NATIONAL HEPATITIS B VACCINATION PROGRAMME:
COST-BENEFIT ASSESSMENT OF INTRODUCTION OF UNIVERSAL HBV VACCINATION OF NEWBORNS IN BULGARIA

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INTRODUCTION

In August 1991 Bulgaria was one of the first countries which decided to introduce mandatory universal immunization of all newborns.

- 3-5% HBsAg carrier prevalence
- More than 30% of population with serological evidence of HBV infection
- Evidence of perinatal transmission (18.8 – 23.4% of HBsAg positive pregnant women are found to be HBeAg positive)
- Significant acute HBV infection incidence and mortality rate

In 1992 the HBV vaccine was included in the National Immunization Schedule as a routine children immunization.
The aim of the study is to present a model-based economic assessment of introduction of universal infant HBV vaccination in Bulgaria by using cost-benefit analysis and comparing two vaccination strategies: “without vaccination” and “universal vaccination of all newborns”.

PURPOSE OF THE STUDY
MATERIALS AND METHODS

➢ The time horizon of the assessment covers a period of 100 years

➢ A static model of the acute and chronic HBV infection evolution is applied for calculation

➢ “Decision tree” method is used for construction of the model

➢ The probabilities of moving between different stages of HBV infection are estimated from published studies in Bulgaria and other countries
MATERIALS AND METHODS

ACUTE SYMPTOMATIC HBV INFECTION

100%  0%

Hospital treated  Ambulatory treated

98.5%  1.5%

Non-Fulminant HBV infection  Fulminant HBV infection

10%  90%

Liver transplant  Death

80%  20%

Recovery  Death
MATERIALS AND METHODS

The demographic, epidemiological and vaccination input setting are estimated from official statistics and published data.

<table>
<thead>
<tr>
<th>Birth cohort size (in 1992)</th>
<th>88 000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age-specific mortality rate (%)</td>
<td>1.46 – 12.33</td>
</tr>
<tr>
<td>Age-specific HBV prevalence</td>
<td>1.0 – 40.0</td>
</tr>
<tr>
<td>Vaccine efficacy (%)</td>
<td></td>
</tr>
<tr>
<td>• First dose</td>
<td>40.0</td>
</tr>
<tr>
<td>• Second dose</td>
<td>80.0</td>
</tr>
<tr>
<td>• Third dose</td>
<td>99.0</td>
</tr>
<tr>
<td>Vaccination schedule</td>
<td>0 – 1 – 6 months</td>
</tr>
<tr>
<td>Length of protection</td>
<td>100 years</td>
</tr>
<tr>
<td>Vaccination coverage (%)</td>
<td>95.0</td>
</tr>
</tbody>
</table>
MATERIALS AND METHODS

- The perspective of the study is budgetary viewpoint. Only direct costs and benefits are included in the assessment.

- All future costs and benefits are discounted with 5% rate.

- The direct medical costs of treating of acute and chronic HBV infection are estimated on the basis of financial reports and hospital files at Infectious Diseases Hospital, Gastroenterology ward of the Fifth City Hospital and City Oncology Dispensary in Sofia for period 1993 – 1998.

- Official data from public tenders for purchase of HBV vaccine of the Ministry of Health are used for vaccination costs assessment.
MATERIALS AND METHODS

- The capital costs (equipment, building and land) as well as the direct non-medical costs are not taken into account.

- Health services, home visits, laboratory tests and hospital stay are estimated on the basis of Regulation 22 and Amendment of Regulation 22 of the Ministry of Health.

- All medical costs are expressed in monetary units – Bulgarian New Lev (BGN).
MATERIALS AND METHODS

- Cost-benefit analysis

Benefit to Cost Ratio (BCR) = \( \frac{\sum B_i}{\sum C_i} \)

- Sensitivity analysis

**B** — benefits of programme “universal infant vaccination”

= Costs without vaccination - Costs with vaccination

**C** — costs of programme “universal infant vaccination”

= Costs of vaccination
## RESULTS

**Direct costs (BGN) of treating per clinical acute and chronic HBV case**

<table>
<thead>
<tr>
<th></th>
<th>Acute HBV infection</th>
<th>Chronic HBV infection</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non fulminant</strong></td>
<td>289.00</td>
<td>876.37</td>
</tr>
<tr>
<td><strong>Fulminant</strong></td>
<td>263.58</td>
<td>3253.38</td>
</tr>
<tr>
<td><strong>Compensated cirrhosis</strong></td>
<td></td>
<td>404.45</td>
</tr>
<tr>
<td><strong>Decompensated cirrhosis</strong></td>
<td></td>
<td>903.38</td>
</tr>
<tr>
<td><strong>Primary hepatocellular carcinoma</strong></td>
<td></td>
<td>1449.72</td>
</tr>
</tbody>
</table>

**Direct costs (BGN) for immunization with HBV vaccine per newborn**

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>1 dose</th>
<th>3 doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Engerix B</td>
<td>7.69</td>
<td>23.07</td>
</tr>
<tr>
<td>Euvax</td>
<td>5.72</td>
<td>17.16</td>
</tr>
</tbody>
</table>
RESULTS

Expected number of HBV cases and deaths
Accumulated yearly number per 1 cohort for 100 years

- Acute (92.91%): No immunization - 28,559, Immunization - 2,025
- Chronic (92.95%): No immunization - 22,681, Immunization - 160
- Deaths (92.80%): No immunization - 361, Immunization - 26
RESULTS
Economic burden of HBV infection

Direct medical costs (BGN) related to HBV infection

- Acute (93.20%): 2,945,933
- Chronic (97.33%): 3,319,837
- Total (95.39%): 6,265,770

NATIONAL CENTRE OF INFECTIOUS AND PARASITIC DISEASES, BULGARIA
RESULTS

Cost-benefit analysis

Discounted benefits (BGN)  46 157 094
Discounted costs (BGN)  38 279 712

Benefit to cost ratio (BCR) = 1.21
RESULTS

Discounted costs and benefits (BGN000) by years after implementation of universal infant immunization
RESULTS

Sensitivity analysis

Effect of discount rate on benefit to cost ratio

![Graph showing the effect of discount rate on benefit to cost ratio. The graph illustrates a downward trend as the discount rate increases, with benefit to cost ratio values of 3.04, 1.21, and 0.46 at different discount rates.]
RESULTS

Sensitivity analysis

Effect of vaccine cost on benefit to cost ratio
RESULTS

Sensitivity analysis

Effect of cost of treating HBV infection on benefit to cost ratio
CONCLUSIONS

1. The presented results show that the vaccination programme of universal immunization of all newborns against HBV infection in Bulgaria will reduce significantly not only direct medical losses but also the economic burden of the disease.

2. The economic evaluation of introduction of universal infant immunization in Bulgaria is substantially underestimated.

3. The low costs for treatment of different stages of HBV infection negatively influence the assessment of the benefit of introduction of the immunization programme.

4. The economic effect of the universal infant immunization strategy will be realized after 19 years when the benefits of the programme will exceed its costs.

5. The results of economic evaluation are in conformity with epidemiological data confirming the high effectiveness of the immunization programme introduced in 1992 in Bulgaria.