

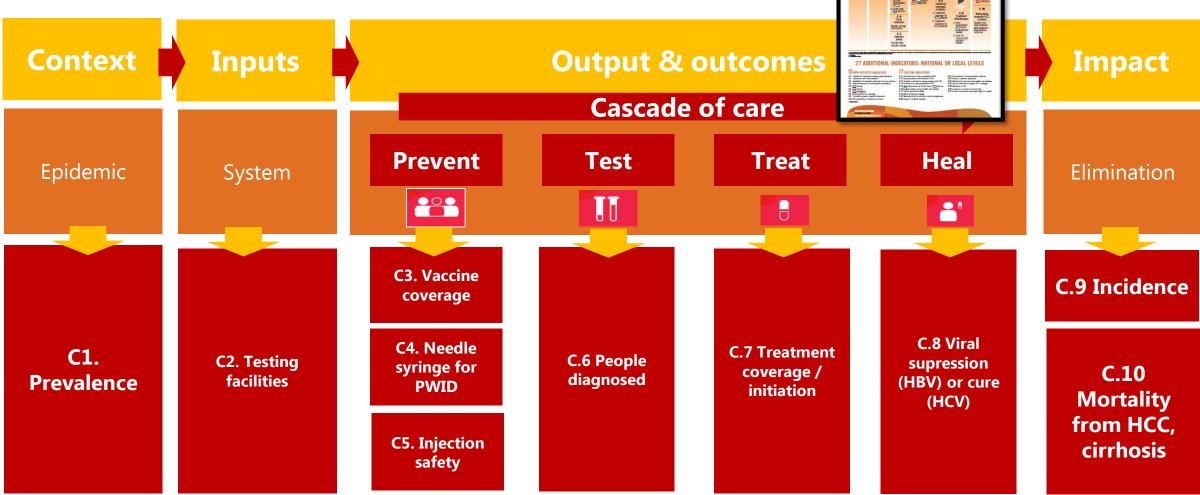
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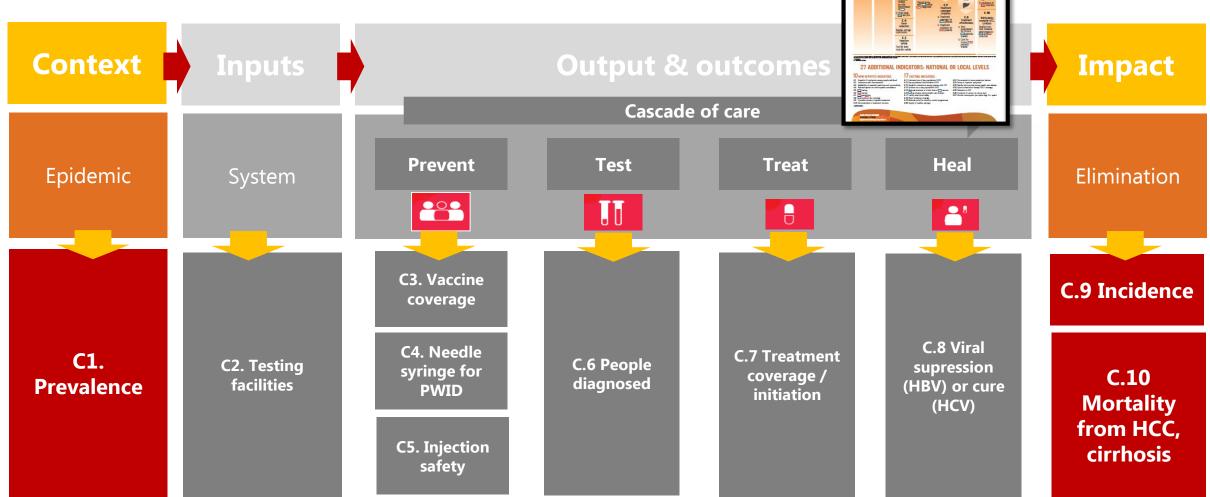
## Monitoring and evaluation (M&E) framework for HBV and HCV





# Components of the M&E framework that require surveillance data





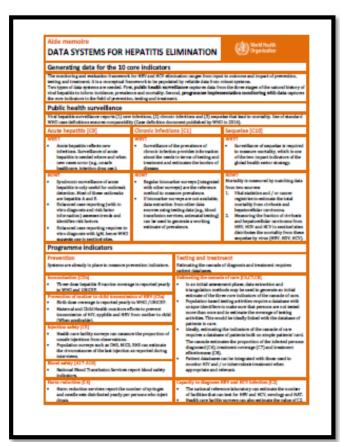
### Data systems for hepatitis elimination

### 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



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



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# Acute hepatitis surveillance: enhanced case reporting for trends, risk factors



	Syndromic surveillance: Usually there	Enhanced case reporting: Needed	
Case definitions	Clinical	Type specific – IgM diagnosis	
Data collection	Basic demographics	Risk factors	
Objectives	Outbreak detection	Trends, risk factors	
Scale	Nationwide	Mostly sentinel	











## Case definitions for acute hepatitis

Level	Acute hepatitis				
Suspect case: Clinical criteria	Discrete onset of an acute illness with signs or symptoms of (a) acute viral illness and (b) hepatic injury (liver enzymes)				
Confirmed case: Clinical criteria AND epidemiological criteria or biomarker criteria	IgM anti-HAV + OR	IgM anti-HEV + OR	HBV IgM anti-HBc +	Anti HCV + AND All IgM – for HAV, HEV, and anti-HBc OR	
	Epidemiological link with a confirmed case	Epidemiological link with a confirmed case		RNA +/ Anti-HCV – OR Sero-conversion Anti- HCV	

Acute hepatitis less common than chronic hepatitis: Definitions must be as specific as possible



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# 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?



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# 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

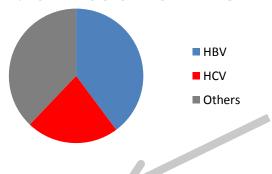
## Mortality envelope

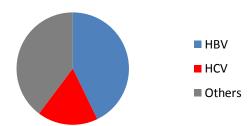


## 2. ATTRIBUTABLE FRACTION IN CENTRES OF EXCELLENCE IN HEPATOLOGY

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

2015 GLOBAL HEALTH ESTIMATES FROM WHO

## **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 be 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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