Development of hepatitis B prevention in Germany – the first ten years

Wolfgang Jilg
Institute for Medical Microbiology and Hygiene
University of Regensburg
marketing authorisation of hepatitis vaccines B in Germany

1982 hepatitis B vaccine ("plasma vaccine")
1986 recombinant hepatitis B vaccine
recommendations for use of hepatitis B vaccine in Germany (STIKO 1983-1995)
STIKO „Ständige Impfkommission“

( = standing committee for vaccination)

- makes recommendations for use and performance of vaccinations
- recommendations addressed to the health authorities of the „Länder“ (the federal states of Germany) which by themselves announce „publicly recommended vaccinations“
publicly recommended vaccinations
recommended by STIKO and the Federal States

vaccinations which are of considerable importance for the whole population or a significant part of it.

- in case of health damage due to unwanted side effects or adverse events the state will pay for compensation.
- usually paid by health insurances
recommendations for use of hepatitis B vaccine in Germany (STIKO 1983-1995)

- recommended for individuals at high risk
risk groups for whom hepatitis B vaccine is recommended in Germany (STIKO 1983-1995)

- health care workers
- contacts of carriers
- recipients of blood products
- patients of institutions for mentally disabled
- hemodialysis patients
- homosexuals
- prostitutes
- parenteral drug users
- prison inmates
- travellers to highly endemic countries
- newborns of carrier mothers
recommendations for use of hepatitis B vaccine in Germany (STIKO 1983-1995)

- recommended for individuals at high risk
- costs reimbursed by employer (e.g. HCWs) or insurance (patients, newborns etc.)
acceptance of hepatitis B vaccine in the public in the first years after its introduction

new vaccine accepted only hesitantly

- poor knowledge of hepatitis B (significance, frequency, modes of transmission)
- concerns on safety of plasma vaccine (inactivation procedure sufficient for destruction of HBV and HIV?)
hepatitis B vaccine in Germany: vaccine coverage 1985-1992

- medical doctors: < 50%

- nurses: 35-59%
  Hallauer, in Occupational health for health care workers. Ecomed, Landsberg 1993

- hemodialysis patients: 60-90%
  Kuratorium für Heimdialyse, Munich 1992

- drug addicts, homosexual men; < 10%
  local health authorities Munich, Hamburg
hepatitis B vaccine in Germany: questions arising

- minimal protective antibody concentration?
- what to do with nonresponders?
- how long does protection last?
an individual with a peak of <10 IU/l (non-responder) after the basic course of vaccination probably lacks protection against HBV infection. Individuals with peak anti-HBs levels of 10-100 IU/l (low responder) generally lack anti-HBs within a few years. A good response is regarded as anti-HBs levels of ≥100 IU/l.

Some of the ... non-responders ... will acquire adequate anti-HBs levels after additional booster doses. For low responders an additional booster within one year should be considered (no unanimity was reached on this point).

Until more data are available one might consider revaccinating individuals when anti-HBs levels fall to <10 IU/l or once after 5-7 years after the initial course of vaccination.

Grob et al, Lancet 1988
hepatitis B vaccine in Germany: questions arising

- minimal protective antibody concentration?
- what to do with nonresponders?
- how long does protection last?
- do we have the right strategy?
hepatitis B in Germany reported cases 1982-1993

- Hep B, old states
- Hep B, old/new states
- Syphilis, old states
- Syphilis, old/new states
hepatitis B in risk groups and in the normal population

- Risk groups:
  - Percentage of total population: 4%
  - Percentage of all hepatitis B cases: 29%

- Normal population:
  - Percentage of total population: 96%
  - Percentage of all hepatitis B cases: 71%
hepatitis B incidence in different age groups

reported cases 1991-1994, n = 19 268
hepatitis in Germany – ANOMO-study
sentinel surveillance of HIV and other sexually transmitted diseases

<table>
<thead>
<tr>
<th>Year</th>
<th>Reported Cases</th>
<th>ANOMO Cases</th>
<th>Under-reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>1993</td>
<td>13,834</td>
<td>86,174</td>
<td>84 %</td>
</tr>
<tr>
<td>1994</td>
<td>13,817</td>
<td>141,560</td>
<td>90 %</td>
</tr>
</tbody>
</table>

*Kirschner and Schwartländer, ANOMO-Studie. Nomos Verlag, Baden-B. 1996*
# Hepatitis B: Epidemiological Situation in Germany 1993

## Reported vs. Calculated Incidence

<table>
<thead>
<tr>
<th></th>
<th>Symptomatic Infections</th>
<th>All Infections</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reported</strong></td>
<td>5,497</td>
<td></td>
</tr>
<tr>
<td><strong>Calculated under the assumption of underreporting of 60-80%</strong></td>
<td>13,743</td>
<td>27,485</td>
</tr>
<tr>
<td><strong>ANOMO-study</strong>*</td>
<td>25,689</td>
<td>51,378</td>
</tr>
<tr>
<td><strong>Expected value due to anti-HBc-prevalence data (1990/91)</strong></td>
<td></td>
<td>52,589</td>
</tr>
</tbody>
</table>

* Kirschner and Schwartländer, ANOMO-Studie. Nomos Verlag, Baden-B. 1996
hepatitis B: epidemiological situation in Germany 1993

- about 50 000 new infections per year
- about 500 000 HBV-carriers
- most infections transmitted sexually
- poor vaccine coverage

→ need for universal vaccination!