



SPAIN

CAN ELIMINATE HEPATITIS

NATIONAL HEPATITIS ELIMINATION PROFILE

UPDATED JUNE 21 2022



Hepatitis B virus (HBV)

Hepatitis C virus (HCV)

YES*

NO

YES*

HBV elimination goal ¹ Elimination of HBV mother to child transmission goal ¹

HCV elimination goal ¹

At least 7 autonomous communities have HCV elimination strategic plans, including Andalusia, Aragon, Basque, the Canary Islands, Cantabria, Catalonia, and Navarre

**Adopted by the Alliance for the Elimination of Viral Hepatitis in Spain (AEHVE)*

THE HEALTH BURDEN OF VIRAL HEPATITIS

0.22 % (0.1-0.34%)

Prevalence of HBsAg, 2018 ³

Adults 20-80 yrs old

Prevalence of anti-HDV among persons HBsAg+, 2018, 7.7% ³



Prevalence

PREVALENCE IN EU/EEA:
HBSAG: 0.9%
ANTI-HCV: 1.1% ⁴²

0.17% (0.08-0.28%)

Prevalence of chronic HCV, 2018 ³

Adults 20-80 yrs old

Prevalence of anti-HCV, Persons who inject drugs, 2014: 64% ⁷

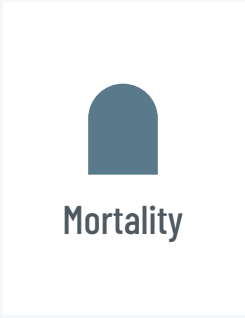
Prevalence of chronic HCV (RNA+), Persons born between 1958-1967, 2018: 0.5% ³

346
 New HBV
 infections, 2019 ⁴
 For acute HBV cases ⁴



1,382
 New HCV
 infections, 2019 ⁴
 For both acute and chronic HCV infections ⁴

954 (732 - 1,212)
 HBV related-deaths, 2019 ⁵
2.07 (1.59 - 2.63)
 Deaths per 100,000, 2019 ⁵



4,817 (4,031 - 5,638)
 HCV deaths, 2019 ⁵
5.9
 Deaths per 100,000, 2019 ¹³

PROGRESS TOWARDS 2020 WHO ELIMINATION GOALS

PREVENTION OF NEW INFECTIONS AND MORTALITY

HBV Percentage change in new infections, 2015-2019 **83%** ↑
 WHO 2020 Target -30% ⁴

HBV Percentage change in deaths, 2015-2019 **NO CHANGE**
 WHO 2020 Target -10% ³

HCV Percentage change in new infections **NO DATA**
 WHO 2020 Target -30%

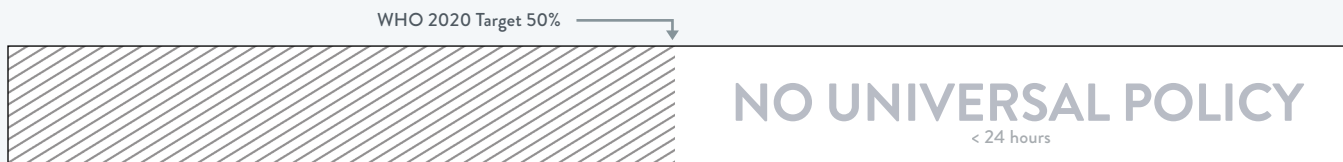
HCV Percentage change in deaths, 2015-2018 **-53%** ↓
 WHO 2020 Target -10% ³

Prevalence of HBsAg in children < 5 years (%) **0.03% (0.02-0.04%)**
 SDG 2020 Target 1% ³

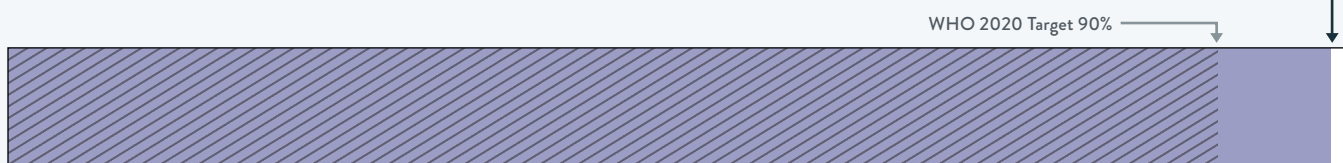


ACCESS TO RECOMMENDED VACCINATION, TESTING AND TREATMENT

Hepatitis B vaccination coverage for newborns



98% HepB 3 dose vaccine coverage for infants, 2020 ⁹



Proportion of persons living with HBV diagnosed



NO DATA **HBV**

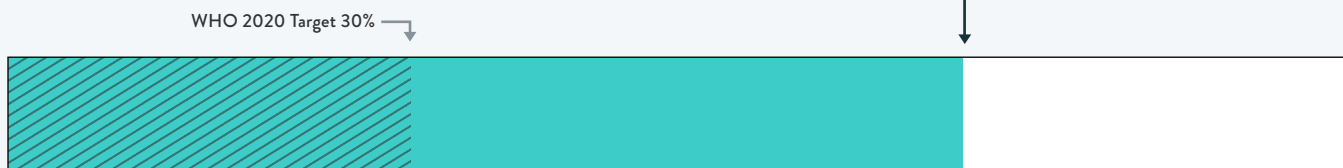
Proportion of diagnosed HBV persons receiving appropriate treatment

119

Number of needles-syringes per PWID per year, 2020 ¹⁰

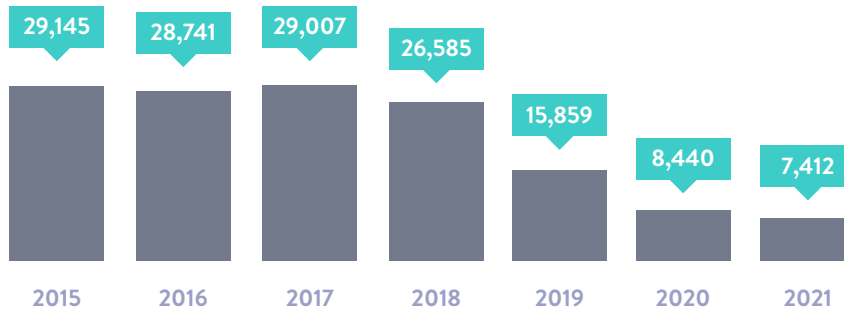
WHO 2020 Target 200

71% Proportion of persons living with HCV diagnosed, 2016 ³



154,080

Number of persons treated for HCV, 2015-2021 ³⁶



In 2018, Spain was one of 12 countries on track for HCV elimination, but the COVID-19 pandemic has hindered efforts to maintain the cascade of care for HCV and many microelimination programs.

In Madrid, over 90% of those in high-risk groups have been tested for HCV and over 96% of individuals eligible for treatment are either in ongoing treatment or treated. ¹²

POLICY ENVIRONMENT FOR THE ELIMINATION OF HEPATITIS



ACHIEVEMENT



INNOVATIONS



ROADBLOCKS

STRATEGIC INFORMATION

Routine official reports to monitor HBV and HCV ¹³

Mortality Incidence Prevalence

Estimates of HBV and/or HCV economic burden ^{15,16,17}

Partially Adopted

No studies for HBV

Monitoring of HBV and HCV diagnosis and treatment ²

Partially Adopted

SITHepaC, the Chronic Hepatitis C Patient Treatment Monitoring Information System, monitors HCV diagnosis and treatment. The autonomous communities report diagnosed cases of chronic HBV. Data on HBV treatments are not collected.



ACHIEVEMENTS

Spain has treated more patients per million population than any other country ¹⁴ and launched the Hepatitis C Approach Plan in the National Health System (PEAHC).

The annual percent decline in HCV-related mortality accelerated 6-fold, from about -3% to -18% after the introduction of direct acting antivirals (2001-2014 vs 2015-2018) ¹³. A decrease in the indications for liver transplantation due to HCV has also been observed in this period





ROADBLOCKS

Reporting of acute and chronic HBV and HCV cases to the Ministry of Health from the autonomous regions can be incomplete and not standardized, impairing interpretation.

SITHepaC does not track total number of HCV tests performed

PREVENTION OF MOTHER TO CHILDREN TRANSMISSION

Policy for hepatitis B vaccination of newborns (within 24 hours) ³⁵

Partially Adopted

Selective policy: newborns born to mothers HBsAg+

Recommendations for:

HBV testing of pregnant women ¹⁹

Adopted

HCV testing of pregnant women ¹⁹

Not Adopted

ACCESS AND REGISTRATION OF MEDICINES AND TESTS

HCV: Registration of originator DAAs ²⁰

Adopted

HCV: Eligible for generic DAAs ²¹

Not Eligible

HCV: Registration of generic medicines

Not Applicable

Licensed point-of-care PCR testing to detect HBV and HCV ²²

Adopted

TESTING TO DIAGNOSE HBV AND HCV INFECTION

Testing recommendations for:

HBV: Risk-based ^{2,25}

Adopted

HBV: Age-Cohort or Universal

Not Adopted



HCV: Risk-based ²

Adopted

HCV: Age-Cohort or Universal

Not Adopted

HDV (for HBsAg+ patients) ²⁵

Partially Adopted

No patient co-pays for HBsAg and anti-HCV testing ²²

Adopted

The region of Cantabria recommends age-cohort screening for persons 40-69 years-old ²⁴. In addition, the Andalusian Plan for Viral Hepatitis will also conduct age-based screening. Recommendations exist but not widely implemented.

The Spanish National Health Service offers free screening to everyone.



ACHIEVEMENTS

In 2019, AEHVE launched the national campaign “Give Hepatitis C a happy ending”, to which the well-known actor Carmelo Gómez lent his image for an ad that was screened in almost all of Spain’s cinemas.

In 2022, integrated screening of HBV, HDV and HCV with one sample was recommended by Asociación Española para el Estudio del Hígado (AEEH), la Alianza para la Eliminación de las Hepatitis Víricas en España (AEHVE), el Grupo de Estudio de las Hepatitis Víricas (GEHEP) de la Sociedad Española de Enfermedades Infecciones y Microbiología Clínica (SEIMC) y la Sociedad Española de Patología Digestiva (SEPD) ²⁵



INNOVATIONS

Many hospitals have implemented programs to find HCV patients loss to follow-up and re-link them to care

Many hospital systems have implemented HCV reflex virologic testing-- reducing the number of clinic visits by 2 from screening to HCV treatment initiation. In two years, the percent of hospitals implementing HCV reflex testing or “diagnosis in one-step” increased from 31% to 89% according to AEHVE ^{23,38}



ROADBLOCKS

Since the majority of patients living with hepatitis C are unaware of their infection, additional screening guidance beyond risk-based recommendations are needed to increase HCV case findings-- either universal or age-cohort screening should be considered. Universal screening or age cohort screening is a recommendation from scientific societies that, until now, has not been incorporated into the Screening Guide of the Ministry of Health.

Point-of-care testing remains underutilized and underappreciated as a critical tool for reaching vulnerable populations. A 2020 study by AEHVE found only between 28-35% of all participating hospitals reporting having dried blood spot technology available

Additional public awareness campaigns are needed to increase demand for testing





ACCESS TO HBV AND HCV TREATMENT

HBV: National treatment guidelines ²⁶

Developed

Simplified care: Simplified treatment and monitoring algorithm for primary care providers

Not Adopted

Simplified care: No patient treatment co-pays ¹⁹

Adopted

HCV: National treatment guidelines ⁸

Developed

Simplified care algorithm: Less than 2 clinic visits during treatment ¹⁹

Not Adopted

Simplified care algorithm: Non-specialists can prescribe treatment ²⁷

Not Adopted

Simplified care algorithm: No patient treatment co-pays ¹⁹

Adopted

No fibrosis restrictions ²⁷

Adopted

In June 2017, the Ministry of Health extended eligibility to all patients, regardless of their level of fibrosis

No sobriety restrictions ²⁷

Adopted

No genotyping ²²

Adopted

HDV: National treatment guidelines ²⁶

Partially Adopted

Included in HBV treatment guidelines but not fully implemented



ACHIEVEMENTS

In 2015, the National Health System in Spain launched a plan to progressively provide access of all HCV-infected patients to the DAAs regimens without treatment restrictions ¹⁴

In February 2017, scientific societies and patient associations created the Alliance for the Elimination of Viral Hepatitis in Spain (AEHVE), to advance progress toward hepatitis elimination

Prior to COVID-19, Spain had the highest number of hepatitis C treatments per million inhabitants



INNOVATIONS

To accelerate the elimination of the disease in Spain, AEHVE created the #hepCityFree program expanding commitments of city councils. Sevilla was the first city to sign-on to #hepCityFreesample



ROADBLOCKS

Primary care providers are not permitted to prescribe HBV and HCV treatment

Some patients receive positive HCV serological tests but are not linked to care

HEALTH EQUITY AND ADDRESSING DISPARITIES

National strategy addresses populations most affected ²

Adopted

National anti-discrimination laws against persons living with hepatitis B and/or C ¹⁹

Not Adopted

National policy for adult hepatitis B vaccination ²⁸

Adopted

For people who inject drugs, people who are incarcerated but lacks other groups with risk behaviors, including contacts of HBsAg+ carriers

National policy for:

Harm reduction for persons who inject drugs (PWID) ²⁹

Adopted

Syringe exchange in federal prisons ³⁰

Adopted

Number of needles/syringes per PWID per year ¹⁰

119

WHO 2020 Target 200

Number of opioid substitution therapy recipients per 100 PWID ^{19,28}

90

Decriminalization of possession of syringes & paraphernalia ²⁹

Adopted

Decriminalization of drug use ²⁹

Partially Adopted





INNOVATIONS

The Prison Hepatitis Project in Catalonia reduced the viremic HCV prevalence from 4.3% in June 2018 to 1.6% in September 2019 through practices such as HCV screening upon admission, HCV treatment without restrictions, and a liaison nurse coordinating continuation of HCV treatment after persons are released from prison ⁴⁰

Micro-elimination project planned in Balearic Islands among persons who inject drugs ¹²

Dried blood spot testing has been shown to be an effective screening strategy for reaching people who inject drugs ³⁷

In Madrid, a simplified point-of-care model (OraQuick rapid HCV antibody test, Xpert HCV VL fingerstick assay) for screening for active HCV infection via a mobile unit with nurse and a navigator/educator achieved 77% linkage to care ⁴¹



ACHIEVEMENTS

Drug consumption rooms are available in all parts of the country

In 2016, Spain initiated an innovative pilot program to screen and treat HCV in prisons. A clinical trial, JAILFREE-C study, evaluated systematic HCV screening and treatment among those residing in El Dueso – a long-stay prison. The program cured > 95% of treated prisoners



ROADBLOCKS

Spain's fragmented health system does not always serve high-risk populations, such as persons who are incarcerated

Late presentation of chronic HCV remains common. Studies by Picchio et al found that about one-fourth of the patients including PWID present with advanced liver disease or late-stage liver disease at first consultation for HCV care ^{32,34}

During COVID-19, a survey of 11 harm reduction centers found that the average number of service users across decreased by 22% in comparison to the same period in the previous year and the average needle distribution decreased by 40% in comparison to 2019 ³⁹

Despite progress in improving access to HCV treatment for persons who are incarcerated, additional barriers include lack of integration of prison health records and comunidades health records, limited number of liver specialists in the prison system, and the need to transfer patients to a hospital setting to deliver treatment

In Catalonia, the HepCdetect II Study found only 32% of PWID with HCV infection are treated. Only 18% of HCV infected migrants who are PWID are treated for HCV ³¹

Additional efforts are needed to monitor reinfection of men who have sex with men and persons who inject drugs



FINANCING

Public budget line for HBV and HCV testing and treatment ³⁴

Adopted

Funds from the Global Fund for TB, AIDS, and Malaria used for co-infected patients, when relevant

Not Applicable



ACHIEVEMENTS

To reduce the total cost of treatment, the Ministry of Health negotiated volume-pricing agreements

The government also offered credit facilities so that the regions' DAA HCV treatment spending would not affect their long-term financial stability—a mechanism similar to those deployed for other public health programmes



ROADBLOCKS

Regional governments concerned by non-drug costs of elimination program, including staffing and infrastructure costs

Additional funding is needed for expanded case finding



NEXT STEPS TOWARD ELIMINATION



Consider expanding HCV screening recommendations for universal (at least once in a lifetime) or age-cohort (i.e. 50-70 yr olds) to increase number of persons diagnosed



Find untreated patients with positive serology tests and re-link to care



Expand “test and treat” program for persons who are incarcerated and simplify treatment algorithm in prison settings



Ensure coordination across autonomous communities on testing and treatment policies



Implement micro-elimination strategies and continue to expand outreach programs and pathways to care for vulnerable populations, including PWID, MSM, and migrants



Seek to implement test and treat strategies for immediate treatment initiation after HCV diagnosis



Implement micro-elimination strategies for PWID, MSM, and immigrants from areas with a high prevalence of HCV infection



Establish coordination pathways between primary care providers and liver specialists



Create HBV and HCV community testing sites and referral centers



Include viral hepatitis prevention, testing, and treatment in the primary care portfolio of common services offered at primary care providers, “la cartera de servicios”



Invest in public awareness campaigns on hepatitis to reduce stigma and improve general understanding of risk behaviors and prevention



Establish indicators to monitor HCV care services and progress toward elimination



Continue to expand reflex HCV testing and simplify the testing algorithm to improve linkage to care



Emphasize the need for follow-up with specialists in the case of F3/ F4 patients to monitor liver cancer risk and liver functioning

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WORKING TOGETHER, WE WILL ACHIEVE ELIMINATION.



COALITION
FOR GLOBAL
HEPATITIS
ELIMINATION

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