

Protection of medical staff through
hepatitis B vaccination:
**Serological and epidemiological data from
hospitals in Bulgaria**

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Background

**Medical
Staff**

HBV Infection

Hepatitis B Vaccination



**Risk of
Occupational Exposure**

Benefit of Protection



Risk for Occupational Transmission of HBV

- ❖ **HBV infection** is a well recognized occupational risk and the major infectious hazard for HCP
- ❖ **Percutaneous injuries** are among the most efficient modes of HBV transmission: 23-37% risk of developing serologic evidence of HBV infection (**HBsAg-positive and HBeAg-negative blood**)
- ❖ In addition, HBV infections occur in result of **direct or indirect blood or body fluid exposures** that inoculated HBV into cutaneous lesions, or on mucosal surfaces
- ❖ Because of the high risk of HBV infection among HCP, **routine pre-exposure hepatitis B vaccination and the use of standard precautions** to prevent exposure to blood and other potentially infectious body fluids have been recommended

Hepatitis B vaccination of HCP

- ❖ **Hepatitis B vaccination** is the most effective measure to prevent HBV infection and its consequences
- ❖ **Recombinant hepatitis B vaccines** have been found to be safe and to confer a long-lasting protection (>95%)
 - **HCP should be vaccinated against HBV** with a standard vaccination schedule
 - **Post-vaccination serology is required** to confirm immunity following vaccination
 - **Responders are protected** against HBV infection
 - **Routine booster doses are not recommended** for known responders, even if **anti-HBs levels become low or undetectable**

European recommendations for the management of HCWs occupationally exposed to HBV and HCV. Euro Surveill 2005; 10(10)

Hepatitis B vaccination of HCP in Bulgaria

- ❖ In Bulgaria, the protection of HCP through immunization is arranged based on the Ministry of Health Regulation №4/2002 on "The protection from occupational exposure to biological agents":
 - *The employer should prepare a list of job classifications in which some employees have occupational exposure;*
 - *The employer should make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure at no cost to the employee.*

Studies assessing protection of HCP through hepatitis B vaccination, Bulgaria

- ❖ **A questionnaire survey** to estimate the immunization coverage and hepatitis B vaccination acceptance in HCP, 2008¹
- ❖ **A seroprevalence study** to assess the protection of HCP based on the serologic markers of HBV, 2007²
- ❖ **A prevalence survey** to assess the hepatitis B vaccination coverage in HCP and **a parallel retrospective review of vaccination and serology data to determine** the duration of protection in previously immunized medical staff, 2010³

¹V. Voynova-Georgieva et al. *Nosocomial Infections* 2008;5(1-2):75-80

²N. Gatcheva et al. *Nosocomial Infections* 2008;5(1-2):69-74

³N. Gatcheva et al. *Nosocomial Infections* 2010;7(1-2):in print

Questionnaire survey, 2008: Study design



❖ **Medical staff** working in high-risk departments/units at 29 acute care hospitals **in 14 regions participated**

❖ A total of **1429 self-report anonymous questionnaires** were analyzed

❖ **The data collected** included: occupation, vaccination status, serologic markers of HBV and HCV, **self assessment of the occupational risk and the importance of preventive measures**

Questionnaire survey, 2008: Results

The participants (20,7% doctors, 52,5% nurses & lab technicians, aged 30-59 years) agreed that:

- ❖ **The risk** of occupational blood-borne infection exists (90%)
- ❖ **There are reliable measures** to prevent VHB infection in HCP (57%)
- ❖ **The most effective preventive method** is:
 - vaccination (54%)
 - use of personal protective equipment (21%)
 - use of both (17%)

Questionnaire survey, 2008: Results

According to the self-report questionnaire data:

- ❖ **Fully vaccinated**, with a routine 3-dose series of hepatitis B vaccination completed, were **76% of ICP**, between 63% (medical services) and 91% (ICU); **additional 10%** had received only 1 or 2 doses
- ❖ **Continuing medical education** in infection control and prevention reported **a total of 21%**:
 - following a comprehensive educational programme of postgraduate courses (8%)
 - a training in short courses (13%)

Seroprevalence study, 2007: Study design

- ❖ The prevalence of HBV serologic markers among HCP at risk for exposure was determined: doctors, nurses & lab technicians (preliminary female staff between 18 and 50 years of age) at 4 acute care hospitals in different regions (2 in the north and 2 in the south of Bulgaria)
- ❖ A total of 324 excess serum samples collected for screening purposes were tested for HBV markers: HBsAg, anti-HBc & anti-HBs by ELISA
- ❖ Based on the HBV serology:
 - the evidence of post-infection and post-vaccination immunity of medical staff, and
 - HBsAg prevalence in HCP was determined

Serologic evidence of HBV infection or immunity in HCP - Bulgaria, 2007

Region	HBsAg-carrier status %	HBV post-infection immunity %	HBV post-vaccination immunity %	Non-immune HBcAb(-) HBsAb(-) %
North 1	1.0	15.8	28.0	56.2
North 2	8.8	19.2	53.4	27.4
South 1	6.3	19.7	50.0	30.3
South 2	4.0	16.7	60.4	22.9
Total	5.0 +/- 2.4	17.8 +/- 4.6	46.1 +/- 6.0	36.1 +/- 5.7

Seroprevalence study, 2007: Results

According to the serologic data:

- ❖ **HBsAg prevalence in HCP (3-7%)**, was similar to the prevalence in the general population born in the pre-vaccine era (before 1992) in Bulgaria - a country with intermediate level of endemicity
- ❖ **Evidence of previous HBV infection was found in 17.8%** of the hospital HCP at higher risk of exposure - **a significant reduction** ($p < 0.001$) when compared to the level found in 1999-2000 (27.5%) and in the 1980s (34-50%) for the general population *
- ❖ **Post-vaccination immunity** was established in **40-52%** of HCP
- ❖ **Susceptibility rate to HBV** among the medical staff tested was found to be **30-42%**

Prevalence study, 2010: Study design

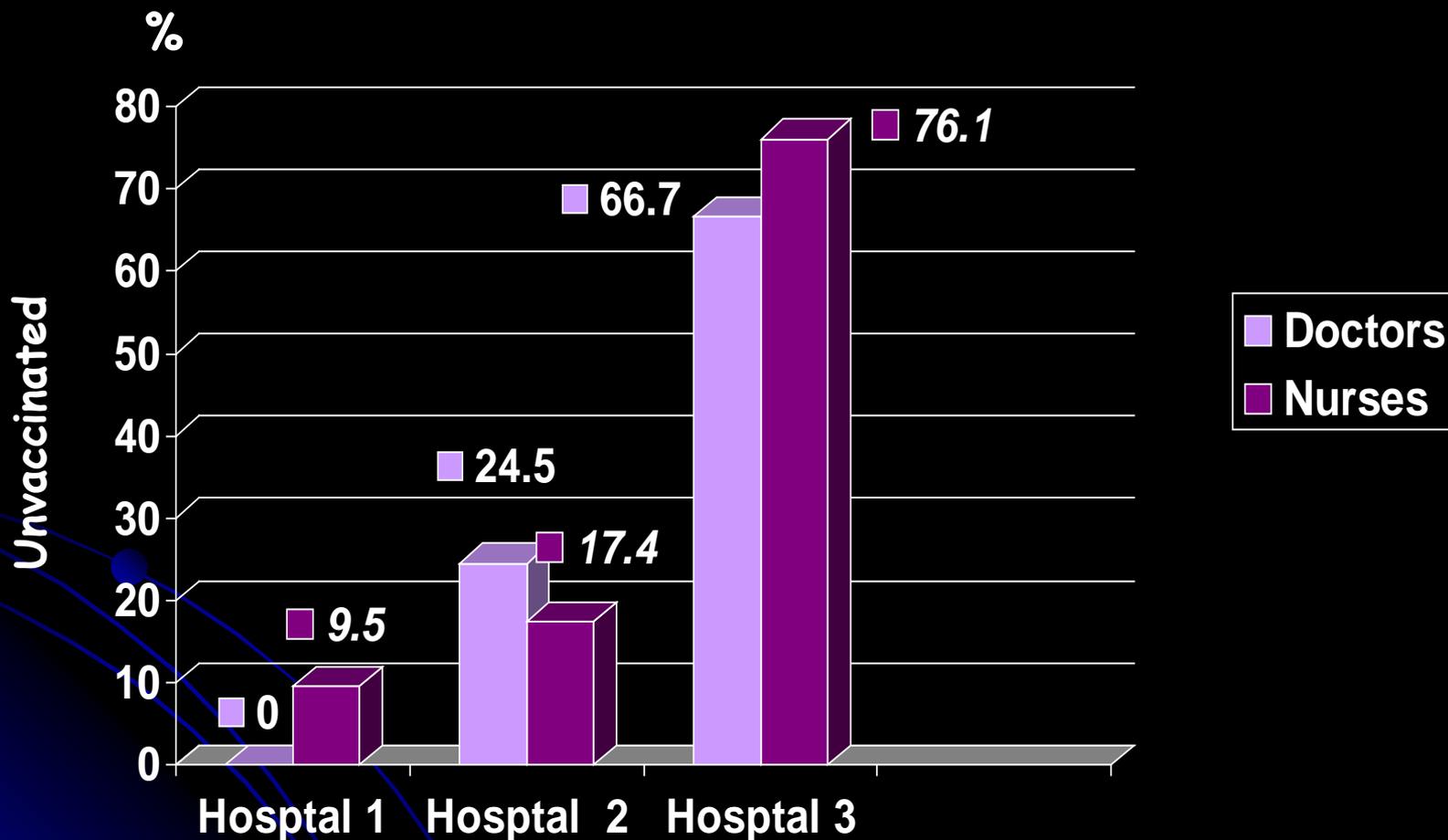
- ❖ A prevalence survey to estimate the hepatitis B vaccination coverage levels among HCP was conducted in 3 regional hospitals in 2010 (N=893, incl. 227 doctors and 666 nursing personnel)
- ❖ In parallel, a retrospective review of medical records was performed for a sample of the staff with anti-HBs post-vaccination serology (N= 167) in an effort to determine antibody persistence and the duration of protection in HCP who were previously vaccinated
- ❖ Data were collected from the hospital records for the immunization history of medical staff at risk of exposure regarding: date of vaccination, number of doses received, whether and when anti-HBs titres were checked and titre results; data of measuring the primary response to vaccination were not available

Prevalence study, 2010: Results

The results of the survey revealed:

- ❖ Significant differences in the proportion of unvaccinated against hepatitis B staff physicians (0-67%) and nurses (10-76%)
- ❖ Hepatitis B vaccination coverage levels among HCP assessed in this study corresponded very well to the levels of seroprotection found in the same hospitals within the seroprevalence study carried out in 2007
- ❖ Both the vaccination coverage and protection were significantly higher among HCP who worked in hospitals with an established IC team and full, visible leadership support

Percentage of HCP unvaccinated against VHB: Prevalence study, Bulgaria, 2010



Parallels between epidemiological and serological data

Hospital	Immunization status		Immune status		IC nurse	Leadership support
	Vaccinated %	Unvaccinated %	Protected %	Non-immune %		
Hospital 1*	85.0	8.0	60.4	22.9	+	+
Hospital 3*	23.4	73.5	28.0	56.2	-	±
Hospital 2	78.4	18.8	NA	NA	+	±

* Hospitals included in the seroprevalence study

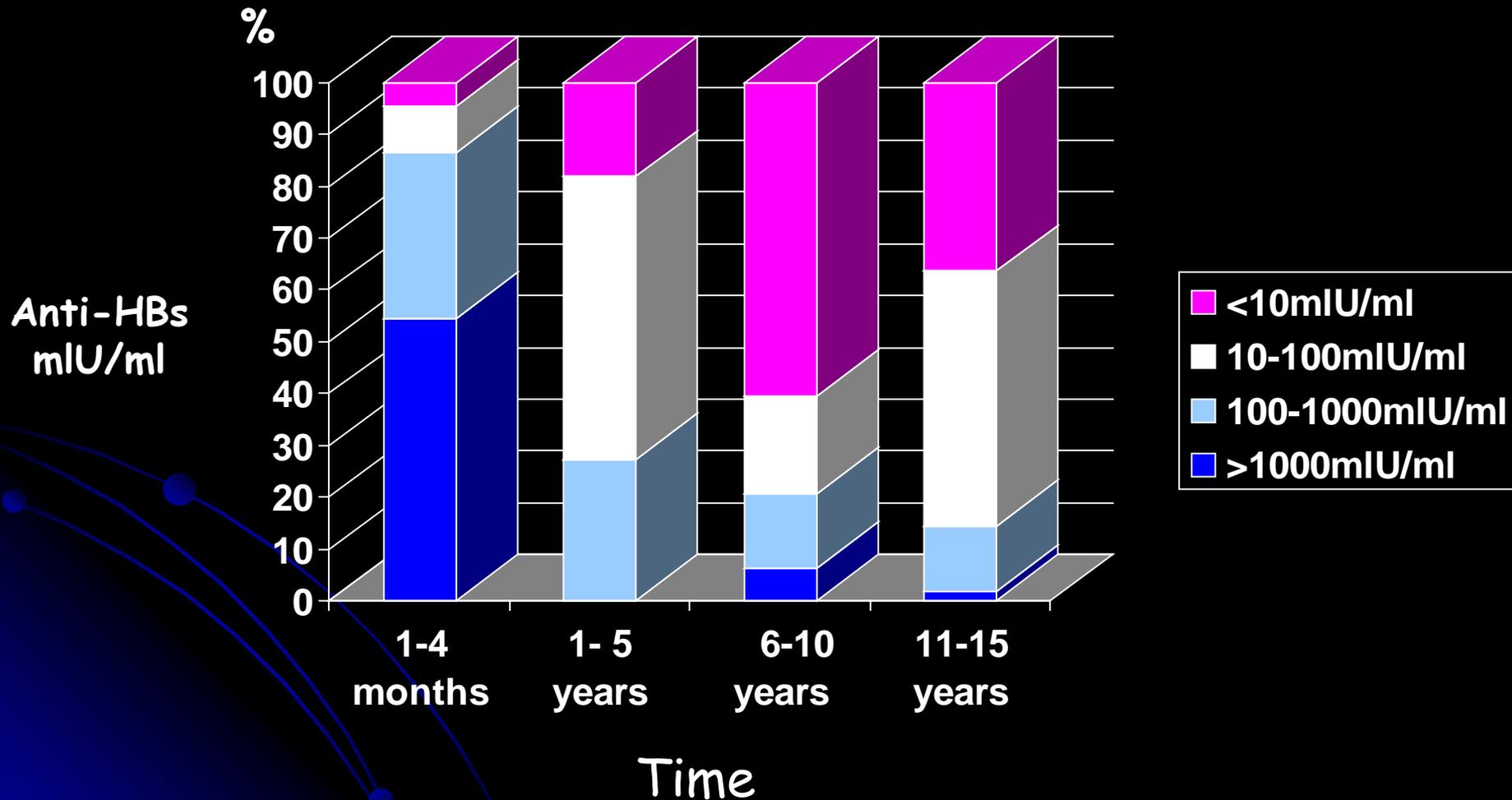
Retrospective review of medical records, 2010

According to our preliminary results:

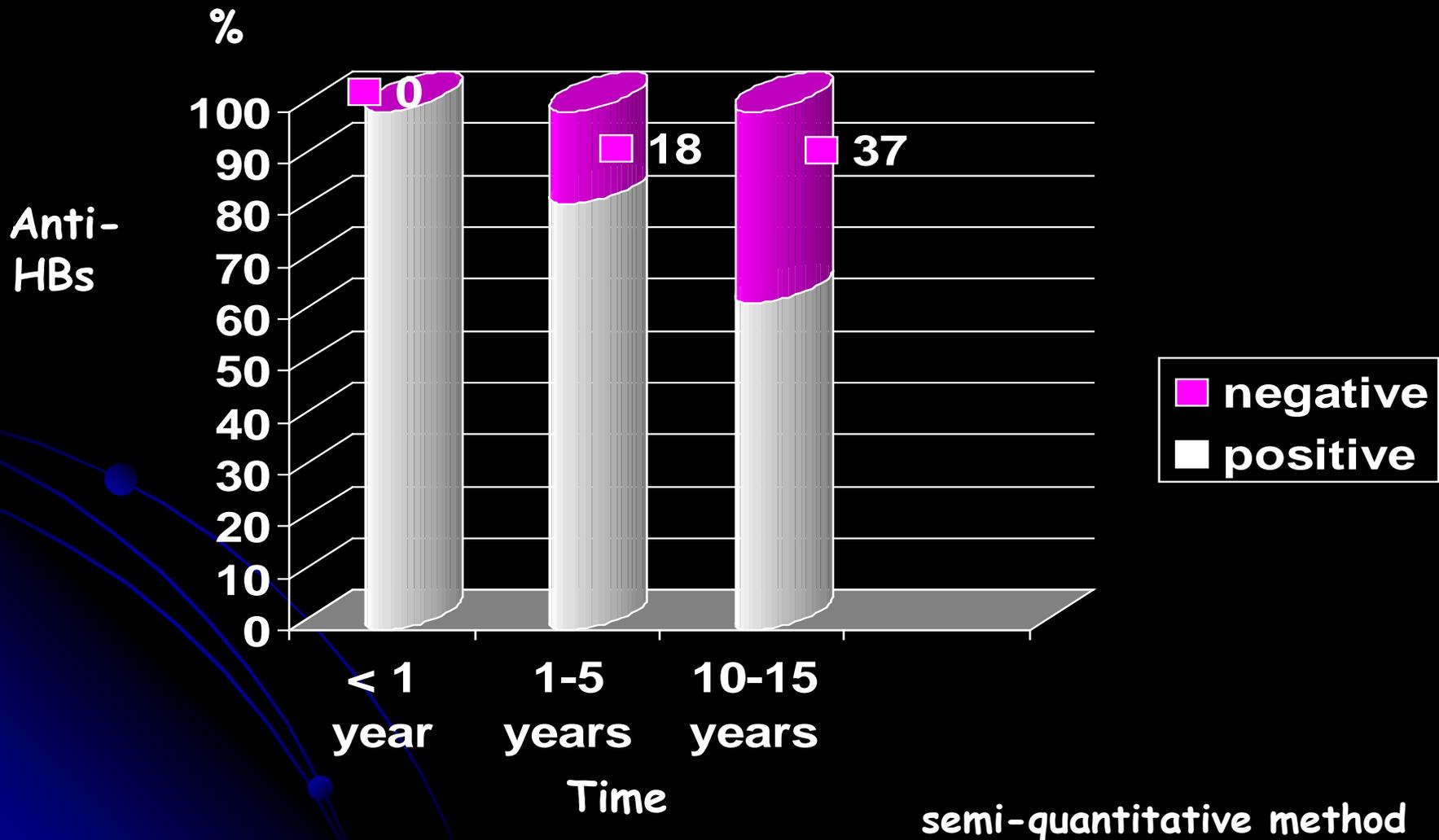
- ❖ The primary 3-dose series of hepatitis B vaccine induces protective anti-HBs concentrations of ≥ 10 mIU/ml among almost all HCP (in 95.5 - 100% of HCP screened during the first 1- 4 months after vaccination)
- ❖ A time-dependent decrease of anti-HBs titres and loss of detectable antibody was demonstrated (in 37% of previously vaccinated staff screened 10-15 years after). If we assume the often-stated non-response rate of 5%, then 32% (37% - 5%) of the HCP surveyed may have lost antibody
- ❖ Similar “theoretical anti-HBs loss rate” have been shown in other studies* on the duration of post-vaccination immunity

* *Arch Intern Med* 1999;159:1482-1483
The Lancet 2005; 366:1379-84

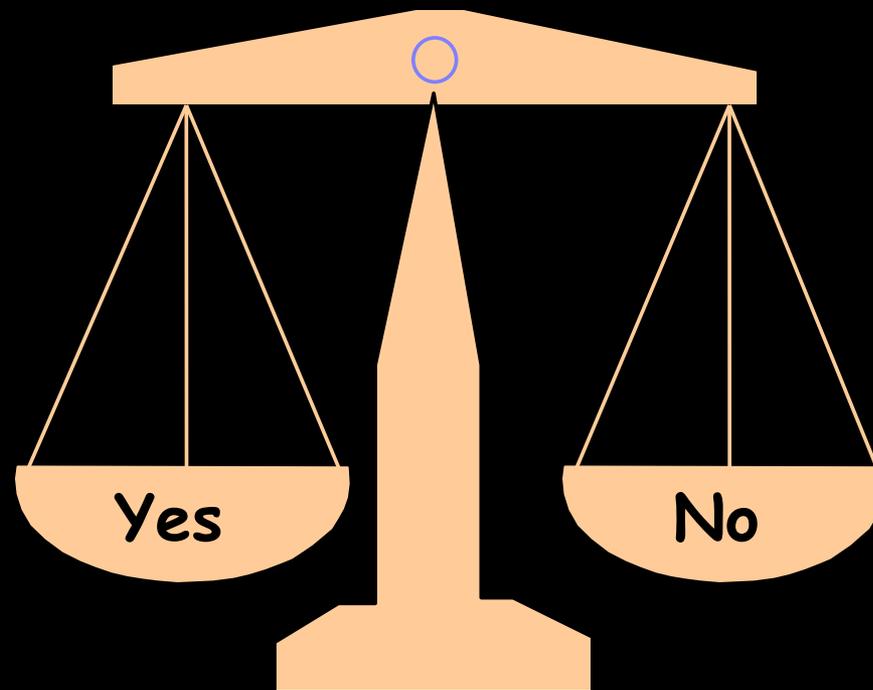
Anti-HBs levels in HCP according to the time since vaccination, 2010 (N = 129)



HCP negative for anti-HBs* according to the time since vaccination



Hospital staff in Bulgaria & Hepatitis B vaccination: The average



Vaccinated (52.9%) versus Unvaccinated (43.8%)

Protected (46.1%) versus Susceptible (36.1%)

Hospital staff in Bulgaria & Hepatitis B vaccination: Behind the average

- ❖ Hepatitis B vaccination coverage levels among HCP in Bulgaria vary substantially:
 - between different hospitals (23% to 85%) according to the prevalence study, 2010
 - between different services/units (63% to 91%) based on the self-report questionnaire survey, 2008
- ❖ Similarly, significant differences between hospitals exist in post hepatitis B vaccination seroprotection rate (28% to 60%) as has been shown in seroprevalence study, 2007

Hospital staff in Bulgaria & Hepatitis B vaccination: Behind the average

- ❖ A substantial reduction of newly acquired HBV infections in HCP was found (up to 3-fold lower anti-HBc prevalence when compared with the general population of the same age groups tested in the 1980s)
- ❖ A high antibody response rate ($\geq 95\%$) in the first months after the primary course of hepatitis B vaccination and a decline of protective antibody to undetectable level in one-third of the staff 10-15 years post vaccination was demonstrated, in line with the other similar studies
- ❖ Among hospital-based medical staff 47% had not received hepatitis B vaccination and 36% were still susceptible to VHB, corresponding to an estimated 36 500 unvaccinated and 30 000 non-immune HCP working in the healthcare system in Bulgaria

Strategies to achieve further improvement

Efforts should be focused on:

- ❖ **Ongoing education of HCP** to improve their knowledge of and to overcome their concerns about the vaccine
- ❖ **Aggressive communication of information** on national, regional and local level regarding the "champions" and the successful approaches they use to achieve better vaccination rates
- ❖ **Incorporating a yearly work plan** in the Hospital Infection Control Programme to promote hepatitis B vaccination of HCP and to ensure the appropriate financial and operational resources
- ❖ Development and implementation of a nationally approved **universal protocol for post-vaccination screening and revaccination of nonresponders**

Study team

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Hospital IC teams in 16 regions of the country



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