ANALYSIS AND USE OF HEALTH FACILITY DATA

Guidance for hepatitis programme managers

WORKING DOCUMENT, FEBRUARY 2019

World Health Organization

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MODULE 5. **Guidance for hepatitis programme managers**

LEARNING OBJECTIVES

This module provides guidance on the analysis and use of routine data collected in health care facilities. The module reviews core facility indicators and analysis, provides suggestions for questions on data quality as well as considerations and limitations for using the data and analysis. By the end of this module, participants will be able to:

- Identify the key hepatitis data elements that needs to be reported to monitor testing and treatment;
- Question data quality in a validation exercise;
- Analyze data to estimate the cascade of care (HBV) and cure (HCV).

AUDIENCE

This module is relevant for different members of the health workforce working on hepatitis including:

- Ministry of health decision makers such as hepatitis programme staff and health information system managers at national and sub-national levels;
- Staff of partner organizations supporting the strengthening of the hepatitis programme or health system strengthening;
- Consultants and staff working at research or public health institutes involved with the analysis of hepatitis data and/or efforts to improve the quality of hepatitis data.

SUGGESTED REFERENCES

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Contents

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Glossary of terms

HBsAg

The hepatitis B virus (HBV) surface antigen (HBsAg) is a marker of current infection HBV.

HBV DNA

The HBV DNA is a marker of replication of the HBV that is being used to determine eligibility to HBV treatment and response to HBV treatment.

ALT

Alanine amino transferase is a marker of inflammation of the liver that is being used to determine eligibility for HBV treatment and response to HBV treatment.

Anti HCV

Antibody against the hepatitis C virus (HCV) that are a serological marker of past or present infection. Persons identified positive for anti HCV must be tested for HCV RNA or HCV core antigen to determine if they are currently infected with HCV.

HCV RNA

HCV RNA is a marker of current HCV infection.

HCV Core Ag

HCV core antigen (HCV Core Ag) is a marker of current HCV infection.

1. About the data

THE HEALTH SECTOR STRATEGY TO ELIMINATE HEPATITIS

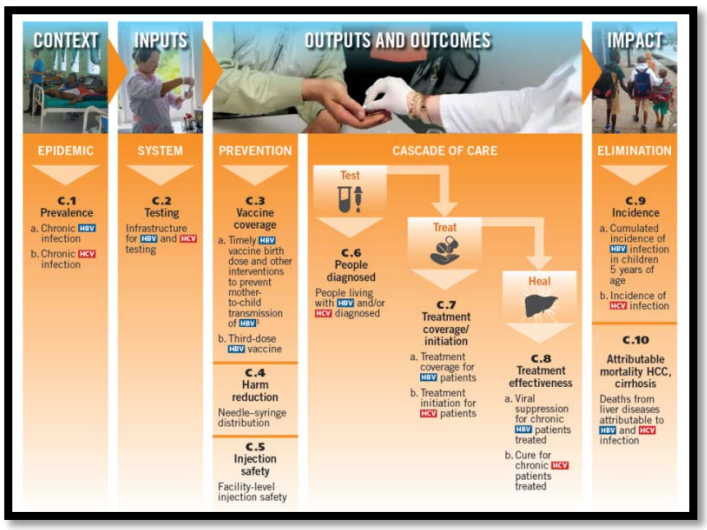
The Global Hepatitis Report indicated that in 2015, 1.34 million persons died from the consequences of viral hepatitis. More than 90% of this burden is due to cirrhosis and hepatocellular carcinoma, the sequelae of infections with hepatitis B virus (HBV) and hepatitis C virus (HCV). In May 2016, the World Health Assembly endorsed the Global Health Sector Strategy (GHSS) for 2016-2021 on viral hepatitis that calls for the elimination of viral hepatitis as a public health threat by 2030. Elimination is defined as a 90% reduction in new chronic infections and a 65% reduction in mortality, compared with the 2015 baseline.

To eliminate viral hepatitis as a public health threat, the GHSS places the focus on five core interventions that need to be brought to a sufficient level of service coverage. These five core interventions are (1) universal immunization of infants with three-dose of hepatitis B vaccine (2030 target: 90%), (2) prevention of mother to child transmission of HBV (2030 target: 90%), (3) blood and injection safety (2030 target: 100%), (4) comprehensive harm reduction services among persons who inject drugs (2030 target: 300 syringes and needles per person who injection drug) and (5) testing and treatment (2030 target: 90% of patients diagnosed and 80% of patients eligible treated. HBV treatment is only indicated for a subset of eligible persons. It is then usually lifelong, improves survival and decreases the risk of hepatocellular carcinoma. Short courses of HCV treatment with direct acting antivirals (DAAs) lead to cure in >90% of patients and reduce mortality.

MONITORING AND EVALUATION FRAMEWORK

The monitoring and evaluation framework for HBV and HCV elimination ranges from input to outcome and impact of prevention, testing and treatment (Figure 1). It's a conceptual framework that needs to be fed by reliable data systems from different sources. It includes prevalence (C.1) that informs context in terms of the proportion of the population infected, testing capacity (C.2) that quantifies the health system capacity to test for HBV and HCV infection, prevention indicators (C.3-C.5), cascade of care and cure (C.6-C.8) and impact measured in terms of incidence (C.9) and mortality (C.10).

Figure 1: Monitoring and evaluation framework for HBV and HCV elimination



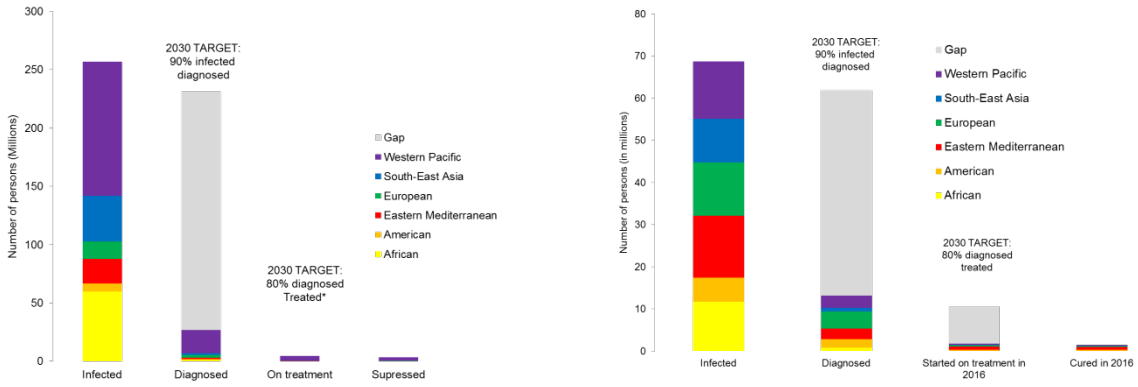
DATA SYSTEMS NEEDED

Two types of data systems are needed. First, public health surveillance generates information on the three components of the natural history of viral hepatitis to inform incidence (C.9), prevalence (C.1) and mortality (C.10). Second, programme implementation monitoring with data captures the core indicators in the field of prevention (C.3-C.5), testing and treatment (C.2; C.6-C.8).

- Viral hepatitis surveillance includes (1) acute hepatitis surveillance that reflect new infections, [1] (2) surveillance of chronic infections through biomarker surveys [2] and (3) surveillance of sequelae (i.e., cirrhosis and hepatocellular carcinoma) [3] that lead to mortality. [4] Surveillance for sequelae is mostly done in sentinel sites. [5]

- Programme implementation monitoring includes collecting service delivery data on (1) prevention (immunization, prevention of mother to child transmission, blood and injection safety, and harm reduction) and (2) testing and treatment (i.e., the cascades of care and cure). The cascade of care and cure estimate the number of persons tested, diagnosed, treated, and virologically suppressed (HBV) or cured (HCV). At global, regional or country level, the cascades are ideally presented in relation to those infected in the population (the C.1 indicator, Figure 2). At subnational level when the denominator of those living 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.

Figure 2: Cascade of care for HBV (left) and cascade of cure for HCV infection (right) by WHO region, 2016



This section is on the use of data routinely collected and reported by health facilities specifically for:

1. data on testing and treatment for viral hepatitis (the cascade of care and cure) as per the reporting requirements (Table 1, Page 7). These reporting requirements are identical for reporting at the health care facility, sub-national and national levels. If the national strategic information plan includes laboratory based reporting of the number of tests conducted and / or new diagnoses of HBV or HCV infection, laboratories could participate as reporting sites (and communicate their data) for the relevant data element (Cells B2, C2, B3, and C3 on Table 1, Page 7). The reporting

[1] Standard operating procedures for enhanced reporting of cases of acute hepatitis . Geneva: WHO; 2019 [WHO/CDS/HIV/19.2] (https://apps.who.int/iris/bitstream/handle/10665/280098/WHO-CDS-HIV-19.2-eng.pdf, accessed 12 February 2019).

[2] Template protocol for surveys to estimate the prevalence of biomarkers of infection with the hepatitis viruses: tool for adaptation and use at country level. Geneva: WHO; 2019 [WHO/CDS/HIV/19.3] (https://apps.who.int/iris/bitstream/handle/10665/280099/WHO-CDS-HIV-19.3-eng.pdf, accessed 12 February 2019).

[3] Protocol for surveillance of the fraction of cirrhosis and hepatocellular carcinoma attributable to viral hepatitis in clinical centres of excellence. Geneva: WHO; 2019 [WHO/CDS/HIV/19.4] (https://apps.who.int/iris/bitstream/handle/10665/280097/WHO-CDS-HIV-19.4eng.pdf , accessed 12 February 2019).

[4] WHO, 2016. Technical considerations and case definitions to improve surveillance for viral hepatitis Surveillance document. Technical report. ISBN 978 92 4 154954. Available at http://apps.who.int/iris/bitstream/10665/204501/1/9789241549547_eng.pdf?ua=1 (Accessed 21 June 2016).

[5] World Health Organization: Protocol for surveillance of the fraction of cirrhosis and hepatocellular carcinoma attributable to viral hepatitis in clinical centres of excellence. WHO/CDS/HIV/18.5. Available at: http://www.who.int/hepatitis/topics/hepatitis-c/hepatitis-surveillance-protocol-2018/en/ (Accessed: 20 March 2018)

requirements on Table 1, Page 7 are also identical to the reporting requirements of the Global Reporting System for Hepatitis (GRSH) for Member States to report to WHO. [1] However, for the GRSH, there is also collection of policy uptake indicators (i.e., Governance, policies and plans) at the national level;

2. surveillance of sequelae that lead to mortality is conducted in sentinel centres of excellence that care for patients with cirrhosis and hepatocellular carcinoma.

This section does do NOT include:

- Data elements already managed by other programmes or initiatives for the purpose of prevention, including immunization coverage, infection control, and harm reduction;
- Reporting for acute hepatitis, whether it is syndromic surveillance for acute hepatitis or enhanced case reporting is conducted in sentinel sites that can conduct biomarker testing for acute hepatitis (IgM tests) and risk factors investigations; [2]
- Surveillance for chronic infections is based on regular biomarker surveys. [3]

REPORTING UNITS

The reporting units that may use the reporting requirements on Table 1, Page 7 include:

- Public health care facilities (All cells, apart from cells B10, B11, C10, and C11 on Table 1, Page 7);
- Private health care facilities can be included if the public health system is willing engage the private health care system (for profit or not for profit). In this case, the public health system would provide reporting forms on paper or reporting credentials in an electronic system. Data from the private sector can then be entered and analyzed with data from the public sector (All cells, apart from cells B10, B11, C10, and C11 on Table 1, Page 7);
- Laboratory who test for HBV and HCV infection and who identify persons newly diagnosed with HBV or HCV infection (Only for cells B2, C2, B3, and C3 on Table 1, Page 7);
- Sentinel sites that report data on the proportion of cirrhosis and hepatocellular carcinoma that have HBV or HCV infection (Only for cells B10, B11, C10, and C11 on Table 1, Page 7). [4]

[1] Global reporting system for hepatitis. http://www.who.int/hepatitis/reporting-database/en/

[2] Standard operating procedures for enhanced reporting of cases of acute hepatitis . Geneva: WHO; 2019 [WHO/CDS/HIV/19.2] (https://apps.who.int/iris/bitstream/handle/10665/280098/WHO-CDS-HIV-19.2-eng.pdf, accessed 12 February 2019).

[3] Template protocol for surveys to estimate the prevalence of biomarkers of infection with the hepatitis viruses: tool for adaptation and use at country level. Geneva: WHO; 2019 [WHO/CDS/HIV/19.3] (https://apps.who.int/iris/bitstream/handle/10665/280099/WHO-CDS-HIV-19.3-eng.pdf, accessed 12 February 2019).

[4] Protocol for surveillance of the fraction of cirrhosis and hepatocellular carcinoma attributable to viral hepatitis in clinical centres of excellence. Geneva: WHO; 2019 [WHO/CDS/HIV/19.4] (https://apps.who.int/iris/bitstream/handle/10665/280097/WHO-CDS-HIV-19.4eng.pdf , accessed 12 February 2019).

DATA ELEMENTS

Table 1: Aggregated reporting form to monitor the cascade from health care facilities to the national level

	Data during the quarterly reporting period									
	Testing and diagnosis (C6)			Treatment initiation and continuation (C7)				Monitoring of treatment effectiveness (C8)		Mortality from sequelae[1] (C10)	
	Number of infected people already identified before the reporting quarter (treated or not)	Number of people tested with serology (HBsAg or anti-HCV) in the reporting quarter [2]	Number of infected people newly diagnosed with infection in the reporting quarter (HBsAg positive or HCV RNA or HCV core antigen positive, treated or not)	Number of people continuing a treatment started before the quarter of reporting[3]	Number of people newly starting treatment in the selected quarter [4]		Number of people completing treatment[5]	Number of people assessed for treatment effectiveness in the reporting quarter [6]	Number of people with effective treatment in the reporting quarter [7]	Proportion (%) of people dying from cirrhosis who were positive for viral hepatitis infection	Proportion (%) of people dying from hepatocellular carcinoma who were positive for viral hepatitis infection
					Total	Among people who injected drugs in the reporting quarter (among the total above)					
HBV	[Cell B1]	[Cell B2]	[Cell B3]	[Cell B4]	[Cell B5]	[Cell B6]	N/A[8]	[Cell B8]	[Cell B9]	[Cell B10]	[Cell B11]
HCV	[Cell C1]	[Cell C2]	[Cell C3]	N/A	[Cell C5]	[Cell C6]	[Cell C7]	[Cell C8]	[Cell C9]	[Cell C10]	[Cell C11]

[1] Estimates from sentinel sites.
[2] Needs to include testing activities conducted with rapid diagnostic tests.
[3] Does not apply to HCV infection.
[4] Regardless of eligibility (HBV infection).
[5] Does not apply to HBV infection.
[6] Tested for viral suppression with ALT or HBV DNA (HBV) or tested for sustained viral response using HCV RNA or HCV core antigen (HCV).
[7] Normal ALT or viral suppression (HBV) or sustained viral response (HCV).
[8] N/A Not applicable

2. Core facility indicators

The data elements collected as per the reporting requirements (Numbered cells in Table 1, Page 7) allow calculation of the following indicators:

Core Indicators	Definition	Formula	Disaggregations
Monitoring testing and treatment			
Testing for viral hepatitis B and C			
HBV tests performed	Number of persons tested for HBsAg during the reporting period (laboratory-based test or rapid test)	[Cell B2]	• By health care facility • Facility based versus community outreach
HCV tests performed	Number of persons tested for anti-HCV during the reporting period (laboratory-based test or rapid test)	[Cell C2]	• Facility based versus community outreach
Persons living with HBV infection diagnosed	Number of persons already identified with positive HBsAg test before the reporting period + Number of persons newly identified with a positive HbsAg serological test during the reporting period	[Cell B1] + [Cell B3]	• By health care facility
Persons living with HCV infection diagnosed	Number of persons already identified with positive HCV RNA (PCR) / HCV core antigen test before the reporting period + Number of persons newly identified with a positive HCV RNA (PCR) / HCV core antigen test during the reporting period	[Cell C1] + [Cell C3]	• By health care facility
Treating for viral hepatitis B and C			
Number of persons newly started on HBV treatment	Number of persons newly started on HBV treatment (tenofovir or entecavir) during the reporting period	[Cell B5]	• By health care facility • By PWID status [Cell B6]
HBV treatment coverage (current)	Number of persons newly started on HBV treatment (tenofovir or entecavir) during the reporting period + Number of persons living with HBV infection who were already receiving tenofovir or entecavir before the reporting period	[Cell B5] + [Cell B4]	• By health care facility
Number of persons started on HCV treatment	Number of persons newly started on HCV treatment (direct acting anti-virals)	[Cell C5]	• By health care facility • By PWID status [Cell C6]
Number of persons completing HCV treatment	Number of persons completing HCV treatment (direct acting anti-virals)	[Cell C7]	• By facility
Monitoring treatment effectiveness for viral hepatitis B and C			
Proportion of persons on HBV treatment assessed for treatment effectiveness	Number of persons who are currently receiving HBV assessed for effectiveness (e.g., ALT, HBV DNA) / Number of persons who are currently receiving HBV treatment	[Cell B8] / [Cell B4+ Cell B5]	• By health care facility
Proportion of persons controlled on HBV treatment	Number of persons with effective treatment / Number of persons assessed for HBV treatment effectiveness (ALT, HBV DNA)	[Cell B9] / [Cell B8]	• By health care facility
Proportion of persons on HCV treatment assessed for treatment effectiveness	Number of persons who completed treatment and were tested with HCV RNA (PCR) or HCV core antigen / Number of persons who completed treatment	[Cell C8] / [Cell C7]	• By health care facility
Proportion of persons cured of HCV	Number with effective treatment (Sustained Virological response) / Number of persons who completed treatment that were tested for SVR	[Cell C9] / [Cell C8]	• By health care facility

3. Core analysis

Data from programme monitoring have four main objectives:

1. To measure coverage in testing activities in terms of initial testing for HBsAg or anti-HCV.
2. To measure progress in diagnosing persons with HBV / HCV infection.
3. To measure treatment uptake, including lifelong treatment for HBV infection and short-term curative treatment for HCV infection.
4. To measure treatment effectiveness, including viral suppression for HBV and sustained viral response (cure) for HCV.

TESTING

Purpose

- Describe progress in testing activities

Analysis

Type of analysis:

- Number of HBsAg and Anti-HCV tests conducted by time, place (facility based versus community based)

Use of the data by managers:

- Describe progress of testing activities by health care facilities according to targets
- Forecasting of needs in diagnostic kits and medicines

Considerations/issues for interpretation

- Data can be disaggregated by facility. Interpretation could compare facilities that conduct facility-based testing with those that conduct community-based testing in terms of the number of tests conducted.

DIAGNOSIS

Purpose

- Describe progress in terms of new patients being identified

Analysis

Type of analysis:

- Number of persons newly diagnosed with HBV infection (HBsAg positive) or HCV infection (HCV RNA or HCV core antigen positive)

- Yield of testing activities:
  - Ratio between the number of persons newly diagnosed with HBV infection per HBsAg test done (stratified by type of facilities).
  - Ratio between the number of persons newly diagnosed with HCV infection (Confirmed with HCV RNA in PCR or core antigen test) per anti-HCV test done (stratified by type of facilities). This is the number of persons anti-HCV positive and HCV RNA positive (or core HCV Ag) divided by the number of anti-HCV tests done.

Use of the data by managers:

- The rate of identification of new patients allows planning treatment activities, including forecasting needs in terms of medicines.
- The yield of testing activities guides the programme to pursue testing activities that lead to the identification of more persons infected.

Considerations/issues for interpretation

- The comparisons of general population testing and focused testing in terms of yield will help planning future testing activities.

TREATMENT

Purpose

- Describe progress in treatment

Analysis

Type of analysis:

HBV

- Number of persons newly started on HBV treatment
- Number of persons on HBV treatment (including newly started and already on treatment) *
- Ratio of persons newly diagnosed / started on treatment for HBV infection

HCV

- Number of persons started on HCV curative treatment
- Ratio of persons new diagnosed / started on treatment for HCV infection †

Use of the data by managers:

- Quantify linkage to care (e.g. treatment uptake among those diagnosed with chronic hepatitis)
- Describe progress of treatment activities
- Forecasting of needs in diagnostic kits and medicines

* This will be influenced also by treatment eligibility. Only a subset of persons with HBV infection are eligible for treatment.
† Unlike for HCV, this should not be influenced by eligibility for treatment as WHO recommends treating all persons with HCV infection apart from children under the age of 12 and pregnant women.

Considerations/issues for interpretation

- The ratio of persons newly diagnosed / started on treatment for HBV infection will be interpreted in light of:
  - The proportion of persons determined to eligible for treatment after assessment and staging;
  - The linkage to care.
- The treatment coverage for HBV can be examined years after year as an indirect way to measure retention in care. Each year, in absolute numbers, coverage should be equal to persons on treatment in the previous period plus those started on treatment during the reporting period. Any difference would reflect mortality among persons treated or issues in terms of retention in care.
- The ratio of persons diagnosed / started on treatment for HCV infection will reflect linkage to care and treatment.

TREATMENT EFFECTIVENESS

Purpose

- Monitor the effectiveness of treatment

Analysis

Type of analysis:

HBV

- Number of persons assessed for HBV treatment effectiveness
- Proportion of persons controlled on treatment among those assessed for HBV treatment effectiveness *

HCV

- Number of persons assessed for HCV treatment sustained virological response
- Proportion of persons with sustained virological response among those assessed for HCV treatment effectiveness †

Use of the data by managers:

- Quantify the loss to follow up for those on HBV treatment or completing HCV treatment
- Describe effectiveness of treatment
- Detect early warning signals in drug resistance

Considerations/issues for interpretation

- The ratio of persons assessed for sustained virological response / started on treatment for HCV infection reflects the loss to follow up in monitoring cure rates. An excessive loss to follow may signal the need of a system to remind people of the need for SVR assessment and / or incentive systems (e.g., cure certificates).

* Tested for viral suppression with ALT or HBV DNA
† Tested for sustained viral response using HCV RNA or HCV core antigen

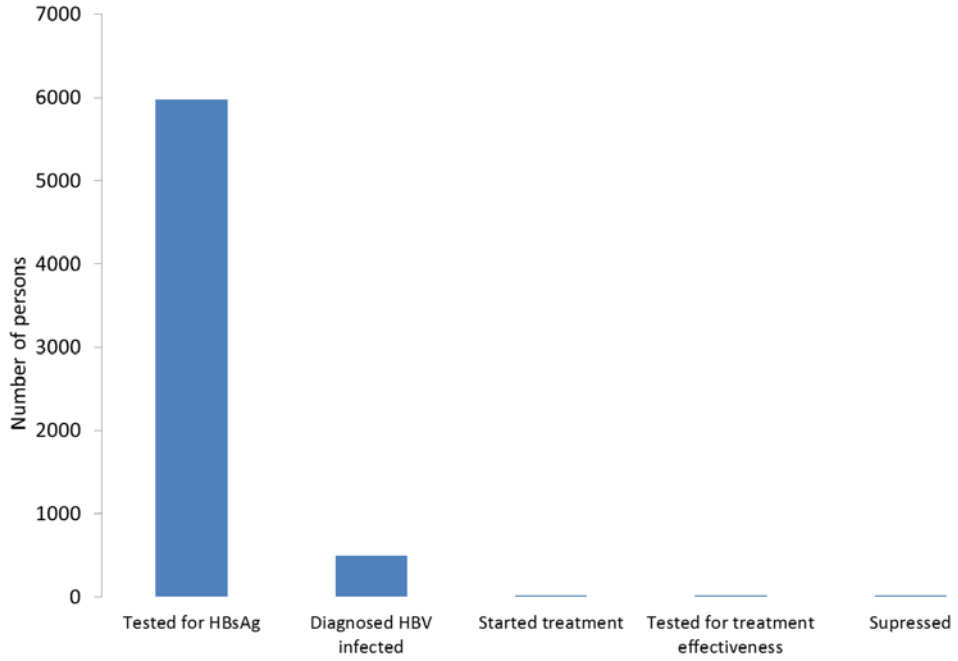
EXAMPLES OF DATA ANALYSIS

Cases studies in the field of HBV (Box 1, Figure 3) and HCV infection (Box 2, Figure 4) illustrate the role of aggregated data for monitoring and evaluation of hepatitis testing and treatment programmes.

Box 1: Case study: Testing and treatment for HBV with the Prolifica project, The Gambia

In 2011-2014, in the Gambia, the Prolifica project tested 5,980 persons for HBV infection in the community. This led to the identification of 495 persons with confirmed HBV infection (Ratio of infections diagnosed per test conducted: 0.08). During the reporting period, 18 eligible persons initiated treatment (Ratio of treatment initiated per persons diagnosed: 0.036, as only a minority of infected persons were eligible for treatment). After a year on treatment, 17 (94%) persons were assessed for viral suppression (treatment effectiveness). Among the persons assessed for virological suppression, all 17 persons (100%) were suppressed. Unlike the global HBV cure cascade (Figure 2), the programmatic cascade for the HBV project in the Prolifica project of the Gambia does not relate to a denominator that would refer to the entire population with HBV infection. The persons tested and treated in the context of the Prolifica project cannot be related to a precise catchment population in which the prevalence of HBV infection would be known. Some persons may not have access to the services in the area where the project operates, or the prevalence of HBV infection could be unknown in the specific area where the project operates. Relating the testing, diagnosis, treatment and viral suppression cascade to a denominator of all persons infected is easier to do at the provincial or national system. For this purpose, testing, diagnosis, treatment and viral suppression data from all providers can be aggregated and related to the provincial or national estimate of the total number of persons infected.

Figure 3: Cascade of care for HBV infection, Prolifica project, The Gambia, 2011-2014 (Source: Data adapted from published studies)[*,†]



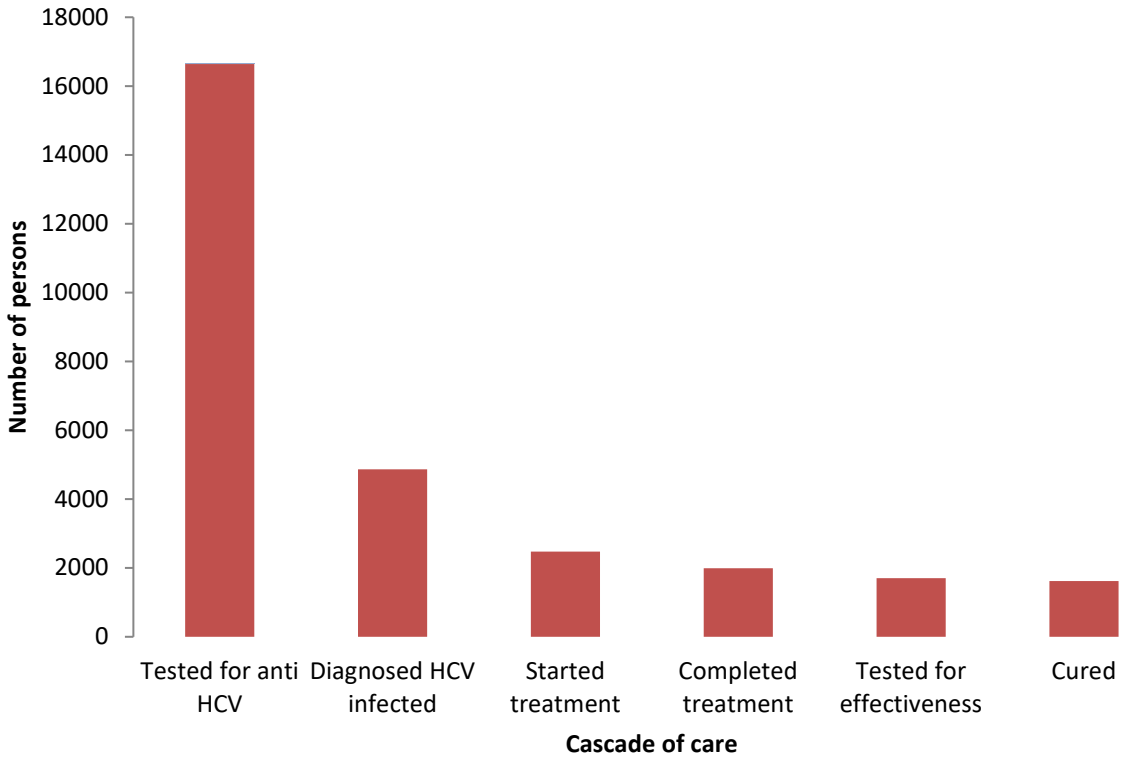
[*] Lemoine M, Shimakawa Y, Njie R, Taal M, Ndow G, Chemin I et al. Acceptability and feasibility of a screen-and-treat programme for hepatitis B virus infection in The Gambia: the Prevention of Liver Fibrosis and Cancer in Africa (PROLIFICA) study. Lancet Glob Health. 2016;4 (8):e559–67. doi: 10.1016/S2214-109X(16)30130-9

[†] Nayagam S, Conteh L, Sicuri E, Shimakawa Y, Suso P, Tamba S et al. Cost-eff ectiveness of community-based screening and treatment for chronic hepatitis B in The Gambia: an economic modelling analysis. Lancet Glob Health. 2016;4 (8):e568–78. doi: 10.1016/S2214-109X(16)30101-2.

Box 2: Case study: MSF testing and treatment project in Karachi, Pakistan.

In 2015-2018, in Karachi, the MSF HCV project tested 16,639 persons for HCV infection. This led to the identification of 4,656 persons with confirmed HCV infection (Ratio of infections diagnosed per test conducted: 0.27). During the reporting period, 2,285 persons initiated treatment (Ratio of treatment initiated per persons diagnosed: 0.49). In the same period, 2,473 person completed treatment and 1,707 were tested for treatment effectiveness (Proportion of persons completing treatment tested for SVR: 86%). Among the persons assessed for SVR, the proportion of SVR was 95% (1,624 / 1,707). Unlike the global HCV cure cascade (Figure 2), the programmatic cascade for the HCV project in Karachi does not relate to a denominator that would refer to the entire population with HCV infection. The persons tested and treated in the context of the MSF project cannot be related to a precise catchment population in which the prevalence of HCV infection would be known. Some persons may not have access to the services in the area where the project operates, or the prevalence of HCV infection could be unknown in the specific area where the project operates. Relating the testing, diagnosis, treatment and cure cascade to a denominator of all persons infected is easier to do at the provincial or national system. For this purpose, testing, diagnosis, treatment and cure data from all providers can be aggregated and related to the provincial or national estimate of the total number of persons infected.

Figure 4: Cascade of cure for HCV infection, MSF intervention project, Karachi, Pakistan, 2015-2018.



4. Data quality

One of the challenges to interpreting health management information system data is that responsibility for data entry, cleaning, and management is distributed across many individuals and facilities. Unlike special studies or surveys, there are often limited resources available for cleaning data impacting the quality and usability of routine monitoring data. Establishing systems and protocols to enhance good data collection and reporting facilitates to some extent the data analysis and use. However, as for all data sources, any analysis must consider whether the results are affected by data quality issues.

Five domains for periodic assessment of data quality are recommended for all core indicators: Completeness, timeliness, internal consistency, external consistency with other data sources, and external comparison with population data. Except for annual comparisons with external sources of data, quality assessments of the health management information system data for the core hepatitis indicators can be examined monthly when collated and reviewed before transmission to higher levels, as well as annually.

Domain	Data quality metric	Frequency
Completeness and timeliness	Completeness and timeliness of reporting (reporting form/data set completeness)	The reporting frequency is quarterly, but this can be adapted to health systems or programmes working on different reporting cycles
	Completeness of indicator data (data element completeness)	Quarterly, annually
Internal consistency	Presence of outliers (e.g., health care facilities reporting unusually high or low numbers). Analyses that could examine this include review of range (minimum, maximum), standard deviation, and marking of specific values for follow up.	Annually
	Consistency over time, i.e. plausibility of reported values compared to previous reporting.	Annually
	Consistency between indicators, i.e. negative dropout rates. Examples include:	Annually
	C6: Are there more people newly diagnosed (e.g., HBsAg positive or HCV RNA positive) than people initially tested for HBsAg or anti-HCV?	
	C7: Are there more people started on treatment than the total number of people diagnosed (already identified + newly diagnosed)?	
	C8: Are there more people with effective treatment than the number of people tested for treatment effectiveness?	
	Note: There could be more people completing HCV treatment than people starting HCV treatment in a reporting period if treatment initiation decreased between two reporting periods.	
External consistency with other data sources	Consistency between routinely reported data and population-based surveys.	Annually
	Example: Are there more people diagnosed than the estimated number of people infected?	

To account for data quality issues in the interpretation and use of hepatitis data from a health management information system module, two indicators that summarize data quality can be assessed routinely:

- The percentage of facilities which meet the standards for reporting completeness;
- The percentage of facilities which meet the standards for reporting timeliness.

5. Data limitations

THE DISTRICT HEALTH INFORMATION SYSTEM IS NOT A COHORT

The key advantage of using the health management information system data over surveys or special study data to measure programme performance is that these data are systematically captured for all patients receiving services resulting in an unbiased view of services provided.

The disadvantage of health management information system data, especially when used for cascade analysis, is that a longitudinal view of patient experience is hard to capture. Detailed characteristics of patients cannot easily be collected at the point of service or entered regularly into data systems. For example, some individuals counted among the number of persons who initiate treatment would not necessarily be among those newly diagnosed. If a person was tested in another setting and then referred to the facility for care and not re-tested at that facility, then that individual would be counted for person newly receiving care but not as testing positive. To account for these limitations, the analysis proposes to use ratios. Examples include the ratio of persons newly diagnosed / started on treatment for HBV and HCV infection. Another example is the ratio of persons assessed for sustained virological response / completing treatment for HCV infection. Use of the ratio allows for a mismatch between the numerator and the denominator (e.g., persons included in the numerator of those starting treatment may not belong to the denominator of those newly diagnosed). However, the ratio are simples and informative if interpreted in light of this limitation. Their monitoring over time should capture events that affect the programme.

Limitations secondary to the use of ratios based on aggregated data rather than individual cohort data include:

- Time lag between services (e.g. individuals who receive service at the end of an analytic period, may not have enough time to initiate the next step in the cascade during the same period), especially during times of rapid scale up or decline;
- Differences in accessibility between services (e.g., when there are fewer treatment sites, patients diagnosed in one geographic unit may not be able or expected to seek treatment in the same geographic unit);
- Patient preferences to seek different services at different facilities for reasons of convenience, perceived quality, or privacy, etc.;
- Inability to avoid miscounting individuals who seek services at multiple sites over time.

Analysis of trends in programme performance must account for changes in service availability and policies impacting service. For example, when countries transition to a “treat all” policy for HCV infected persons, there may be abrupt changes in treatment initiation rates as health facilities adjust to different demands on service or operationalize the policy in different resource contexts. The transition may affect different geographic regions differently, if some areas are designated as priority areas.

ESTIMATING THE PROPORTION OF INFECTED PERSONS DIAGNOSED

The district health information system can provide a tool for the health system to monitor testing, new diagnoses, treatment and treatment effectiveness. However, estimation of the proportion of persons infected that are diagnosed would be challenging to do at the sub-national level on the basis of this tool. Estimations need to take place at the national level on the basis of the estimated number of persons living with HBV and HCV and the overall number of persons diagnosed as reported in district health information system and possibility other sources of information.

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