Long-term immunogenicity of hepatitis B vaccination and policy for booster: an Italian policy

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Long-term immunogenicity and policy for booster - 1

- How long does immunity last?
- Will vaccinated babies maintain immunity until adolescence and adulthood when the risk behaviour may be expected?
- Is there a need for booster vaccination(s) to sustain immunity?

Long-term immunogenicity and policy for booster - 2

Is long-term immunity influenced by:
- the age at which subjects are vaccinated?
- the schedule of primary vaccination?
- the amount of HBsAg included in the vaccine used for immunisation?

Study 1

Aim: to study the persistence of immunological memory and need for booster

1212 healthy children
446 healthy Italian Air Force recruits
Vaccinated as infants
Vaccinated as adolescents (12 years old)
3 doses Engerix B (10 µg) at 3, 5 and 11m of age
3 doses Engerix B (20 µg) at time 0, 1 and 6m

Pre-booster anti-HBs concentrations in children and recruits primed 10 years previously

GMC 32.1 mIU/ml
GMC 234.8 mIU/ml

\* p=0.0001
Conclusions

- The use of routine booster doses of hepatitis B vaccine was not required to maintain long-term protection in immunocompetent individuals primed as infants or teenagers 10 years earlier.

Subjects enrolled in 2010

Year 2003

1212 children studied

Year 2010

571/1212 (47.1%) agreed to participate

Demographic characteristics of 571 individuals enrolled in 2010

<table>
<thead>
<tr>
<th>Gender</th>
<th>Number</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Female</td>
<td>296</td>
<td>51.9%</td>
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<tr>
<td>Male</td>
<td>275</td>
<td>48.1%</td>
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| Mean age at enrollment (years; SD) | 17 (0.7) |
| Mean time from primary vaccination (years; SD) | 16.7 (0.7) |

Long-term immunogenicity and policy for booster

Study 2

- 297 healthy children
  - Vaccinated as infants 17-18 years earlier
  - 3 doses of Engerix B (10 µg) at 3, 5 and 11m of age

- 409 blood donors
  - Vaccinated as adolescents 17-18 years earlier
  - 3 doses of Engerix B (20 µg) at time 0, 1 and 6m

Preliminary conclusions – 1

- Approx 50% of teenagers and nearly 90% of young adults retained protective levels of antibody 17-18 years after primary vaccination.

- Both antibody concentrations and proportion of individuals with protective antibody levels were higher in young adults than in teenagers.
Preliminary conclusions – 2

• Difference could be attributed to:
  
  – different response to the primary course of vaccination due to the different age at which immunization was given;
  
  – different vaccine dose (paediatric i.e. 10 µg vs adult i.e. 20 µg)
  
  – different degree of exposure to natural booster

Conclusions

• 17-18 years after immunisation with hepatitis B vaccine, immunological memory still persists in teenagers with anti-HBs lower than 10 mIU/ml, suggesting that booster dose(s) are not needed at this time.

• Anamnestic response to boosting of donors vaccinated as adolescents and who lost antibody over time, will help to clarify this issue even further.