

VHPB meeting 2003

Prevention of viral hepatitis in Germany and Scandinavia:
lessons learnt and the way forward

Berlin, October 13-14

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

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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%**
Zachoval and Deinhardt, Münch Med Wschr 1988; 19:363-366
- **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?**

the Ising meeting

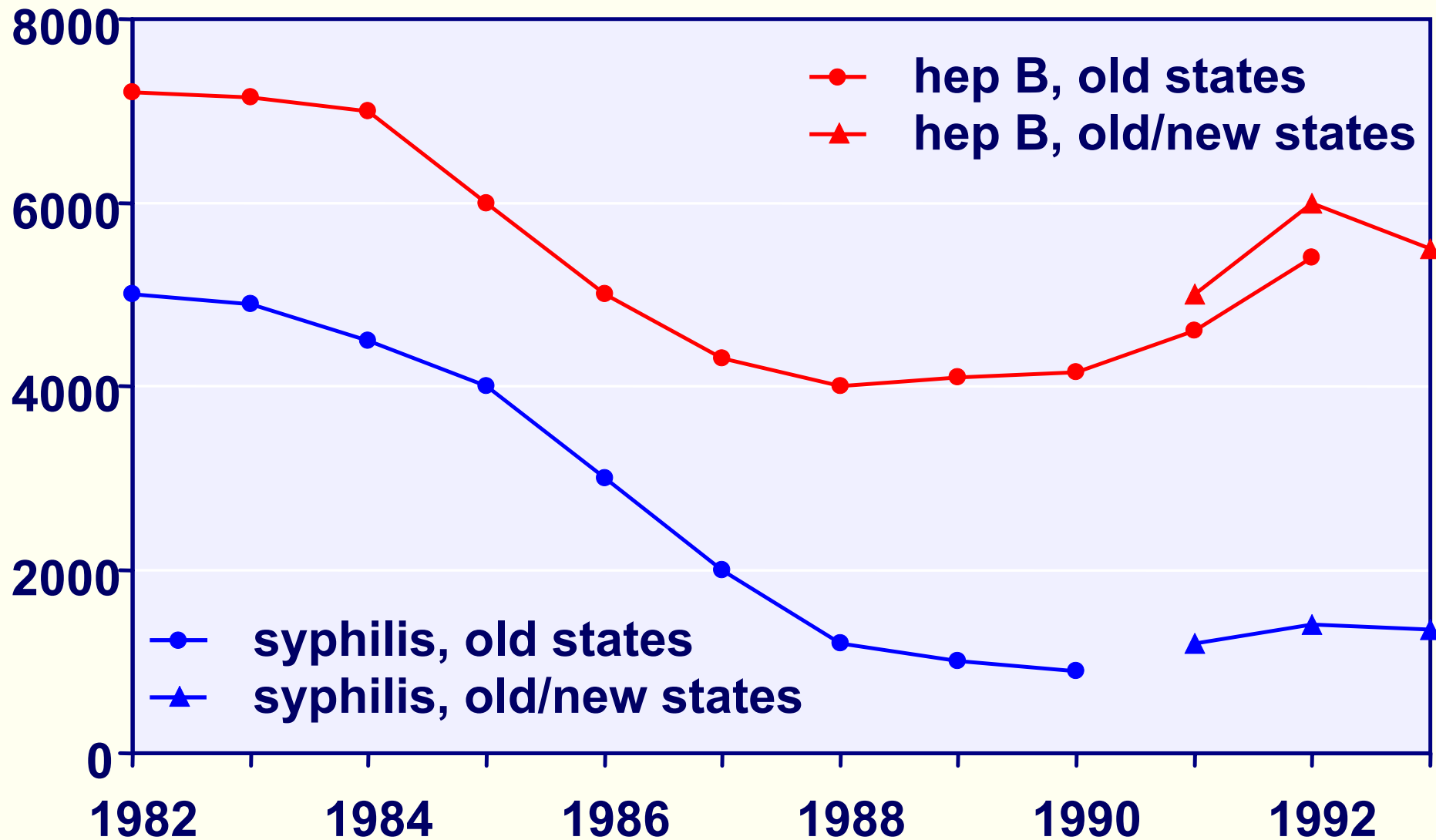
Ising, Bavaria, February 1988

- 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.

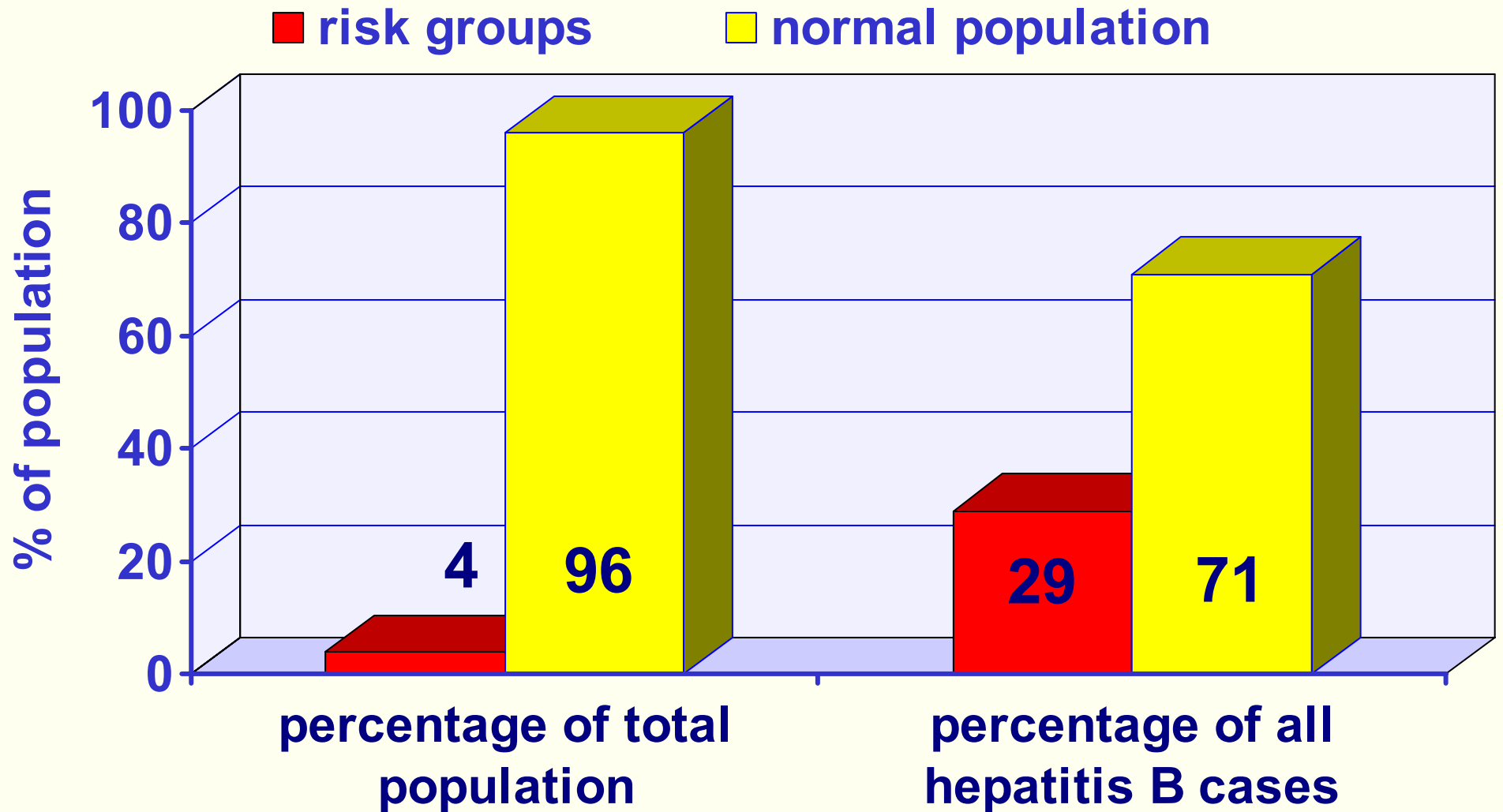
hepatitis B vaccine in Germany: questions arising

- **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

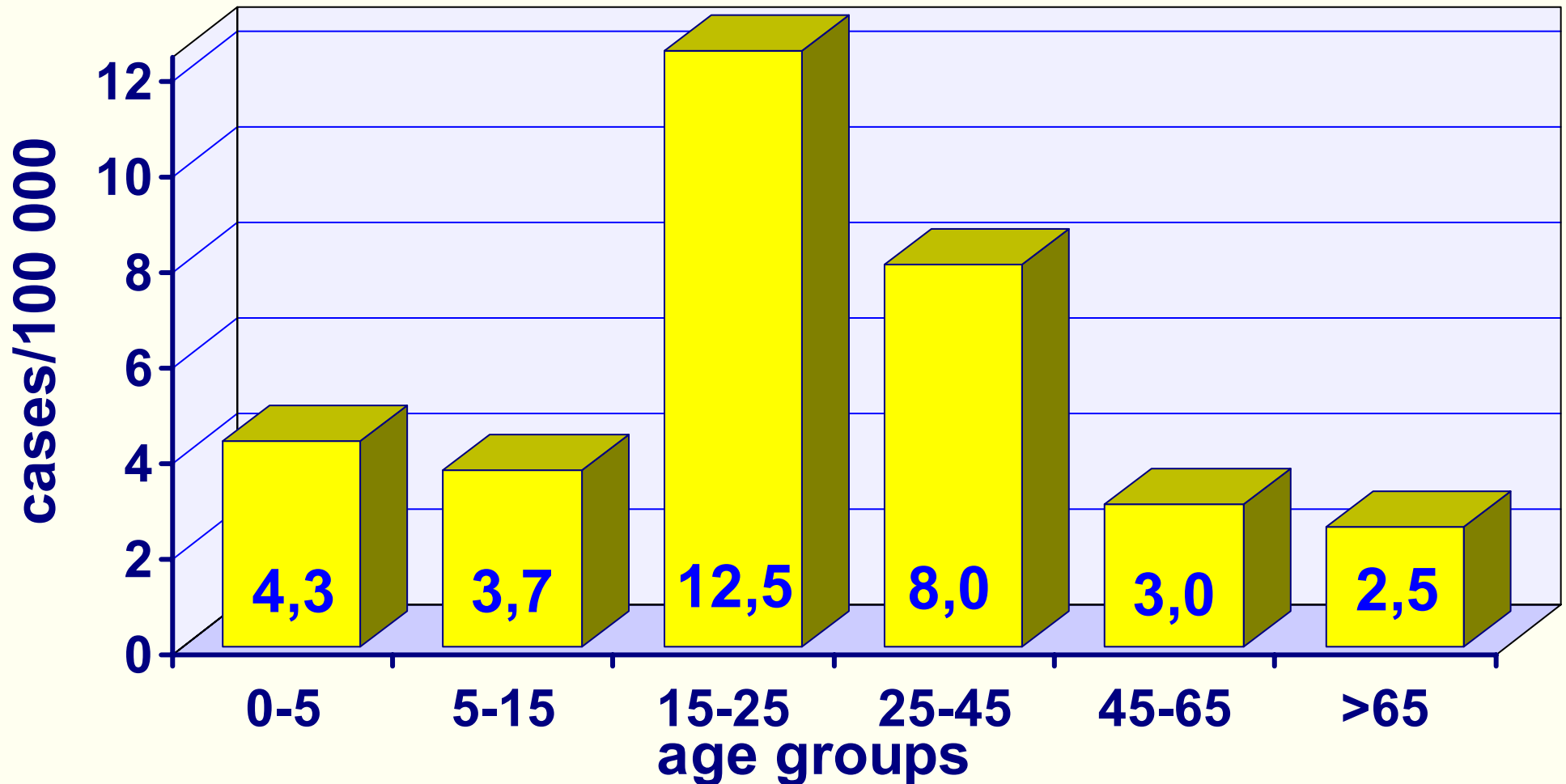


hepatitis B in risk groups and in the normal population



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

| | reported cases | ANOMO | under- reporting |
|-------------|---------------------------|----------------|-----------------------------|
| 1993 | 13 834 | 86 174 | 84 % |
| 1994 | 13 817 | 141 560 | 90 % |

Kirschner and Schwartländer, ANOMO-Studie. Nomos Verlag, Baden-B. 1996

hepatitis B: epidemiological situation in Germany 1993

reported vs. calculated incidence

| | symptomatic infections | all infections |
|----------------------------------------------------------------|---------------------------|--------------------|
| reported | 5 497 | |
| calculated under the assumption of underreporting of 60-80% | 13 743 - 27 485 | 27 485 - 54 970 |
| ANOMO-study* | 25 689 | 51 378 |
| expected value due to anti-HBc- prevalence data (1990/91)** | | 52 589 |

* *Kirschner and Schwartländer, ANOMO-Studie. Nomos Verlag, Baden-B. 1996*

***Thefeld et al Bundesgesundhbl 1994; 37: 374-377*

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 !*

