

Primary and Secondary Hepatitis Prevention and Control Programmes in Italy

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Sources

- Medical literature
- Data, recommendations and official documents of the Italian Association for the Study of the Liver (AISF)
- Joint documents with other scientific societies
- Data from Italian National Institute of Statistics (ISTAT) and from the Italian National Institute of Health (ISS)

Burden of disease in Italy

Chronic liver disease (CLD) is a leading health problem

- ~10,000 deaths/year due to cirrhosis or HCC
- ~ 2.5 million are infected by HBV or HCV
- Costs for the management of CLD continuously increasing due to:
 - Relative increase of individuals with long lasting HBV and HCV infections
 - Introduction of novel high costs therapies (HCC, antivirals)
 - Increase of metabolic and behavioral causes of liver disease (overweight, alcohol use, physical inactivity)

Epidemiological data on HCV and HBV

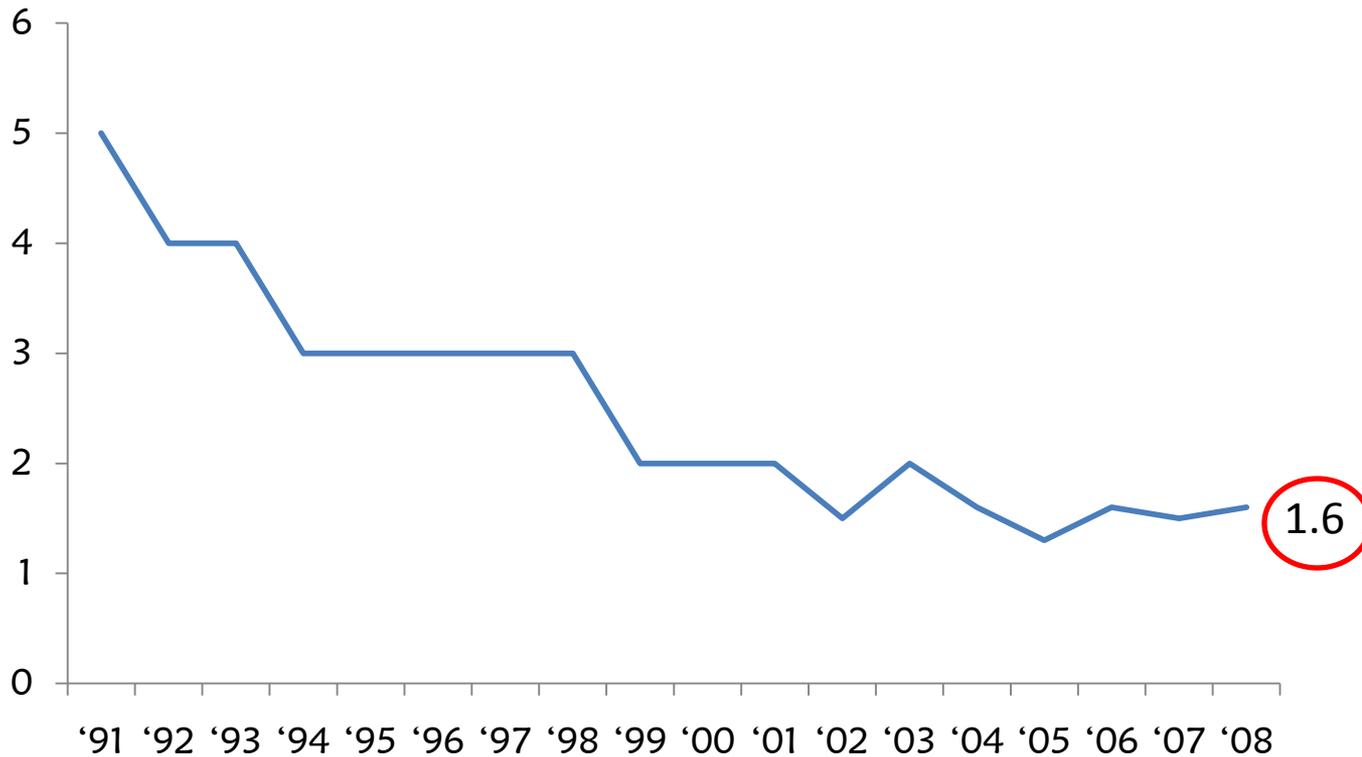
- **Prevalence:**

- Good quality general population studies, but outdated (1990s, early 2000s), conducted in small towns or communities, not including immigrants and other fragile populations
- Large, national, up to date epidemiological studies are lacking
- However, a reasonable estimate of current prevalence in the Italy is ~3% for HCV (higher in Southern regions and increasing with age); <1% for HBsAg among Italian born citizens (higher in immigrants)

- **Incidence:**

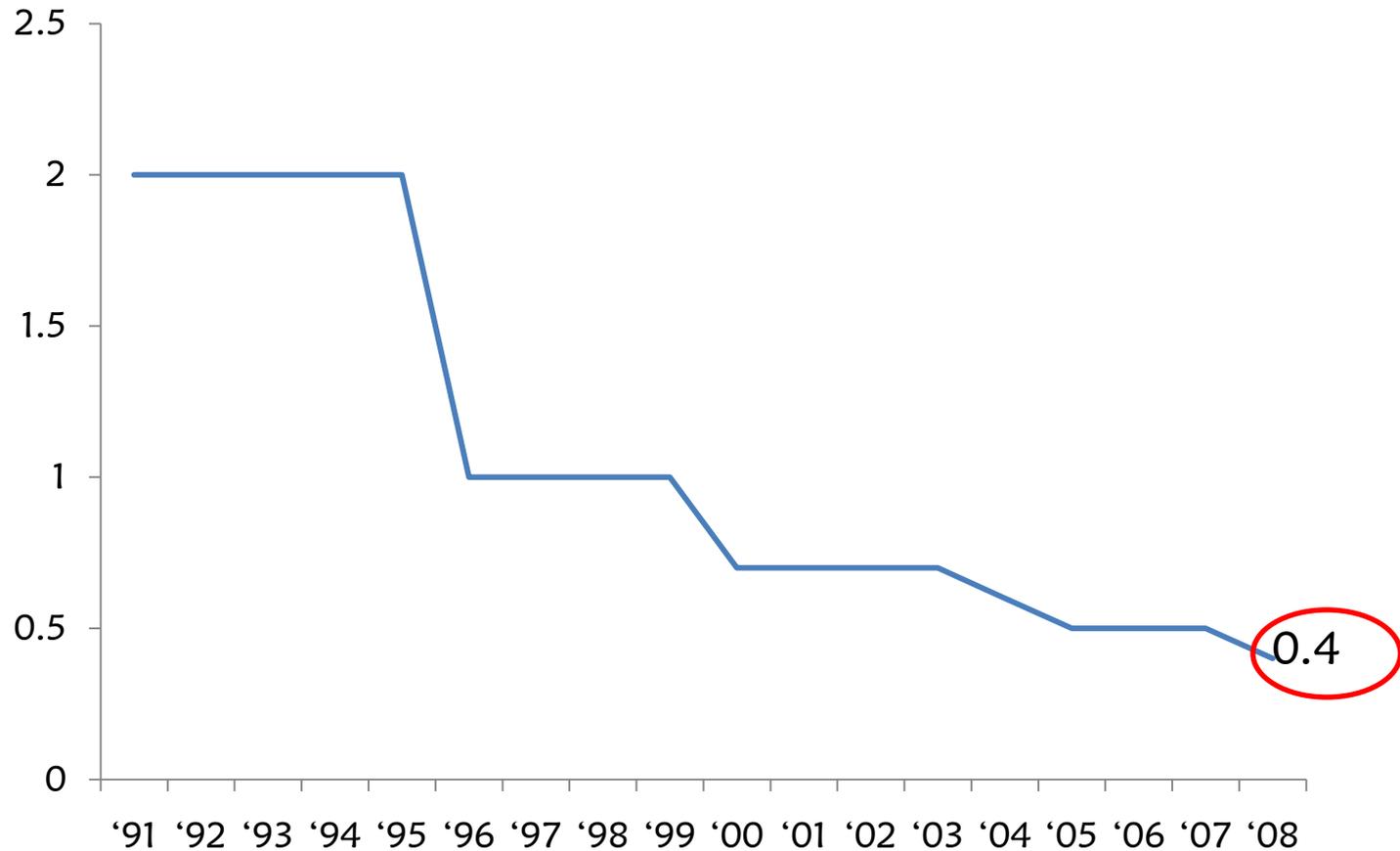
- National registry SEIEVA
- Acute hepatitis B and C is continuously decreasing due to HBV vaccination and improvement of safety in healthcare
- Most residual acute cases of HBV occur among middle aged and elderly subjects

Incidence (x 100,000) of acute hepatitis B per year



Courtesy from A. Mele, ISS; SEIEVA 1991-2008

Incidence (x 100,000) of acute hepatitis C per year



Courtesy from A. Mele, ISS; SEIEVA 1991-2008

Residual risk for HCV and HBV in Italy calculated per year until 2009 (with NAT screening)

(n of cases/10⁶ blood units and 95% C.I.)

| | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 |
|-----|-------------------------|-------------------------|-------------------------|-------------------------|--------------------------|-------------------------|
| HCV | 0.3 <i>(0.1-0.6)</i> | 0.2 <i>(0.1-0,4)</i> | 0.2 <i>(0.1-0.3)</i> | 0.2 <i>(0.1-0.3)</i> | 0.1 <i>(0.1-0.2)</i> | 0.1 <i>(0.1-0.2)</i> |
| HBV | - | - | 1.6 <i>(0.3-1.8)</i> | 1.9 <i>(0.9-2.7)</i> | 1.6 <i>(0.6- 2.1)</i> | 1.6 <i>(0.6-2.1)</i> |



The screening strategy in Italy

HBV and HCV: preventive measures currently adopted in Italy

- HBV vaccination in children and persons at risk (vaccine covers age Italian-born individuals until 30 years)
- Mandatory HBsAg screening of pregnant women
- Highly sensitive tests for blood donations (including NAT for HBV and HCV)
- Screening for risk factors of viral hepatitis and subsequent testing (HBsAg, anti-HCV) of those who are positive

Screening Strategy

- In Italy, it is currently agreed that testing for Hepatitis B and C among risk groups with elevated prevalence (i.e., *case finding*) is likely to be more cost-effective than a *mass screening* approach.
- **Well managed** screening for signs and symptoms of liver disease and risk factors for infection is therefore seen as the a key instrument of prevention.

Who should be screened

Anti HCV and HBsAg:

- Signs of chronic liver disease
- Sexual partners and family members of infected individuals
- Sexually promiscuous subjects
- Current and former IV drug users
- Prisoners
- Immigrants from highly endemic areas
- Children born to positive mothers
- HIV carriers
- Patients on dialysis
- Healthcare workers
- Other parenteral risk factors (e.g., unsafe tattoo or piercing)

HCV only:

- Blood transfusion and transplant recipients (before 1992)
- Hemophilia patients receiving blood derivatives before 1987

Open issues

- Is case finding **well managed** in Italy?
 - Subjects with increased ALT levels
 - “Vulnerable” subjects
 - Immigrants from endemic areas
 - Prisoners
 - Intravenous drug users

ALT evaluation by General Practitioners in Italy

- Data from 418 Italian General Practitioners using electronic clinical record (648,091 patients)
 - 70% of patients underwent at least one ALT determination
 - The prevalence of ALT increase was substantial (on average 10%, up to 29% in males of 45-54 years)
 - Only 37% of patients with ALT increase underwent anti-HCV testing
 - Only 54% of anti-HCV positive patients underwent HCV RNA testing
- *Recommendations are not properly followed*

HBV and HCV screening in Italian IVDU Primary Care Centers (2008 Report)

HCV

Percent tested for anti-HCV: 46%

Percent of reactivity: 59.2%

HBV

- Percent tested for HBV makers: 42%
- Percent of reactivity: 32.3%

National data on HBV vaccination and HCV treatment are currently not available.

HBV and HCV screening in Italian prisoners

- 973 Italian inmates
 - 87.0% males,
 - median age of 36 years
 - 30.4% intravenous drug users
- High seroprevalence rates were found
 - HIV: 7.5%
 - HCV: 38.0%
 - anti-HBc: 52.7%
 - HBsAg: 6.7%.

No comprehensive strategy to identify infected persons

Foreign citizens in Italy

- At the start of 2010 there were 4,279,000 foreign nationals resident in Italy and registered with the authorities.
- This amounted to 7.1% of the country's population and represented a year-on-year increase of 388,000.
 - Romania (953,000),
 - Albania (472,000)
 - Morocco (433,000)
 - China (181,000)
 - Ecuador (85,000)
 - Peru (83,000)
 - Senegal (71,000)

HBV and HCV in immigrants

- Small, scattered, mainly unpublished studies
- Prevalence of HBsAg ranged between 7.7% in Apulia, (South) to 8.9% in Northern Italy, to 39% in Tuscany (Centre); it was 3.1% in pregnant women
- Prevalence of anti HCV was 2.7%-4% (not higher than in autochthonous citizens)
- No comprehensive strategy to identify and treat infected persons or for vaccination

Future Plans

- Reinforce dissemination of case-finding guidelines, including screening programs among high risk groups;
- Encourage the implementation of best practice in targeted screening strategies
- Support awareness raising campaigns on viral hepatitis and increase uptake of screening;
- Help reduce health inequalities, addressing those most vulnerable and least likely to actively manage their health (prisoners, IVDUs, immigrants);
- Promote research on prevention and cure of Hepatitis B and C;
- Promote healthy lifestyles and behaviors



- **fire**: The Italian Foundation for Research in Hepatology
- Founded in 2009 by the Italian Association for the Study of the Liver (AISF)
- Specific aims (not addressed by AISF):
 - Improve fund raising to help scientific research, also encouraging cooperation with non-pharmaceutical companies
 - Support awareness raising campaigns on liver disease and increase uptake of screening
 - Promote healthy lifestyles and behaviors

Conclusions

(What is needed in Italy)

- Good quality, nation based epidemiological data
- To translate good recommendations and guidelines into good clinical practice
- A coordinated effort to increase awareness on liver disease
- A transparent discussion and disclosure of interests among the parties involved in improving screening policies
 - Patients (including the most vulnerable categories)
 - Physicians
 - National Health System
 - Pharmaceutical companies