Waste management

Document: waste management at country level

- Count at all levels the waste
- Report from aggregated from local, district to national level
- Multidose versus monodose vial has implications on waste amount
- Multidose increases the amount of managerial work
- Multidose management only valid for non-lyophilized vaccines

Waste management

- If vaccine doses and waste amount remains stable: improve waste management
- If vaccine doses decrease and waste increase: problem with cold chain
- If both increase: better outreach and therefore waste augments

Vaccine preparations

Available on DR-ROM in Russian & English

- Thiomersal - ETAGE 2004
- Thermo-stability - freezing (avoid!!) versus heating to a certain extent
- Purchase - be careful with manufacturer provided information
  - All vaccines are safe and efficacious
  - Vaccines are interchangeable

Vaccine preparations

- Diversity of schedules!
  - 3rd dose at least 2 months after 2nd dose
  - 3rd dose at least at 6 months of age
  - Make it fit into the national/EPI program - scheme is flexible
- Dosage: vaccine not a generic product - but protection same
- Perinatal transmission
  - 1st dose within 12-24 hours - decreased efficacy if given later
  - HBIg adds 2-3% increase in protective efficacy - not available everywhere - added value rather small

Vaccine preparations

- BCG & hepatitis B vaccine given together: OK
- Simultaneous administration with other vaccine: OK
- WHO: most important - prevent perinatal transmission (feasibility)
- Monovalent vaccines to be used at birth - do not use combined vaccines at birth
- 22 out of 43 countries have a newborn program

Duration of protection

- Protection with >10 IU/l anti-HBs
- Decrease of anti-HBs titres after 3rd dose is low/flat after 18-24 months
  - Kinetics similar in individuals irrespective of peak antibody levels (standard vaccination)
  - Half-life is a function of time
  - Influenced by disorders of immune system
  - After 10 years: 50-85% of individuals still positive

Duration of protection

- Risk of infection inversely related of maximal antibody response
- Negative individuals are again susceptible to infection
  - breakthrough infections possible - 0-14%
  - no acute disease, no clinical signs - protection against clinically apparent disease
- presence of immunologic memory
  - memory cells lead to rapid anamnestic response
  - prevents disease and chronic infection

Duration of protection

- how long does memory last?
  - > 95% of vaccinees after 10 years
  - Presence of HBsAg specific T- and B-cells last for at least 15 years
  - Correlates with primary response
  - Depends on antigen dose
  - More than 15 years: wait for more studies

Current experience in Italy

- Hepatitis B and D widespread in the 1980s
- Italy introduced a double cohort approach in infants and adolescents (age 12) 1991
- Double cohort stopped in 2003 (catch-up). Only infant immunisation since 2004
- High coverage at 24 months
- Incidence (Tuscany data 1994-2001) decreased from
  - 14.3 to 3.7 /100'000 in 20-24 age group
  - 7.3 to 1.3/100'000 in the 15-19 age group

Current experience in Italy

- Anti-HBc present in 0.3% of vaccinated vs. in 6.6% of non-vaccinated
- Persistence of anti-HBs after 11 years
  - 64% positive in children
    - 98.5 % responded to booster
  - 87% positive in recruits
    - 100% responded to booster
  - Only 0.3% remain negative after booster overall (infants + adolescents)
- No public health problem with HBsAg mutants as of 2004
- Very limited number of asymptomatic infections in infants born to HBsAg positive mothers
- Deep impact in the population of national HB vaccine campaign

hepatitis B vaccine booster *(WHO/V&B/01.31)*

Management guidelines, including information for health workers and parents
WHO, Department of Vaccines and Biologicals, November 2001

- Many studies have shown that infants, children and adults who have responded to a three-dose hepatitis B immunization series are protected from the disease for as long as 15 years, even if they lose protective antibodies over time.
- Long-term protection relies on immunological memory, which allows a protective anamnestic response after exposure to HBV.
- **Booster doses of vaccine are not, therefore, recommended.**

hepatitis B vaccine booster

WHO priorities remain

- infant immunization
- prevention of perinatal transmission through neonatal programmes
- catch up programmes
- of consideration /no recommendations/ for specific groups like HCW, patient groups,
- booster may be used for reasons of reassurance
- booster may be used for immunocompromised patients

Pre-vaccination testing

- HB vaccine can even be administered to HBsAg positive individuals
- Pre-vaccination screening is NOT recommended routinely
  - Identifies infected or immune individuals
  - Refer for counselling
  - Defer immunization
- Only considered for cost effectiveness
  - Cost of vaccine
  - Cost of testing
  - Prevalence of infection
  - Compliance of individuals - always administer first dose at time of testing

Post-vaccination testing

- Post-vaccination testing NOT routinely recommended
  - >95% seroconvert
  - Test 1-2 months after 3rd dose
  - Use quantitative test if possible
- Infants of HBsAg positive mothers: test at 9 months

Management of adult non-responders

- re-administer additional vaccine doses
- % 30responders after 1st dose
- 50% responders after 3rd dose
- If exposed, administer HBIG
- Conclusions: Little benefit of these programs from public health perspective

country	booster	schedules
Kazakstan	no	0,2,4,newb
Ukraine	booster in 0,1,2 immunized newborns at 12 mo	yes
Russian Fed	booster in 0,1,2 immunized newborns at 12 mo	yes
Poland	no, only persons with chronic disease	yes
Georgia	no	yes
Csech Rep	mandatory for HCW in case of incident	yes
Hungary	no	yes, post v
Bielo Russia	no	2000 infant
Moldovoa	no	0,1,6 newb
Lattvia	no	0,1,6 HCW,
Littuania	no	0,1,6, newb
Turkey	no, Private practice have boosters, HCW unofficial	
Estonia	no	no policy is