



## Progress towards elimination of viral hepatitis: a Lancet Gastroenterology & Hepatology Commission update

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The top 20 highest burdened countries (in disability-adjusted life years) account for more than 75% of the global burden of viral hepatitis. An effective response in these 20 countries is crucial if global elimination targets are to be achieved. In this update of the *Lancet Gastroenterology & Hepatology* Commission on accelerating the elimination of viral hepatitis, we convene national experts from each of the top 20 highest burdened countries to provide an update on progress. Although the global burden of diseases is falling, progress towards elimination varies greatly by country. By use of a hepatitis elimination policy index conceived as part of the 2019 Commission, we measure countries' progress towards elimination. Progress in elimination policy has been made in 14 of 20 countries with the highest burden since 2018, with the most substantial gains observed in Bangladesh, India, Indonesia, Japan, and Russia. Most improvements are attributable to the publication of formalised national action plans for the elimination of viral hepatitis, provision of publicly funded screening programmes, and government subsidisation of antiviral treatments. Key themes that emerged from discussion between national commissioners from the highest burdened countries build on the original recommendations to accelerate the global elimination of viral hepatitis. These themes include the need for simplified models of care, improved access to appropriate diagnostics, financing initiatives, and rapid implementation of lessons from the COVID-19 pandemic.

### Background

The first *Lancet Gastroenterology & Hepatology* Commission on accelerating the elimination of viral hepatitis was published in 2019.<sup>1</sup> It brought together a broad range of stakeholders to produce recommendations for national and international bodies. Since its publication, there has been substantial progress in many areas, as summarised in table 1. There have also been new challenges, including the COVID-19 pandemic, which has reshaped many areas of global health. One of the key themes of the first report was the focus on national policies, funding, and monitoring of national progress towards elimination goals. It recommended the formation of the Coalition for Global Hepatitis Elimination, which was founded in 2019<sup>2</sup> and has advanced much of this nationally focused agenda, providing a forum for sharing practical and technical expertise and supporting advocacy.

The focus for this Commission is national progress among the 20 countries most heavily burdened with viral hepatitis (figure 1). Burden is not just the total number of hepatitis infections in a population. The Global Burden of Diseases, Injuries, and Risk Factors Study (GBD) 2019 uses disability-adjusted life years (DALYs) as the preferred metric, because they incorporate not only years of life, but also years living with disability, in this case because of chronic infection. DALYs are calculated on the basis of data collated for the GBD 2019 (figures 1, 2). Table 2 summarises key data for the top 20 most heavily burdened countries, ranked in order of modelled DALY burden in 2019. The top 20 most heavily burdened countries account for more than 75% of the global burden of viral hepatitis, such that an effective response

in these countries is crucial if global elimination targets are to be achieved. 17 of the top 20 countries are among the 20 most populous countries in the world, with Myanmar, South Korea, and Ukraine accounting for the other three countries with the highest burden of viral hepatitis.

Working with the Coalition for Global Hepatitis Elimination, this Commission convened national experts from each country to provide an update on progress and data in parallel to the development of detailed national hepatitis elimination profiles. Each author was initially provided with a structured questionnaire (appendix p 1) that aided in developing each update, providing a bottom-up approach to identify key issues and priorities.

### The top 20 most heavily burdened countries

#### (1) China

From 2016 to 2022, the proportion of people living with viral hepatitis in China who have been diagnosed increased from 19% to 24% for HBV<sup>4,6</sup> and from 22% to 33% for HCV (CDA Foundation Polaris Observatory unpublished data). Estimated prevalence of HBV and HCV remained unchanged over the same period, at approximately 6% and 0.9%, respectively. HBV vaccination coverage in 2020 was 96% of the birth-dose and 99% in individuals 3 years and older.<sup>7</sup> The proportion of people living with HBV receiving treatment has improved from 11% in 2016 to 15% in 2022.<sup>4,6</sup> The proportion of people diagnosed with HCV infection receiving treatment increased from 3% in 2016 to 10% in 2020.

Although China has published guidelines for the prevention, management, and treatment of HBV and

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	Actions required	Exemplars of progress
Investments to support countries with greatest burden of viral hepatitis	Recognition of need to focus on high-burden countries and support for national policy development	Egypt received US\$530 million from the World Bank in 2018 for its campaign to eliminate HCV
Funding for national elimination plans	Support national policy makers in their activities (WHO, Unitaid, and non-governmental organisations); provide international support for financing measures (Unitaid, The Global Fund, and bilateral donors)	Launch of the Coalition for Global Hepatitis Elimination <sup>2</sup>
Prevention	Support countries to decriminalise injecting drug use and ensure equitable access to services for all (non-governmental organisations, WHO, and civil society); ensure appropriate funding for HBV vaccines, including birth-dose (Gavi, the Vaccine Alliance, and WHO); support research and development into HCV vaccine development (research funders and pharmaceutical companies)	Commitment from Gavi for funding of birth-dose vaccination paused during the COVID-19 pandemic, but now unpaused <sup>3</sup>
Testing and models of care	Support operational research into simplified care pathways (research funders and Unitaid)	Simplified pathways for HCV care firmly on agenda for HCV self-testing and forthcoming WHO HBV guidelines with emphasis on simplified service delivery
Diagnostics	Ensure access to quality diagnostics through essential diagnostic list and prequalification (WHO and funders); support implementation science for models of care and research and development into novel diagnostics suitable for decentralised settings (research funders, FIND, and industry)	Three new rapid diagnostic tests undergoing prequalification assessment; HCV viral load finger prick test undergoing prequalification assessment (Cepheid); dual antigen and antibody assay (Roche)
Access to treatment	Ensure all essential medicines are prequalified and either available through voluntary licensing or the MPP (WHO, non-governmental organisations, civil society, and funders); support shared procurement mechanisms for treatment (Pan-American Health Organization)	All key hepatitis drugs now available for voluntary licensing (from originator or via the MPP); Clinton Health Access Initiative and the Hepatitis Fund price agreement
Monitor progress	Progress of individual countries needs to be closely monitored towards elimination goals (Polaris, WHO, and creation of elimination index); develop greater capacity for advocacy in high-burden regions (all)	Creation of elimination index to promote national priority setting and comparison of progress across countries with a high burden (Coalition for Global Hepatitis Elimination)

HBV=hepatitis B virus. HCV=hepatitis C virus. FIND=Foundation for Innovative New Diagnostics. MPP=Medicines Patent Pool.

**Table 1: Progress towards the priorities for international action identified as part of the Lancet Gastroenterology & Hepatology 2019 Commission on accelerating the elimination of viral hepatitis<sup>4</sup>**

HCV infections,<sup>8–10</sup> considerable barriers to elimination remain, including insufficient public awareness and education about viral hepatitis, stigma associated with infection, and insufficient resourcing of large-scale testing and treatment initiatives.<sup>11,12</sup> High out-of-pocket drug costs for patients are also an impediment to increasing treatment uptake.<sup>13</sup> However, the implementation of the National Centralised Drug Procurement pilot programme in 2019 reduced the cost of HBV treatment by 90% by 2021 and reduced the cost of HCV direct-acting antiviral (DAA) medications by more than 70%.<sup>14</sup> These cost reductions have facilitated the expansion and simplification of treatment indications for HBV in the latest guidance,<sup>15</sup> and have improved access to HCV treatment.<sup>13</sup>

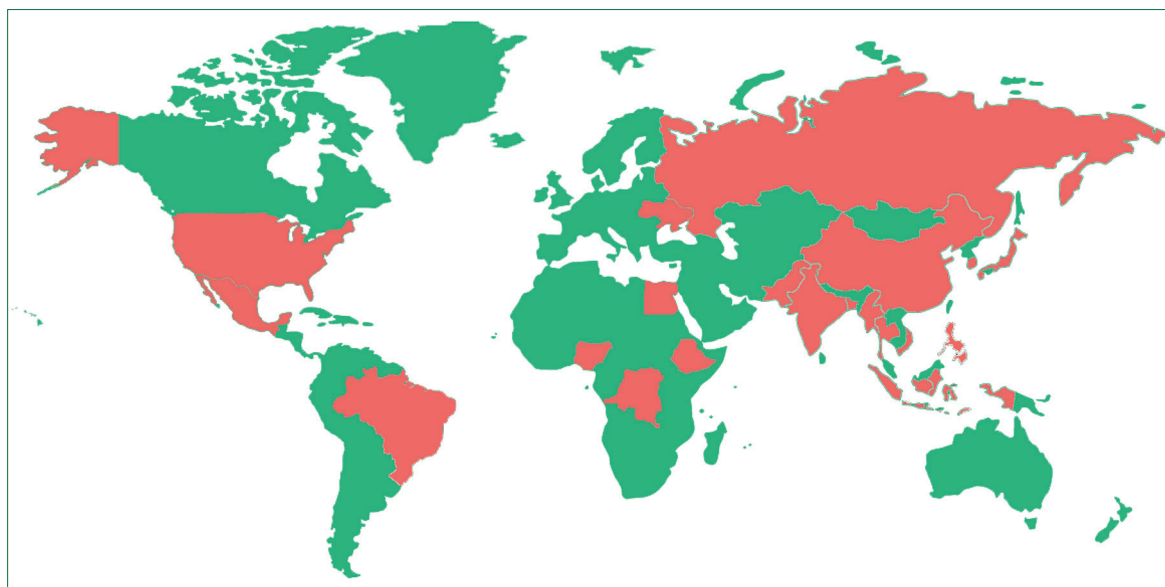
The National Action Plan for Eliminating HCV as a Public Health Threat, released in 2021, focuses on WHO proposals to eliminate HCV.<sup>16</sup> With continued high HBV vaccination coverage and the expansion of viral hepatitis testing and treatment programmes, further progress towards viral hepatitis elimination is expected.

## (2) India

Advances in India have included the launch of the National Viral Hepatitis Control Program (NVHCP)

in 2018, the publication of national treatment guidelines, the expanded delivery of treatment in 844 clinics, and the provision of antiviral drugs at no cost to patients.<sup>17</sup> Progress continues to be made towards WHO elimination targets, with 83% coverage of the three-dose childhood HBV vaccination and 75% coverage of birth-dose vaccination in 2019.<sup>18</sup> An estimated 22·2 million people have been screened for HBsAg and 8 million people for anti-HCV antibodies since 2017, via the NVHCP (Aggarwal R, unpublished data). As of the middle of 2022, of the 176 000 people found to have an HBV infection, 17 000 were receiving HBV treatment. In addition, of 147 000 people found to have an HCV infection, 111 000 commenced HCV therapy (Aggarwal R, unpublished data). NVHCP service coverage data does not include the private sector, where most health care is delivered, and therefore probably underestimates the total number of people accessing treatment.

Preventive measures include routine antenatal HBsAg screening, HBV vaccination of health-care workers, and, in some states, needle and syringe programmes for people who inject drugs. Blood banks screen approximately 10 million people for HBsAg and anti-HCV antibodies annually and communicate results to seropositive donors. However, data to monitor trends



**Figure 1: The 20 countries most heavily burdened with viral hepatitis**

Shown in red are the 20 countries with the highest burden of viral hepatitis on the basis of *The Lancet Gastroenterology & Hepatology* 2019 Commission on accelerating the elimination of viral hepatitis.<sup>3</sup>

in viral hepatitis incidence, prevalence, morbidity, and mortality over the past 5 years are absent.

Barriers to elimination include low public awareness about viral hepatitis screening and transmission routes, and the absence of nationally representative population-based surveys or routine surveillance.<sup>19</sup> Screening and treatment programmes are voluntary instead of mandatory and links to care remain weak. Opportunities to facilitate elimination include investments in HCV RNA testing technology and telemedicine arising from the COVID-19 pandemic. The development of accurate, real-time viral hepatitis surveillance is a major objective of the NVHCP and will further support elimination efforts.<sup>17</sup>

### (3) Indonesia

In the absence of large seroprevalence surveys or routine surveillance, progress towards elimination in Indonesia is hard to quantify. Modelled data from the CDA Foundation Polaris Observatory estimates that in 2022, HBV infection prevalence was 6.4%;<sup>4</sup> the prevalence of HCV viraemia in 2020 was estimated to be less than 1%.<sup>5</sup> A National Action Plan for Hepatitis Control 2020–24<sup>20</sup> focuses efforts on clinically susceptible and at-risk populations (eg, people using dialysis and people who inject drugs). Preventing mother-to-child transmission of HBV has long been a health priority, with the three-dose HBV vaccination introduced in 1997, and the mandatory HBV birth-dose in 2002. However, the country's topography—spread across 17 504 islands with hundreds of different ethnic groups and dialects—challenges timely HBV vaccine delivery to remote rural areas. Consequently, HBV birth-dose coverage remained at

around 84% in 2019.<sup>21</sup> Maternal screening for HBsAg was initiated in 2017, and coverage has improved from around 11% in 2017, to 60% up to in 2022.<sup>22</sup> According to Indonesia's Ministry of Health, birth-dose vaccine and hepatitis B immunoglobulin (HBIG) coverage in infants of mothers positive for HBsAg was 97.8% and 96.9%, respectively, in 2019.<sup>22</sup> However, only 26% of these infants were followed up at 9–12 months, highlighting difficulty in retaining individuals in care.<sup>22</sup> Tenofovir prophylaxis for pregnant women with high HBV viral loads commenced in some provinces in 2021, and has since been expanded into other provinces. Simplified service delivery models are also being implemented, including decentralised HBV testing and treatment to primary care, non-specialist health facilities.

For HCV, the national elimination action plan has not yet been adequately implemented. The government piloted the provision of free generic DAA therapy in seven of 38 provinces in 2017, and this expanded to 31 provinces in 2022.<sup>22,23</sup> Of 10 798 individuals diagnosed with HCV, 9093 were treated with DAAs (in tertiary care centres); 6409 completed treatment, and 2606 had 12-week post-therapy evaluation.<sup>23</sup> Although fixed-dose combination tablets of sofosbuvir–velpatasvir in Indonesia are among the most expensive in Asia, prices of sofosbuvir–daclatasvir are competitive, at around US\$102 for a 12-week course.<sup>24</sup> Major challenges to hepatitis elimination are the implementation of effective HBV and HCV surveillance, scale up of HCV screening in high-risk populations (eg, people who inject drugs, sex workers, and dialysis users), decentralisation of hepatitis services, and increasing public awareness of viral hepatitis.

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See Online for appendix

For more on the CDA Foundation Polaris Observatory see <https://cdafound.org/polaris-countries-dashboard>

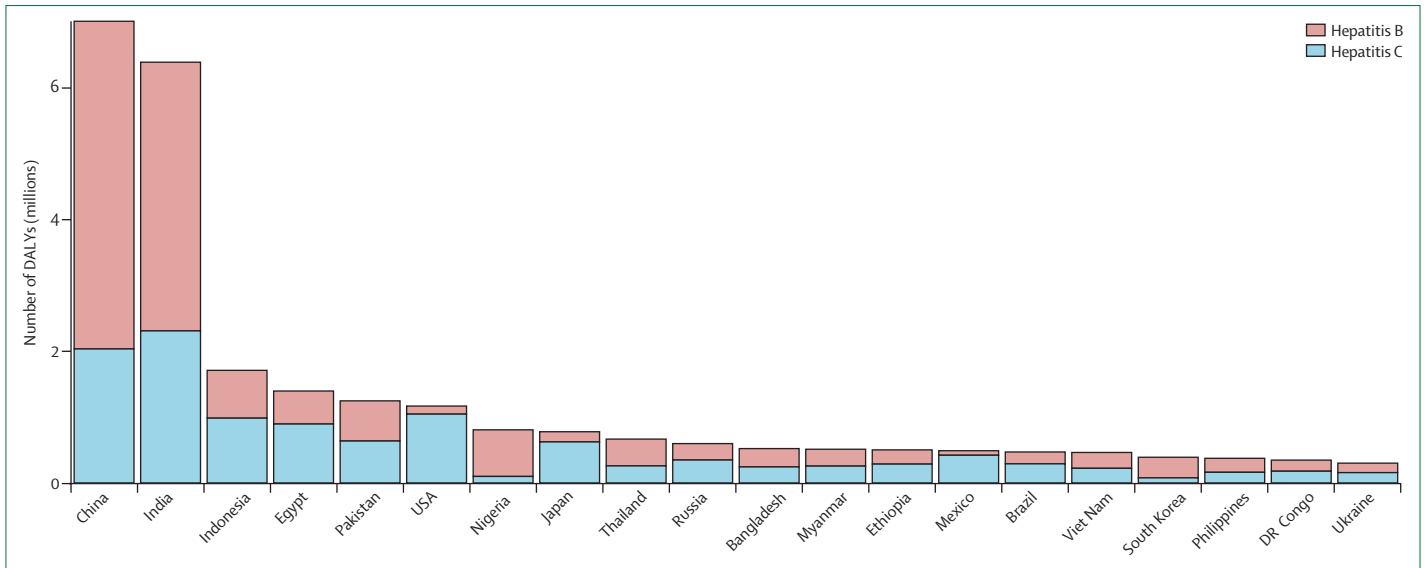


Figure 2: Total DALYs due to hepatitis B and C in 2019 in the 20 countries most heavily burdened by viral hepatitis. Data are from the Global Burden of Disease, Injuries, and Risk Factors Study 2019 estimates. DALYs=disability-adjusted life years.

For more on the 2019 Global Burden of Disease study estimates see <https://vizhub.healthdata.org/gbd-compare/>  
 For more on the Hepatitis Information System see [https://sihepi.kemkes.go.id/hepc/dashboard/dashboard\\_main.php](https://sihepi.kemkes.go.id/hepc/dashboard/dashboard_main.php)

#### (4) Egypt

In 2008, Egypt had the highest seroprevalence of HCV in the general population of any country in the world, estimated at 14.7%.<sup>25</sup> However, Egypt is an exemplar of what can be achieved in lower-middle income settings, as per the World Bank classifications. In 2018–19, a mass screening and treatment programme was implemented (100 Million Healthy Lives) with the aim of screening all adults for HCV, hypertension, and diabetes. It resulted in 49.6 million people being screened for HCV and a further 1.6 million people treated by 2020, with 96% of those infected now estimated to be diagnosed.<sup>26</sup> The programme is estimated to have reduced the HCV viraemic prevalence in Egypt to 0.4%.<sup>27</sup> This reduction has coincided with marked reductions in HCV incidence, from 610 new infections per 100 000 people in 2005, to an estimated ten new infections per 100 000 people in 2020, and a reduction in HCV-related deaths from 30 000 in 2015, to 18 000 in 2020.<sup>27</sup>

However, similar reductions in HBV during the same timeframe have not been possible, with prevalence remaining static at around 0.9% between 2015 and 2020; the estimated HBV-related mortality rate in 2020 was 1.3 per 100 000 population.<sup>28</sup> This discrepancy between the HCV and HBV responses is apparent in low diagnosis rates and treatment uptake for HBV (10–15% diagnosed, of whom 25% are receiving treatment) compared with HCV (95% diagnosed, of whom >90% are already treated, with a further 10 000 still being treated annually<sup>27</sup>).

To improve the management of both infections, children and adolescents aged 6–18 years were given access to HCV treatment and the HBV birth-dose vaccination was implemented in 2016 (90% coverage by 2019<sup>29</sup>). The introduction of universal screening for pregnant

women aims to screen 2.5 million women for HCV and HBV annually. As of 2019, HBV treatment has become state-subsidised.<sup>30</sup> Although improvements have occurred, criminalisation of drug use and insufficient access to harm reduction services (eg, needle and syringe programmes), remain crucial barriers to reducing the burden of viral hepatitis in Egypt. Opportunities for improving progress towards elimination include increased targeted screening for HBV in high-prevalence regions (south of the Nile Valley, such as Qena, Luxor, and Aswan) and among populations at highest risk (eg, people who inject drugs and patients using dialysis) and state-funded HBV treatment.

#### (5) Pakistan

The most recent CDA Foundation Polaris Observatory prevalence estimates in Pakistan were 1.6% for HBV (2022) and around 3% for HCV (2020).<sup>4,5</sup> However, epidemiological surveys from Punjab and Sindh in 2020–21 indicate HBsAg prevalence might be lower (approximately 1%).<sup>31</sup> The incidence of HCV is rising: as of 2023, Pakistan has more than 10% of the global burden of HCV<sup>32</sup> and it is estimated a third of new HCV infections globally occur in Pakistan, with most infections apparently resulting from health-care related exposures.<sup>31</sup>

Uptake of the three-dose HBV vaccination in infants younger than 1 year is low (83–86%)<sup>33,34</sup> and HBV treatment is also minimal, with approximately 2% of people with HBV receiving treatment annually via the public sector.<sup>35</sup> Approximately 22% of people living with chronic HCV infection were tested by 2020, and approximately 215 000 were treated in 2020.<sup>36</sup> Encouragingly, testing and treatment is free, and with access to locally manufactured

For more on the **Taskforce for Global Health and Coalition for Global Hepatitis Elimination** see <https://www.globalhep.org/countryregions-data-dashboards>

Population	Population ranking	Nominal GDP (global ranking)	World Bank Classification of economy	Number of people who are HBsAg positive	HBsAg prevalence	Proportion of population with HBV diagnosed	HBV deaths per year	HBV DALYs	Number of people with HCV viraemia	HCV prevalence	Proportion of population with HCV diagnosed	HCV deaths per year	HCV DALYs	Combined HBV and HCV DALYs
China	1	19 373 586 (2)	Upper middle	79 747 000	5.6%	24%	401 000	4 979 058	9 487 000	<1%	25%	51 927	2 035 683	7 014 741
India	2	3 736 882 (5)	Low middle	29 764 000	2.1%	2%	81 900	4 082 215	6 137 000	<1%	4%	27 946	2 310 156	6 392 371
Indonesia	4	1 391 778 (16)	Low middle	17 544 000	6.4%	3%	51 100	726 398	1 364 000	<1%	12%	6 033	984 315	1 710 713
Egypt	14	378 110 (41)	Low middle	3 800 736	0.9%	3%	19 190	501 700	531 000	<1%	64%	32 94	895 021	1 396 721
Pakistan	220 425 254	376 493 (42)	Low middle	37 960 000	1.6%	29%	12 400	610 163	7 395 000	3.3%	27%	25 836	637 172	1 247 334
USA	334 951 000	26 854 599 (1)	High	1 646 000	<1%	20%	3 100	122 498	2 494 000	<1%	39%	12 423	1 045 700	1 168 197
Nigeria	218 541 000	506 601 (32)	Low middle	14 441 000	6.6%	<1%	26 700	708 162	1 362 000	<1%	5%	5 484	98 685	806 847
Japan	124 500 000	4 409 738 (3)	High	949 000	<1%	62%	7 100	155 088	562 000	<1%	87%	10 884	622 776	777 864
Thailand	68 263 022	574 231 (27)	Upper middle	1 838 000	2.6%	12%	12 800	407 723	378 000	<1%	25%	19 666	258 247	665 969
Russia	146 424 729	2 062 649 (11)	Upper middle	1 651 000	1.1%	30%	11 500	237 653	4 255 000	2.9%	43%	5 502	356 480	594 133
Bangladesh	169 828 911	420 516 (37)	Low middle	7 865 325	5%	<1%	23 400	278 925	1 019 000	<1%	NR	8 296	243 371	522 296
Myanmar	55 770 232	63 988 (90)	Low middle	4 376 047	8%	<1%	7 900	256 334	993 500	2%	NR	6 829	256 038	512 373
Ethiopia	105 163 988	156 083 (59)	Low	7 793 000	6.3%	5%	9 600	215 942	684 000	<1%	5%	3 068	286 234	502 176
Mexico	128 665 641	1 663 164 (14)	Upper middle	117 000	<1%	11%	430	68 854	751 000	<1%	12%	2 953	420 886	489 740
Brazil	203 062 512	2 081 235 (10)	Upper middle	1 039 000	<1%	34%	2 000	180 112	604 000	<1%	22%	27 011	290 133	470 245
Viet Nam	99 460 000	449 094 (34)	Low middle	6 520 000	6.6%	42%	25 400	240 613	914 000	<1%	7%	4 041	222 519	463 132
South Korea	51 439 038	1 721 909 (12)	High	1 379 000	2.7%	82%	10 300	313 344	90 000	<1%	12%	1 081	77 114	390 458
Philippines	110 820 018	440 901 (36)	Low middle	5 660 000	4.9%	11%	23 600	212 649	439 000	<1%	20%	2 908	161 865	374 514
DR Congo	99 010 000	69 474 (87)	Low	2 785 000	2.8%	2%	4 100	168 517	418 000	<1%	13%	2 675	178 302	346 819
Ukraine	41 130 432	148 712 (60)	Low middle	505 000	1.3%	9%	1 400	144 035	1 342 000	3.1%	7%	7 890	156 656	300 691

**Table 2: HBV and HCV data from the top 20 most heavily burdened countries in order of highest number of DALYs due to viral hepatitis**

With the exception of Egypt, Myanmar, and Bangladesh, data for HBV infections and proportion diagnosed are from 2022; data for HCV infections and proportion diagnosed are from 2020.<sup>1</sup> Estimates for Egypt, Myanmar, and Bangladesh, where available, are taken from the Taskforce for Global Health and Coalition for Global Hepatitis Elimination. Deaths and DALY estimates are derived from the Global Burden of Diseases, Injuries, and Risk Factors Study 2019 estimates of prevalence and deaths (figure 2). GDP=gross domestic product. HBV=hepatitis B virus. DALYs=disability-adjusted life-years. HCV=hepatitis C virus. NR=not reported.

generic HCV DAAs, treatment uptake has increased (eg, from approximately 134 000 people in 2015, to around 434 000 people in 2019).<sup>37,38</sup> Precise epidemiological data on HBV and HCV are scarce, with scant data available from the private sector.<sup>33,38</sup> In 2017, the Government of Pakistan launched its National Hepatitis Strategic Framework (2017–21),<sup>39</sup> and continued work is needed on the widespread scale up of HBV and HCV testing and treatment strategies nationally.<sup>40,41</sup> Both HBV and HCV testing and treatment are entirely decentralised to primary care. Ambitious targets have been set to test 50% of the eligible population by 2025; however, core interventions, such as testing blood products for HBV, HCV, and HIV must be strengthened.

Several strategies are available to enhance viral hepatitis care, namely, the use of novel COVID-19 infrastructure for surveillance, vaccination, testing, and treatment. Increased engagement with the private sector (including improved access to data); focused attention on marginalised populations with a high burden of viral hepatitis, especially people who inject drugs; and evaluation and monitoring of the National Hepatitis Strategic Framework's activities.

#### (6) USA

In the USA, acute cases of HBV remain uncommon, with an estimated 20 700 acute cases in 2019, followed by a drop to approximately 14 000 new cases in 2020, possibly as an artefact of the COVID-19 pandemic.<sup>42,43</sup> People affected by HBV are primarily not born in the USA, with overall prevalence estimates of chronic HBV infection for 2013–18 at approximately 880 000 people (0.3% of non-institutionalised people [people who are not incarcerated, living in institutions, or experiencing homelessness] older than 6 years).<sup>44</sup> HBV-related mortality was estimated at 0.45 per 100 000 people in 2020.<sup>45</sup> Only 32% of people estimated to have a chronic HBV infection are diagnosed, strengthening support for enhanced testing strategies.<sup>44</sup>

Acute HCV infection increased by 97% between 2015 and 2020 (from 33 900 to 66 700, respectively), largely driven by the opioid epidemic.<sup>43</sup> Before DAAs, approximately 50% of people were aware of their anti-HCV antibody status, 27% received HCV RNA testing, and 16% were treated.<sup>46</sup> Estimates from 2014 to 2022 suggest that an increasing proportion of the population are diagnosed and RNA tested (63%), but treatment of those with chronic HCV remains low (34%).<sup>47</sup> In 2020, only 83 740 of more than 2 million people with chronic HCV were treated, a sharp reduction from 2015, when 164 232 people were treated.<sup>48</sup> Nonetheless, HCV-related mortality declined from 2015 to 2020 (from 4.9 to 3.5 per 100 000 people, respectively).<sup>43</sup>

Greater access to harm reduction services is required to reach WHO elimination targets,<sup>49</sup> and a greater focus on reaching people who inject drugs would be beneficial, including universal opt-out HCV testing in correctional

settings and the provision of free antiviral drugs.<sup>50</sup> The previously mentioned low uptake of new DAA prescriptions in 2020 indicates that progress is slow.<sup>48,51</sup> However, there have been successes since 2015, including micro-elimination strategies for HCV effectively implemented among First Nations and military veteran populations, reductions in cirrhosis incidence among high-risk populations, such as people who inject drugs, and reduced reimbursement restrictions for accessing HCV therapies.<sup>52–54</sup> In its 2024 fiscal year budget proposal, the Biden–Harris administration has put forward a US\$12.3 billion, 5-year programme to put the nation on course to eliminate hepatitis C. The proposal focuses on point-of-care diagnostics, affordable treatment, and comprehensive public health outreach.<sup>55</sup>

#### (7) Nigeria

CDA Foundation Polaris Observatory estimates for Nigeria suggest the prevalence of HBV is 6.6% (2022) and that for HCV is less than 1%.<sup>45</sup> Despite national viral hepatitis guidelines released in 2016, related mortality has risen from 19 700 (95% uncertainty interval 13 700–28 400) in 2016, to 20 200 (13 500–29 600) in 2019.<sup>56</sup> In 2018, HBV birth-dose vaccination coverage was estimated to be 53%.<sup>57</sup> By the end of 2019, treatment for viral hepatitis remained inadequate, with only 2% of individuals infected with HBV and 1% of those infected with HCV having received treatment. As of 2023, publicly funded testing and treatment is not available, such that viral hepatitis care is paid for mostly out-of-pocket. Furthermore, funding to support diagnosis and treatment is scarce, adversely affecting the implementation of the country's hepatitis guidelines. Low public awareness, insufficient diagnostic capacity, emigration of trained personnel, inadequate vaccine uptake, and the high cost of treatment all hinder progress towards viral hepatitis elimination.

Despite these considerable barriers, the increased availability of data over the past 5 years—including data from a 2018 nationwide survey<sup>58</sup>—have enabled enhanced advocacy and treatment promotion efforts. In 2018, patient groups partnered with the Federal Ministry of Health to convene the first Nigeria Hepatitis Summit to enhance advocacy and foster collaboration towards national viral hepatitis elimination. There is now a new national strategic framework for viral hepatitis control,<sup>59</sup> the national viral hepatitis guidelines and surveillance indicators are being updated, and four Nigerian states have established plans for the statewide elimination of viral hepatitis (eg, Nasawara state, supported by the Clinton Health Access Initiative, has developed an HCV elimination plan).<sup>60</sup> These efforts have benefited from increased political commitment and public awareness and the increased diagnostic capacity resulting from the COVID-19 pandemic. There is a need to expand training in viral hepatitis to all health-care workers, to improve birth-dose HBV vaccine delivery outside of

public health facilities, and to work with communities to reduce stigma around infection. Further partnerships and bulk purchasing agreements can be leveraged to reduce the cost of viral hepatitis diagnosis and treatment, and enable the national health insurance scheme to cover free access to care.

### (8) Japan

Japan has long been a success story in its efforts to eliminate viral hepatitis. The number of people estimated to be living with HBV fell from 1.11–1.19 million in 2015, to 1.00–1.07 million in 2020; the number living with HCV also decreased from 0.89–1.30 million to 0.47–0.84 million over the same period.<sup>61</sup> Decentralisation of hepatitis screening, surveillance, and treatment to the prefecture level has played a major role in this success.<sup>62</sup> More than a million individuals access free HBV and HCV screening each year through local health centres, as Japan approaches its goal of ensuring everyone in the population is tested at least once in their lifetime.<sup>62</sup> In 2016, HBV prevention shifted from targeted vaccination of infants of mothers with an HBV infection, to universal vaccination at birth, and HBV prevalence in children younger than 5 years is estimated to have dropped from 0.2% (95% CI 0.0–0.4) in 2010, to 0.08% (0.06–0.10) in 2019.<sup>63</sup>

However, although previous modelling indicated Japan was on track to achieve WHO elimination targets, treatment data from 2016 indicate that achieving those goals might be more challenging than expected.<sup>64</sup> The number of patients treated annually for HBV remains static,<sup>62</sup> and the number of people commencing DAAs for HCV fell from 90 000 in 2015, to less than 30 000 in 2018, before rising again in 2019 to around 90 000.<sup>65</sup> The main obstacle is still identifying cases and linking individuals with an infection to care: it is estimated that 28% and 56% of people living with HBV and HCV, respectively, remained undiagnosed in 2020, and among those diagnosed, only around two-thirds attended follow-up.<sup>66</sup> The Basic Act on Hepatitis Control from 2009 was revised in 2022 with the aim of completely overcoming viral hepatitis.<sup>67</sup> The report specifies promotion of testing and follow-up, reducing barriers to referral and treatment, and further promoting local autonomy in facilitating access to care.

### (9) Thailand

There is a considerable burden of HBV and HCV in Thailand, with an estimated prevalence of 3.2% and 1.1%, respectively, in 2017.<sup>68</sup> Modelling data from the CDA Foundation Polaris Observatory suggest an HBV prevalence of 2.6% (2022) and of less than 1% for HCV (2020).<sup>4,5</sup> Additional epidemiological data, including the incidence of new infections, and the proportion of people screened and treated annually, are insufficient. In 2023, Thailand launched a universal screening programme for HBV and HCV for individuals born

before 1992.<sup>69</sup> Thailand's successful incorporation of HBV immunisation into the childhood vaccine schedule (begun in 1992) has led to sustained control of mother-to-child transmission, with prevalence of HBV infection among children younger than 5 years remaining lower than 1% since 1999.<sup>70</sup> There are few data on the proportion of those living with HBV and HCV who have been diagnosed (estimated to be approximately 12% of people with HBV in 2022 and 25% of people with HCV in 2020).<sup>4,5</sup> Approximately 15 000 people (1.9%) receive HCV treatment annually,<sup>67</sup> but restrictive treatment criteria and reimbursement restrictions affect those who are able to receive treatment.<sup>71</sup> There are no available data on the proportion of people with HBV who are receiving treatment but birth-dose HBV vaccination coverage is high, at more than 99%.<sup>72</sup>

In 2022, Thailand developed National Strategies to Eliminate Viral Hepatitis, which have committed to regional recommendations aligned with global goals, and several initiatives over the past 3 years will improve progress towards viral hepatitis elimination. These include the addition of a pan-genotypic HCV treatment regimen (sofosbuvir–velpatasvir) to Thailand's National List of Essential Medicines and the removal of barriers to reimbursement for treatment.<sup>73,74</sup> The use of tenofovir to prevent vertical transmission of HBV is also now recommended in national guidelines.<sup>70</sup> Several studies have assessed novel strategies to address viral hepatitis, including simplified testing,<sup>75</sup> the use of telemedicine,<sup>70</sup> and prison-based HCV microelimination strategies.<sup>76,77</sup> Despite these efforts, ongoing systemic barriers to viral hepatitis elimination exist, including insufficient screening and surveillance, complex care pathways, and considerable restrictions for the receipt of treatment. Simplification of care models and expansion of the population eligible for treatment could improve progress towards elimination.

### (10) Russia

Routine epidemiological surveillance of HBV and HCV began in Russia in the early 1990s and a federal register of patients with viral hepatitis was introduced in 2012.<sup>78</sup> According to modelled data, the prevalence of HBV in 2022 was 1.1% and the prevalence of HCV in 2020 was estimated at 2.9%.<sup>4,5</sup> The incidence of acute and chronic viral hepatitis has steadily decreased in the past 5 years, but varies greatly by region. Overall, in 2019, 0.6 acute cases of hepatitis B and 1.0 acute cases of hepatitis C were registered per 100 000 people (a total of 2300 cases).<sup>79</sup>

Targeted three-dose vaccination against HBV began in 1997, and universal birth-dose vaccination began in 1998. Mass immunisation programmes for adolescents were initiated in 2001, and for adults younger than 55 years in 2007.<sup>80</sup> Coverage with three doses of HBV vaccine for children younger than 1 year has exceeded 95% since 2004, but has declined in some regions due to parent

refusal.<sup>81</sup> The total number of Russian residents vaccinated against HBV at the end of 2020 was 107·3 million people (73% of the population).<sup>82</sup>

National clinical guidelines for the prevention, diagnosis, and treatment of hepatitis B and C in adults and children have been approved by the Ministry of Health.<sup>83–88</sup> The national screening programme is funded by the government and includes all blood donors, pregnant women (in the first and third trimesters), medical staff, patients with chronic diseases, and other groups. Up until 2020, more than 17 million people (about 12% of the population) were being tested for HBV and HCV annually.<sup>82</sup> However, HCV treatment uptake has been restricted by the high cost of DAAs and most patients are unable to pay out-of-pocket. A national action plan for HCV has been approved by the government and aims to raise public awareness, improve surveillance, decentralise treatment, and optimise hepatitis care.<sup>89</sup> Barriers to elimination are the high cost of treatment and insufficient public awareness of the problem. Rigorous evaluation of the social and economic burden of viral hepatitis will expedite the implementation of additional programmes for HCV microelimination.

### (11) Bangladesh

In 2019, Bangladesh achieved success in efforts to eliminate HBV—as defined by WHO—with prevalence estimates of less than 1% among children aged 5 years, due to high rates of childhood immunisation, although coverage of birth-dose vaccination is poor.<sup>90</sup> Modelled estimates of HBV-related mortality vary from around 6000 deaths per year to 12000 deaths per year.<sup>90</sup> There is insufficient surveillance data on HCV; estimates of prevalence are approximately 0·6%, with an estimated 8296 deaths per year attributed to HCV in 2019.<sup>90</sup> All medical institutions are required to screen for HBV in all pregnant women and in patients who undergo hospitalisation, surgery, haemodialysis, and invasive diagnosis or treatment.<sup>91</sup> However, low numbers of trained medical staff and laboratory facilities and historically limited funding for viral hepatitis control initiatives has made progress towards WHO 2030 targets challenging.

In the past 5 years, Bangladesh has made substantial progress: more than 5000 government-based physicians (approximately 10%) have received training in the management of viral hepatitis, the majority of health-care providers working in government colleges have been vaccinated, and government-led strategies to increase HBV vaccinations among the adult population have commenced. Additionally, initiatives to raise public awareness of viral hepatitis have occurred, with the Prime Minister delivering an annual address on World Hepatitis Day. The national government's response to the COVID-19 pandemic has also instilled opportunities for growth in the viral hepatitis field. Specifically, an expansion of PCR laboratories across the country has meant improved infrastructure for viral hepatitis testing

and greater government attention to the delivery of health-care services (from primary to tertiary settings) has created possibilities for new models of care.

Key priorities are a need to strengthen awareness of the burden of hepatitis among the public and non-governmental organisations; improve coverage of HBsAg testing in pregnant women; include the HBV birth-dose vaccination in national immunisation programmes; and remove co-pays for HBV and HCV testing and treatment to reduce out-of-pocket costs for populations at high risk of hepatitis infection.

### (12) Myanmar

A 2019 national cross-sectional serosurvey of 64193 adults in Myanmar done by a non-governmental organisation found HBsAg prevalence to be 5·5% and HCV antibody prevalence to be 3·1% (Cooke G S, personal communication). These percentages are more than double the GBD-modelled estimates,<sup>92</sup> indicating that Myanmar might be further from elimination targets than previously thought. A national surveillance system with HCV care cascade data has been initiated but is not yet fully implemented. HBV birth-dose vaccination was greater than 90% before the COVID-19 pandemic, but fell to 82% in 2020, and 37% in 2021, before recovering to 70% in 2022.<sup>93</sup>

Blood donor and antenatal screenings remain free of charge, but HBV and HCV monitoring and treatment must be paid for out-of-pocket. Antiviral prices have decreased over the past 5 years, such that a 12-week course of sofosbuvir–daclatasvir in 2023 costs US\$150,<sup>94</sup> which is less expensive than most countries in southeast Asia.<sup>94</sup> In 2017, the National Hepatitis Control Programme (NHCP) launched an HCV initiative in eight states and regions.<sup>95</sup> 11000 individuals were started on treatment either free of charge or through subsidised public–private partnerships from 2017 to 2019, with plans for annual incremental expansion.<sup>96</sup> However, the COVID-19 pandemic and political unrest have resulted in restricted health service functions, and although this has accelerated decentralisation of care to general practitioners, viral hepatitis initiatives have inevitably been deprioritised.

As of 2023, HCV testing and treatment rates are insufficient to meet national HCV targets of 50% diagnosed and 50% treated by 2030, for which around 55000 people will need to be treated each year. Without scale up, 333000 new HCV infections and 97000 HCV-related deaths are projected to occur from 2020 to 2030.<sup>97</sup> Long-term needs include political commitment and public awareness and, in the short term, regional free treatment programmes cofunded by the NHCP and international non-governmental organisations remain the optimal path to progress.

### (13) Ethiopia

Despite the release of the second National Strategic Plan for Prevention and Control of Viral Hepatitis in 2021,<sup>98</sup>



the prevalence of both HCV and HBV in Ethiopia remains high, with a dearth of epidemiological data to effectively address the burden of disease.<sup>98</sup> In 2016, the prevalence of infection was estimated to be between 7.3% and 9.4% for HBV,<sup>99</sup> and a 2021 review found seroprevalence of HCV to be 2%.<sup>100</sup> No data are available on the incidence of new HBV or HCV infections. Annual deaths attributed to HBV and HCV are estimated to be 6300 and 9400, respectively, although no official measurements of mortality are available.<sup>101</sup> Testing and treatment data are also unavailable, with no data on annual HCV or HBV screening rates or on the number of people who receive HBV and HCV treatment. The proportion of people who are infected who are diagnosed is estimated to be approximately 10% for both HBV and HCV (CDA Foundation Polaris Observatory; unpublished data).

The lack of epidemiological data is a major barrier to progressing towards viral hepatitis elimination and highlights the need for national survey data to develop testing and treatment programmes. Inadequate funding for viral hepatitis programmes has also limited progress towards elimination targets. Although the transfer of viral hepatitis from the non-communicable disease programme to the HIV programme in 2021 has resulted in improved sharing of resources and funding,<sup>102</sup> it will take time for this to practically affect the hepatitis response. Furthermore, the high out-of-pocket cost of testing and treatment has substantially reduced Ethiopia's ability to address the burden of disease. Despite these barriers, there has been an increased commitment to address viral hepatitis with the release of a new strategic plan in 2021,<sup>98</sup> the distribution of national training guidelines for viral hepatitis, and the implementation of several pilot studies to increase HBV vaccination and treatment.

#### (14) Mexico

In Mexico, the National System of Epidemiological Surveillance reported just 483 newly diagnosed cases of HBV infection in 2021,<sup>103</sup> which is an underestimation of transmission that highlights imperfect surveillance in the absence of a centralised registry. The National Centre of Blood Transfusion noted that from 2000 to 2012, the prevalence of HBV in donated blood decreased from 0.47% to 0.15%, although populations at high risk of hepatitis infection (people with hepatic illnesses, a history of using injection drugs, or high-risk sexual behaviours—eg, sex workers) are excluded from giving blood.<sup>104</sup> Although universal and mandatory HBV vaccination at birth has been implemented in Mexico since 1999, the COVID-19 pandemic resulted in a reduction in coverage. In 2020–21, only 49–60% of newborns received their first HBV dose within 24 h of birth, compared with 99% in 2018.<sup>105</sup> Over the same time period, the coverage of a three dose HBV vaccine was 79–91%.<sup>105,106</sup> There are no robust data on the number

of people screened for HBV or receiving treatment. Several strategies can help to reduce HBV burden, the top priority of which is a national action plan addressing the genomic, cultural, ethnic, and environmental factors that drive the hepatitis epidemic in the Mexican Mestizo and Amerindian populations and distinguish Mexico from other countries of similar size or gross domestic product.<sup>107</sup> An improved health budget, broader vaccination coverage, enhanced prenatal screening, a centralised reporting registry, and increased educational programmes for health-care providers are also urgently required.

In 2021, there were a reported 2666 newly diagnosed cases of HCV infection, equating to an estimated incidence of 2.0 per 100 000 people.<sup>103</sup> As with HBV, this underestimates the true burden of disease. In 2019, the Ministry of Health released a National Action Plan for Hepatitis C Control 2020–24 in conjunction with the National Centre for the Prevention of Control of HIV.<sup>108</sup> This coordinated national response plan ensures free access to HCV screening, diagnosis, and treatment; a primary health-care approach to hepatitis care (eg, pragmatic decentralised assessment of liver fibrosis with fibrosis-4 scoring); a telementoring network of specialists to support and train primary care practitioners (approximately 120 000 health workers enrolled); and a universal online registry for patients with HCV.<sup>109</sup> The number of health centres providing free DAA therapy for patients with HCV expanded from 17 units in 2019 (in 11 of 32 states), to 394 units (in all 32 states) by 2022.<sup>105</sup> National centralised drug procurement since 2019 has reduced DAA acquisition costs by 52% and, as of 2023, both sofosbuvir–velpatasvir and glecaprevir–pibrentasvir are included in the list of essential medicines.<sup>108</sup> HCV treatment access has been further broadened by the removal of restrictions to reimbursed therapies (eg, no liver disease stage restrictions). Ongoing monitoring of these HCV initiatives will ensure continued political and financial support and hopefully serve as a successful approach to be extended to HBV.

#### (15) Brazil

Between 2000 and 2022, 276 646 new HBV diagnoses and 298 738 HCV diagnoses were reported to the Brazilian National Health System.<sup>110–112</sup> HBV incidence was estimated at 4.3 cases per 100 000 people in 2022, a substantial decrease from 2011 (8.4 cases per 100 000 people).<sup>110–112</sup> HCV incidence has also decreased since 2015, with 6.6 estimated new cases per 100 000 people in 2022, compared with 12.5 estimated cases per 100 000 people in 2015.<sup>110–112</sup> To identify people with an undiagnosed infection, the Ministry of Health provides free point-of-care testing for all individuals older than 20 years, which has resulted in approximately 8 million rapid tests for HBV and HCV being distributed annually.<sup>110–112</sup>

The Brazilian public health system provides free HBV and HCV treatment, but as of 2023, only

approximately 40 000–50 000 people receive HBV treatment annually, which is less than 25% of the people who require treatment.<sup>113</sup> Official government figures indicate that approximately 61 000 HCV DAA treatment courses were distributed nationally between January, 2019, and September, 2020. However, only 19 219 people were treated in 2020.<sup>113</sup> This discrepancy probably resulted from a reduction in HCV diagnoses and referrals during the COVID-19 pandemic. The devastating effects of the pandemic in Brazil are well documented, with reallocation of health professionals, closure of outpatient clinics, and altered health-care seeking behaviours all jeopardising the Brazilian plan for eliminating HCV by 2030.<sup>114</sup> According to the Brazilian National HCV Elimination Plan, 154 811 individuals have been treated for HCV since October, 2015, equating to 27% of their 2030 elimination target. Originally, the elimination plan had estimated that 40% of the elimination target would be achieved by the end of 2022.<sup>110–112</sup> Advances include the incorporation of tenofovir alafenamide as a second-line HBV therapy for people with contraindications to tenofovir disoproxil fumarate or entecavir, and several microelimination strategies targeted to populations at risk of HBV and HCV transmission (eg, people experiencing homelessness, men who have sex with men, and people who are incarcerated). A national strategy that incorporates the use of existing infrastructure for HIV diagnosis and treatment could further advance this goal by, for example, providing antiviral drugs at local pharmacies.<sup>113</sup>

#### (16) Viet Nam

Viet Nam is one of the top five fastest growing economies in the world and has increasingly channelled resources towards viral hepatitis elimination.<sup>115</sup> However, greater attention is needed; HBV prevalence was estimated to exceed 9% in 2021<sup>115,116</sup> and HBV-related mortality continues to climb.<sup>117</sup> Despite an immunisation campaign at district obstetric facilities, HBV birth-dose vaccination coverage remains lower than WHO targets, at around 80% nationally in 2021.<sup>115</sup> There are no data from the past 5 years on the HBV cascade of care, but in 2017, WHO estimated 1·34% of patients eligible for treatment were on antiviral therapy.<sup>118</sup> HBV antivirals (for all those needing treatment) have been covered by government insurance since 2015, but passive immunisation of newborns of mothers who are HBsAg positive must still be paid for by parents or guardians.<sup>119</sup>

HCV prevalence in the general population might be lower than previous estimates (0·26%, 95% CI 0·09–0·51),<sup>116</sup> but HCV antibody prevalence among people who inject drugs (72·5%, 71·4–73·6)<sup>116</sup> is far higher than the estimated global average (52·3%, 42·4–62·1).<sup>120</sup> The availability of opioid agonist therapies and needle and syringe programmes has expanded since 2015<sup>121</sup> and DAA therapy has been subsidised by 50% since 2019, but individuals still need to pay

hundreds of dollars for HCV screening and treatment. DAA costs remain high compared with other countries in the Western Pacific region (>US\$900 for 12 weeks of sofosbuvir–velpatasvir or sofosbuvir–daclatasvir in 2022),<sup>24</sup> despite generic options being available.

A new national action plan for 2021–25 is funding improved surveillance and screening, promoting HBV vaccination, optimising health-care safety, and implementing harm reduction services.<sup>115</sup> Thus far, newly established online surveillance has been hampered by technical shortcomings and little progress at the district level, recording just 52 086 cases of HBV and 6792 cases of HCV by the end of 2019.<sup>115</sup> Improved awareness of the scale of the problem is required to implement an ambitious elimination strategy.

#### (17) South Korea

In 2019, estimates indicated that HBsAg prevalence (in people 10 years or older) was 2·0% in South Korea, a substantial decrease from 3·1% in 2015.<sup>122</sup> New diagnoses of HBV infection have remained constant, with 391 reported HBV infections in 2017 and 382 in 2020.<sup>123</sup> Approximately 262 000 people received HBV treatment in 2019.<sup>123</sup> Since 2002, South Korea has had considerable success with its nationally led prevention of HBV perinatal transmission initiative; approximately 98% of children born in 2019 received HBV birth-dose vaccination.<sup>122</sup> Between 2012 and 2016, data from the Korea National Health and Nutrition Examination Survey showed that HCV antibody prevalence (in people older than 10 years) was 0·66% and HCV RNA prevalence was 0·22%.<sup>124</sup> In 2019, the crude estimate for HCV incidence was 17·2 per 100 000 person-years.<sup>125</sup> There have been no liver disease-based restrictions to DAA therapy reimbursement since 2015, when the drugs first became available in South Korea—helping to broaden HCV treatment access.<sup>126</sup> In 2019, among people recently diagnosed with HCV infection, approximately 58% received HCV treatment.<sup>127</sup>

The Korean Association for the Study of the Liver in collaboration with the Korean Disease Control and Prevention Agency have set national targets to eliminate HBV (antibody target of 1%; treatment uptake 95%) and HCV (antibody target of 0·3%; treatment uptake 90%).<sup>128</sup> To reach these targets, additional efforts will be needed to increase general HCV awareness and testing uptake, acquire data on HCV prevalence among people who inject drugs, and implement cost-effective HCV antibody testing as part of national health screening programmes.<sup>128,129</sup>

#### (18) Philippines

Viral hepatitis surveillance in the Philippines is still developing, so prevalence estimates remain imprecise. A 2013 study estimated HBsAg serorevalence to be 16·7%,<sup>130</sup> but modelled data suggest HBV prevalence was 9·3% (95% CI 8·80–10·90) in 2019.<sup>131</sup> The prevalence of

infections in children have decreased since the birth-dose HBV vaccination was introduced in 2007, with a decrease from greater than 10% (in children aged 5–7 years) in 2003,<sup>130</sup> to 0·8% (0·4–1·7) in 2020.<sup>131</sup> Chronic HCV prevalence remained static over this period at around 1%.<sup>132</sup> Hepatitis-related morbidity and mortality continue to rise because of previous inaction.<sup>133</sup> There were more than 840 000 new cases of primary liver cancer in 2018,<sup>133</sup> approximately two-thirds of which were attributable to chronic HBV or HCV.<sup>134</sup>

Care cascade data are sparse, but in 2016, it was estimated that 38763 individuals were newly diagnosed with HBV and around 1200 people were on HBV therapy annually.<sup>132</sup> There is no national screening programme, but patient access to treatment has increased since government financing of HBV and HCV testing and treatment was piloted in 2019,<sup>135</sup> with the nationwide expansion of decentralised, nurse-led hepatitis treatment in April, 2020.<sup>136</sup> However, outside the pilot programmes, HBV outpatient monitoring and HCV DAA drug costs must be covered by patients. For example, a 12-week course of sofosbuvir–daclatasvir for HCV was priced at US\$800 in 2020,<sup>24</sup> the second highest price in the Western Pacific region behind Viet Nam,<sup>24</sup> and prohibitively expensive for most individuals with HCV.

A further challenge has arisen from faltering HBV vaccine uptake, with birth-dose coverage falling by 29% between 2018 and 2019, predating disruptions due to the COVID-19 pandemic.<sup>137</sup> This decrease has been attributed to increasing vaccine hesitancy since the dengue vaccine rollout in 2017.<sup>138</sup> Policy priorities include establishing a robust national surveillance system, renewing the vaccine drive, increasing the rollout of point-of-care diagnostics, and expanding access to an archipelago of 7641 islands by developing hubs for testing and treatment.

### (19) DR Congo

At US\$544 per capita, DR Congo has the lowest gross national product of the top 20 most heavily burdened countries. Despite this, HBV vaccination has been adopted into the extended programme for immunisation since 2007.<sup>139</sup> Coverage of three-dose HBV vaccination fell from 70% in 2020 to 65% in children younger than 1 year in 2021,<sup>29</sup> but there has been a reduction in HBsAg prevalence in children aged younger than 5 years to less than 2%.<sup>140</sup> There is restricted access to HBV treatment, with an estimated 8000 individuals on therapy by 2022.<sup>141</sup> Access to HCV treatment is also restricted, with no robust estimates of patients treated, despite an estimated national seroprevalence of approximately 0·9%.<sup>141,142</sup>

DR Congo has started to develop a strategic plan and national strategy to combat hepatitis, alongside national guidance for the management of HBV and HCV. The plan is being adopted by national health bodies, but implementation is hampered by low funding and insufficient good-quality data on disease burden. To

address these problems, there has been reactivation of the National Programme for the Fight Against Viral Hepatitis, incorporation of viral hepatitis into national surveillance programmes, and investment in the Regional Disease Surveillance Systems Enhancement Project in Central Africa, Phase IV project, to set up regional laboratories with the capacity to test for viral hepatitis.

### (20) Ukraine

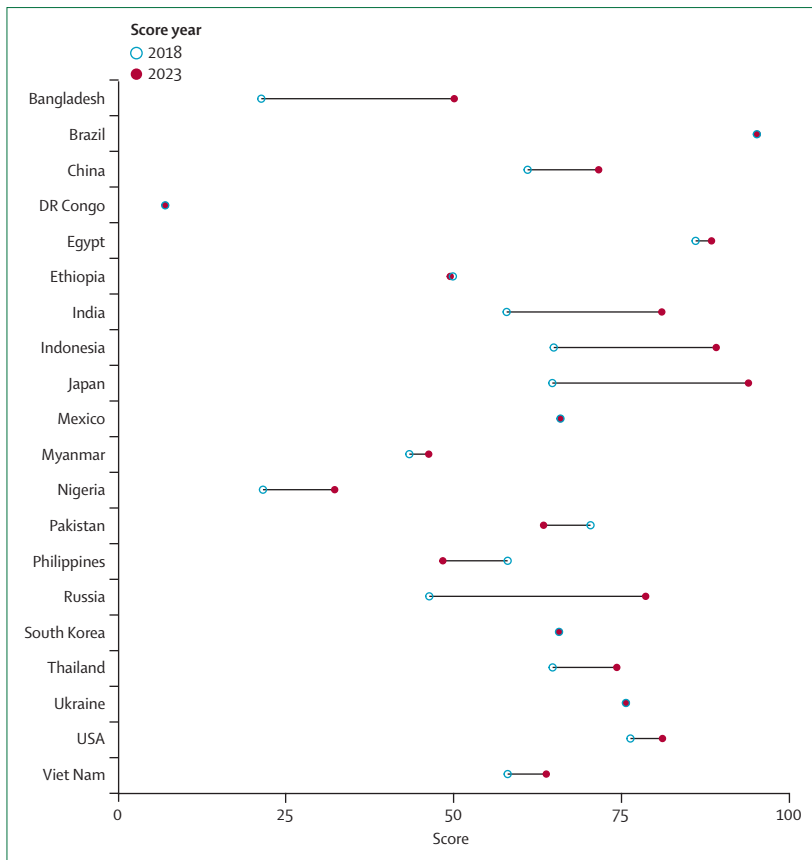
A 2017 WHO mission to Ukraine found its hepatitis surveillance system was outdated and incapable of providing the strategic information needed for a focused response.<sup>143</sup> HBV and HCV prevalence estimates remain scarce and are based on small unpublished surveys and expert consensus. In 2016, the estimated prevalence of HBsAg was 2·2% (1·15–3·24) and the estimated seroprevalence of HCV was 3·6% (0·9–4·5). The WHO report also expressed concerns regarding HBV vaccination, with birth-dose and third-dose vaccine coverage estimated at 37% and 26%, respectively, in 2016.<sup>143</sup> As well as issues with supply and distribution, vaccine hesitancy was highlighted as a key obstacle to elimination. A Wellcome Trust survey in 2019 found only 29% of Ukrainians thought vaccines were safe, and only 50% thought they were effective.<sup>144</sup>

In response to WHO recommendations, Ukraine committed to a National Viral Hepatitis Elimination Programme in November, 2019, with the target that 90% of individuals with an HBV or HCV infection should be treated by 2030. In 2020, the national hepatitis guidelines were updated, encouraging scale up and decentralisation of care. The number of treatment centres has since expanded from 40 to 230.<sup>145</sup> The Ministry of Health also committed to standardised DAA procurement through generic manufacturers, and in 2020, 30 000 HCV treatment courses were distributed by use of state budget funds, meeting regional demand for the first time. In the past 2 years, Ukraine's hepatitis response has been derailed by the COVID-19 pandemic<sup>146</sup> and ongoing geopolitical conflict. Insufficient hepatitis care and imperfect epidemiological surveillance remain major barriers to elimination for the foreseeable future.

### Policy progress in the top 20 most heavily burdened countries

Although the focus of this Commission is national, there has been substantial progress in a range of areas for international action identified in the 2019 Commission (table 1). Among these, a hepatitis policy index was developed to track countries' progress in 11 key elimination policies.<sup>147</sup> Figure 3 shows changes in policy index scores for the top 20 most heavily burdened countries from 2018 to 2023. Countries with the strongest policy responses (Brazil, Egypt, and USA) have continued to make progress, with Egypt remaining an example of what can be achieved in more resource-constrained settings. In October, 2023, Egypt was awarded the first

For more on the Ukraine National Viral Hepatitis Elimination Programme see <https://phc.org.ua/>



**Figure 3: Hepatitis policy index score changes between 2018 and 2023, for viral hepatitis-related policies in the top 20 most heavily burdened countries**

Hepatitis policy index scores build on previous work by Palayew and colleagues.<sup>147</sup> Scores are on the basis of 11 key policies: (1) the existence of a national viral hepatitis elimination plan; (2) reliable national epidemiological data; (3) formal estimation of national economic burden of viral hepatitis; (4) mandatory screening of donated blood; (5) availability of harm reduction programmes; (6) provision of free HBV birth-dose vaccination; (7) three-dose HBV vaccine coverage; (8) availability of publicly funded hepatitis screening programmes; (9) availability of HBV treatment on the National Essential Medicines List or government subsidies; (10) availability of HCV treatment on the National Essential Medicines List and government subsidies; and (11) if HCV treatment is free for nationals. The policies are categorised as either not implemented, in progress, or in place, and scores are then generated by use of a correspondence analysis. The weights from the 2018 analysis were used to calculate the 2023 scores. The scores are then changed to range from 0–100 by use of the min-max transformation. HBV=hepatitis B virus. HCV=hepatitis C virus.

gold tier status for HCV elimination efforts by WHO.<sup>148</sup> Egypt has one of the most ambitious testing programmes in the world and state-funded provision of HBV birth-dose vaccination and antiviral treatment,<sup>149</sup> and Brazil has championed free, sustainable access to HCV therapy since 2015, providing another example of what can be achieved with sufficient political will.<sup>150</sup> However, even these countries can go further, as both still have policies criminalising drug use, which is a barrier to further elimination efforts.

Overall, progress has been made in 14 of the top 20 countries since 2018, with the most substantial gains observed in Bangladesh, India, Indonesia, Japan, and Russia. Among the countries who have made progress, most improvements are attributable to formalised national action plans, provision of publicly funded screening, and

government subsidisation of antiviral treatment (appendix pp 2–3). India and Bangladesh are the only two countries in the top 20 to have advanced harm reduction policies in the past 5 years. Bangladesh and Thailand have become the first countries in the WHO South-East Asian region certified as having HBV control.<sup>72</sup> Development of a national policy is the crucial first step towards elimination, with substantial progress in treatment and prevention of viral hepatitis following this intervention in Indonesia, Bangladesh, and India.

Policy progress in Ukraine, Myanmar, and Ethiopia has been static or slow since 2018, impeded by war, political unrest, and the global challenges caused by the COVID-19 pandemic. Policy index scores for Pakistan and the Philippines have decreased since 2018, reflecting more stringent scoring of indicators rather than removal or cessation of existing policies. Elimination policy progress in DR Congo and Nigeria lags behind the rest of the top 20. In Nigeria, although a national programme has not yet been implemented, four subnational regions have hepatitis elimination plans and costs of drugs have fallen substantially in the past 2 years, to prices similar to Pakistan and Ukraine.<sup>151</sup>

Globally, there has been progress in the pricing of treatment, but more still needs to be done. The availability of voluntary licenses from originator companies and via the Medicines Patent Pool has led to considerable falls in price for HCV drugs in many countries.<sup>151</sup> However, prices have not decreased by the same amount in all countries and still remain a barrier for public sector and personal procurement. In May, 2023, the Clinton Health Access Initiative and the Hepatitis Fund announced agreements with pharmaceutical companies that set ceiling prices for key medications, which is a welcome step forward.<sup>152</sup>

## Discussion

### Themes emerging from national experts

In this Commission, via discussion between national commissioners from highly burdened countries, key themes have emerged that build on the original recommendations; namely, a greater emphasis on simplified models of care, the ongoing importance of access to appropriate diagnostics, funding of hepatitis care, and potential lessons from the COVID-19 pandemic. These themes are summarised in table 3.

### Simplification

Simplifying models of viral hepatitis care and treatment remains a priority to achieve rapid scale up of services. There has been progress with HCV,<sup>167</sup> but a greater emphasis on HBV is needed to overcome the challenges to developing testing and treatment programmes.

As of 2023, algorithms for the management of HBV infection recommend treatment and monitoring with markers, such as biochemical liver enzyme tests, HBeAg, anti-HBe, HBV DNA titre, assessment of liver fibrosis,

	Actions required	Exemplars of progress
Simplification of care	Validation and roll out of simplified strategies for hepatitis B: minimising monitoring, simplifying investigations, reducing clinical visits, and decentralising care; long-acting injectable treatments	Validation of minimal monitoring approaches; <sup>153</sup> incorporation of simplified treatment strategies into guidelines <sup>154,155</sup>
Improved diagnostics	Investment in simplified diagnostics; innovation with novel or existing diagnostics <sup>156-158</sup>	Evaluation of rapid diagnostic tests and point-of-care tests; <sup>7,156,159</sup> incorporation into guidelines <sup>6,154,160</sup>
Financing	Global investment; domestic prioritisation; innovative financing of HBV and HCV care; incorporation into existing services	New funding sources; <sup>161,162</sup> market analysis and transparency; <sup>10,163</sup> success stories <sup>164,165</sup>
Lessons from the COVID-19 pandemic	Responding to setbacks; telemedicine and decentralisation of care; improving surveillance	Greater acceptance of self-testing; incorporation of remote care into guidelines <sup>155,166</sup>

HBV=hepatitis B virus. HCV=hepatitis C virus.

**Table 3: Emerging priorities for the elimination of viral hepatitis**

and surveillance of hepatocellular carcinoma.<sup>163,168,169</sup> Such complexity of care, with multiple investigations required in different locations, can lead to loss in follow-up before treatment initiation and challenges in routine monitoring. These tests are costly, and in several countries, expenditure on them can exceed the cost of anti-HBV drugs.<sup>94</sup> There is therefore a need for simplification of management guidelines to reduce the need not only for complex tests, but also for frequent visits to the clinic, to reduce costs and increase adherence. Some of the approaches that have been proposed include the use of HBsAg tests if HBV DNA testing is not available,<sup>170</sup> use of dried blood spot molecular tests,<sup>171</sup> increasing the hepatocellular carcinoma surveillance interval for those with very low risk of hepatocellular carcinoma,<sup>172</sup> and less frequent testing once individuals have sufficient viral suppression.<sup>154</sup>

WHO guidelines have greatly simplified hepatitis C management,<sup>155,173</sup> which have enabled rapid progress in many countries. However, as patients already linked to care are treated, new approaches are needed to find and treat those that health systems still struggle to engage, such as point-of-care screening in methadone clinics and facilities for people experiencing homelessness with seamless linkage to care. Lessons should be learned from tuberculosis management, for example, in which intermittent regimens suitable for supervised therapy have become commonplace and there has been a continual push for ever-shorter treatment.<sup>174</sup> Simplified approaches that allow short-course therapy will enable greater access for those struggling to adhere to and afford treatment.

Long-acting treatments suitable for injection should also be developed, as they have been for HIV, contraception, and mental health disorders. Such treatments would provide important therapeutic choices for people living with chronic hepatitis and help to overcome the programmatic obstacles of regular drug dispensing and supervised treatment to implementing existing elimination tools. For example, long-acting formulations of tenofovir and related prodrugs, which are already in clinical trials for HIV, might be offered to pregnant women with chronic HBV to reduce infant infection.

This strategy could be especially impactful in rural Asia and Africa, where lack of provision of birth-dose HBV vaccine have been the leading obstacle to elimination. With HCV, long-acting formulations might cure infection with a single injection, allowing a test and cure framework, removing linkage to treatment as a major elimination obstacle. Such treatments are feasible, but prioritisation of global funding and appropriate licensing agreements are required to expedite development.

### Diagnostics

Simplified care algorithms will require increased diagnostic capacity. Elimination goals are critically dependent on scaling up testing to identify the people who are infected.<sup>175</sup> The 2019 Commission emphasised the limitations of the standard of care and the need to develop point-of-care tests (ie, tests on capillary blood obtained via fingerprick or oral fluids by clinic staff without any specialised equipment) or rapid diagnostic tests (RDTs; tests done near the patient or treatment facility with a fast turnaround time [20–30 min]) that might lead to a change in patient management.<sup>1</sup> The response to the COVID-19 pandemic has brought rapid testing further into the public consciousness. Since 2017, several tests with good sensitivity and specificity for the detection of HBsAg in blood and anti-HCV in blood and saliva have become available.<sup>176-178</sup> These tests are particularly useful for populations who struggle to access medical care and often do not return for follow-up, such as people who inject drugs or people experiencing homelessness. These tests also do not often need a cold chain for transport and storage. Point-of-care HCV RNA tests have also facilitated single visit test and treat models<sup>179</sup> with feasible national scale up<sup>180</sup> and reduced loss to follow-up of people who inject drugs or people who are incarcerated.

Further effort is needed to find alternative technologies to allow greater access to viral detection and quantification and make them the standard of care.<sup>181</sup> Wider access to dried blood spot testing is one approach,<sup>156,171</sup> but innovation in antigen testing also holds promise, such as rapid diagnostic tests (RDTs) for HBV core-related antigen (HBcrAg-RDT) to detect individuals with high

viraemia.<sup>182</sup> Such tests can enable rapid access to treatment for people who need it, including pregnant women in rural communities. A study in Gambian women of childbearing age showed that the HBcrAg-RDT test had 100% sensitivity and 87.5% specificity and highlighted the potential usefulness of HBV DNA-free algorithms with HBcrAg-RDT to establish treatment eligibility.<sup>182</sup>

### Financing

Around US\$6 billion a year is required to meet global HBV and HCV elimination goals, but as of 2023, financial investment in hepatitis services is estimated to be less than 10% of this figure.<sup>161</sup> Unlike HIV/AIDS or tuberculosis, there are no specific international funding bodies for viral hepatitis and the overstretched national health budgets of low-income and lower-middle-income countries have been expected to shoulder much of the financial burden of elimination. The Global Fund,<sup>162</sup> Gavi, the Vaccine Alliance,<sup>3</sup> and the World Bank<sup>164</sup> have all contributed to funding in the past 10 years<sup>161</sup> and in May, 2023, the Clinton Health Access Initiative and the Hepatitis Fund announced two new memoranda of understanding to dramatically lower the price of WHO-prequalified HBV and HCV drugs in low-income and middle-income countries.<sup>152</sup>

In addition to greater funding, for every additional dollar invested, improved value and efficiency are urgently required (ie, cost-saving strategies to make the available funds go further). This could be achieved through optimising procurement of generic antivirals, as shown in Rwanda,<sup>183</sup> India,<sup>184</sup> Egypt,<sup>185</sup> and Pakistan,<sup>151</sup> structural investments in diagnostics systems rolled out for other programmes (eg, HIV), integration of training and management into existing systems, and meaningful involvement of affected communities in harm reduction service designs.<sup>186</sup>

### Health systems disruptions

The past 3 years have seen major disruptions to health systems, impeding progress to viral hepatitis elimination.<sup>187</sup> Four of the top 20 most heavily burdened countries are heavily affected by conflict: the effects of the geopolitical crisis between Russia and Ukraine are recognised globally, but unrest in Ethiopia and Myanmar also poses major challenges to health care and health systems. In addition, all countries have had to deal with the unprecedented challenge of the COVID-19 pandemic, which has heavily affected all health-care activities, disrupting short-term elimination plans<sup>153,166</sup> and specific viral hepatitis programmes, such as HBV vaccine initiatives and HCV screen and treat programmes.<sup>157</sup>

However, the pandemic has also brought a greater acceptance of decentralised care, remote technologies, and self-testing, all of which have long been identified as vital to achieving hepatitis elimination. These health-care advances and adaptations should aid hepatitis control and

feature in the latest WHO strategy.<sup>158</sup> Planning for the prevention and mitigation of future pandemics is an area of policy focus globally. Part of this preparation requires strengthening diagnostics systems for surveillance and response. Such investments could yield benefits for on-going public health challenges, including viral hepatitis.

### Limitations

The definition here of the top 20 most heavily burdened countries is based on data from GBD 2019. Although this study is the most definitive effort to systematically quantify the effects of disease on health across countries, we acknowledge that it inevitably relies on data that are variable in range and quality. Nonetheless, this approach is better able to place diseases in a national context, than, for example, the total number of people infected or total number of deaths.

This Commission aimed to develop a community of experts, and considerable effort was made to bring in authors from all countries involved. Authors were provided with a structured questionnaire, but also encouraged to tailor their response to their national experience. This narrative approach is complemented by alignment with newly created national hepatitis elimination profiles, referenced throughout the Commission, but is also prone to subjectivity.

Finally, we acknowledge that our work is limited by only focusing on a few key issues. Some of these, such as financing, are broad, beyond the scope of this Commission, and will be addressed in future work. A focus on the top 20 most burdened countries is not intended to suggest that important lessons cannot be learned from other countries, particularly those with more access to health-care resources or smaller countries where substantial progress has been made. For example, innovative deals with drug providers in the UK and Australia allow the potential for expanded access to treatment for HCV.<sup>159</sup> Similar arrangements could be considered in a range of other higher burden settings. Likewise, progress towards elimination in smaller countries, such as Iceland<sup>160</sup> and Georgia,<sup>165</sup> can serve as a model for larger countries with fewer resources.

### Conclusion

This Commission for the countries with the highest viral hepatitis burdens shows that although progress has been made in the past 5 years, we still have a long way to go to meet WHO elimination targets. Important areas of practice and policy not addressed in detail here include the global pricing of antivirals and insufficient progress towards decriminalisation of drug use in many high-burden settings. The decriminalisation of drug use will become increasingly important as programmes make progress in elimination and focus more on marginalised populations (eg, people who inject drugs, people who are incarcerated, and people experiencing homelessness). Finally, we consider that a focus on the most heavily

burdened countries remains a helpful means of achieving hepatitis elimination goals, complementing broader international policy, and emphasising the need for political commitment at the national level. Further investment to support local clinicians, scientists, advocates, and activists is essential if national plans across these countries are to be developed, monitored, and implemented effectively.

#### Contributors

JJ, RA, MA-M, YT, S-HJ, KP, IW, PMK, DA-P, JFS-A, CM, DHM, OL, HD, SH, AdA, HC, CAO, RM, II, DLT, NP, and VC drafted country narratives. BF, EC, ADM, JG, JWW, and GSC edited national reports and drafted the manuscript. AP, MAD, and HH contributed to data, analysis, and figure production. JVL, JWW, LH and GSC supervised and led this Commission.

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