HBV elimination goal: Goals planned for in upcoming action plan

Elimination of HBV mother to child transmission goal:

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

HCV elimination goal:

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

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

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.

Prevalence of HBsAg, 2020

0.68% (0.54–0.82%)

Prevalence of chronic HCV, 2020

0.18

HBV cases per 100,000 persons, 2021

SEIEVA underestimates incidence because only tracks symptomatic disease

0.05

HCV cases per 100,000 persons, 2021

Based on Integrated Epidemiologic System of Acute Hepatitis

1,714 (1,517-1,927)

HBV-related deaths, 2019

Modelled estimate from Global Burden of Disease Study 2019

2.84 (2.52-3.19)

Deaths per 100,000, 2019

8,050 (7,096 -8,856)

HCV-related deaths, 2019

Modelled estimate from Global Burden of Disease Study 2019

13.3 (11.80-14.70)

Deaths per 100,000, 2019
PROGRESS TOWARDS 2020 WHO ELIMINATION GOALS

PREVENTION OF NEW INFECTIONS AND MORTALITY

**HBV**
- Percentage change in new infections, 2015-2020: -67%
  - WHO 2020 Target: -30%
- Percentage change in deaths, 2015-2019: -4%
  - WHO 2020 Target: -10%

**HCV**
- Percentage change in new infections, 2015-2020: -75%
  - WHO 2020 Target: -30%
- Percentage change in deaths, 2015-2019: -3%
  - WHO 2020 Target: -10%

Prevalence of HBsAg in children < 5 years (%): 0.03 (0.02-0.03)
- Modelled estimate
  - SDG 2020 Target: 1%

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

ACCESS TO RECOMMENDED VACCINATION, TESTING AND TREATMENT

**Hepatitis B vaccination coverage for newborns**
- WHO 2020 Target: 50%
- NO UNIVERSAL POLICY

**HepB 3 dose vaccine coverage for infants, 2020**
- 94%
  - WHO 2020 Target: 90%
**ITALY • HEPATITIS ELIMINATION PROFILE**

**COALITION FOR GLOBAL HEPATITIS ELIMINATION**

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**NO DATA**

Proportion of diagnosed HBV persons receiving appropriate treatment

**HBV**

**NO DATA**

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

WHO 2020 Target 200

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**44%**

Proportion of persons living with HCV diagnosed, 2020

WHO 2020 Target 30%

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**65%**

Proportion of diagnosed persons who have been cured, 2019

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**231,879**

Number of persons treated for HCV, 2015-2021

<table>
<thead>
<tr>
<th>Year</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>30,161</td>
</tr>
<tr>
<td>2016</td>
<td>34,066</td>
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<tr>
<td>2017</td>
<td>44,660</td>
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<tr>
<td>2018</td>
<td>56,499</td>
</tr>
<tr>
<td>2019</td>
<td>36,348</td>
</tr>
<tr>
<td>2020</td>
<td>15,664</td>
</tr>
<tr>
<td>2021</td>
<td>14,481</td>
</tr>
</tbody>
</table>

*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

STRAIGHT INFORMATION

Routine official reports to monitor HBV and HCV

Estimates of HBV and/or HCV economic burden

Monitoring of HBV and HCV diagnosis and treatment

Mortality

Monitoring of HBV and HCV diagnosis and treatment

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

Adopted

No system in place for tracking HCV testing

Currently no register exists for patients diagnosed with Hepatitis in Italy.

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

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.

ROADBLOCKS

No system in place for tracking HCV testing

Currently no register exists for patients diagnosed with Hepatitis in Italy.

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) **Partially Adopted**

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

Recommendations for:

- **HBV testing of pregnant women** **Adopted**
- **HCV testing of pregnant women** **Adopted**

As of 2019, 97.7% coverage of antenatal HBV screening **Adopted**
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. **Partially Adopted**

ACCESS AND REGISTRATION OF MEDICINES AND TESTS

**HCV:** Registration of originator DAAs **Adopted**

**HCV:** Eligible for generic DAAs **Not Eligible**

Licensed point-of-care PCR testing to detect HBV and HCV **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) ▼ ▼ ▼ 
  ▶ Adopted

- **HBV**: Birth-Cohort or Universal
  ▶ Not Adopted

- **HCV**: Risk-based ▼
  ▶ Adopted

- **HCV**: Universal ▼
  ▶ Partially Adopted

- **HDV** ▼
  ▶ Partially Adopted

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

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

**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 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. ▼ ▼ ▼
Screening policies not fully implemented. Cost-effective screening strategies such as laboratory-based reflex testing are not yet fully implemented. Barriers limit general practitioners because it is defined by the system as a two-step 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
- Simplified care: Simplified treatment and monitoring algorithm for primary care providers
- Simplified care: No patient treatment co-pays

**HCV:**
- National treatment guidelines
- Simplified care algorithm: Less than 2 clinic visits during treatment
- Simplified care algorithm: Non-specialists can prescribe treatment
- Simplified care algorithm: No patient treatment co-pays
- No fibrosis restrictions
- No sobriety restrictions

**HDV:**
- National treatment guidelines

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**Access to HBV and HCV treatment**

- **HBV:**
  - National treatment guidelines
  - Partially Developed
  - Simplified care: Simplified treatment and monitoring algorithm for primary care providers
  - Partially Adopted
  - Simplified care: No patient treatment co-pays
  - Adopted

- **HCV:**
  - National treatment guidelines
  - Developed
  - Simplified care algorithm: Less than 2 clinic visits during treatment
  - Partially Adopted
  - Simplified care algorithm: Non-specialists can prescribe treatment
  - Not Adopted
  - Simplified care algorithm: No patient treatment co-pays
  - Adopted
  - No fibrosis restrictions
  - Adopted
  - No sobriety restrictions
  - Adopted
  - No genotyping
  - Not Adopted

- **HDV:**
  - National treatment guidelines
  - In Development

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

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.
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.

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.

HEALTH EQUITY AND ADDRESSING DISPARITIES

National strategy addresses populations most affected

Adopted

National policy for adult hepatitis B vaccination

Adopted

National policy for:

Harm reduction for persons who inject drugs (PWID)

Developed

Syringe exchange in federal prisons

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.

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

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

Adopted

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

ACHIEVEMENTS

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.

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

Adopted

The government negotiated discounts for affordable HCV medicines.

ACHIEVEMENTS

The initial investment in HCV therapies is estimated to be recovered in 5.5 years.
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
11. Communication with Dr. Loreta Kondili, Istituto Superiore di Sanità Rome, on 8 February 2022.
18. MINISTERO DELLA SALUTE. Decreto del 7 marzo 2022. https://www.gazzettaufficiale.it/eli/id/2022/04/07/22A02179/5G
HCV-14_12_20.pdf


30. Communication with Dr. Alessio Agehmo, Associazione Italiana Studio del Fegato (AISF), on 22 February 2022.


WORKING TOGETHER,
WE WILL ACHIEVE ELIMINATION.

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