EPIDEMIOLOGICAL EFFECTIVENESS OF
THE UNIVERSAL NEWBORN
HBV VACCINATION:
20 YEARS AFTER

VIRAL HEPATITIS PREVENTION BOARD MEETING
SOFIA, BULGARIA
24-25 MARCH 2011

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BACKGROUND

1. Hepatitis B in Bulgaria

• Bulgaria is a country in an area of intermediate endemicity of Hepatitis B, with 3-5% HBV carrier prevalence and more than 30% of the population with serological evidence of HBV infection.

• All acute cases of HBV infection clinically manifested with jaundice as well as all laboratory positive cases are subject of mandatory notification in Bulgaria since 1983. The EU case definition¹ and case classification have been adopted since 2005.

## 2. Hepatitis B Immunization in Bulgaria

**HBV Vaccines used:** Recombinant DNA vaccines

**Immunization Schedule:** 0 – 1 – 6

At birth → 1 month of age → 6 months of age (within 24 hours)

**Immunization strategy:**

- **1983 – 1987**  
  No immunization

  Selective immunization of newborns to HBsAg - positive mothers

- **August 1991**  
  Start of the universal newborn immunization

- **1992 up to date**  
  Routine universal newborn HBV immunization
PURPOSE OF THE ANALYSIS

• To assess the impact of the newborn immunization on the incidence of acute manifested HBV infection in Bulgaria during the period 1988-2010 and to analyze the changes in hepatitis B epidemiology 19 years after the start of the program for routine universal newborn HBV vaccination.
MATERIALS AND METHODS

• Age-specific annual incidence of acute HBV infection in Bulgaria is estimated on the ground of the data obtained from the National surveillance system, requiring compulsory notification and laboratory confirmation of acute clinically manifested cases of HBV (Regulation No 21 of the MoH from 18 July 2005 on the procedure for registration, notification and reporting of communicable diseases, State Gazette, No 62 of 29 July 2005).

• Surveillance on the universal newborn HBV immunization is based on the reports from the GPs to Regional public health authorities (RHI) and the reports from the RHI to the Immunization Information System. The national immunization coverage with HBV vaccine is estimated at the NCHI.
HEPATITIS B IMMUNIZATION COVERAGE IN NEWBORNS IN BULGARIA, 1988 – 2010

<table>
<thead>
<tr>
<th>YEAR</th>
<th>NUMBER OF IMMUNIZED INFANTS (HBV-3)</th>
<th>IMMUNIZATION COVERAGE (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1988</td>
<td>1 300 до 2 886</td>
<td>No data</td>
</tr>
<tr>
<td>1989</td>
<td>861</td>
<td>No data</td>
</tr>
<tr>
<td>1990</td>
<td>1 646</td>
<td>No data</td>
</tr>
<tr>
<td>1991</td>
<td>≈ 20 000</td>
<td>No data</td>
</tr>
<tr>
<td>1992</td>
<td>68 393</td>
<td>71.3%</td>
</tr>
<tr>
<td>1993</td>
<td>78 359</td>
<td>95.7%</td>
</tr>
<tr>
<td>1994</td>
<td>73 519</td>
<td>94.2%</td>
</tr>
<tr>
<td>1995</td>
<td>70 565</td>
<td>95.4%</td>
</tr>
<tr>
<td>1996</td>
<td>66 591</td>
<td>93.5%</td>
</tr>
<tr>
<td>Year</td>
<td>Vaccinated (Children)</td>
<td>Vaccination Coverage (%)</td>
</tr>
<tr>
<td>------</td>
<td>-----------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>1997</td>
<td>46,144</td>
<td>77.2%</td>
</tr>
<tr>
<td>1998</td>
<td>72,384</td>
<td>97.1%</td>
</tr>
<tr>
<td>1999</td>
<td>65,988</td>
<td>97.3%</td>
</tr>
<tr>
<td>2000</td>
<td>63,756</td>
<td>93.7%</td>
</tr>
<tr>
<td>2001</td>
<td>63,143</td>
<td>93.3%</td>
</tr>
<tr>
<td>2002</td>
<td>57,647</td>
<td>88.3%</td>
</tr>
<tr>
<td>2003</td>
<td>65,895</td>
<td>95.8%</td>
</tr>
<tr>
<td>2004</td>
<td>61,673</td>
<td>93.8%</td>
</tr>
<tr>
<td>2005</td>
<td>62,576</td>
<td>96.0%</td>
</tr>
<tr>
<td>2006</td>
<td>63,629</td>
<td>95.9%</td>
</tr>
<tr>
<td>2007</td>
<td>63,378</td>
<td>95.4%</td>
</tr>
<tr>
<td>2008</td>
<td>65,808</td>
<td>95.7%</td>
</tr>
<tr>
<td>2009</td>
<td>68,043</td>
<td>95.6%</td>
</tr>
<tr>
<td>2010</td>
<td>68,527</td>
<td>95.0%</td>
</tr>
</tbody>
</table>

As of 2010, a total of 1,270,618 children had been fully vaccinated with 3 doses of hepatitis B vaccine.
ACUTE HEPATITIS B INCIDENCE IN BULGARIA, 1983 – 2010
• **Before the introduction of the immunization**

HBV incidence in newborns and children 1-3 yrs of age was 31.1 and 31.6 per 100 000. The incidence was highest in persons 4-7, 15-19 and 20-29 years of age: 55.9; 52.0 and 50.2 per 100 000 respectively.

• During 1988-1991, **the period of selective immunization**, the HBV incidence declined (40.9%) only in infants.

• The greatest decline of acute hepatitis B in Bulgaria occurred after the adoption of the strategy of **universal newborn immunization**. Among children 0 to 14 years of age the decline of the HBV incidence (94.2% in 2007) corresponded to the gradual increase of the cumulative number of immunized infants.
HEPATITIS B INCIDENCE IN CHILDREN 0-14 YRS OF AGE DURING THE DIFFERENT PERIODS OF THE IMMUNIZATION PROGRAM


- **0 yrs**: 31.1, 55.9, 10.3, 26.8
- **1-3 yrs**: 31.6, 46.7, 19.9
- **4-7 yrs**: 27.7, 55.9
- **8-14 yrs**: 60.6, 48.7

**Graph 2: 2006 - 2007**

- **0 yrs**: 2.9, 1.4
- **1-4 yrs**: 2.2, 1.1
- **5-9 yrs**: 3.7, 1.9
- **10-14 yrs**: 5.2, 4.6

**Legend:**
- 0 yrs
- 1-3 yrs
- 4-7 yrs
- 8-14 yrs
- 0 yrs
- 1-4 yrs
- 5-9 yrs
- 10-14 yrs

**Note:** The incidence rates are provided per 100,000.
NUMBER OF ACUTE HBV CASES AND INCIDENCE RATE BY AGE GROUPS IN BULGARIA IN 2006 AND 2010

2006

2010

Age groups

Number cases
Incidence per 100 000

Number cases
Incidence per 100 000

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CUMULATIVE NUMBER OF IMMUNIZED WITH HBV VACCINE NEWBORNS AND HEPATITIS B INCIDENCE (PER 100 000) IN CHILDREN 0-14 AND 15-19 YEARS OF AGE IN BULGARIA, 1983 – 2010
CONCLUSIONS (1)

• The immunization strategy focusing on universal newborn vaccination beginning at birth has been implemented with considerable success during the last 20 years in Bulgaria.

• The universal newborn immunization along with the complex of public health measures have led to the significant decrease of the HBV infection in Bulgaria as a whole.

• The annual incidence of reported acute HBV cases among children 0-14 yrs of age and adolescents 15-19 yrs of age decreased significantly.
CONCLUSIONS (2)

• The full effect of the introduced in August 1991 immunization program, dramatically reducing the incidence of acute hepatitis B in targeted age groups is expected to be achieved in 2011, when all adolescents up to 19 years of age will be protected by the immunization.

• The annual incidence of reported acute HBV cases among young adults 20-24 yrs is the highest at present. The decline of HBV incidence in this age group is expected during the next 5 years in correspondence with the gradual increase of the number of covered by immunization cohorts.