PUERTO RICO VIRAL HEPATITIS ELIMINATION PLAN

2023-2027

Revised April 2024

DEPARTAMENTO DE SALUD

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ABBREVIATIONS LIST

AIDS - Acquired Immunodeficiency Syndrome

ASES - Spanish acronym for Puerto Rico Health Insurance Administration

ASSMCA - Spanish acronym for Puerto Rico Mental Health and Anti-Addiction Services Administration

CDC - Centers for Disease Control and Prevention

CPTET - Spanish acronym for Centers for Prevention and Treatment of Transmissible Diseases

CSTE - Council of State Territorial Epidemiologists

DAA - Direct Acting Antiviral

DNA - Deoxyribonucleic Acid

ELR - Electronic Laboratory Report

ETAA - Spanish acronym for Food- and/or Water-Borne Diseases

HAV - Hepatitis A Virus

HBV - Hepatitis B Virus

HCV - Hepatitis C Virus

HHS - United States Department of Health and Human Services

HIV - Human Immunodeficiency Virus

IDU - Injectable Drugs Users

MSM - Men who have Sex with Men

NAAT - Nucleic Acid Amplification Test

NEDSPRS - National Electronic Disease Surveillance Puerto Rico System

NNDSPRS - National Notifiable Disease Surveillance Puerto Rico System

NORS - National Outbreak Reporting System

NPO - Non-Profit Organization

PRDoH - Puerto Rico Department of Health

SASA - Spanish acronym for Auxiliary Secretariat of Environmental Health

STD - Sexually Transmitted Diseases

VFC - Vaccines for Children

VH - Viral Hepatitis

VHEAC - Viral Hepatitis Elimination Advisory Committee

WHO - World Health Organization

INTRODUCTION

Viral Hepatitis (VH) represents a global public health care priority that affects millions of people. Fortunately, there are effective prevention and treatment methods that are vital to provide a more integrated and coordinated response in the fight against these viruses. In this context, the United States Department of Health and Human Services (HHS) published the *Viral Hepatitis National Strategic Plan for the United States: A Roadmap to Elimination (2021–2025)* (National Strategic Plan) which covers the three most common types of VH, which are Hepatitis A, Hepatitis B and Hepatitis C. This National Strategic Plan is aligned with the strategies of the World Health Organization (WHO) for the elimination of VH by 2030.

The Puerto Rico Department of Health (PRDoH) through its STD/HIV/VH Prevention Program together with various sectors such as the government, non-profit organizations, professional associations, the Academia, and other stakeholders, in a collaborative effort have developed this Puerto Rico Viral Hepatitis Elimination Plan 2023-2027 (Plan). This Plan establishes a roadmap for the jurisdiction, based on the identified needs and the current context of Puerto Rico. The Plan is framed within the five goals of the National Strategic Plan, which includes the following:

- Prevent new viral hepatitis infections;
- Optimize the health outcomes of people with a positive diagnosis of viral hepatitis;
- Reduce health disparities and inequities related to viral hepatitis;
- Strengthen surveillance and data use of viral hepatitis; and
- Achieve integrated and coordinated efforts among all partners and stakeholders addressing the viral hepatitis epidemic.

To achieve these purposes, the Plan incorporates objectives, strategies and specific activities aligned with the National Strategic Plan. As next steps, it is sought to develop specific Action Plans for the different strategies and the corresponding indicators and metrics to evaluate its compliance.

METHODOLOGY

For developing the Plan, the Viral Hepatitis Elimination Advisory Committee (VHEAC) was created. To constitute this Committee, a group of experts and stakeholders related to the surveillance, prevention, and treatment of Viral Hepatitis in Puerto Rico were invited. Among the people invited to be part of the Committee, there are representatives of the government sector, non-profit organizations, professional associations, the Academy, and other stakeholders.

Through a series of meetings, this group of experts was able to examine the background of Viral Hepatitis in Puerto Rico and identify the needs, define the objectives of the Plan, and develop strategies and activities to address previously identified needs. During the first meeting, a background on the subject was presented, including available data on viral hepatitis in Puerto Rico, summary of the Gap Assessment in Hepatitis Surveillance and Prevention Services in Puerto Rico 2022 from the STD/HIV/VH Prevention Program of the PRDoH and a summary of other research on viral hepatitis developed in the past years. Then, the members participated in group exercises to identify the needs in the jurisdiction.

For the second meeting, a summary of the results of the exercises on needs in the first meeting was shown. This served as a guide for a structured discussion in two groups to define objectives and develop strategies and activities that meet the previously identified needs.

Finally, in the third meeting, the draft of the Plan was presented to validate the objectives, strategies, and activities with the Committee before publishing the draft to receive comments.

Illustration 1: Committee's work organization

Overall, 33 stakeholders participated in the three Committee meetings held. The final draft of the Plan was published on April 24, 2023, on the PRDoH website (https://www.salud.gov.pr/eliminacion_hep_virales) to receive comments from citizens and different interest groups. Comments were received through May 1, 2023. As a result of this process, comments were received from three entities, which are addressed in this document.

A fourth meeting of the Committee was held in April 2024 to validate the Plan. Likewise, 11 stakeholders were integrated as members of the Committee (some replacing former members and others as new ones).

EPIDEMIOLOGICAL PROFILE OF VIRAL HEPATITIS IN PUERTO RICO

The epidemiological profile presented below allows a better understanding of the disease burden and serves to plan and execute effective and efficient prevention and treatment programs in Puerto Rico. The data presented could help identify the population groups that are at higher risk of contracting VH, allowing health professionals to focus their efforts on prevention and risk education. The profile may also help in the planning of preventive strategies and facilitate the allocation of resources and adequate financing for the prevention and the treatment of VH. The goal of the Viral Hepatitis Elimination Plan is to significantly reduce the disease burden of viral hepatitis worldwide and to eventually eliminate the disease as a public health problem by 2030.

Reporting parameters for epidemiological surveillance

According to Administrative Order No. 358[1] of the PRDoH, all licensed health providers on the Island have the duty to report to the Epidemiology and Research Division of the PRDoH the diagnosis or suspicion of any of the mandatory notifiable diseases, within the established period according to the category of disease. For diseases classified under Category I, the report to the PRDoH must be made in a period not exceeding 5 working days. For Category III diseases and/or conditions, the PRDoH must be reported immediately (within 24 hours). At the time of writing this document, the PRDoH is in the process of modernizing its information systems, with the aim of replacing paper reporting mechanisms with electronic data transfers. Currently, the PRDoH Epidemiology and Research Division receives a proportion[2] of 96.3% of Hepatitis A[3], results, 62.7% of Hepatitis B results, and 77.9% of Hepatitis C results using the electronic laboratory report format. (ELR).

Hepatitis A in Puerto Rico, 2020-2023

Introduction

Food and water-borne diseases (ETAA, as its Spanish acronym) are a major cause of morbidity and mortality and a significant impediment to socioeconomic development worldwide.

[1] The referenced document can be accessed at: https://www.salud.gov.pr/CMS/DOWNLOAD/3005.

[2] Electronic reporting proportions were calculated as follows: number of electronic results divided by the total number of results received electronically and on paper multiplied by 100 (number of electronic reports / (number of electronic reports + number of paper reports) X 100). The data is preliminary, subject to changes in the research process.

[3] The proportion of paper reporting of Hepatitis A was estimated for the year 2022.

A foodborne infection is the result of eating food contaminated with infectious microorganisms such as *Salmonella, Shigella*, Hepatitis A Virus, *Campylobacter*, among others. Each year, 1 in 6 people in the United States become ill from eating contaminated food. The Centers for Disease Control and Prevention (CDC) estimates that every year, 48 million people contract a foodborne illness, 128,000 are hospitalized and 3,000 die.

According to the CDC, in 2021 a total of 5,728 cases of Hepatitis A were reported in the United States. In addition, according to the CDC, 1.7 cases of acute hepatitis A are reported per 100,000 U.S. population in 2021. The reported cases in 2021 are four times more than those reported in 2015.

Epidemiological Surveillance of Diseases Transmitted by Food and/or Water

The PRDoH, like the CDC, has an epidemiological surveillance system for diseases that are transmitted by food and/or water that allows the investigation of cases and identification of outbreaks. The PRDoH Epidemiology and Research Division works in collaboration with the Environmental Health Division and the Puerto Rico Public Health Laboratory, in the prevention, detection and investigation of events associated with food and water.

The PRDoH also participates in various surveillance at the national level:

1. National Notifiable Disease Surveillance System (NNDSPRS): CDC's surveillance system that enables monitoring of notifiable diseases to control and prevent public health threats.

2. National Outbreak Reporting System (NORS): Surveillance system used to report outbreaks of food and waterborne diseases, and outbreaks of enteric diseases.

3. PulseNet: National network of laboratories that allows the linking of cases of diseases transmitted by food and water in order to detect outbreaks. PulseNet analyzes the desoxyribonucleic acid (DNA) of disease-causing bacteria to detect local and multi-state outbreaks.

Table 1: Diseases and/or Conditions Transmissible by Food and/or Water of Mandatory Notification to the Puerto Rico Department of Health

Disease or Condition	Category I	Category III
Amoebiasis	✓	
Botulism		✓
Campylobacteriosis	✓	
Cyclosporiasis	✓	
Ciguatera	✓	
Cholera		✓

Disease or Condition	Category I	Category III
Cryptosporidiasis	✓	
E. coli O157:H7 (STEC)	✓	
Giardiasis	✓	
Food poisoning		✓
Hepatitis A (acute)	✓	
Legionellosis	✓	
Listeriosis	✓	
Salmonellosis	✓	
Shigellosis	✓	
Trichinosis	✓	
Vibriosis	✓	
Yersiniosis	✓	

Hepatitis A

Hepatitis A is caused by the Hepatitis A virus (HAV). HAV is transmitted by the oral-fecal route, usually through direct person-to-person contact or through consumption of contaminated food or water.

Hepatitis A case definition

According to the Council of State Territorial Epidemiologists (CSTE), a confirmed case of hepatitis A must meet the following clinical, laboratory and epidemiological criteria:

Clinical criteria: Acute illness with discrete onset of any signs or symptoms consistent with acute viral hepatitis (e.g., fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, abdominal pain, or dark urine) **AND** jaundice or elevated total bilirubin levels ≥3.0mg/dL, **OR** serum alanine aminotransferase (ALT) levels >200 IU/L, **AND** absence of a more likely diagnosis.

Laboratory Criteria: Positive immunoglobulin M (IgM) antibodies for hepatitis A virus (anti-HAV) **OR** positive nucleic acid amplification test (NAAT) for Hepatitis A virus RNA.

Epidemiological criteria: Close contact (e.g., household or sexual) with a laboratory-confirmed case of hepatitis A, 15 to 50 days prior to symptom onset.

A confirmed case meets clinical criteria and is positive for anti-HAV IgM **OR** is positive for HAV RNA **OR** is a close contact (e.g., household or sexual) with a laboratory-confirmed case of Hepatitis A 5 to 50 days prior to symptom onset.

Hepatitis A Symptoms

The most common symptoms of Hepatitis A are fever, fatigue, loss of appetite, nausea, vomiting, abdominal pain, dark urine, diarrhea, grayish stools, joint pain, and jaundice. The incubation period of Hepatitis A averages 30 days, with a range of 15 to 50 days.

People at higher risk of acquiring Hepatitis A

Anyone can get infected with the HAV, but certain groups of people are more likely to get sick and have more severe illness, such as people with weakened immune systems due to conditions such as chronic liver disease and HIV/AIDS. In turn, there are people at greater risk of infection by HAV, among these are:

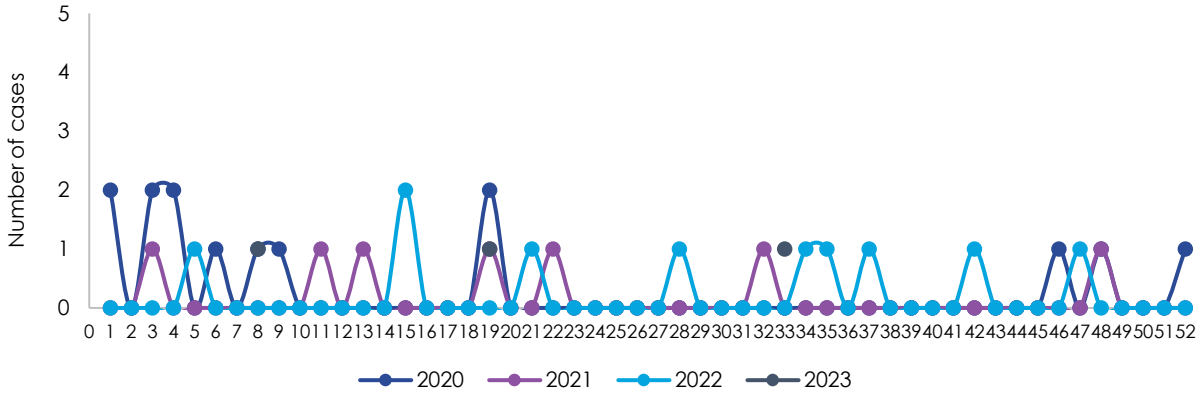
- International travelers
- Men who have sex with men
- People experiencing homelessness
- People who use injection or non-injection drugs
- People with occupational risk of exposure
- People who anticipate close personal contact with a child adopted outside the United States.

ETAA investigations

The following section describes the cases of food- and/or water-borne diseases (ETAA, as its Spanish acronym) that have been investigated by the PRDoH Epidemiology and Research Division in 2023. The integrated information system known as NBS (National Electronic Disease Surveillance System (NEDSPRS) Base System) allows national case reporting to CDC's NNDSPRS. According to the NNDSPRS[4], an epidemiological week is assigned to mandatory notification cases in order to establish the incidence of diseases over time. The assignment of this epidemiological week is made according to the following hierarchy: date of onset of symptoms, date of diagnosis, date of laboratory result, date of report to the PRDoH. Graph 1 shows the cumulative incidence of Hepatitis A by epidemiological weeks from 2020 to 2023.

[4] The referenced document can be accessed on: https://ndc.services.cdc.gov/wp-content/uploads/MMWR_Week_overview.pdf.

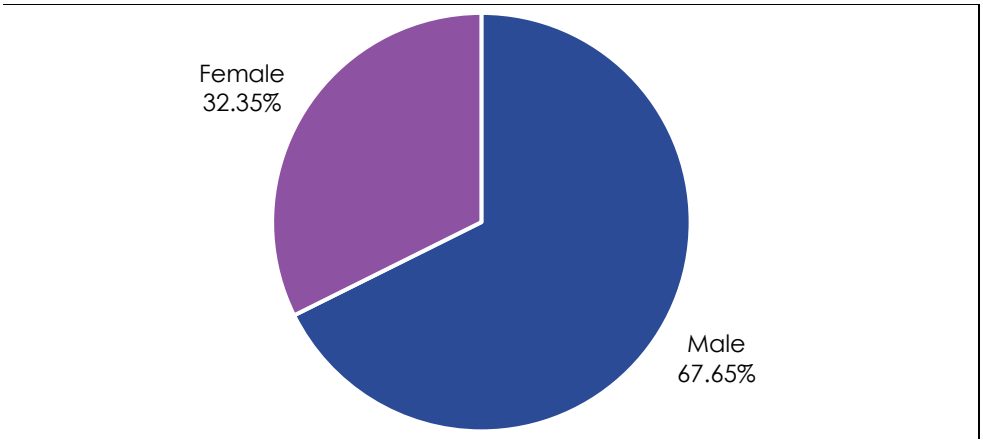
Graph 1: Cumulative incidence of Hepatitis A by epidemiological week, 2020-2023 (N=34)



Note: Data obtained from the National Electronic Disease Surveillance System (NEDSPRS) Base System (NBS). 2020 N=14, 2021 N=7, 2022 N=10, 2023 N=3 (Data for 2023 are preliminary).

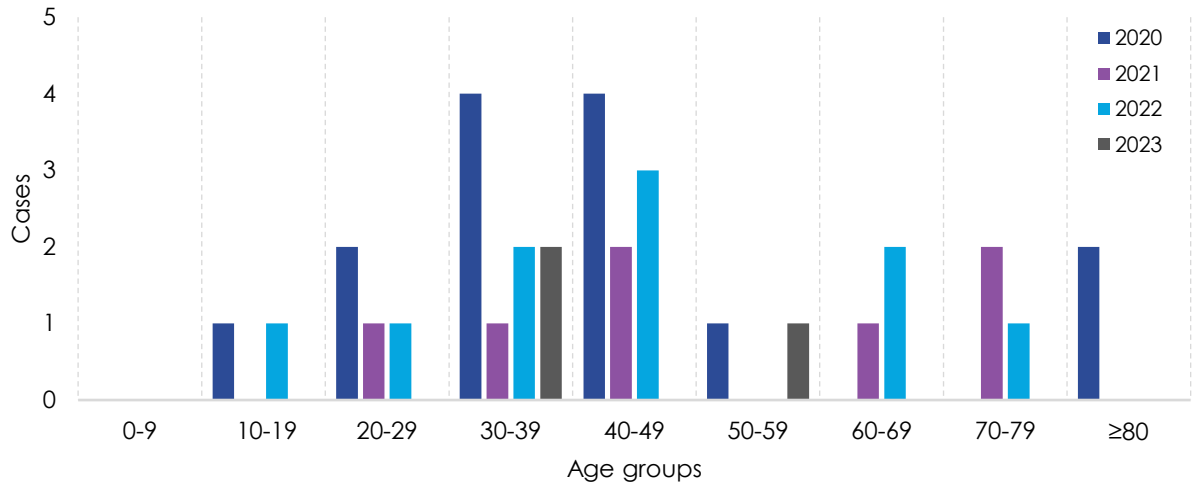
Graphs 2, 3 and 4 present the distribution by sex of Hepatitis A cases, cumulative incidence of hepatitis A by sex, age group, and PRDoH region, respectively. Of all the cases reported (2020-2023), 67.65% were male (Graph 2). The age groups with the highest number of cases for the 2020-2023 period were 30-39 years and 40-49 years with nine (9) cases each (26.47%) (Graph 3). On the other hand, the region with the highest number of reported cases for 2020 was Caguas (35.71%), for 2021 it was the region of Ponce and Aguadilla, both with 28.57% of the reported cases, for 2022 the region with the most cases reported was Caguas (50.0%), and for 2023 the region with the most cases reported was Metro with 66.7% (Graph 4).

Graph 2: Distribution by sex of Hepatitis A cases, 2020-2023 (N=34)



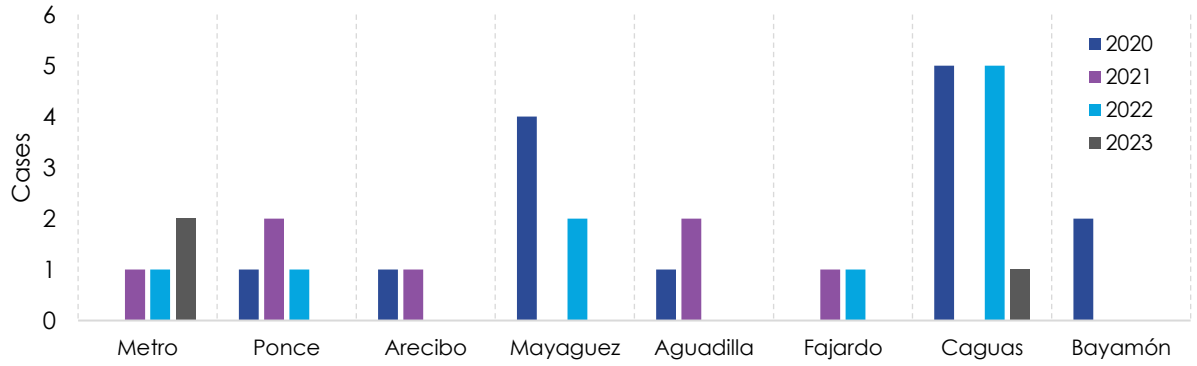
Note: Data obtained from the National Electronic Disease Surveillance System (NEDSPRS) Base System (NBS). 2020 N=14, 2021 N=7, 2022 N=10, 2023 N=3 (Data for 2023 are preliminary).

Graph 3: Cumulative incidence of Hepatitis A by age group, 2020-2023 (N=34)



Note: Data obtained from National Electronic Disease Surveillance System (NEDSPRS) Base System (NBS). 2020 N=14, 2021 N=7, 2022 N=10, 2023 N=3 (Data for 2023 are preliminary).

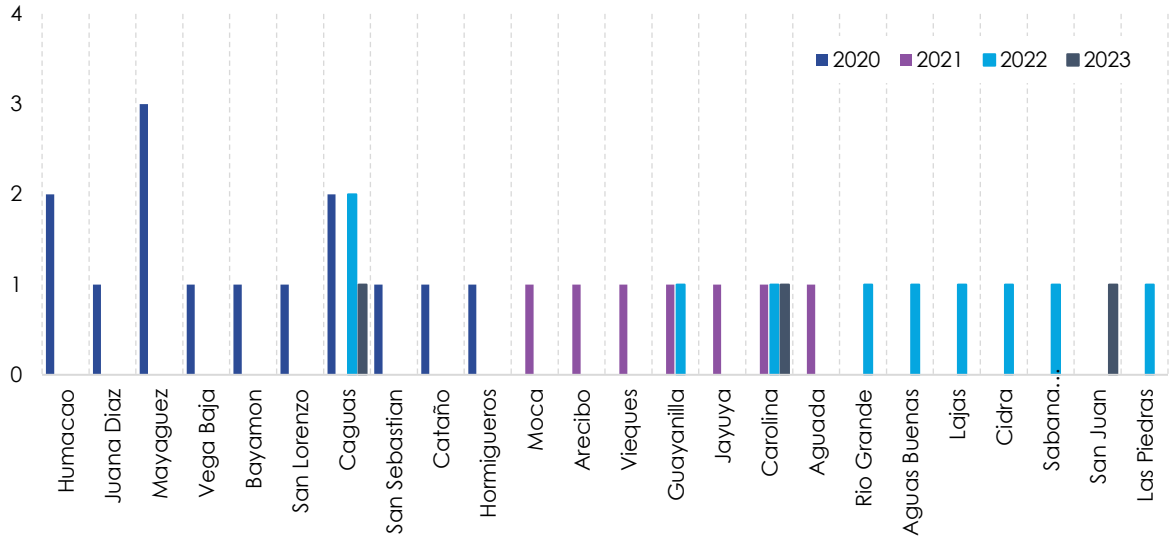
Graph 4: Cumulative incidence distribution of Hepatitis A by PRDoH region, 2020-2023 (N=34)



Note: Data obtained from National Electronic Disease Surveillance System (NEDSPRS) Base System (NBS). 2020 N=14, 2021 N=7, 2022 N=10, 2023 N=3 (Data for 2023 are preliminary).

Graph 5 presents the distribution of accumulated cases of Hepatitis A by municipality for 2020, 2021, 2022, and 2023. For the year 2020, the municipality that reported the most cases of Hepatitis A was Mayagüez (21.43%). In 2022, the municipality that reported the most cases of Hepatitis A was Caguas (20.0%).

Graph 5: Distribution of accumulated cases of Hepatitis A by municipality, 2020 (N=14), 2021 (N=7), 2022 (N=10), 2023 (N=3*)

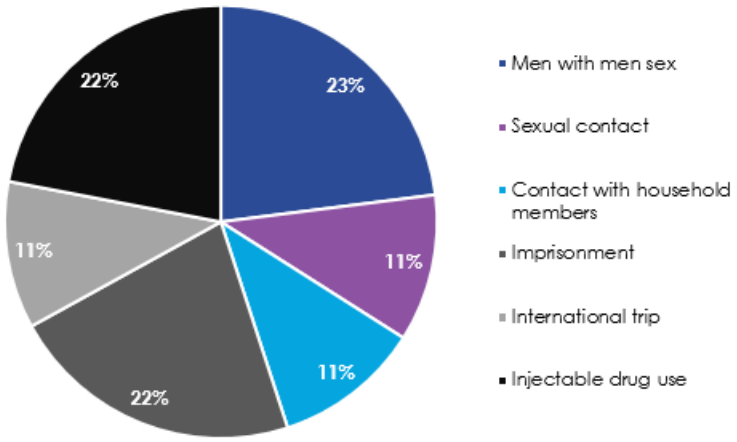


Note: Data obtained from National Electronic Disease Surveillance System (NEDSPRS) Base System (NBS). *Data is preliminary.

Hepatitis A risk factors

There are some factors or behaviors that can increase the risk of contracting the Hepatitis A virus, such as injection drug use, sexual contact, contacts with household members, men who have sex with men (MSM), international travel, incarceration, non-injectable drug use, not having a fixed or stable home, among others. Graph 6 presents the risk factors reported by people with Hepatitis A in Puerto Rico.

Graph 6: Distribution of risk factors in cases of Hepatitis A in Puerto Rico, years 2020-2023 (N=9)



Note: Data obtained from National Electronic Disease Surveillance System (NEDSPRS) Base System (NBS). Nine cases indicated yes to one or more risk factors.

Final comments

The data presented is preliminary as of the date of preparing this report. All the information presented is subject to data updating as the investigation processes take place. The Council of State Territorial Epidemiologists (CSTE) establish case definitions.

Hepatitis B en Puerto Rico, 2019-2023

Introduction

Hepatitis B is a disease caused by the Hepatitis B virus (HBV); a double-stranded DNA virus classified as a member of the hepadnaviridae family. The virus replicates in the liver and can cause both acute (short duration) and chronic (>6 months) forms. For its acute phase, about 85-90% of cases may be asymptomatic, although it is usually accompanied by signs of impaired liver function. The evolution to chronicity is much more frequent. The earlier the age at which the infection is acquired; increases the risk of developing liver failure, liver cancer or cirrhosis; and death. The virus is found in the tissues, organs, and body fluids of infected people (blood and blood products, semen and vaginal secretions, and saliva).

HBV is transmitted by percutaneous exposure and by mucosal exposure to contaminated body fluids. Its incubation period is generally 45 - 180 days, with an average of 60 - 90 days. Whereas the transmission period coincides with the appearance of the surface antigen (HBsAg) of the hepatitis B virus, between 1 and 2 months after infection, and therefore in some cases before the appearance of symptoms, and it lasts as long as HBsAg positivity is maintained.

Globally, statistics reveal that Hepatitis B affects 296 million people, including over 6 million children under 5 years of age and contributing to an estimated 820,000 deaths per year; and 25% of chronic hepatitis B infections progress to liver cancer (data current as of July 27, 2022, CDC). Fortunately, Hepatitis B is a vaccine-preventable disease, and it has been available since 1980; being a safe and highly effective vaccine for the prevention of this disease.

Surveillance of Vaccine-Preventable Diseases (VPD)

The PRDoH Epidemiology and Research Division collects and analyzes health information through its epidemiological surveillance systems and field investigations. The fundamental purpose of surveillance for Hepatitis B and investigations of these cases is to identify contacts of cases that require post-exposure prophylaxis, detect outbreaks, identify infected people who can be referred for medical management, monitor incidence and prevalence; as well as determine epidemiological characteristics (profile) of infected people. National surveillance for viral hepatitis is based on case definitions

developed and approved by the PRDoH in collaboration with the CDC; in order to have a uniform criterion for the classification of cases. It is required that the Hepatitis B viral infection meets clinical, laboratory and epidemiological criteria, to be classified as a case.

Hepatitis B case definition

According to the CSTE, a case of Hepatitis B must meet the following clinical and laboratory criteria:

Acute hepatitis B

Clinical case definition

Acute illness with:

- discrete onset of symptoms * **AND**
- jaundice or elevated serum alanine aminotransferase levels (>100 IU/L).

*Negative laboratory result for HBsAg prior to 6 months of a positive test (e.g., HBsAg, Hepatitis B e-Antigen [HBeAg], or HBV nucleic acid test [NAT] including genotyping) does not require an acute clinical presentation, to have surveillance case definition.

Laboratory criteria for diagnosis

- Positive HBsAg **AND**
- Immunoglobulin M (IgM) antibody to Hepatitis B Core antigen (IgM anti-HBc) positive.

Case Classification

Confirmed: A case that meets the clinical case definition and is laboratory confirmed, and does not have chronic Hepatitis B.

Chronic hepatitis B

Clinical description

People with chronic Hepatitis B may have no evidence of liver disease or may have a spectrum of disease ranging from chronic hepatitis to cirrhosis or liver cancer. People with chronic infection may be asymptomatic.

Laboratory criteria for diagnosis

- Negative anti-HBV IgM **AND** a positive result to one of the following tests: HBsAg, HBeAg, **OR** NAT for HBV DNA (including qualitative, quantitative, and genotype testing).

OR

- HBsAg positive **OR** NAT for HBV DNA positive (including qualitative, quantitative, and genotyping) **OR** HBeAg positive twice at least 6 months apart (any combination of these tests performed 6 months apart is acceptable).

Case Classification

Confirmed: A case that meets the laboratory criteria, for diagnosis

Probable: One case with positive HBsAg or positive HBV DNA (including qualitative, quantitative, and genotype testing).

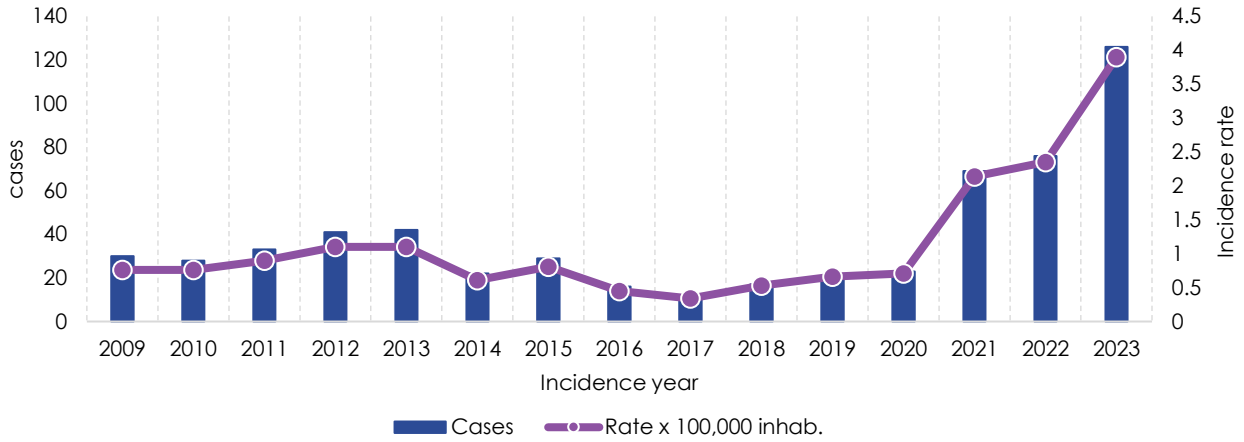
Hepatitis B symptoms

The vast majority of people with acute Hepatitis B will not necessarily have symptoms, which can be mild to severe; and may vary with age. The disease usually begins with fever, headache, general malaise, anorexia, nausea, vomiting, diarrhea, dark urine, and abdominal pain, followed by jaundice (yellow skin and eyes) a few days later and/or increased levels of aminotransferase (specific antibody titer). It is important to highlight that Hepatitis B is a vaccine-preventable and treatable disease.

Hepatitis B data

The following section describes the Hepatitis B cases that have been investigated by the PRDoH Office of Epidemiology and Investigation. Graph 7 presents the cumulative incidence of reported cases of Hepatitis B (acute/chronic) for the period 2009 – 2023 in Puerto Rico. Focusing on the period of interest of this epidemiological profile from 2019-2023, a peak is observed from 2021 with a rate of 2.2 X 100,000 inhabitants, which shows a sustained increase in cases during 2022, with a rate of 2.4 X 100,000 inhabitants and rises to a rate of 4.1 in 2023.

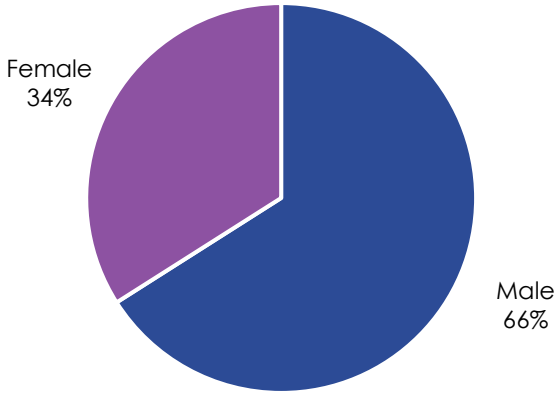
Graph 7: Incidence rates of Hepatitis B cases in Puerto Rico, years 2009-2023*



Source: Epidemiology and Research Division. N=21 (2019); N=23 (2020); N=69 (2021) N=76 (2022); N=126 (2023).
*Preliminary data as of March 11, 2024.

Regarding the distribution of cases by sex, during the period from 2019 to 2023, two out of three (66%) of the cases were registered in people identified as male. On the other hand, one in three (34%) cases occurred in people who identify themselves as female (Graph 8).

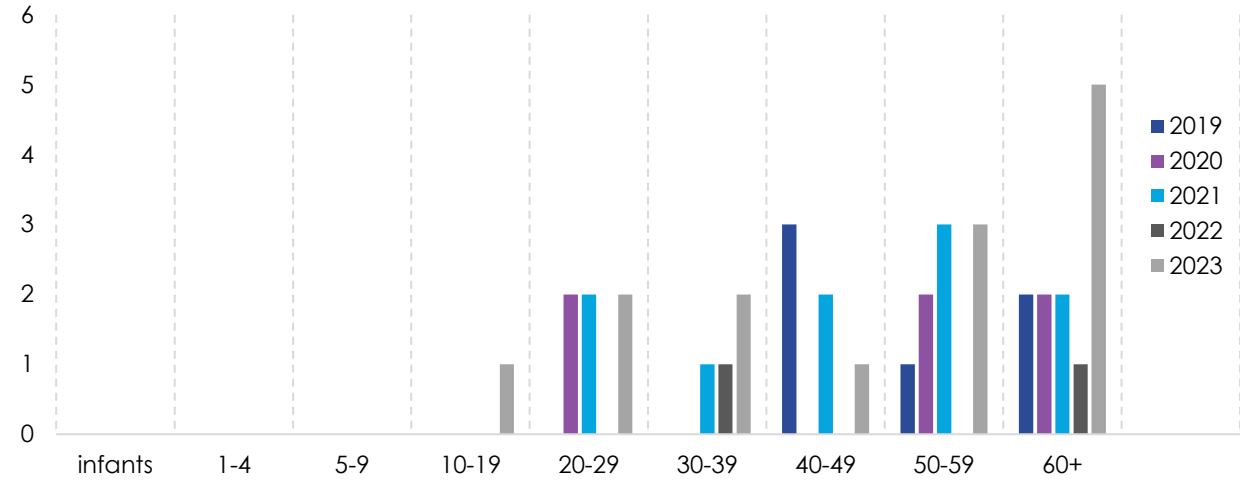
Graph 8: Distribution of Hepatitis B cases by gender in Puerto Rico, years 2019-2023* (N=315)



Source: Epidemiology and Research Division. N=315 (Female=108; Male=207). *Preliminary data as of March 11, 2024.

Regarding acute Hepatitis B, for the year 2019, all cases were identified in the age ranges of 40 years and older. In 2020, two cases were identified in people 20 to 29 years old and the rest in people 50 years or older. In 2021, a total of 10 cases were registered, with the most cases being identified in the age range of 50 to 59 years (three cases). For the year 2022, four cases were registered. As for 2023, 14 cases were identified, including one in the age range of 10 to 19 years old (Graph 9).

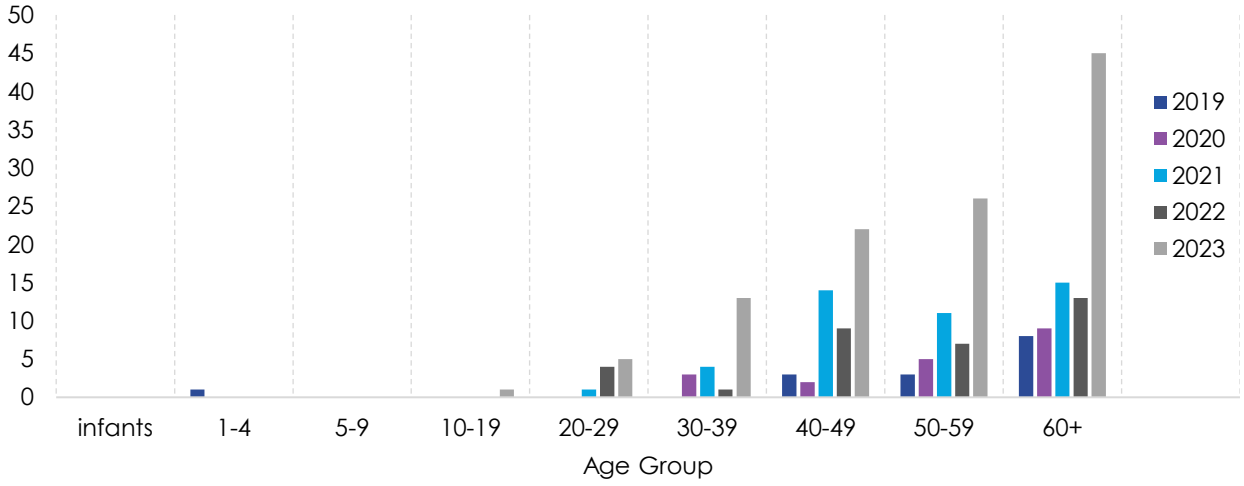
Graph 9: Distribution of acute Hepatitis B cases by age group in Puerto Rico, years 2019-2023* (N=38)



Source: Epidemiology and Research Division. N=38. N=6 (2019); N=4 (2020); N=10 (2021) N=4 (2022); N=14 (2023). *Preliminary data as of March 11, 2024.

Regarding chronic Hepatitis B, the vast majority of cases are identified in people aged 40 or over every year from 2019 to 2023. The age range of people aged 60 or over stands out as registering the highest number of cases in the aforementioned five-year period (Graph 10).

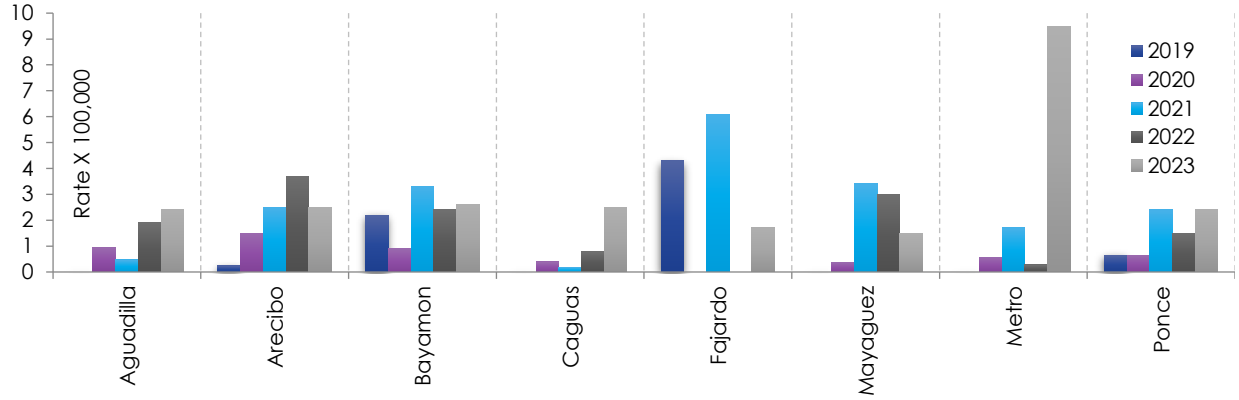
Graph 10: Distribution of chronic Hepatitis B cases by age group in Puerto Rico, years 2019-2023* (N=277)



Source: Epidemiology and Research Division. N=15 (2019); N=19 (2020); N=59 (2021) N=72 (2022); N=112 (2023). *Preliminary data as of March 11, 2024.

Graph 11 presents the incidence rates of reported cases of Hepatitis B (acute/chronic) by health region for the years 2019 to 2023 in Puerto Rico. We observed that the highest incidence rates occurred in the regions of Fajardo in 2021, and Metro during 2023.

Graph 11: Incidence rates of Hepatitis B by health region of Puerto Rico, 2019-2023 (N=315)*



Source: Epidemiology and Research Division. N=315. *Preliminary data as of March 11, 2024.

Hepatitis C in Puerto Rico, 2023

Introduction

Hepatitis C is a liver infection caused by the Hepatitis C virus (HCV). Hepatitis C is transmitted by contact with the blood of an infected person. Currently, most people become infected with the HCV by sharing needles or other equipment used to prepare and inject drugs. For some people, Hepatitis C is a short-lived illness, but for more than half of the people who become infected with the HCV, it becomes a long-term chronic infection. Chronic Hepatitis C can cause serious, even life-threatening health problems, such as cirrhosis and liver cancer. People with chronic Hepatitis C often have no symptoms and do not feel sick. When symptoms do appear, they are usually a sign of advanced liver disease. There is no vaccine for Hepatitis C. The best way to prevent hepatitis C is to avoid behaviors that can spread the disease, especially injection drugs. Getting tested for Hepatitis C is important, because treatments can cure most people with Hepatitis C in 8 to 12 weeks.[5]

CDC estimates that 2.4 million people in the United States were living with Hepatitis C during 2013 to 2016. In 2019, a total of 4,136 cases of acute Hepatitis C were reported to CDC. After adjusting for underestimation and underreporting, an estimated 57,500 cases of acute Hepatitis C occurred in 2019. Out of every 100 people infected with HCV, approximately 5%-25% will develop cirrhosis within 10-20 years. Patients who develop cirrhosis have a 1%-4% annual risk of developing hepatocellular carcinoma and a 3%-6% annual risk of hepatic decompensation; for the latter patients, the risk of death in the following year is 15%-20%.

[5] https://www.cdc.gov/hepatitis/index.htm

Epidemiological Surveillance of Hepatitis C Epidemiological Surveillance of Hepatitis C

PRDoH, like CDC, has a Hepatitis C epidemiologic surveillance system that allows for case investigation and outbreak identification. PRDoH's Epidemiology and Research Division works in collaboration with the Hepatitis C Surveillance System and the STD/HIV/VH Prevention Program in the prevention, detection, and investigation of events associated with Hepatitis C.

The PRDoH also participates in the nationwide surveillance known as the National Notifiable Disease Surveillance System (NNDSPRS): CDC's surveillance system that allows for the monitoring of notifiable diseases in order to control and prevent public health threats.

Table 2: Diseases and/or Conditions of Mandatory Notification to the Puerto Rico Department of Health

Disease or Condition	Category I
Hepatitis C (acute)	✓
Hepatitis C (past or present) (chronic)	✓
Viral Hepatitis, other (perinatal)	✓

Hepatitis C symptoms

A. Acute infection

1. Fever
2. Fatigue
3. Dark urine
4. Clay-colored, pale, or white stools
5. Abdominal pain
6. Loss of appetite
7. Nausea
8. Vomiting
9. Joint pain
10. Jaundice

In people who do develop symptoms, the median time from exposure to onset of these symptoms is 2-12 weeks with an interval of 2-26 weeks.

B. Chronic infection

Most people with chronic HCV infection are asymptomatic or have nonspecific symptoms such as chronic fatigue and depression. Many end up developing chronic liver disease, which can range from mild to severe, including cirrhosis and liver cancer. Chronic liver disease in HCV-infected people is usually insidious and slowly progresses without signs or symptoms over several decades. In fact, HCV infection is often unrecognized until asymptomatic people are identified as HCV seropositive when they donate blood or when elevated levels of liver enzymes such as alanine aminotransferase (ALT) are detected.[6]

According to the CDC, seven (7) genotypes and sixty-seven (67) subtypes have been identified. As a result, people can become infected with HCV again after the initial infection has been cleared. Previous HCV infection does not protect against subsequent infection with the same or different genotypes of the virus. This is because people infected with HCV often have an ineffective immune response.

Hepatitis C screening tests

1. Antibody detection (anti-HCV)

Anti-HCV seroconversion occurs 8 to 11 weeks after exposure to the virus, although cases of slow seroconversion have been documented in immunocompromised individuals.

2. HCV RNA detection (molecular or confirmatory test)

People with a newly acquired acute infection usually have detectable levels of HCV RNA as early as 1 to 2 weeks after exposure to the virus.

Outbreaks associated with Hepatitis C

As of the date of preparing this report, the PRDoH Epidemiology and Research Division did not identify outbreaks associated with Hepatitis C for the year 2022.

Hepatitis C Investigations

The following section describes the 2022 hepatitis C test reports that have been assigned a classification based on the case definitions for chronic, acute, or perinatal hepatitis C established by the CDC and the Council of State and Territorial Epidemiologists (CSTE). The integrated reporting system known as NBS (National Electronic Disease Surveillance System (NEDSPRS) Base System) enables nationwide case reporting to CDC's NNDSPRS.

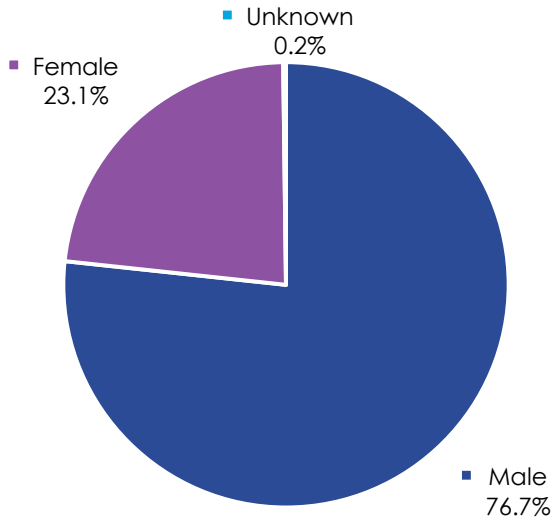
[6] https://www.cdc.gov/hepatitis/index.htm

According to the NNDSPRS, an epidemiological week is assigned to mandatory notification cases in order to establish the incidence of diseases over time. The epidemiological weeks are assigned according to the following hierarchy: date of onset of symptoms, date of diagnosis, date of laboratory results, and date of report to the PRDoH. Graph 11 presents the cases of chronic Hepatitis C by case classification preliminarily reported for the year 2023. It shows that 70% of the cases of Hepatitis C were classified as probable (3,105).

Graph 12: Distribution of chronic Hepatitis C cases in Puerto Rico, year 2023 (N=4,279)

Graph 13 presents the distribution by sex of the confirmed and probable cases reported to the NBS (National Electronic Disease Surveillance System (NEDSPRS) Base System) for the year 2023. The male sex was the most reported with 76.7% of the cases (3,282 persons).

Graph 13: Distribution of Hepatitis C cases by sex in Puerto Rico, year 2023



Graph 14 presents the distribution by age of the confirmed and probable cases reported to the NBS (National Electronic Disease Surveillance System (NEDSPRS) Base System) for the year 2022. The age group with the highest number of cases was 55 to 64 years with 28.9% of cases.

Graph 14: Distribution of Hepatitis C cases by age group in Puerto Rico, year 2023

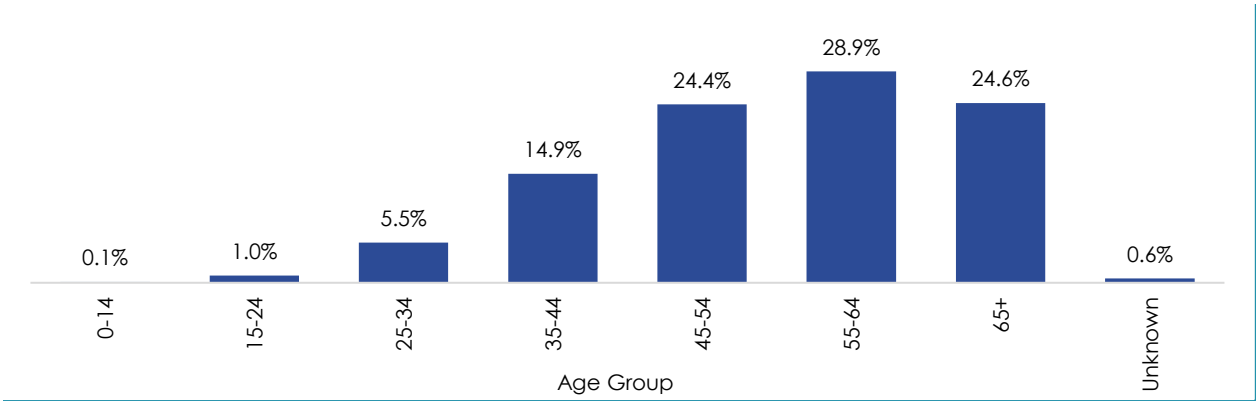
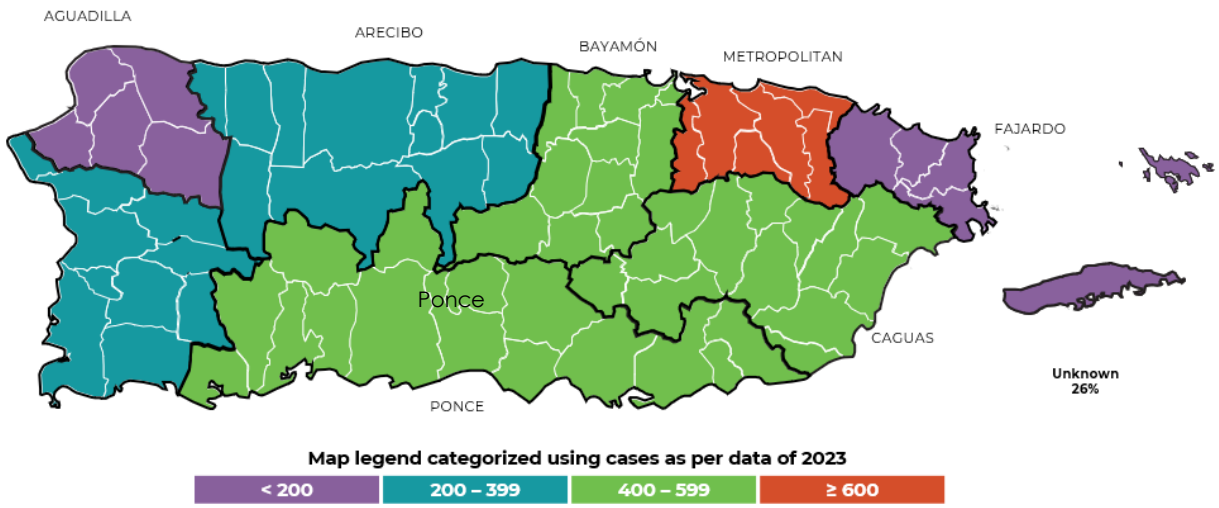


Illustration 2 shows the number of confirmed and probable cases of Hepatitis C by PRDoH region. In it, we observed that the largest number of cases was reported in the Metropolitan region. The regions with the least number of cases were the Fajardo and Aguadilla regions.

Illustration 2: Geographic distribution of confirmed and probable cases of Hepatitis C by PRDoH regions in Puerto Rico, year 2023 (N=4,284)



Note: The map was built with the Datawrapper tool. Source: Lorenz, M.; Aisch, G.; Kokkelink, D. (2012) Datawrapper: Create Charts and Maps [Software]. Recovered from https://www.datawrapper.de/

Limitations of the Report

- Most of the results are descriptive, and there are no incidence rates (crude or adjusted).
- Although there is data in the PRDoH for other years, as of November 2021, the implementation of Hepatitis C Surveillance in Puerto Rico was completed.
- The data presented in this report is preliminary as of the date of writing. All the information presented is subject to data updating as the evidence reporting and case investigation processes take place. Patients who do not reside in Puerto Rico are referred to other jurisdictions and are not included in the total number of reported cases.

SITUATIONAL ANALYSIS

Hepatitis Surveillance, Prevention and Treatment Services Gap Assessment in Puerto Rico, 2022

Introduction

The PRDoH, through its STD/HIV/VH Prevention Program, contracted the services of *Estudios Técnicos, Inc.* to conduct this Gap Assessment in Viral Hepatitis (VH) surveillance and prevention services in Puerto Rico. Its objective consisted of guiding the efforts for the creation of a Multisectoral VH Elimination Advisory Committee (VHEAC). The information derived from the assessment, along with the Committee's recommendations, will provide the basis for the VH Elimination Plan.

The study focused on PRDoH clinics that provide specialized services, but also collected information from other providers and external opinion leaders. The tasks to carry it out were organized into three phases: (1) Organization and exploration, (2) data collection and analysis, and (3) conclusions.

The most outstanding findings of the research are presented below. This summary focuses on the following core aspects of the study:

- Summary of the methodology used for the purposes of the study;
- Results of the survey to the specialized clinics of the PRDoH;
- Results of the interviews with representatives of the specialized clinics of the PRDoH and external actors related to the subject; and
- Conclusions.

Methodology

Methodological approach

In terms of the reference framework from which the design of the methodology was based, we worked with an adaptation of the manual for the study of gaps in sexually transmitted infection prevention services published by the CDC (hereinafter, the Manual). In addition, work was done within the framework of the National Strategic Plan to Eliminate Viral Hepatitis, 2021-2025.

According to the CDC (2016), this type of evaluation usually includes five main objectives:

1. Document the clinical and prevention services available to address infections in a given geographic area or for a defined population;
2. Identify gaps and duplication of services;
3. Learn more about the facilities that provide services;
4. Learn more about partnerships and collaborations between organizations; and
5. Use the information to improve clinical and prevention services.

The model proposed by CDC involves a research process comprising three main components: 1) planning the evaluation; 2) conducting the evaluation; and 3) managing and analyzing the data (see Illustration 3).

Based on these three components, the *Estudios Técnicos* team organized the project into three phases, which are described in detail in the following sections. The type of methodology used focused on a multi-method approach in order to be able to rely on information from various sources and to contrast and validate the findings.

Illustration 3: Gap Assessment Process Components

Research construct

For purposes of the gap analysis, three categories of infection were considered, as defined by the CDC:

Hepatitis A: It is a vaccine-preventable liver infection caused by the Hepatitis A virus (HAV). HAV is found in the feces and blood of infected people. Hepatitis A is very

contagious. It is spread when someone unknowingly ingests the virus, even in microscopic amounts, through close personal contact with an infected person or by eating contaminated food or drink. The symptoms of Hepatitis A can last up to 2 months and include fatigue, nausea, stomach pain and jaundice. Most people with Hepatitis A do not have long-term illness. The best way to prevent Hepatitis A is to get vaccinated.[7]

Hepatitis B: It is a vaccine-preventable liver infection caused by the Hepatitis B virus (HBV). Hepatitis B is spread when blood, semen, or other body fluids from a person infected with the virus enter the body of a person who is not infected. This can happen through sexual contact; sharing needles, syringes, or other drug injection equipment; or from mother to child at birth. Not all people newly infected with HBV have symptoms, but for those who do, symptoms can include fatigue, poor appetite, stomach pain, nausea, and jaundice. For many people, Hepatitis B is a short-term illness. For others, it can develop into a long-term, chronic infection that can lead to serious, even life-threatening health problems, such as cirrhosis or liver cancer.[8]

Hepatitis C: It is an infection of the liver caused by the Hepatitis C virus (HCV). Hepatitis C is transmitted through contact with the blood of an infected person. Today, most people become infected with the HCV by sharing needles or other equipment used to prepare and inject drugs. For some people, Hepatitis C is a short-term illness, but for more than half of the people who become infected with the HCV, it becomes a chronic, long-term infection. Chronic Hepatitis C can cause serious, even life-threatening health problems, such as cirrhosis and liver cancer. People with chronic Hepatitis C can often have no symptoms and not feel sick. When symptoms do appear, they are often a sign of advanced liver disease. There is no vaccine for Hepatitis C. The best way to prevent Hepatitis C is to avoid behaviors that can spread the disease, especially injecting drugs. It is important to get tested for Hepatitis C, because treatments can cure most people with Hepatitis C in 8 to 12 weeks.[9]

Regarding the services, we worked based on five categories related to aspects of prevention and care, which included: education, vaccination (as applicable), screening or tests, link to treatment and treatment for the condition (as applicable), as well as to treat coinfections.

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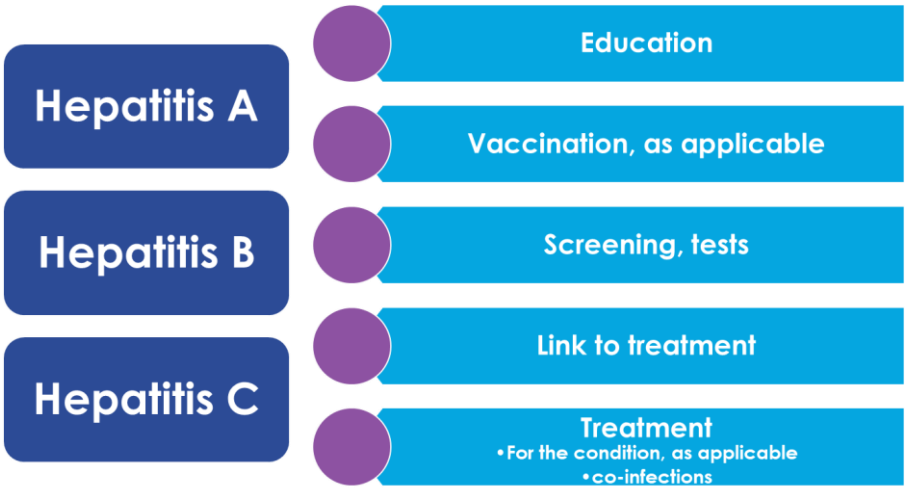
[7] Taken from https://www.cdc.gov/hepatitis/hav/index.htm (our translation).

[8] Taken from https://www.cdc.gov/hepatitis/hbv/index.htm (our translation).

[9] Taken from https://www.cdc.gov/hepatitis/hcv/index.htm (our translation).

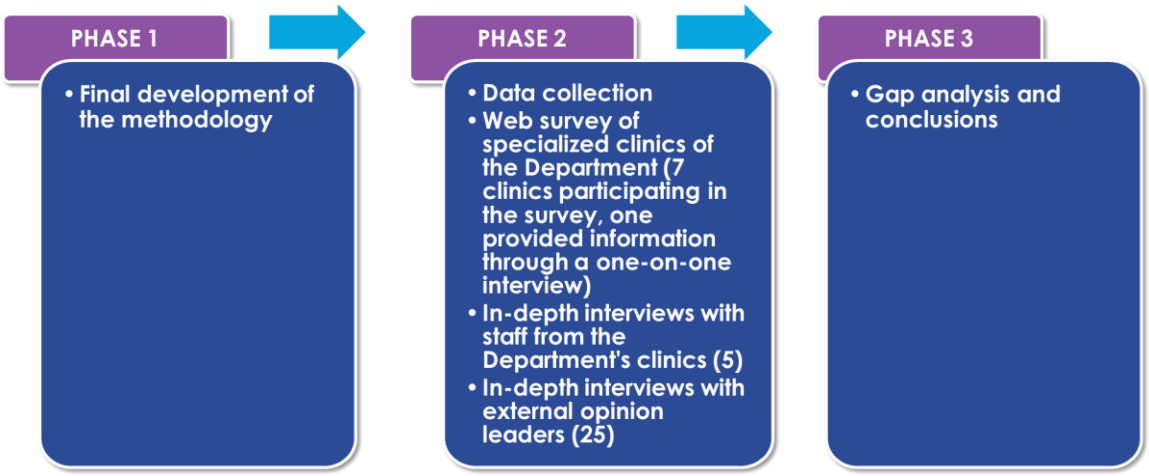
Illustration 4: Research construct



Stages of the evaluation process

As indicated in a previous section, according to the model proposed by the CDC, the research was organized in three phases, which are described in the following sections:

Illustration 5:Phases of the study and the work period



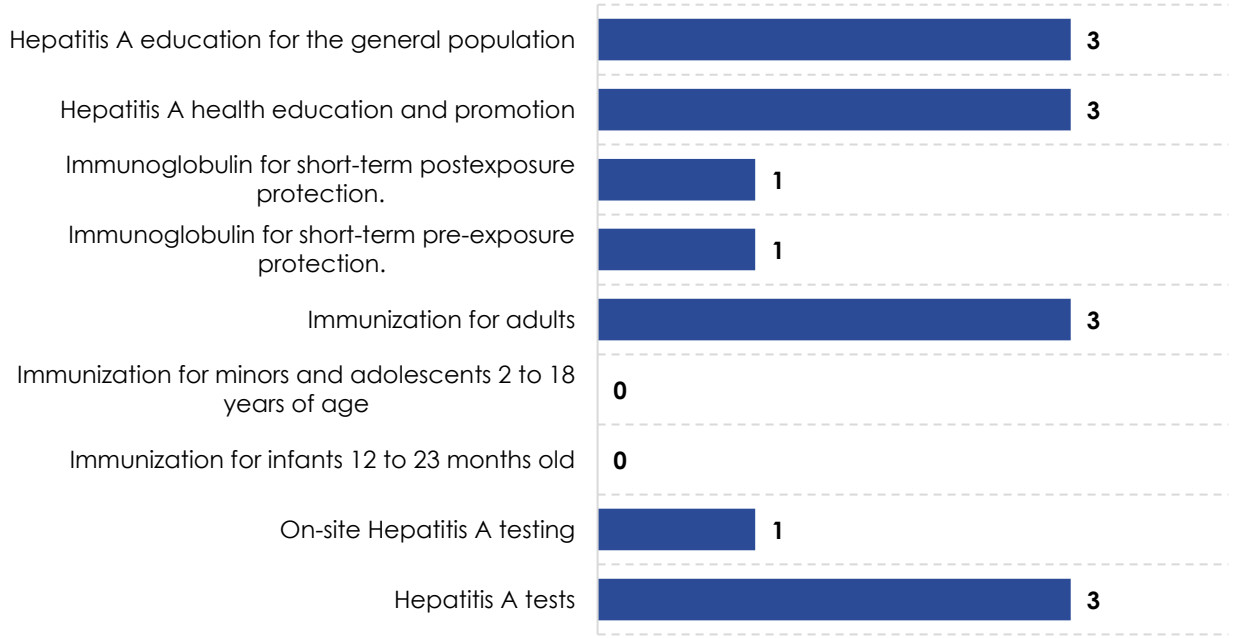
Supplier Survey Results

This section presents the results of the survey conducted in the specialized clinics of the PRDoH. The responses of the nine clinics that provided the information in its entirety are collected.

Services and populations of impact

As illustrated in the next graph, the main services available at PRDoH Hepatitis A clinics are related to education, adult immunization, and Hepatitis A testing. These are offered by 3 of the 9 clinics participating in the survey. In the case of immunization services for minors and for infants between 12 and 23 months, none of the clinics offer them.

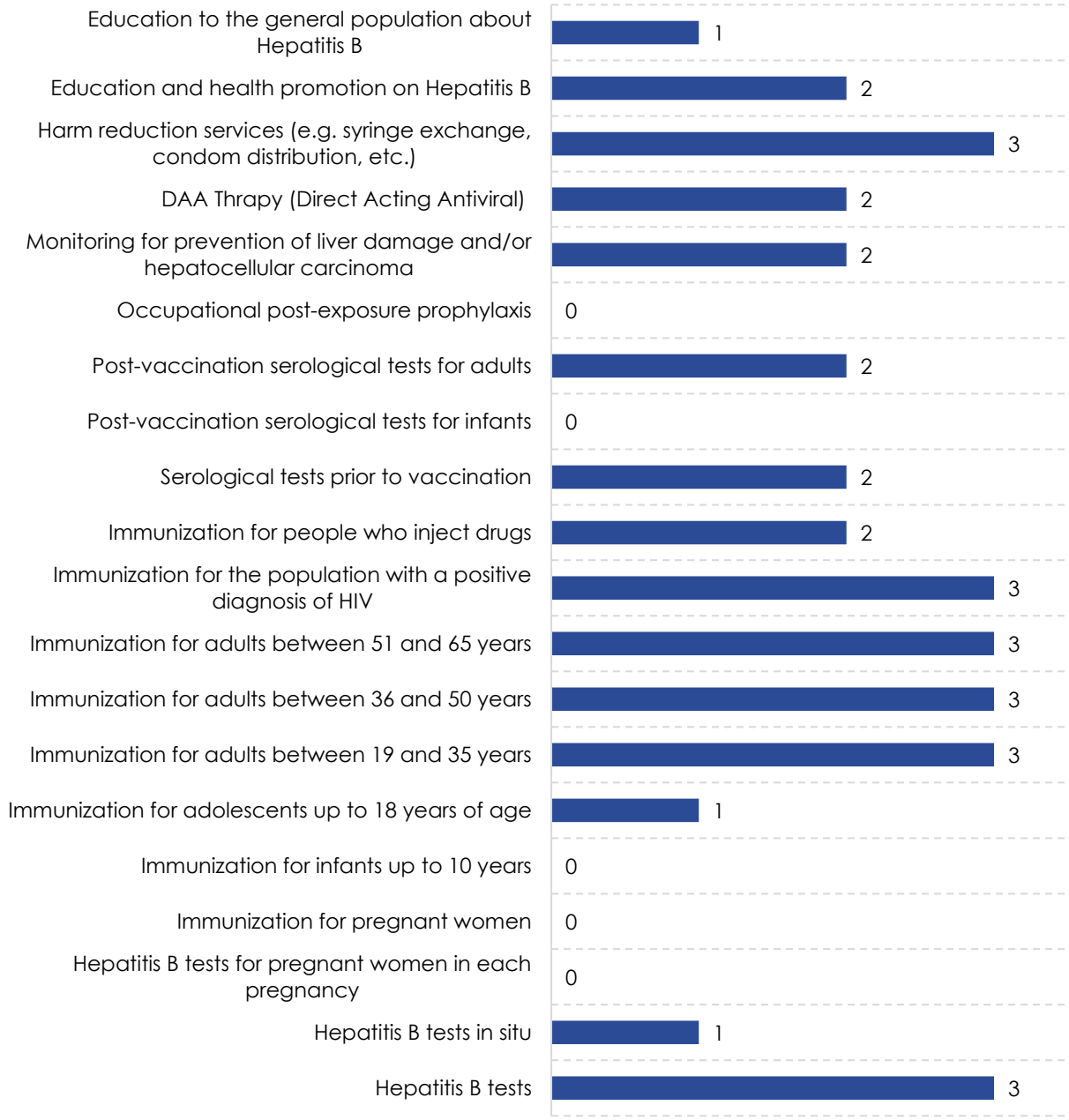
Graph 15: Services provided by the specialized clinics of the Department of Health related to Hepatitis A



Note: This illustration is based on the 9 clinics that participated in the survey

In the case of Hepatitis B-related services, the main services provided by the clinics are adult immunization services and screening tests. These are provided by three clinics, to which harm reduction services are added. Other services provided by two of the clinics include educational services, therapies, prevention monitoring and Direct Acting Antiviral (DAA) therapy. Infant immunization and prophylaxis services are not provided by any of the clinics.

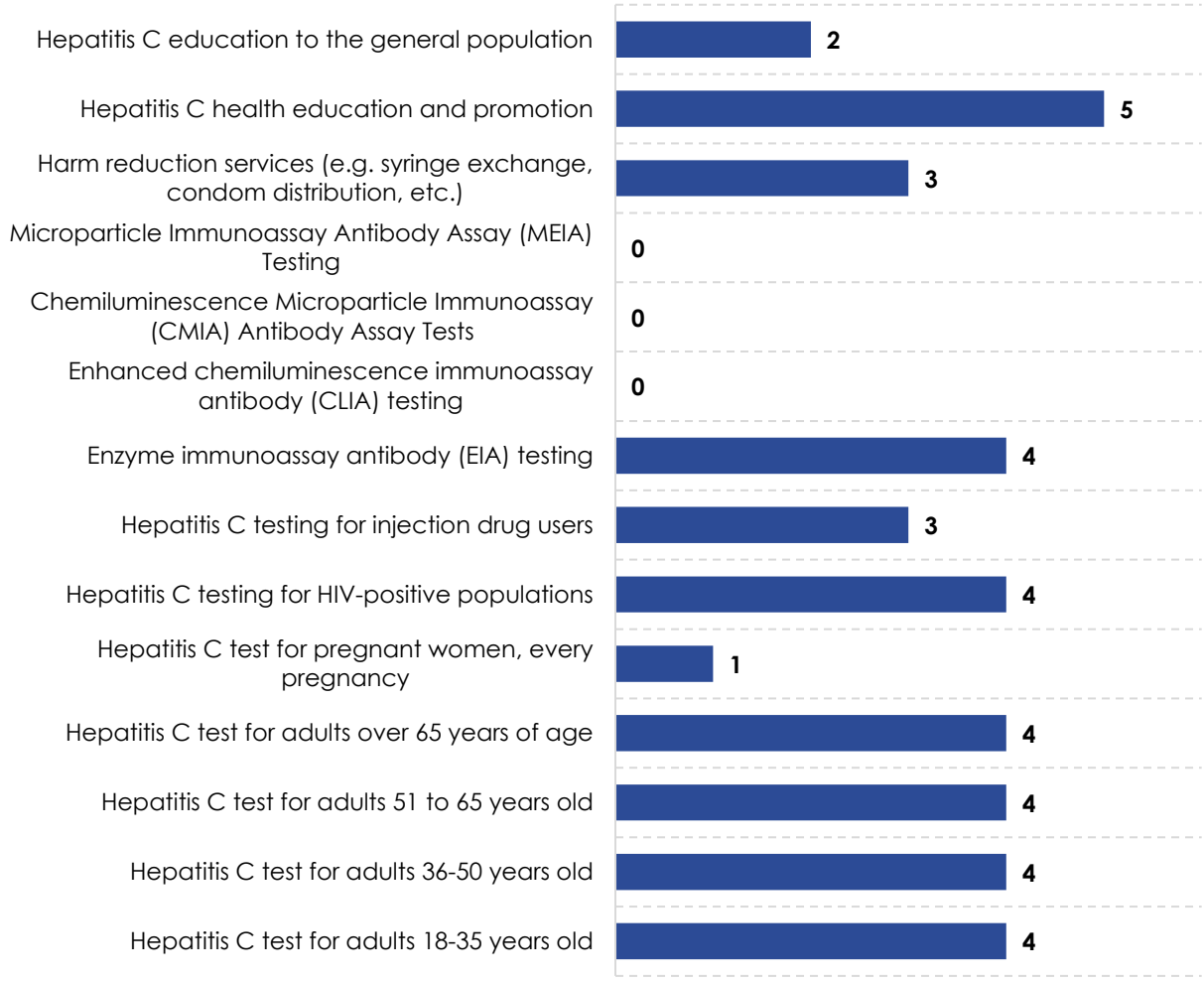
Graph 16: Services provided by the Department of Health's specialized clinics related to Hepatitis B



Note: This illustration is based on the 9 clinics that participated in the survey.

In general terms, it was observed that in the case of Hepatitis C, a higher proportion of the clinics provide services related to the virus. Health education and promotion services are provided by more than half of the clinics (5 out of 9 survey participants), while testing services for adults are provided by four of the nine clinics. Antibody testing is not provided by any of the clinics.

Graph 17: Services provided by the Department of Health's specialized clinics related to Hepatitis C



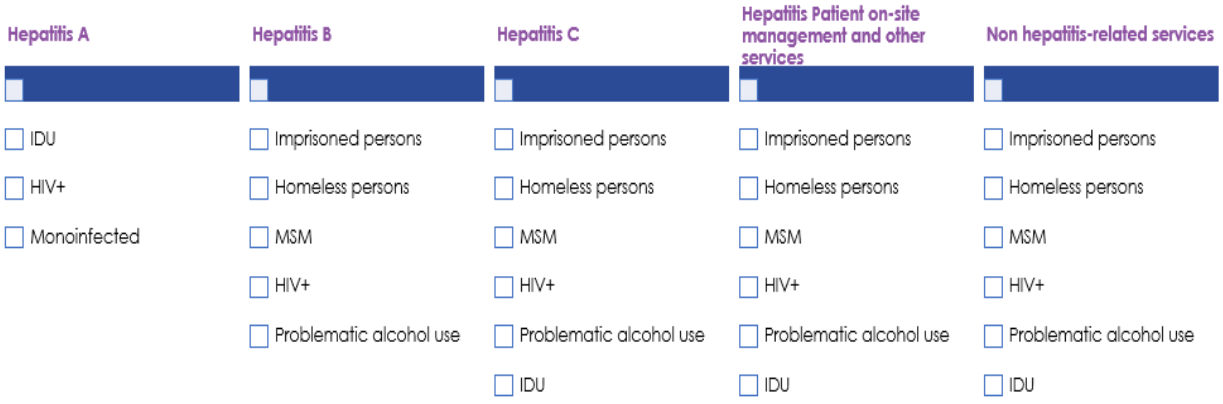
Note: This illustration is based on the 9 clinics that participated in the survey.

With respect to on-site hepatitis patient management and other services, it was noted that six of the clinics provide behavioral counseling intervention sessions on sexually transmitted infections and HIV, as well as brief counseling intervention sessions.

Graph 18: On-site hepatitis patient management and other services

Note: The basis for this illustration is the 9 clinics that participated in the survey.

Illustration 6: Main Populations to which the Services are directed



Results of In-Depth Interviews with Internal and External Opinion Leaders

Profile of participants

For the study, 30 people were interviewed using a semi-structured guide. Half of these participants were in the laboratory sector, while one out of six (16.7%) belonged to the sector of personnel working in the Puerto Rico Department of Health centers. In addition, participants from hospitals, NPOs, the Department of Education, a methadone center, and the PRDoH who were not stationed in the Centers for Prevention and Treatment of Transmissible Diseases (CPTET, as its Spanish acronym) also participated.

Table 3: Sector in which the participants in the study stand out

	Freq.	%
Laboratory	15	50.0%
CPTETs	5	16.7%
Hospital	4	13.3%
Department of Health	2	6.7%
Non-Profit Organization	2	6.7%
Methadone Center	1	3.3%
Department of Education	1	3.3%
Total	30	100.0%

Among those who participated in the study were:

- Physicians,
- Chemists,
- Epidemiologists,
- Medical Technologists,
- Nurses,
- Nutritionists,
- Administrators of health-related professional associations,
- Hospital administrators,
- Systems administrators, and
- School health.

Opinions on the prevention and detection of Hepatitis A, B and C

Almost all of the people who participated in the study treated the issues of prevention and detection as highly linked, facing problems in expressing themselves in one area without going into the other. When thinking about prevention of Hepatitis A, B and C, those who participated in the study usually identify four general areas:

- Education about the condition,
- Vaccination,
- Performance of hepatitis screening tests, and
- Clinics in non-hospital settings.

It should be noted that those who participated in the study do not usually directly link services such as harm reduction and condom distribution with those offered for hepatitis prevention. This type of activity is mainly associated with HIV prevention services.

Of the areas mentioned above, education about the condition is the main activity considered by the people who participated in the study. Based on this consideration, for the most part these people believe that the level of prevention, particularly in Hepatitis A and B, is low. Regarding Hepatitis C, although some of the people indicated that they understood that it was also low, others understood that there is more information for this type of hepatitis compared to the other two. For few of these people, the levels of prevention are non-existent because the public policy of the Puerto Rican government is more focused on reactive mechanisms that attend to these cases once the person acquires the virus.

Paradoxically, some of the people point out that, despite the fact that there is more information regarding Hepatitis C as a preventive mechanism, it is from this that a greater number of cases is usually reported. For one of the persons, this situation does not reveal mysteries, but rather reflects a phenomenon that occurs in other conditions in which the context of contagion leads people to make risky decisions, even when they have the information about the decision that would avoid contagion.

The CPTETs reported being active in providing preventive information. However, with regard to the extent of their actions, they point out that they reach particular populations. This particularity, according to them, restricts their level of impact at a general level.

On the other hand, one of the respondents pointed out that in the southwestern area of the Island, there are regional offices of the PRDoH that offer preventive services, mostly in the form of education. According to this person, these services are not accessible to

the population because they are unknown to them. In addition, he points out that, although the PRDoH may make an effort to make them available, it does very little to promote them.

With regard to vaccination, only two of the people interviewed spoke spontaneously on the subject when asked about the level of hepatitis prevention. Subsequently, when asked about preventive services for perinatal Hepatitis B and C, many of the other respondents broached the subject. The primary reason for many of these individuals to mention the topic of vaccines at that time is because they understand that part of the gynecological tests that are ordered for pregnant women contain those related to hepatitis.

According to one of the people who participated in the study, the main reason there are not many cases of Hepatitis B in Puerto Rico is due to the inclusion of this vaccine as part of the requirements for schools. According to the study, activities related to the vaccination of minors are supported by programs such as Vaccine for Children (VFC), even though this does not include Hepatitis A.

In addition to gynecological services requesting hepatitis testing of pregnant women as a preventive mechanism, most people do not identify those other types of physician's request hepatitis-related testing on a frequent basis as a preventive mechanism; some understand that physicians are making the request, but only when they have a suspicion of infection. In the case of prevention and treatment centers, although it is recognized that they actively offer preventive services, these services are mainly focused on adult populations, including pregnant women when they are among the populations they usually serve.

In summary, those who participated in the study identified the following areas as the main barriers in the hepatitis prevention framework:

- That prevention strategies for hepatitis do not form part of Puerto Rico's public policy so that the PRDoH provides greater emphasis on them;
- Lack of knowledge of the general population of available places with preventive services;
- Lack of information about the condition by the general population and some professionals who provide health services;
- Limitations of CPTETs to have a greater impact on the general population; and

- Lack of skills to deal with contextual conditions and encouragement that lead people to make known low-risk decisions when faced with them, particularly in populations at higher risk of contagion.

When asking those who participated in the study about their perception regarding hepatitis screening services, this division was part of their arguments. For some people, these services may be enhanced by more physician orders, while others find the services adequate. Despite this difference, the vast majority concur in two areas:

- There are enough places to process test orders for the different types of hepatitis; and
- Detection could be increased if there were non-clinical scenarios to reach people.

Regarding hepatitis prevention and detection services and medical coverage, the majority of those who participated in the study expressed similar opinions. Regarding prevention, very few people were able to identify activities related to medical plans. The areas they identified are:

- Exhortation of medical plans so that doctors perform routine tests;
- Inclusion of hepatitis in STD prevention programs sponsored by the PRDoH; and
- Payment of immunization for hepatitis B through VFC funds.

Regarding detection services, in general terms they highlight that, once the medical order is received, both private health plans and the public health plan usually cover the service. However, some of the people point out that this coverage is not always an easy one to achieve. This argument was particularly insistent among the CPTETs, who point out that this follow-up can take up a lot of their time considering their other medical activities. As they argue, the more specific the order or process, the greater follow-up efforts are required.

For another person, the process required in the public health plan, although it ends up covering the service, could lead those who need the service to give up on it. According to her, the plan requires referrals for this service as additional steps that the patient would have to take, which can have a dissuasive effect.

Opinions on treatment for Hepatitis B and C

The vast majority of those who participated in the study indicated that they did not know about the treatments for Hepatitis B and C, so they reserved their opinion in relation to this topic. Among those who expressed their opinion, their opinions revolved mostly around Hepatitis C. According to some of these people, this is because the availability of Hepatitis B vaccines means that few cases reach treatment. Those people who

expressed their opinion on the treatment of Hepatitis C maintained that its offer is limited and is mostly concentrated in the metropolitan area.

These characteristics related to the treatment of Hepatitis C led these people to describe the level of services, as well as the level of offer, as low. However, within what is available, they indicate that they are advanced services. In part, this opinion was based on two arguments:

- New treatment alternatives and
- Inclusion of medicines for treatment in the catalog.

For those who highlighted the new treatment alternatives, they point out that the entry of pill-based treatments makes it easier for some populations to be treated. This type of treatment, which indicates that it is a recent one, for which he considers that it can have a positive impact on the population, which stands out, has a high incidence of Hepatitis C.

Regarding the inclusion of drugs related to treatment in the catalog, there were three aspects in the opinions. On the one hand, as highlighted in the previous quote, it is recognized that this allows people with scarce resources to have access to them. In the second instance, it is indicated that, although there are two drugs in the catalogue, the health insurance companies are inclined towards one of them being the one that is mainly used. This preference, as they point out, leads to medical criteria having to be justified, making these treatment processes difficult.

According to these people, the factors that influence the fact that there are no better treatment services in relation to their availability are:

- Cost level of treatments;
- Treating the condition requires more training and complications for health professionals in their practices; and
- Treatments must be justified to health insurers so that they can be covered.

According to some of the people who participated in the study, treatments for Hepatitis B and C could be offered by hepatologists and gastroenterologists. For these participants, there is no further offer of services because this would require these health professionals to take additional training focused on the condition. In this regard, they argue that it is more comfortable for these professionals to remain doing other types of interventions that are remunerative for them, instead of treating hepatitis with the complications that this could entail.

Regarding treatment costs, these participants perceive that, if medical plans do not cover these treatments, the only people who could be treated would be those who, in addition to hepatitis, have HIV. According to them, the funds that cover HIV status allow comorbidities, such as hepatitis, to be treated.

Recommendations from the interviewees

As part of the study, participants were asked for related recommendations aimed at increasing the prevention, detection, and treatment of hepatitis, including perinatal hepatitis. This section shows all the recommendations offered, including those that have already been mentioned throughout the previous discussions. As in previous discussions, recommendations were sometimes made that could be placed in more than one area.

Recommendations related to prevention

- Increase educational activity on the condition in public schools from middle school and university settings;
- To educate the Department of Education personnel who are responsible for teaching students in the system's public schools about the condition;
- Educational activities in senior centers or homes;
- Educational activities in centers that provide services to people who inject drugs;
- Increasing the number of harm reduction programs;
- Maintain drinking water quality;
- Conduct needs assessments to identify the groups with the highest incidence and root cause;
- Have updated statistics on the incidence of the different hepatitis;
- Maintain hygiene surveillance and infection prevention practices in businesses that perform tattoos, including eyebrow tattooing estheticians;
- Conduct educational campaigns to the general public in mass media and social networks with visual information that is easy and quick to understand;
- Establish prevention clinics that go outside of hospital settings, as is done with HIV and more recently with COVID-19;
- Implement hepatitis C testing as routine and mandatory by law;

- Establish hepatitis testing as part of requirements for various activities, e.g., acquiring a health certificate or acquiring certain licenses;
- Include advertisements in matchmaking applications; and
- Promote Hepatitis A vaccination.

Recommendations related to detection

- Incorporate different entities, including municipalities, in screening activities;
- Have tests that can be done in places where it is known that behaviors with a higher risk of contagion may occur;
- Educate the medical class for screening, incorporating medical groups, pharmaceuticals, and health insurance companies;
- Implement routine and mandatory Hepatitis C testing by law; and
- Establish prevention clinics outside of hospital settings, as is being done with HIV and more recently with COVID-19.

Recommendations related to treatment

- Encourage the opening of hepatitis treatment centers outside the metropolitan area;
- Train medical personnel, such as gastroenterologists, to include hepatitis treatment as part of their services; and
- Work with health plans to streamline processes to cover treatment services.

Recommendations regarding the reporting of hepatitis cases

The recommendation made by most of the study participants regarding the reporting of hepatitis cases is the digitization of the report. According to these participants, reporting should be done digitally, similar to the way it is currently done for COVID-19. Other recommendations are:

- An increase in staff at the PRDoH to process the manual faxed reports submitted more quickly;
- Weekly reporting, as is done for HIV; and
- Include more information, e.g., physical address, of persons being reported.

Identified needs

Viral Hepatitis Testing

Regarding the supply of screening services (tests) for Hepatitis A, B and C, in general, it is understood that the tests are available. However, there are barriers that limit their access by the population. This is most evident in certain populations and particularly for Hepatitis B and C.

Three main types of barriers to access to testing were identified: those related to the population, those of the service delivery system, and those of the institutional and public policy framework. Among the population barriers, the following stand out:

- Population empowerment on the subject,
- Lack of patient information to navigate testing services; and
- Population limitations to cover deductibles.

In addition, there are barriers in the service provision system, such as:

- The tests are not ordered routinely or preventively, only when symptoms are observed, and this makes it difficult to detect viral hepatitis in people without symptoms.
- Health professionals do not necessarily order the full panel of tests, which is necessary to confirm diagnoses.
- Limitation of testing in non-clinical scenarios.
- Lack of inclusion of viral hepatitis tests in the coverage of tests by health insurance plans.
- Lack of knowledge of service providers regarding protocols related to medical orders.
- Limitation in the availability of laboratories offering tests due to the payment stipulated to the providers by the insurers. This causes some laboratories to be unable to acquire the tests due to lack of financial resources.
- Communication and relationship between health service providers, which causes fragmentation and lack of communication in the system.

The third type of barrier to access to testing is linked to the institutional and public policy framework. Two barriers stand out:

- The issue of viral hepatitis is not a public policy priority, which causes insufficient resources to be allocated to address it, and
- Fragmentation of the system

On the other hand, several main populations are identified that face more barriers in accessing tests. These are:

- General population without symptoms,
- People with low and moderate incomes (below or slightly above the poverty level),
- People who inject drugs, and
- Other vulnerable populations (e.g., people experiencing homelessness and the incarcerated population).

Level of prevention of Hepatitis A, B and C in Puerto Rico

Regarding Hepatitis A, it is perceived that there are vaccines available, however, in most cases this vaccine is recommended and is only required exceptionally. Furthermore, there are no frequent educational campaigns to encourage or promote vaccination. Limitations are also perceived in the educational efforts from the State due to institutional barriers and the only ones who are educating are understood to be the NPOs. There is also a need to educate parents about the importance of vaccination for their children. The need to adjust communication efforts to the characteristics of the population and to view prevention in an integrated manner is identified.

Regarding Hepatitis B, it is understood that there are additional tools to address it compared to Hepatitis A, but in particular with respect to cases of people coinfected with HIV. The need to adjust the messages to new ways of communicating and through various channels is identified. It is very important that the issue of Hepatitis B (and viral Hepatitis in general) constitutes a public policy priority. Similar to Hepatitis A, there are also perceived limitations in education efforts.

Regarding Hepatitis C, institutional limitations are identified that do not facilitate efforts to reach out to tests and link to treatment for populations at higher risk (for example, people who use injection drugs). There are also affected populations due to social determinants, which require differentiated strategies and community outreach. As with Hepatitis A and B, there are perceived limitations in educational efforts.

Access to treatment

In examining perceptions of access to viral hepatitis treatment, six main areas for attention were identified:

- Problems due to lack of information and fragmentation of the system;
- Pre-authorization process for drugs or drug switching (particularly for Hepatitis C);
- Lack of knowledge of the population about available treatments and ways to access them;
- Need to receive support for linkage and retention in treatment, among vulnerable populations;
- Lack of directories or information on available services; and
- Need for clinics that specialize in serving vulnerable populations and that are integrated with other services.

Changes in the population groups that require services

The demographic changes experienced in Puerto Rico have also impacted the populations requiring viral hepatitis services. In this regard, there has been a reduction in pregnant women and an increase in the number of older adults. Likewise, people with private medical plans without the financial capacity to pay the deductibles are another group with the greatest need for services. In addition, there are geographic barriers to accessing services, particularly for people residing in the island municipalities of Vieques and Culebra and those residing in central Puerto Rico. People who inject drugs and those with problematic substance use are other groups that stand out as having the greatest need for services.

Perceptions on the statistics and information available in Puerto Rico on Hepatitis A, B and C

In general, there is a perception that information is limited, particularly with respect to data related to the adult population. This lack of information limits decision-making and access to services. A need is identified to strengthen surveillance systems and to prioritize the availability of information through public policy.

Recommendations

Finally, the following recommendations to address the identified needs are highlighted:

- Promote public policy that focuses on the issue of viral hepatitis in an integrated manner (system and actors);
- Develop protocols for interaction between the different parts of the provider system;
- Strengthen information and surveillance systems;
- Allocate funds at the local level to address the issue; and
- Strengthen educational efforts directed at providers and the community.

GOALS AND OBJECTIVES

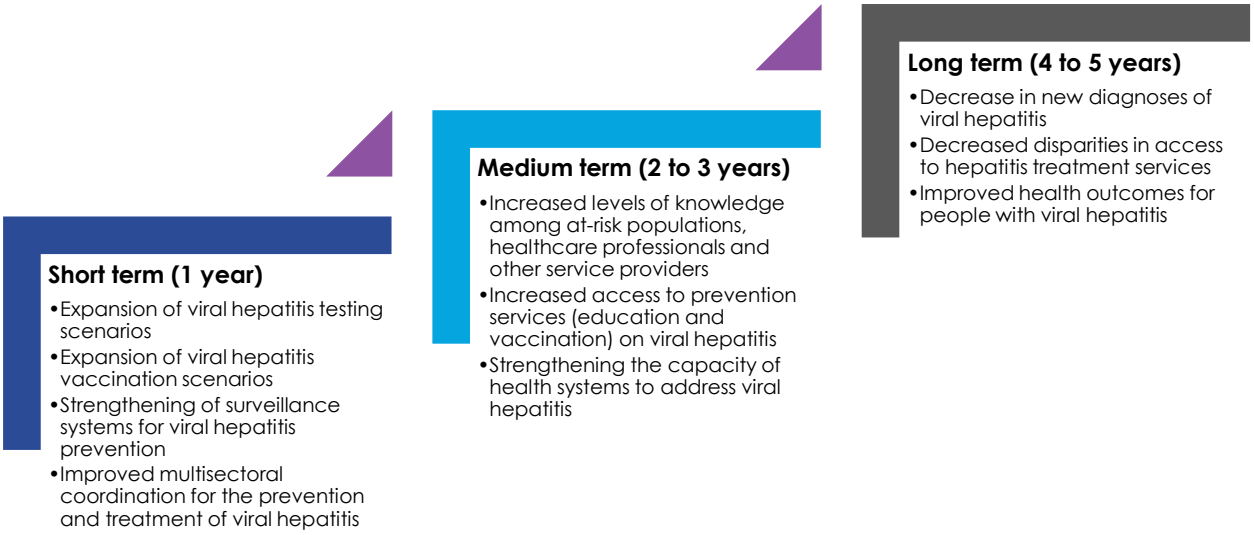
In this section, the goals and objectives that emerged from the planning process, as well as the strategies and actions to achieve them are presented. From the conducted process, five goals frame in the National Strategic Plan and the objectives were develop as follows.

Illustration 7: Plan goals and objectives

1	2	3	4	5
Prevent new viral hepatitis infections	**Optimize health outcomes for people with a positive diagnosis of viral hepatitis**	**Reduce health disparities and inequities related to viral hepatitis**	**Strengthen surveillance and data use of viral hepatitis**	**Achieve integrated and coordinated efforts among all partners and stakeholders addressing the viral hepatitis epidemic**
1. Increase viral hepatitis prevention and treatment services for people with problematic substance use 2. Increase the capacity of public health, health care systems and health personnel to prevent and manage viral hepatitis	1. Improve the quality of care and increase the number of people with viral hepatitis receiving and continuing (Hepatitis B) or completing (Hepatitis C) treatment, including people who use drugs and people in correctional settings	1. Reduce disparities in new viral hepatitis infections, knowledge of status, and along the cascade/ continuum of care 2. Expand culturally competent and linguistically appropriate viral hepatitis prevention, care, and treatment services	1. Strengthen public health surveillance through data collection, case reporting, and investigation in the Puerto Rico Department of Health	1. Integrate programs to address the syndemic of viral hepatitis, HIV, STIs, and substance use disorders 2. Improve mechanisms to measure, monitor, evaluate, report, and disseminate progress towards achieving organizational, local, and national goals

According to the established goals, by the end of the Plan's implementation period in 2027, it is expected to have achieved short, medium, and long-term results.

Illustration 8: Expected results



Description of Goals and Objectives

Goal 1: Prevent new viral hepatitis infections

Objective 1.1: Increase viral hepatitis prevention services for people with problematic substance use		
Strategy: Educate communities, individuals, and health professionals	**Activities**	**Responsible stakeholders**
	Conduct a demographic study that integrates information from different agencies and organizations to contribute to knowledge about viral hepatitis	PRDoH – STD/HIV/VH Prevention Program
	Identification of best practices for the prevention of viral hepatitis for people with problematic substance use	PRDoH – STD/HIV/VH Prevention Program
	Disseminate information on best practices for the prevention of viral hepatitis among health professionals	PRDoH – STD/HIV/VH Prevention Program
	Develop an information and referral center for the population with problematic use of substances at risk of contracting viral hepatitis	PRDoH, Health providers, NPOs and community

Objective 1.2: Increase the capacity of public health, health care systems and health personnel to prevent and manage viral hepatitis			
Strategy: Expand access to tests and vaccines, including reflex testing for HCV	**Activities**	**Target population**	**Responsible stakeholders**
	Identify at the administrative level the necessary actions to promote tests in clinical and non-clinical settings	Concerned State Agencies	VH Advisory Committee
	Approval for testing in non-clinical settings	Concerned State Agencies	Relevant State Agencies
	Training of health professionals on the test in clinical and non-clinical settings	Healthcare professionals	PRDoH, Private Health Insurance Companies, ASES
	Promote the necessary actions to make viable the increase in the coverage of adult vaccines by private medical plans	Concerned State Agencies	VH Advisory Committee
	Conduct a study for estimating costs and expenses for adult persons with a VH positive diagnosis to identify out of pocket costs to cover insurance deductibles for vaccines	Adult persons with a VH positive diagnosis	PRDoH – STD/HIV/VH Prevention Program

Goal 2: Optimize health outcomes for people with a positive diagnosis of viral hepatitis

Objective 2.1: Improve the quality of care and increase the number of people with viral hepatitis receiving and continuing (Hepatitis B) or completing (Hepatitis C) treatment, including people who use drugs and people in correctional settings			
Strategy: Improve link to care for people diagnosed in NPOs, government and correctional institutions	**Activities**	**Target population**	**Responsible stakeholders**
	Identification of best practices (link to Best Practice Guides)	Service providers	PRDoH, Service Providers, Academia
	Creation of a Directory of Services	General population, population at risk, case managers and service providers	PRDoH, VH Committee
	Service Directory Release	General population, population at risk, case managers and service providers	PRDoH

	Strengthen the human resources pool (agreements with universities; promote internship scenarios)	Academia	PRDoH, Service Providers

Goal 3: Reduce health disparities and inequities related to viral hepatitis

Objective 3.1: Reduce disparities in new viral hepatitis infections, knowledge of status and along the cascade/continuum of care			
Strategy:	**Activities**	**Target population**	**Responsible stakeholders**
Advance health disparities research to understand data on the social determinants associated with viral hepatitis and inform interventions to reduce and eliminate disparities	Examine available data and categorize by Hepatitis A, B, and C to identify determinants of health and disparities in access to services	Populations at higher risk and with limited access to treatment	PRDoH, Academia, Providers, Community Groups, Professional Associations, Health Insurance Plans, Laboratories, Pharmaceutical companies

Objective 3.2: Expand culturally competent and linguistically appropriate viral hepatitis prevention, care, and treatment services			
Strategy:	**Activities**	**Target population**	**Responsible stakeholders**
Promote education taking diversity into account to combat stigma	Training on cultural competency, stigma, and harm reduction in service delivery	PRDoH, Service Providers, Correctional agencies, elderly population	PRDoH, ASES, Service Providers, Community Based Organizations, Professional Associations, Pharmaceutical companies
	Develop and implement a navigation service in the system aimed at populations with difficult access	PRDoH, Service Providers, Correctional agencies, elderly population	PRDoH, ASES, Service Providers, Community Based Organizations, Professional Associations, Pharmaceutical companies

Goal 4: Strengthen viral hepatitis surveillance and data use

Objective 4.1: Strengthen public health surveillance through data collection, case reporting, and investigation in the Puerto Rico Department of Health			
Strategy: Increase access to confirmatory tests	**Activities**	**Target population**	**Responsible stakeholders**
	Provider education on test reporting	General population without symptoms, low-income people, drug users and vulnerable people	PRDoH, ASES, Service Providers, Laboratories and Clinics, Insurance Commissioner
	Review test reporting protocols	Providers	PRDoH
	Annually review Standard Operating Procedures (SOP) for VH surveillance	PRDoH	PRDoH- Epidemiology and Research Division
	Strengthen the human resources pool (agreements with universities; promote internship scenarios)	PRDoH	PRDoH- Epidemiology and Research Division
	Increase labs electronic reports through PRHIE	PRDoH	PRDoH- Epidemiology and Research Division

Goal 5: Achieve integrated and coordinated efforts among all partners and stakeholders addressing the viral hepatitis epidemics

Objective 5.1: Integrate programs to address the syndemic of viral hepatitis, HIV, STIs, and substance use disorders			
Strategy:	**Activities**	**Target population**	**Responsible stakeholders**
Develop collaboration and training agreements	Identify areas of collaboration between the programs, analyze their gaps and strengths, and provide training to prepare a joint Work Plan	State, service providers, NPOs and Community Based	PRDoH, ASSMCA, ASES, Service Providers, Laboratories, Pharmaceuticals, Academia

Objective 5.2: Improve mechanisms to measure, monitor, evaluate, report, and disseminate progress toward achieving organizational, local, and national goals			
Strategy: Strengthen reporting system (monitoring)	**Activities**	**Target population**	**Responsible stakeholders**
	Develop and maintain an interactive dashboard to share and disseminate viral hepatitis epidemiological data	Service providers, organizations, institutions	PRDoH
	Development of mechanisms to disseminate information related to viral hepatitis on a monthly basis	Organizations, PRDoH	PRDoH

IMPLEMENTATION AND EVALUATION

Plan Implementation Approach

Implementation

The Viral Hepatitis Elimination Plan 2023-2027 establishes a roadmap to carry out systematic efforts with a comprehensive approach among the different stakeholders linked to the issue. Once the Plan is presented to the Federal Government, it is expected to develop the corresponding Action Plans aimed at its implementation. In terms of the structure for its implementation, it is recommended that the Committee established for purposes of the planning process be kept active and members be added according to the needs identified to implement the Plan. The objective of this working group will be to promote, provide guidance and follow-up on the development and implementation of the work plans derived from this Plan. For this, bi-monthly work meetings will be held. In addition, through the process, reporting and accountability mechanisms will be established for the stakeholders who participated in the planning process. This has the objective of reporting on the level of progress in the implementation of the Plan and obtaining their input to refine aspects that are pertinent in the implementation.

Evaluation and monitoring

As a complementary document to this Plan, the PRDoH will develop a detailed evaluation plan that will allow monitoring the implementation of this Plan, focusing on the principles of process, performance, and impact evaluation.

Through an approach that will use various sources of information, data and indicators will be collected on the products of the activities established for each strategy and the results with respect to the five goals of the Plan and their corresponding objectives.

The information that is collected through the different sources will be aggregated and presented during the Committee meetings.

At the end of each calendar year, an accountability activity aimed at participants in the planning process and the general public will be carried out, and a report summarizing the products and results achieved will be published. The report will be shared and discussed with the Committee to identify changes to ensure compliance and progress with the Plan. Likewise, the report will be available on the PRDoH's website, to receive feedback from the public.

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