



ITALY

CAN ELIMINATE HEPATITIS

NATIONAL HEPATITIS ELIMINATION PROFILE

UPDATED JUNE 21 2022



Hepatitis B virus (HBV)

HBV elimination goal:
Goals planned for in
upcoming action plan ¹

**Elimination of HBV mother
to child transmission goal: ¹**

Italy achieved the 2020
interim goal for prevention of
perinatal HBV transmission

Hepatitis C virus (HCV)

In 2019, Italy was one of only nine countries
on track to eliminate HCV by 2030 ²

HCV elimination goal:
Goals planned for in upcoming action plan. National
HCV screening program for elimination in place. ¹

Draft national guidelines on diagnosis and
treatment for hepatitis C virus infection released
as part of forthcoming national plan ⁴⁰

THE HEALTH BURDEN OF VIRAL HEPATITIS

~1%

Prevalence of HBsAg, 2020 ¹⁰*Modelled estimate*

Prevalence of HBsAg among Italian-born persons less than 42 years of age is very low due to vaccine protection. The majority of Italian-born carriers are in their fifth decade of life who acquired infection when younger.



Prevalence

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



0.68% (0.54–0.82%)

Prevalence of chronic HCV, 2020 ⁵*Modelled estimate*

Regional prevalence of HCV chronic active infection (HCV RNA positive), 2020 ⁵

North: 0.47% to 0.67%

Central: 0.74% to 1.04%

South: 0.64% to 1.01%

Isles regions: 0.66% to 0.76%

Modelled estimate

Prevalence of anti-HCV, Persons who inject drugs (PWID), 2019, 62% ⁶

Prevalence of anti-HCV, Persons who are incarcerated, 10–14% ³³

A large number of HCV infections occurred in the 1950s and 1960s via iatrogenic transmission due to the use of unsterilized tools/materials (e.g., glass syringes used for vaccinations and injecting antibiotics and vitamins and dental tools). This was followed by a second wave of infection in the period 1980–1990 associated with injection drug use. Today, the blood supply is screened and is very safe. ²

0.18

HBV cases per
100,000 persons, 2021 ¹³

SEIEVA underestimates incidence because
only tracks symptomatic disease



Incidence

0.05

HCV cases per
100,000 persons, 2021 ¹³

Based on Integrated Epidemiologic
System of Acute Hepatitis

SEIEVA underestimates incidence because
only tracks symptomatic disease

1,714 (1,517–1,927)

HBV-related deaths, 2019 ⁴

*Modelled estimate from Global
Burden of Disease Study 2019*

2.84 (2.52–3.19)

Deaths per 100,000, 2019 ⁴

Mortality

8,050 (7,096 –8,856)

HCV-related deaths, 2019 ⁴

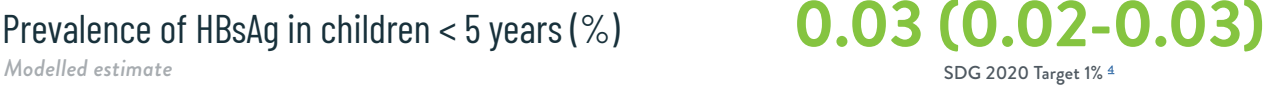
*Modelled estimate from Global
Burden of Disease Study 2019*

13.3 (11.80–14.70)

Deaths per 100,000, 2019 ⁴

PROGRESS TOWARDS 2020 WHO ELIMINATION GOALS

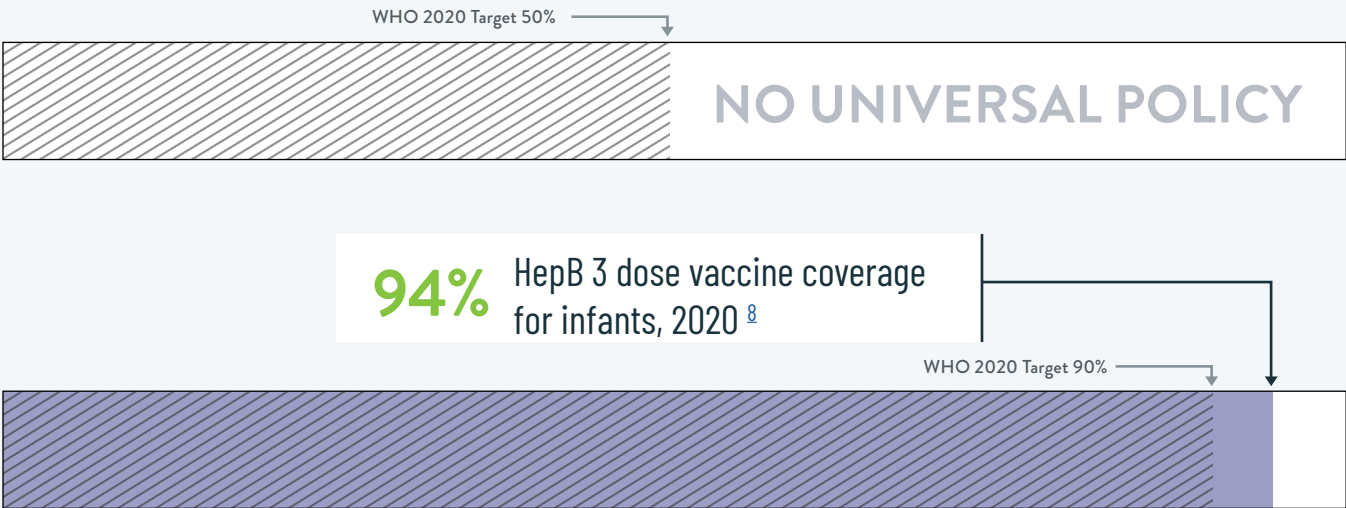
PREVENTION OF NEW INFECTIONS AND MORTALITY

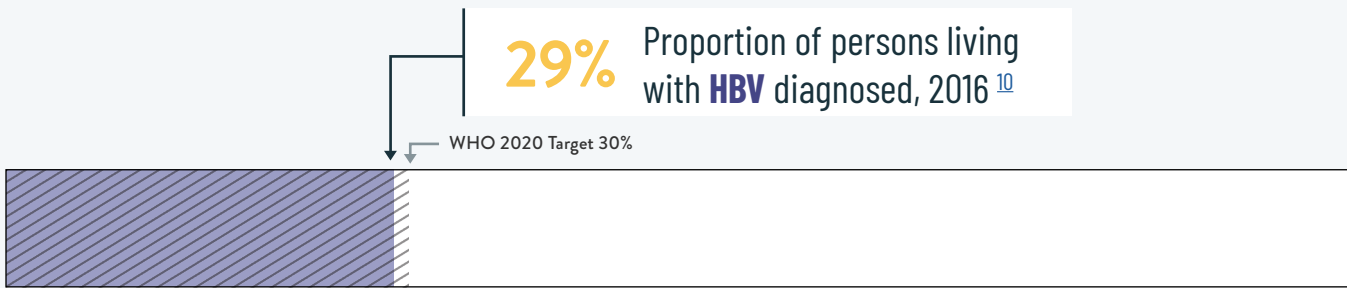


Due to the extensive roll-out in treatment since 2015, a 65% reduction in liver-related death is forecasted in Italy by 2022-2025 ¹⁹

ACCESS TO RECOMMENDED VACCINATION, TESTING AND TREATMENT

Hepatitis B vaccination coverage for newborns





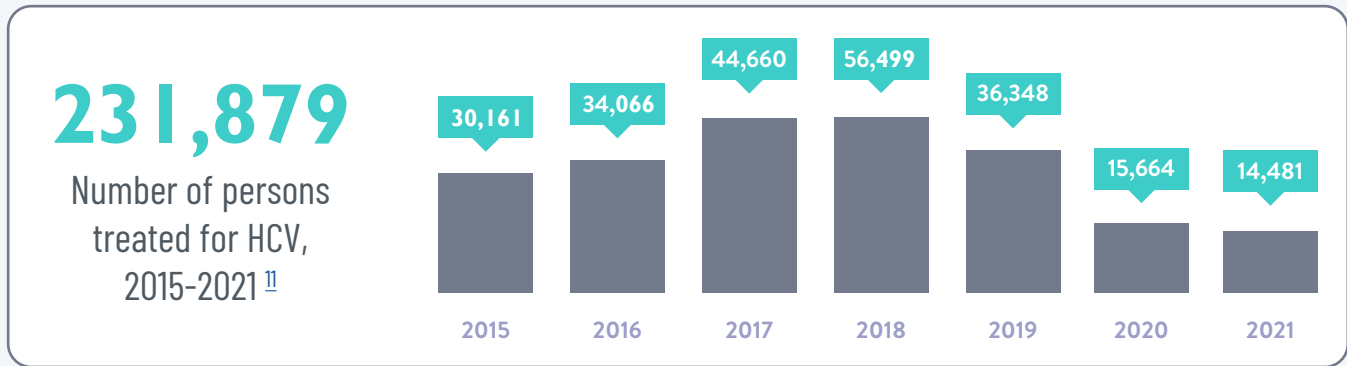
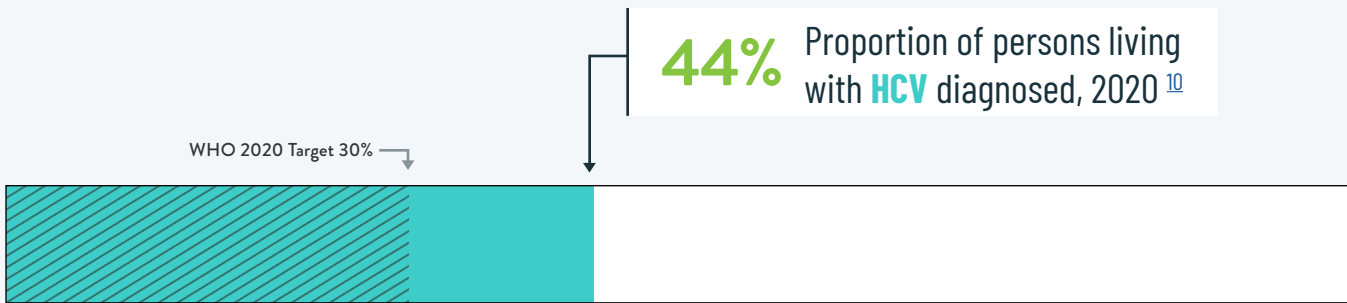
NO DATA **HBV**

Proportion of diagnosed HBV persons receiving appropriate treatment

NO DATA

For persons who inject drugs (PWID), number of sterile needles-syringes per year, 2020 ⁹

WHO 2020 Target 200



Note: Discrepancies among the number of treatments per year and the cumulative number 2015-2021 are due to overlap in reporting periods or missing time periods in reported data





POLICY ENVIRONMENT FOR THE ELIMINATION OF HEPATITIS



ACHIEVEMENT



INNOVATIONS



ROADBLOCKS

STRATEGIC INFORMATION

Routine official reports to monitor HBV and HCV ^{1,13}

Mortality

Modelled annually, but there is no national or official registry.

Incidence

The SEIEVA (Integrated Epidemiological System of Acute Viral Hepatitis) Surveillance system was created in 1985

Prevalence

Estimates of HBV and/or HCV economic burden ^{14,15,35,36}

Adopted

Monitoring of HBV and HCV diagnosis and treatment ¹¹

Partially Adopted

The Italian Medicines Agency (AIFA) releases weekly reports of number of persons treated for HCV.

No monitoring data for HBV



ACHIEVEMENTS

The Italian Medicines Agency releases weekly reports on number of HCV treatments prescribed.

Recently, a law decree was established that requires all newly diagnosed acute and chronic hepatitis cases to be reported to the local health authority within 48 hours.¹⁶



ROADBLOCKS

No system in place for tracking HCV testing
Currently no register exists for patients diagnosed with Hepatitis in Italy. ²

Lack of data to guide policy development for key populations, including migrants and refugees, persons who inject drugs, and persons who are incarcerated.



PREVENTION OF MOTHER TO CHILDREN TRANSMISSION

Policy for hepatitis B vaccination of newborns (within 24 hours, in addition to 3-dose schedule starting at 1 month) ¹⁷

Partially Adopted

Selective HepB birth dose policy only for infants born to HBsAg+ mothers

Recommendations for:

HBV testing of pregnant women ¹⁷

Adopted

HCV testing of pregnant women ¹²

Adopted

As of 2019, 97.7% coverage of antenatal HBV screening ¹⁷. Mandatory by law since 1991. Following screening, babies born to infected mothers will be treated at birth with HBIG and receive HepB vaccine (monovalent) and then they will receive 3 additional doses of vaccine (hexavalent) at 1, 2 and 12 months. In reality, most of them receive also the dose of hexavalent vaccine at 4 months even if hep B vaccine at that time would not be prescribed.



ACHIEVEMENTS

In January 2020, Italy became one of the first counties in Europe to be validated for achieving the regional hepatitis B countries control targets. ¹⁷

ACCESS AND REGISTRATION OF MEDICINES AND TESTS

HCV: Registration of originator DAAs ¹¹

Adopted

HCV: Eligible for generic DAAs ¹⁸

Not Eligible

Licensed point-of-care PCR testing to detect HBV and HCV ¹⁹

Partially Adopted

Recommended only for HCV testing among persons who inject drugs in settings where the HCV prevalence has been confirmed to very high.



ROADBLOCKS

Point-of-care PCR testing is not broadly used, limited to only persons who inject drugs in settings that have been confirmed to have a high HCV prevalence.



TESTING TO DIAGNOSE HBV AND HCV INFECTION

Testing recommendations for:

HBV: Risk-based (including pregnant women) ¹

Adopted

HBV: Birth-Cohort or Universal

Not Adopted

HCV: Risk-based ¹

Adopted

Risk-based HCV testing policy adopted in 2015 national action plan, including policies for screening migrants.

HCV: Universal ³⁹

Partially Adopted

HDV ¹²

Partially Adopted

HDV screening is recommended for patients living with HBV but not widely implemented. HDV RNA testing is not free of charge

No patient co-pays for HBsAg and anti-HCV testing ¹⁹

Partially Adopted

No patient co-pays for HCV testing for persons recommended for testing as part of “Milleproroghe Decree.”

Universally recommended for adults born between 1948-1988. The “Milleproroghe Decree” includes free-of-charge HCV screening for the general population born between 1969 and 1989, persons receiving public drug addiction services (SerT), and persons who are incarcerated.

Co-pays required for HBsAg testing.



ACHIEVEMENTS

In March 2020, the Italian government approved the “Milleproroghe Decree”, allocating €71.5 million for 2020- 2021 to screen at no charge persons born 1969- 1989, persons receiving public drug addiction services (SerT), and persons who are incarcerated.



INNOVATIONS

A number of pilot projects have been underway to explore integration of SARS-CoV-2 testing and/or COVID-19 vaccination with HCV screening. ^{20,37}



ROADBLOCKS

Screening policies not fully implemented.

Cost-effective screening strategies such as laboratory-based reflex testing are not yet fully implemented ³². Barriers limit general practitioners because it is defined by the system as two steps process and it is not changed yet for the lack of a clear roadmap in different regions among GP and regional System, but not because of perceptions of additional cost. The cost is the same, but there is not a defined path in the administrative system of each region

Effective implementation of the Milleproroghe Screening Decree will require additional planning, including investments in raising awareness, and the mapping of public and private affiliated laboratories that will be reimbursed, with the development of specific exemption codes for reimbursement.

Limited implementation of HCV point-of-care testing for key populations, including persons who inject drugs and persons who are incarcerated.

ACCESS TO HBV AND HCV TREATMENT

HBV: National treatment guidelines ^{21,22}

Partially Developed

Simplified care: Simplified treatment and monitoring algorithm for primary care providers ²²

Partially Adopted

Simplified care: No patient treatment co-pays ¹²

Adopted

HCV: National treatment guidelines ^{23,40}

Developed

Simplified care algorithm: Less than 2 clinic visits during treatment ²³

Partially Adopted

Monthly dispensing of DAAs with monitoring is required, but no blood tests are needed.

Simplified care algorithm: Non-specialists can prescribe treatment ²²

Not Adopted

Recommendations on HCV treatment in key populations is forthcoming that will encourage a model of care that leverages telemedicine for initiation of treatment and monitoring by specialists

Simplified care algorithm: No patient treatment co-pays ²⁴

Adopted

No fibrosis restrictions ²⁵

Adopted

No sobriety restrictions ²⁵

Adopted

No genotyping ²⁵

Not Adopted

HDV: National treatment guidelines ²¹

In Development



ACHIEVEMENTS

The Italian Association for the Study of the Liver (AISF) and the Italian Society of General Medicine published “Practical guidelines for a model shared management between General Practitioners and Hepatologist Specialist of the patient with hepatitis chronic hepatitis B virus and hepatitis C virus.”



INNOVATIONS

The HCV Network Sicily is a web-based, hub-and-spoke model connecting 41 clinical centres and 101 specialist physicians (e.g gastroenterologists, hepatologists) managing HCV care. The network strategies for linking specialists with General Practitioners (GPs) include 1) communication of HCV therapeutic innovation to 1180 GPs in collaboration with SIMF 2) a web-based platform for GPs to follow the course of HCV diagnosis and treatment for their patients and 3) of “round tables of specialists and GPs.

Prior to implementation of the national HCV screening program, a structured communication strategy for sensitizing the targeted birth cohort and key populations was developed.



ROADBLOCKS

Italy is divided into twenty regions which have broad discretion in planning, organizing, and financing health care services within their territory, thus additional regional planning for hepatitis elimination is needed. ³⁸

Only specialists can prescribe hepatitis C treatment.

Additional coordination is needed between general practitioners, reference laboratories, and specialists to improve linkage to care.

In 2019, about 20% of HCV patients in the treatment monitoring registry had cirrhosis, which could suggest the need for early access to HCV testing and prompt linkage to care ⁵

HEALTH EQUITY AND ADDRESSING DISPARITIES

National strategy addresses populations most affected ¹

Adopted

National policy for adult hepatitis B vaccination ^{6,27}

Adopted

HBV vaccination recommended for health professionals, hospital staff and care personnel, private nursing homes and certain all other groups indicated in the Ministerial Decree of 4 October 1991. HBV vaccination is available to persons who are incarcerated and persons in drug treatment.

National policy for:

Harm reduction for persons who inject drugs (PWID) ²⁸

Developed

Syringe exchange in federal prisons ²⁸

Adopted

The northern regions are estimated to have the largest burden of PWID living with HCV, estimated at a total of 151,296 individuals. ⁵



Number of needles/syringes per PWID per year

No Data

WHO 2020 Target 200

Number of opioid substitution therapy recipients per 100 PWID

No Data

OST is available in all drug abuse services across the country

Decriminalization of possession of syringes & paraphernalia ²⁹

Adopted

There are about 150,000 persons receiving opioid agonist therapy nationally. About 54% have been screened and about 40% are anti-HCV positive. Linkage to care remains limited.

Decriminalization of drug use ²⁹

Adopted



ACHIEVEMENTS

HCV testing is guaranteed in all Italian prisons by the Essential Level of Assistance (LEA); about 90% of persons who are incarcerated are screened for HCV



INNOVATIONS

Linkage-to-care is high amongst PWID in prisons.



ROADBLOCKS

For PWID diagnosed with HCV in OST programs, linkage to HCV care is limited. In Campania, of the 14,630 patients followed in drug treatment centers, 9,931 (67.9%) had been tested and of these 3,796 (38.2%) were HCV positive. However, among the latter, only 20.7% had been treated ³¹

Not all populations with a high burden or at risk of infection were included in the HCV screening law decree, such as men who have sex with men. Until 40 years of age, the entire Italian population is covered free-of-charge hepatitis B vaccination.

FINANCING

Public budget line for HBV and HCV testing and treatment ¹⁹

Adopted



ACHIEVEMENTS

The government negotiated discounts for affordable HCV medicines.

The initial investment in HCV therapies is estimated to be recovered in 5.5 years. ¹⁵





ROADBLOCKS

The budget for national purchase of HCV therapies expired in April 2020. The lack of a dedicated fund for DAAs could stress overburdened regional budgets.

NEXT STEPS TOWARD ELIMINATION



Conduct additional epidemiological studies on burden of HBV and HCV in key populations, such as migrants and refugees, persons who inject drugs, and persons who are incarcerated



Implement and promote recommendations for HCV point-of-care screening for PWID, persons who are incarcerated, and other vulnerable populations



Expand HCV screening beyond the first investment in age-cohort screening and select high-risk groups



Strengthen efforts to link newly diagnosed patients to treatment



Simplify HCV care through broad adoption of reflex testing and removal of barriers for general practitioners to treat their patients for HCV



Improve HCV testing and linkage to care for PWID, particularly those in OST programs



Invest in restoring HCV testing and treatment to pre-pandemic levels



Encourage regions to develop hepatitis elimination implementation plans and funding for HCV treatment



Explore integration of SARS CoV-2 and HCV screening



Fully implement current screening recommendations



Strengthen awareness-building campaigns amongst the public and clinicians for risk factors associated with hepatitis and encourage reflex testing and the promotion of effective screening programs



Renew the national dedicated fund of the Italian State for “Innovative-Non Oncological-Drugs” for purchase of HCV medications



Promptly guarantee free-of-charge HCV screening and diagnosis for those in the 1948-1968 birth cohort excluded from the “free-of-charge screening” provided by the Milleproroghe Fund that only currently covers the 1969-1989 cohort and key populations





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WORKING TOGETHER, WE WILL **ACHIEVE ELIMINATION.**



COALITION
FOR **GLOBAL
HEPATITIS
ELIMINATION**

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