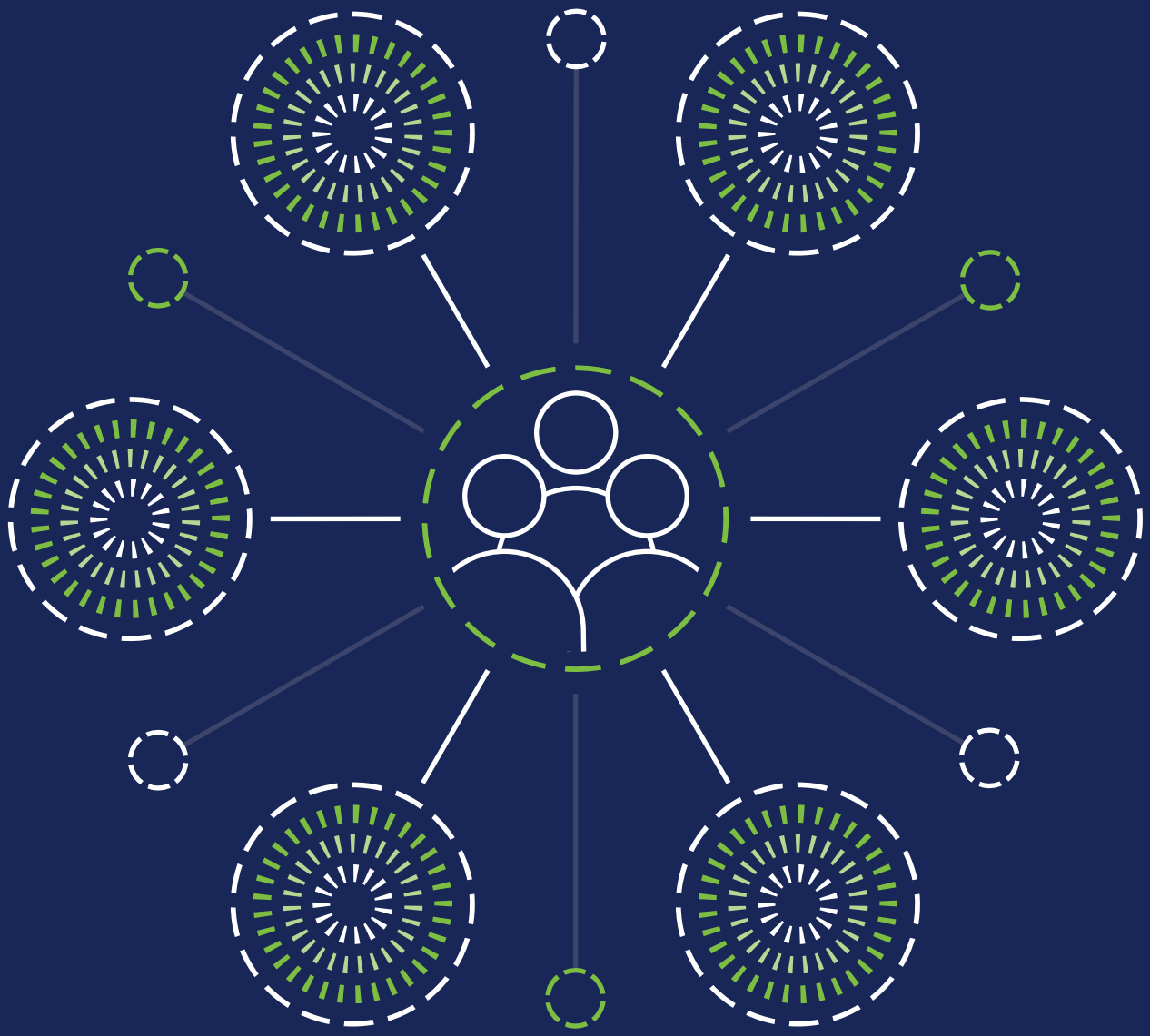
Consolidated guidelines on person-centred viral hepatitis strategic information

Using data to support country scale-up of hepatitis prevention, diagnosis and treatment services



World Health Organization

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Using data to support country scale-up of hepatitis prevention, diagnosis and treatment services

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Consolidated guidelines on person-centred viral hepatitis strategic information: using data to support country scale-up of hepatitis prevention, diagnosis and treatment services

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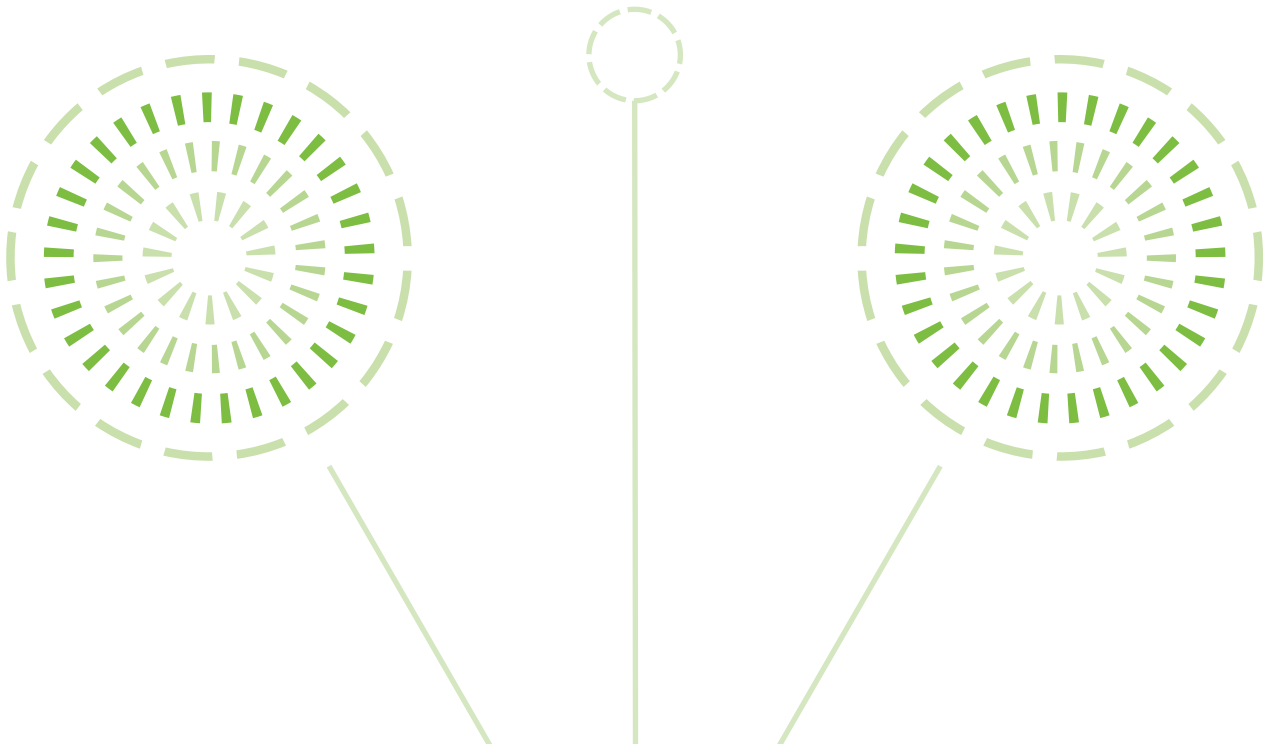
Acronyms

ALT	alanine aminotransferase
antenatal care	antenatal care
anti-HAV	antibody against hepatitis A virus
anti-HBc	antibody against hepatitis B core antigen
anti-HDV	antibody against hepatitis D virus
anti-HEV	antibody against hepatitis E virus
ART	antiretroviral therapy
HAV	hepatitis A virus
HBsAg	hepatitis B surface antigen
HBV	hepatitis B virus
HCC	hepatocellular carcinoma
HCV	hepatitis C virus
HDV	hepatitis D virus
HEV	hepatitis E virus
IARC	International Agency for Research on Cancer
ICD	International Statistical Classification of Diseases
IgM	immunoglobulin M
PCR	polymerase chain reaction

Glossary of terms

Acute viral hepatitis	Discrete-onset clinical manifestations of a recent infection with a hepatitis virus
Alanine amino transferase	A marker of inflammation of the liver that is being used to determine eligibility for hepatitis B treatment and response to treatment
Anti-HCV (HCV antibody)	Antibody against the hepatitis C virus (HCV) that is a serological marker of past or present infection. People identified positive for anti-HCV must be tested for HCV RNA or HCV core antigen to determine whether they are currently infected with HCV
Chronic infection	Persistence of replication of a hepatitis virus in the body six months after the initial infection
Chronic viral hepatitis	Chronic inflammation of the liver that results from a chronic infection with a hepatitis virus
Data	Values of qualitative or quantitative variables that are collected and recorded and are the raw building blocks of strategic information and knowledge
Evaluation	Periodic, rigorous review of information about programme activities, characteristics and context and their relationship to programme outcomes. Evaluation aims, from an objective viewpoint, to review, prove and improve a programme's overall value
Health sector	The sector of society comprising organized public and private health services, the policies and activities of government health departments and ministries, health-related nongovernmental organizations and community groups and professional associations, including health promotion, disease prevention and diagnostic, treatment and care services
Hepatitis B virus DNA	A marker of replication of the hepatitis B virus that is being used to determine eligibility for treatment and response to hepatitis B virus
Hepatitis B virus surface antigen	A marker of current infection with hepatitis B virus
Hepatitis C virus core antigen	A marker of current hepatitis C virus infection

Hepatitis C virus RNA	A marker of current hepatitis C virus infection
Indicator	In the context of monitoring and evaluation, a quantitative or qualitative variable that provides a valid and reliable way to measure achievement, assess performance or reflect changes connected to an activity, project or programme. The sources of data for indicators should be clearly identified
Information	Through interpretation or analysis, a pattern of aggregated data that can inform a programme Monitoring and evaluation system
Monitoring	Ongoing, routine reporting of priority information about a programme, its inputs and intended outputs, outcomes and impact to observe and track progress
Monitoring and evaluation system	A set of mechanisms built into the routine operations of a programme that generates data or information on a periodic and ongoing basis to provide evidence for programme decisions
Recent infection	A newly acquired infection, whether symptomatic or asymptomatic
Strategic information	Information that is interpreted and used for planning and decision-making to improve the direction and focus of a programme. Relevant data may be derived from a wide variety of sources (for example, monitoring systems, evaluations, programme reviews, surveys and case studies) and should be analysed holistically and strategically to improve the direction of the programme
Viral hepatitis	Inflammation of the liver that results from an infection with a hepatitis virus



Executive summary

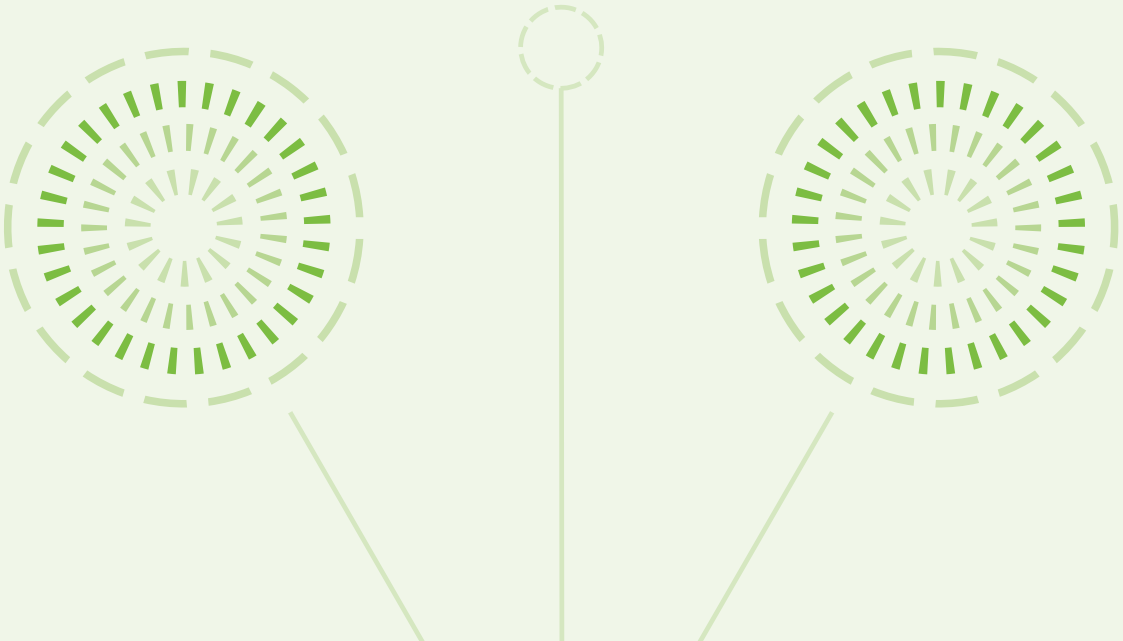
This publication summarizes the approach proposed by WHO to collect, analyse, report, disseminate and use strategic information on viral hepatitis at the subnational, national and global levels. These guidelines strengthen person-centred monitoring – with a priority for indicators that support person-centred health services, the core prevention, diagnosis and treatment interventions. The key new additions to the guidelines are:

(I) an updated strategic information framework that includes (a) a set of 10 core global indicators for regular reporting; (b) a menu of core and additional hepatitis indicators; (c) an updated monitoring and evaluation framework in accordance with the accountability framework for the global health sector strategies 2022–2030; and (d) cascade of care indicators for viral hepatitis B and C;

(II) a new section on person-centred data monitoring for chronic viral hepatitis – including (a) a minimum data set and key definitions for chronic hepatitis monitoring and (b) an updated template patient management card in accordance with the new hepatitis B and hepatitis C testing and treatment guidelines;

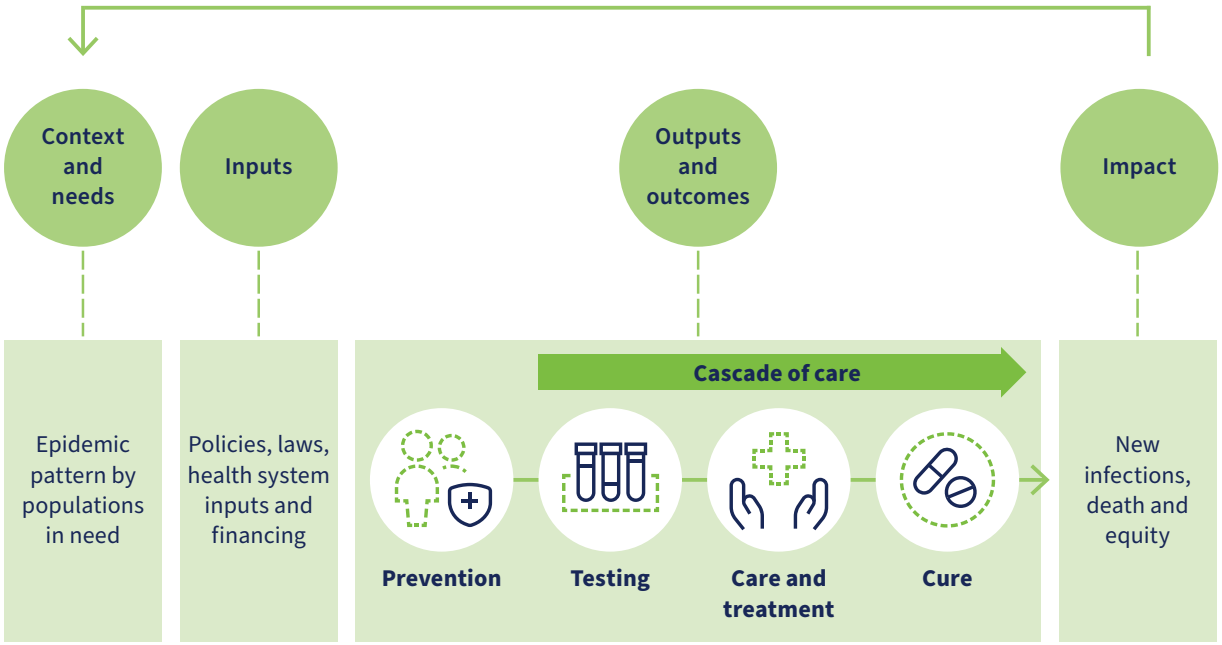
(III) a stepwise recommendation for implementing country surveillance at different levels of country maturity to strengthen the use of data to improve programmes and fill gaps; and

(IV) a consolidated metadata tables that provide information on viral hepatitis-related indicator definitions and measurement methods.



The monitoring and evaluation framework organizes 10 core indicators along the results chain from inputs, outputs and outcomes to impact to better focus hepatitis programmes on programmatic gaps and impact.

Core indicators for viral hepatitis B and C monitoring



C1. Prevalence of chronic hepatitis B and C

C2. Existence of a costed national strategic plan for eliminating viral hepatitis

C3. HBV vaccination and elimination of mother-to-child transmission of HBV

C4. Harm reduction among people who inject drugs: needles and syringes distributed and opioid agonist maintenance treatment

C5. Facility-level injection safety and blood safety

C6. Testing and diagnosis coverage

C7. Treatment coverage

C8. Cure for HCV and HBV DNA suppression

C9. Incidence of hepatitis B and C

C10. Mortality from hepatitis B and C

The guidelines provide a stepwise approach to strengthen country surveillance.

1. **Use available data:** the most important first step to strengthen country data is to use it. Most countries have data on hepatitis B and C burden and treatment available. The health ministry should validate available data, highlight gaps and strengthening measures and use them for planning, investment cases and scaling up services.

2. **Strengthen burden and care cascade data:** **(1)** implement a prevalence survey – nationally or in populations with a known denominator including antenatal care, blood donors, and existing Demographic and Health Survey; **(2)** create a person-centred treatment database to identify gaps and manage attrition; and **(3)** use manufacturer drug consumption data to triangulate treatment data and identify gaps.

3. **Using hepatitis data for decision making:** Use all available data to scale up viral hepatitis prevention and treatment services. Use data from facilities/hospitals at all levels (national- and sub-national), completeness studies that are locally available, the numbers of persons tested and those who tested positive and other available data.

4. **Strengthen person-centred routine health management information system:** Integrate hepatitis diagnosis and treatment data in the health management information system or district health information system for routine use where relevant and with interoperability.

5. **Strengthen analysis of outcomes:** Enhance analysis of outcome to improve the estimation of hepatitis sequalae. This may be implemented in selected sentinel tertiary reference centres especially in countries where treatment and care for viral hepatitis and for cirrhosis and HCC is provided in specialised centres (e.g., oncology clinics, hepatology or gastroenterology centres, tertiary hospitals).

The full set of priority indicators is provided in the following table.

Viral hepatitis, monitoring and evaluation indicators and global reporting platforms

	Indicators	Reference number		Indicator tier	Global reporting platforms		
					WHO Global Hepatitis Reporting System	Validation of viral hepatitis elimination and path to elimination	Other reporting system
	Context and needs: epidemic pattern by population in need						
1.	Prevalence of chronic hepatitis B	1	C1a	Global + core	✓	✓	
2.	Prevalence of chronic hepatitis C		C1b	Global + core	✓	✓	
	Inputs: policies, laws, health system inputs and financing						
3.	Planning – existence of a costed strategic plan for eliminating hepatitis	2	C2	Global + core	✓	✓	
4.	Availability and readiness of HBV and HCV drugs and diagnostics		A2	Additional			Health facility surveys
	Outputs and outcomes						
5.	Coverage of timely hepatitis B birth dose vaccine	3	C3a	Global + core		✓	WHO/UNICEF reporting form
6.	Coverage of third-dose hepatitis B vaccine among infants		C3b	Global + core		✓	WHO/UNICEF reporting form
7.	Coverage of HBV testing among pregnant women[a]		C3c	Global + core	✓	✓	Global AIDS Monitoring
8.	Coverage of antiviral therapy among eligible HBsAg-positive pregnant women[a]		C3d	Global + core	✓	✓	Global AIDS Monitoring
9.	Number of needles and syringes distributed per person who injects drugs per year	4	C4a	Core		✓	Global AIDS Monitoring
10.	Coverage of opioid agonist maintenance treatment among people who inject drugs		C4b	Core		✓	Global AIDS Monitoring
11.	Proportion of health-care facilities with safe injections	5	C5a	Core		✓	Health facility surveys
12.	Proportion of blood units screened for bloodborne disease		C5b	Core		✓	WHO Global Database on Blood Safety
13.	Proportion of people with chronic hepatitis B who have been diagnosed	6	C6a	Global + core	✓	✓	
14.	Proportion of people with chronic hepatitis C who have been diagnosed		C6b	Global + core	✓	✓	

(continued) Viral hepatitis, monitoring and evaluation indicators and global reporting platforms

	Indicators	Reference number		Indicator tier	Global reporting platforms		
					WHO Global Hepatitis Reporting System	Validation of viral hepatitis elimination and path to elimination	Other reporting system
15.	Proportion of people diagnosed with chronic hepatitis B initiating treatment[b]	7	C7a	Global + core	✓	✓	
16.	Proportion of people with chronic hepatitis B currently receiving treatment		C7b	Global + core	✓		
17.	Proportion of people diagnosed with chronic hepatitis C initiating treatment		C7c	Global + core	✓	✓	
18.	Proportion of people with chronic hepatitis B with annual follow-up among those not initiating treatment		A7	Additional			
19.	Proportion of treatment attrition among people with chronic hepatitis B in the reporting year	8	C8a	Global + core	✓		
20.	Proportion of people with chronic hepatitis C treated and achieving cure		C8b	Core		✓	
21.	Proportion of people with chronic hepatitis B treated and achieving HBV DNA viral suppression		A8	Additional			
	Impact: new infections, deaths and equity						
22.	Incidence of hepatitis B (HBsAg prevalence among children five years and younger)	9	C9a	Global + core		✓	WHO Sustainable Development Goals estimates
23.	Incidence of hepatitis C		C9b	Global + core	✓	✓	WHO Sustainable Development Goals estimates
24.	Mother-to-child-transmission rate of HBV		A9	Additional		✓	
25.	Deaths from hepatocellular carcinoma, cirrhosis and chronic liver diseases attributable to chronic hepatitis B and C	10	C10	Global + core	✓	✓	

Core indicators: those deemed feasible to collect, monitor and track in most contexts. Additional indicators: those considered desirable but not necessarily deemed feasible for all contexts to collect and use. Global indicators: a small subset of core indicators that are considered highly relevant for global monitoring and reporting to the World Health Assembly.

[a]Countries with targeted timely HepB-BD

[b]Of those eligible for treatment. About 20–30% of the people with hepatitis B may develop progressive liver disease or hepatocellular carcinoma cirrhosis and are eligible for treatment with nucleoside analogue therapies.

1. Introduction

Hepatitis B virus (HBV) and hepatitis C virus (HCV) infections are major diseases in terms both of prevalence and mortality. Together they account for a significant global disease burden and increasing mortality from cirrhosis and hepatocellular carcinoma (HCC). In 2022, WHO estimated that 254 million people were living with chronic HBV and 50 million people with chronic HCV worldwide *(1)*. About 1.3 million people died from chronic HBV and HCV infections in 2022, and 2.2 million new HBV and HCV infections occurred annually. The greatest burden of chronic HBV and HCV infections is concentrated by geography and population with two-thirds of the global burden in the 10 most severely affected countries. About 5% of the general population in the WHO African Region and Western Pacific Region are living with chronic HBV infection. Only 13% of people living with chronic HBV infection had been diagnosed and close to 3% had received antiviral therapy at the end of 2022. Only 36% of people living with chronic HCV had been diagnosed between 2015 and 2022, and 20% had received curative treatment; highlighting the opportunity for better linkages between diagnosis and provision of care.

The sharing of equipment among people who inject drugs is a major contributor of the chronic HCV epidemic globally *(2)*, estimated to account for 44% new HCV infections globally in 2022 *(1)*. Other affected population groups include health-care workers, people in prisons or closed settings and people receiving frequent blood transfusions (people with haemophilia or thalassaemia and people undergoing dialysis).

Considerable progress has been made towards eliminating the perinatal transmission of HBV through universal infant HBV immunization, including the timely hepatitis B birth dose, which has been highly effective in reducing new infections among children *(3)*. However, in 2022 hepatitis B birth-dose coverage was only 45% globally, with the lowest coverage (18%) in the WHO African Region.

In May 2016, the World Health Assembly endorsed the global health sector strategy on viral hepatitis 2016–2021, which calls for eliminating viral hepatitis as a public health threat by 2030. To eliminate viral hepatitis as a public health threat and achieve impact, it focused on five core, effective interventions that need to be implemented at a sufficient level of service coverage. Table 1.1 describes the global impact and coverage target and the path to elimination targets for viral hepatitis *(4,5)*. Four of the interventions address prevention:

- HBV vaccination among infants (birth dose and three doses of hepatitis B vaccine for infants);
- preventing the mother-to-child-transmission of HBV;
- blood and injection safety;
- comprehensive harm-reduction services for people who inject drugs; and
- testing and treatment coverage: WHO recommends that people with hepatitis B who meet certain criteria should receive lifelong treatment, whereas people with hepatitis C should receive short-course curative treatment.

The new global health sector strategy on viral hepatitis for 2022–2030 reaffirmed the ambitious targets set in 2016 and further defined absolute global impact and coverage targets for eliminating viral hepatitis by 2030, with interim global targets for 2025 (Table 1.1). Although the global targets and key indicators remain the same, significant changes have been agreed on. The new strategy is a joint strategy across HIV, hepatitis and sexually transmitted infections, with five joint strategic directions indicators: **(1)** deliver high-quality, evidence-based, people-centred services, **(2)** optimize systems, sectors and partnerships for impact, **(3)** generate and use data to drive decisions for action, **(4)** engage empowered communities and civil society, and **(5)** foster innovations for impact, together with regular reporting global, regional and country progress to the World Health Assembly.

GHSS 2022-2030 Strategic direction 3:

Generate and use data to drive decision for action

- *Expand person-centred monitoring for viral hepatitis to support people-centred viral hepatitis services (Action 74)*
- *Invest in strengthening information systems for viral hepatitis and integrating them more fully into broader health information systems (Action 75)*

A key component of the global health sector strategies for 2022–2030 is the need to generate and use data to drive decisions for actions (strategic direction 3). Member states are recommended to have robust information systems and capacity for collecting, managing, analysing and using person-centred data for monitoring the progress of viral hepatitis elimination at the national level. Moreover, countries are encouraged to invest in strengthening information systems for viral hepatitis and integrating them more fully into broader health information systems to enable data triangulation for analysis. For instance, strengthening surveillance and monitoring of advanced liver diseases and HCC across health sector actors to enable data triangulation for analysis of mortality attributable to viral hepatitis. This publication is intended to provide guidance to countries on building person-centred strategic information systems for planning and regular tracking their progress in accordance with the global health sector strategies for 2022–2030 *(4)*.

Table 1.1. Impact and programme coverage targets and milestones for viral hepatitis by 2030

	Indicator	Baseline – 2020[a]	Targets – 2025	Targets – 2030	Path-to-elimination targets[a]	Indicator number
Viral hepatitis impact targets	Hepatitis B surface antigen (HBsAg) prevalence among children younger than five years[b]	0.94%	0.5%	0.1%		C9a
	Number of new HBV infections per year	20 per 100 000 population	11 per 100 000 population	≤2 per 100 000 population		
	Number of new HCV infections per year	20 per 100 000 population	13 per 100 000 population	5 per 100 000 population		C9b
	Number of new HCV infections per year among people who inject drugs	8 per 100	3 per 100	2 per 100		
	Number of people dying from hepatitis B per year	10 per 100 000 population	7 per 100 000 population	Combined ≤6 hepatitis C–related and hepatitis B–related deaths per 100 000 population		C10
	Number of people dying from hepatitis C per year	5 per 100 000 population	3 per 100 000 population			
Viral hepatitis programme coverage targets	Hepatitis B – percentage of people with hepatitis B diagnosed and treated[d,e]	30%/30%	60%/50%	90%/80%	≥80% /≥70% for gold tier ≥70% /≥60% for silver tier ≥60% /≥50% for bronze tier	C6a/C7a
	Hepatitis C – percentage of people with hepatitis C diagnosed and cured[d,f]	30%/30%	60%/50%	90%/80%	≥80% /≥70% for gold tier ≥70% /≥60% for silver tier ≥60% /≥50% for bronze tier	C6b/C7c
	Percentage of newborns who have benefitted from a timely birth dose of hepatitis vaccine	50%	70%	90%	≥90% for gold tier ≥50% for silver tier	C3a
	hepatitis B vaccine coverage among children (third dose)	90%	90%	90%	≥90% for gold tier ≥90% for silver tier ≥90% for bronze tier	C3b
	Coverage of HBsAg testing of pregnant women[h]			≥90%	≥30% for gold tier Not applicable for silver tier	C3c

Table 1.1. (continued) Impact and programme coverage targets and milestones for viral hepatitis by 2030

	Indicator	Baseline – 2020[a]	Targets – 2025	Targets – 2030	Path-to-elimination targets[a]	Indicator number
Viral hepatitis programme coverage targets	Coverage with antiviral therapy among HBsAg-positive pregnant women eligible for prophylaxis or treatment[h]			≥90%		C3d
	Number of needles and syringes distributed per person who injects drugs	200	200	300	≥150 needles and syringes per year among people who inject drugs for gold tier[g] Needle-syringe program present in the country for silver tier NSP present in the country for bronze tier	C4a
	Coverage (%) of opioid agonist maintenance therapy among people who inject drugs			≥40%	>20% opioid agonist maintenance therapy coverage for gold tier[g] opioid agonist maintenance therapy present in the country for silver tier	C4b
	Blood safety – proportion of blood units screened for bloodborne diseases	95%	100%	100%	100% for gold tier 100% for silver tier ≥95% for bronze tier”	C5a
	Safe injections – proportion (%) of safe injections administered in health-care settings	95%	100%	100%	100% for gold tier 100% for silver tier ≥95% for bronze tier	C5b

[a]Some targets are based on data from 2019 because of COVID-19-related service disruptions in the data reported for 2020. All data will be disaggregated by age and sex and, where relevant, key and focus populations specific to the disease. Path to elimination targets are only included in the pro-gramme coverage targets, (not in impact targets).
[b]The targets in this table are global targets and should be adapted by Member States according to the national context when setting country targets. For example, in some countries a target for the prevalence of HBsAg among children younger than five years old may be less than 0.1% or 0.2%, although the overall global target is 0.1%. The ≤0.1% HBsAg prevalence can be measured among five-year-olds, one-year-olds or those 1–5 years old according to existing country surveillance and data collection activities. For the regions and countries with a long history of high HBV vaccination coverage and that already conduct school-based serosurveys, there could be flexibility in conducting serosurveys in children older than five years.
[c]Differential thresholds may not be relevant or practical at the country level since the relative contribution of HBV and HCV may vary considerably from one country to another. It has been agreed to use combined targets (*5*).
[d]For validation of elimination and path to elimination, the proportion of people with chronic hepatitis B who have been treated and the proportion of people with chronic hepatitis C who are cured are calculated based on the number who have been diagnosed.
[e]Not all people diagnosed with chronic hepatitis B are eligible for treatment. Treatment eligibility differs across countries and regions and should be defined in accordance with current WHO guidelines or regional or national guidelines.
[f]Because of the high effectiveness of direct-acting antiviral drugs in treatment for hepatitis C, reporting on the proportion of people who have attained sustained viral response will not be necessary for validation, although data should be provided if available.
[g]Or doubling coverage (100% coverage increase) in the past two years.
[h]This is required for countries that provide targeted timely HBV birth-dose vaccine for validating the elimination of hepatitis B as a public health problem and elimination of mother-to-child transmission of HBV.

1.1. Objectives and scope of the guidelines

This document summarizes and simplifies the overall approach proposed by WHO to collect, in an integrated manner where feasible, analyse, report, disseminate and use strategic information on viral hepatitis at local, subnational, national and global levels. These guidelines strengthen person-centred monitoring – with a priority for indicators that support person-centred health services, the core prevention, diagnosis and treatment interventions, which can also be consolidated for reporting. The guidelines recommends the stepwise guidance to build country health information systems so countries use data to strengthen the scaling up of viral hepatitis programmes.

The publication describes the use of strategic information at various stages of the response in the context of strengthening broader health information systems. Strategic information can be defined as data collected at all service delivery and administrative levels to inform policy and programme decisions.

1.2. Target audience

This guide is intended primarily to serve the needs of national health sector programme staff engaged in collecting, analysing and using viral hepatitis–related strategic information. National and regional programme managers can use this publication as overall high-level guidance on strategic information for viral hepatitis.

These guidelines are relevant for various health workers focused on hepatitis, including:

- health ministry decision-makers such as hepatitis programme staff and health information system managers at the national and subnational levels;
- the staff of partner organizations supporting the strengthening of the hepatitis programme or health system strengthening; and
- consultants and staff working at research or public health institutes involved in analysing hepatitis data and/or efforts to improve the quality of hepatitis data.

1.3. Related WHO guidelines and documents

- Global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections for the period 2022–2030. Geneva: World Health Organization; 2022 (https://iris.who.int/handle/10665/360348).
- Consolidated strategic information guidelines for viral hepatitis. Planning and tracking progress towards elimination. Guidelines. Geneva: World Health Organization; 2019 (https://iris.who.int/handle/10665/310912).
- Technical considerations and case definitions to improve surveillance for viral hepatitis: technical report. Geneva: World Health Organization; 2016 (https://iris.who.int/handle/10665/204501).
- Monitoring and evaluation for viral hepatitis B and C: recommended indicators and framework. Geneva: World Health Organization; 2016 (https://iris.who.int/handle/10665/204790).
- Guidance for country validation of viral hepatitis elimination and path to elimination: technical report. Geneva: World Health Organization; 2023 (https://iris.who.int/handle/10665/373186).

1.4. What's new in the guidelines

The key new additions to the guidelines include:

- an updated strategic information framework that includes (a) a set of 10 core global indicators for regular reporting; (b) a menu of core and additional hepatitis indicators; (c) an updated monitoring and evaluation framework in accordance with the accountability framework for the global health sector strategies for 2022–2030; and (d) cascade of care indicators for viral hepatitis;
- a new section on person-centred data monitoring for chronic viral hepatitis to support the delivery of the five key prevention, diagnosis and treatment person-centred health interventions, including (a) a list of minimum data-set and key definitions for chronic hepatitis monitoring and (b) an updated template patient management card in accordance with the new hepatitis B and C treatment guidelines;
- a stepwise recommendation for implementing country surveillance at different levels of country maturity, to strengthen the use of data to improve programmes and fill gaps; and
- a consolidated metadata table that provides information on hepatitis-related indicator definitions and measurement methods.

2. Epidemiology of Viral Hepatitis

Five hepatitis viruses (hepatitis A virus (HAV), HBV, HCV, hepatitis D virus (HDV) and hepatitis E virus (HEV)) can infect humans and cause hepatitis (Table 2.1). HBV and HCV infection can become chronic and cause cirrhosis and liver cancer. Several clinical and epidemiological characteristics that are specific to the five hepatitis viruses influence how surveillance is conducted. Considering these elements will help in designing or improving surveillance systems. Specific aspects of viral hepatitis epidemiology are highlighted below.

Multiple disease outcomes: infection with hepatitis viruses may be asymptomatic or cause acute and chronic hepatitis. Although death can occur from fulminant acute hepatitis (mainly from hepatitis B), it is most often secondary to chronic hepatitis. After a number of years, chronic hepatitis B or C can lead to cirrhosis, hepatic decompensation and/or HCC. Decompensated cirrhosis (such as chronic liver failure) and the consequences of HCC commonly result in death. It may also lead to non-Hodgkin lymphoma *(6)*. Thus, surveillance needs to address acute hepatitis, chronic infections and their sequelae.

Similar clinical presentation: the symptoms and signs of acute and chronic viral hepatitis are similar for all the hepatitis viruses. In addition, new infections are difficult to differentiate clinically from chronic infections. Thus, in vitro diagnosis, including laboratory and point-of-care tests, is key to diagnosing the type of hepatitis (HAV, HBV, HCV, HDV or HEV infection) and differentiating recent infection from chronic hepatitis B or C.

Asymptomatic nature of most infections: many new or chronic infections are asymptomatic, leading to many affected people not seeking health care. They are neither reported nor counted. Thus, estimating the burden of chronic infection requires biomarker surveys to identify those with chronic infection and the type of virus causing it.

Multiplicity of modes of transmission and population at risk: whereas HAV and HEV are transmitted through the faecal-oral route, HCV and HBV are transmitted through exposure to blood and body fluids, and HDV comes as an opportunist of HBV. The modes of transmission can significantly differ between countries. For instance, in some countries, injecting drug use is the primary mode of HCV transmission, whereas in other countries, health care–related exposure and unsafe non-medical injections play a major role in transmitting hepatitis B and hepatitis C. Thus, surveillance approaches need to be tailored to each country so that the relevant populations with higher transmission risks are included. This will help identify the modes of transmission that account for the majority of new infections and direct prevention activities.

Need for laboratory diagnosis: laboratory diagnosis is essential for viral hepatitis surveillance **(i)** to identify the virus that may be causing acute or chronic hepatitis and **(ii)** to differentiate between recent infection, past exposure that resulted in resolved infection and chronic infection. In addition, among people with serological evidence of past or present HBV or HCV infection, laboratory diagnosis can identify active infections that may require treatment.

Table 2.1. Key characteristics of HAV, HBV, HCV, HDV HEV and the infections that cause hepatitis

Characteristics	HAV	HBV	HCV	HDV	HEV
Incubation period	2–6 weeks	2–6 months	2–6 months	3–7 weeks	2–10 weeks
Estimated incidence of clinical acute hepatitis among new infections	<10% for children younger than six years and increases with age	Children younger than five years are asymptomatic; 30–50% among people older than five years	<20%	Not applicable	10% of children younger than 10 years and up to 50% in adults
Characteristics of acute hepatitis	Case fatality increases with age	Acute hepatitis more common among adults	Acute hepatitis uncommon, almost never fulminant *(7)*	Superinfection with HDV in chronic hepatitis B may lead to fulminant disease	Higher case fatality among pregnant women
Chronic infection	None	Chronic infection leading to sequelae	Chronic infection leading to sequelae	Chronic hepatitis that complicates chronic hepatitis B	Very rare[a]
Cirrhosis, chronic liver failure and HCC	No	Yes	Yes	Yes	No
Biomarker of recent infection	Immunoglobulin M (IgM) antibody against HAV (anti-HAV)	IgM antibody against HBV core antigen (anti-HBc)	None[b]	IgM antibody against HDV (anti-HDV)	IgM antibody against HEV (anti-HEV)
Routes of transmission	Person-to-person Foodborne Waterborne	Perinatal Bloodborne (health-care settings and people who inject drugs) Sexual	Bloodborne (health-care settings and people who inject drugs) Perinatal (less common)[c] Sexual (uncommon)[c]	Bloodborne	Waterborne Foodborne Person-to-person[d]
Treatment options	None	Treatment available	Treatment available	Modified treatment of hepatitis B	None
Vaccine	Yes	Yes	No vaccine	No vaccine[e]	Yes[f] *(8)*
Prevention of new infections	Water, sanitation and hygiene Vaccination	Vaccination Safe injection practices Blood safety Safe sex Harm reduction for people who inject drugs	Safe injection practices Blood safety Safe sex Harm reduction services for people who inject drugs	Prevention of HBV infection	Water, sanitation and food hygiene Vaccination

[a] Chronicity was reported among people with immunodeficiency (solid organ transplant recipients, HIV and blood cancer).
[b] RNA or core antigen positive in the absence of anti-HCV suggests recent HCV infection.
[c] Risk of mother-to-child transmission higher among pregnant women living with HIV and risk of sexual transmission higher among men who have sex with men living with HIV.
[d] Less common than for hepatitis A but reported during outbreaks.
[e] HBV vaccine protects against HDV infection since HDV cannot replicate in the absence of HBV.
[f] Vaccine licensed in China. Currently, there are no WHO prequalified vaccines against HEV.

3. Purpose of Surveillance for Viral Hepatitis

Viral hepatitis surveillance includes **(i)** acute hepatitis surveillance that reflect new infections *(9)*, **(ii)** surveillance of chronic infections through biomarker surveys *(10)* and **(iii)** surveillance of sequelae that lead to mortality (cirrhosis and HCC) *(11)*, which is mostly done at sentinel sites. Viral hepatitis surveillance has three main purposes, and surveillance information addressing these three may also be used to evaluate hepatitis prevention and control programmes:

- detect outbreaks, monitor trends in incidence and identify risk factors for new infections;
- estimate the prevalence of chronic infections and monitor trends in the general population and high-risk groups (selected population samples chosen to represent the relevant experience of particular groups, such as pregnant women and people who inject drugs); and
- estimate the burden of sequelae of chronic hepatitis, including decompensated cirrhosis and HCC.

3.1. Detect outbreaks and monitor trends in incidence, guiding prevention

Syndromic surveillance uses presumptive case definitions, mostly based on clinical features, for reporting at all health-care facilities. Syndromic surveillance captures undifferentiated, acute viral hepatitis. It is a baseline surveillance standard that is not resource intensive. However, its usefulness is limited to detecting large outbreaks, which are usually outbreaks of hepatitis A or acute hepatitis E infection.

Surveillance of type-specific acute hepatitis may be used to guide where prevention efforts should be implemented or intensified and evaluate the impact of programmes that prevent new infections, including HAV and HBV immunization, water and food safety, condom use, injection safety, blood safety, infection control, and harm reduction.

Enhanced case reporting uses confirmed case definitions based on a combination of clinical and biomarker criteria, usually at fixed sentinel sites. The reporting captures cases of acute hepatitis by type (HAV, HBV, HCV, HDV or HEV) following in vitro diagnosis (IgM tests), and also collects information on possible exposure. The WHO template protocol for enhanced case reporting is available from WHO *(9)*. When captured with case definitions of sufficient specificity (based on an IgM diagnostic test), cases of acute hepatitis are uniquely informative since they denote recent infection. Hence, collecting information on possible exposure during the referent exposure period (or the incubation period) provides information on sources of infection.

In most high-income countries, enhanced case reporting exists countrywide as part of the communicable disease surveillance system. If the national system for acute hepatitis surveillance is based on syndromic case definitions, enhanced case reporting can be established in a small number of fixed sentinel facilities with access to IgM in vitro diagnosis and staff who can collect information on potential risk factors. Building on universal syndromic surveillance to implement enhanced case reporting enables a description of trends in type-specific acute hepatitis and contributes to the generation of hypotheses regarding the predominant modes of transmission.

Surveillance for acute hepatitis is conducted in many countries but may require technical improvement and clarification of objectives. Use of standardized case definitions based on the clinical presentation and on the presence of biomarkers enables cases of acute hepatitis to be differentiated from cases of chronic infection. WHO has published standardized case definitions for surveillance of acute hepatitis (Table 3.1) *(12)*. These case definitions can be used to differentiate acute hepatitis from newly diagnosed cases of chronic infection.

Enhanced case reporting of acute hepatitis is particularly important in places where the incidence of new HBV or HCV infection remains high (such as because of unsafe health care or injection drug use).

3.2. Estimate the burden of chronic infections, guiding testing and treatment

Regular biomarker surveys are the method of reference to estimate the prevalence of chronic infections and guide testing and treatment. Accurate estimates of prevalence are key to predicting future mortality from present infections and deciding on a testing approach *(13)*. The WHO template protocol for conducting biomarker surveys for viral hepatitis is available *(10)*. Viral hepatitis biomarker surveys can be expensive. Hence, they should be implemented along with other health-related population surveys with biomarkers that examine chronic diseases, the impact of HBV immunization, HIV *(14)* and tuberculosis prevalence *(15,16)*. Planning integration of surveillance for hepatitis B and C into other health-related surveys as part of the survey objectives is preferable to testing stored specimens without appropriate planning. Testing stored sera may raise methodological issues when specimens are not available from all study participants *(17)*. It can also raise ethical issues. Participants may not have consented to additional testing, and those identified with hepatitis B or C cannot be linked to care. When studies for different diseases are planned (such as HIV or COVID-19), viral hepatitis should be included in other health-related population survey biomarkers, including consent for the future testing of stored samples in the consent form.

Surveillance of chronic hepatitis B and C may be used to evaluate the impact of **(i)** universal HBV immunization, **(ii)** programmes preventing hepatitis B and C through injection safety, blood safety, and harm reduction and **(iii)** programmes for testing for hepatitis B and C and treating the people infected.

3.3. Estimate the burden of sequelae, evaluating impact

Surveillance from vital registrations of deaths and from routine clincal records may be used to evaluate the impact of prevention and treatment programmes for viral hepatitis on long-term sequelae (cirrhosis and HCC) and specific mortality. Measuring the fraction of cirrhosis and HCC attributable to hepatitis B and C is key to measuring how eliminating hepatitis affects morbidity and mortality. The WHO protocol for surveillance of sequelae is available *(5)*. In vital registration systems, viral hepatitis–associated deaths are mostly recorded under deaths from acute hepatitis, cirrhosis or HCC *(18)*. However, certificates documenting cirrhosis or HCC deaths usually do not capture the causes (whether the sequelae resulted from viral infection, alcohol or other causes). For these deaths to be attributed to hepatitis B or C, the percentage of deaths caused by hepatitis B or C must be estimated (often referred to attributable fractions) *(19)*. The percentage of sequelae caused by hepatitis B and C can be estimated through data abstraction of routine clinical records at selected sentinel sites in health-care facilities caring for chronic liver diseases or liver cancer or in cancer registries *(5,11)*.

No single method will completely describe the country's epidemiological profile. The epidemiological situation may vary between population groups. In addition, in large countries, the epidemiological situation may vary between geographical areas. Hence, national officials will benefit from combining data from multiple sources *(5)*.

Table 3.1. WHO surveillance case definitions for viral hepatitis[a]

		HAV	HEV	HBV	HCV
Acute hepatitis	Clinical criteria identifying presumptive cases	Discrete onset of an acute illness with signs or symptoms of **(i)** acute infectious illness (such as fever, malaise and fatigue) and **(ii)** liver damage, such as anorexia, nausea, jaundice, dark urine, right upper quadrant tenderness or raised alanine aminotransferase (ALT) levels[b]			
	Biomarker/epidemiological criteria to confirm cases	IgM anti-HAV positive or Epidemiological link with a confirmed case	IgM anti-HEV positive or Epidemiological link with a confirmed case	IgM anti-HBc positive[c]	HCV RNA positive and anti-HCV negative or seroconversion to anti-HCV[d]
					Or Anti-HCV positive and IgM anti-HBc negative and Anti-HAV IgM negative and Anti-HEV IgM negative
Chronic hepatitis	Confirmed cases only, requiring biomarker criteria	Not applicable	Rare event, no WHO standard case definition	Person not meeting the case definition for acute hepatitis[e] and	
				HBsAg positive[f]	HCV RNA positive[g] or HCV antigen positive

[a]Case definitions are for the purpose of reporting and surveillance and may differ from the criteria to be used for managing people with hepatitis.
[b]Threshold defined by the United States' State and Territorial Epidemiologists (https://ndc.services.cdc.gov/conditions/hepatitis-viral-acute/).ALT levels can be different for different type of viral hepatitis. Countries may also select lower (more sensitive) or higher (more specific) thresholds.
[c]Hepatitis test panels usually include HBsAg with anti-HBc IgM test (positive predictive value of anti-HBc IgM higher if HBsAg positive). Specific test or threshold needed to exclude transient appearance of IgM during flares in chronic hepatitis B.
[d]Among people tested regularly at short time intervals, seroconversion to anti-HCV suggests recent HCV infection. Seroconversion to anti-HCV should be followed by a reflex RNA test (when available). Seroconversion indicates a new HCV infection, but acute symptoms are necessary to meet the case definition of acute hepatitis C.
[e]Person tested in the context of evaluation for a chronic liver disease, a check-up or a survey.
[f]Most testing strategies would also test for total anti-HBc. The combination of total anti-HBc and HBsAg is more specific for chronic hepatitis B than HBsAg alone.
[g]People who are anti-HCV positive have serological evidence of past or present infection.

Table 3.2 Surveillance activities needed to describe the epidemiology of viral hepatitis

Technical approaches	Hepatitis surveillance objectives for		
	1. Acute hepatitis	**2. Chronic, prevalent hepatitis**	**3. Sequelae of hepatitis infection**
Objective of the surveillance activity	• Detect outbreaks • Describe trends in type-specific acute hepatitis and identify risk factors	• Estimate the prevalence of infections • Model incidence trends	• Estimate mortality from hepatitis B– or hepatitis C–associated HCC and decompensated cirrhosis
Surveillance methods	• Syndromic surveillance in the general population • Event-based surveillance[a] • Enhanced case reporting (with in vitro diagnosis and collection of information on risk factors), countrywide or in sentinel sites[b] • Regular testing of a defined population when screening registries are available (such as in prisons and among pregnant women with multiple antenatal care visits)	• Regular and repeated biomarkers surveys	Sentinel surveillance sites for estimating the fraction of HCC and decompensated cirrhosis attributed to hepatitis B and C Data on the mortality envelope is obtained from death registries
Population	People presenting with acute hepatitis in health-care facilities (discrete onset of symptoms)	People without acute symptoms tested during population surveys	People diagnosed with cirrhosis and HCC
Case definitions	• Presumptive case of acute hepatitis • Confirmed case of acute hepatitis (by type)	• Chronic hepatitis B and C • Serological evidence of past or present HCV infection	• Cases of HCC or decompensated cirrhosis • Chronic hepatitis B or C • HDV coinfection among people with HBV infection
Source/Implementer	• Communicable disease surveillance • Communicable disease surveillance (if countrywide) • Hepatitis programme (if sentinel sites)	• Hepatitis programme in coordination with the other actors implementing biomarker surveys	• Vital registration • Sentinel sites caring for people with decompensated cirrhosis and HCC • Cancer registries
Existing guidelines and protocols	Standard operating procedures for enhanced reporting of cases of acute hepatitis (*9*)	Template protocol for surveys to estimate the prevalence of biomarkers of infection with the hepatitis viruses: tool for adaptation and use at country level (*10*)	Protocol for surveillance of the fraction of decompensated cirrhosis and HCC attributable to viral hepatitis in clinical centres of excellence (*11*)

[a] In vitro diagnosis needs to be organized on a sample of cases when an outbreak is reported.
[b] High-quality data (reliable in vitro diagnosis, good information on risk factors) from a smaller number of tertiary centres is preferable and more efficient than poor-quality data from many sites.

4. A Consolidated Strategic Information Framework

This guidance consolidates, sets priorities among and describes key indicators to monitor the responses of the health sector to chronic hepatitis B and C. Its goal is to help countries choose, collect and systematically analyse strategic information to guide the health sector response to chronic hepatitis B and C. The aim of consolidation is to ensure that all indicators, are organized by priority and linked in a result chain and can be used to support high-quality care along the health sector cascade of chronic viral hepatitis services. This strategic information framework builds on the globally and regionally established conceptual and monitoring frameworks for health system strengthening, primary health care and universal health coverage *(20)*. It supports the primary health care theory of change and provides a logical and results-based framework for monitoring performance and progress in primary health care.

By bringing together indicators and setting priorities, this consolidated guide seeks to help programmes to:

- select and set priorities for the indicators most relevant to national and global monitoring and reporting;
- consolidate measurements along the cascade of care: prevention, care, treatment and cure;
- link services to their outcomes to better assess coverage, quality and impact;
- strengthen analysis, disaggregation and use of data to improve linkage and identify bottlenecks and priorities along the cascade;
- align reporting across programmes (for example, of testing, treatment, care and cure) and globally for simpler and better coordination;
- simplify hepatitis programme monitoring with 10 indicators that track the health sector cascade of prevention, diagnosis, treatment, care and cure and reflect progress toward the targets for eliminating viral hepatitis; and
- provide consolidated support for country data systems and analysis aligned with the 2030 viral hepatitis elimination targets outlined in the global health sector strategy for 2022–2030.

4.1. Categories of indicators – from country monitoring to regional and global reporting

Based on the primary health care conceptual framework *(20)*, a menu of indicators has been provided to countries to assess, track and monitor progress towards eliminating viral hepatitis. Provided indicators have covered each domain of the result chain. Table 4.1 presents the menu of indicators and outlines the core, global and additional indicators for viral hepatitis. Annex 2 provides a metadata table for each of the indicators. To help national programmes select indicators, this guide categorizes proposed indicators into three groups in accordance with the primary health care measurement framework *(20)*: a set of 25 indicators, including 10 core indicators designated for global reporting:

- core indicators: those deemed feasible to collect, monitor and track in most contexts;
- global indicators: a subset of 10 core indicators that are considered highly relevant for global monitoring and reporting to the World Health Assembly; and
- additional indicators: those considered desirable but not necessarily deemed feasible for all contexts to collect and use.

Countries are encouraged to select and adapt a parsimonious set of indicators from the menu according to the country context, priorities, needs and health system maturity. Indicators should be selected in a balanced manner across the results chain and the domains of the conceptual framework, enabling a broader list of indicators in domains of high priority for the context. Of note, many of the indicators draw from globally agreed standards that are already being reported through various programmes and regularly in many countries.

Table 4.1. List of core, global and additional indicators for monitoring viral hepatitis B and C

	Indicators	Reference number		Indicator tier	Global reporting platforms		
					WHO Global Hepatitis Reporting System	Validation of viral hepatitis elimination and path to elimination	Other reporting system
	Context and needs: epidemic pattern by population in need						
1.	Prevalence of chronic hepatitis B	1	C1a	Global + core	✓	✓	
2.	Prevalence of chronic hepatitis C		C1b	Global + core	✓	✓	
	Inputs: policies, laws, health system inputs and financing						
3.	Planning – existence of a costed strategic plan for eliminating hepatitis	2	C2	Global + core	✓	✓	
4.	Availability and readiness of HBV and HCV drugs and diagnostics		A2	Additional			Health facility surveys
	Outputs and outcomes						
5.	Coverage of timely hepatitis B birth dose vaccine	3	C3a	Global + core		✓	WHO/UNICEF reporting form
6.	Coverage of third-dose hepatitis B vaccine among infants		C3b	Global + core		✓	WHO/UNICEF reporting form
7.	Coverage of hepatitis B testing among pregnant women[a]		C3c	Global + core	✓	✓	Global AIDS Monitoring
8.	Coverage of antiviral therapy among eligible HBsAg-positive pregnant women[a]		C3d	Global + core	✓	✓	Global AIDS Monitoring
9.	Number of needles and syringes distributed per person who injects drugs per year	4	C4a	Core		✓	Global AIDS Monitoring
10.	Coverage of opioid agonist maintenance treatment among people who inject drugs		C4b	Core		✓	Global AIDS Monitoring
11.	Proportion of health-care facilities with safe injections	5	C5a	Core		✓	Health facility surveys
12.	Proportion of blood units screened for bloodborne disease		C5b	Core		✓	WHO Global Database on Blood Safety

Table 4.1. (Continued) List of core, global and additional indicators for monitoring viral hepatitis B and C

	Indicators	Reference number		Indicator tier	Global reporting platforms		
					WHO Global Hepatitis Reporting System	Validation of viral hepatitis elimination and path to elimination	Other reporting system
14.	Proportion of people with chronic hepatitis C who have been diagnosed		C6b	Global + core	✓	✓	
15.	Proportion of people diagnosed with chronic hepatitis B initiating treatment[b]	7	C7a	Global + core	✓	✓	
16.	Proportion of people with chronic hepatitis B currently receiving treatment		C7b	Global + core	✓		
17.	Proportion of people diagnosed with chronic hepatitis C initiating treatment		C7c	Global + core	✓	✓	
18.	Proportion of people with chronic hepatitis B with annual follow-up among those not initiating treatment		A7	Additional			
19.	Proportion of treatment attrition among people with chronic hepatitis B in the reporting year	8	C8a	Global + core	✓		
20.	Proportion of people with chronic hepatitis B treated and achieving cure		C8b	Core		✓	
21.	Proportion of people with chronic hepatitis B treated and achieving HBV DNA viral suppression		A8	Additional			
	Impact: new infections, deaths and equity						
22.	Incidence of hepatitis C (HBsAg prevalence among children five years and younger)	9	C9a	Global + core		✓	WHO Sustainable Development Goals estimates
23.	Incidence of hepatitis C		C9b	Global + core	✓	✓	WHO Sustainable Development Goals estimates
24.	Mother-to-child-transmission rate of HBV		A9	Additional		✓	
25.	Deaths from hepatocellular carcinoma cirrhosis and chronic liver diseases attributable to chronic hepatitis B and C	10	C10	Global + core	✓	✓	

Core indicators: those deemed feasible to collect, monitor and track in most contexts. Additional indicators: those considered desirable but not necessarily deemed feasible for all contexts to collect and use. Global indicators: a small subset of core indicators that are considered highly relevant for global monitoring and reporting to the World Health Assembly.

[a] Countries with targeted timely HepB-BD

[b] Of those eligible for treatment. About 20–30% of the people with hepatitis B may develop progressive liver disease or hepatocellular carcinoma cirrhosis and are eligible for treatment with nucleoside analogue therapies.

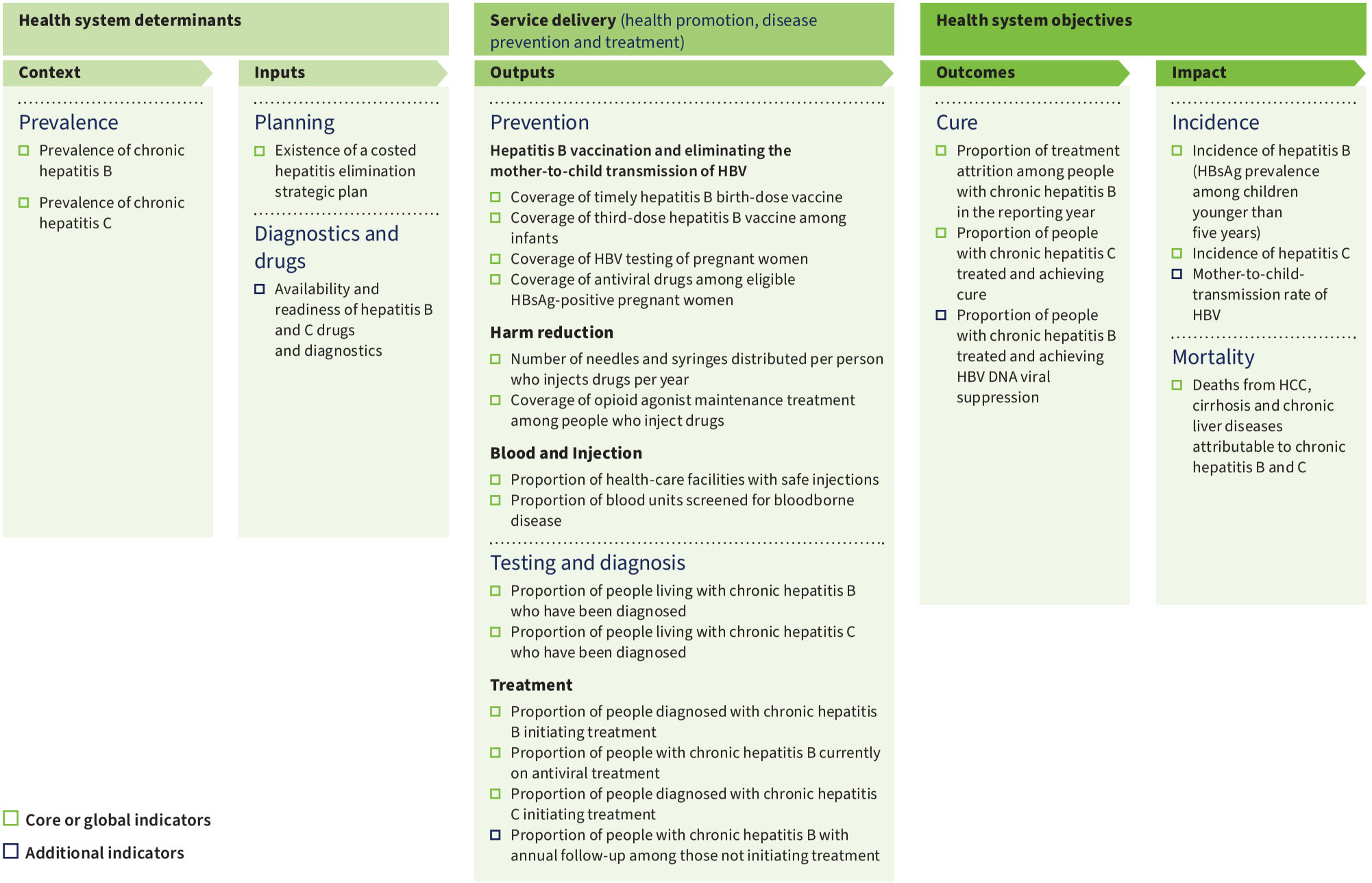
4.2. Data disaggregation

Disaggregation separates data into component parts to identify and highlight differences and inequalities that may exist. Disaggregation enables focus on the country's responses related to the people, places, and situations where they will achieve impact. Disaggregation is important to assess if services reach people in need equitably and to ensure that no one is left behind in eliminating viral hepatitis.

In most cases, viral hepatitis data should be disaggregated according to:

- **age:** standard age groups of 1–4, 5–14, 15–19, 20–24, 20–49 and 50+ years, with regular data extraction (such as annually) recommended to report on these age groups in paper-based systems;
- **sex:** for example, to assess differences by sex in infection and service coverage along the cascade;
- **high-risk population groups:** including people who inject drugs, people who are incarcerated, migrants, people in prisons and other closed settings, sex workers and transgender people; confidentiality, security and participation of high-risk populations in data collection and analysis are critical;
- **geographical location:** data should be regularly disaggregated subnationally according to administrative levels of epidemiological importance so that they can be used at the district and site levels;
- **pregnancy status:** especially for chronic viral hepatitis B and acute hepatitis E;
- **coinfection status:** HIV infection status, hepatitis D coinfection status, HBV and HCV coinfection status or past HCV infection; and
- **facility type:** helps to discern the performance of the other types of health facilities from primary care and their relationship; possible disaggregation related to level or setting of care should be tailored to the country settings, which may include community health posts or centres, primary care facilities, general practitioner cabinets or practices, specialty outpatient facilities, first-referral hospitals, specialty hospitals, long-term care facilities and continuing-care facilities.
- **Managing authority:** allows comparison between key indicators in the public and private sectors, which is particularly important in many countries in which the private sector delivers substantial chronic viral hepatitis care and treatment.

Figure 1. Strategic information measurement framework and menu of indicators for viral hepatitis monitoring



5. The Monitoring and Evaluation Framework for Viral Hepatitis B and C

To monitor and report progress on the global health sector strategies for HIV, viral hepatitis and sexually transmitted infections 2022–2030 at the global level, WHO proposed a measurement framework *(4,20)*. At the country level, the global health sector strategies call for national accountability frameworks that accompany national strategies, including indicators and targets that are aligned with standardized global guidance. Such a monitoring and accountability framework is intended to facilitate the collection and analysis of standardized data with a balance between the need to remain parsimonious and obtain the minimum information required and to promote evidence-informed decision-making and ensure accountability.

Although the measurement framework reflects the theory of change, the country-level monitoring and accountability framework, or monitoring and evaluation framework, may continue to follow the result chain domains, from context and needs to inputs, outputs, outcomes and impact *(20)*. Countries are encouraged to select, set priorities for and adapt actions in relation to local epidemiological and health system contexts, while upholding human rights. WHO encourages countries to undertake regular multistakeholder reviews of the implementation of their strategies at the national level, bringing together disease-specific and broader health sector actors, with strong civil society participation and transparent assessment and reporting *(4)*.

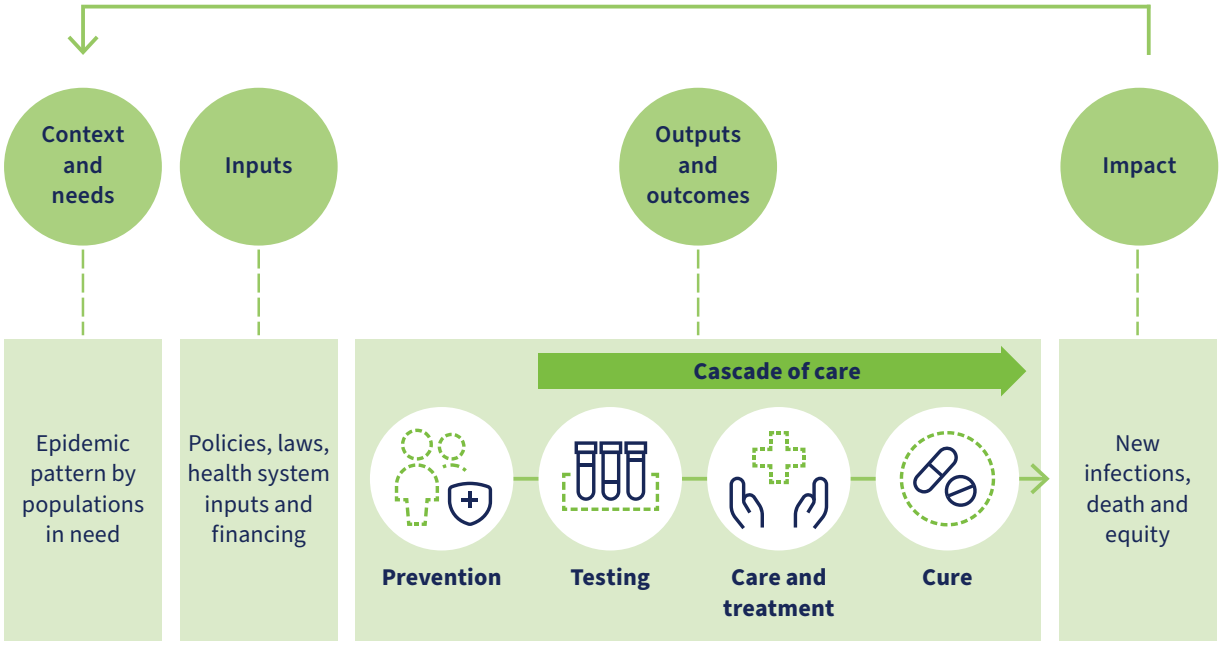
These indicators enable reviews of the entire result chain at the country level to identify bottlenecks and, by addressing them, improve the overall quality of the programmatic response. The result chain provides a structure for analysis and facilitates alignment in support of country data systems. Disaggregated data and person-centred monitoring are critical in improving monitoring and evaluation of hepatitis. Joint efforts to strengthen health information systems should lead to better data. All stakeholders should align and coordinate such efforts.

The monitoring and evaluation framework (Fig. 2) for the viral hepatitis result chain uses surveillance and programmatic information and lists 10 core indicators numbered C1 to C10. It has the following elements.

- **Context and needs:** the results chain starts with an overall contextual review to “know your epidemic”, particularly which populations are most affected and the size and location of those populations. Disaggregating data by age, sex, people at high risk for viral hepatitis and geographical location is crucial at this stage. Over time, information about the epidemic also serves as the baseline for tracking progress; many of the indicators that describe the epidemic and needs are also used to measure programme impact.
- **Inputs:** inputs are the resources invested in the health sector response to viral hepatitis. In addition to financial resources, they include human resources, health services infrastructure and governance (that is, policy and management), such as a costed national strategic action plan.
- **Outputs:** the activities of the programme constitute its outputs. Examples of output measures include the number of people tested positive, needles and syringes distributed, treatment initiation and number of infants receiving timely hepatitis B birth dose vaccine and three doses of hepatitis B vaccine (HepB3).
- **Outcomes:** the proximate health effects of programme outputs are their outcomes. For example, viral suppression (hepatitis B) or cure (hepatitis C) and retention in treatment are treatment programme outcomes. Outcomes can occur at any stage of the prevention and treatment response, including changes in behaviour, such as prevention outcomes in harm-reduction programmes.
- **Impact:** the ultimate gauge of a programme is the nature and extent of its impact on epidemiologic measures such as hepatitis B and C incidence (among adults, children and at-risk populations), mortality and the rate of mother-to-child transmission of HBV in the population. Other impact measures reflect progress toward goals such as equity and improved quality of life for people with hepatitis B.

The monitoring and evaluation framework needs to be fed by reliable data systems from different sources. It includes prevalence (C1) that informs context in terms of the proportion of the population infected; availability of drugs and diagnostics (A2) that quantifies the health system capacity to test and treat for hepatitis B and C; prevention indicators (C3–C5); cascade of care and cure (C6–C8); and impact measured in terms of incidence (C9) and mortality (C10). Table 5.1 summarizes information on data sources and measurement approaches for the 10 global indicators. The metadata in Annex 2 provide further description and information for each indicator.

Figure 2. Core indicators for viral hepatitis B and C monitoring



C1. Prevalence of chronic hepatitis B and C

C2. Existence of a costed national strategic plan for eliminating viral hepatitis

C3. HBV vaccination and elimination of mother-to-child transmission of HBV

C4. Harm reduction among people who inject drugs: needles and syringes distributed and opioid agonist maintenance treatment

C5. Facility-level injection safety and blood safety

C6. Testing and diagnosis coverage

C7. Treatment coverage

C8. Cure for HCV and HBV DNA suppression

C9. Incidence of hepatitis B and C

C10. Mortality from hepatitis B and C

Table 5.1. 10 core indicators to monitor and evaluate the health sector response to viral hepatitis B and C along the result chain in countries

Level	Domain	Indicators	Measurement approaches		Data management and analysis
			Reference measurement methods	Alternative option (other sources)	
Context and needs	Prevalence of infection	**C1a.** Prevalence of chronic hepatitis B **C1b.** Prevalence of chronic hepatitis C	Recent nationally representative biomarker survey	Data mining and triangulation from routine testing data (such as blood donors and pregnant women), published literature Regional average, modelled estimates. Estimates may be modelled from older biomarker surveys or from testing data	Prevalence expressed in percentage. The age- and sex-disaggregated prevalence is then applied and used to calculate the total population infected[a]
Input	Health system capacity	**C2.** Existence of a costed strategic plan for eliminating hepatitis **A2.** Availability and readiness of HBV and HCV drugs	Desk review Health facility survey (such as harmonized health facility assessment) (*21*) Drug and diagnostics access survey	Data from accreditation bodies, national reference laboratory Data from drug or diagnostic manufacturers, procurers and suppliers	The results are expressed as the percentage of facilities offering drugs or diagnostic facilities with available drugs available or as the number of facilities per 100 000 population
Outputs	Hepatitis B vaccination and elimination of mother-to-child transmission	**C3a.** Coverage of hepatitis B birth-dose vaccine **C3b.** Coverage of three doses of hepatitis B vaccine **C3c.** Coverage of HBV testing among pregnant women **C3d.** Coverage of antiviral therapy among eligible HBsAg-positive pregnant women **A3.** Coverage of hepatitis B immunoglobulin among HBV-exposed newborns	Recent immunization coverage survey, Routine data from Expanded Programme on Immunization Antenatal care and maternity registries	Sentinel surveillance or special studies	Coverage expressed in percentage

Table 5.1. (Continued) 10 core indicators to monitor and evaluate the health sector response to viral hepatitis B and C along the result chain in countries

Level	Domain	Indicators	Measurement approaches		Data management and analysis
			Reference measurement methods	**Alternative option (other samples)**	
	Prevention	**C4a.** Needles and syringes distributed per person who injects drugs per year **C4b.** Coverage of opioid agonist maintenance therapy among people who inject drugs	Data from harm reduction programmes	Global AIDS Monitoring, integrated HIV biobehavioural surveillance Regional estimates reported by WHO	Results are expressed as sets per person who injects drugs per year.
		C5a. Proportion of health-care facilities with safe injections **C5b.** Proportion of blood units screened for bloodborne disease	Demographic and health surveys Health facility survey, such as harmonized health facility assessment (*21*) Routine data from blood services WHO Global Database on Blood Safety	Regional estimate reported by WHO	The results are expressed as the proportion of injections given with new, sterile syringes
	Testing and diagnosis	**C6a.** Proportion of HBV infections diagnosed **C6b.** Proportion of HCV infections diagnosed	Programme or patient monitoring tools; reports from routine testing centres	Modelled estimates; national notification or registry; physician or expert opinion Blood bank	Results expressed in percentage
	Treatment coverage	**C7a.** Proportion of people with hepatitis B initiating antiviral therapy **C7b.** Proportion of people with hepatitis B currently receiving antiviral therapy **C7c.** Proportion of people with hepatitis C initiating treatment **A7.** Proportion of people with hepatitis B not initiating treatment with annual follow-up	Programme or patient monitoring tools	Reports from treatment centres Physician or expert opinion Drug sales or drug export data	Results expressed in percentage

Table 5.1. (Continued) 10 core indicators to monitor and evaluate the health sector response to viral hepatitis B and C along the result chain in countries

Level	Domain	Indicators	Measurement approaches		Data management and analysis
			Reference measurement methods	**Alternative option (other samples)**	
Outcome	Treatment effectiveness	**C8a.** Proportion of treatment attrition among people with chronic hepatitis B in the reporting year	Programme or patient monitoring tools Viral hepatitis drug resistance surveillance	Cohort studies Population-based surveys that collect data on antiviral therapy (ART) coverage and viral suppression and cure Estimates based on sentinel sites	Lifelong HBV treatment. Coverage is the proportion treated, and effectiveness is the proportion virally suppressed. Short curative HCV treatment. Coverage is treatment initiation, and effectiveness is the proportion cured
		C8b. Proportion of people with hepatitis C treated and achieving cure			
		A8. Proportion of people with chronic hepatitis B treated and achieving HBV DNA viral suppression			
Impact	Incidence	**C9a.** Incidence of hepatitis B	Recent biomarker survey Repeated cross-sectional biomarker surveys Prospective or retrospective cohort studies HBsAg biomarker prevalence survey among children younger than five years old	Estimates modelled by WHO Other validated models Data from routine surveillance systems	
		C9b. Incidence of hepatitis C	Direct estimation of hepatitis C incidence based on prospective or retrospective cohort (HCV retesting of people who initially tested negative for HCV antibodies or HCV RNA)	Infectious disease models based on previous survey data and routine surveillance data	
		A9. Mother-to-child transmission rate of HBV	Programme or patient monitoring tools	Mother–child paired surveys	

Table 5.1. (Continued) 10 core indicators to monitor and evaluate the health sector response to viral hepatitis B and C along the result chain in countries

Level	Domain	Indicators	Measurement approaches		Data management and analysis
			Reference measurement methods	**Alternative option (other samples)**	
	Mortality	**C10.** Mortality from hepatitis B and C	Data from vital registration and cancer registries combined with the fraction of sequelae attributable to hepatitis B and C from fixed sentinel centres	WHO global health estimates by country available on the WHO website through the Global Health Observatory Institute for Health Metrics and Evaluation	Requires collaboration between vital statistics and fixed sentinel centres managing end-stage liver disease

[a]It is crucial that the age- and sex-disaggregated prevalence be made available and used to estimate the total infected population. This is because hepatitis B and C prevalence tends to be higher in older populations and most countries have a larger younger population. Therefore, applying the same prevalence estimate to the entire population would overestimate the size of the infected population.

S

5.1. Cascade of care for hepatitis B and C

A major reason for consolidating strategic information is to support the delivery of a cascade of linked services. Cascades are frameworks for monitoring gaps in programme services needed to achieve goals and health outcomes, comprising a result chain or a series of sequential events in which each event is linked to achieve a health outcome *(22)*. Health sector services in the cascade encompass prevention, treatment, care and cure interventions. The term cascade emphasizes that a sequence of services is needed to achieve the desired impact. The cascade of care concept also informs the tracking of patients from one service to the next and highlights the gradual attrition of coverage of the eligible population over the steps of the sequence *(23)*. The function of a cascade is to depict how many members of a population have progressed through each stage in a sequence of stages required for effective disease control, from prevention to cure.

Cascade metrics can be used to communicate in simple terms the extent to which national and subnational governments are advancing on key targets *(22)*. cascade of care findings can inform strategic decision-making regarding how to maximize the progression of hepatitis-infected individuals to diagnosis, treatment and cure.

Monitoring people receiving HBV treatment

For people receiving treatment, the following are recommended to be monitored at least annually:

- Non-invasive tests (APRI score or transient elastography) to assess stage of disease and progression of fibrosis or cirrhosis; and
- ALT levels (and AST for APRI), HBV DNA levels (when HBV DNA testing is available), HBsAg and HBeAg/anti-HBe.
- Treatment adherence should be monitored regularly and at each visit.
- More frequent on-treatment monitoring (every 3-6 months for the first year) may be performed for: people with more advanced disease (compensated or decompensated cirrhosis); during the first year of treatment to assess treatment response and adherence; if treatment adherence is a concern; for people co-infected with HIV; and for people with renal impairment.

Monitoring for people not receiving HBV treatment

People who do not currently meet the criteria for antiviral therapy (persistently normal serum aminotransferase results and HBV DNA levels below 2000 IU/mL (when HBV DNA testing is available) or who have expressed a desire to defer treatment may be monitored annually for disease progression and ALT and HBV DNA levels (when HBV DNA testing is available).

Monitoring people receiving HCV treatment

Assess cure: sustained virological response (SVR) at 12 weeks after the end of treatment (HCV RNA SVR, qualitative or quantitative nucleic acid test [NAT])

Detection of hepatocellular carcinoma (HCC) in persons with cirrhosis (every 6 months) with ultrasound or alpha-fetoprotein (AFP)

Monitoring the cascade of care requires a consolidated set of indicators covering the entire sequence. Setting priorities for indicators is important so that greater efforts can be focused on data quality, disaggregation, analysis and use to improve programmes along the cascade of prevention, care and treatment. Besides the estimated number of people infected, programme data that focus on the cascade of care and treatment include: number of people diagnosed, number of people assessed for treatment eligibility, number of people initiating treatment, number of people assessed for treatment effectiveness, number of people achieving viral suppression or cure and number of people retained in care. Analysis of these data generate the cascade of care indicators for hepatitis B and C.

For hepatitis B (Fig. 3a and b):

- proportion of people with chronic hepatitis B (HBsAg positive) who have been diagnosed (C6a);
- proportion of people diagnosed with hepatitis B assessed for hepatitis B treatment eligibility (non-invasive tests for staging [APRI score], HBV DNA and ALT);
- proportion of people diagnosed with hepatitis B eligible for hepatitis B treatment among those assessed for eligibility;
- proportion of people diagnosed with hepatitis B and eligible for treatment initiating treatment (C7a);
- proportion of people with chronic hepatitis B and eligible for treatment currently receiving antiviral therapy (C7b);
- proportion of people with chronic hepatitis B diagnosed and not receiving treatment who have an annual follow-up visit for disease progression evaluation (A7);
- proportion of people with chronic hepatitis B initiating antiviral therapy with treatment attrition (C8a);
- proportion of people currently receiving treatment who have an annual viral load test (annual HBV DNA assay); and
- proportion of people achieving viral HBV DNA suppression (annual HBV DNA suppression) among those currently receiving treatment who have a viral load test (A8).

For hepatitis C (Fig. 3c)

- proportion of people diagnosed with chronic hepatitis C (HCV viraemic infection) of the estimated population with hepatitis C (C6b);
- proportion of people assessed for hepatitis C treatment eligibility of those who diagnosed with chronic hepatitis C non-invasive tests for staging (APRI score), ALT);
- proportion of people diagnosed with chronic hepatitis C initiating treatment (C7c);
- proportion of people with chronic hepatitis C initiating treatment who have an HCV viral load test as a test of cure (sustained viral response at week 12); and
- proportion of people with chronic hepatitis C initiating treatment and achieving sustained viral response at week 12 (C8b).

At the initial stage of a programme, the cascade of care may be estimated by using ad hoc mechanisms, such as surveys, treatment cohorts from tertiary hospital data and sales of medicines (see Chapter 7 on stepwise recommendation on implementing country surveillance). However, the best approach to monitoring a national programme for testing and treatment of hepatitis B and C is to establish a patient-centred data monitoring system that will capture these services as part of the blueprint coordinated and decided by the broader governance framework of the national health management information system (see Chapter 6 on person-centred patient monitoring).

At the global, regional or country level, the cascades are ideally presented in relation to those infected in the population. Modelled cascades of care may be used to track progress at the regional and global levels *(24)*. At the subnational level, when the denominator of those with chronic infection might not be available for provinces or districts or when the catchment area of a health-care facility is difficult to estimate, the cascade is only presented in terms of service delivery data.

Various platforms are used for reporting the cascade of care on programme coverage targets. This guidance publication should be used as an instrument for clarifying what is being measured when countries generate cascades that depict the numbers and proportions of people with hepatitis C or B who have progressed to diagnosis, treatment, care and cure. Programme officers are encouraged to use the guidance provided here for carrying out national monitoring and reporting and then using the resulting data for the WHO global reporting or for validating hepatitis elimination. Importantly, reporting should include enough details of methods for calculating the cascade of care data, including in government reports and websites. Table 5.2 summarizes the variation in the reporting of the cascade of care in different platforms.

Figure 3. Visualization of core and additional indicators in cascade of care for (a) hepatitis B, and (b) hepatitis C

Figure 3a

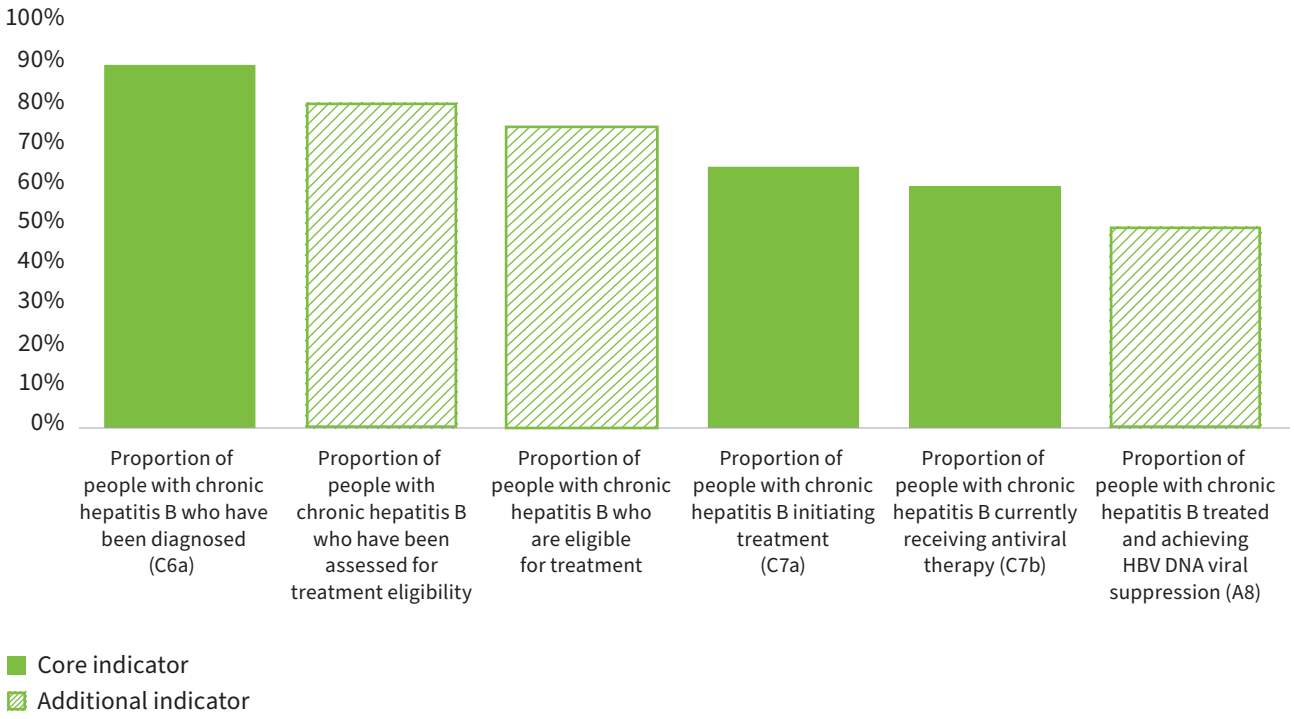


Figure 3b

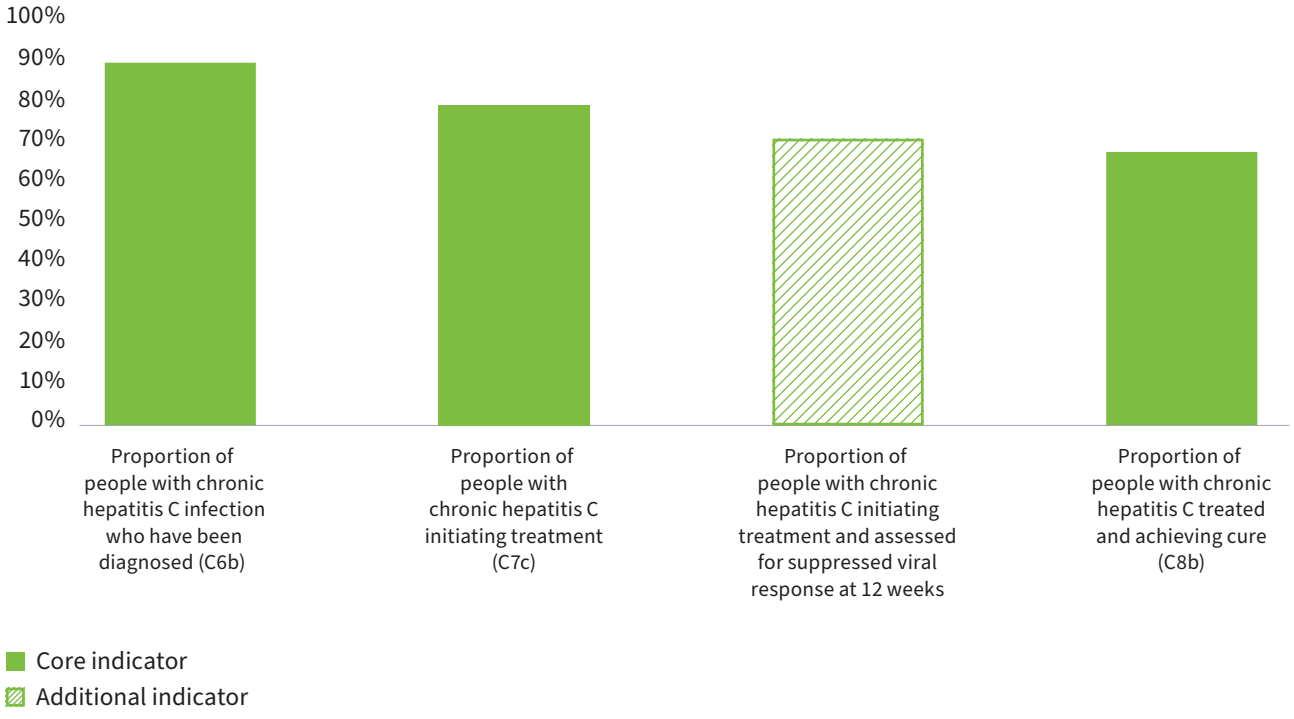


Table 5.2 Description of cascade indicators for programme reporting

Indicator	Description	Numerator	Denominator
C6a **% hepatitis B diagnosed**	Proportion of people with chronic hepatitis B who have been diagnosed with hepatitis B	Number of people with chronic hepatitis B who have been diagnosed (defined by HBsAg-positive serological status)	Estimated total number of people with chronic hepatitis B
C7a **% hepatitis B initiating treatment**	Proportion of people diagnosed with chronic hepatitis B initiating antiviral therapy of those eligible	Number of people diagnosed with chronic hepatitis B and eligible for treatment initiating antiviral therapy[a] at the end of the reporting period	Number of people with chronic hepatitis B infection who have been diagnosed and are eligible for treatment for the specified time period
C7b **% hepatitis B currently receiving treatment**	Proportion of people diagnosed with chronic hepatitis B who are currently receiving treatment of those eligible	Number of people diagnosed with chronic hepatitis B and eligible for treatment who are currently receiving antiviral therapya at the end of the reporting period	Number of people with chronic hepatitis B infection who have been diagnosed and are eligible for treatment
A7 **% hepatitis B on active follow-up among those not initiating treatment**	Proportion of people diagnosed with chronic hepatitis B and not initiating treatment who have an annual follow-up visit for disease progression	Number of people diagnosed with chronic hepatitis B not initiating antiviral therapy who have an annual follow-up	Number of people diagnosed with chronic hepatitis B infection not initiating antiviral therapy
C8a **% hepatitis B attrition from antiviral therapy**	Proportion of attrition from antiviral therapy among people with chronic hepatitis B in the reporting year (attrition from antiviral therapy)	Number of people with chronic hepatitis B reported on antiviral therapy at the end of the last reporting period *plus* Number of people with chronic hepatitis B newly initiating antiviral therapy during the current reporting period *minus* Total number of people with chronic hepatitis B on antiviral therapy at the end of the current reporting period	Number of people reported to be receiving antiviral therapy at the end of the last reporting period plus those newly initiating antiviral therapy during the current reporting period
A8 **% hepatitis B with suppressed viral load**	Proportion of people with chronic hepatitis B on treatment with suppressed HBV viral load	Number of people with chronic hepatitis B on treatment for at least one year who have a suppressed viral load (HBV DNA not detectable), based on viral load measurement in the past 12 months	Number of people with chronic hepatitis B on treatment for at least one year and assessed for viral load in the past 12 months
C6b **% hepatitis C diagnosed**	Proportion of people with chronic hepatitis C who have been diagnosed with hepatitis C	Number of people with chronic hepatitis C (positive RNA [PCR] or HCV core antigen) who have been diagnosed	Estimated total number of people with chronic hepatitis C

Table 5.2. (continued) Description of cascade indicators for programme reporting

Indicators	Reference number	Indicator tier	
C7c **% hepatitis C initiated treatment**	Proportion of people diagnosed with chronic hepatitis C infection initiating treatment	Number of people diagnosed with chronic hepatitis C infection and eligible for treatment who have initiated treatment	Number of people with chronic hepatitis C (RNA positive or HCV core antigen positive) who have been diagnosed and are eligible for treatment
C8b **% hepatitis C cured**	Proportion of patients with chronic hepatitis C cured among those who initiated treatment and were assessed for sustained viral response at week 12[2]	Number of people initiating treatment who achieved cure	Number of people who initiated hepatitis C treatment and were assessed for sustained viral response, (qualitative or quantitative nucleic acid testing), 12 weeks after the end of treatment[b]

[a]Not all people diagnosed with chronic hepatitis B infection are eligible for treatment. Treatment eligibility differs across countries and regions and should be defined in accordance with the most current WHO guidelines or regional or national guidelines.
[b]Sustained viral response at 24 or 48 weeks is also acceptable.

6. Person-Centred Data Monitoring for Chronic Viral Hepatitis

6.1. Use of person-centred data

Health services should be organized around the health needs and expectations of people and communities rather than diseases: the person-centred care approach. Person-centred data are organized to support person-centred health services for an individual. Individual-level data, such as patient records, are critical to client care to support the longitudinal monitoring of clients, including those with hepatitis infection, to improve the quality and continuity of care a client receives. The investments in digital health information systems, including electronic medical records and the adoption of unique identifiers, have been rapidly improving data collection, recording, use and reporting and strengthening person-centred patient monitoring and service delivery.

These data systems can also improve the quality of aggregated data and are increasingly valuable for reporting purposes for surveillance as person-centred data are integrated into electronic health information systems. Automatic aggregation of individual-level data is more advantageous than paper-based or manual approaches, to improve completeness, eliminate transcription errors and reporting delays and reduce the burden on human resources for reporting *(25,26)*. This information also can be used to document outcomes and impact. Person-centred routine data systems are vital sources of strategic information for hepatitis. Analysing such data can provide detailed characteristics of people with hepatitis as well as various contexts and underlying factors enabling better understanding of programmes and well-informed decision-making.

This guidance section seeks to enable national hepatitis programmes to update their chronic hepatitis B and C monitoring systems to better test, diagnose, link, manage, monitor, retain, trace and re-engage into care people with chronic hepatitis along the entire cascade. Its primary purpose is to guide the prevention of HBV and HCV infections and the clinical management of people with chronic hepatitis B and C and ensure the quality and continuity of hepatitis prevention, testing, early diagnosis, access to treatment and care services.

6.2. Person-centred data on prevention, testing, care and treatment

Person-centred monitoring generates data that track the health status of people with chronic viral hepatitis over time and support case management, enable tracking of viral hepatitis epidemic trends, measure programme performance across health facilities and support efficient allocation of resources.

Viral hepatitis information systems are complex since they need to capture new or acute infections, as well as chronic infections and sequelae that lead to morbidity and mortality. Since 20–30 years can elapse between people being infected with hepatitis B or C and dying, different parts of the health system capture these data, viral hepatitis information systems need to be integrated and enable data triangulation for analysis.

Service providers can use person-centred individual data on hepatitis prevention to improve services. If, for example, clients have missed appointments, providers can appropriately follow-up, such as by sending reminders, with consideration given to clients' privacy. Person-centred data on the prevention of hepatitis B and C can be used to understand various factors affecting the accessibility and coverage of interventions for different subpopulations who attend health services and to measure changes in patterns of new diagnoses. Different interventions will necessitate monitoring a variety of measurements, such as incident infection, known risk factors, initiation of prevention interventions and regular follow-ups with services or regular receipt of commodities *(25)*.

The collection of individual-level data across intervention programmes will facilitate monitoring of how well programmes meet the needs of individuals and inform the setting of priorities for interventions. Even at the level of the site or facility, aggregating routinely collected individual-level data on prevention can provide important information on trends, programmatic gaps and various other aspects of prevention intervention programmes *(25)*. This would include whether individuals continue to face elevated risk, which prevention methods they choose, whether hepatitis sequelae (HCC or liver cirrhosis) are present and whether they remain free from HCV reinfection.

The extent to which an intervention reaches beneficiaries and the level at which it is provided may be tracked by the number of (unique) individuals receiving the intervention within a reporting period and the volume of commodities that they receive. In particular, key core and global prevention indicators for hepatitis are needle and syringe distribution and opioid agonist therapy coverage. In addition, routine individual-level data enable cohort-type longitudinal analyses, such as calculating person-years of follow-up and examining the incidence of various outcomes and the coverage of interventions over time.

Person-centred data enable comprehensive and accessible prevention, testing, treatment and follow-up services through linking various programmes and interventions as an integrated approach. This is critical for the triple elimination of mother-to-child transmission of HIV, syphilis and hepatitis B. Eliminating the vertical transmission of HBV requires a comprehensive approach that includes scaling up universal access to the hepatitis B birth-dose vaccine (as part of the national immunization programme) and routine screening of all pregnant women for chronic hepatitis B as well as antiviral prophylaxis or treatment for those who are eligible. Screening in pregnancy in endemic regions or among people at elevated risk for hepatitis B can provide the opportunity for case finding and linkage to hepatitis B prophylaxis or care and treatment. The following core and global indicators are relevant to eliminating mother-to-child transmission: coverage of timely hepatitis B birth-dose vaccine, coverage of third-dose hepatitis B vaccine among infants, coverage of HBsAg testing of pregnant women and coverage of antiviral prophylaxis among eligible HBsAg-positive pregnant women. The use of person-centred data monitoring provides an opportunity to track HBV-exposed infant–mother pairs to estimate the mother-to-child transmission rate.

Person-centred data on testing can be collected and analysed using a combination of client monitoring and routine programme-based data for both client management and programme monitoring purposes *(25)*. Understanding testing history, patterns of testing, retesting and test results is necessary to guide the provision of support and clinical care to clients, especially for high-risk populations such as people who inject drugs and immigrant populations. To improve care and service delivery, standard approaches to data are needed across a wide variety of testing settings and levels of health-care facilities, including integrated services. Understanding reasons why testing is promoted in different testing contexts is critical to interpreting the testing indicators and has important implications for collecting, aggregating and analysing data *(25)*. Data on testing uptake logistics and information management system. Finally, retesting is critical to ascertain whether people receiving prevention intervention remain negative and, when seroconversion (including HCV reinfection) is identified, to ensure that they are linked to treatment. The key core and global indicators relevant to testing include the number of people with hepatitis B diagnosed and the number of people with hepatitis C diagnosed.

For hepatitis B and C, linkage to treatment and care is essential to achieve programmatic impact and effective patient management and care. Person-centred data on treatment and care with unique identifiers is key to strengthening referral and linkage to treatment and care services following diagnosis. All people found positive for hepatitis B or C should have access to treatment, with person-centred care organized around the health needs, preferences and expectations of people and communities *(25)*. Monitoring of hepatitis B should be person-centred and enable longitudinal monitoring of people with hepatitis B as they access hepatitis B treatment and care services and, where relevant, re-engage in care and reinitiate treatment. People receiving hepatitis B treatment should also have opportunities to monitor viral load suppression annually (where HBV DNA testing is available). Similarly, it is important to record the completion of hepatitis C treatment and also the cure once confirmed by testing with HCV RNA (PCR) or HCV core antigen.

Patient monitoring for chronic viral hepatitis along the cascade should be integrated as closely as possible with, and leverage, patient monitoring for other frequently associated diseases or health conditions, especially HIV, sexually transmitted infections and tuberculosis. This is critical in all settings in which treatment of chronic hepatitis is initiated or maintained, including maternal, newborn and child health services as well as ART and pre-exposure prophylaxis (PrEP) sites. Over the long term, countries should also seek to integrate chronic hepatitis patient monitoring systems with monitoring of individuals receiving care for other conditions such as metabolic dysfunction–associated steatotic liver disease and diabetes. They should also be integrated with other databases used to monitor hepatitis sequelae, such as liver cirrhosis and cancer registries (particularly HCC) and death registries. Ideally, various databases are linked and integrated into the overall health information system. This is especially important to monitor progress and to enable the country to gather data needed for validating the elimination of viral hepatitis.

The template patient management card (Annex 1) can be used in paper form or electronically in electronic medical records to document and frame good care practices in health-care facilities.

A subset of variables (a minimum data set with priorities set) can then be entered in a computer or extracted from the electronic medical records to feed into a case surveillance database (database of patients). When a person is initially diagnosed (newly identified with chronic infection), the record is added to the database. The record is completed when the person is cured (hepatitis C) or dies. Health-care providers can use such databases to manage data on personal characteristics, diagnosis, treatment, monitoring and viral suppression or cure.

Interoperability of data systems and unique identifiers are necessary to identify the same individuals and remove duplicate reports (deduplication). Interoperability enables exchanges of data between different sources and systems and a common understanding of these data. As more countries expand their digital health information systems, national authorities should develop interoperability standards, data use rules and obligations and transparent data governance in digital health systems to enable the secure exchange and use of health data. Unique identifiers are an anonymous alphanumeric code that can replace names and personal information and support individuals to identify themselves when accessing a variety of health services over time and across facilities, districts, health and disease programmes while helping health-care workers in linking relevant health information and deduplicating records when providing services. Integrating various data sources with unique identifiers with interoperability enables automated analysis and aggregation of individual data from different sources with minimum duplications and calculation of core indicators along the cascade of care, which can then be reported to the national level and ultimately to WHO through the Global Hepatitis Reporting System.

It is a prerequisite to ensure data confidentiality and security regarding the use and storage of health data. Since health-care data include highly personal information, including potential implications of stigmatization or discrimination, sometimes by health-care workers, and even criminal arrest, such risk may discourage individuals from using health-care services. Countries should invest in secure and confidential data systems, protected by policies and rights, with different data security levels for different data elements and different health-care users. WHO encourages sharing person-centric data for the purpose of public interest with the patient's consent, when it is built on trust, protects patient privacy, secures digital systems and protects against inappropriate use (*27*).

6.3. Minimum data set for monitoring people with hepatitis

A minimum data set is a standardized set of essential data elements relevant to client management and programme monitoring. The minimum data set contains core demographic, clinical and laboratory data. It defines the key data to collect in health information systems in either paper or electronic formats. The minimum data set captures key interactions of clients with the health system along the cascade of prevention, testing, treatment and other related services and can be transformed into the key indicators in the cascade.

By integrating and aligning the components of these systems, such as linking the electronic patient monitoring system to a case surveillance data repository and/or to aggregate reporting systems, country programmes benefit from the efficiency of a common data source to serve all three fundamental data functions: patient care, programme management and programme monitoring. The principle is to collect data once and use them many times.

Table 6.1 shows the minimum data set by topic areas, which are critical for hepatitis patient monitoring reflected in the patient management card (Annex 1). These also enable reporting on core indicators for viral hepatitis, lists the minimum data elements including definition and purpose for each and describes how data can be used to improve individual patient care and programme monitoring. The data elements are aligned and linked to the core and additional indicators for chronic viral hepatitis. Programmes may choose to collect additional information depending on local needs and context.

Table 6.1. Minimum data set by topic area

Topic area	Minimum data set
Demographic	• Site • Unique identifier • Name • Sex • Date of birth • Telephone • Address, including village and district • Visit date
Hepatitis testing and diagnosis	*Chronic hepatitis B* • HBV test (HBsAg) date and results • Date of first hepatitis B diagnosis • HBV viral load test date and results • Hepatitis B e antigen test date and results • Anti-HDV test date and results • HDV RNA test date and results *Chronic hepatitis C* • Anti-HCV test date and results • Date of first hepatitis C diagnosis • HCV core antigen and/or HCV RNA test date and results
Comorbidities and risk factors	• Injecting drug use • Other known probable routes of transmission: unsafe medical injections, blood transfusion, blood products, organ or tissue donations, piercing, circumcision or acupuncture • Daily alcohol consumption units • Pregnancy status • HIV status • Metabolic dysfunction–associated steatotic liver disease
Treatment initiation and continuation	• Hepatitis B treatment initiation date • Hepatitis B regimen prescribed • Hepatitis C treatment initiation date • Hepatitis C regimen prescribed • Hepatitis C sustained viral response test date and results • Transfer out (date, to where) • Treatment interruption (date and reasons)
Viral hepatitis sequelae	• Death (date) • Alpha fetoprotein test date and results • Ultrasound date and results • HCC evaluation date and results (alpha fetoprotein etc

7. Implementing Country Surveillance

Most countries should use data now to scale up hepatitis programmes yet also require stepwise actions to strengthen the epidemiological information needed to plan, implement, monitor, evaluate and update health sector strategic plans, including preventing and controlling viral hepatitis or national strategic plans specifically for preventing and controlling hepatitis. A national health sector strategy provides the basis for a country's health information, monitoring and related planning, and review processes provide a key entry point for policy dialogues that can influence priority setting and resource allocation. Countries are, therefore, encouraged to embed and align hepatitis surveillance planning within existing national health sector planning processes, monitoring and review of national health sector plans, related health sector strategies and accountability mechanisms.

To establish data systems for viral hepatitis, a stepwise approach is recommended depending on the maturity of the countries' information system – using the data available while strengthening the data system. In the first phase, a survey is needed to generate estimates for the epidemiology as well as the natural history of hepatitis in the country. These surveys can be population based, include hepatitis testing in existing Demographic and Health Surveys or HIV surveys, or include surveys among particular groups where there is a denominator, including antenatal care, blood donors and vulnerable populations. In the second phase, person-centred routine programme data are needed to manage and monitor viral hepatitis testing and treatment coverage. Person-centred data systems benefit service delivery, diagnosis and, critically, a treatment, which should be stored in a database. Treatment data should be supplemented by drug consumption data to validate the numbers of people treated in the country.

Countries should explore the availability, the source, the quality and the accessibility of available data. A clear framework on how to collect, use data systems and extract integrate or mine data is necessary. Linkage between data sets should be defined and analysis methods described: identifying denominators or/and numerators, specific groups and the reporting period and calculating the absolute number, the proportion or attributable fraction of hepatitis B and C sequelae.

A stepwise approach outlined below can be adapted and used depending on the stage of the viral hepatitis programme in the country.

7.1. Stepwise approach for establishing surveillance for viral hepatitis

Phase 1: Using and improving available data

At the initial stage, it is important to implement a hepatitis prevalence survey and collect individual testing data from testing centres. This will provide data on the prevalence of chronic hepatitis B and/or C (C1), number of people diagnosed with chronic hepatitis B and C (C6) and the components of incidence (C9) and mortality (C10). It is important to validate officially these data. This will inform the baseline burden of hepatitis B or C disease and enable priority setting.

Step 1: Use available data

WHO-estimated burden and hepatitis B and C care cascade data are available for most countries through the WHO global reporting for viral hepatitis. Countries can gather any other relevant data sets, review, triangulate and validate these data and their quality, highlight gaps and inconsistencies and use the information for planning. If there is no biomarker survey of hepatitis burden, countries should plan to conduct one using the available estimates as a benchmark.

Step 2: Strengthen burden and cascade data

Survey of burden: countries should make efforts to include HBV and HCV testing in existing population-based biomarker surveys, such as Demographic and Health Surveys and Population-based HIV Impact Assessment surveys. Biomarker surveys are the most robust method of estimating the prevalence of chronic hepatitis B and C in the population. Countries such as Nigeria, Uganda, and the United Republic of Tanzania incorporated HBV and HCV testing in their Population-based HIV Impact Assessment survey (*28*). In Uzbekistan and Georgia, HBV and HCV testing was included as part of a COVID-19 survey. In addition, surveys should be implemented

among particular groups where there is a, known, representative denominator, such as among antenatal care attendees, blood donors and key populations.

Repeating such surveys using standardized methods as part of routine strategic information systems provides comparable information over time. Surveys can estimate the prevalence of serological evidence of past HCV infection (proportion of those surveyed who are positive for anti-HCV), current infection (proportion of those surveyed positive for HCV RNA) and fibrosis (proportion of those surveyed positive for non-invasive markers of fibrosis) in addition to understand the most common risk factors for transmission. They can estimate the proportion of infected people who know their status, are eligible for treatment and are receiving antiviral therapy. WHO has published a template protocol with guidance on viral hepatitis biomarker surveys for HBV and HCV *(10)* of chronic infections through regular biomarker surveys, which may be done by specific programmes or through a central mechanism (such as a national centre for research or epidemiology).

In addition to surveys conducted in the general population, surveys or regular surveillance among specific groups (such as antenatal care attendees, blood donors, key populations including people who inject drugs, men who have sex with men, sex workers and prisoners) can provide information on risk behaviour and the prevalence of infection in these groups *(14)*. This type of surveillance is often conducted in the context of HIV programmes, such as integrated HIV bio- behavioural surveillance, and can be extended to viral hepatitis. The prevalence ratio (the prevalence in specific groups divided by the prevalence in the general population) guides focused testing in specific groups *(13)*. People who inject drugs, prisoners and persons exposed to high risk health care exposure such as haemodialysis three groups most likely to have a higher prevalence of hepatitis C in most settings *(1)*. Groups among which the prevalence is not substantially higher than in the general population do not need to be given priority for subsequent surveillance and/or focused testing.

Many countries conduct routine testing for HBV and HCV infections, mandated or offered for various purposes like blood donation, antenatal care, employment, travel, immigration and premarital assessments. These routine testing datasets offer an alternative method for estimating infection rates and the burden of chronic infections. Their value is particularly significant when analysed through a triangulation approach, integrating meta-analyses and meta-regressions to maximize data utilization for accurate estimations. Additionally, these data sets can serve as inputs for mathematical models, enabling the estimation of infection rates and chronic infection burdens. Several countries have successfully used these analytical methods *(29)*. One major advantage of this approach lies in its cost–effectiveness, using existing health system data, and that it supports the provision of people-centred health services, for example in antenatal care *(30)*.

Estimate cascade data from existing treatment cohorts. Most patients are treated at tertiary centres, where robust historical data exists. Hospital data in tertiary, gastroenterology centres can be used to **(i)** assess the proportion of diagnosed people receiving treatment and **(ii)** assess treatment outcomes – including virally suppressed, cured, hepatitis sequelae (HCC and cirrhosis) and mortality. Reporting of chronic hepatitis B and C in health-care facilities can also be used to estimate the number of cases identified and managed in health-care services. This information can be used to assess cascades of care or cure, providing assumptions relevant for the setting that can be used in modelling estimates on the burden of disease. Note that modelling based on health-care facility data does not necessarily constitute a robust method of estimating burden, since many people with chronically hepatitis infection never seek care. On the other hand, repeated visits to health-care facilities may lead to duplicate reporting that needs to be eliminated through deduplication. Countries should consolidate, deduplicate and update these data regularly.

Estimates of the core indicators of the cascade of diagnosis and treatment can be generated in a simpler way using aggregated data reported from all health-care facilities involved in hepatitis treatment, such as tertiary and teaching hospitals, in both the public and private sectors. Aggregated data management is much less labour intensive and probably best suited for programmes at the early stages of scale-up.

Use drug manufacturer consumption data. Drug data are a major source to estimate treatment numbers in a country, triangulate the above data with data available at logistics management information systems and/or manufacturer's consumption data (including the private sector). They might not match exactly but can indicate levels and trends and/or by geography.

Step 3: Using hepatitis data for decision making

Data from the above step are sufficient to use by the country for planning, reporting and management, filling in gaps with modelling and developing an investment case where needed. Countries with scarce data may use mathematical models to complement empirical data for estimating the prevalence, incidence and mortality of viral hepatitis, with various limitations and low accuracy. Modelling should always be used to extend data and is not a separate activity. Similarly, data sources almost always require some triangulation and extrapolation to use for estimation, for example if a prevalence survey occurs 2–3 years in the past or needs to be age standardized to the total population. Information on antiviral agents and their consumption can also compliment this data and would enable private clinic data to be adjusted. In addition, countries should plan how to address data gaps and weaknesses and strengthen data systems in the future.

Managers can use surveys, routine data and modelled estimates to make decisions on managing programmes and taking action. Disaggregated data may indicate which geographies or population groups may be at higher risk, requiring more attention and resources. Monitoring and managing viral hepatitis testing and treatment coverage, through the cascade will show what is working well and what is working less well and where linkage should be further strengthened to address these programme gaps in a systematic manner with priorities set.

Phase 2: Building and strengthening patient data systems

Countries need to monitor differential service coverage and quality and to address these programme gaps in a systematic, manner with priorities set.

Step 4: Strengthen person-centred routine health management information systems

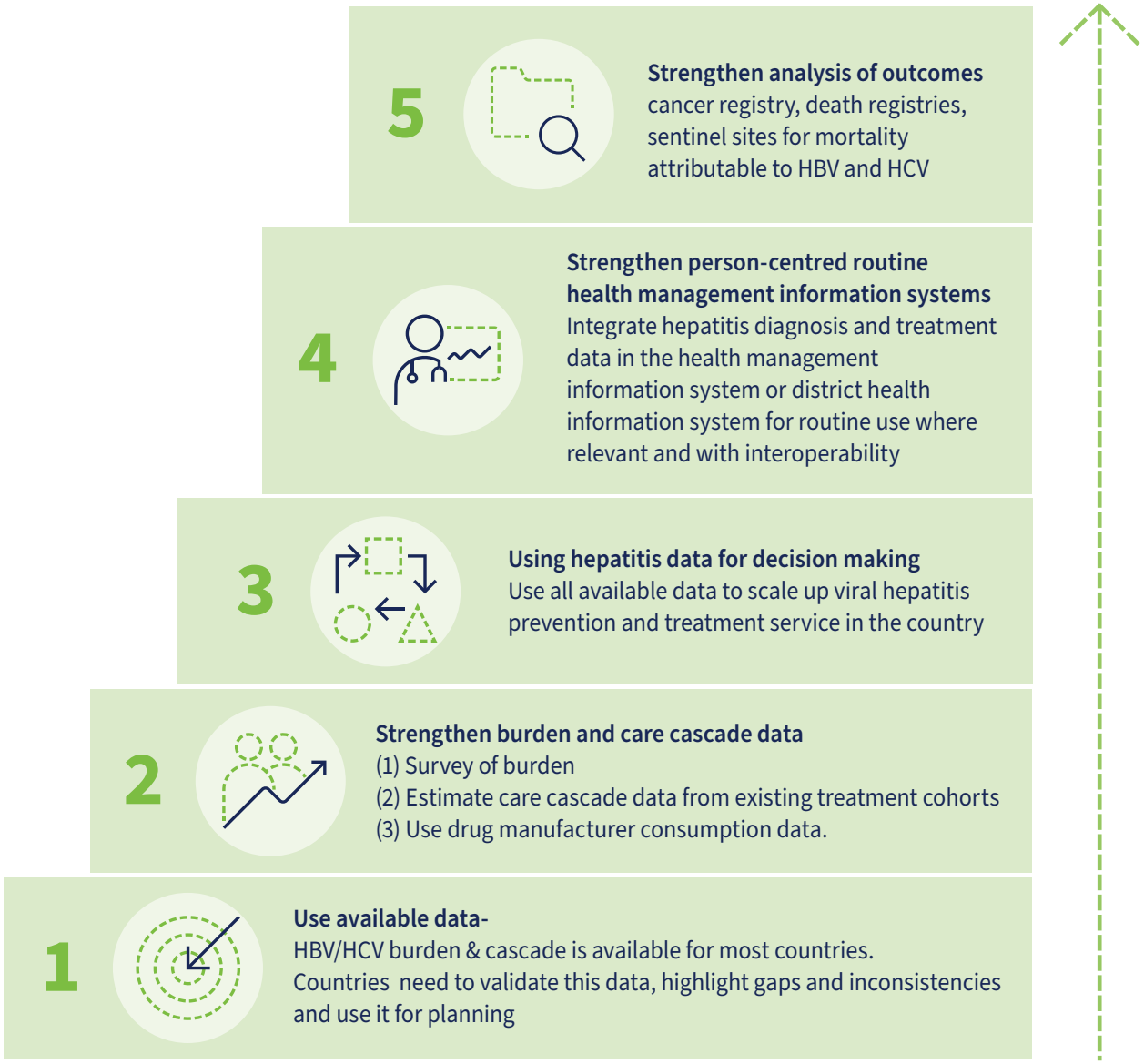
Hepatitis programmes may be able to leverage existing case surveillance used to monitor the cascade of care from individual patient monitoring at the facility level to aggregate reporting to the central level.

Databases of people with chronic infection can provide longitudinal data based on individual records. Individual patient records are a critical tool in patient care, supporting the longitudinal monitoring of clients and improving the quality and continuity of care a client receives by ensuring that multiple aspects of health care are visible to the provider over time, such as related infections, treatment gaps or other aspects that require follow-up. Similarly, tracking prevention services (such as PrEP or harm-reduction services) to individuals also benefits from the ability to observe individual-level data. Data entry and management of databases comprising individual patient records are resource intensive. Where such systems already exist, they are often used in settings with a high burden of hepatitis infection with electronic platforms (such as electronic reporting systems, medical records and health records) and reflect primary clinical tools.

Step 5: Strengthen analysis of outcomes

Countries need to enhance the analysis of outcomes to improve the estimation of the burden of hepatitis B and C and the assessment of hepatitis sequelae. This may be implemented in selected sentinel tertiary reference centres, especially in countries in which treatment and care for viral hepatitis and for cirrhosis and HCC is provided in specialized centres (such as oncology clinics, hepatology or gastroenterology centres and tertiary hospitals). This analysis is achieved by the prevalence of hepatitis B and C among cases of decompensated cirrhosis and HCC. By using a case report form, treatment centres can extract data on hepatitis B or C diagnoses and diagnoses with cirrhosis (if possible, decompensated cirrhosis) and HCC. Extracted data can also include demographic characteristics such as age and sex, data on HDV coinfection status and data on other potential risk factors for liver disease including alcohol consumption and metabolic syndromes (such as diabetes and dyslipidaemia). Multiplying the estimated number of deaths from decompensated cirrhosis, HCC and liver failure by the fractions of sequelae attributable to hepatitis B and C can estimate the burden. A WHO guide is available to provide guidance on surveillance of sequelae *(5)*.

Figure 4. A stepwise recommendation for strengthening country surveillance



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Annex 1. WHO template for chronic hepatitis B and C patient management card

WHO template for chronic hepatitis B and C patient management card

Identification:

Name:

Gender: |_| Female |_| Male |_|Transgender male |_|Transgender female |_|Other Sex assigned at birth: |_| Female |_| Male |_| Other

Date of birth (DD/MM/YYYY): _____ / _____ / _____ Age (years): _____ Marital status: |_| Single |_| Married |_|Divorced or separated |_|Widowed|_|N/A

Address: ___________________Residing district___________________ Telephone number______________ Unique identifier |_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_
Patient clinic

ID number: |_|_|_|_|_|_|_|_|_|_||_|_|_|_|_|_|_|_|_|_| Enrolment date: ___ / ___ / ___ Health district _________________ Health unit/Facility _________________

antiviral therapy/direct-acting antiviral drugs initiation site __________________ clinician/team__________________

Laboratory:

HBsAg: |_|Positive|_| Negative|_|Indeterminate |_| Not done Date of first diagnosis of HBV infection: ___ / ___ / ___

HBV DNA (IU/mL): |___|Value|_| Negative |_|Indeterminate |_| Not done HBeAg: |_|Positive|_| Negative |_|Indeterminate |_| Not done

HDV RNA (IU/mL): |_|Positive|_|Negative |_|Indeterminate |_| Not done Anti-HDV (to be done if HBV positive): |_|Positive|_| Negative |_|Indeterminate |_| Not done

Anti-HCV: |_|Positive|_| Negative |_|Indeterminate |_| Not done Date of first diagnosis of HCV infection: ___ / ___ / ___

HCV RNA (IU/mL): |_|Value|_| Negative |_|Indeterminate |_| Not done HCV genotype: |_| HCV core antigen: |_|Positive|_| Negative |_|Indeterminate |_| Not done

HIV: |_|Positive|_| Negative |_| |_|Indeterminate Not done Latest HIV viral load (copies/mL): _______|_| Not done CD4 count:_______ × 109/L |_| Not done

Comorbodities, risk factors and concomitant treatment

Appendix 1: WHO Template for chronic hepatitis B and C patient management card (continued)

HIV treatment regimen: _____ Date HIV treatment started___ / ___ / ___ Tuberculosis: |_|Active|_| On treatment|_| No

Injecting drug use:|_|Active (last 12 months) |_| Past history |_| No Daily alcohol consumption units: |_| Metabolic syndrome: |_|

liver and renal assessment and disease staging: **Staging date: ___ / ___ / ___**

ALT: ___ IU/L AST: ___ IU/L PLT:____ /mL Clinical diagnosis of cirrhosis:|_|Yes|_| No If yes, Child–Pugh score:

APRI score: ___ |_| Not done FIB4: ____ |_| Not done Transient elastography (kPa):_____ |_| Not done Liver biopsy stage (F): _____ |_| Not done

Bilirubin: Total____µmol/L and direct: _____µmol/L__ Ultrasound scan: _____Prothrombin time/INR:_____

Creatinine_____ eGFR _____Serum albumin_____

Hepatitis b treatment and care:

Past experience with treatment: |_|Yes|_| No Past treatment regimen: ____ Hepatitis B treatment regimen started: _____Date started: __ / ___ / __ Date stopped: __ / ___ / __

First annual viral response assessment Date tested: ___ / ___ / ___ HBV DNA(IU/mL: |_|Positive|_|Negative |_| Not done ALT: ____ IU/L

Hepatitis c treatment:

Past experience with treatment: |_|Yes|_| No Past treatment regimen:___ Hepatitis C treatment regimen started____: Date started: ___/ ___/ __ Date completed: __ / __/__

12 weeks post-treatment RNA test date: ___ / ___: |_|Yes|_| No. HCV RNA(IU/mL: |_|Positive|_|

Hepatitis Sequalae

Cirrhosis: |_|Yes|_| No. If yes cirrhosis, Ascites: |_|Yes|_| No. If yes ascites, degree of ascites: |_| mild |_| moderate |_|severe.

History of hepatic encephalopathy: |_|Yes|_| No. Presence of oesophageal/fundal varices : |_|Yes|_| No.

Hepatocellular carcinoma (HCC): if yes, BCLC stage _____. Number of focal lesions _____. Largest in size _____ cm. Extrahepatic spread |_|Yes|_| No.

Others_____

Annex 2. Meta-data tables

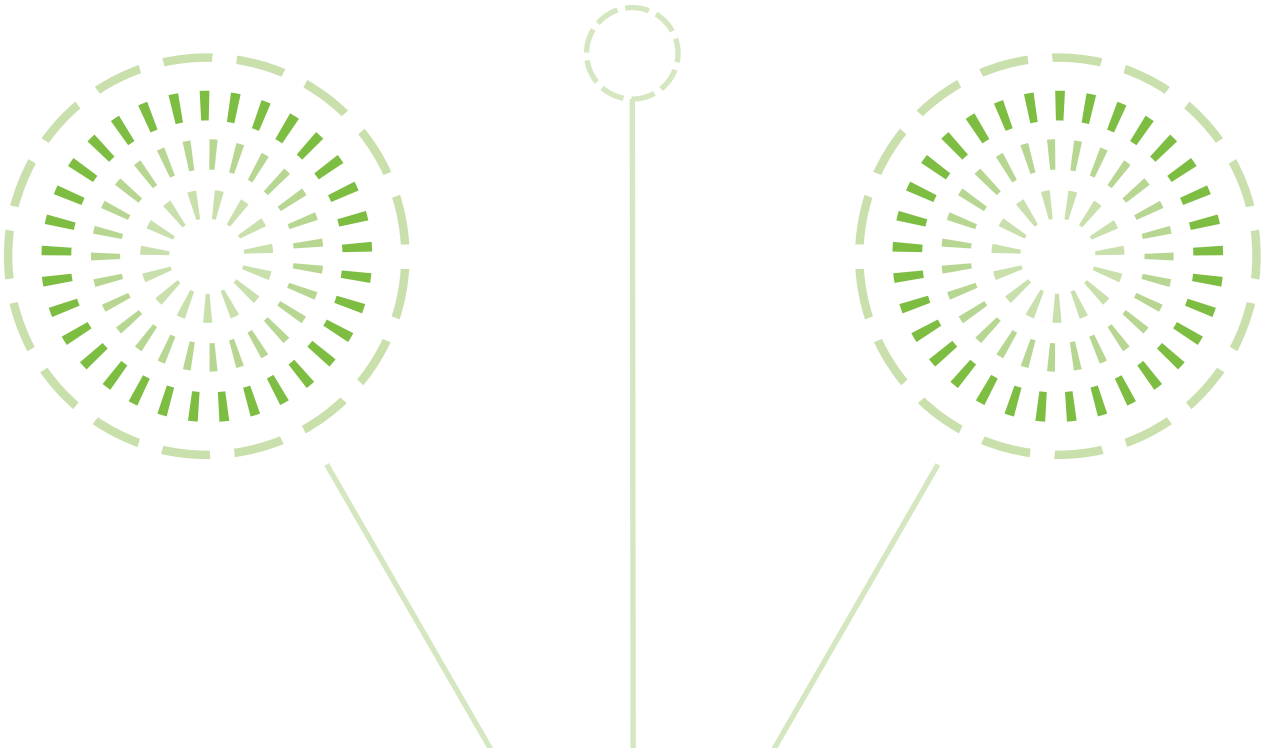
This section of the guidance details the recommended hepatitis indicators, including core and additional indicators.

For each indicator, the rationale for collecting the indicator data is provided, how the numerator and denominator (if applicable) data should be obtained and potential disaggregation categories.

Disaggregated data are needed to identify inequalities between subpopulations and to track trends. The most common disaggregation categories are sex, age, HIV status, populations at high risk of infection and geographical location (cities and other administrative regions of epidemiological importance). With respect to age, the age bands might differ between the indicators, and small age bands are recommended in settings with robust electronic health information systems.

Disaggregation by key populations (such as men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers and transgender people) should only be done where feasible and when data security and confidentiality can be ensured. Additional disaggregation for specific indicators is listed when recommended.

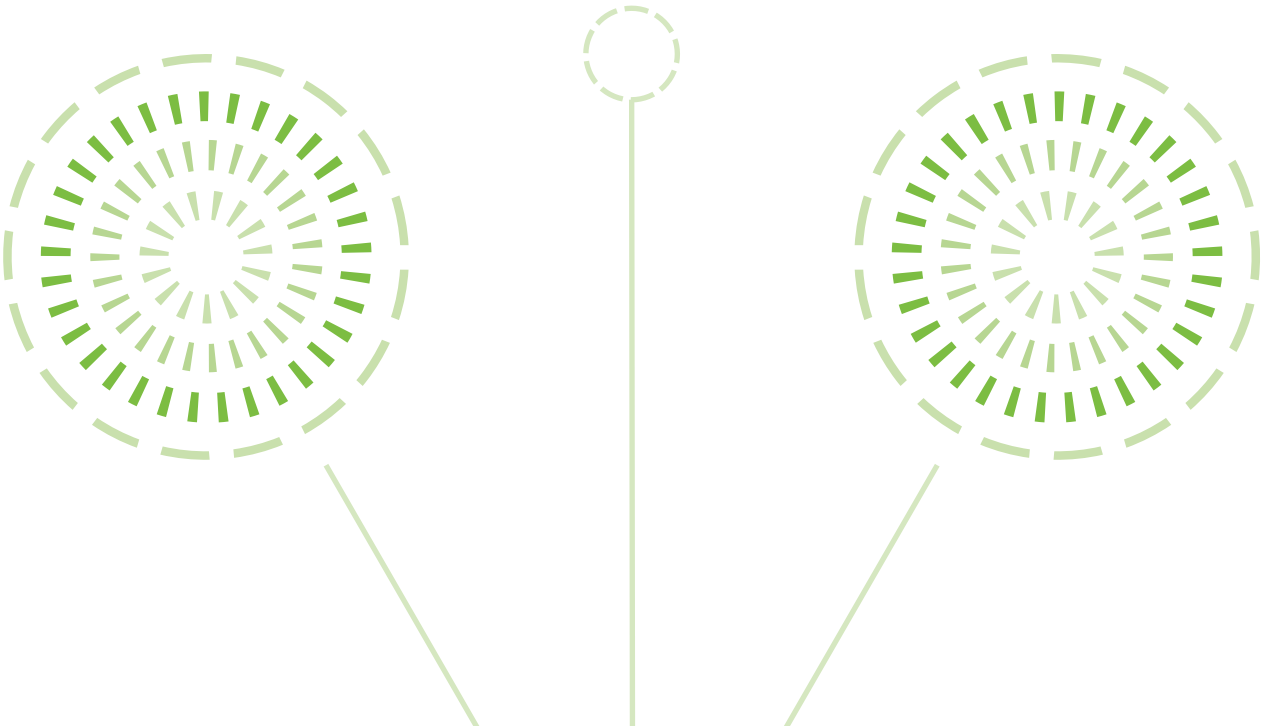
When possible, the core indicators use an unspecified reporting period and can be calculated over different periods of time to answer programme management questions at different levels and as required for differing reporting purposes. Some indicators have specific reporting periods (for example, in the past 12 months) that are important because they reflect recommended service delivery guidelines or the way the indicator is collected. As a general recommendation, data should be recorded daily and reported quarterly to the national or subnational level. They should also be consolidated annually and reported to WHO in the specified reporting platforms.



Reference number	C1a
Indicator	Prevalence of chronic hepatitis B
Category	Core, global
Monitoring and evaluation domain	Context and needs
Health domain	Morbidity (prevalence)
What it measures	Number and proportion of people with chronic hepatitis B (HBsAg positive)
Rationale	• This indicator reflects epidemic and service needs, since it serves as numerator or denominator for several other indicators along the result chain and cascade (coverage and impact indicators). • The biomarker of HBV infection is HBsAg. Given the low incidence of HBV infection, any person who is HBsAg positive during a cross-sectional survey is most likely to have chronic hepatitis B (the probability of coming across a recent infection is low). • By analysing the prevalence of chronic hepatitis B, programmes can understand the burden of hepatitis B and plan testing, care and treatment accordingly.
Global targets	Not applicable
Numerator	Number of people with chronic hepatitis B defined by HBsAg-positive serological status
Denominator	Number of people (total population)
Method of measurement, data sources	• Extrapolate from recent biomarker surveys. • Modelled prevalence estimates. Estimates may be modelled from older biomarker surveys and/or contemporaneous surveys in various populations of interest. Modelling can be used alongside available programme data, such as routine surveillance testing data, taking note of the methodological limitations and representativeness of the population. Such models need to consider relevant input parameters such as number of people treated over time, vaccination coverage, HBV infection incidence and deaths (liver-related deaths and background deaths in the general population). • Data mining and triangulation from routine surveillance testing data (such as blood donors and pregnant women).
Disaggregation	• Sex/gender, age groups, geographical location, pregnancy status, populations at high risk of infection for or with a high burden of viral hepatitis B • If possible, separate: – current infection (HBsAg) versus evidence of past or present infection (antibody against anti-HBc) – HIV infection status – HDV coinfection status The age- and sex-disaggregated prevalence must then be applied and used to calculate the total population infected.
Global reporting platforms	• WHO Global Hepatitis Reporting System

Reference number	C1b
Indicator	Prevalence of chronic hepatitis C
Category	Core, global
Monitoring and evaluation domain	Context and needs
Health domain	Morbidity
What it measures	Number and proportion of people with chronic hepatitis C (HCV RNA positive or HCV core antigen positive)
Rationale	• This indicator reflects epidemic and service needs, since it serves as numerator or denominator for several other indicators along the result chain and cascade (coverage and impact indicators). • Presence of anti-HCV antibodies provides evidence of past or present HCV infection without distinction between either past or resolved or present or active infection. • Recommended biomarkers of chronic hepatitis C include HCV RNA and HCV core antigen. • By analysing the prevalence of chronic hepatitis C, programmes can understand the burden of hepatitis C and plan testing, care and treatment accordingly.
Global targets	Not applicable
Numerator	Number of people with chronic hepatitis C defined as positive for HCV RNA or positive for HCV antigen
Denominator	Number of people (total population)
Method of measurement, data sources	• Extrapolate from recent biomarker surveys. • Modelled prevalence estimates. Estimates may be modelled from older biomarker surveys and/or contemporaneous surveys in different populations of interest. Modelling can be used alongside available programme data, such as routine surveillance testing data, taking note of the methodological limitations and representativeness of the population. Such models need to consider relevant input parameters such as number of people treated over time, hepatitis C incidence and deaths (liver-related deaths and background deaths in the general population). • Data mining and triangulation from routine surveillance testing data (such as blood donors and people who inject drugs and screening among other higher-risk populations)
Disaggregation	• Sex, age, geographical distribution, populations at risk for, or with a high burden of, viral hepatitis C The age- and sex-disaggregated prevalence must then be applied and used to calculate the total population infected.
Global reporting platforms	• WHO Global Hepatitis Reporting System

Reference number	C.2
Indicator	Planning – existence of a costed strategic plan for eliminating hepatitis
Category	Core
Monitoring and evaluation domain	Inputs
Health domain	Policies, laws, health system inputs and financing
What it measures	It indicates whether or not the country has a national strategic plan for eliminating hepatitis that is costed.
Rationale	• National planning of the hepatitis response is the building block from which the elimination of viral hepatitis can ultimately be validated. • The plan may be part of the broader health sector plan or a stand-alone strategic plan that is linked and integrated to the health sector plan.
Global targets	Not applicable
Numerator	Whether the country has a fully costed strategic plan for eliminating hepatitis or not.
Denominator	Not applicable
Method of measurement, data sources	• The national planning process should be informed by a comprehensive assessment of disease epidemiology and dynamics, population characteristics and country context, health system capacity and multisectoral national response to viral hepatitis. The process should be guided by setting national impact and programmatic targets that are consistent with the global approach to elimination and targets of the global health sector strategy on viral hepatitis (2022–2030) and are ideally presented as absolute thresholds aligned to this guidance. • The strategic plan should be operationalized through a fully costed viral hepatitis action plan, which defines the core interventions and resources needed to achieve national elimination targets. • An official response by the health ministry to WHO and key informant interview.
Disaggregation	• Not applicable
Global reporting platforms	• WHO Global Hepatitis Reporting System



Reference number	A2
Indicator	Availability and readiness of HBV and HCV drugs and diagnostics
Category	Additional
Monitoring and evaluation domain	Input
Health domain	Health system capacity (service availability and readiness)
What it measures	Service readiness measures extend to which resources and conditions are in place to provide services according to defined minimum standards, including the presence and functionality of basic amenities, trained staff, guidelines, equipment, diagnostics capacity, medicine and commodities *(12)*. Service availability refers to the physical presence of services (such as infrastructure, staff and beds) as well as the availability of specific services in facilities • Percentage of facilities offering hepatitis B birth-dose vaccination among designated immunization clinics • Percentage of facilities offering onsite testing for hepatitis B and C according to the following testing methods: – molecular methods (HCV RNA, HBV DNA) – serological methods (HBsAg, anti-HBc, anti-HCV) – rapid test methods (HBsAg, anti-HCV) • Percentage of facilities offering antiviral therapy for hepatitis B (or for prophylaxis among pregnant women) • Percentage of facilities offering direct-acting antiviral drugs for hepatitis C treatment
Rationale	• Measures trends in the availability of laboratory services for viral hepatitis B and C testing • The programme can ensure sufficient capacity to test and treat
Global targets	Not applicable
Numerator	Number of facilities that: • Offer HBV birth-dose vaccination • Offer onsite testing for hepatitis B and C according to the following testing methods: – molecular methods (HCV RNA, HBV DNA) – serological methods (HBsAg, anti-HBc, anti-HCV) – rapid test methods (HBsAg, anti-HCV) • Offer antiviral therapy for hepatitis B (or for prophylaxis among pregnant) • Offer direct-acting antiviral drugs for hepatitis C
Denominator	Number of facilities assessed Note: Ratios may be used to describe density of facility infrastructure (number of items per population), such as the number of health facilities per 10 000 population. However, density indicators should only be calculated using Harmonized Health Facility Assessment data if it has involved a census of all facilities in the country and reliable population estimates are available.
Method of measurement, data sources	• Information for this indicator is derived from programme data, Harmonized Health Facility Assessment and a survey of access to drugs and diagnostics. • Tests to be used depend on national recommendations based on WHO guidelines. Facilities include point-of-care testing provided by health-care workers, health facilities and laboratories.
Disaggregation	• Chronic hepatitis B and C testing capacity • Testing facility (such as a clinical laboratory) • Geographical location • National and subnational levels including facility type (tertiary, secondary and primary, managing authority (public or private)
Global reporting platforms	• WHO Global Hepatitis Reporting System • Harmonized Health Facility Assessment

Reference number	C3a
Indicator	Coverage of timely hepatitis B birth-dose vaccine
Category	Core
Monitoring and evaluation domain	Outcome
Health domain	HBV vaccination and elimination of mother-to-child transmission
What it measures	Proportion of newborns who have benefitted from timely birth dose of hepatitis B vaccine (within 24 hours)
Rationale	• hepatitis B birth-dose coverage is a good indicator of access to vaccination at birth and progress towards eliminating the vertical transmission of HBV.
Global targets	≥90% coverage of timely hepatitis B birth-dose vaccine (for countries that provide universal timely hepatitis B birth-dose vaccine) ≥90% coverage of infants at risk with targeted timely hepatitis B birth-dose vaccine (for countries that provide targeted timely hepatitis B birth-dose vaccine)
Numerator	Number of newborns receiving timely birth dose of hepatitis B vaccine within 24 hours
Denominator	• Number of all live births within the same calendar year (for countries that provide universal timely hepatitis B birth-dose vaccine) • Number of live births born to mothers with hepatitis B within the same calendar year (for countries that provide targeted timely hepatitis B birth-dose vaccine)
Method of measurement, data sources	Routinely collected from programme data (vaccine administrative coverage data and facility information systems) or through periodic immunization validation surveys (household surveys) and disseminated by WHO and UNICEF (https://immunizationdata.who.int/pages/coverage/HEPB.html?GROUP=Countries&ANTIGEN=HEPB_BD&YEAR=&CODE=). • An explanatory remark or footnote should be added when a country uses a universal birth-dose policy or targeted birth dose: screening of pregnant women to target children born to HBsAg-positive mothers for vaccination. • Another remark or footnote should also identify countries that have no hepatitis B birth-dose policy vaccination policy at all
Disaggregation	• Age, place of birth and residence, sex, socioeconomic status
Global reporting platforms	• WHO/UNICEF joint reporting form • Validation of triple elimination (elimination of mother-to-child transmission of HBV, HIV and syphilis) • Validation of hepatitis B elimination and path to elimination

Reference number	C3b
Indicator	Coverage of third-dose hepatitis B vaccine among infants
Category	Core, global
Monitoring and evaluation domain	Outcome
Health domain	hepatitis B vaccination and elimination of mother-to-child transmission
What it measures	Proportion of infants (younger than 12 months of age) who received the third dose of hepatitis B vaccine (percentage)
Rationale	• This indicator monitors and guides immunization programmes as proposed by WHO and UNICEF. It is also included in the WHO global reference list of 100 core health indicators *(31)*: immunization coverage rate by vaccine for each vaccine in the national schedule • This indicator also monitors programmatic targets used for validating the elimination of mother-to-child transmission of HBV and elimination and path to elimination of hepatitis B as a public health threat.
Global targets	≥90% coverage of three doses of hepatitis B vaccine
Numerator	Number of infants (younger than 12 months of age) who received the third dose of HBV vaccine
Denominator	Number of infants (younger than 12 months of age in a year) surviving to age one year
Method of measurement, data sources	• Routinely collected from programme data (administrative and official data reported annually through the WHO/UNICEF Joint Reporting Form on Immunization (https://immunizationdata.who.int/pages/coverage/hepb.html),or estimates by WHO/UNICEF using available administrative data and WHO vaccination coverage survey (https://www.who.int/teams/immunization-vaccines-and-biologicals/immunization-analysis-and-insights/global-monitoring/immunization-coverage/who-unicef-estimates-of-national-immunization-coverage).
Disaggregation	• Age, place of residence, sex, socioeconomic status
Global reporting platforms	• WHO/UNICEF Joint Reporting Form on Immunization • Validation of triple elimination (elimination of mother-to-child transmission of HBV, HIV and syphilis) • Validation of hepatitis B elimination and path to elimination

Reference number	C3c
Indicator	Coverage of HBV testing among pregnant women
Category	Core, global
Monitoring and evaluation domain	Outcome
Health domain	HBV vaccination and elimination of mother-to-child transmission
What it measures	Proportion of pregnant women who were tested for HBsAg during pregnancy
Rationale	• Testing pregnant women for HBV in pregnancy is important for their own health, and it is also the first step in preventing the mother-to-child transmission of HBV. It also informs programmes about the interventions needed to strengthen the elimination of mother-to-child transmission of HBV and the need to monitor exposed infants. • Knowing the testing coverage contributes to quality assessment across the full scope of antenatal care services. • This indicator also monitors programmatic targets used for validating the elimination of mother-to-child transmission of HBV and elimination and path to elimination of hepatitis B as a public health threat. • It provides information on the prevalence of chronic hepatitis B among pregnant women and can still serve as a guide to epidemic dynamics.
Global targets	≥90% coverage of antenatal testing for HBsAg among pregnant women (for countries with targeted timely hepatitis B birth dose vaccine or without universal timely hepatitis B birth-dose vaccine)
Numerator	Number of pregnant women tested for HBsAg
Denominator	Number of pregnant women attending antenatal care services
Method of measurement, data sources	• Patient monitoring tools (electronic or paper), for example, hepatitis and HIV testing service records, lab registers, antenatal care registers, logbooks and reporting forms at the facility and community levels. • Ideally, national programme records aggregated from health-facility data should be used. However, if such data are not available, data from sentinel surveillance or special studies can be reported. In this case, information on the source and coverage of the data should be provided as well as information on the representative of the national situation.
Disaggregation	Age, geographical location
Measurement frequency	Data should be recorded daily and reported quarterly to the national or subnational level. They should also be consolidated annually and reported to WHO.
Global reporting platforms	• Global AIDS Monitoring • WHO Global Hepatitis Reporting System • Validation of triple elimination (elimination of mother-to-child transmission of HBV, HIV and syphilis) • Validation of hepatitis B elimination and path to elimination

Reference number	C3d
Indicator	Coverage of antiviral therapy among eligible HBsAg-positive pregnant women
Category	Core, global
Monitoring and evaluation domain	Outcome
Health domain	HBV vaccination and elimination of mother-to-child transmission
What it measures	Proportion of pregnant women attending antenatal care services who received antiviral drugs (for prophylaxis or treatment) according to national policy, in accordance with WHO guidelines
Rationale	• Antiviral coverage is a further measure of sustained service quality throughout antenatal care. This indicator also monitors programmatic targets used for validating the elimination of mother-to-child transmission of HBV and elimination and path to elimination of hepatitis B as a public health threat.
Global targets	≥90% coverage with antiviral drugs for the HBsAg-positive pregnant women eligible for prophylaxis or treatment (for countries with targeted timely hepatitis B birth-dose vaccine or without universal timely hepatitis B birth-dose vaccine).
Numerator	Number of HBsAg-positive pregnant women who meet eligibility criteria and received hepatitis B antiviral therapy for their own health and those on antiviral prophylaxis to reduce mother-to-child transmission
Denominator	Number of pregnant women who were eligible for either hepatitis B antiviral prophylaxis or treatment for their own health
Method of measurement, data sources	• Information may be sourced from specific programme or clinical patient monitoring tools (electronic or paper medical records), maternity and antenatal care registers. • Ideally, national programme records aggregated from health-facility data should be used. However, if such data are not available, data from sentinel surveillance or special studies can be reported. In this case, information on the source and coverage of the data should be provided as well as information on the representative of the national situation. Not all pregnant women who test positive for HBsAg are eligible for antiviral therapy but rather need to be on antiviral prophylaxis to reduce the risk for mother-to-child transmission of HBV.
Disaggregation	• Age, geographical location, HIV infection status • Tested at any visit, tested at first visit • Antiretroviral eligibility criteria: prophylaxis or treatment
Global reporting platforms	• Global AIDS Monitoring • WHO Global Hepatitis Reporting System • Validation of triple elimination (elimination of mother-to-child transmission of HBV, HIV and syphilis) • Validation of hepatitis B elimination and path to elimination

Reference number	A3
Indicator	Coverage with hepatitis B immunoglobulin among exposed newborns
Category	Additional
Monitoring and evaluation domain	Outcome
Health domain	HBV vaccination and elimination of mother-to-child transmission
What it measures	Proportion of exposed newborns receiving HBV immunoglobulin according to national policy, in accordance with WHO guidelines
Rationale	• This indicator also monitors programmatic targets used for validating the elimination of mother-to-child transmission of HBV and elimination and path to elimination of HBV as a public health threat.
Global targets	Not applicable
Numerator	Number of newborns receiving HBV immunoglobulin
Denominator	Number of newborns born to HBV e antigen–positive mothers
Method of measurement, data sources	• Information may be sourced from specific programme or clinical patient monitoring tools (electronic or paper medical records), maternity and antenatal care registers. • Ideally, national programme records aggregated from health-facility data should be used. However, if such data are not available, data from sentinel surveillance or special studies can be reported. In this case, information on the source and coverage of the data should be provided as well as information on the representative of the national situation.
Disaggregation	• Age, geographical location
Global reporting platforms	• Global AIDS monitoring • WHO Global Hepatitis Reporting System • Validation of triple elimination (elimination of mother-to-child transmission of HBV, HIV and syphilis) • Validation of hepatitis B elimination and path to elimination

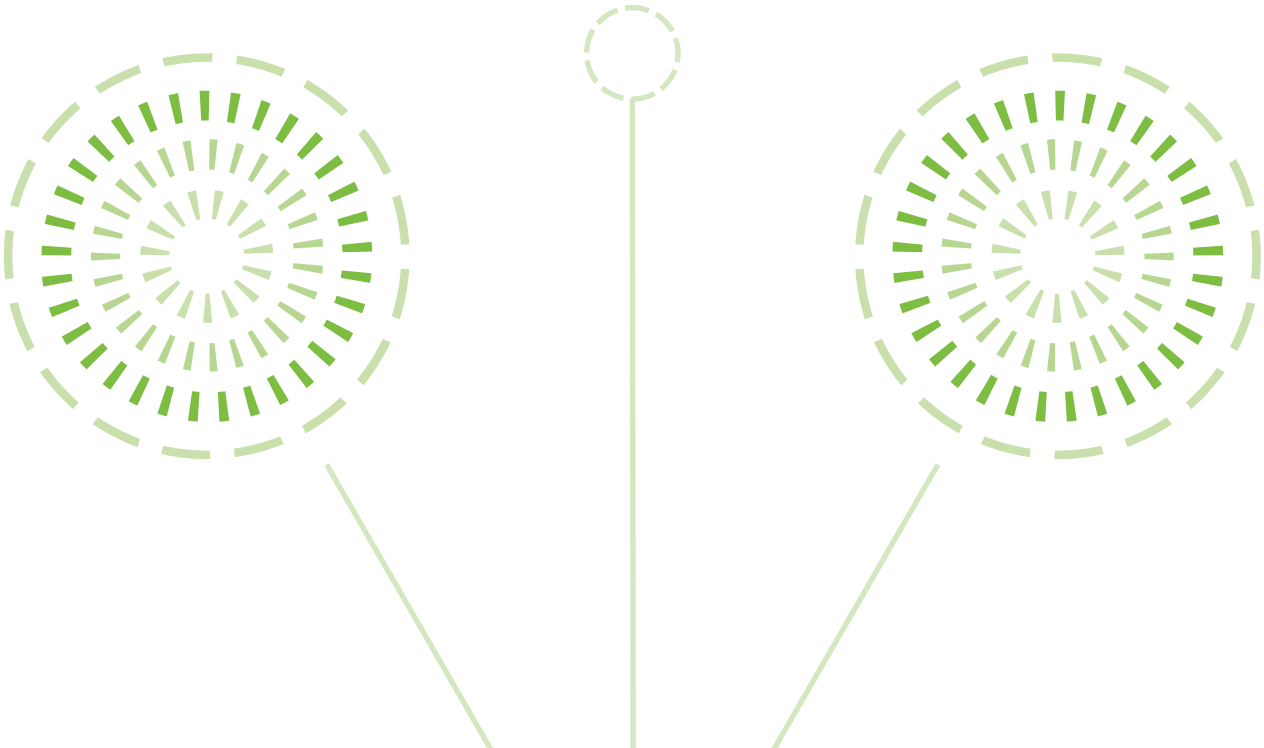
Reference number	C4a
Indicator	Number of needles and syringes distributed per person who injects drugs per year
Category	Core,
Monitoring and evaluation domain	Output
Health domain	Prevention
What it measures	• Number of needles and syringes distributed per person who injects drugs per year by needle and syringe programmes. • This measures progress in improving the coverage of the provision of new, sterile needles and syringes, an essential prevention service for people who inject drugs. • When measured at the programme or service provider level among people who inject drugs accessing needle and syringe programmes, this indicator measures the average number of needles and syringes provided to people who inject drugs who access the programme or service. • When measured at the population level, this indicator measures the total number of clean units of injecting equipment in circulation that might be used by the overall population of people who inject drugs, noting that secondary distribution of equipment within networks is a significant source of sterile equipment among people who inject drugs.
Rationale	• Needle and syringe programmes are included as an essential health sector intervention in the WHO comprehensive package of interventions for HIV prevention and treatment among key populations. Needle and syringe programmes greatly enhance hepatitis prevention for people who inject drugs. • When measured at the population level with a denominator that is the estimated number of people who inject drugs, this indicator enables understanding of the country's progress towards national coverage of needle and syringe programmes for all people who inject drugs. • When measured at the programme or service provider level with the denominator that is the number of people who inject drugs reached by the programme, this indicator may enable understanding of the quality of the programme and whether adequate needles and syringes are being distributed to programme recipients. • This is a core indicator for HIV (PRV.10) in WHO's consolidated guidelines on person-centred HIV strategic information *(25)*. Additional indicators can be found in these guidelines that measure people who inject drugs provided with needles and syringes (PRV.8 NSP coverage) and the frequency that people who inject drugs access a needle and syringe programme (PRV.9 Regular NSP access)
Global targets	≥300 syringes and needles distributed per person who injects drugs per year
Numerator	a. number of needles and syringes distributed by needle and syringe programmes in the reporting period b. number of needles and syringes sold to people who inject drugs by pharmacies or other outlets in the reporting period
Denominator	a. Programme or service provider level: number of people who inject drugs accessing service b. Population level: population size estimate of people who inject drugs in relevant geographical area

Reference number	C4a
Method of measurement, data sources	• *For the numerator:* Programme data used to count the number of needles and syringes distributed. New sterile needles and syringes may be available from pharmacies or other sources in addition to needle and syringe programmes. If data on pharmacy distribution are available, they can be included in this indicator. • *For the denominator:* Estimate of the number of people who inject drugs in the country
Disaggregation	• Sex, age, type of provider (public services, key population–led organization, nongovernmental organizations or other entities). Cities and other administrative regions or areas of epidemiological importance. Setting: facility-based services (including hospitals, health clinics and general practice offices) or community-based services (including drop-in centres, community service delivery points, mobile clinics or vans, outreach teams and community support groups).
Global reporting platforms	• Global AIDS Monitoring • WHO Global Hepatitis Reporting System • Validation of hepatitis C elimination and path to elimination

Reference number	C4b
Indicator	Coverage of opioid agonist maintenance treatment among people who inject drugs
Category	Core
Monitoring and evaluation domain	Output
Health domain	Prevention
What it measures	Measures the percentage of people who inject drugs who are opioid dependent receiving opioid agonist maintenance therapy. Measured at either the service provider or population level. It measures a programme's ability to deliver opioid agonist maintenance therapy among people who inject drugs as a method of directly reducing injecting frequency.
Rationale	• Opioid agonist maintenance therapy represents a commitment to treat opioid dependence and reduce the frequency of injecting as part of harm-reduction services. It provides crucial support for treating other health conditions, including HIV, tuberculosis and viral hepatitis.
Global targets	≥40% of opioid-dependent people who inject drugs receiving opioid agonist therapy (measured at the population level)
Numerator	Number of opioid-dependent people who inject drugs and are receiving opioid agonist maintenance therapy at a specified date
Denominator	a. Programme or service provider level: number of opioid-dependent people who inject drugs accessing services b. Population level: population size estimate of opioid-dependent people who inject drugs in the relevant geographical area in the latest year with available data Note: Not all opioid agonist maintenance therapy recipients will have a history of injecting and not all people who inject drugs will use or be dependent on opioids. It is important that the population size estimate used as the denominator match the numerator for these indicators with respect to *(a)* people who inject versus those who use opioids by other routes of administration and *(b)* including only those who are opioid dependent.
Method of measurement, data sources	• For the numerator: programme records: for example, opioid agonist maintenance therapy registries. • For the denominator: size estimation of opioid dependent people who inject drugs. • This is Global AIDS Monitoring indicator 1.10.
Disaggregation	• Gender (female, male, other) • Age (<25, 25+ years) • Provider type (key population-led or community-led organization, public sector provider, other entities such as private for-profit and not-for-profit organizations, including faith-based, international and nongovernmental organizations) • Setting: facility-based service (including hospitals, health clinics and general practice offices) or community-based service (including drop-in centres, community service delivery points, mobile clinics or vans, outreach teams and community support groups) • Cities and other administrative regions of epidemiological importance
Global reporting platforms	• Global AIDS Monitoring • WHO Global Hepatitis Reporting System • Validation of hepatitis C elimination and path to elimination

Reference number	C5a
Indicator	Proportion of health-care facilities with safe injections (health facility-level injection safety)
Category	Core
Monitoring and evaluation domain	Output
Health domain	Prevention
What it measures	Proportion of health-care facilities with single-use standard disposable or auto-disable syringes
Rationale	• Assesses the implementation of policies to ensure that all health-care facilities implement injection safety. • WHO and the Safe Injection Global Network Alliance have designed a tool for the assessment of injection safety and the safety of phlebotomy, lancet procedures, intravenous injections and infusions. The indicator proposed comes from this tool, which has been used successfully to conduct national injection safety surveys. • The Harmonized Health Facility Assessment questionnaire includes questions to assess facilities for availability of consumables for standard precautions for infection prevention, including disposable syringes with disposable needles and auto-disable syringes *(21)*
Global targets	100% safe health-care injections
Numerator	Number of sampled health-care facilities where all therapeutic injections are given with single-use, standard disposable or auto-disable syringes
Denominator	Number of facilities assed
Method of measurement, data sources	• This indicator is measured through health facility surveys (Harmonized Health Facility Assessment). The questions outlined in the standard precautions for infection prevention control ask for, observe and report on the presence of resources and supplies for infection control (basic consumable commodity availability) as well as at specific service delivery areas (immunization, emergency department, obstetric services, surgical services, laboratory services and outpatient and inpatient services) ref • An alternate approach is to use population surveys. Demographic and Health Surveys estimate the proportion of the last injections received that have been given from a new, unopened package based on individual data. Even though the source of data and measurement differ, the estimates of the frequency of reuse of injection equipment from population surveys are often comparable to the data from health facility surveys.
Disaggregation	• National and subnational levels including facility type (tertiary, secondary and primary and managing authority (public or private)
Global reporting platforms	• Harmonized Health Facility Assessment • National Demographic Health Surveys • Revised injection safety assessment tool (Revised injection safety assessment tool: tool C – revised. Geneva: World Health Organization; 2008 (https://iris.who.int/handle/10665/330070)) • Health facility surveys

Reference number	C5b
Indicator	Proportion of blood units screened for bloodborne disease
Category	Core
Monitoring and evaluation domain	Output
Health domain	Prevention
What it measures	Proportion of blood donated by donors screened for bloodborne infection using quality-assured procedures
Rationale	• Assesses the implementation of policies to ensure that all blood units are screened for HBV and HCV
Global targets	100%
Numerator	Number of blood units screened for bloodborne diseases, including hepatitis B and C
Denominator	Total number of blood units donated in the reporting year
Method of measurement, data sources	• Proportions (%) of donations (whole blood and apheresis) that were screened for HBV and HCV • Data sources: programme records, Harmonized Health Facility Assessment
Disaggregation	• Facility type
Global reporting platforms	• WHO's Global Database on Blood Safety • Health facility surveys • National Demographic Health Surveys



Reference number	C6a
Indicator	Proportion of people with chronic HBV who have been diagnosed
Category	Core, global
Monitoring and evaluation domain	Output
Health domain	Testing and diagnosis
What it measures	Proportion of people with chronic hepatitis B (HBsAg positive) who have been diagnosed
Rationale	• Estimating the proportion of people with chronic hepatitis B who know their infection status measures the entry point to the continuum of care. • Disaggregated estimates can point to gaps in diagnosing people with chronic viral hepatitis.
Global targets	≥90% of people with chronic hepatitis B who have been diagnosed
Numerator	Number of people with chronic hepatitis B infection who have been diagnosed with a positive HBsAg test by the end of the reporting year
Denominator	Estimated total number of people with chronic hepatitis B infection (HBsAg positive)
Method of measurement, data sources	*Numerator:* Information may be sourced from specific programme or clinical patient monitoring tools (electronic or paper medical records), hepatitis testing records, laboratory registers, antenatal care registers, logbooks and reporting forms from health facility and community levels. This method estimates the number of people with hepatitis B newly identified or newly reported, which, after identification of duplicates, may be cumulated over the reporting period. *Denominator:* Information is derived ideally from nationally representative biomarker surveys but can be derived from nationally representative modelled estimates. • The size of the population infected with chronic hepatitis B should be estimated from a nationally representative biomarker survey. Detailed information on the biomarker survey should be provided to demonstrate that the study population is representative and measures were taken to minimize potential sampling and information bias. • Modelling can be used alongside available routine programme data to estimate the size of the population infected. For example, prevalence data obtained from a population survey conducted at one time may be used to estimate prevalence at a more recent time. Such models need to consider relevant input parameters such as number of people treated over time, vaccination coverage, hepatitis B incidence and deaths (liver-related deaths and background deaths in the general population).
Disaggregation	Age, sex, geographical location, higher-risk populations, pregnancy status, HIV infection status, HDV coinfection status
Global reporting platforms	• WHO Global Hepatitis Reporting System

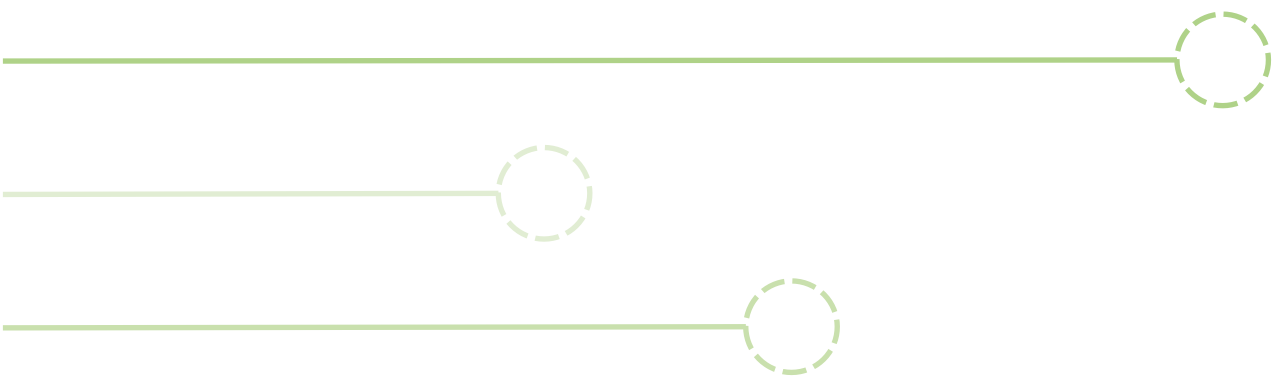
Reference number	C6b
Indicator	Proportion of people with chronic hepatitis C who have been diagnosed
Category	Core, global
Monitoring and evaluation domain	Output
Health domain	Testing and diagnosis
What it measures	Proportion of people with chronic hepatitis C (positive RNA [PCR] or HCV core antigen) who have been diagnosed
Rationale	• Estimating the proportion of people with chronic hepatitis C who know their infection status measures the entry point to the continuum of care. • Disaggregated estimates can point to gaps in diagnosing people with chronic viral hepatitis.
Global targets	≥90% of people with chronic hepatitis C are diagnosed
Numerator	Number of people with chronic hepatitis C who have been diagnosed with a positive HCV RNA (PCR) or HCV core antigen by the end of the reporting period Note: Chronic HCV infection is defined as the presence of viraemia (HCV RNA or HCV core antigen) in association with positive serology for HCV antibody.
Denominator	Estimated total number of people with chronic hepatitis C infection (positive RNA [PCR] or HCV core antigen)
Method of measurement, data sources	*Numerator:* Information may be sourced from specific programme or clinical patient monitoring tools (electronic or paper medical records), hepatitis testing records, laboratory registers, logbooks and reporting forms at the facility and community levels. *Denominator:* Information is derived ideally from biomarker surveys but can be derived from nationally representative modelled estimates. • The size of the population with chronic hepatitis C should be estimated from a nationally representative biomarker survey. Detailed information on the biomarker survey should be provided to demonstrate that the study population is nationally representative, and measures were taken to minimize potential sampling and information bias. • Modelling can be used alongside available routine programme data to estimate the size of the population infected. For example, prevalence data obtained from a population survey conducted at one time may be used estimate prevalence at a more recent time. Such models need to consider relevant input parameters such as the number of people treated and cured over time, hepatitis C incidence and deaths (liver-related deaths and other causes of death in the general population).
Disaggregation	Age, sex, HIV status, geographical location, higher-risk populations
Global reporting platforms	• WHO Global Hepatitis Reporting System

Reference number	C7a
Indicator	Proportion of people diagnosed with chronic hepatitis B initiating treatment among those eligible
Category	Core, global
Monitoring and evaluation domain	Output
Health domain	Treatment and care
What it measures	Measures progress towards providing treatment to all people with chronic hepatitis B, that is treatment coverage for people with hepatitis B among those eligible
Rationale	• WHO currently recommends treatment for all eligible people with chronic hepatitis B to achieve viral suppression • This indicator measures the number of people with hepatitis B who were evaluated for hepatitis disease progression and found to be eligible for and placed on treatment. • Disaggregation can indicate the degree of equity in the enrolment of specific priority populations. Trends over time reflect on progress in treating people with hepatitis B. • National representativeness: if this indicator is measured only in a subset of facilities, comments should be added on the source of information, sample size and whether the information is representative of all sites where hepatitis treatment and care are delivered. • This indicator monitors trends among people newly infected with HBV placed on antiviral therapy and provides managers with important information for forecasting the need for antiviral drugs and allocation of staff to ensure quality of care for antiviral therapy. • This indicator is essential to measure the programmatic targets of the path to elimination and full validation of elimination of hepatitis B as a public health threat by 2030.
Global targets	≥80% of people diagnosed with chronic hepatitis B infection are initiating antiviral therapy
Numerator	Number of people diagnosed with chronic hepatitis B and eligible for treatment who have initiated antiviral therapy by the end of the reporting period • Not all people diagnosed with chronic hepatitis B are eligible for treatment. Treatment eligibility differs across countries and regions and should be defined in accordance with current WHO guidelines or regional or national guidelines.
Denominator	Number of people with chronic hepatitis B infection who have been diagnosed and are eligible for treatment by the end of the reporting period
Method of measurement, data sources	• *Numerator:* programme records (clinical records of health-care facilities providing hepatitis treatment and care) • *Note: Data on treatment in low-income countries may not be easy to obtain if there is no centralized treatment programme.* Until nationwide data become easily available, extrapolation from select sites may be necessary. Additional data on treatment courses sold in the country (from pharmaceutical companies or pharmacies) could provide an indication of treatment coverage. • *Denominator:* Information may be sourced from specific programme or clinical patient monitoring tools (electronic or paper medical records), hepatitis testing records, laboratory registers, antenatal care registers, logbooks and reporting forms at the facility and community levels.
Disaggregation	Age, sex, geographical location, higher-risk populations, pregnancy status, HIV infection status, HDV coinfection status.
Global reporting platforms	• WHO Global Hepatitis Reporting System

Reference number	C7b
Indicator	Proportion of people with chronic hepatitis B currently receiving treatment of those eligible
Category	Core, global
Monitoring and evaluation domain	Output
Health domain	Treatment and care
What it measures	Measures progress towards providing treatment to all eligible people with chronic hepatitis B: treatment coverage for people with hepatitis B among those eligible
Rationale	• WHO currently recommends treatment for all eligible people with chronic hepatitis B to achieve viral suppression • Trends over time reflect on progress in treating people with hepatitis B. • This indicator is central to accountability for national health sector strategic plans, effective programme management and donor programming.
Global targets	Not applicable
Numerator	Number of people diagnosed with chronic hepatitis B and eligible for treatment who are currently receiving antiviral therapy by the end of the reporting period • Not all people diagnosed with chronic hepatitis B are eligible for treatment. Treatment eligibility differs across countries and regions and should be defined in accordance with current WHO guidelines or regional or national guidelines. • Generated by determining the number of people with chronic hepatitis B receiving antiviral therapy at the end of the last reporting period plus the number of people with hepatitis B initiating antiviral therapy during the current reporting period, taking into account retention and attrition status by the end of the reporting period. Retention and attrition analysis should be conducted as part of reporting on this indicator. The numerator should not include people who have stopped treatment, died or were otherwise lost to follow-up during this period. These status classification categories should be reported separately to the national level and used to calculate the number of people with chronic hepatitis B who are receiving antiviral therapy.
Denominator	Number of people with chronic hepatitis B infection who have been diagnosed and were initiating antiviral therapy by the end of the reporting period
Method of measurement, data sources	• *Numerator:* programme records (clinical records of health-care facilities providing hepatitis treatment and care) • *Denominator:* Information may be sourced from specific programme or clinical patient monitoring tools (electronic or paper medical records), hepatitis testing records, laboratory registers, antenatal care registers, logbooks and reporting forms at the facility and community levels.
Disaggregation	• Age, sex, geographical location, higher-risk populations, pregnancy status, HIV infection status, HDV coinfection status. • Treatment outcome categories: died, stopped treatment, lost to follow-up
Global reporting platforms	• WHO Global Hepatitis Reporting System

Reference number	C7c
Indicator	Proportion of people with chronic hepatitis C initiating treatment
Category	Core, global
Monitoring and evaluation domain	Output
Health domain	Treatment and care
What it measures	Measures progress towards providing treatment to all people with chronic hepatitis C: treatment coverage for people with hepatitis C among those eligible
Rationale	• WHO currently recommends treatment for all people with chronic hepatitis C to achieve hepatitis C cure. • This indicator measures the number of people with hepatitis C who were evaluated for hepatitis disease progression and found to be eligible for and placed on treatment. • Disaggregation can indicate the degree of equity in enrolment of specific priority populations. Trends over time reflect on progress in treating people with hepatitis C. • National representativeness: if this indicator is measured only in a subset of facilities, comments should be added on the source of information, sample size and whether the information is representative of all sites where hepatitis treatment and care are delivered. • This indicator is central to accountability for national health sector strategic plans, effective programme management and donor programming. • This indicator is essential to measurement of the programmatic targets for the path to elimination and full validation of elimination of hepatitis C as a public health threat by 2030.
Global targets	≥80% of people diagnosed with chronic hepatitis C infection who have initiated treatment
Numerator	Number of people diagnosed with chronic hepatitis C infection who have initiated treatment by the end of the reporting period
Denominator	Number of people with chronic hepatitis C who have been diagnosed with a positive HCV RNA (PCR) or HCV core antigen by the end of the reporting period Note: All those already diagnosed to date but treated and cured or spontaneously cleared the infection would be excluded.
Method of measurement, data sources	• *Numerator:* Information may be sourced from specific programme or clinical patient monitoring tools (electronic or paper medical records). • *Denominator:* Information may be sourced from specific programme or clinical patient monitoring tools (electronic or paper medical records), hepatitis testing records, laboratory registers, logbooks and reporting forms at the facility and community levels.
Disaggregation	• Age, sex, HIV status, geographical location, higher-risk populations
Global reporting platforms	• WHO Global Hepatitis Reporting System

Reference number	A7
Indicator	Proportion of people with chronic hepatitis B not initiating treatment with annual follow-up
Category	Additional
Monitoring and evaluation domain	Output
Health domain	Treatment and care
What it measures	Measures progress towards promoting antiviral therapy initiation and retention on treatment among those eligible. Also mitigating loss: attrition from antiviral therapy.
Rationale	• WHO currently recommends treatment for all eligible people with chronic hepatitis B to achieve viral suppression • For those not receiving hepatitis B treatment, WHO recommends annual monitoring for disease progression and ALT and HBV DNA levels
Global targets	Not applicable
Numerator	Number of people diagnosed with chronic hepatitis B infection and not initiating antiviral therapy who have annual follow-up
Denominator	Number of people with chronic hepatitis B not initiating treatment
Method of measurement, data sources	• *Numerator:* Information may be sourced from specific programme or clinical patient monitoring tools (electronic or paper medical records), hepatitis testing records, laboratory registers, logbooks and reporting forms at the facility and community levels. • *Denominator:* Information may be sourced from specific programme or clinical patient monitoring tools (electronic or paper medical records).
Disaggregation	• Age, sex, geographical location, higher-risk populations • Treatment deferred criteria: Persistently normal serum aminotransferase results or HBV DNA levels below 2000 IU/mL (where HBV DNA testing is available) or who have expressed a wish to defer treatment
Global reporting platforms	• WHO Global Hepatitis Reporting System



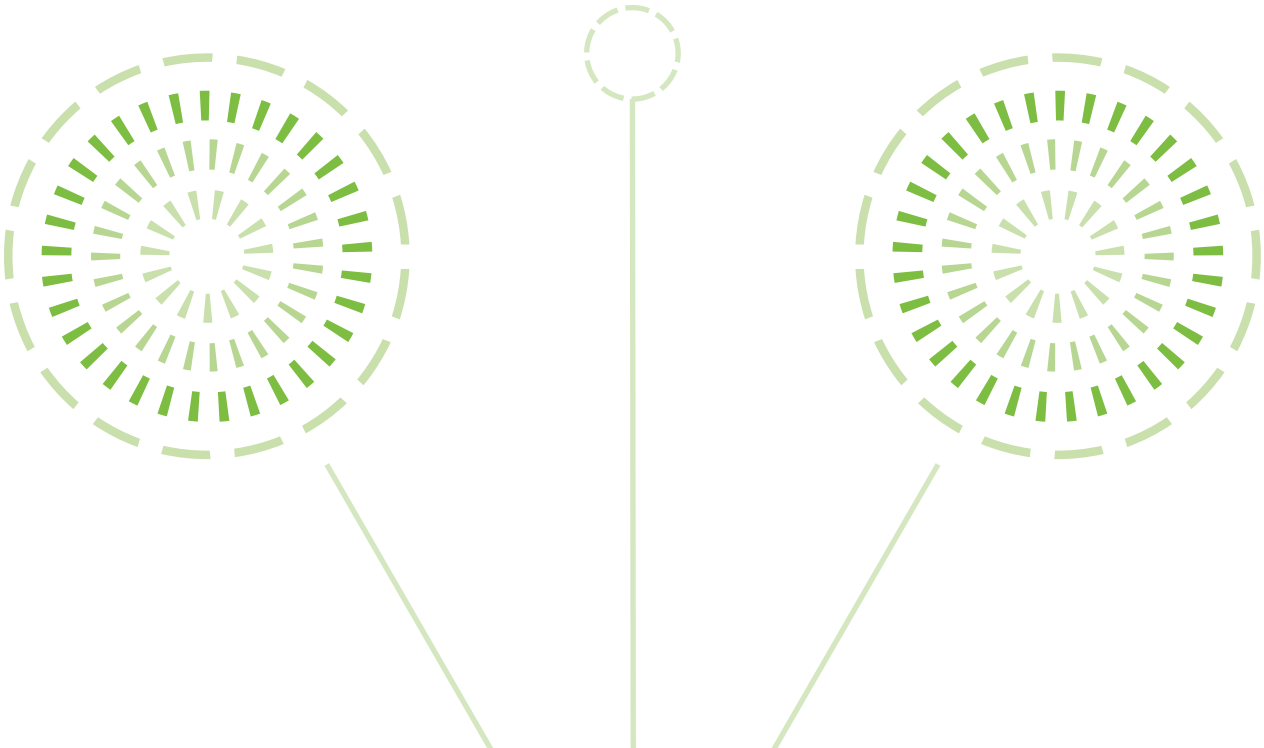
Reference number	C8a
Indicator	Proportion of attrition from antiviral therapy among people with chronic hepatitis B in the reporting year (attrition from antiviral therapy)
Category	Core, global
Monitoring and evaluation domain	Outcome
Health domain	Treatment and care
What it measures	Proportion of people with chronic hepatitis B receiving antiviral therapy at the end of the last reporting period and those newly initiating antiviral therapy during the current reporting period who were not receiving antiviral therapy at the end of the reporting period.
Rationale	• WHO currently recommends treatment for all eligible people with chronic hepatitis B. • Measures progress towards promoting retention on antiviral therapy and mitigating loss, that is, attrition from antiviral therapy. This indicator is central to understanding total attrition (loss) from antiviral therapy during a reporting period. • This indicator is closely related to C7b – people with chronic hepatitis B currently receiving antiviral therapy.
Global targets	Not applicable
Numerator	Number of people with chronic hepatitis B reported on antiviral therapy at the end of the last reporting period *plus* Number of people with chronic hepatitis B newly initiating antiviral therapy during the current reporting period *minus* Total number of people with chronic hepatitis B on antiviral therapy at the end of the current reporting period
Denominator	Number of people with chronic hepatitis B reported on antiviral therapy at the end of the last reporting period plus those newly initiating antiviral therapy during the current reporting period
Method of measurement, data sources	*Numerator and denominator:* Information may be sourced from specific programme or clinical patient monitoring tools (electronic or paper medical records) Calculation of numerator (attrition): ***Attrition* = [(total on antiviral therapy at the end of the last reporting period) + (total newly initiating antiviral therapy during current reporting period)] – (total on antiviral therapy at the end of the current reporting period)** • This will calculate the total number of individuals who are classified as having died, stopped treatment and/or been lost to follow-up by the end of the current period. The definitions of treatment outcomes should remain consistent with hepatitis B treatment guidelines. The recommended threshold for designating people with chronic hepatitis B receiving antiviral therapy as being lost to follow-up is one year after the last missed appointment. Note: This indicator is not intended to capture data on pregnant women initiating antiviral drugs for prophylaxis.
Disaggregation	Age, sex, geographical location, higher-risk populations, pregnancy status, HIV infection status, HDV coinfection status Treatment outcome categories: died, stopped treatment lost to follow-up
Global reporting platforms	WHO Global Hepatitis Reporting System

Reference number	C8b
Indicator	Proportion achieving cure among people treated for chronic hepatitis C
Category	Core, global
Monitoring and evaluation domain	Outcome
Health domain	Treatment and care
What it measures	Measures how many are cured among all those who completed treatment. Proportion of people with chronic hepatitis C cured among those who initiated treatment and were assessed for sustained viral response at week 12
Rationale	• This indicator does not give the coverage of assessment for sustained viral response. It is recommended that this indicator include information on whether sustained viral response is assessed among all or only a few people with chronic hepatitis C and give the proportion of sustained viral response assessment coverage.
Global targets	Not applicable
Numerator	Number of people who initiated treatment for chronic hepatitis C and had a sustained viral response test based on HCV RNA sustained viral response, qualitative or quantitative nucleic acid testing, assessed at 12 weeks after the end of treatment. Note: Point-of-care HCV RNA assays with comparable limit of detection to laboratory-based assays can be used as an alternative approach as test of cure. Sustained viral response after 24 or 48 weeks is also acceptable.
Denominator	Number of people who initiated hepatitis C treatment and were assessed for sustained viral response 12 weeks after the end of treatment by the end of the reporting period
Method of measurement, data sources	• Programme records, cohort studies, patient records, combined with best estimates for the population with no viral load data.
Disaggregation	• Age, sex, HIV status, geographical location, higher-risk populations and medicine type (interferon or direct-acting antiviral drugs)
Global reporting platforms	• WHO Global Hepatitis Reporting System • Validation of hepatitis C elimination and path to elimination

Reference number	A8
Indicator	Proportion of people with chronic hepatitis B treated and achieving HBV DNA viral suppression
Category	Additional
Monitoring and evaluation domain	Outcome
Health domain	Treatment and care
What it measures	Measures clinical outcomes, specifically viral suppression of people with chronic hepatitis B receiving treatment regardless of treatment initiation date
Rationale	• Measures suppression of viral load achieved among everyone receiving treatment, regardless of when they started. Viral load suppression is also the best available measure of adherence to antiviral therapy. • Viral suppression represents the expected outcome of hepatitis B treatment programmes. • This indicator does not give the coverage of viral load testing. It is recommended that this indicator include information on whether viral load is tested for all or only a few people with chronic hepatitis B, and give the proportion of viral load testing coverage.
Global targets	Not applicable
Numerator	Number of people with chronic hepatitis B receiving treatment for at least one year who have a suppressed viral load (HBV DNA not detectable) based on viral load measurement in the past 12 months
Denominator	Number of people with chronic hepatitis B receiving treatment for at least one year and assessed for viral load in the past 12 months Note: First routine viral load testing is recommended at one year after treatment initiation. More frequent on-treatment monitoring (every 3–6 months for the first year) is indicated for: people with more advanced disease (compensated or decompensated cirrhosis); during the first year of treatment to assess treatment response and adherence; if treatment adherence is a concern; among pregnant women; for people with renal impairment.
Method of measurement, data sources	*Numerator and denominator:* programme or clinical patient, monitoring tools (electronic or paper medical records), cohort studies, viral hepatitis drug resistance surveillance, patient records, combined with estimates for the population with no viral load data. This indicator must be interpreted along with viral load testing coverage to assess the potential for bias, that is, whether viral load testing occurs in only a particular subset of people receiving antiviral therapy.
Disaggregation	Age, sex, geographical location, higher-risk populations, pregnancy status, HIV infection status, HDV coinfection status
Global reporting platforms	WHO Global Hepatitis Reporting System

Reference number	C9a
Indicator	Incidence of HBV infection (HBsAg prevalence among children among children five years or younger)
Category	Core
Monitoring and evaluation domain	Impact
Health domain	Morbidity incidence
What it measures	Proportion of children five years or younger with serological evidence of past or present chronic hepatitis B (HBsAg positive). It measures the proportion of children five years or younger who have developed chronic hepatitis B.
Rationale	• The purpose is to describe the reduction in chronic hepatitis B. Most of the burden of disease from HBV infection comes from infections acquired before the age of five years. Therefore, prevention of HBV infection focuses on children five years or younger . Children five years or younger have not yet gone through the risk period during which infections are most likely to result in chronicity. • The United Nations selected the cumulative incidence of chronic hepatitis B at five years of age as an indicator of the Sustainable Development Goal for combating hepatitis. • Anti-HBc reflects the cumulated risk of infection over five years. This estimate is most useful from an epidemiological perspective. HBsAg estimates the proportion of children with chronic infection who are likely to develop chronic hepatitis and subsequent sequelae. This estimate is most useful from a public health perspective. • Trends in the incidence of HBV infection among adults and the general population are reflected through surveillance for acute hepatitis B. However, the incidence among adults and the general population is less informative, since infections at this age and in this population result in less chronicity than infections among children.
Global targets	≤0.1% HBsAg prevalence among children five years and younger
Numerator	Number of surveyed children five years of age with biomarkers of past or present infection and/or chronic infection (HBsAg-positive test)
Denominator	Number of children five years of age in surveys with HBsAg result

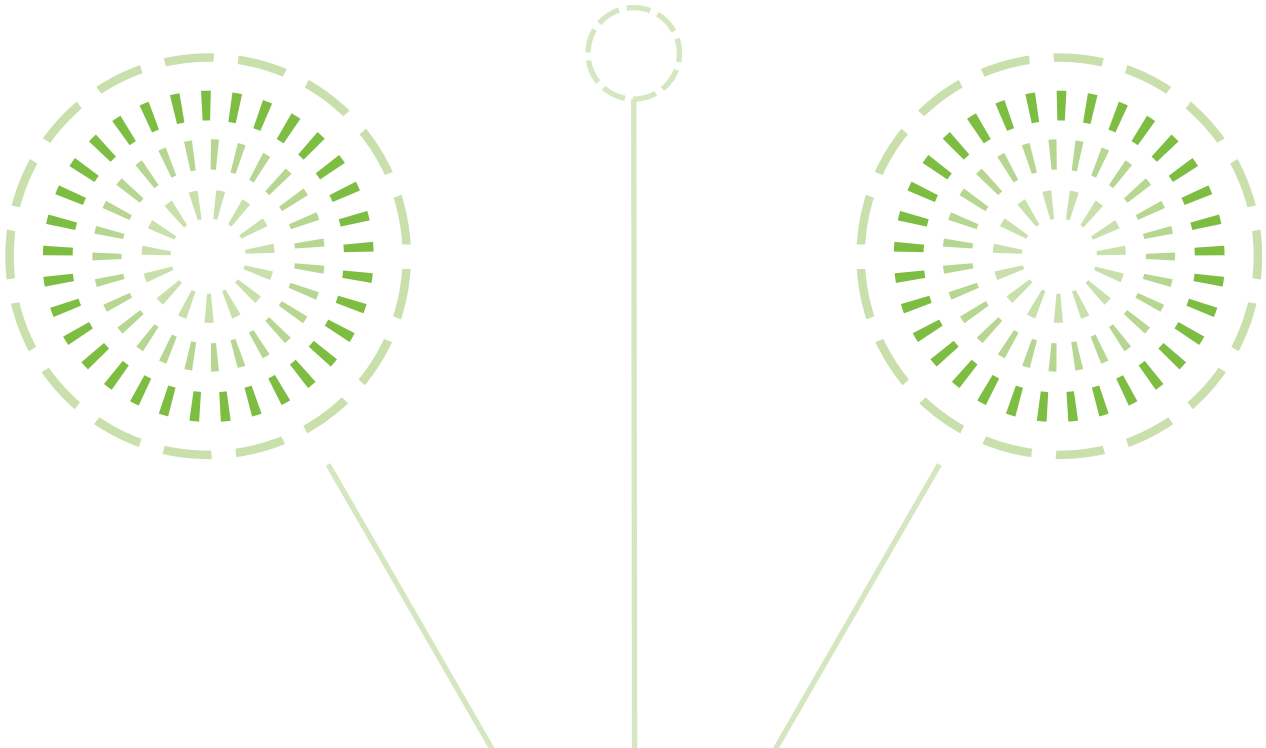
Method of measurement, data sources	HBsAg biomarker prevalence survey among children five years of age (also immunization coverage surveys and administrative vaccination coverage data) The serosurvey sample should be drawn from the specific geographical region to be verified. For example, if the purpose is to estimate national childhood HBV transmission (including mother-to-child transmission), then the sampling should be geographically representative of the population. Convenience sampling is not appropriate. The ≤0.1% HBsAg prevalence can be measured among five-year-olds, one-year-olds or those aged 1–5 years according to existing country surveillance and data collection activities. For the regions and countries with a long history of high HBV vaccination coverage and that already conduct school-based serosurveys, there could be flexibility in conducting serosurveys among older children older than five years. Data on HBV birth-dose exposure and completion of three doses of hepatitis B vaccine should be drawn from official records. If these are not available, testing for HBsAb may be considered for the serosurvey. This is less preferable since it is more costly but can also be done in addition. Specimen collection and transport should be appropriate to minimize bias though specimen degradation in rural and remote areas. If possible, it is advantageous to collect blood specimens for enzyme-linked immunosorbent assay laboratory testing because the accuracy (sensitivity and specificity) is higher than for rapid tests. However, in some locations only rapid tests will be available, and hence test selection is resource dependent. This should be considered in designing overall study methods. When an appropriate sampling strategy and size are used and quality testing assays and laboratory procedures are employed, the HBsAg prevalence in the serosurvey should be representative of the incidence of childhood HBV transmission in the specific geographical region (or country) in this age group. Other measurement approaches: systematic review of peer-reviewed literature reporting hepatitis B prevalence in children younger than five years published followed by modelling to estimate the surface antigen prevalence
Disaggregation	Dependent on sampling method, exposure to hepatitis B vaccine birth dose (official records), exposure to three doses of hepatitis B vaccine, place of residence, place of birth, sex, age groups (younger that five years, five years and older)
Global reporting platforms	• Sustainable Development Goals • Validation of triple elimination (elimination of mother-to-child transmission of HBV, HIV and syphilis) • Validation of hepatitis B elimination and path to elimination



Reference number	C9b
Indicator	Incidence of hepatitis C
Category	Core
Monitoring and evaluation domain	Impact
Health domain	Morbidity incidence
What it measures	Estimated number of new HCV infections per 100 000 population per year Estimated number of new HCV infections per 100 people who inject drugs per year
Rationale	• This indicator measures progress towards reducing new HCV infections and the global health sector strategy hepatitis C elimination impact targets by 2030. • Evidence-informed prevention strategies and highly effective curative treatments are available for hepatitis C. This indicator therefore reflects both the outcome and impact of hepatitis C prevention and treatment on new HCV infections. It monitors trends, detects possible shifts in patterns and projects the future direction of the epidemic. • High-level programme coverage of evidence-informed prevention, including safe injections in health-care settings, viral hepatitis testing in high-quality blood product services, harm reduction for people who inject drugs and access to high coverage of HCV testing, diagnosis, treatment and cure, especially in populations with ongoing high rates of transmission, should result in decreasing hepatitis C incidence.
Global targets	≤5 new annual HCV infections per 100 000 population ≤2 new annual HCV infections per 100 people who inject drugs
Numerator	Number of new HCV infections (primary infection or reinfections)
Denominator	Total number of people at risk (or person-years exposed) Note: The population at risk includes those with no active infection: negative HCV antibodies or HCV RNA

Reference number	C9b
Method of measurement, data source	Direct estimates based on prospective or retrospective cohort studies, repeated cross-sectional studies (in specific populations), modelled estimates (based on existing programme data) **Preferred direct measures (general population or people who inject drugs)** a. *Direct estimation of hepatitis C incidence based on prospective cohort* (HCV retesting of people who initially tested negative for HCV antibodies or RNA). This gold-standard method involves ascertaining new hepatitis C cases prospectively among individuals at risk of infection who are followed up over time; this approach is, however, not efficient if hepatitis C incidence is a rare outcome. Suitable mainly if: **(1)** expected hepatitis C incidence is sufficiently high to balance sample size requirements and **(2)** financial and logistical resources are available to use this approach among a representative population sample. It is important to recognize that this requires registering people testing negative at baseline with a unique identifier. b. *Direct estimation of hepatitis C incidence based on retrospective cohorts* (HCV retesting of people who initially tested negative for HCV antibodies or RNA). This method comprises using routinely collected health data to ascertain new HCV infection cases among susceptible individuals who receive multiple HCV tests over time as part of routine care. Can be used to estimate primary HCV infection or HCV reinfection. Suitable only if: **(i)** the expected hepatitis C incidence is insufficient high to justify a prospective study or **(ii)** financial and logistical resources are limited and do not enable nationwide prospective surveillance among a representative sample and **(iii)** high-quality and representative data collected through medical records are available. c. *Using infectious disease models to estimate hepatitis C incidence*. Infectious disease models can be used to generate hepatitis C incidence estimates from prevalence data and routine programmatic surveillance data. Suitable where **(i)** at least two country-specific prevalence serosurveys are available, and **(ii)** routine surveillance data (such as testing and treatment coverage data as well as hepatitis C cure rates) assumptions about hepatitis C natural history and HCV transmission are sufficiently available to inform the model input parameters. Where available, hepatitis C models that have been peer-reviewed, validated and published should be used. **Additional methods for estimating incidence in specific populations with ongoing risk behaviour and HCV exposure** d. *Direct estimation based on linked repeated cross-sectional surveys.* In repeat cross-sectional surveys, a new sample of participants is recruited with each round. If some participants appear in multiple rounds and individual-level data can be linked over time, then these surveys can be used to estimate hepatitis C incidence. This method has been used to estimate hepatitis C incidence (primarily among people who inject drugs) in settings such as Australia, Canada and Greece. There is a limitation in settings or populations with low baseline hepatitis C incidence and/or large populations since very large sample sizes are necessary and since a small proportion of individuals typically participate in multiple survey rounds. Consequently, this method is likely to be primarily applicable to populations (people who inject drugs and men who have sex with men) at risk of high incidence of HCV infection. Note: The hepatitis C incidence measured should be representative of the adult population at the country level or representative of the adults who inject drugs at the country level. If direct measurement of hepatitis C incidence based on nationally representative data across the general population or people who inject drugs population is not feasible, incidence can be measured in severely affected geographical areas (high baseline hepatitis C prevalence or incidence) and/or among certain settings of people who inject drugs at particularly high risk for HCV transmission (such as recent injectors).
Disaggregation	• Age, sex, HIV status, geographical location, higher-risk populations or probable route of transmission (injecting drug use, unsafe medical injections, blood transfusion, blood products, organ or tissue donations, piercing, circumcision or acupuncture)
Global reporting platforms	• WHO Global Hepatitis Reporting System • Validation of hepatitis C elimination and path to elimination

Reference number	A9
Indicator	Mother-to-child transmission rate of HBV
Category	Additional
Monitoring and evaluation domain	Impact
Health domain	Morbidity incidence
What it measures	The mother-to-child transmission rate measures the proportion of HBsAg-positive infants (numerator) among the infants exposed. This indicator measures the impact of providing interventions that reduce the vertical transmission of HBV.
Rationale	This indicator is measured as part of the requirement for eliminating hepatitis B.
Global targets	Mother-to-child-transmission rate ≤2% for settings using targeted timely hepatitis B birth-dose vaccine
Numerator	Number of infants newly infected with HBV in the previous 12 months from vertical transmission
Denominator	Number of births to women with chronic hepatitis B in the previous 12 months (infants of HBsAg-positive mothers)
Method of measurement, data sources	Measuring this transmission rate requires high coverage (>90%) of both antenatal HBsAg testing to identify positive mothers and post-vaccination serological testing of exposed infants. Countries providing targeted timely hepatitis B birth-dose vaccine need to develop capacity for the required data collection systems and linkage between programmes.
Disaggregation	
Global reporting platforms	Validation of hepatitis C elimination and path to elimination



Reference number	**C10**
Indicator	Deaths from HCC cirrhosis and chronic liver diseases attributable to chronic hepatitis B and C
Category	Core
Monitoring and evaluation domain	Impact
Health domain	Mortality
What it measures	Deaths from HCC, cirrhosis and chronic liver diseases attributable to hepatitis B and C
Rationale	• This indicator shows trends in deaths from chronic liver diseases among people with chronic hepatitis B and C. • Interpreting these indicators involves estimating an attributable fraction. Given the strong association between hepatitis B and C and chronic liver disease, as a first approximation, the proportion of people with HCC, decompensated cirrhosis and chronic liver disease who have chronic hepatitis B or C can be used to estimate the fraction of these sequelae that are attributable to hepatitis B and C. • This indicator measures the ultimate outcome of activities for prevention, testing, care and treatment for viral hepatitis. • Ongoing improvement of vital registration will facilitate measurement of this indicator by analysing sample and site mortality data. • Data may be available at the regional and sometimes national level for long time series. • Improving cancer registration coverage worldwide will facilitate the measurement of the indicator and improve the estimates available in the IARC GLOBOCAN database (https://gco.iarc.fr/today/home).
Global targets	A combined hepatitis B– and C–related mortality rate of ≤6 per 100 000 population per year
Method of measurement and data sources	*Step 1:* Estimate the fraction of HCC and decompensated cirrhosis attributable to hepatitis B and C. This is done from the medical records of people with HCC and decompensated cirrhosis at selected sentinel sites for hepatitis sequelae surveillance (A to D below). [A] % of people with HCC with chronic hepatitis B $A = \frac{No.of\ people\ with\ HCC\ with\ chronic\ hepatitis\ B}{Total\ number\ of\ people\ with\ HCC}$ [B] % of people with HCC with chronic hepatitis C $B = \frac{No.of\ people\ with\ HCC\ with\ chronic\ hepatitis\ C}{Total\ number\ of\ people\ with\ HCC}$ [C] % of people with decompensated cirrhosis with chronic hepatitis B $C = \frac{No.of\ people\ with\ decompensated\ cirrhosis\ with\ chronic\ hepatitis\ B}{Total\ number\ of\ people\ with\ decompensated\ cirrhosis}$ [D] % of people with decompensated cirrhosis with chronic hepatitis C $C = \frac{No.ofpeople\ with\ decompensated\ cirrhosis\ with\ chronic\ hepatitis\ C}{Total\ number\ of\ people\ with\ decompensated\ cirrhosis}$

Reference number	C10
	Step 2: Calculate the number of deaths from HCC and decompensated cirrhosis. This information should be retrieved using ICD-10 or ICD-11 codes from the national civil registration and vital statistics, including mortality registers. [E] Number of deaths from HCC in the specified year (ICD-10 or ICD-11 codes C22.0, C22.9) [F] Number of deaths from cirrhosis and decompensated cirrhosis in the specified year (ICD-10 or ICD-11 codes K74.0, K74.2, K74.3, K74.4, K74.5, K74.6, K72.0, K72.1, K72.9, K76.6, K76.7, I85, I86.4 [G] Number of deaths from fulminant acute hepatitis B in the specified year (ICD-10 or ICD-11 codes IB17.1) *Step 3:* Compute the numbers of deaths from HCC, cirrhosis and fulminant hepatitis caused by hepatitis B and C based on the above estimates: • **Deaths attributable to hepatitis B = (*AxE*)+(*CxF*)+ G** • **Deaths attributable to HCV = (*BxE*)+(*DxF*)** *Step 4:* Mortality rate $\text{Mortality rate} = \frac{\textit{No.of deaths attributable to hepatitis B+no.of deaths attributable to hepatitis BC}}{\textit{Total population}}$ Alternate source of data • Number of deaths from hepatitis B and C retrieved from national vital registries and cancer registries • Global disease burden estimates from the Institute for Health Metrics and Evaluation (aggregated data) • WHO mortality databank (using the ICD-10 or ICD-11 code C22 only) • IARC Cancer Incidence in Five Continents (CI5) databases (liver cancer and HCC data) • Global estimated data (modelling) • IARC GLOBOCAN database (liver cancer ICD-10 code C22 only)
Disaggregation	• Age, sex, HIV status, geographical location, higher-risk populations
Global reporting platforms	• WHO Global Hepatitis Reporting System • Validation of hepatitis B and C elimination and path to elimination

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