Methods to Evaluate Infant Hepatitis B Immunization Programs

Summary of Workshop 7A
Kiev, May 2004
Why Do We Need to Evaluate Hepatitis B Immunization Programs?

• Prove that what we are doing is working
  – Immunization leads to decreased morbidity and mortality
• Increase public confidence in immunizations
  – Important in light of recent vaccine/vaccination safety concerns
• Advocate for sustainable immunization programs
  – GAVI won’t last forever
Methods to Evaluate Hepatitis B Immunization Programs

- Immunization coverage
- Serologic surveys
- Surveillance for acute hepatitis B
- Surveillance for HBV-related mortality
Immunization Coverage

Pros
- Data routinely collected
- Inexpensive

Cons
- Does not directly measure impact on disease burden
- Can have high coverage and low vaccine efficacy (i.e., frozen vaccine) or low vaccination program effectiveness (i.e., not administered properly)
**Objective:** Compare seroprevalence of infection in target population before and after commencement of immunization program

**Requirements:**

- Representative Population
- Laboratory Capacity
Serologic Surveys

Pros

• Direct measure of disease burden (prevalence of chronic infection)
• Can evaluate impact of infant vaccination within a few years of commencement of program

Cons

• Requires laboratory capacity
• May be logistically difficult to conduct – need representative population
• Expensive
Serologic Surveys

Issues

• Are there convenience samples that approximate the general population?

• Integrate with other surveys
  – DHS
  – Nutrition surveys

• Use opportunity of drawing blood to test for other serologic/blood markers
Surveillance for Acute Viral Hepatitis

Requirements

• Sufficient number of cases among children
  – Likely in most countries CEE/NIS
• Mechanism to identify ill children
  – Hospital-based vs. community-based
• Laboratory capabilities
  – Clinical presentation of acute hepatitis of all etiologies similar
  – Diagnosis requires laboratory confirmation
Acute Viral Hepatitis Surveillance

**Pros**
- Direct measure of disease burden (acute symptomatic disease)
- Measure impact of infant and adult immunization programs
- Collect risk factor data
- Determine etiology of viral hepatitis (A, B, C, D, E, other)

**Cons**
- Mechanism to identify cases
- Requires **very strong and consistent** lab capacity
- Requires sophisticated surveillance infrastructure
- Expensive
Acute Viral Hepatitis Surveillance

Issues

• Must have standard case definition
• Must have laboratory confirmation
• National vs. sentinel surveillance
• Age of population under surveillance
  – children vs. all age groups
Hepatitis B-Related Mortality

• Deaths from
  – Acute hepatitis B
  – Cirrhosis
  – Hepatocellular carcinoma

• Outcomes rare among children

• Not good measure of immediate impact of infant vaccination

• Better suited for long-term evaluation
Comparison of Methods to Evaluate Hepatitis B Immunization Programs

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<thead>
<tr>
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<th>Coverage Survey</th>
<th>Serosurvey</th>
<th>Acute Disease Surveillance</th>
<th>Morbidity &amp; Mortality</th>
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<tbody>
<tr>
<td>Feasibility</td>
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<td>Expense</td>
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<tr>
<td>Frequency of evaluation</td>
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<td>I or C*</td>
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<td>Program effectiveness</td>
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<tr>
<th>Information collected</th>
<th>Coverage data</th>
<th>Prevalence of infection</th>
<th>Incidence new infection</th>
<th>Incidence chronic sequelae</th>
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<td>Risk factor information</td>
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* I=intermittent; C=continuous