The Lessons learned from the use of combined Vaccine in Europe
Viral Hepatitis Prevention Board Meeting

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Hepatitis B Vaccination Targets
45th World Health Assembly, 1992

Integrate hepatitis B vaccine into national childhood vaccination programs

• By 1995 in countries with HBsAg prevalence ≥ 8%
• By 1997 in all countries
Viral Hepatitis Prevention Board

- VHPB is established in 1992. First actions related to hepatitis B as an occupational risk.
- World Health Assembly sets in 1992 Hepatitis B Vaccination targets on the integration of hepatitis B vaccine into national childhood vaccination programmes.
- In 1993, VHPB started a second major initiative and focused on hepatitis B as a community health risk.
- The geographical focus was initially Western Europe, its actions are extended to include all 51 countries in the WHO/EURO
Meetings and Recommendations

• The VHPB has already covered a broad range of control and prevention strategies for all forms of hepatitis
  – Surveillance
  – Universal programs
  – Injection safety and safe blood supply
  – HBV mutants and variants
  – Prevention and control of viral hepatitis in migrants and refugees
  – Behavioural issues in hepatitis B vaccination
  – How to reach risk groups
  – Combined vaccines
  – Economic evaluations
Hep B immunization programmes in WHO/EURO region, 1993
Hep B immunization programmes in WHO/EURO region, 1996

- Green: Universal immunization
- White: No universal immunization
Hep B immunization programmes in WHO/EURO region, 1998
Hep B immunization programmes in WHO/EURO region, 2002
Hep B immunization programmes in WHO/EURO region, 2008

- Universal immunization
- No universal immunization
Hep B immunization programmes in WHO/EURO region, 2013

47/53 (89%) universal programme remaining 6: risk group vaccination
Hepatitis B disease burden
WHO European Region

• 13 million people are chronically infected
• 60,000 deaths annually due to hepatitis B related liver cancer and cirrhosis
• Hep B epidemiology is diverse:
  • <1% HBsAg prevalence in North and Central European countries
  • >10% HBsAg prevalence in Central Asian countries
**Route of transmission**

The data on transmission were complete for only 5,346 (18.2%) of the reported hepatitis B cases in 2016 (30.8% completeness for acute cases, 15.0% for chronic cases). For the 778 acute cases with complete information, heterosexual transmission was most commonly reported (30.2%), followed by nosocomial transmission (16.6%), transmission among men who have sex with men (12.4%), non-occupational injuries (10.9%) and injecting drug use (9.6%) (Figure 5). Italy, Poland and Romania accounted for more than two thirds (69.1%) of the acute cases attributed to nosocomial transmission. Nosocomial transmission and mother-to-child transmission were the most common routes of transmission reported for the 2,641 chronic cases with complete information (32.6% and 31.6% respectively). Poland reported 91.9% of chronic cases attributed to nosocomial transmission. Among cases attributed to mother-to-child transmission, 91.7% were reported by three countries (Denmark, the Netherlands, and Sweden). Of the chronic cases attributed to mother-to-child transmission, 92.7% were classified as being imported. Due to incompleteness and variation of reporting over time, trends are difficult to interpret.
Figure 5. Transmission category of hepatitis B cases by acute and chronic disease status, EU/EEA, 2016*

Source: Country reports from Austria, Denmark, Estonia, Finland, France**, Germany, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Spain and Sweden.

* Cases where transmission status is known.
** Underreporting of acute hepatitis B in France was estimated at 76.5% in 2013.

Importation status

In 2016, of 9535 cases (32.5%) with information on importation status, 4482 (47.0%) were reported by 24 countries as being imported. The majority of these imported cases (86.8%) were chronic infections; 3283 (73.2%) were reported by three countries (Netherlands, Norway, and Sweden). The proportion of chronic cases (73.9%) reported as imported was higher than the proportion of acute cases (11.6%). The data completeness varied across countries, but among countries with complete data (>75%) on importation status, the proportion of chronic cases classified as imported ranged from 0% (Czech Republic, Malta, Portugal, and Romania) to over 85% (Denmark, Luxembourg, Norway, and Sweden).
Comparison of deaths by major communicable diseases in the European Region, 2012*

- Viral hepatitis: 145 thousand (2010)
- HIV / AIDS: 92 thousand
- Tuberculosis: 37 thousand

* Viral hepatitis - 2010
Global Disease Burden Estimate 2010, 2012
Deaths due to selected vaccine preventable diseases, WHO European Region, 2012*

- Hepatitis B: 3281
- Cervical cancer: 855
- Streptococcus pneumoniae: 326
- Haemophilus influenzae: 111
- Rotavirus: 39
- Pertussis: 27984
- Tetanus: 15100
- Influenza: 60878

 Hepatitis B deaths - 2010
Estimated prevalence of HBsAg, WHO European Region

V.D. Hope et al. / Epidemiol. Infect (2013) 1-17
Hep B immunization programmes in WHO/EURO region, 1993
Hep B immunization programmes in WHO/EURO region, 1996
Hep B immunization programmes in WHO/EURO region, 2002
Universal adolescent programmes in WHO/EURO region, 2002
Prenatal screening in WHO/EURO region, 2002
Reported immunization coverage rate
WHO/EURO, 1990-2001

Years
%    
BCG OPV3/DTP3 MCV HepB3

WHO Regional Office for Europe
Outcome evaluation of an universal hepatitis B immunisation programme

- Acute disease surveillance
- Sero-surveys
- Immunisation coverage surveys
- Monitor adverse events
- Quality control
Acute disease surveillance

Incidence of acute hepatitis B

- Mandatory notification
- Laboratory notification
- Sentinel system
- Hospital reporting
- Death registry
Acute disease surveillance report data sets may include:

- Patient demographics
- Specimen type
- Diagnosis
- Date
- Method of identification
- Lab name
- District and region
- Reason for testing
- Clinical features
- Relevant risk factors
- Occupational information
- Overseas travel
- Contact information
Surveillance of chronic consequences

- Morbidity and mortality data on cirrhosis
- Morbidity and mortality data on HCC
- Data on number of liver transplants
- Hospital discharge register
### common denominators: example age categories

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Immunisation coverage surveys

- Survey of immunisation certificates
- National survey at school entry
- Child health registry
- Vaccine sales figures
- Prescription for vaccine doses
- Doses of imported or licensed vaccine
- Doses of distributed vaccine
Measurement and reporting of vaccination effectiveness of Hepatitis B
Results of the EUROHEP.NET feasibility survey

Objectives
- To give an overall picture of the effectiveness of the existing hepatitis B vaccination programmes in the participating countries.
- To study the feasibility to formulate guidelines to enable uniform measurement and reporting of the vaccination effectiveness.

Birth cohorts covered by universal hepatitis B vaccination

Coverage rates of the universal hepatitis B vaccination programmes

Universal programmes for neonates and infants

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Universal programmes for children and adolescents

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Methods
- 20 countries (AT, BE, BG, CZ, EE, DE, GR, IL, IT, LV, LT, LU, MT, NL, PL, RO, SK, SL, UK) participated in the EUROHEP.NET survey (2003).
- Based on the results of this survey, an overview is given of:
  - the existing universal hepatitis B vaccination programmes
  - the birth cohorts already covered by these programmes
  - the available coverage rates for the universal programmes.
- The country-specific incidence data for hepatitis B over the period 1990-2001 were used to get a rough estimate of the effectiveness of these programmes (data not shown here).
WHAT IS HEXAVAC® (1): Composition and Presentation

- A unique ready to use, preservative-free, liquid formulation, combining all 6 antigens in 0.5 ml
  - purified diphtheria toxoid, 20 IU (30 Lf)
  - purified tetanus toxoid, 40 IU (10 Lf)
  - adsorbed purified pertussis toxoid, 25 μg
  - adsorbed purified FHA, 25 μg
  - Polio type 1 (Mahoney strain), 40 D units
  - Polio type 2 (MEF 1 strain), 8 D units
  - Polio type 3 (Saukett strain), 32 D units
  - PRP-T, 12 μg (PRP)

B. Soubeyrand - VHPB October 2001
Malte
WHAT IS HEXAVAC® (2): Critical timelines

- Start of the project Feb. 94
- 1st clinical lot available Jan. 95
- 1st inclusion phase 1 Feb. 95
- 1st inclusion phase 2 May 95
- 1st consistency batch (development scale) July 95
- 1st inclusion phase 3 June 96
- 1st consistency batch (industrial scale) Dec. 98
  i.e. - 5 years and 5 months: time to develop
  - 6 years and 8 months: time to register / market
- 1st industrial lot April 99
## Simplifying Vaccination Schedules (I)

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19th VHPB meeting on "combined hepatitis B vaccines", Malta 22-23.10.01, Dr. M. Pfleiderer, PEI
## Simplifying Vaccination Schedules (II)

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19th VHPB meeting on "combined hepatitis B vaccines", Malta 22-23.10.01, Dr. M. Pfleiderer, PEI
Advantages Provided by Combined Vaccines

- Increased compliance
- Increased vaccine coverage
- Improved vaccination documentation
- Reduced overall costs of vaccination campaigns
- Reduced storage requirements
- Reduced doctors visits
- Reduced number of injections
Potential Efficacy Concerns Identified During Dossier Evaluation

• Combining antigens to formulate a multivalent vaccine is more than just mixing
  – Changes may occur in the immunogenicity due to interference of vaccine antigens
  – Reliable potency testing may become increasingly complicated
  – Do the established surrogates/correlates for protection need reconsideration?

19th VHPB meeting on "combined hepatitis B vaccines", Malta 22-23.10.01, Dr. M. Pfleiderer, PEI
Impact of Hepatitis B Vaccination

- Reduction in incidence of acute hepatitis B infections
- Decrease of carrier rate in immunized cohorts
- Reduction in hepatitis-B–related mortality
Italy

- Acute hepatitis B cases reduced from 11/100,000 in 1987 to 1.6/100,000 in 2006
- Generation of young adults (27-year age cohorts) is emerging with almost no markers of HBV
- In South Italy the rate of HBsAg dropped from 13.4% before vaccination to 0.9% 20 years after implementation of vaccination
- The prevalence of anti-HBc antibody in the same population decreased from 66.9% to 7.6%
Impact of Hepatitis B vaccination on the incidence of acute Hepatitis B infection, Moldova

Source: National Center of Preventive Medicine, Moldova
Hepatitis B incidence in children under 5, Kyrgyzstan, 2000-2005

Source: CDC/CAR
• Bring vaccine delivery to the neonate: participating countries have achieved success in vaccinating neonates, but challenges remain in terms of coverage and timeliness

• HBV vaccination provides a safety net against perinatal transmission of hepatitis B virus, and also prevents early childhood, parenteral and later sexual transmission of HBV, and also protects against D (example of Italy where HBV vaccination lead to elimination of D)

• Combined vaccines have good immunogenicity and can replace separate vaccines in areas of high hepatitis B endemicity

• Vaccine procurement: need to involve finance as well as health ministries

• Need for clear specifications in tenders for vaccines, e.g. provision of vaccines with VVMs, restatement of open-vial policy, provision of instructions in appropriate languages
Major Achievements
Conclusions CDC-UNICEF-VHPB-WHO meeting Istanbul 2006

• Hep B vaccine was introduced in routine immunization programmes in most countries
• The poorest countries successfully introduced Hep B vaccine with GAVI support
• All high endemic countries provide birth dose
• HepB vaccine was combined with existing successful programmes
• Impact of universal childhood immunization on Hepatitis B diseases burden was demonstrated
• Hepatitis B vaccine introduction was used as a model for introduction of other underutilized and new vaccines
Systematic review on hepatitis B and C prevalence in the EU/EEA
WHO – EURO
Regional hepatitis B control targets

• Sustainable universal immunization programmes in all countries with 95% coverage with three doses of hepatitis B vaccine
• Universal newborn immunization (within 24 hours after birth) or effective universal screening of pregnant women and post exposure prophylaxis of carrier children
• Prevalence of HBsAg in children in vaccinated cohorts of children 0.5% or lower confirmed by serosurvey
European Vaccine Action Plan 2016-2020

• Set regional goals for immunization and control of vaccine-preventable diseases:
  • Sustain polio-free status
  • Eliminate measles and rubella
  • Control hepatitis B infection
• Meet regional vaccination coverage targets at all administrative levels throughout the Region
• Make evidence-based decisions on the introduction of new vaccines
• Achieve financial sustainability of national immunization programmes
• Proposed a set of actions to achieve the goals