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# **Methods to Evaluate Infant Hepatitis B Immunization Programs**

**Summary of Workshop 7A  
Kiev, May 2004**

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# Why Do We Need to Evaluate Hepatitis B Immunization Programs?

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- 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

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

# Immunization Coverage

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## Pros

- Data routinely collected
- Inexpensive

## Cons

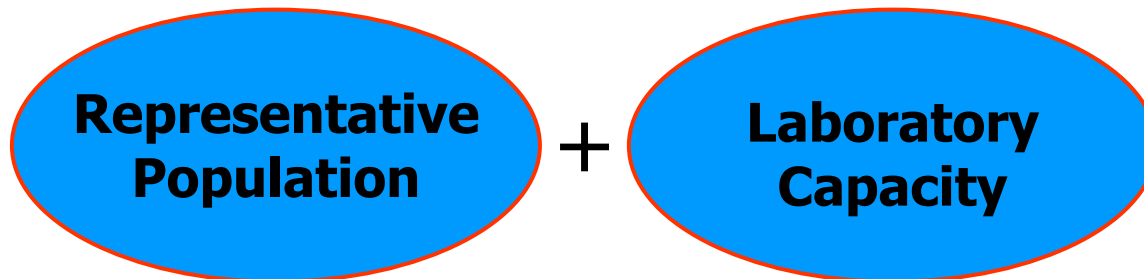
- Does not directly measure impact on disease burden
- Can have high coverage and low vaccine efficacy (i.e., frozen vaccine) or low vaccination program effectiveness (i.e., not administered properly)

# Serologic Surveys

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***Objective:*** Compare seroprevalence of infection in target population before and after commencement of immunization program

***Requirements:***



# Serologic Surveys

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## 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

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## 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

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## 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

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## 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

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## 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

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- 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

	Coverage Survey	Serosurvey	Acute Disease Surveillance	Morbidity & Mortality
<b>Feasibility</b>	+	+++	+++	+++
<b>Expense</b>	+	+++	+++	++
<b>Frequency of evaluation</b>	I*	I	I or C*	I or C
<b>Program effectiveness</b>				
<b>short-term</b>	-	+++	+	+
<b>long-term</b>	-	+++	+++	+++
<b>Information collected</b>	<b>Coverage data</b>	<b>Prevalence of infection</b>	<b>Incidence new infection</b>  <b>Risk factor information</b>	<b>Incidence chronic sequelae</b>

\* I=intermittent; C=continuous