established on the calendar of major public health celebrations in the Region. By the 2019, 17 countries and territories have reported celebrations related to viral hepatitis day early (10). Indicator partially met target.</p>

Strategic Line of Action 2: Fostering equitable access to preventive care

10. Important progress has been made to prevent mother-to-child and early childhood transmission of hepatitis B, with immunization being the most effective intervention. More than 90% of the live birth cohort of the Region are in countries providing the universal hepatitis B birth dose and most countries report high vaccination coverage ($\geq 90\%$) for the third dose of hepatitis B-containing vaccine in infants. In addition, most countries have expanded HBV vaccination for health care workers, and key populations of adults at high risk.

11. Regarding hepatitis A, the PAHO's Technical Advisory Group on Vaccine-preventable Diseases encouraged countries to conduct epidemiological and cost-effectiveness studies for the introduction of hepatitis A vaccine to support evidence-based decisions. Currently ten countries have introduced hepatitis A vaccine in their routine immunization program, and eight additional ones are recommending it for selected risk groups.

Objective 2.1: Maintain and expand HBV immunization programs in order to increase coverage for all children and for members of key populations and vulnerable groups	
Indicator, baseline, and target	Status
<p>2.1.1 Number of countries that maintain high HBV coverage (95% or above) as part of their routine childhood vaccination schedule (below 1 year of age)</p> <p>Baseline: 15 in 2013 (12) Target: 25</p>	<p>By 2019 15 countries and territories (12), reported coverage higher than 95%, and additional 13 countries, for a total of 28, are currently, reporting at least 90% coverage of the third dose of hepatitis B vaccine. Indicator met target.</p>
<p>2.1.2 Number of countries that have included immunization of newborns against HBV within the first 24 hours in their vaccination programs</p> <p>Baseline: 18 in 2013 (12) Target: 25</p>	<p>By the end of 2019, 33 countries and territories provide the hepatitis B birth dose (BD) (12). 31 that providing universal birth dose to all newborns, and 2 providing BD only neonates of HBsAg-positive mothers. Indicator exceeded target.</p>

Objective 2.2: Encourage countries to conduct epidemiological, burden of disease, and health technology assessment, such as cost-effectiveness analyses to support evidence-based decisions regarding the introduction of hepatitis A vaccine	
Indicator, baseline, and target	Status
2.2.1 Number of countries that have conducted HAV epidemiological, burden of disease, and health technology assessment, such as cost-effectiveness analyses to inform vaccine introduction Baseline: 5 in 2013 (13 – 18) Target: 10	By 2019, 10 countries and territories in the Region have introduced HAV vaccine into their national immunization schedule for children. Indicator met target
Objective 2.3: Strengthen the capacity of the health sector to conduct the necessary actions to promote the strictest application of norms, protocols, and recommendations to prevent viral hepatitis infections in healthcare settings	
Indicator, baseline, and target	Status
2.3.1 Number of countries with measures for the prevention of hepatitis B among health workers Baseline: 13 in 2015 (9) Target: 10	By 2019, 34 countries and territories have specific strategies in place to prevent HBV transmission among health workers (10). Indicator exceeded target.
Objective 2.4: Strengthen the capacity of the health sector to develop and implement policies and strategies to prevent viral hepatitis infections among people who use drugs and other key populations	
Indicator, baseline, and target	Status
2.4.1 Number of countries with viral hepatitis prevention and control strategies, such as HBV vaccine, targeting key populations Baseline: 8 in 2015 (11) Target: 20	By 2019, 43 countries and territories have introduced hepatitis B vaccination for high-risk groups (11). Indicator exceeded target.

Strategic Line of Action 3: Fostering equitable access to clinical care

12. Since the development of the Regional Action Plan in 2015 there has been a revolution in hepatitis therapeutics. Consequently, WHO guidelines both for hepatitis B (in 2015) and hepatitis C (2016 and 2018, and the Spanish version in 2018) changed clinical care dramatically. The uptake of these new guidelines has been progressive and effective across most of the Region. In addition, there has been a marked expansion in the number of countries offering publicly-funded testing and treatment for hepatitis. This is increasing as prices (especially for HCV medicines which still remain high in commercial markets) continue to fall. Since 2019, generic hepatitis C medicines have been

available to countries where patents are not applicable, for approximately US\$ 130⁴ per treatment course, down from the \$1,200 previously charged.

Objective 3.1: Adapt and implement norms and standards for screening, diagnosis, care, and treatment of viral hepatitis	
Indicator, baseline, and target	Status
<p>3.1.1 Number of countries that have developed guidelines for prevention, care, and treatment of hepatitis B in line with latest WHO recommendations</p> <p>Baseline: 16 in 2012 (11) Target: 25</p>	<p>The major shift in recommended treatment occurred in 2015, with therapy limited to oral antivirals with a high barrier to resistance, and by 2019 19 countries and territories have national guidelines consistent with these new regimens. Indicator partially met target.</p>
<p>3.1.2 Number of countries that have developed guidelines for screening, diagnosis, care, and treatment of hepatitis C in line with latest WHO recommendation</p> <p>Baseline: 6 in 2015 (9) Target: 15</p>	<p>New WHO recommendations were published in 2018, and by the end of 2019, 16 countries and territories have guidelines consistent with this most recent guidance (10). Indicator exceeded target.</p>
<p>3.1.3 Number of countries that have started offering publicly funded HBV diagnosis and treatment</p> <p>Baseline: 11 in 2015 (9) Target: 20</p>	<p>Currently, 30 countries and territories offer publicly funded treatment (although in many countries access remains limited) (10). Indicator exceeded target.</p>
<p>3.1.4 Number of countries that have started offering publicly funded HCV diagnosis and treatment</p> <p>Baseline: 6 in 2015 (9) Target: 10</p>	<p>By 2019, 17 countries and territories offer some form of publicly funded hepatitis C treatment. The number of treated patients remains limited in many countries (10). Indicator exceeded target.</p>
<p>3.1.5 Number of countries that include in their national essential medicine lists and/or formularies one or more drugs recommended in WHO 2015 guidelines for HBV treatment</p> <p>Baseline: 10 in 2015 (9) Target: 15</p>	<p>By 2019, 27 countries and territories have included in their national essential medicine list and/or formularies one or more drugs recommended by most recent edition of WHO guidelines for HBV treatment was published in 2015 (10). Indicator exceeded target.</p>

⁴ Unless otherwise indicated, all monetary figures in this report are expressed in United States dollars.

Objective 3.1: Adapt and implement norms and standards for screening, diagnosis, care, and treatment of viral hepatitis	
Indicator, baseline, and target	Status
<p>3.1.6 Number of countries that include in their national essential medicine lists and/or formularies one or more drugs recommended in WHO 2014 guidelines for HCV treatment</p> <p>Baseline: 8 in 2015 (9) Target: 15</p>	<p>By 2019, 17 countries and territories have included in their national essential medicine list and/or formularies one or more drugs recommended by most recent edition of WHO guidelines for HCV treatment was published in 2018 (10). Indicator exceeded target.</p>
Objective 3.2: Adapt and implement norms and standards for treatment of viral hepatitis (B and C) in HIV co-infected patients	
Indicator, baseline, and target	Status
<p>3.2.1 Number of countries that have updated their antiretroviral treatment criteria, including the recommendation of initiating antiretroviral therapy (ART) regardless of CD4 count in HIV patients with severe HBV-related chronic liver disease</p> <p>Baseline: 24 in 2014 (19) Target: 30</p>	<p>By 2019, 35 countries and territories have updated their antiretroviral treatment criteria (10). This number includes 30 countries and territories that recommend HIV treatment for all infected individuals and 5 in which HIV treatment is indicated for people living with HIV and severe HBV-related liver disease. Indicator exceeded target.</p>

Strategic Line of Action 4: Strengthening strategic information

13. In line with expanded action to address hepatitis across the Region and at the country level, data systems to support this action have markedly increased. The majority of countries in the Region now report some kind of strategic information system to monitor hepatitis epidemics and response, with 16 countries now publishing national reports on hepatitis, twice as many as in 2015. The Global Hepatitis Reporting System (a web-based platform for data collection and a repository for hepatitis epidemiology and policy status) was rolled out in 2018 and continued into its second year in 2019. PASB supported the rollout in the Americas.

Objective 4.1: Increase and strengthen countries' capacity to develop and implement strategies for the surveillance, prevention, control, and/or elimination of viral hepatitis	
Indicator, baseline, and target	Status
<p>4.1.1 Number of countries that report cases of acute and chronic hepatitis B</p> <p>Baseline: 8 in 2015 (9) Target: 16</p>	<p>By 2019, 25 countries and territories have included hepatitis B in their national surveillance system and are able to report cases of hepatitis B infection (10). Indicator exceeded target.</p>

Objective 4.1: Increase and strengthen countries' capacity to develop and implement strategies for the surveillance, prevention, control, and/or elimination of viral hepatitis	
Indicator, baseline, and target	Status
4.1.2 Number of countries that report cases of hepatitis C infection Baseline: 13 in 2015 (9) Target: 26	By 2019, 29 countries and territories have included hepatitis C in their national surveillance system and are able to report at least some cases of acute or chronic hepatitis C. Indicator exceeded target.
4.1.3 Number of countries conducting surveys on prevalence of viral hepatitis B or C in general population and/or key populations Baseline: 11 in 2015 (9) Target: 18	By 2019, 29 countries and territories have reported at least one prevalence survey on HBV or HCV (10). Indicator exceeded target.
Objective 4.2: Increase countries' capacity to analyze, publish, and disseminate national data on viral hepatitis and impact of responses disaggregated by age, gender, and cultural diversity	
Indicator, baseline, and target	Status
4.2.1 Number of countries that have published a national report on viral hepatitis Baseline: 8 in 2015 (9) Target: 15	By 2019, 16 countries and territories have published national viral hepatitis baseline reports through the country-level hepatitis data mining initiative (10). Indicator exceeded target.

Strategic Line of Action 5: Strengthening laboratory capacity to support diagnosis, surveillance, and safe blood supply

14. With the publication of the WHO hepatitis B and C testing guidelines in 2017, standardization of diagnostic algorithms became feasible. In general, PASB recommended that hepatitis testing guidance should be integrated into treatment guidance in order to harmonize systems. Since 2017, the Regional Revolving Fund for Strategic Public Health Supplies has made available the key WHO-prequalified diagnostic tests for screening and confirmation of hepatitis B and C, including multiplex platforms and cartridges, and critically, rapid test kits. Rapid test kits will form the basis of large-scale population screening in the Region.

15. There is nearly universal screening of blood products for hepatitis in the Region and access to hepatitis testing continues to increase, although molecular tests for HCV confirmation of viremia remain out of reach for many living outside major urban centers.

Objective 5.1: Implement innovative technologies for laboratory diagnosis and monitoring of treatment responses	
Indicator, baseline, and target	Status
5.1.1 Number of countries that implement standardized and effective technologies for HBV patient monitoring Baseline: 10 in 2015 (9) Target: 20	As of 2019, 25 countries and territories conduct HBV monitoring in line with WHO-recommended laboratory tests (10). Indicator exceeded target.
5.1.2 Number of countries that implement standardized and effective technologies for HCV confirmation, including serology, genotyping, and patient monitoring Baseline: 8 in 2015 (9) Target: 15	As of 2019, 25 countries and territories conduct HCV monitoring in line with WHO-recommended laboratory tests (10). Indicator exceeded target.
Objective 5.2: Implement norms to improve the safety of blood supplies and blood components	
Indicator, baseline, and target	Status
5.2.1 Number of countries that screen 100% of blood transfusion units for HBV and HCV Baseline: 39 in 2014 (19) Target: 41	Coverage of blood donation screening continues to be very high at the regional level, with 41 countries and territories reporting 100% screening by 2019. Differences in reporting processes in some countries and territories explain the lack of increase (since 2015) in the number of countries that screen 100% of transfusion units. Indicator met target.

Action Necessary to Improve the Situation

16. While the Action Plan has seen a marked shift in the Region's response to hepatitis, elimination will require full implementation of the policies discussed above. Recommendations for future improvements in the situation are:

- a) Following the completion of the Regional Action Plan for Viral Hepatitis, PASB and Member States will continue to implement national action to address viral hepatitis in accordance with the lines of action and goals of WHO Global Health Sector Strategy for Viral Hepatitis 2016-2021, and aligned with PAHO Disease Elimination Initiative: A Policy for an Integrated Sustainable Approach to Communicable Diseases in the Americas (CD57/7 [2019]) (21), all within the rubric of Universal Health Care (UHC).

- b) Support subregional political commitment to hepatitis elimination initiatives to engage countries and promote south-south cooperation in order to efficiently utilize the availability of human and financial resources.
- c) Strengthen the capacity of Member States to generate and report strategic information on viral hepatitis, disaggregated by gender, age, key population status, and ethnicity, to assist in the continued development of an evidence base for strategic planning in viral hepatitis prevention, care, and control. This include the development of burden estimates and economic analysis towards the elimination goals.
- d) Maintain and strengthen efforts to prevent hepatitis transmission in healthcare settings, including universal blood screening, universal use of sterile medical injections, and boosting HBV vaccination coverage among healthcare workers. In addition, support expanded efforts to reduce hepatitis transmission among people who use or inject drugs by increasing access to effective harm reduction interventions.
- e) Promote, the urgent expansion of access to hepatitis B and C prevention, diagnosis, care, and treatment—consistent with WHO recommended practice—within national health systems and health insurance systems, including for key populations and Indigenous peoples. Support from the Regional Revolving Fund for Strategic Health Supplies and the Revolving Fund for Access to Vaccines can minimize the financial barriers to accessing quality hepatitis prevention, testing and treatment.
- f) Promote further interprogrammatic cooperation at the national level between immunization, hepatitis, and HIV programs and (liver) cancer services in order to systemize hepatitis-related national action in health systems.
- g) Promote further engagement and integration of civil society organizations and groups representing affected communities in national response and policy development aimed at accelerating the uptake of testing, treatment, and demand for other hepatitis-related services.

Action by the Directing Council

17. Considering the extraordinary and unprecedented circumstances presented by the COVID-19 pandemic, and in accordance with Resolution CE166.R7, this report will be published for information purposes only, and will not be discussed by the Directing Council.

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