Understanding your epidemic: WHO tools for hepatitis surveillance

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Monitoring and evaluation (M&E) framework for HBV and HCV

Context
- Epidemic

Inputs
- System
  - C1. Prevalence
  - C2. Testing facilities
  - C3. Vaccine coverage
  - C4. Needle syringe for PWID
  - C5. Injection safety

Output & outcomes
- Prevent
- Test
- Treat
- Heal
  - C.9 Incidence
  - C.10 Mortality from HCC, cirrhosis

Impact
- Elimination
  - C8 Viral suppression (HBV) or cure (HCV)
  - C7 Treatment coverage / initiation
  - C6 People diagnosed
  - C4 Needle syringe for PWID
  - C5 Injection safety
  - C3 Vaccine coverage

Cascade of care
- Prevent
- Test
- Treat
- Heal
Components of the M&E framework that require surveillance data

Context
- Epidemic
- C1. Prevalence
  - C2. Testing facilities
  - C3. Vaccine coverage
  - C4. Needle syringe for PWID
  - C5. Injection safety

Inputs
- Prevent
- Test
- Treat
- Heal

Output & outcomes
- Cascade of care
- Prevent
- Test
- Treat
- Heal

Impact
- Elimination
- C.9 Incidence
- C.10 Mortality from HCC, cirrhosis
Data systems for hepatitis elimination

Hepatitis surveillance
1. Acute hepatitis that reflect new infections
2. Chronic infections
3. Sequelae

Programme data
• Prevention indicators
• Patient databases for the cascade of care and cure
# The specificity of viral hepatitis surveillance

## Large time lag between incidence, prevalence and mortality

### Classical communicable disease surveillance

- Acute infections
- Deaths from acute infections, rapidly after initial infection
- Need to capture incidence of acute cases, including case fatality
- Cases definitions limited to acute cases

### Viral hepatitis surveillance

- Acute, then chronic infections
- Deaths many years later from sequelae of chronic infections
- Need to capture incidence, prevalence and mortality. Time lag incidence / deaths.
- Cases definitions for acute cases, chronic cases and sequelae
The 3 legs of viral hepatitis surveillance

1. Detect outbreaks, monitor trends in incidence and identify risk factors for new, incident infections

2. Estimate the prevalence of chronic infections and monitor trends in sentinel groups

3. Estimate the burden of sequelae

- **Surveillance for acute hepatitis**: Impact monitoring
- **Surveillance for chronic infections**: Initial assessment
- **Surveillance for cirrhosis and HCC**: Impact monitoring

Impact monitoring

Initial assessment

- **World Health Organization**
The 3 legs of viral hepatitis surveillance

1. Detect outbreaks, monitor trends in incidence and identify risk factors for new, incident infections

Surveillance for acute hepatitis
Impact monitoring

2. Estimate the prevalence of chronic infections and monitor trends in sentinel groups

Surveillance for chronic infections
Initial assessment

3. Estimate the burden of sequelae

Surveillance for cirrhosis and HCC
Impact monitoring
Acute hepatitis surveillance: enhanced case reporting for trends, risk factors

<table>
<thead>
<tr>
<th></th>
<th>Syndromic surveillance: Usually there</th>
<th>Enhanced case reporting: Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case definitions</td>
<td>Clinical</td>
<td>Type specific – IgM diagnosis</td>
</tr>
<tr>
<td>Data collection</td>
<td>Basic demographics</td>
<td>Risk factors</td>
</tr>
<tr>
<td>Objectives</td>
<td>Outbreak detection</td>
<td>Trends, risk factors</td>
</tr>
<tr>
<td>Scale</td>
<td>Nationwide</td>
<td>Mostly sentinel</td>
</tr>
</tbody>
</table>

Syndromic surveillance:
- Usually there

Enhanced case reporting:
- Needed

HBV
HAV
HEV
HBV
HCV
# Case definitions for acute hepatitis

<table>
<thead>
<tr>
<th>Level</th>
<th>Acute hepatitis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Suspect case:</strong> Clinical criteria</td>
<td>Discrete onset of an acute illness with signs or symptoms of (a) acute viral illness and (b) hepatic injury (liver enzymes)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Confirmed case: Clinical criteria AND epidemiological criteria or biomarker criteria</th>
<th>HAV</th>
<th>HEV</th>
<th>HBV</th>
<th>HCV</th>
</tr>
</thead>
<tbody>
<tr>
<td>IgM anti-HAV + OR</td>
<td>IgM anti-HEV + OR</td>
<td>IgM anti-HBc +</td>
<td>Anti HCV + AND All IgM – for HAV, HEV, and anti-HBc OR</td>
<td></td>
</tr>
<tr>
<td>Epidemiological link with a confirmed case</td>
<td>Epidemiological link with a confirmed case</td>
<td></td>
<td>RNA +/ Anti-HCV – OR</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Sero-conversion Anti-HCV</td>
<td></td>
</tr>
</tbody>
</table>

Acute hepatitis less common than chronic hepatitis: Definitions must be as specific as possible
The 3 legs of viral hepatitis surveillance

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Surveillance for acute hepatitis
Impact monitoring

Surveillance for chronic infections
Initial assessment

Surveillance for cirrhosis and HCC
Impact monitoring

HCC: Hepatocellular carcinoma
Integrations are key to reduce cost of biomarker surveys

**Viral hepatitis**
- Add adults to surveys to estimate impact of hepatitis B vaccine
  - Children: Estimate impact among those vaccinated
  - Adults: Estimate size of infected population

**HIV surveys**
- Demographic and health surveys [DHS] (Left over specimens)
- AIDS indicator surveys

**Immunization**
- Coverage surveys
- Population surveys of measles /rubella immunity
Context analysis

Lots of guidance available
- Immunization manual
  - General
  - Sampling methods
- HIV
  - WHO / UNAIDS guide

Protocol writing remains a road block
- Writing is time consuming
- Technical issues needs attention
8 questions for stakeholders to address

1. What hepatitis viruses require estimates?
2. For what population(s) are (the) estimate(s) needed?
3. For what sub-groups are estimates needed? e.g., age groups
4. Are synergies envisaged for the survey?
5. How will participants be sampled from the population?
6. What techniques will be used for specimen collection?
7. What kind of in vitro-diagnosis will be used?
8. What strategy will be used to return results?
The 3 legs of viral hepatitis surveillance

1. Detect outbreaks, monitor trends in incidence and identify risk factors for new, incident infections

2. Estimate the prevalence of chronic infections and monitor trends in sentinel groups

3. Estimate the burden of sequelae

- Surveillance for acute hepatitis
- Impact monitoring

- Surveillance for chronic infections
- Initial assessment

- Surveillance for cirrhosis and HCC
- Impact monitoring

HCC: Hepatocellular carcinoma

Impact monitoring
Sequelae surveillance protocol: 
Introduction

Justification
• Most countries lack a system to estimate the proportion of cirrhosis/HCC attributable to hepatitis viruses versus other causes
• Sentinel surveillance in sites of excellence can generate data on the attributable fraction

Objectives
• Recruit a sample of patients with cirrhosis and HCC
• Assess the HBV and HCV status of cirrhosis and HCC patients
• Estimate the proportion of cirrhosis and HCC with HBV/HCV infection
• Provide input to national mortality systems so that they can estimate the fraction of cirrhosis / HCC mortality that comes from hepatitis
Sequelae surveillance protocol: Overview

1. **Population under surveillance:**
   Patients with cirrhosis or hepatocellular carcinoma in hepatology/gastroenterology centres

2. **Investigators:**
   Clinicians functioning as investigators

3. **Case definitions:**
   ICD-10 codes

4. **Data collection:**
   Interview and review of patients’ records (case report form).
   - Part of normal clinical practice
   - Data on outcome (Cirrhosis / HCC)
   - Data on exposure (hepatitis and other causes of chronic liver diseases)
Analysis plan: Example using global data

1. NATIONAL MORTALITY STATISTICS

1.16M deaths from cirrhosis
0.79M deaths from HCC

2. ATTRIBUTABLE FRACTION IN CENTRES OF EXCELLENCE IN HEPATOLOGY

40% cirrhosis from HBV
22% cirrhosis from HCV
43% HCC from HBV
17% HCC from HCV

1.19 million deaths from chronic HBV and HCV infections in 2015
Expected outcomes

• Improved national mortality estimates
• Capacity built for surveillance of cirrhosis and HCC
• Lessons learned for extension of the project
• Community of practice created

Future perspectives

1. Initial pilot projects
2. Scaling up in more centres
3. Engage centres of clinical excellence as resource partners for testing and treatment activities
Viral hepatitis surveillance: Summary

The three parts of viral hepatitis surveillance capture key information along the three components of the viral hepatitis epidemic

• If incidence of new infections is a problem, monitor acute hepatitis that reflect new infections through enhanced case reporting

• The prevalence of chronic infections is best estimated through population based biomarker surveys. In the absence of surveys, data extraction can lead to working estimates

• Surveillance of the fraction of cirrhosis and HCC that come from HBV and HCV infection can be used to carve out the proportion of cirrhosis and HCC deaths that are attributable to HBV and HCV infections and estimate mortality
Thank you

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