



Viral Hepatitis Prevention Board

20 YEARS VHPB: ACHIEVEMENTS, IMPACT AND REMAINING
CHALLENGES IN PREVENTION AND CONTROL OF VIRAL HEPATITIS
12-14 Nov 2014 – Antwerp, Belgium

Beyond 20 years of universal vaccination in Italy: achievements and the way forward

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Hepatitis B vaccination in Italy (policy)

Selective
vaccination of
high risk groups

1983

February

1991

May, 27

- Universal vaccination of infants and adolescents (restricted to the first 12 years of vaccination)
- Screening of pregnant women
- Vaccination of high risk groups



HBV vaccination in Italy

Current status

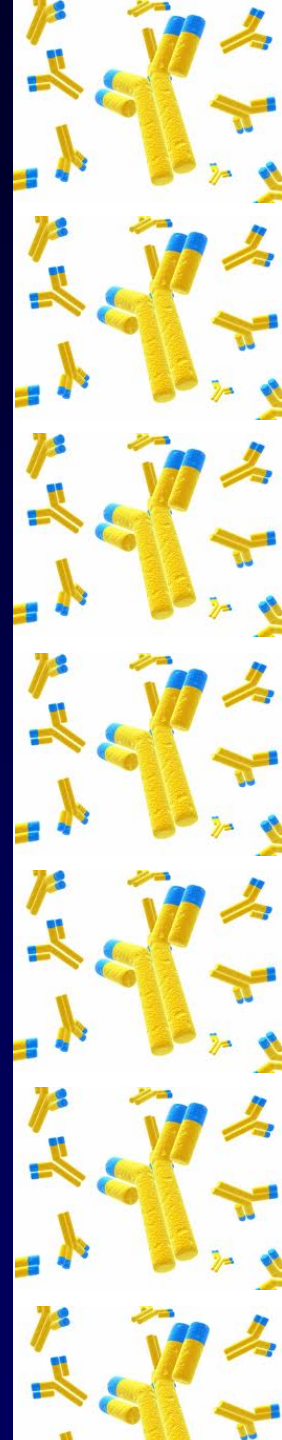
✓ Over 95% coverage rate

✓ Over 21 million individuals
(< 34 years) vaccinated



Hepatitis B vaccination: safety & immunogenicity

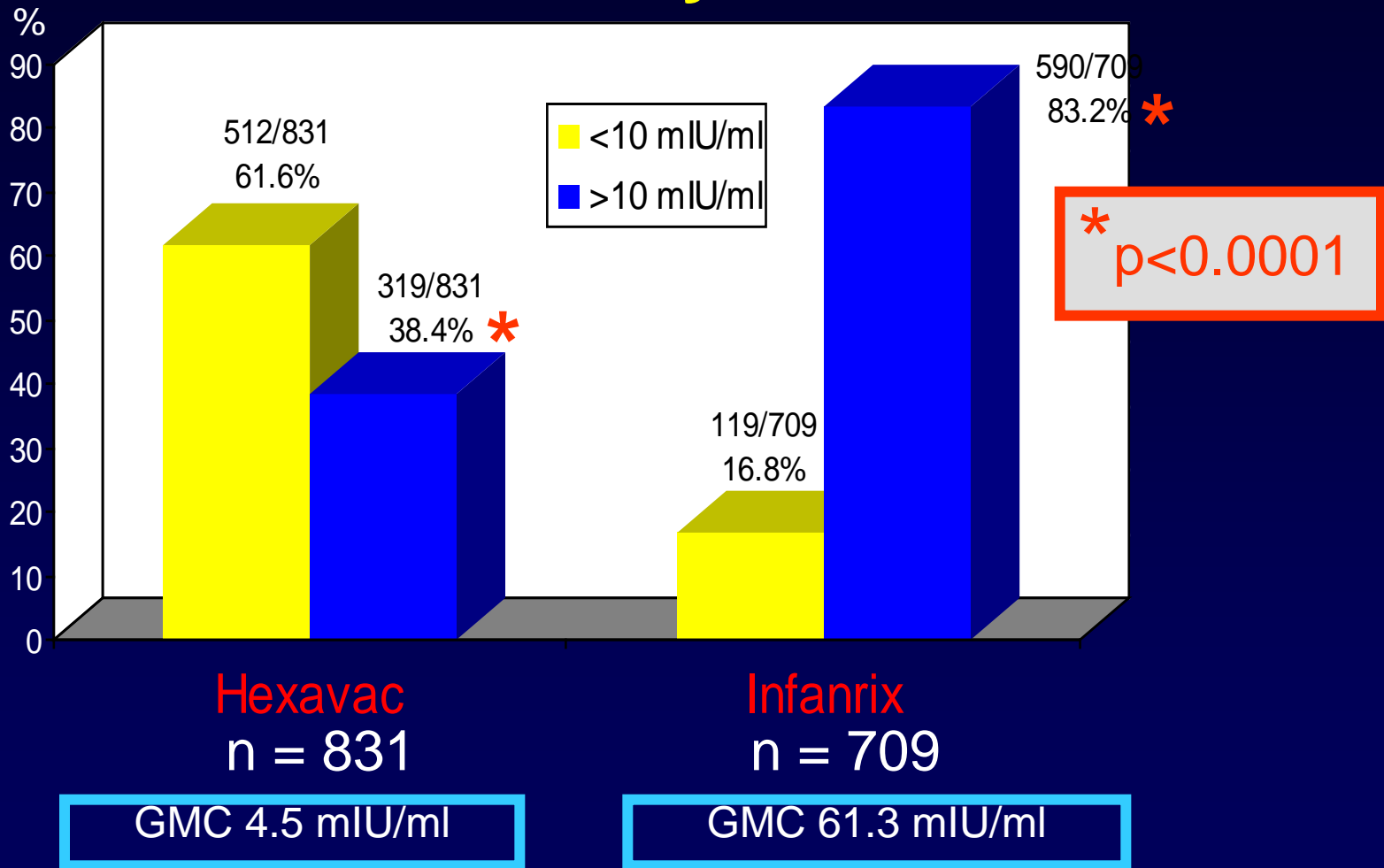
- Good safety profile and highly immunogenic.
- Seroprotection rates to anti-HBs close to 95-100 % in healthy vaccinees.
- Antibody declines over time, but immunological memory for HBsAg can outlast the antibody detection providing long-term protection.
- Vaccinees who lost Ab usually show a rapid and strong anamnestic response when boosted or exposed to HBV.



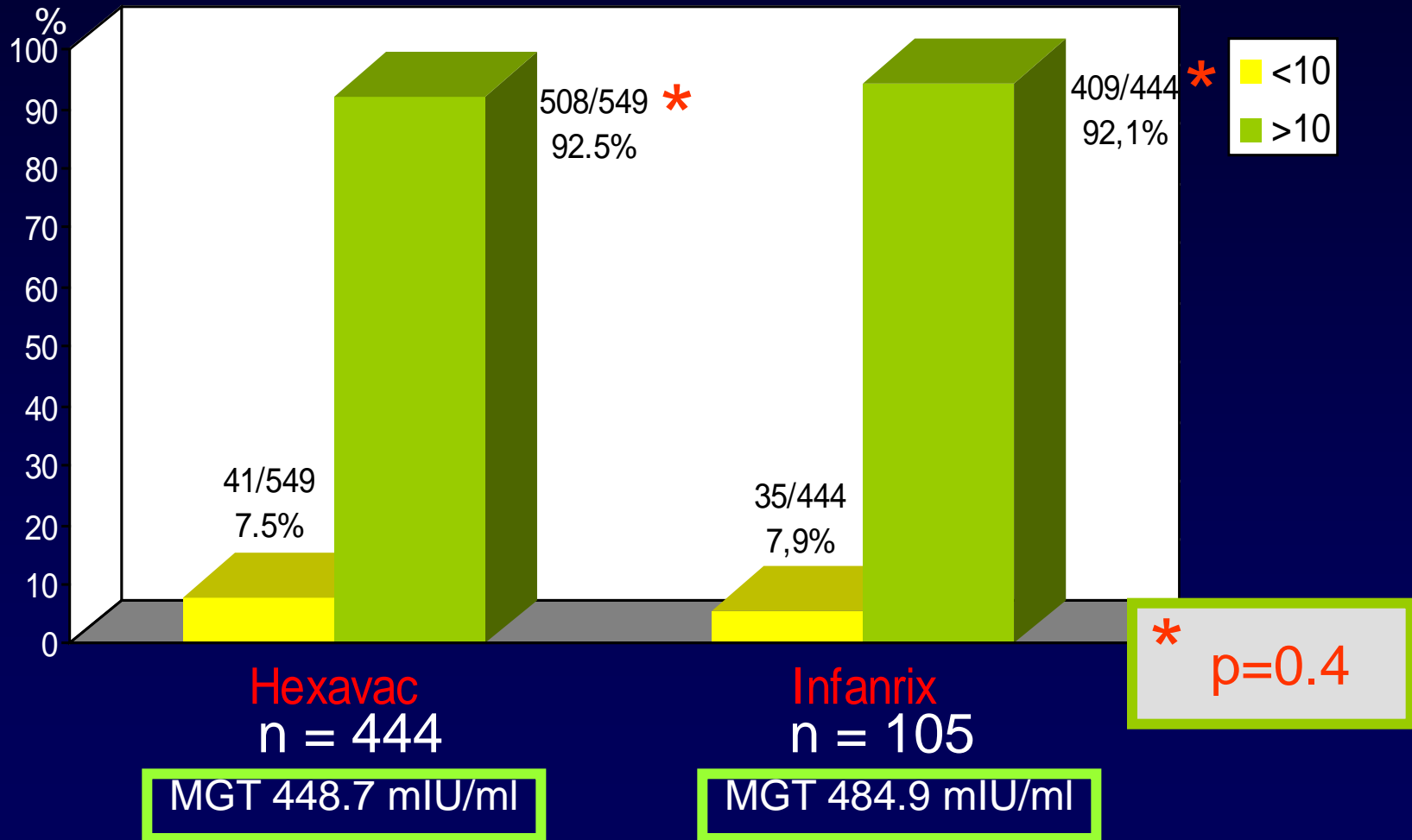
The issue of hexavalent vaccines

- 2000: two Hexavalent vaccines (Hexavac[®] and Infanrix Hexa[®]) licensed in EU
- 2005: Hexavac suspended
- 10 million doses of Hexavac distributed globally
- ~ 1.2 million children vaccinated in Italy with Hexavac

Concentration of anti-HBs in 1540 children primed with Hexavac or Infanrix Hexa, 5 years earlier



Post-booster anti-HBs concentrations

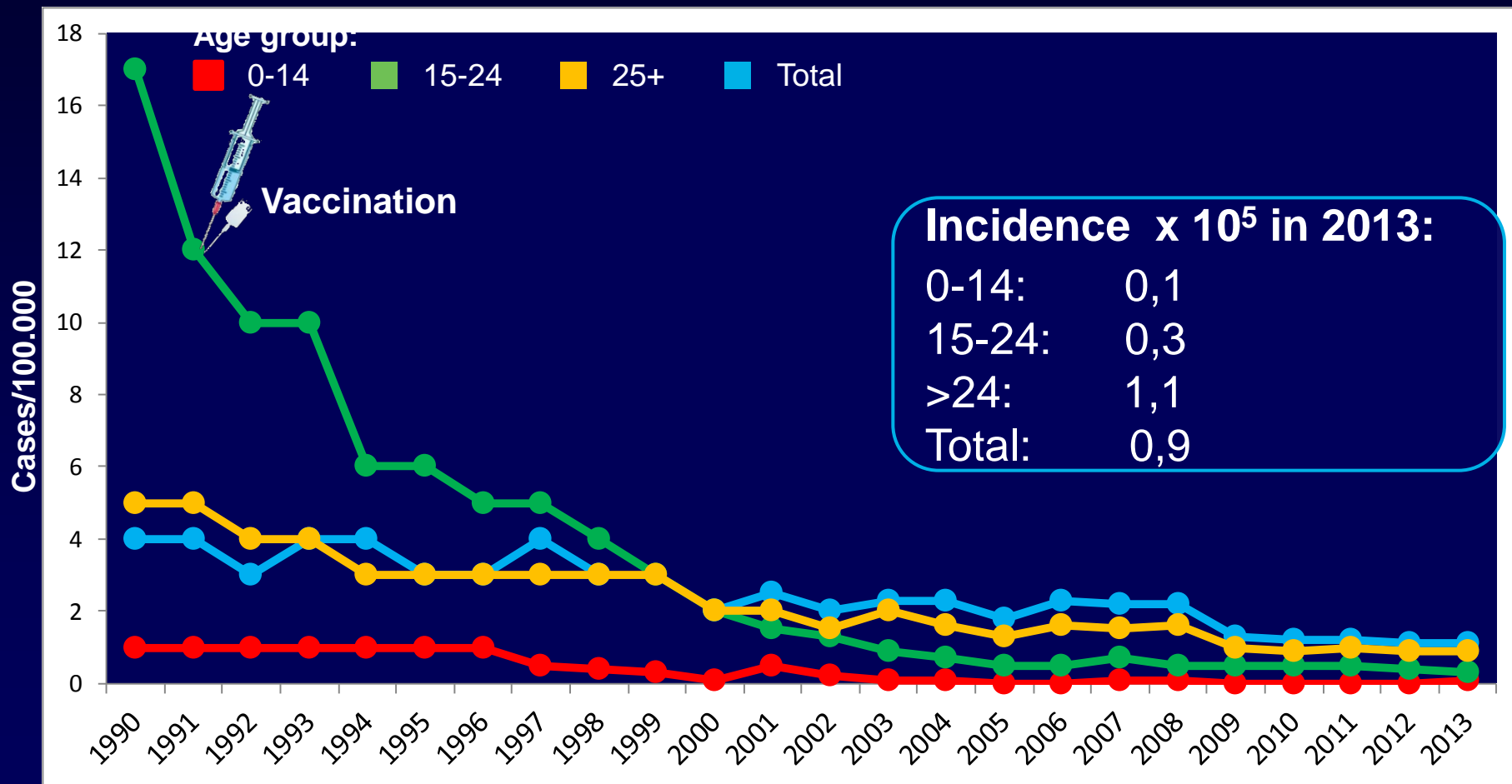




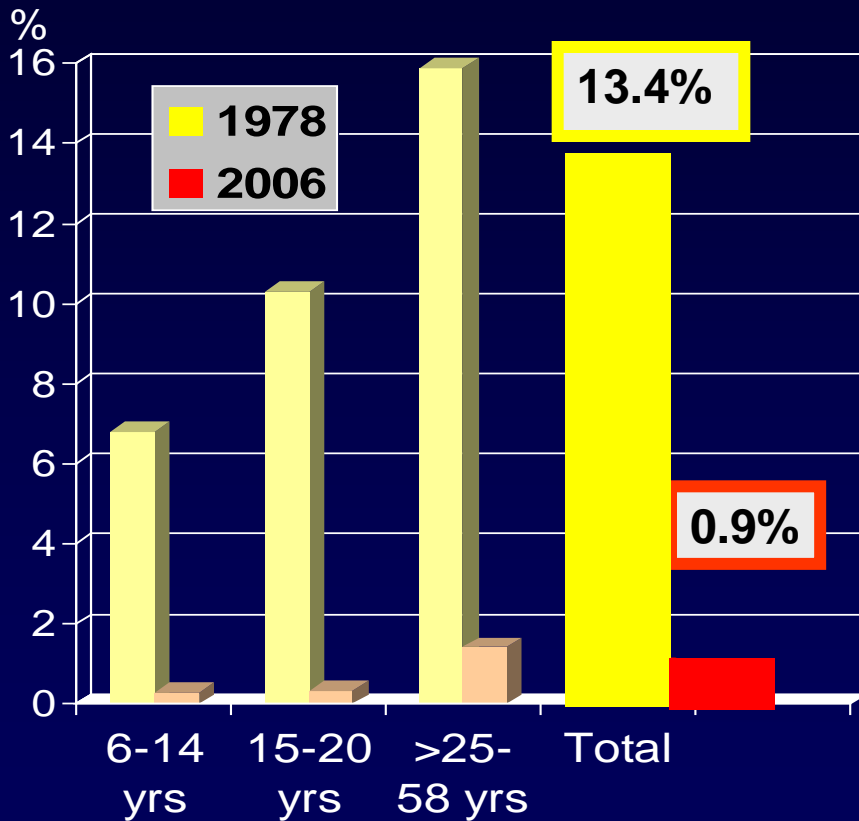
Conclusions

- ❖ No need for booster injections of vaccine to sustain immunity in children vaccinated in infancy with hexavalent vaccines.
- ❖ This observation was specific to the 5-year checkpoint .
- ❖ A follow up study - at 10 years distance from priming - is currently in progress.

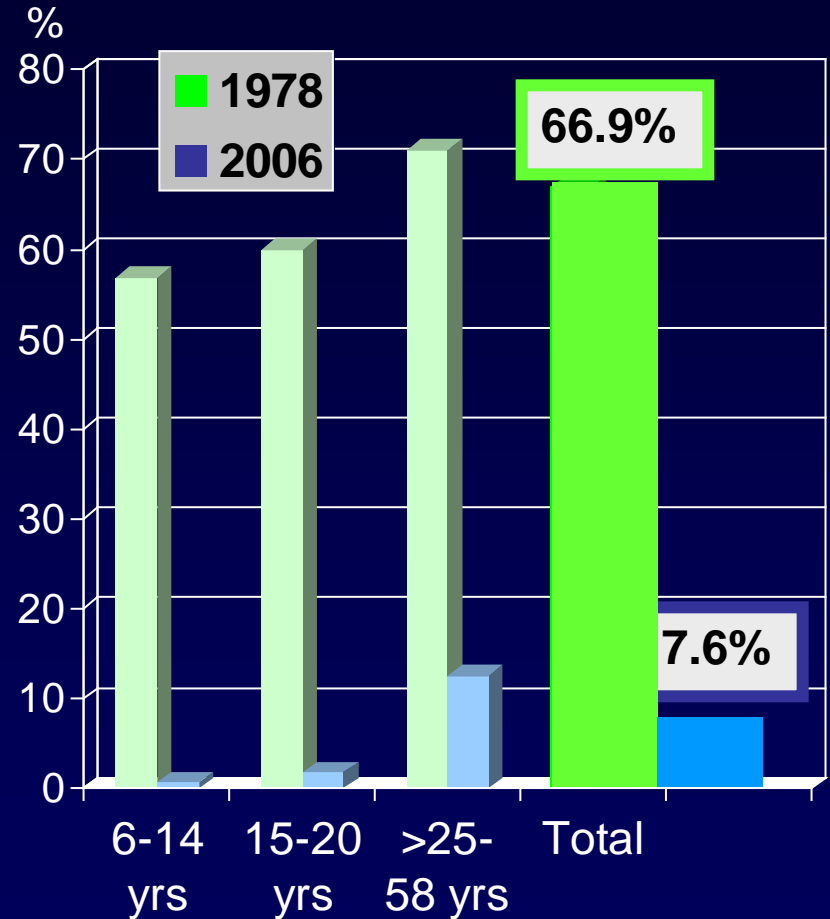
Morbidity rate (x 10⁵ inhabitants) of hepatitis B in Italy, according to age (1990-2013)



Impact of hepatitis B vaccination in a highly endemic area of southern Italy (Afragola) (Vaccine, 2007)



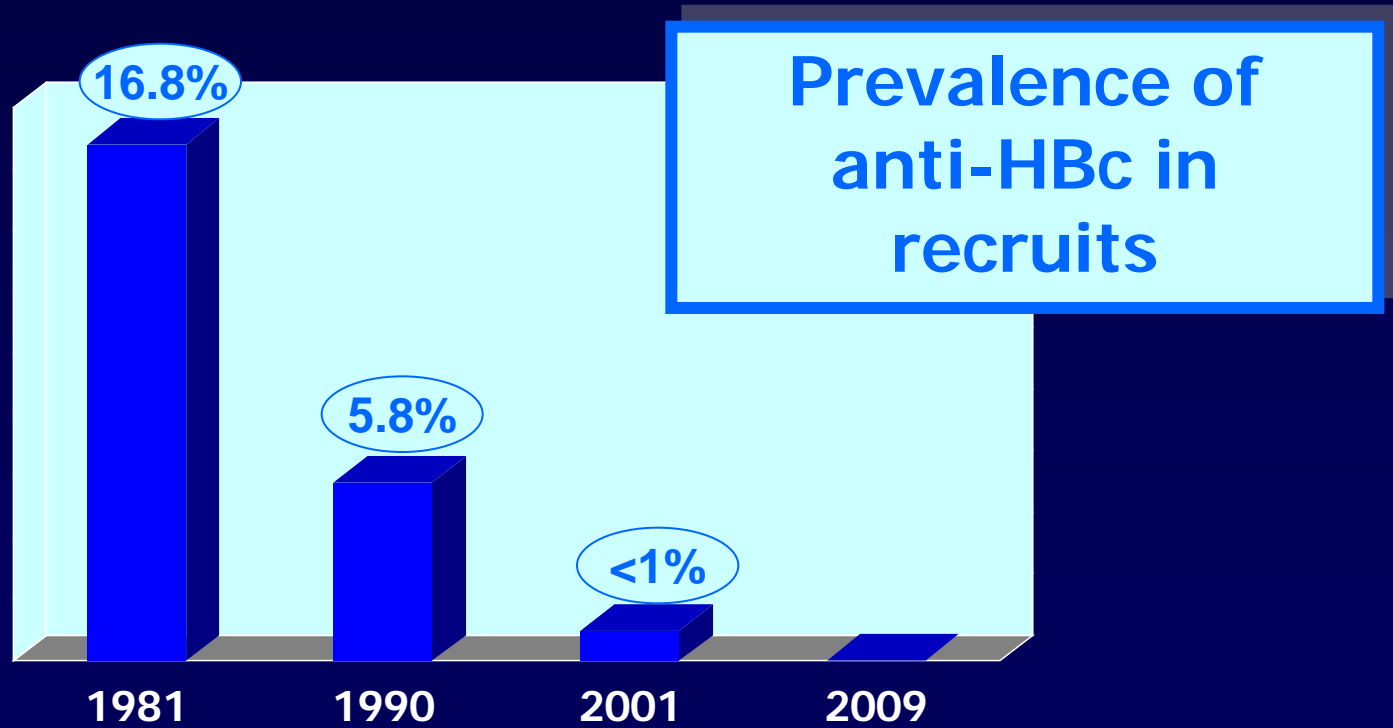
Age-specific prevalence of HBsAg



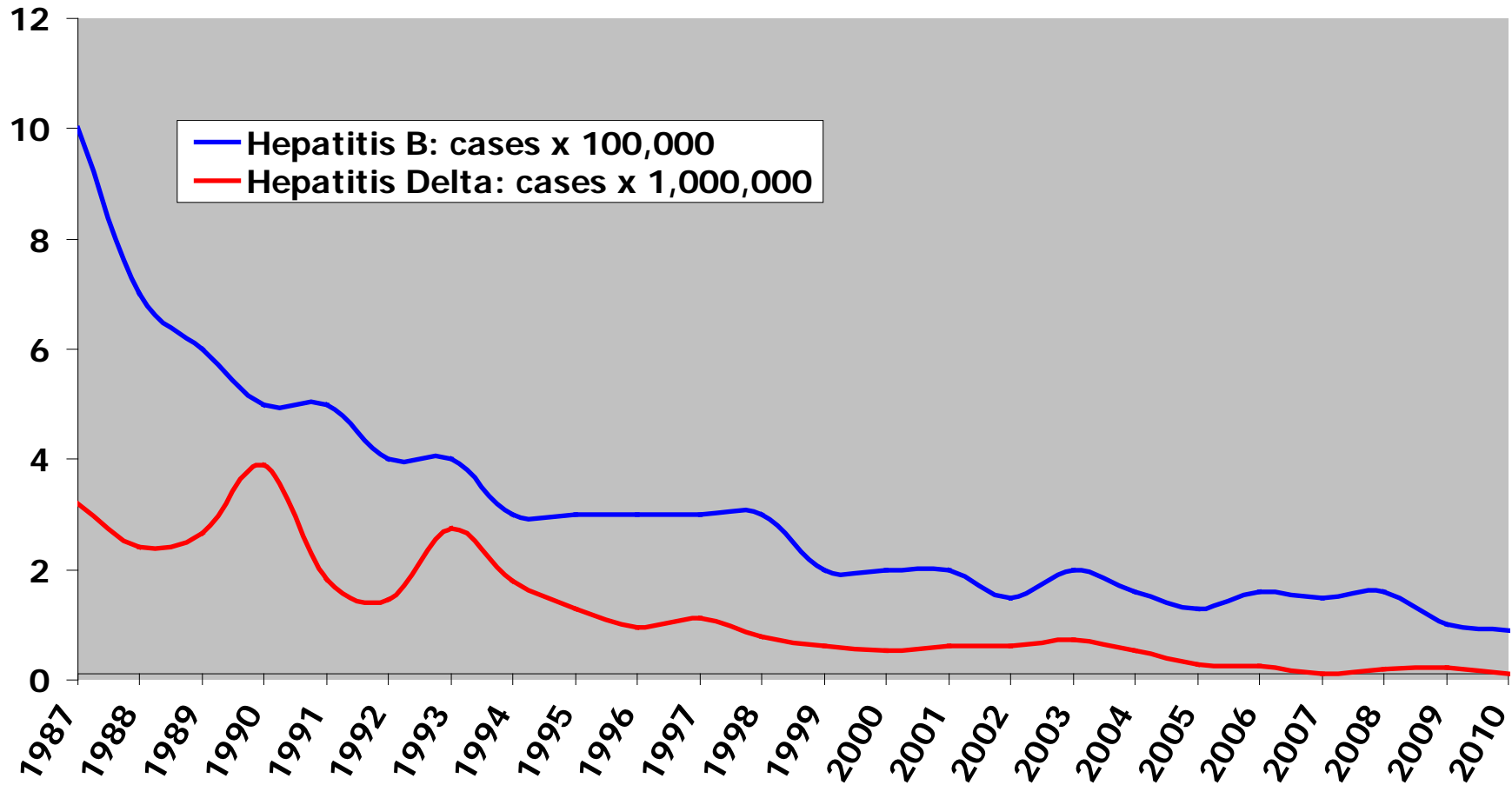
Age-specific prevalence of anti-HBc

Impact of HBV vaccination in Italy

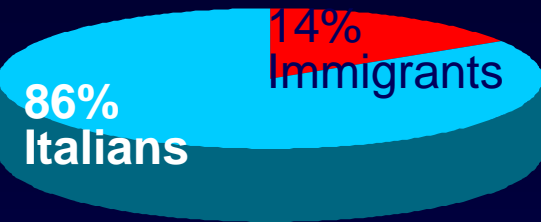
- A generation of children and young people is emerging with at present practically no markers of HBV infection.



Incidence rates of acute hepatitis B and hepatitis Delta SEIEVA 1987-2010



Acute hepatitis B in vaccinated people in Italy (SEIEVA, 2001-2012)



5,671 cases

5,156 (91%)

vaccination status known

5,000 (97%)
subjects not
vaccinated

156 (3%) subjects
vaccinated

mean age 35,9 yrs

67,7% males

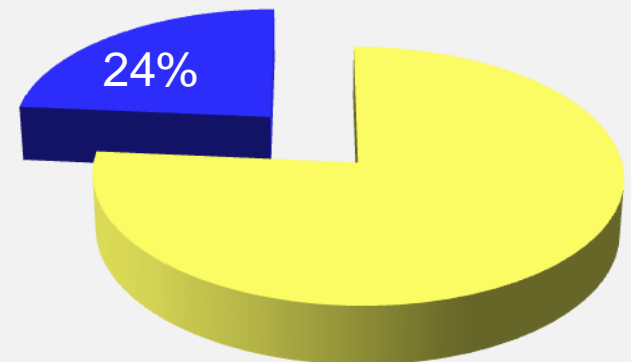
325 (6.5%)
escaped mandatory
vaccination

Hepatitis B in vaccinated people in Italy (SEIEVA, 2001-2012)

37 cases
vaccinated
properly

156 cases of
hepatitis B in
vaccinated people

Correctly vaccinated



Molecular
characterization:
- 14/21 wild type
- 7/21 escape mutants

In Italy, estimated 3-4
vaccination failures annually

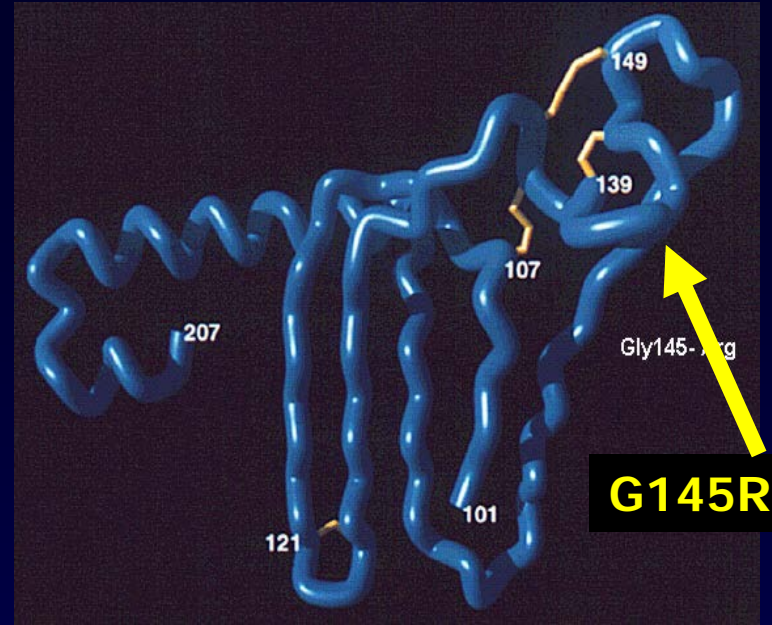
Changing patterns of hepatitis B in Italy

Conclusions

Hepatitis B has progressively declined during the last 20 years as a result of:

- ✓ Social, behavioural, and demographic changes.
- ✓ General improvements in the standards of living and hygiene.
- ✓ Introduction of public health measures such as refinement in blood screening, use of universal precautions in medical settings and implementation of vaccination programmes.

HBV infections in vaccinees



- ✓ Cases of hepatitis B in vaccinated people are very rare and generally confined to those who did not complete schedule of vaccination properly.
- ✓ Infections of vaccinated people with S-gene mutants (G145R) are rare and do not pose a public health threat.



Italy *versus* other countries



- ❖ Italy's programme of vaccination has resulted in substantial progress towards the prevention and control of hepatitis B.
- ❖ Our findings compare well with data reported elsewhere (e.g. Taiwan, the Gambia, Alaska) where the impact of vaccination in terms of reduction in incidence, in carrier rate, and in HBV-related mortality has been impressive.

HBV vaccination in Italy: what the future holds

- Maintaining vaccination of infants.
- HBsAg testing of pregnant women.
- Increasing HB vaccination coverage in high-risk groups, including households of HBsAg carriers, immigrants and travellers to and from highly endemic countries.

