World Health Organization

MONITORING AND EVALUATION FOR VIRAL HEPATITIS B AND C:

RECOMMENDED INDICATORS AND FRAMEWORK

TECHNICAL REPORT

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ABBREVIATIONS AND ACRONYMS

Ag	antigen
ANC	antenatal care
anti-HAV	antibody against hepatitis A virus
anti-HBc	antibody against hepatitis B core antigen
anti-HCV	antibody against hepatitis C virus
anti-HDV	antibody against hepatitis D virus
anti-HEV	antibody against hepatitis E virus
CRVS	civil registration and vital statistics
DAA	direct-acting antiviral (drug)
DBS	dried blood spot
DHS	Demographic and Health Survey
DNA	deoxyribonucleic acid
EIA	enzyme immunoassay
EML	Essential Medicines List
EPI	Expanded Programme on Immunization
GHSS	WHO Global Health Sector Strategy (on viral hepatitis)
HAV	hepatitis A virus
HBsAg	hepatitis B surface antigen
HBV	hepatitis B virus
HCV	hepatitis C virus
HCW	health-care worker
HDV	hepatitis D virus
HepB_BD	hepatitis B birth-dose vaccination in newborns (within first 24 hours of life)
HepB3	hepatitis B vaccination with 3 doses in infants
HEV	hepatitis E virus
HIV	human immunodeficiency virus
IARC	International Agency for Research on Cancer
ICD-10	International Statistical Classification of Diseases and Related Health Problems, tenth revision
IHP+	International Health Partnership
IPC	infection prevention and control
M&E	monitoring and evaluation
MICS	Multiple Indicator Cluster Survey
MSM	men who have sex with men
NCD	noncommunicable disease
NSP	needle and syringe programme
OST	opioid substitution therapy
POC	point of care
PWID	people who inject drugs
RNA	ribonucleic acid
SDG	Sustainable Development Goal
SIGN	Safe Injection Global Network (Alliance)
STI	sexually transmitted infection
SVR	sustained virological response
TTI	transfusion-transmissible infection
VL	viral load
WHO	World Health Organization

TERMINOLOGY

High-risk/-burden populations for viral hepatitis refer to populations at higher epidemiological risk for acquiring and transmitting viral hepatitis or to populations where the prevalence of infection is high. It includes the four key populations for acquiring HIV (i.e. sex workers, men who have sex with men [MSM], people who inject drugs [PWID], transgender persons), and populations specific to viral hepatitis, such as the general population in some settings.

Viral hepatitis terminology

- **Viral hepatitis:** inflammation of the liver that results from an infection with a hepatitis virus
- **Acute viral hepatitis:** discrete-onset clinical manifestations of a recent infection with a hepatitis virus
- **Chronic viral hepatitis:** chronic inflammation of the liver that results from a chronic infection with a hepatitis virus
- **Recent infection:** a newly acquired infection, regardless of whether symptomatic or asymptomatic
- **Chronic infection:** persistence of replication of a hepatitis virus in the body six months after the initial infection

Strategic information: information interpreted and used for planning and decision-making to improve the direction of a programme. The data that constitute strategic information can come from a wide variety of sources – for example, monitoring systems, evaluations, programme reviews, surveillance, surveys and case studies.

Monitoring is the routine tracking of service and programme performance using input, process and outcome information collected on a regular and ongoing basis from policy guidelines, routine record-keeping, surveillance and, occasionally, from observational surveys of health facilities and clients. This information is used to assess the extent to which a policy or programme is achieving its intended activity targets on time. In a well-designed monitoring and evaluation system, monitoring will contribute greatly to evaluation. "Monitor" comes from the Latin word "to warn".

Evaluation is the periodic assessment of results that can be attributed to programme activities; it uses monitoring data and often indicators that are not collected through routine information systems. Evaluation allows exploration of the causes of failure to achieve the expected results on schedule, and any necessary corrections to be applied.

Monitoring and evaluation (M&E) system: a set of mechanisms built into the routine operations of a programme to generate data or information on a periodic and ongoing basis to provide evidence for programme decisions

Indicator: in the context of M&E, 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

Result chain: a logical framework built along a sequence of context analysis, inputs, outputs, outcomes and impact. This framework shows how inputs into the system (e.g. resources, infrastructure) and processes (e.g. training, logistics systems) translate into outputs (e.g. availability of services and interventions) that lead to outcomes (e.g. intervention coverage) and, ultimately, to impact (e.g. mortality).

Cascade (or continuum of care): health services in the cascade encompass prevention, treatment and care interventions. The term "cascade" emphasizes that a sequence of services is needed to achieve the desired impacts. The "cascade" concept also informs 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. Monitoring the cascade of services requires a consolidated set of indicators that cover the entire sequence.

Metadata are data that provide information about other data.

EXECUTIVE SUMMARY

A monitoring and evaluation framework for the Global Health Sector Strategy on viral hepatitis
To monitor and evaluate the Global Health Sector Strategy (GHSS) on viral hepatitis, the World Health Organization (WHO) proposes a monitoring and evaluation framework. This framework should facilitate collection and analysis of standardized data with a balance between the need to remain parsimonious and obtain the minimum information required.

Objectives of this framework
- Guide monitoring of the response nationally and globally.
- Reduce excessive data collection and/or reporting requirements.
- Enhance the availability and quality of data.
- Improve transparency and accountability.

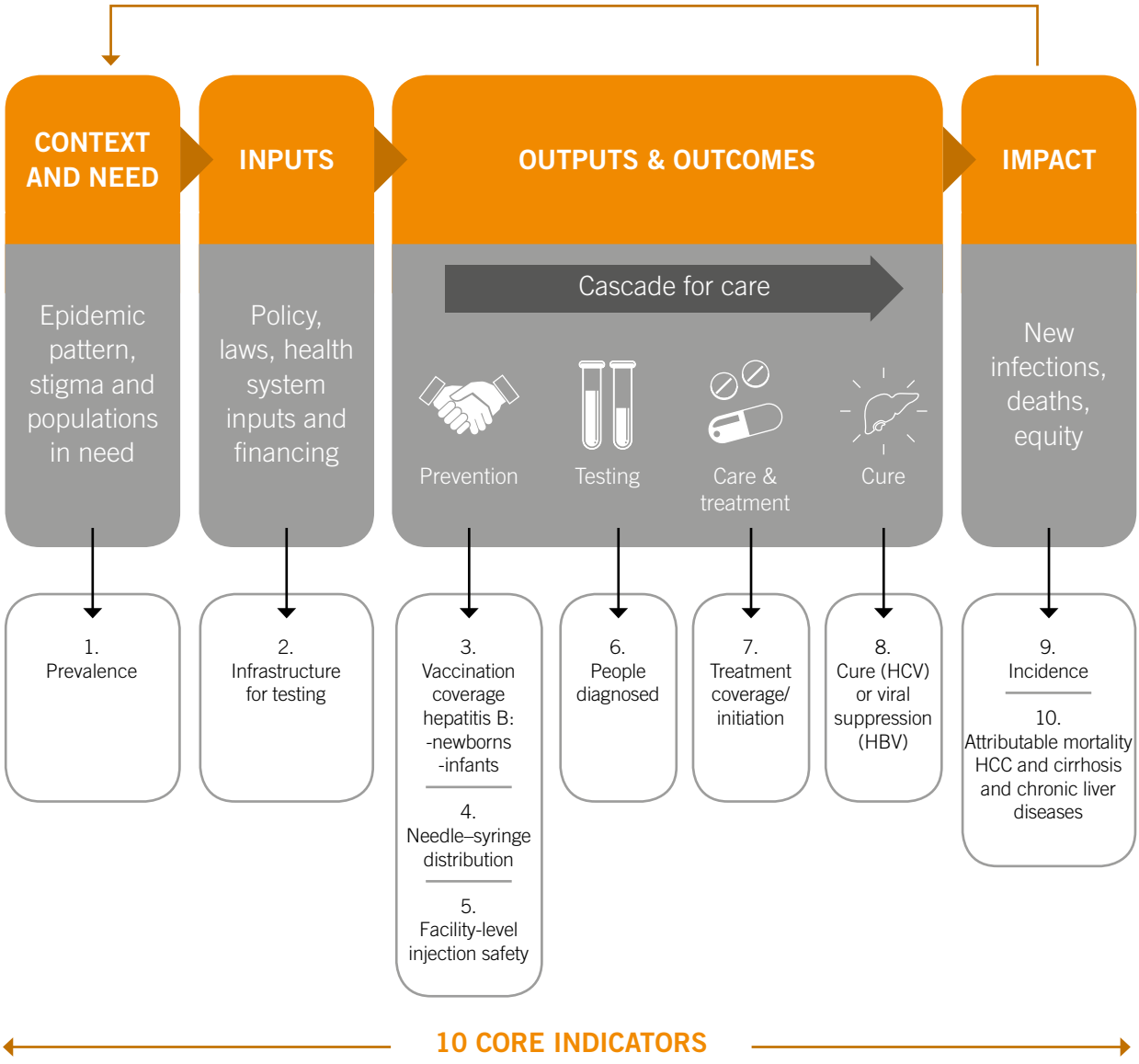
Thirty-seven indicators along the result chain
The result chain is a logical framework built along a sequence of inputs (e.g. resources, infrastructure) and processes (e.g. training, logistics systems) that translate into outputs (e.g. availability of services and interventions), which lead to outcomes (e.g. intervention coverage) and, ultimately, to impact (e.g. mortality).

WHO has selected **10 core indicators** (Fig. 1) that are *(1)* prominent in the monitoring of international public health initiatives or used by international organizations; *(2)* robust, useful, accessible and understandable; *(3)* documented by some past experience in data collection, analysis and use; and *(4)* used by countries for the monitoring of national plans and programmes.

WHO has also selected **27 additional indicators**. Of these, **10 indicators are specific to viral hepatitis** and **17 have been used in the past by other programmes**, including HIV/sexually transmitted infection (STI) (four indicators), immunization (two indicators), blood safety (two indicators), injection safety and infection control, harm reduction (two indicators) and noncommunicable diseases, cancer (two indicators).

Data sources
Data sources for these indicators will include biomarker surveys (specific or combined), cancer registries, vital registration statistics, health-care facility surveys, surveillance and estimates through mathematical modelling.

FIGURE 1 Monitoring and evaluation framework: minimum set of 10 core indicators to monitor and evaluate the health sector response to viral hepatitis B and C along the result chain in countries



1. INTRODUCTION

1.1 Purpose

This document supports the strategy of elimination of viral hepatitis B and C, which was prepared in response to the World Health Assembly's request to examine "the feasibility of and strategies needed for the elimination of hepatitis B and hepatitis C" *(1–4)*. It presents a minimum set of indicators and a monitoring and evaluation (M&E) framework for assessing the health sector's response to viral hepatitis B and C. The set of indicators provides concise information on the health situation and trends, including responses at the national and global levels.

This document is intended to facilitate collection of standardized data and to help in analysing these data, so that interpretation and dissemination of this information improves the health sector response at the subnational and national levels, and evidence-based decision-making at the global level.

The World Health Organization (WHO) attempted to find the right balance between remaining parsimonious and obtaining the minimum information required *(5)*. This document proposes to consider only the most important and critical indicators for measuring the health sector's response to viral hepatitis B and C. It also encourages countries to build on existing indicators that are already collected through other disease or programme monitoring systems via an incremental approach.

1.2 Objectives

The objectives of this document are:

- to guide monitoring of the health sector's response to viral hepatitis B and C nationally and globally;
- to reduce excessive and duplicative data collection and/or reporting requirements;
- to enhance the availability and quality of data; and
- to improve the transparency and accountability of viral hepatitis programmes.

1.3 Content

The document presents:

(1) a minimum set of **core** indicators that can become the basis for streamlining WHO and partners' country data requests and needs;

(2) a list of **additional** indicators that are divided in two categories:

(2a) consists of indicators specific to hepatitis B and C; and

(2b) consists of previously published indicators that have been used to monitor and evaluate infections with bloodborne pathogens (e.g. in the field of injection safety, harm reduction and HIV) or noncommunicable diseases (NCDs; e.g. cancers).

National country programmes may choose among these additional indicators to further strengthen their M&E framework for viral hepatitis B and C *(6)*. Overall, as much of the data are currently not collected, implementation of this framework will require setting up new data-collection mechanisms.

1.4 Audience

The proposed audience for this document is persons who will coordinate the national response to hepatitis B and C. However, this document should also be useful for consultants and international partners who may be advising national health officials on the M&E of their national response plans.

1.5 Scope

This document focuses on **hepatitis B** *(7)* **and C** *(8)*, which constitute most of the burden of disease associated with viral hepatitis. Although not explicitly addressed in this document, elimination of **hepatitis caused by hepatitis D virus** (HDV)[1] is directly linked to successful elimination of hepatitis B virus (HBV) *(9)*. Hence, elimination of hepatitis B through immunization should ultimately eliminate hepatitis D. It does not address the M&E of programmes that may target **hepatitis A** *(10)* and **hepatitis E** *(11)*. However, the WHO *Technical considerations and case definitions to improve surveillance for viral hepatitis (12)* can be used to improve or set up surveillance for hepatitis A and E. If the vaccine against hepatitis A virus (HAV) is included in the Expanded Programme on Immunization (EPI), the key indicators will be vaccine coverage (outcome) and reported rates of hepatitis A (impact). Hepatitis due to the hepatitis E virus (HEV) is rarely the focus of a dedicated national programme; however, reported rates of hepatitis E and/or occurrence of outbreaks may be a useful outcome indicator of water and sanitation programmes in countries where hepatitis E is highly endemic.

1.6 Companion documents

Additional information that may be useful to users of this document include (i) *Technical considerations and case definitions to improve surveillance for viral hepatitis (12)* and (ii) the WHO *Manual for the development and assessment of national viral hepatitis plans (13)*.

- The surveillance document provides resources that should be useful to evaluate, set up, or improve viral hepatitis surveillance, including (a) acute hepatitis, (b) chronic infections with hepatitis viruses, and (c) sequelae (hepatocellular carcinoma and cirrhosis).
- The manual on development of national plans outlines the process of engaging stakeholders, assessing the situation and formulating a plan.

1.7 Elimination agenda and global targets

In 2016, WHO proposed a *Global health sector strategy on viral hepatitis, 2016–2021 (14)* that aims to eliminate hepatitis B and C as public health problems. It includes a set of a few focused targets that cover impact, including incidence, prevalence and mortality. These impact targets will be supported by key intervention targets, and associated with equity and financing targets. This document provides the indicators that will help monitor and evaluate this strategy. Table 1 summarizes the list of targets of the Global Health Sector Strategy on viral hepatitis (GHSS) and related indicators.

[1] Hepatitis D replicates only in presence of hepatitis B virus (HBV). Transmission of HDV can occur either via simultaneous infection with HBV (coinfection) or superimposed on chronic HBV infection (superinfection). Both superinfection and coinfection with HDV results in more severe complications compared to infection with HBV alone.

TABLE 1. Targets of the WHO Global Health Sector Strategy on viral hepatitis, 2016–2021 *(14)*

Impact	
Targets	**Indicators proposed**
Incidence: Reduce new cases of chronic viral hepatitis B and C infections	**C.9.a:** Cumulated incidence of HBV infection in children 5 years of age 
	C.9.b: Incidence of HCV infection
Mortality: Reduce deaths due to viral hepatitis B and C	**C.10:** Deaths from hepatocellular carcinoma (HCC), cirrhosis and chronic liver diseases attributable to HBV and HCV infections 
Intervention: expand and enhance services	
Targets	**Indicators proposed**
1. Hepatitis B vaccination: Give three doses to infants	**C.3.b:** Coverage of third dose of hepatitis B vaccine among infants 
2. Prevention of mother-to-child transmission of hepatitis B virus: Use birth-dose vaccination or other approach to prevent mother-to-child transmission	**C.3.a:** Coverage of timely hepatitis B vaccine birth dose (within 24 hours) and other interventions to prevent mother-to-child transmission of HBV 
3. Harm reduction: Provide sterile needles and syringes for persons who inject drugs (PWID)	**C.4:** Needle–syringe distribution 
4. Blood safety: Reduce rates of transmission of transfusion-transmissible infections (TTIs)	**A.18:** Blood screening coverage
5. Injection safety: Administer injections with safety-engineered devices in and out of health facilities	**C.5:** Facility-level injection safety 
6. Viral hepatitis B and C diagnosis: Diagnose persons with chronic hepatitis infections	**C.6:** People living with HCV and/or HBV diagnosed 
7. Viral hepatitis B and C treatment: Treat persons with chronic hepatitis infection	**C.7.a and C.7.b:** Treatment coverage/ initiation for HBV /HCV infections 
	C.8.a and C.8.b: Viral suppression (HBV) and cure (HCV) 

2. METHODS AND PROCESSES

2.1 Incremental approach: adding to the result chain M&E framework developed for HIV and other programmes

Information on viral hepatitis is collected from different sources, including immunization/EPI, HIV and sexually transmitted infection (STI), cancer, injection safety, blood transfusion safety programmes and others. National response plans to hepatitis only build upon already existing programmes such as those cited above; hence, many indicators already exist. WHO selected relevant existing indicators and then created new ones to fill the gaps identified. As a result, this document details only new indicators proposed for viral hepatitis B and C. Other already existing indicators from various M&E guidelines are cross-referenced. This is especially the case for the HIV indicators from the WHO *Consolidated strategic information guidelines for HIV in the health sector (15)*. WHO also developed this document using a result chain framework and a cascade approach that are identical to those used for HIV (Fig. 1) *(16,17)*. More detailed description of these concepts is included in other guidance *(15,16)*.

2.2 Process and criteria for selecting indicators *(18)*

Methods used in the WHO *2015 Global reference list of 100 core health indicators (19)* guided the process of selecting indicators for viral hepatitis B and C.

- The approach must be parsimonious while reflecting the full spectrum of public health priorities across the epidemiological history of disease and continuum of care so as to address all aspects of the M&E result chain (input through impact).
- The indicators must be as robust, useful, accessible and understandable as possible. Very few indicators meet all the criteria and the ultimate choice is a trade-off.
- Existing indicator sets are drawn from global health initiatives, such as EPI, IARC Globocan *(20)*, IARC Cancer Incidence in Five Continents *(21)*, Safe Injection Global Network (SIGN) *(22)*, and from other programme-specific M&E and technical evaluation groups.

a. Core indicators for global and national monitoring and reporting: 

Ten indicators that meet the following criteria are prioritized as "core":[1]

1. The indicator is prominent in the monitoring of international public health initiatives (e.g. Sustainable Development Goals [SDGs], World Health Assembly viral hepatitis resolutions *(2,3)* or the WHO GHSS on viral hepatitis *(14)*, EPI) or is used by international organizations (e.g. IARC *(23)*, WHO Regional Office for the Americas *(24)*).
2. The indicator is robust, useful, accessible and understandable.
3. There is a track record of measurement experience with the indicator, possibly supported by an international database.
4. Countries use the indicator for the monitoring of national plans and programmes.

The symbol  identifies the core indicators along the document.

[1] Adapted from criteria used by the Global reference list of 100 core health indicators. WHO, 2015.

If reporting countries and partners adhere to the definitions of these indicators, this will ensure comparability.

b. Additional indicators for national-level monitoring and reporting

Indicators are considered as "additional" if they meet at least one of the four criteria, but do not fully meet the full set. Countries may choose to collect data on those additional indicators to inform their health sector viral hepatitis programme. They may be considered at the national or subnational level in case this additional information is useful to understand a particular country's epidemic context, needs and capacity. Countries can choose and adapt these indicators to meet their specific needs.

2.3 Indicator classification

This document presents the lists of indicators according to multiple dimensions *(5)*.

- First, indicators are presented according to levels of the **result chain framework (input, output, outcome and impact)**, called **M&E domains** *(16)*.
- Second, indicators are further categorized into **health domains**. These include: populations in need, stigma and discrimination, policy, health systems, prevention, testing, treatment and care, morbidity, mortality and equity.
- Third, indicators are further categorized according to **sub-health domains** (e.g. harm reduction, injection safety, vaccination, blood safety, condom use, prevalence, incidence).

2.4 Indicator metadata

Metadata are data that provide information about other data. For all the indicators in this document, a simple metadata set includes the following:

- **definition,** including **numerator** and **denominator**;
- **disaggregation** that includes equity categories such as age and sex, geography, socioeconomic status, and place of residence, among others;
- **data sources** that specify the main data source or data collection methods (e.g. biomarker surveys, surveillance, cancer registry, health facility surveys, programme records, Demographic and Health Surveys [DHS], immunization validation surveys, mathematical modelling);
- **relevance and interpretation** that discuss the strengths and limitations of the indicators;
- **reporting periodicity (to be added by country according to context)** – rationalization of an indicator framework includes rationalization of reporting requirements. For some indicators that matter for decision-making, can change rapidly and can be measured with great accuracy, annual reporting by the local and national levels is desirable.

3. METHODOLOGY FOR MONITORING AND EVALUATION OF ACTIVITIES FOR VIRAL HEPATITIS

3.1 Monitoring systems for viral hepatitis: an integrated incremental approach

As for HIV *(15)* or TB/HIV *(25)*, M&E ensures that resources going into a programme are being utilized, services are being accessed, activities are occurring in a timely manner, and expected results are being achieved. This management function facilitates the most effective and efficient use of human and financial resources for maximizing the health benefit to the population served. This is especially relevant in resource-limited settings. The M&E framework for viral hepatitis B and C (Fig. 1) is a visual concept of how the elements of the programme fit together. However, in the post-2015 era characterized by the SDGs – health systems strengthening and universal health coverage – M&E of viral hepatitis programmes will attempt to make the most of data gathered by other programmes. Independent M&E systems, such as those that have been put in place for TB and HIV might be harder to implement for viral hepatitis.

3.2 Measurement methods and sources of data

Most health sector data on viral hepatitis B and C are obtained through either routine (continuous) or periodic data collection mechanisms. The main measurement methods or data sources to monitor and report on the 10 core indicators are given below:

1. Biomarker surveys conducted either specifically for viral hepatitis or in combination with other health programmes (e.g. DHS, Multiple Indicator Cluster Survey [MICS]). These surveys address infections with
    - HBV, conducted among children 5 years of age;
    - HCV, in the general population or special populations.
2. Cancer registries/case reporting for hepatocellular carcinoma (HCC) and cirrhosis;
3. Programme data (e.g. needle–syringe programme, laboratory infrastructure for testing, clinical patient records of health care, laboratory records);
4. Specific surveys (e.g. immunization, injection safety);
5. Routine surveillance system for acute and chronic hepatitis B and C cases;
6. Estimates through mathematical modelling.

3.3 Confidentiality and ethical considerations

Providing optimal care for viral hepatitis B and C involves knowing patient-sensitive information. M&E for viral hepatitis needs to comply with principles of confidentiality and ethical considerations *(12,15)*.

4. MONITORING AND EVALUATION INDICATORS

4.1 Summary of indicators

Table 2 summarizes core indicators (Section 1) and the 27 additional indicators (Section 2).

TABLE 2. Summary of indicators for monitoring and evaluation of viral hepatitis B and C

Section 1. Core indicators: essential indicators to monitor and report progress at global and national levels			
Indicator number		**Indicator name**	**Programmatic area**
C.1	a	Prevalence of chronic HBV infection	Viral hepatitis
	b	Prevalence of chronic HCV infection	
C.2		Infrastructure for HBV and HCV testing	
C.3	a	Coverage of timely hepatitis B vaccine birth dose (within 24 hours) and other interventions to prevent mother-to-child transmission of HBV	Immunization
	b	Coverage of third-dose hepatitis B vaccine among infants	Immunization
C.4		Needle–syringe distribution	HIV, harm reduction
C.5		Facility-level injection safety	Injection safety
C.6		People living with HCV and/or HBV diagnosed	Viral hepatitis
C.7	a	Treatment coverage for hepatitis B patients	
	b	Treatment initiation for hepatitis C patients	
C.8	a	Viral suppression for chronic hepatitis B patients treated	
	b	Cure for chronic hepatitis C patients treated	
C.9	a	Cumulated incidence of HBV infection in children 5 years of age	
	b	Incidence of HCV infection	
C.10		Deaths from hepatocellular carcinoma (HCC), cirrhosis and liver diseases attributable to HBV and HCV infection	Noncommunicable diseases, cancer
Section 2. Additional indicators: for national- or local-level monitoring and reporting			
Indicator number		**Indicator name**	**Programmatic area**
2.a Viral hepatitis-specific indicators not yet collected			
A.1		Hepatitis D coinfection among people living with chronic HBV infection	Viral hepatitis
A.2		Experience with discrimination against people living with viral hepatitis	
A.3		Availability of essential medicines and commodities	
A.4		National system for viral hepatitis surveillance	
A.5		Hepatitis B testing	
A.6		Hepatitis C testing	
A.7		HCV genotyping	
A.8		Viral hepatitis B and C care coverage	
A.9		Equitable access to hepatitis treatment	
A.10		Documentation of treatment effectiveness	
2.b Indicators already formulated and sometimes collected through other programmes and national health system			
A.11		Estimated size of key populations (HIV)	HIV, STI
A.12		Key population experience with discrimination (HIV)	
A.13		Hepatitis coinfections among persons with HIV infection	
A.14		Condom use in key populations (HIV)	
A.15		National provision of a birth dose of hepatitis B vaccine	Immunization
A.16		Hepatitis B vaccination among health-care workers	
A.17		Facility-level blood safety	Blood safety
A.18		Blood screening coverage	
A.19		National policy for infection prevention and control programmes	Injection safety, infection control
A.20		Supply of needles–syringes	
A.21		Procurement of reuse prevention devices	
A.22		Reuse of injection equipment	
A.23		Needle-stick injuries (NSIs) among health-care workers	
A.24		Opioid substitution therapy (OST) coverage	Harm reduction, HIV
A.25		Retention in OST	
A.26		Incidence of cancer, by cancer type	Noncommunicable diseases, cancer
A.27		Total alcohol per capita (age 15+ years) consumption	

4.2 Ten core indicators

The 10 indicators at a glance

Figure 1 (page 9) describes the minimum set of 10 core indicators needed in every country, as described in Section 2: Methods and processes.

Metadata for the 10 core indicators

TABLE 3. Metadata tables for each of the 10 core indicators for viral hepatitis B and C

Indicator C.1.a	**Prevalence of chronic HBV infection**
Indicator category	Core 
M&E domain	Context and needs
Health domain (sub-domain)	Morbidity (prevalence)
Definition	Number and proportion of people living with chronic HBV infection (*hepatitis B surface antigen [HBsAg] positive*)
Numerator	Number of persons with chronic HBV infection defined by HBsAg-positive serological status
Denominator	Number of persons (total population)
Disaggregation	Sex/gender, age groups, pregnancy status, high-risk/-burden populations for viral hepatitis B If possible, separate: - current infection (HBsAg) versus evidence of past or present infection (antibody against hepatitis B core antigen [anti-HBc]) - persons coinfected with hepatitis D virus (HDV), and - persons coinfected with HIV
Measurement method, sources of data	Information for this indicator is derived ideally from surveys, but can be derived from programme data, special studies and modelling.
Programme relevance and interpretation	This indicator reflects epidemic and service needs, as 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 HBV infection (the probability of coming across a recent infection is low).
Indicator C.1.b	**Prevalence of chronic HCV infection**
Indicator category	Core 
M&E domain	Context and needs
Health domain (sub-domain)	Morbidity (prevalence)
Definition	Number and proportion of people living with chronic HCV infection *(HCV RNA positive or HCV antigen [Ag] positive*)
Numerator	Number of persons with chronic HCV infection defined as positive for HCV RNA or positive for HCV Ag
Denominator	Number of persons (total population)
Disaggregation	Sex, age, pregnancy status, high-risk/-burden populations for viral hepatitis C
Measurement method, sources of data	Information for this indicator is derived ideally from surveys, but can be derived from programme data, special studies and modelling. Modelling may be used initially, if data are available only for anti-HCV.
Programme relevance and interpretation	This indicator reflects epidemic and service needs, as 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/resolved or present/active infection. Recommended biomarkers of chronic HCV infection include HCV RNA and HCV core antigen (HCV Ag).

Indicator C.2	Infrastructure for HBV and HCV testing
Indicator category	Core 
M&E domain	Input
Health domain (sub-domain)	Technology and commodities (in vitro diagnostics)
Definition	Ratio of facilities with capacity to test individuals for chronic hepatitis HBV and/or HCV per 100 000 population according to the following testing methods: - molecular methods (HCV RNA, HBV DNA) - serological methods (HBsAg, anti-HBc, anti-HCV)
Numerator	Number of facilities with capacity to test for chronic hepatitis - Tests to be used depend on national recommendations based on WHO guidelines. - Facilities include health workers using point-of-care (POC) testing, health facilities, laboratories.
Denominator	Number of persons (total population)
Disaggregation	- Chronic HBV and chronic HCV infection testing capacity - Testing facility (e.g. clinical laboratory, etc.) - Geographical location - Participation in an external quality assurance programme
Measurement method, sources of data	Information for this indicator is derived from programme data. Tests to be used depend on national recommendations based on WHO guidelines.
Programme relevance and interpretation	Measures trends in availability of laboratory services for viral hepatitis B and C testing

Indicator C.3.a	Coverage of timely hepatitis B vaccine birth dose (within 24 hours) and other interventions to prevent mother-to-child transmission of HBV
Indicator category	Core 
M&E domain	Outcome
Health domain (sub-domain)	Prevention (vaccination)
Definition	Proportion of newborns who have benefited from *timely* birth dose of hepatitis vaccine (within 24 hours) or from other interventions to prevent mother-to-child transmission of HBV (percentage)
Numerator	Number of newborns receiving timely birth dose of hepatitis vaccine within 24 hours (HepB_BD) or benefiting from other interventions to prevent mother-to-child transmission of HBV (e.g. testing of the mother followed by immunoprophylaxis,[1] or in the future, treatment)
Denominator	Number of live births
Disaggregation	Age, place of residence, sex, socioeconomic status *(26)*
Measurement method, sources of data	Routinely collected from programme data (vaccine administrative coverage data, facility information systems) or through periodic immunization validation surveys (household surveys) and disseminated by WHO and United Nations Children's Fund (UNICEF) (http://apps.who.int/immunization_monitoring/globalsummary/timeseries/tswucoveragedtp3.html).
Programme relevance and interpretation	This indicator monitors and guides immunization programmes and other activities to prevent mother-to-child transmission of HBV. - An explanatory remark or footnote should be added when a country uses a strategy based on screening of pregnant women to target vaccination at children born to HBsAg-positive mothers. - Another remark or footnote should also identify countries that have no HepB_BD vaccination policy at all. Coverage of timely hepatitis B vaccine birth dose is extracted from an article published in 2008: WHO and UNICEF estimates of national infant immunization coverage: methods and processes *(27–29)*. This indicator was also cited as one of the WHO Global reference list of 100 core health indicators and is referenced there as "Immunization coverage by vaccine for each vaccine in the national schedule" *(26,30,31)*. In the context of the new plans to eliminate viral hepatitis as a public health problem, the scope of this indicator is being expanded from timely birth dose only to other interventions to prevent mother-to-child transmission of HBV.
Indicator C.3.b	**Coverage of third dose of hepatitis B vaccine among infants**
Indicator category	Core 
M&E domain	Outcome
Health domain (sub-domain)	Prevention (vaccination)
Definition	Proportion of infants (<12 months of age) who received the third dose of hepatitis B vaccine (HepB3) (percentage)
Numerator	Number of infants (<12 months of age) who received the third dose of hepatitis B vaccine (HepB3)
Denominator	Number of infants (<12 months of age in a year) surviving to age 1 year *(26)*
Disaggregation	Age, place of residence, sex, socioeconomic status *(26)*
Measurement method, sources of data	Routinely collected from programme data (vaccine administrative coverage data, facility information systems) or through periodic immunization validation surveys (household surveys) and disseminated by WHO and UNICEF (http://apps.who.int/immunization_monitoring/globalsummary/timeseries/tswucoveragedtp3.html).
Programme relevance and interpretation	This indicator monitors and guides immunization programmes as proposed by WHO and UNICEF *(27,29,32)*. It is also included in the WHO *Global reference list of 100 core health indicators (19)* where it is referenced as "Immunization coverage rate by vaccine for each vaccine in the national schedule" *(26,30,31)*.

[1] In the case of testing of the mother followed by immunoprophylaxis, "newborns benefiting from other interventions to prevent mother-to-child transmission of HBV" would include children born to HBsAg-negative mothers and children born to HBsAg-positive mothers and who received immunoprophylaxis. Children born to mothers who were not tested and children born to HBsAg-positive mothers and who did not receive immunoprophylaxis would be excluded.

Indicator C.4	Needle–syringe distribution
Indicator category	Core
M&E domain	Outcome
Health domain (sub-domain)	Prevention (PWID)
Definition	Number of needles–syringes distributed per person who injects drugs
Numerator	Number of sterile needles–syringes distributed in the past 12 months by needle–syringe programmes (NSPs)
Denominator	Number of people who inject drugs
Disaggregation	Sex, age, type of setting (community, prison/closed setting)
Measurement method, sources of data	Numerator: programme records, e.g. NSP logbooks Denominator: population size estimation exercises *(34)*
Programme relevance and interpretation	This indicator is cited as "KPOP.2" in the WHO *Consolidated strategic information guidelines for HIV (15).* [1]

Indicator C.5	Facility-level injection safety
Indicator category	Core
M&E domain	Outcome
Health domain (sub-domain)	Prevention (injection safety)
Definition	Proportion of health-care facilities where all therapeutic injections are given with new, disposable, single-use injection equipment
Numerator	Number of sampled health-care facilities where all therapeutic injections are given with new, disposable, single-use injection equipment
Denominator	Number of facilities sampled
Disaggregation	Facility type
Measurement method, sources of data	- This indicator is measured through health facility surveys (facility data). - An alternate approach is to use population surveys. DHS estimate the proportion of the last injections received that have been given from a new, unopened package on the basis of 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 data from health facility surveys.
Programme relevance and interpretation	Assesses the implementation of policies to ensure that all health facilities implement injection safety WHO and the Safe Injection Global Network (SIGN) Alliance have designed a tool for the assessment of injection safety and the safety of phlebotomy, lancet procedures, intravenous injections and infusions *(33)*. The indicator proposed comes from this tool, which has been used successfully to conduct national injection safety surveys. This indicator is cited as "PREV.6" in the WHO *Consolidated strategic information guideline for HIV (15).*

[1] More information on this indicator is available in the WHO, UNODC, UNAIDS technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users, 2012 revision, available at: http://apps.who.int/iris/bitstream/10665/77969/1/9789241504379_eng.pdf (Indicator NSP.C.1c).

Indicator C.6	People living with HCV and/or HBV diagnosed
Indicator category	Core 
M&E domain	Output
Health domain (sub-domain)	Testing
Definition	Proportion of people living with chronic HBV and/or HCV infection who have been diagnosed with HBV and/or HCV
Numerator	Number of persons with chronic HBV and/or HCV infection who have been diagnosed
Denominator	Estimated number of persons with chronic HBV and/or HCV infection
Disaggregation	Sex, age (adults/children, more than 15 and less 15 years), high-risk/-burden population for viral hepatitis B and C, pregnant women HIV infection
Measurement method, sources of data	Two measurement methods are possible: *1) Counting persons reported with chronic infection and dividing this number by the estimated size of the population infected.* In that case, the numerator is the number of persons reported with chronic HBV and/or HCV infection from health-care facilities (case reporting) and/or laboratories, while the denominator is the estimated size of the population infected (modelled or estimated from a biomarker survey). This method estimates the number of persons newly identified or newly reported, which, after identification of duplicates, may be cumulated over time. *2) Using survey data where persons are asked if they are aware of their viral hepatitis infection status in population surveys.* In that case, the numerator is the number of persons reporting that they are aware of their chronic HBV and/or HCV infection during the survey, while the denominator is the number of persons identified as infected during the survey. This method estimates the cumulated number of persons aware of their status.
Programme relevance and interpretation	Estimating the proportion of persons with chronic HBV and/or HCV infection who know their infection status measures the entry point to the continuum of care. Disaggregated estimates can point to gaps in diagnosing people chronically infected with viral hepatitis.

Indicator C.7.a	Treatment coverage for hepatitis B
Indicator category	Core 
M&E domain	Outcome
Health domain (sub-domain)	Treatment and care
Definition	Proportion of HBV-infected persons who are currently on treatment
Numerator	Number of persons with chronic HBV infection (defined by HBsAg-positive serological status) who are currently receiving treatment
Denominator	Number of persons with chronic HBV infection
Disaggregation	Sex, age, high-risk/-burden populations, HIV status
Measurement method, sources of data	Numerator: programme records (clinical records of health-care facilities providing hepatitis treatment and care) *Note*: Data on treatment in developing countries may not be easy to obtain where there is no centralized treatment programme. Additional data on treatment courses sold in the country (from pharmaceutical companies/pharmacies) could provide an indication on treatment coverage. Denominator: modelling estimates of the number of HBV-infected persons
Indicator C.7.b	**Treatment initiation for hepatitis C**
Indicator category	Core 
M&E domain	Outcome
Health domain (sub-domain)	Treatment and care
Definition	Proportion of persons diagnosed with chronic HCV infection started on treatment during a specified time frame (e.g. 12 months)
Numerator	Number of persons already diagnosed with chronic HCV infection (defined as positive for HCV RNA or positive for HCV Ag) who initiated treatment during a specified time frame (e.g. 12 months)
Denominator	Number of persons already diagnosed with chronic HCV infection (defined as positive for HCV RNA or positive for HCV Ag) for the specified time period (12 months) *Note:* All those already diagnosed to date but treated and cured would be excluded.
Disaggregation	Sex, age, high-risk/-burden populations, medicine type (interferon or based on direct-acting antivirals [DAAs]), HIV status
Measurement method, sources of data	Numerator: programme records (clinical records of health-care facilities providing hepatitis treatment and care) Denominator: programme records and/or modelling estimates
Programme relevance and interpretation	This C.7 indicator measures the number of people living with HBV/HCV infection who were evaluated for hepatitis disease progression, found to be eligible for and placed on treatment. Disaggregation can indicate degree of equity in enrolment of specific priority populations. Trends over time reflect on progress in treating patients. 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.

Indicator C.8.a	Viral suppression for chronic hepatitis B patients treated
Indicator category	Core 
M&E domain	Outcome
Health domain (sub-domain)	Treatment and care
Definition	Proportion of patients with chronic HBV infection on treatment in whom HBV viral load (VL) is suppressed
Numerator	Number of patients with chronic HBV infection on treatment who have a suppressed VL (HBV DNA not detectable), based on VL measurement in the past 12 months
Denominator	Number of patients with chronic HBV infection on treatment and assessed for VL in the past 12 months
Disaggregation	Sex, age
Measurement method, sources of data	Programme records, cohort studies, patient records, combined with estimates for the population with no VL data
Programme relevance and interpretation	Measures virological suppression achieved among all those currently on treatment, regardless of when they started This indicator does not give the coverage of VL testing. It is recommended that this indicator should include information on whether VL is tested in all or only a few patients, and give the proportion of VL testing coverage (Indicator A.10.a). The denominator for the indicator C.8.a is the numerator for indicators A.10.a (Documentation of treatment effectiveness).
Indicator C.8.b	**Cure for chronic hepatitis C patients treated**
Indicator category	Core 
M&E domain	Outcome
Health domain (sub-domain)	Treatment and care
Definition	Proportion of patients with chronic hepatitis C cured among those who completed treatment
Numerator	Number of patients who completed hepatitis C treatment and had a sustained virological response (SVR) based on VL measurement 12–24 weeks after the end of treatment (in the past 12 months)
Denominator	Number of patients who completed hepatitis C treatment and were assessed for SVR 12–24 weeks after the end of treatment (in the past 12 months)
Disaggregation	Sex, age, medicine type (interferon or DAA based)
Measurement method, sources of data	Programme records, cohort studies, patient records, combined with best estimates for the population with no VL data
Programme relevance and interpretation	Measures how many are cured among all those who completed treatment This indicator does not give the coverage of assessment for SVR. It is recommended that this indicator should include information on whether SVR is assessed in all or only a few patients, and give the proportion of SVR assessment coverage (Indicator A.10.b). The denominator for the indicator C.8.b is the numerator for indicator A.10.b (Documentation of treatment effectiveness).

Indicator C.9.a	Cumulated incidence of HBV infection in children 5 years of age
Indicator category	Core 
M&E domain	Impact
Health domain (sub-domain)	Morbidity (incidence)
Definition	Proportion of children 5 years of age with serological evidence of past or present HBV infection (*anti-HBc positive*) and/or chronic infection *(HBsAg positive) (35).*
Numerator	Number of survey children 5 years of age living with biomarkers of past or present infection and/or chronic infection *(35)*
Denominator	Number of children aged 5 years of age in surveys *(35)*
Disaggregation	Sex, place of residence, exposure to HepB_BD (immunization records), exposure to HepB3
Measurement method, sources of data	HBsAg biomarker prevalence survey in children 5 years of age (immunization coverage surveys and administrative vaccination coverage data) *(35)*
Programme relevance and interpretation	This indicator is referenced in the WHO Global reference list of 100 core health indicators as "Prevalence of hepatitis B surface antigen"*(35)*. Incidence data from children are most important. Infections acquired in the first 5 years of life lead to chronicity in 20–30% of cases and account for the majority of the burden of chronic infection in adults. Children under the age of 5 years have not yet gone through the risk period during which infections are most likely to result in chronicity. 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 in adults/general population are reflected through surveillance for acute hepatitis B. However, incidence in adults/general population is less informative, as infections at this age/in this population result in less chronicity than infections in children *(12,36–38)*.
Indicator C.9.b	**Incidence of HCV infection**
Indicator category	Core 
M&E domain	Impact
Health domain (sub-domain)	Morbidity (incidence)
Definition	Number and rate of new infections with HCV (anti-HCV positive)
Numerator	Total number of new infections with HCV defined as anti-HCV positive per year
Denominator	Total population minus people living with hepatitis C
Disaggregation	Sex, age, defined populations
Measurement method, sources of data	Modelled with inputs from repeated surveys of HCV infection: - general population (in selected countries with a high prevalence) at least every 10 years - people who inject drugs (PWID), at least every 3 years - antenatal care (ANC), at least every 3 years - other relevant groups according to national context
Programme relevance and interpretation	As estimates of incidence are hard to obtain, incidence may be modelled using point prevalence in the targeted population. In theory, incidence estimate must take into account primary infections, reinfections and spontaneous recoveries. An anti-HCV positive test will not distinguish between these three events. In practice, reinfection may be difficult to measure in routine surveys and may require cohorts of high-risk persons assessed in the context of research projects. This indicator reflects both the outcome and impact of hepatitis C prevention and treatment. It monitors trends, detects possible shifts in pattern and projects the future direction of the epidemic.

Indicator C.10	Deaths attributable to HBV and HCV infection
Indicator category	Core 
M&E domain	Impact
Health domain (sub-domain)	Mortality
Definition	Deaths from hepatocellular carcinoma (HCC), cirrhosis and chronic liver diseases attributable to HBV and HCV infections
Numerator	Number of deaths from HCC, cirrhosis and chronic liver diseases attributable to HBV and HCV infection: - number of hepatocellular carcinoma (ICD-10 code C22.0) deaths multiplied by the proportion of HCC with chronic HBV and HCV infections - number of cirrhosis deaths (ICD-10 codes K74.3, K74.4, K74.5, K74.6) multiplied by the proportion of cirrhosis with chronic HVB and HCV infections - number of chronic liver disease deaths (ICD-10 codes K72–K75) with chronic HBV and HCV infections
Denominator	Not applicable
Disaggregation	Sex, age (adults/children)
Measurement method, sources of data	- Country cancer registry files *(39)* - National civil registration and vital statistics (CRVS) including mortality registers - Hospital-/clinic-based registers monitoring service provision - Global databases (aggregated data): - WHO mortality databank *(40)* (liver cancer ICD-10 code C22 only) - IARC Cancer Incidence in Five Continents (CI5) databases (liver cancer and HCC data) *(21)* - Global estimated data (modelling) - IARC GLOBOCAN database *(20)* (liver cancer ICD-10 code C22 only) - Prevalence of HBV and HCV infections among patients with HCC, cirrhosis and chronic liver diseases in sentinel sites
Programme relevance and interpretation	This indicator shows trends in deaths from chronic liver diseases among people infected with chronic hepatitis B or C. Interpretation of these indicators involves the estimation of an attributable fraction. Given the strong association between HBV and HCV infections and chronic liver disease, as a first approximation, the proportion of patients with HCC, cirrhosis and chronic liver disease who are chronically infected with HBV and HCV can be used as an estimate of the fraction of these sequelae that are attributable to HBV and HCV infections *(41,42)*. This indicator measures the ultimate outcome of activities for prevention, testing, care and treatment of viral hepatitis. Ongoing improvement of vital registration will facilitate measurement of this indicator through the analysis of 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 estimates available in the IARC GLOBOCAN database *(20)*.

ICD-10: International Statistical Classification of Diseases and Related Health Problems, tenth revision

4.3 Additional indicators: metadata table

Viral hepatitis-specific indicators

TABLE 4. List and metadata of additional indicators specific to viral hepatitis B and C

Indicator category (Core or Additional) and number	M&E domain	Health domain (sub-domain)	Indicator name and definition	Numerator	Denominator	Disaggregation	Measurement method, sources of data	Programme relevance and interpretation
A.1	Context and needs	Morbidity (prevalence)	**HDV coinfection among people living with chronic HBV infection** Number and proportion of people infected with HDV among those living with hepatitis B	Number of people living with hepatitis B (HBsAg positive) coinfected with hepatitis D (antibody against hepatitis D virus [anti-HDV positive])	Number of people living with hepatitis B (HBsAg positive)	Sex, age (adults/ children), pregnancy status, high-risk/-burden populations for viral hepatitis B and C	- Survey - Programme data (e.g. presence of anti-HDV in people diagnosed with hepatitis B)	Guides as to whether the frequency of HDV infection among people living with hepatitis B is such that a public health approach is needed to address HDV infection
A.2	Context and needs	Stigma and discrimination	**Experience with discrimination against people living with viral hepatitis** Proportion of people living with viral hepatitis who experienced discrimination	Number of people living with viral hepatitis who experienced discriminatory attitudes or actions towards them within the past 12 months	Number of people living with viral hepatitis	Viral hepatitis virus type: B and C	- Population interviews	Measures stigma and discrimination against populations infected with viral hepatitis, which may prevent them from seeking care
A.3	Context and needs	Health system (service access and availability)	**Availability of essential medicines and commodities** Hepatitis C direct-acting antiviral (DAA) agents and hepatitis B medicines in national essential medicines list (EML)	Presence of the medicines for the treatment of hepatitis B and C that are included in the WHO model EML in the national EML	Not applicable		- Programme data - Review of documents	In 2015, WHO updated its *Model list of essential medicines (43)* to include all medicines relevant for the treatment of hepatitis C and B. This indicator is adapted from the indicator named "Availability of essential medicines and commodities" *(44)* from the WHO *Global reference list of 100 core health indicators (19).*
A.4	Input	Policy (data collection system)	**National system for viral hepatitis surveillance** Existence of a system for viral hepatitis surveillance	A national system for viral hepatitis surveillance includes the following functions: - reporting of acute hepatitis - estimating the prevalence of chronic HBV and HCV infection - estimating the mortality from cirrhosis, hepatocellular carcinoma and chronic liver diseases that are attributable to HBV and HCV infections	Not applicable	Many countries have surveillance for acute hepatitis cases but few have chronic infections under surveillance. Some countries do not distinguish between acute and chronic hepatitis. Disaggregation by types of surveillance system when possible (acute hepatitis, chronic infections and sequelae)	- Desk review and interviews with selected stakeholders	Further information is available in the WHO *Technical considerations and case definitions to improve surveillance for viral hepatitis (12).*

Table 4: List and metadata of additional indicators specific to viral hepatitis B and C (continued)

Indicator category (Core or Additional) and number	M&E domain	Health domain (sub-domain)	Indicator name and definition	Numerator	Denominator	Disaggregation	Measurement method, sources of data	Programme relevance and interpretation
A.5	Output	Testing	**Hepatitis B testing** Testing for hepatitis B	Number of persons who were tested for hepatitis B during the reporting period (e.g. 1 year) ***using HBsAg testing***	Population size	Sex, age (adults/ children – more than 15 and less 15 years), high-risk/-burden population for viral hepatitis B, pregnant women, HIV status	- Clinical and/ or laboratory records of health-care facilities, or - Programme data	This indicator monitors progress of testing in a population – an intervention that is critical for assessing further needs related to the management of hepatitis B. Disaggregation by HIV status monitors hepatitis B testing activities among persons in HIV care. A.5 and A.6 are more suited for monitoring. They can be calculated with routine data. C.6 (The proportion of persons living with HBV or HCV diagnosed) is more suited for evaluation as it may require survey data.
A.6	Output	Testing	**Hepatitis C testing** Testing for hepatitis C	Number of persons who were tested for hepatitis C during the reporting period (e.g. 1 year) ***- using HCV RNA testing*** ***- using anti-HCV testing***	Population size	Sex, age (adults/ children – more than 15 and less 15 years), high-risk/-burden population for viral hepatitis C, pregnant women, HIV status	- Clinical and/ or laboratory records of health-care facilities, or - Programme data	This indicator monitors progress of testing in a population – an intervention that is critical for assessing further needs related to the management of hepatitis C. Disaggregation by HIV status monitors hepatitis C testing activities among persons in HIV care. A.5 and A.6 are more suited for monitoring. They can be calculated with routine data. C.6 (The proportion of persons living with HBV or HCV diagnosed) is more suited for evaluation as it may require survey data.
A.7	Output	Treatment and care	**HCV genotyping** Proportion of chronic HCV infections with genotyping information	Reported cases of chronic HCV infection that have been genotyped	Reported cases of chronic HCV infection	Sex, age (adults/ children – more than 15 and less 15 years), high-risk/-burden population for viral hepatitis C, pregnant women, HIV status	- Programme data, or - Laboratory information systems, or - Special studies	Pan-genomic treatments for HCV are not yet universally available. In the meantime, genotype distribution guides the choice of regimen, estimates treatment costs and advocates for faster introduction of pan-genomic treatments. This indicator is used by the WHO Region for the Americas *(24)*.

Table 4: List and metadata of additional indicators specific to viral hepatitis B and C (continued)

Indicator category (Core or Additional) and number	M&E domain	Health domain (sub-domain)	Indicator name and definition	Numerator	Denominator	Disaggregation	Measurement method, sources of data	Programme relevance and interpretation
A.8	Outcome	Treatment and care (linkage to care)	**Viral hepatitis B and C care coverage** Number and proportion of persons with chronic HBV and HCV infections who are receiving care	Number of HBV and/or HCV-infected persons who received care in the past 12 months; as proxied by receipt of at least one of the following: - clinical assessment of liver function/ staging OR -virological biomarker testing OR - treatment	Estimated population of persons with chronic HBV and HCV infection	Age, sex, high-risk/-burden populations for viral hepatitis, vaccination and treatment status	-Numerator comes from programme records, visit records - Population-based denominator: modelling-based estimates Facility-based denominator: programme records, e.g. testing records and mortality data Proxy of "care" could be derived from treatment/ laboratory/ patient monitoring database	Even if this indicator is not available or feasible currently, it is an important element of the continuum-of-care cascade, as it reflects the linkage to care. This indicator helps to track global trends in coverage of care and treatment across populations of persons with chronic HBV and HCV infection. It measures programme efforts to provide persons with chronic viral infection acccess to counselling, care and clinical assessement. Adapted from LINK.2 indicators from WHO *Consolidated strategic information guidelines for HIV (15)*
A.9	Impact	Equity	**Equitable access to hepatitis treatment** Ratio of treatment access between high-risk/-burden populations and the general population	Number of persons from high-risk/-burden populations receiving HBV treatment/ initiated on HCV treatment during the reporting time (i.e. C.7.a and C.7.b indicators in high-risk/-burden populations)	Number of persons from the general population receiving HBV treatment/ initiated on HCV treatment at a specified date (i.e. C.7.a and C.7.b indicators in the general population)	Viral hepatitis virus type: B and C	Programme records or surveys depending on the subpopulation group being compared Data on high-risk/-burden populations, such as PWID, are often collected through surveys. The type of high-risk/-burden populations is to be chosen by country according to epidemic patterns.	Equity in access to hepatitis treatment informs as to whether subgroups are accessing treatment or whether they are disadvantaged. Poor access to treatment may be due to stigma, prejudice, or to stock-outs of medicines in specific facilities. Analysis of the obstacles to treatment access informs policy improvements that could address these inequities.
A.10	Outcome	Treatment and care	**Documentation of treatment effectiveness** Proportion of patients with documentation of treatment effectiveness	**A.10.a.** Number of patients with chronic HBV infection on treatment who have had a VL measurement in the past 12 months [1]	Number of patients with chronic HBV infection on treatment in the past 12 months		- Programme data	The numerators for indicators A.10.a and A.10.b are the denominators for the indicators C.8.a and C.8.b.
				A.10.b. Number of patients who completed hepatitis C treatment and were assessed for SVR 12–24 weeks after the end of treatment (in the past 12 months)	Number of patients who completed hepatitis C treatment (in the past 12 months)			

[1] HBV DNA is the method to measure VL, but hepatitis B e antigen (HBeAg) or HBsAg may be used as surrogate methods if there is no access to HBV DNA.

Indicators already formulated and/or collected through national health system or other programmes

TABLE 5. List and metadata of additional indicators for viral hepatitis B and C already formulated and/or collected through other programmes or national health system

Indicator category (Core or Additional) and number	M&E domain	Health domain (sub-domain)	Indicator name and definition	Programmatic area	Reference	Relevance and remark
A.11	Context and needs	Population in need	**Estimated size of key populations (HIV)** Estimated size of key populations	**HIV, STI**	Indicator NEEDS.2 from the WHO *Consolidated strategic information guidelines for HIV (15)*	Most of the HIV key populations are also high-risk/-burden populations for viral hepatitis B and C (depending on the national context). WHO and UNAIDS recommend an approach to estimating the size of populations most at risk for HIV *(34)*.
A.12	Context and needs	Stigma and discrimination	**Key population experience with discrimination (HIV)** Proportion of people from key populations who have experienced discrimination by health workers		Indicator NEEDS.6 and KPOP.7 from the WHO *Consolidated strategic information guidelines for HIV (15)*	Most of the HIV key populations are also high-risk/-burden populations for viral hepatitis B and C (depending on the national context).
A.13	Context and needs	Morbidity (prevalence)	**Hepatitis coinfections among persons with HIV infection** Number and proportion of people living with HIV who are coinfected with HBV and/or HCV		Indicator NEEDS.3 from the WHO *Consolidated strategic information guidelines for HIV (15)*	A national programme for testing and treatment of viral hepatitis needs to take into account the frequency of hepatitis coinfections among persons with HIV infection. This indicator serves as a basis for estimating national and subnational needs for and coverage of prevention, care and treatment of comorbidities of HIV *(45)*.
A.14	Outcome	Prevention (condom use)	**Condom use in key populations (HIV)** Proportion of key populations for HIV reporting condom use		From the UNAIDS Global AIDS response progress reporting *(46)* and the WHO *Consolidated strategic information guidelines for HIV (15)*, disaggregated into 4 subindicators: - PPREV.1.a: Condom use among sex workers - PPREV.1.b: Condom use among men who have sex with men - PPREV.1.c: Condom use among people who inject drugs - PPREV.1.d: Condom use among general population This indicator is also included in the WHO *Global reference list of 100 core health indicators (19)* (Condom use at last sex with high-risk partner *(47)*).	Condom use in key populations guides interventions for safer sex that are relevant to viral hepatitis programmes.
A.15	Input	Policy (prevention – vaccination)	**National provision of a birth dose of hepatitis B vaccine** National policy, implementing rules and regulations for the provision of a birth dose of hepatitis B vaccine within 24 hours of birth	**Immunization**	WHO/UNICEF *Joint reporting process (29)* and *Hepatitis B position paper (7,32)*	This policy indicator helps to interpret indicator C.3.a (Coverage of timely hepatitis B vaccine birth dose, within 24 hours). Coverage may be low in the absence of a policy and plans.
A.16	Outcome	Prevention (vaccination)	**Hepatitis B vaccination among health-care workers** Proportion of health-care workers who received three doses of hepatitis B vaccine		WHO/UNICEF *Joint reporting process (29)* and *Hepatitis B position paper (7,32)*	A 2007 World Health Assembly resolution has called for immunization of health-care workers. WHO recommends including this intervention in national viral hepatitis plans.

TABLE 5. List and metadata of additional indicators for viral hepatitis B and C already formulated and/or collected through other programmes or national health system (continued)

Indicator category (Core or Additional) and number	M&E domain	Health domain (sub-domain)	Indicator name and definition	Programmatic area	Reference	Relevance and remark
A.17	Outcome	Prevention (blood transfusion safety)	**Facility-level blood safety** Proportion of health facilities providing blood transfusion that meets requirements for sufficient and safe blood transfusion	**Blood safety**	Indicator PREV.8 from from the WHO *Consolidated strategic information guidelines for HIV (15)* reflecting blood transfusion safety *(48–54)*	This indicator reflects blood safety that is one of the prevention interventions of the Global Health Sector Strategy (GHSS) on viral hepatitis.
A.18	Outcome	Prevention (blood transfusion safety)	**Blood screening coverage** Proportion of blood units screened for bloodborne diseases		Indicator PREV.9 from the WHO *Consolidated strategic information guidelines for HIV (15)* reflecting screening of blood donations *(48,55)*	This indicator reflects blood safety that is one of the prevention interventions of the GHSS.
A.19	Input	Policy (prevention – infection prevention and control [IPC])	**National policy for infection prevention and control programmes** Existence of national policy regarding IPC in health-care and other settings	**Injection safety, infection control**	WHO *Core components for infection prevention and control programmes (56,57)*	This policy indicator reflects infection control that is one of the prevention interventions of GHSS.
A.20	Output	Prevention (injection safety)	**Supply of needles–syringes** Proportion of facilities with no stock-outs of quality-assured needles–syringes and matching quantities of safety boxes		Indicator PREV.7 from the WHO *Consolidated strategic information guidelines for HIV (15)* reflecting supply chain management for injection devices *(58)*	This output indicator helps to interpret indicator C.5 (Facility-level injection safety). Only single-use injection devices are considered. WHO no longer recommends the use of sterilizable injection devices.
A.21	Outcome	Prevention (injection safety)	**Procurement of reuse prevention devices** Proportion of devices with safety-engineered features (for reuse prevention /sharps injury protection) among those procured at national and/or local level		WHO *Injection safety guidelines 2015 (57)*	This output indicator helps to interpret indicator C.5 (Facility-level injection safety).
A.22	Output	Prevention (injection safety)	**Reuse of injection equipment** Rate of reuse of syringes		WHO *Injection safety guidelines 2015 (57)* reflecting safe injection practices *(59)*	This output indicator helps to interpret indicator C.5 (Facility-level injection safety).
A.23	Outcome	Prevention (injection safety)	**Needle-stick injuries (NSIs) in health-care workers** Reported incidence of needle-stick injuries in health-care workers		WHO *Injection safety guidelines 2015 (57)*	This outcome indicator of injection safety documents the risk to the injection provider.
A.24	Outcome	Prevention (PWID)	**OST coverage** Proportion of people who inject drugs (PWID) receiving opioid substitution therapy (OST)	**Harm reduction**	Indicator KPOP.4 from the WHO *Consolidated strategic information guidelines for HIV (15)*	This outcome indicator adds on C.4 and further documents prevention activities among PWID, one of the prevention interventions of the GHSS. [1]
A.25	Outcome	Prevention (PWID)	**Retention in OST** Proportion of PWID receiving OST for 6 months		Indicator KPOP.5 from the WHO *Consolidated strategic information guidelines for HIV (15)*	This outcome indicator adds on C.4 and further documents prevention activities among PWID, one of the prevention interventions of the GHSS.[1]

[1] OST is only for persons who are dependent on opioids (Though injection or other modes of administration). More information on this indicator is available in the WHO, UNODC, UNAIDS technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users, 2012 revision, available at: http://apps.who.int/iris/bitstream/10665/77969/1/9789241504379_eng.pdf (Indicators OST.C.1b and OST.Q.3c).

TABLE 5. List and metadata of additional indicators for viral hepatitis B and C already formulated and/or collected through other programmes or national health system (continued)

Indicator category (Core or Additional) and number	M&E domain	Health domain (sub-domain)	Indicator name and definition	Programmatic area	Reference	Relevance and remark
A.26	Impact	Morbidity (incidence)	**Cancer incidence, by cancer type** Number of new cancers of a specific site/ type occurring per 100 000 population	**Noncommunicable diseases (NCDs), cancer**	This indicator is included in the WHO *Global reference list of 100 core health indicators (19)* (Cancer incidence, by type of cancer *(60)*)	Following disaggregation by type of cancer, the number of liver cancers obtained needs to be interpreted after applying the proportions of HCC among liver cancers from published studies. Most liver cancers are metastatic cancers (e.g. from colon and other gut cancers. The IARC Cancer Incidence in Five Continents (CI5) database provides data on liver cancer and HCC *(21)*.
A.27	Input	Prevention (risk factor)	**Total alcohol per capita (age 15+ years) consumption** Age-standardized prevalence of current alcohol use among persons aged 15+ years		This indicator is included in the WHO *Global reference list of 100 core health indicators (19)* (Total alcohol per capita (age 15+ years) consumption *(61)*).	As alcohol consumption is a risk factor for progression of cirrhosis and HCC among persons with chronic HBV and HCV infection, this indicator informs as to what extent alcohol consumption needs to be taken into account in national viral hepatitis plans.

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Monitoring and evaluation for viral hepatitis B and C: recommended indicators and framework

To monitor and evaluate the Global Health Sector Strategy (GHSS) on viral hepatitis, the World Health Organization (WHO) proposes a monitoring and evaluation framework along the result chain.

The result chain is a logical framework built along a sequence of inputs (e.g. resources, infrastructure) and processes (e.g. training, logistics systems) that translate into outputs (e.g. availability of services and interventions), which lead to outcomes (e.g. intervention coverage) and, ultimately, to impact (e.g. mortality).

WHO has selected **10 core indicators** and **27 additional indicators**. Of these, **10 indicators are specific to viral hepatitis** and **17 have been used in the past by other programmes**, including HIV/sexually transmitted infection (STI) (four indicators), immunization (two indicators), blood safety (two indicators), injection safety and infection control, harm reduction (two indicators) and noncommunicable diseases, cancer (two indicators).

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