Global reporting of progress towards elimination of hepatitis B and hepatitis C

Fuqiang Cui, Sarah Blach, Casimir Manzengo Mingiedi, Monica Alonso Gonzalez, Ahmed Sabry Alaama, Antons Mozalevskis, Nicole Séguy, Bharat Bhushan Rewari, Po-Lin Chan, Linh-vi Le, Meg Doherty, Niklas Luhmann, Philippa Easterbrook, Mae Dirac, Catherine de Martel, Shevanthi Nayagam, Timothy B Hallett, Peter Vickerman, Homie Razavi, Olufunmiayo Lesi, Daniel Low-beer

Summary

Background The 69th World Health Assembly endorsed the global health sector strategy on viral hepatitis to eliminate viral hepatitis as a public health threat by 2030. Achieving and measuring the 2030 targets requires a substantial increase in the capacity to test and treat viral hepatitis infections and a mechanism to monitor the progress of hepatitis elimination. This study aimed to identify the gaps in data availability or quality and create a new mechanism to monitor the progress of hepatitis elimination.

Methods In 2020, using a questionnaire, we collected empirical, systematic, modelled, or surveyed data—reported by WHO country and WHO regional offices—on indicators of progress towards elimination of viral hepatitis, including burden of infection, incidence, mortality, and the cascade of care, and validated these data.

Findings WHO received officially validated country-provided data from 130 countries or territories, and used partner-provided data for 70 countries or territories. We estimated that in 2019, globally, 295·9 million (3·8%) people were living with chronic hepatitis B virus (HBV) infection and 57·8 million (0·8%) people were living with chronic hepatitis C virus (HCV) infection. Globally, there were more than 3·0 million new infections with HBV and HCV and more than 1·1 million deaths due to the viruses in 2019. In 2019, 30·4 million (95% CI 24·3–38·0) individuals living with hepatitis B knew their infection status and 6·6 million (5·3–8·3) people diagnosed with hepatitis B received treatment. Among people with HCV infection, 15·2 million (95% CI 12·1–19·0) had been diagnosed between 2015 and 2019, and 9·4 million (7·5–11·7) people diagnosed with hepatitis C infection were treated with direct-acting antiviral drugs between 2015 and 2019.

Interpretation There has been notable global progress towards hepatitis elimination. In 2019, 30·4 million (10·3%) people living with hepatitis B knew their infection status, which was slightly higher than in 2015 (22·0 million; 9·0%), and 6·6 million (22·7%) of those diagnosed with hepatitis B received treatment, compared with 1·7 million (8·0%) in 2015. Mortality from hepatitis C has declined since 2019, driven by an increase in HCV treatment ten times that of the strategy baseline. However, an estimated 89·7% of HBV infections and 78·6% of HCV infections remain undiagnosed. A new global strategy for 2022–30, based on these new estimates, should be implemented urgently to scale up the screening and treatment of viral hepatitis.

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Introduction

In May, 2016, the World Health Assembly (WHA) endorsed the Global Health Sector Strategy on Viral Hepatitis 2016–21 (GHSS-VH).[1] This strategy aims to eliminate viral hepatitis as a public health threat by 2030, with elimination defined as a 90% reduction in incidence and a 65% reduction in mortality;[1] these targets also contribute to the achievement of the UN 2030 Agenda for Sustainable Development. The GHSS-VH covered the first 6 years after the 2015 health agenda,[1] and built on two resolutions on viral hepatitis adopted by WHA in 2010[2] and 2014.[3] The GHSS-VH addresses all five hepatitis viruses (hepatitis A, B, C, D, and E), but has a particular focus on hepatitis B and hepatitis C because of their public health burden. The GHSS-VH focuses on priority indicators (eg, disease burden and interventions) that can be scaled up towards access, prevention coverage, harm reduction, blood safety, testing, and treatment for viral hepatitis that are universal.[1] The GHSS-VH presents data for five strategic directions (ie, strategic information, interventions, equity, financing, and innovation), which are key pillars to facilitate monitoring progress.

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School of Public Health, Peking University, Beijing, China (Prof F Cui PhD); **WHO Headquarters, Geneva, Switzerland** (M Doherty MD, N Luhmann MScPH, Prof P Easterbrook MD, O Lesi MD, D Low-beer PhD); **Center for Disease Analysis Foundation, Lafayette, CO, USA** (S Blach MSH, H Razavi PhD); **WHO Regional Office for Africa, Brazzaville, Republic of Congo** (C Manzengo Mingiedi MD); **WHO Regional Office for the Americas, Washington, DC, USA** (M A Gonzalez MD); **WHO Regional Office for the Eastern Mediterranean, Cairo, Egypt** (A Sabry Alaama MPH); **WHO Regional Office for Europe, Copenhagen, Denmark** (A Mozalevskis MD, N Séguy PhD); **WHO Regional Office for South- East Asia, New Delhi, India** (B B Rewari MD); **WHO Regional Office for the Western Pacific, Manila, Philippines** (P-L Chan MD, L-v Le PhD); **Institute for Health Metrics and Evaluation, Seattle, WA, USA** (M Dirac PhD); **Early Detection, Prevention and Infections Branch, International Agency for Research on Cancer (IARC/WHO), Lyon, France** (C de Martel MD); **Faculty of Medicine, School of Public Health, Imperial College London, London, UK** (S Nayagam PhD, Prof T B Hallett PhD); **Population Health Sciences, University of Bristol, Bristol, UK** (Prof P Vickerman DPhil)

Correspondence to:
Dr Daniel Low-beer, Department of Global HIV, Hepatitis and Sexually Transmitted Infections Programmes, WHO Headquarters, Geneva 1211, Switzerland.
lowbeerd@who.int

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Research in context

Evidence before this study

We searched PubMed on April 12, 2022, for articles on the diagnosis of and treatment coverage for viral hepatitis, published before Jan 1, 2017, using the search terms "hepatitis" AND "testing" OR "treatment" AND "coverage" AND "global". We did not find any articles, only a few disease burden publications by research groups and some commentaries. In May, 2016, the 69th World Health Assembly endorsed the Global Health Sector Strategy on Viral Hepatitis 2016–21, to eliminate viral hepatitis as a public health threat by 2030. In 2017, WHO released global and regional estimates on viral hepatitis, setting the baseline for tracking progress in implementing the global strategy. In 2019, WHO published the first global HIV, viral hepatitis, and sexually transmitted diseases progress report, but key data (eg, incidence and mortality) were unavailable for viral hepatitis, making it difficult to assess and validate overall trends since May, 2016. Previous reports from WHO contained insufficient information, and in many parts of the world, data systems were not in place to generate the necessary strategic information data to inform global, regional, and national programmes and policies.

Added value of this study

Given low coverage for testing and treatment, increased efforts were needed to expand the testing and treatment of hepatitis B and hepatitis C. This Article marks a major increase in the availability of data on the burden, testing, and treatment of viral hepatitis, and provides a strong baseline for the new strategy for 2022–30. This study describes the global reporting process for viral hepatitis and the factors that increased reporting—with more indicators (validated by ministries of health) and high reporting coverage, quality and completeness has improved compared with previous reporting efforts. The new estimates were based on 130 countries or territories that provided validated data, plus 70 countries or territories for which there was only partner-provided data, and the completeness of data has been improved substantially in comparison with 2017 estimates. This Article reviews the progress made, both globally and by region, towards the elimination of hepatitis B and hepatitis C and provides updated figures on global burden, incidence, mortality, and coverage of testing and treatment. Furthermore, this Article assesses key gaps in data availability and completeness issues and actions required to accelerate progress for the next viral hepatitis strategy, 2022–30.

Implications of all the available evidence

Accurate and reliable data are important to monitor progress and to support countries in prioritising the elimination of viral hepatitis and with policy making. As a key component of the Global Health Sector Strategy, each country has to monitor its progress using systematically collected data, so a robust national system and a strong capacity to collect data are essential. Remarkable progress has been made in the first stage of expanding treatment. However, the next stage, from 2022 to 2030, requires much more rapid acceleration. Treatment access and screening were negatively affected by social distancing rules and disruptions related to the COVID-19 pandemic. The new global strategy should therefore be implemented urgently, to resume service and substantially scale up screening for, and the treatment of, viral hepatitis.

The 2017 WHO Global Hepatitis Report[4] described for the first time global and regional estimates for viral hepatitis and thereby set the baseline for tracking progress for the new global strategy. The report estimated that viral hepatitis caused 1·34 million deaths in 2015. The increase since 2000 in such deaths highlighted the urgency of tackling the hepatitis disease burden, given there is a cure for hepatitis C, a vaccine for prevention of hepatitis B, and highly effective treatment to reduce risk of death from hepatitis B virus (HBV). Most viral hepatitis deaths in 2015 were due to chronic liver disease (eg, 720 000 deaths due to cirrhosis) and primary liver cancer (eg, 470 000 deaths due to hepatocellular carcinoma).[4] Global estimates for 2015 were of 257 million people living with chronic HBV infection and 71 million people living with chronic hepatitis C virus (HCV) infection.[4] Access to affordable testing was low, with 22 million (9·0%) people infected with HBV and 14 million (20·0%) people infected with HCV diagnosed.[4] Treatment reached only a small proportion of people who had been diagnosed; in 2015, 1·7 million (7·7%) people diagnosed with HBV infection were on treatment, compared with 1·1 million (7·4%) of those diagnosed with HCV.[4] In 2019, WHO released its first progress report on HIV, viral hepatitis, and sexually transmitted infections.[5] This report contained important data obtained from only 124 (64%) of 194 countries and territories; furthermore, key data (including incidence and mortality) were not available at all globally, making it difficult to assess and validate overall trends since the launch of GHSS-VH in 2016. The 2019 progress report also identified that global targets for reducing mortality from viral hepatitis would not be met without massively accelerating universal access to testing, hepatitis B treatment, and hepatitis C cure. For instance, in 2019, global coverage for hepatitis B vaccine (third dose) was 85% and 43% for hepatitis B vaccine timely birth dose.[6]

The previous documents[4,5] provided baseline data for monitoring progress towards elimination of viral hepatitis, but many parts of the world did not have strong systems in place to generate the necessary strategic information, and required stronger mechanisms to collect, transfer, analyse, and disseminate data on viral hepatitis. Incidence and mortality were poorly measured at the national level, owing to the inadequacy of routine

reporting systems, and inherent challenges with timely identification of incident infections and deaths related to viral hepatitis. Since most infections are asymptomatic, patients might not seek medical care until many years after infection, making it challenging to register new infections in a timely way. For a death to be classified as being related to viral hepatitis, the person's infection must be diagnosed before death. Therefore, reliable population-based estimates of HBV and HCV infection incidence and mortality were not available in many countries. The 2017 report[4] found that services and interventions were crucial for the prevention and control of viral hepatitis infection, but service coverage, including the establishment of data systems for treatment and testing for viral hepatitis, was poorly monitored. In the 2017 report,[4] most of the data used to estimate the cascade of care for HBV, and cure for HCV, were based on various ad-hoc sources that were often cross-sectional.

For the purposes of this study, WHO has been working with partners (the Center for Disease Analysis Foundation, Imperial College London, and the University of Bristol) to assess viral hepatitis disease burden and service delivery by country and territory in its 194 member states. The approach has been to develop global and regional reports to monitor and evaluate the progress of elimination of viral hepatitis, validate data and estimates with member states, assist member states with the development of evidence-based strategies for the elimination of viral hepatitis, and track member states' progress towards achieving elimination targets. At the end of 2021, progress was reviewed and gaps (such as data incompleteness or quality issues—eg, no data, out of date data, or use of inadequate data methods) were identified to inform viral hepatitis strategies for 2022–30. The partners provided member states with established data sources and models (with which to estimate epidemiological data, disease burden, and economic impact), intervention strategies, access to affordable diagnostics and treatments, innovative financing models, and knowledge-sharing partnerships.

Since WHA endorsed the GHSS-VH in 2016, data sources have changed substantially and methods for disease surveillance have been developed. This Article describes the global reporting process for viral hepatitis established in 2018, and the factors that increased reporting. We also review progress (globally and by region) and provide updated data on hepatitis B and hepatitis C global burden, incidence, mortality, and progress in testing and treatment coverage. Finally, we assess the key gaps and actions required to accelerate progress for the next phase of the viral hepatitis elimination strategy.

Methods

Global reporting and validation process: timing and involvement of WHO regions and countries

In April 2020, WHO defined the scope for the global reporting of viral hepatitis (focusing on hepatitis B and hepatitis C, which are responsible for 96% of viral hepatitis-related mortality) and ten key indicators for monitoring progress towards elimination. In June 2020, WHO regional offices and country offices began communicating with national focal points (ie, WHO country office staff responsible for data collection and reporting in member states) to request data from each country's ministry of health. Data reports were returned to WHO in November–December, 2020, after which WHO worked with the national focal points and partners to validate the data, before finalising estimates in April, 2021. To validate the data objectively, WHO established a reference group consisting of relevant WHO departments, the Institute for Health Metrics and Evaluation (responsible for Global Burden of Disease [GBD] research), Imperial College London, the University of Bristol, and the International Agency for Research on Cancer. Data validation was done virtually, because of the COVID-19 pandemic. The indicators of progress that the reference group normally reviewed were burden of infection, incidence, mortality, the cascade of diagnosis and care or cure for testing and diagnosis, and the cascade of diagnosis and care or cure for the treatment of viral hepatitis, and the other requested indicators were testing facilities, vaccine coverage, access to sterile needles and syringes for people who inject drugs, injection safety, and the output of the cascade of care for viral suppression (HBV) or cure (HCV). The data to be reported were requested for 2019 only, and the number of indicators and forms to complete, for which the number of indicators and forms to complete were substantially simplified, to include only the first five of the indicators listed previously, which improved the response rate in 200 countries and territories.[1]

Validation process for systematically collected country-level data

Two sequential processes were used to validate the data. In step one, the WHO regional office reviewed with the national focal points the data supplied by the ministry of health, supported the country in the collection of updated data, and provided comments on the data collection process, quality, and completeness issues, as necessary. The validated data (ie, country-provided data validated by the regional office) were then shared with WHO headquarters for step two: review by the reference group. The reference group served as a quality control and reviewed the step one data and any partner-provided data, and compared these datasets on the basis of sources, time period, representativeness, completeness, and reliability. The validation process (ie, steps one and two) gave primacy to country-provided data from either the national surveillance system or the national disease registry. Step one data was prioritised over modelled estimates for the development of the cascade of care or disease burden. If the WHO regional office and country had completed a data reporting

See Online for appendix

process with countries to validate hepatitis data before this process, those data were selected. Countries were also given the option to use any of the available partner-provided data if there were major gaps in the national data. For countries without step one data, partner-provided data were sent to the national focal points. The countries then decided which partner-provided data most closely represented the likely burden in the country and could reject partner-provided data that did not align with their expectations. The country sent the approved partner-provided data to the reference group for review. All members of the reference group reviewed all data. Partners did not validate or approve any country-provided data; however, if a country modified the partner-supplied data it submitted without providing a supporting explanation, the partners highlighted this to the national focal point, the regional focal point, and the reference group, and asked the country to clarify why. If none of the above data were available, a regional average was applied to the country by the national and regional focal points, with priority being given to the regional average provided by the WHO regional office. When estimating regional and global figures (both for point estimates and for 95% CI), data (validated before this project) from WHO regional offices took priority over other sources but followed the same two-step validation procedure described previously (figure 1).

Review by countries: algorithm and emphasis on country data

To collect and analyse the data (appendix p 1), first WHO developed a template data form for member states, which included key indicators, a definition and description of each indicator, the years for which data were required, and suggested data sources (eg, country-provided data, partner-provided data, and regional averages; appendix pp 1–4). Second, WHO communicated with regional focal points and strategic-information officers in regional offices to request inputs about the accuracy of the indicator definitions, periods of data collection, and procedures of reporting for the region. Third, WHO worked with partners to prefill the data forms as far as possible, an approach taken in response to requests from regional and national WHO offices. WHO did not accept this prefilled data at that point, but did agree with the partners or countries which datasets would be valuable resources for countries, and it was the country's responsibility to decide whether to accept, reject, or update the prefilled data. Fourth, WHO shared preliminary results of the data collection with regional offices and initiated the validation process. WHO regional offices coordinated the validation process for their member states, during which countries were given a clear timeline and procedure for validation and were asked to prepare data for review. The focus of WHO HQ was on priority countries (ie, those with a high hepatitis

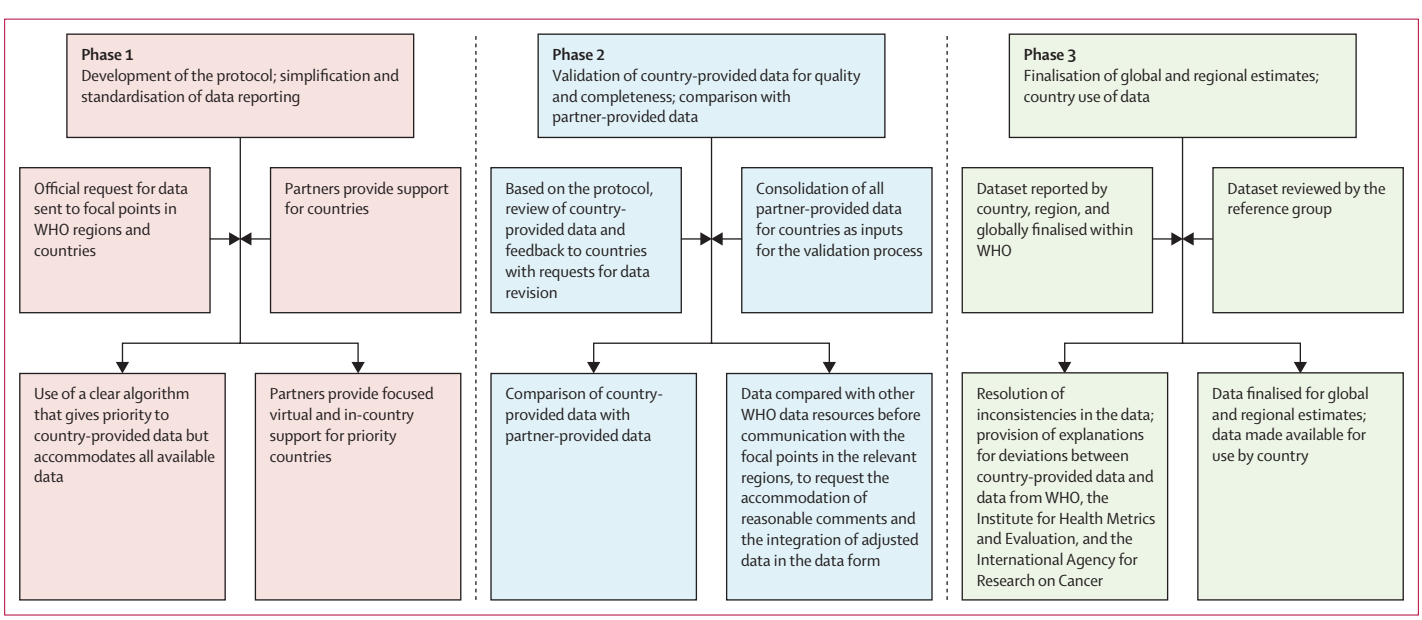

Figure 1: **Process for data collection and validation**

The partners were the Center for Disease Analysis Foundation, Institute for Health Metrics and Evaluation, Imperial College London, University of Bristol, and the International Agency for Research on Cancer. Focal points were the people in WHO regional and country offices who were responsible for the data collecting and reporting. Country offices were asked to provide the data inputs and the regional focal points were asked to comment on the data collection process and parameters. The reference group consisted of relevant WHO departments and the Institute for Health Metrics and Evaluation, Imperial College London, the University of Bristol, and the International Agency for Research on Cancer. The protocol for data collection and reporting was developed by WHO headquarters, together with WHO regional offices and the partners. Virtual and in-country data validation was organised by WHO and focused on priority countries (ie, those with a high viral hepatitis disease burden; appendix p 5) and countries with data quality issues (eg, countries such as the USA have adopted multipliers to estimate true new infections based on reported acute infections; however, we thought such multipliers to be country specific and unsuitable for use by other countries). Other WHO data resources included data from the WHO Immunization, Vaccines and Biologicals department, baseline data, and the latest data from WHO. Data indicators and definitions are defined in the appendix (p 3).

disease burden [appendix p 5]) in the region, and meetings between the reference group and the WHO country office were scheduled with these countries as needed. Fifth, WHO regional offices gave the collected data to the WHO country offices, for validation with each country. During the data-validation process, country offices were asked to provide the data, which were then reviewed by WHO regional and headquarters teams. Any questions related to data availability, sources, time period, collection methods, completeness, or quality were relayed back to the country offices, who made adjustments on the basis of comments from reference group or adopted the partner-provided data. After validation, a final decision was made by the reference group to either accept the data if it met requirements, update the data if there were gaps that required improvement, or reject the data if there were strong concerns about them. Sixth, WHO provided support to regions in which help was most needed, focusing mainly on priority countries with high disease burden and the Africa region. In the last step to finalise country data, WHO HQ coordinated closely with country offices about partner-provided data and made it transparently available to the country, which was considered to be an important component of the improved use of data. The reference group reviewed all the validated data and comments, compared the validated data with partner-provided data and WHO data resources (eg, data from the WHO Immunization, Vaccines and Biologicals department, 2015 baseline data, and the latest data released by WHO[7,8]) on the basis of source, time period, representativeness, completeness, and reliability, and communicated with the relevant regions again, to request that they accommodate reasonable comments and integrate the adjusted data (figure 1). For example, if the reference group identified differences between country-provided data and partner-provided data, the country was asked to provide comments on the data source and methods used to collect data; if the country's comments showed that the country-provided data met indicated criteria, the country-provided data were incorporated in the data form.

We calculated CIs using three methods and used the lowest and highest bounds from the three estimates (for each indicator and region) to ensure the maximum amount of uncertainty was reflected in the final range. First, we calculated traditional 95% CIs using the mean and SD of country point estimates. Second, the aggregated minimums and maximums of all country-level estimates (including: all partner-provided data when multiple partners provided data for a common indicator; country-provided data; and region-provided data) were summed at the regional and global levels. Third, we permitted variance in regional estimates for data that had been reported at an earlier time point or a variance of up to (+ or –) 20% for indicators for which ranges had not previously been reported.

The PRoGReSs Model is a Microsoft Excel-based (version 365) compartmental, deterministic, dynamic Markov disease progression model for HBV infection. It was used to estimate country-level HBV infection point estimates and 95% uncertainty intervals. It models the population with HBV infection from infection (vertically or horizontally acquired) to progression of liver disease to eventual death and allows for the incorporation of interventions such as prophylaxes and treatment.[9] The Bright Model is a Microsoft Excel-based (version 365) Markov model for HCV disease progression. Models were parameterised for countries using national demographic data (population, all-cause mortality, births, and sex ratio at birth), HCV epidemiological data (anti–HCV prevalence, viraemic rate, and age and sex distribution) and annual HCV intervention coverage data (screening, diagnosis, antiviral treatment, and sustained viral response).[10]

Limitations of the data

During the study, effort was concentrated on the evaluation of the cascade of care and estimation of viral hepatitis incidence and mortality, as these areas had the most data incompleteness. WHO asked countries to complete their reports on the basis of the data sources available, and to either provide data or clarification if data were not available, and to comment on the reasons for any data gaps.

For the prevalence of HBV infection among children younger than 5 years, country-provided or partner-provided data, validated by the WHO Immunization, Vaccines and Biologicals department, which reports on the progress of the Sustainable Development Goals, were aligned with data of that same WHO department, and differences between countries were tabulated to improve future reporting. If there were gaps in country or regional reporting, data modelling by partners (based on country-provided data and consultations with countries) was included.

Role of the funding source

WHO staff contributed to the study design, data collection, data analysis, data interpretation, and writing of the report.

Results

As of April 1, 2021, WHO had received validated data reports from 130 countries or territories, and partner-provided data for another 70 countries or territories. The validated data from the 130 countries or territories were included directly in the global and regional datasets. For the 70 countries or territories for which reporting was not provided, partner-provided data from the Center for Disease Analysis Foundation, Imperial College, University of Bristol, the Institute for Health Metrics and Evaluation, and WHO Immunization, Vaccines and Biologicals department were included in the datasets.

On the basis of prevalence data from the WHO Immunization, Vaccines and Biologicals department,[7,8] WHO estimated that globally in 2019, 295·9 million (95% CI 228·2–422·6) people (ie, 3·84% of 7713·4 million) were living with chronic HBV infection and 57·8 million (46·2–75·9) people (ie, 0·75% of 7713·4 million) were living with chronic HCV infection. Table 1 shows the estimated number of infections and prevalence for chronic HBV and HCV, both globally and by region. The African region had the highest HBsAg prevalence (7·53% [95% CI 5·68–10·49]), followed by the Western Pacific region (5·92% [4·87–7·26]), whereas the region of the Americas had the lowest HBsAg prevalence (0·53% [0·30–1·21]). HBsAg prevalence in the African region was 14 times higher than that in the region of the Americas. For the number of HBV infections, the Western Pacific region (115·7 [95% CI 95·2–141·9] million) and African region (82·3 [62·1–114·7] million) had the largest number of infections owing to their large population sizes and high prevalences of HBsAg.

Globally, HBsAg prevalence among children aged under 5 years was 0·94% (95% CI 0·65–1·59). HBsAg prevalence among those aged under 5 years was higher in the African region (2·53% [95% CI 1·69–3·96]) and Eastern Mediterranean region (0·84% [0·49–1·10]) than in the Western Pacific region (0·30% [0·20–0·46]), the European region (0·26% [0·13–0·52]), and the Americas (0·07% [0·04–0·18]; table 1). The UN 2030 Agenda for Sustainable Development and interim WHO 2020[11] global target of reducing HBsAg prevalence among children under 5 years of age to less than 1% by 2020 was achieved; five of the six WHO regions also met this target (the exception being the African region). The region of the Americas also met the 2030 target of a decrease to 0·1% or less.[1] However, this progress was not matched among the general adult population, in which prevalence increased from 3·50% in 2015 to 3·84% in 2019.

Current hepatitis C infection prevalence for all ages globally was 0·75% (95% CI 0·60–0·98; table 1). The Eastern Mediterranean region had the highest HCV prevalence (1·64% [95% CI 1·36–1·81]), followed by the European region (1·34% [1·07–1·48]). The largest numbers of HCV infections were in the European region (12·5 million [95% CI 10·0–13·7]) and the South-East Asia region (11·8 million [9·7–13·0]). HCV prevalence and infection numbers were lower in the region of the Americas (prevalence 0·47% [95% CI 0·4–0·54]; 4·8 million [4·1–5·5] infections) and the Western Pacific region (prevalence 0·49% [0·42–0·70]; 9·5 million [8·2–13·6] infections) than in other regions.

Table 2 provides estimates of new chronic infections and deaths, globally and by region. New data show that hepatitis B and hepatitis C caused more than 3 million new chronic infections among the general population (all ages) in 2019, with 1·5 million [95% CI 1·1–2·6) people newly infected with chronic HBV infection and 1·5 million [1·3–1·8] people newly infected with chronic HCV infection. New HBV infections occurred mainly in the African region (990·7 thousand [95% CI 660·5–1552·1]; 64·9% of global new infections) and the South-East Asia region (256·7 thousand [183·3–586·7]; 16·8% of global new infections). New HCV infections occurred mainly in the Eastern Mediterranean region (473·6 thousand [95% CI 240·6–521·0]; 31·3% of global new infections) and the European region (297·1 thousand [241·9–317·1]; 19·6% of global new infections). The African region accounted for 39·6% of the global new infections caused by HBV and HCV, and the Eastern Mediterranean region accounted for 19·0%. The overall numbers of new infections of HBV and HCV in 2019 (ie, 1·5 million each) were still high compared with 1·75 million HCV infections in 2015,[4] and the estimate for HBV was higher than the previous estimates of HBV infection (1·1 million) in 2017, owing to improved data.

	Hepatitis B in the general population		Hepatitis B in children younger than 5 years		Hepatitis C in the general population	
	Estimated number of infections (millions)	Prevalence of HBsAg	Estimated number of infections (thousands)	Prevalence of HBsAg	Estimated number of infections (millions)	Prevalence of HCV
Global	295·9 (228·2–422·6)	3·84% (2·96–5·48)	6367·3 (4408·2–10 775·5)	0·94% (0·65–1·59)	57·8 (46·2–75·9)	0·75% (0·60–0·98)
African region	82·3 (62·1–114·7); 27·8%	7·53% (5·68–10·49); 196·1%	4309·6 (2873·0–6751·7); 67·7%	2·53% (1·69–3·96); 269·1%	9·2 (6·0–14·7); 15·9%	0·84% (0·55–1·35); 112·0%
Region of the Americas	5·4 (3·1–12·2); 1·8%	0·53% (0·30–1·21); 13·8%	51·5 (25·7–128·7); 0·8%	0·07% (0·04–0·18); 7·4%	4·8 (4·1–5·5); 8·3%	0·47% (0·40–0·54); 62·7%
South-East Asia region	60·5 (45·3–120·9); 20·4%	3·02% (2·27–6·04); 78·6%	722·1 (424·5–947·8); 11·3%	0·38% (0·27–1·02); 40·4%	11·8 (9·7–13·0); 20·4%	0·50% (0·40–0·94); 66·7%
European region	13·6 (10·2–22·1); 4·6%	1·46% (1·09–2·37); 38·0%	147·1 (73·6–294·3); 2·3%	0·26% (0·13–0·52); 27·7%	12·5 (10·0–13·7); 21·6%	1·34% (1·07–1·48); 178·7%
Eastern Mediterranean region	18·2 (14·3–23·8); 6·2%	2·54% (2·00–3·31); 66·1%	644·9 (460·6–1736·0); 10·1%	0·84% (0·49–1·10); 89·4%	10·0 (8·0–18·9); 17·3%	1·64% (1·36–1·81); 218·7%
Western Pacific region	115·7 (95·2–141·9); 39·1%	5·92% (4·87–7·26); 154·2%	363·7 (242·5–560·1); 5·7%	0·30% (0·20–0·46); 31·9%	9·5 (8·2–13·6); 16·5%	0·49% (0·42–0·70); 65·3%

Data are estimate (95% CI) or estimated (95% CI); % of global estimate. HBV=hepatitis B virus. HCV=hepatitis C virus.

Table 1: **Estimated disease burden of HBV and HCV infections globally and by region, 2019**

About 1·1 million people died from HBV and HCV in 2019 (821·1 thousand [95% CI 453·0–945·1] for HBV and 287·7 [226·1–575·2] for HCV; table 2). The highest number of new deaths caused by HBV occurred in the Western Pacific region (470·8 thousand [95% CI 195·2–485·3]) and the South-East Asia region (179·2 thousand [142·4–296·0]). The highest numbers of new deaths from HCV were in the Western Pacific region (77·3 thousand [95% CI 76·8–143·7]) and the European region (64·2 thousand [39·4–72·2]). Of new deaths globally caused by HBV, 57·3% occurred in the Western Pacific region, and for those caused by HCV, 26·9% were in the Western Pacific region. Of global deaths caused by HBV and HCV combined, 49·4% were in the Western Pacific region, and 19·6% were in the South-East Asia region (table 2).

Global hepatitis B mortality decreased by 7%, and therefore the target of a 10% reduction by 2020[11] was not achieved by 2019. Although the Eastern Mediterranean, African, and Americas regions had achieved this target (each with a reduction of over 10%), progress has been uneven and the South-East Asia and the Western Pacific regions were lagging far behind (table 2). Deaths caused by HBV remained high, after decreasing from 887·0 thousand deaths in 2015 to 821·1 thousand deaths in 2019, whereas those caused by HCV showed a declining trend, from 400 thousand in 2015 to 287 thousand in 2019.

In terms of progress in diagnosis and treatment, among people living with hepatitis B, 10·3% (30·4 million [95% CI 24·3 –38·0]) of all people living with hepatitis B knew their status and in 2019, 21·8% (6·6 million [5·3–8·3]) received treatment in line with WHO or regional treatment criteria. 70·3% of diagnosed infections and 84·2% of total infections treated globally were in the Western Pacific region. In 2019, 21·4% (15·2 million [95% CI 12·1–19·0]) of the 71 million people estimated to be living with HCV in 2015 knew their status. 9·4 million (7·5–11·7) had been treated using direct-acting antiviral drugs between 2015 and 2019 (table 3). 36·7% of diagnosed HCV infections and 52·4% of HCV treatments globally were in the Eastern Mediterranean region.

Mortality from hepatitis C has declined since 2015, driven by the number of people treated for HCV increasing by ten times compared with the strategy baseline. However, overall treatment coverage extended to only 9·4 million (13·2%) of the 71·0 million people living with HCV in 2015.

The global diagnosis targets of 30% for 2020,[1] were not met in 2019. Hepatitis B diagnosis coverage was only 10·3% globally, with the highest rates in the European (18·7%), Western Pacific (18·5%), and the Americas (18·5%) regions, whereas the lowest rates were in the African (2·2%) and the South-East Asia (2·1%) regions. Overall treatment coverage for chronic HBV infection was 2·2% (10·3% diagnosed and 21·8% treated,

	New HBV infections (thousands)	New HCV infections (thousands)	Deaths caused by HBV (thousands)	Deaths caused by HCV (thousands)
Global	1525·8 (1056·3–2582·2)	1513·5 (1272·8–1832·5)	821·1 (453·0–945·1)	287·7 (226·1–575·2)
African region	990·7 (660·5–1552·1); 64·9%	211·9 (152·2–373·0); 14·0%	80·4 (46·9–113·4); 9·8%	45·2 (23·0–71·8); 15·7%
Region of the Americas	10·2 (5·1–25·5); 0·7%	67·0 (62·8–73·4); 4·4%	14·6 (8·5–23·2); 1·8%	31·4 (19·2–83·9); 10·9%
South-East Asia region	256·7 (183·3–586·7); 16·8%	234·1 (198·2–427·3); 15·5%	179·2 (142·4–296·0); 21·8%	38·3 (36·9–129·3); 13·3%
European region	18·9 (9·4–37·7); 1·2%	297·1 (241·9–317·1); 19·6%	43·1 (34·0–50·8); 5·3%	64·2 (39·4–72·2); 22·3%
Eastern Mediterranean region	104·9 (78·7–137·7); 6·9%	473·6 (240·6–521·0); 31·3%	32·8 (26·0–60·4); 4·0%	31·4 (30·8–74·4); 10·9%
Western Pacific region	144·5 (96·3–208·7); 9·5%	230·0 (215·4–256·8); 15·2%	470·8 (195·2–485·3); 57·3%	77·3 (76·8–143·7); 26·9%

Data are estimate (95% CI) or estimate (95% CI); % of global estimate. HBV=hepatitis B virus. HCV=hepatitis C virus.

Table 2: **Estimated HBV and HCV new infections and deaths globally and by region, 2019**

	Diagnosis		Treatment	
	People with HBV infection diagnosed up to Dec 31, 2019 (thousands)	People with HCV infection diagnosed up to Dec 31, 2019 (thousands)	People receiving HBV treatment up to Dec 31, 2019 (thousands)	Cumulative people initiating HCV treatment, 2015–2019 (thousands)
Global	30 393·4 (24 314·7–37 991·7)	15 190·4 (12 152·3–18 988·0)	6636·6 (5309·3–8295·7)	9392·0 (7513·6–11 740·0)
African region	1792·2 (1433·8–2500·2); 5·9%	502·0 (401·6–627·5); 3·3%	105·0 (51·4–131·3); 1·6%	51·0 (16·9–63·8); 0·5%
Region of the Americas	989·4 (791·5–1236·7); 3·3%	1544·9 (1235·9–1931·1); 10·2%	154·5 (123·6–193·1); 2·3%	1292·0 (1033·6–1615·0); 13·8%
South-East Asia region	1236·5 (429·9–1893·4); 4·1%	727·8 (262·4–909·8); 4·8%	136·2 (108·9–170·2); 2·1%	504·0 (126·4–630·0); 5·4%
European region	2542·7 (2034·2–3178·4); 8·4%	3331·2 (2665·0–4164·0); 21·9%	209·0 (167·2–261·2); 3·1%	1168·0 (735·0–1460·0); 12·4%
Eastern Mediterranean region	2464·1 (904·9–3080·1); 8·1%	5581·0 (4464·8–6976·3); 36·7%	440·8 (130·3–551·0); 6·6%	4922·0 (3937·6–6152·5); 52·4%
Western Pacific region	21 368·5 (17 094·8–26 710·7); 70·3%	3503·4 (2802·7–4379·3); 23·1%	5591·1 (4472·9–6988·9); 84·2%	1455·0 (1164·0–1818·8); 15·5%

Data are estimate (95% CI) or estimate (95% CI); % of global estimate. HBV=hepatitis B virus. HCV=hepatitis C virus.

Table 3: **Reported HBV and HCV infection diagnosis and treatment by location, 2019**

6·6 million [2·2%] treated out of 295·9 million living with HBV), with the highest (5%) in the Western Pacific region and the lowest (<1% in the African region; figure 2A). However, the number of people on treatment surpassed the 2020 target set in the GHSS-VH 2016–21[1] (5 million [10·0%] of those eligible for treatment as stated by WHO in 2016). For hepatitis C, diagnosis coverage was only 21% globally, with the highest in Eastern Mediterranean region (37%), followed by the Western Pacific region (25%), and the lowest in the African region (5%), followed by the South-East Asia region (7%). The overall treatment coverage was 13%, with the highest in Eastern Mediterranean region (33%), and the lowest in the African region (<1%; figure 2B). The number of HCV infections treated also surpassed the 2020 target (3 million treated) set in GHSS-VH[1] 2016–21. The Eastern Mediterranean region was the only region that reached the 2020 HCV diagnosis and treatment target.

Discussion

Improved data are important to monitor progress and support countries in policy making. The new estimates presented here for 2019 were based on 200 countries or territories with country reports and additional partner-provided data. We also compared the new data with previous reports and data from other sources to ensure quality and reliability. The completeness of data has been improved substantially,[6] and this Article describes the data collected and the improved data-collection process transparently. There were many challenges in data collection. In particular, monitoring incidence and mortality in line with a focus on the effects of the Sustainable Development Goals requires robust national systems and strong capacity to collect data. Hence, a system to monitor the progress in all countries is needed, and building capacity is essential in those countries with a low performance in data reporting.[12] Furthermore, countries without a national, population-based estimate of the prevalence of HBV and HCV infections might need to consider planning a biomarker survey with the support of partners and urgently investing in national surveillance capacity to measure viral hepatitis. Bridging the data gap requires enhanced cooperation between WHO and its member states, strengthened disease surveillance systems for data collection, the establishment of information systems to monitor progress, integration of disease diagnosis and death registries, and improved data quality.

Based on the new data, there were 295·9 million people living with HBV infection in 2019,[6] 39 million more than estimated in 2017,[4] owing to improved data completeness and quality, and an increase (from 124 in 2018 to 200 in 2021) in the number of countries or territories reporting data.[5] There were 57·8 million people living with HCV infection, 1·3 million less than the previous estimate, which might be related to increases in treatment and cure, and decreases in HCV liver-related mortality.[6] The new data provide evidence that the global target of the Sustainable Development Goals and the GHSS-VH, to reduce HBsAg prevalence to less than 1% by 2020 among children younger than 5 years old, has been met. However, major gaps in data quality or completeness remain in some regions, such as the African and South-East Asia regions. Although HBsAg prevalence was lower in the Americas than in the African region, it is still a major health problem. A birth dose of hepatitis B vaccine and prevention of mother-to-child transmission is a key strategy for the prevention and elimination of HBV and, indeed, the prevention of liver cancer.[13] Furthermore, catch-up vaccination for children and adults at risk should also be considered in high-prevalence countries.

Global targets aim to reduce the number of people newly infected with HBV and HCV by 30% by 2020, and by 90% by 2030.[1] The new data provide updated estimates for new viral hepatitis infections and deaths. It is estimated that 65% of HBV new infections occurred in the African region, in which hepatitis B vaccine coverage is low, and 31% of new HCV infections occurred in the Eastern Mediterranean region, in which HCV prevalence is the highest (1·64%). HCV prevalence in the Eastern

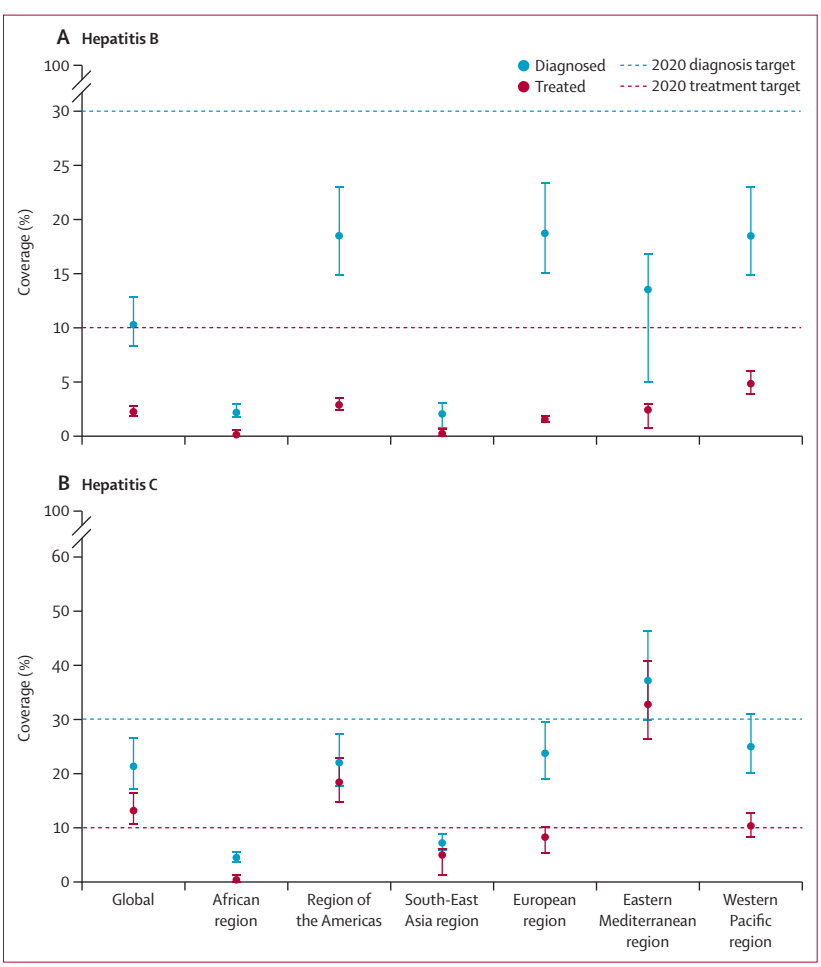

Figure 2: **Estimated diagnosis and treatment coverage of hepatitis B and hepatitis C by region, 2019**
(A) Hepatitis B. (B) Hepatitis C. Circles represent the estimated percentage and error bars represent 95% CIs.

Mediterranean region remains high despite massive efforts made by champion countries such as Egypt, which led to the treatment of 3·5 million people with HCV infection, thereby reducing regional prevalence from 2·30% in 2015 to 1·64% in 2019. Of new HBV and HCV infections globally, the African region accounted for 40% and the Eastern Mediterranean region for 19%, and should therefore be given increased priority to reduce their number of new infections. Regions should provide increased support for member states, and member states should take accountability for reducing new infections and invest in prevention. Primary interventions such as vaccination and health promotion will have a key role in these regions.[14] Given the effectiveness of the hepatitis B vaccine, the expansion of such vaccination for infants, beginning at birth, and for adults at high-risk in the African region, is a priority. For the Eastern Mediterranean region, expanded treatment for HCV infections should be maintained, which in itself will help to reduce new infections and further reduce mortality. Global targets call for a 10% reduction by 2020 in the number of people dying from viral hepatitis B and hepatitis C, and for a 65% reduction by 2030. New estimates showed that 1·1 million people died from viral hepatitis in 2019, which was unacceptably high. This Article provides the first evidence of a global decline in HCV mortality, attributed to highly effective antiviral drugs and universal screening and treatment policies implemented in countries like Egypt. The continued scale up of treatment for HCV infection is crucial to reduce the HCV mortality.[12] Furthermore, countries need to strengthen their mortality data by using death registry or national cancer registry data.

Globally, 90% of HBV infections remain undiagnosed and 98% of HBV infections have not been treated. By contrast, 79% of HCV infections remain undiagnosed, and 87% of HCV infections have not been treated. Treatment for HBV is progressing much too slowly, despite affordable treatments, as is HCV prevention and harm reduction among people who inject drugs. Most viral hepatitis infections are not diagnosed or treated. Price reductions have made HCV treatment an affordable, highly effective intervention, but the 13% coverage needs to increase another five and a half times in the next decade to reach the 2030 target (72%) for elimination,[15] which will require a huge scale up and simplification of diagnosis and treatment.[12] In addition, WHO needs to support reaching the 2025 interim targets and to develop an investment strategy to improve coverage for diagnosis and treatment. In the South-East Asia region and the African region, such coverage is lower than average for both HBV and HCV, and far behind the 2030 target.

In terms of progress in service coverage, there has been remarkable progress in the first stage of expanding access to treatment, with diagnosis coverage reaching 10% for HBV and 21% for HCV. However, early treatment provision appears inadequate, with large inequities in access between countries or regions. The next stage, from 2022 to 2030, requires considerable acceleration,[16] for which improved diagnosis coverage is key, as people with hepatitis B or hepatitis C infection need to know their infection status. Screening costs and testing inefficiencies need to be reduced radically and access simplified. Only the Eastern Mediterranean region has reached the 2020 HCV diagnosis target, and without Egypt, this target would not have been met.[17] All regions should improve disease surveillance, leverage the COVID-19 pandemic response as an opportunity to improve data for viral hepatitis, and make increased efforts to improve diagnosis coverage. Priority should be given to the African and South-East Asia regions, in which diagnosis coverage is far behind the global average.

Only 2% of HBV and 13% of HCV infections have been treated. An accelerated global strategy to improve treatment coverage is needed, which requires national action plans and financial support. All countries should develop tailored policies to improve treatment coverage, develop guidelines, and improve surveillance, to measure progress and better highlight gaps in data quality or completeness.[12] Low-income and middle-income countries still cannot afford the cost of drugs for elimination of viral hepatitis, so access to generic drugs is needed.[18] Countries should invest in the treatment of viral hepatitis to prevent future deaths, and as a cost-saving investment.[19,20]

The COVID-19 pandemic has negatively affected access to screening and treatment for viral hepatitis, owing to mobility restriction rules, inadequate access to health facilities, and other disruptions, so all stakeholders should explore new models of care that address such barrier to access. Telemedicine and self-testing could help maintain treatment provision.[18,21] The decentralisation of care and its integration into primary health-care support has improved access to testing and linkages to care and treatment, and such strategies could expand service accessibility and improve equity and efficacy in health care.[22]

There are limitations to this study. Selection bias because of missing data or unequal probability sampling, and measurement bias due to measurement error in the hepatitis variables, both exist. Furthermore, estimates still suffered from incompleteness and data quality issues, and data on the cascade of care was less complete in the Global Hepatitis Reporting System in 2018 and burden estimates were less accurate than the target set by WHO. Also, available data do not allow for the assessment of new infections among various age groups to inform epidemiological trends. A further limitation is that we estimated prevalence, incidence, and mortality, but did not estimate cirrhosis and cancers caused by viral hepatitis and did not study the natural history of viral hepatitis. Additionally, countries did not report adherence to diagnosis and treatment, so we did not estimate how many people were informed of their

diagnosis and completed treatment. Last, some differences existed between multiple sources of estimates. Given changes over time in data collection methods and sources, we estimated the indicator results using the best methods available at the time; however, methods and sources are still limitations of this study and these issues should be considered in the next strategy for 2022–30.

The strengths of the estimates include improved reporting completeness, the data validation process done by the ministry of health of each country, and validation by a reference group, which increased the reliability of the estimates. In addition, the data are built on the GHSS-VH and are consistent with previous estimates, which made them comparable across time. The new data in 2019 are the baseline for the next decade and will guide development of the new strategy for global, regional, and national implementation. Furthermore, partner-alignment meetings occurred with the Center for Disease Analysis Foundation, the International Agency for Research on Cancer, and the Institute for Health Metrics and Evaluation to reduce the uncertainty, and improve the quality, of estimates.

WHO has been working with member states and partners to eliminate viral hepatitis as a public health threat, through developing strategic information,[1,23] disease surveillance guidelines,[24] testing and treatment guidelines,[25,26] monitoring and evaluating progress,[4,5,23] and providing technical support to countries as needed. Notable progress has been observed. WHO will continue to increase efforts to eliminate viral hepatitis, by: delivering high-quality, evidence-based, people-centred services; optimising systems, sectors, and partnerships for impact; generating and using data to drive decisions for action; engaging empowered communities and civil society; and fostering innovations for impact.

In summary, there has been remarkable global progress towards elimination of viral hepatitis since 2016, and strategic information for action has been strengthened substantially. The new data provide evidence for the baseline for, and the development of, the new global strategy. However, there is no room for complacency. 3 million new infections and more than 1 million deaths are still caused by HBV and HCV each year. Global diagnosis and treatment coverage is still low, with major gaps across regions. Programme services for viral hepatitis were affected by the COVID-19 pandemic, which brought new challenges to the global elimination process. The new global strategy based on the new estimates should be implemented to scale up screening for, and treatment of, viral hepatitis.[15] This strategy considers recent epidemiological, technological, and contextual shifts and identifies opportunities to integrate multiple disease interventions, innovate, implement people-centred health services in all health-care facilities and, ultimately, expand universal health coverage. Achieving the 2030 target requires national accountability and investment in viral hepatitis to fill the gaps in data reporting identified by the improved data, particularly in low-income and middle-income countries.

Contributors

FC, SB, MD, HR, and DL were involved in study concept and design, data analysis, interpretation of data, and drafting of the manuscript. CMM, MAG, ASA, AM, NS, BBR, PC, and LL contributed to data acquisition and provided critical revision of the manuscript. MD, NL, PE, MD, CdM, SN, TBH, and PV were involved in the interpretation of data and provided important guidance for this study. FC, SB, MD, HR, OL, and DL were involved in the final revision of the manuscript. MD and DL supervised the study. CMM, MAG, ASA, AM, NS, BBR, PC, LL, MD, NL, PE, MD, CdM, SN, TBH, PV, and OL had access to and verified the data. All authors had full access to the data and had the final responsibility for the decision to submit for publication.

Declaration of interests

We declare no competing interests.

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Data sharing

All regional data (but not individual country's data) collected for the study can be obtained upon the request to corresponding author. Related documents are in the appendix, including indicators for monitoring the Global Health Sector Strategy on Viral Hepatitis 2016–21 (pp 1, 3) the process to strengthen and simplify reporting at each stage (p 4), and the list of priority countries (p 5).

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