

The case for simplifying and using absolute targets for viral hepatitis elimination goals

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The case for simplifying and using absolute targets for viral hepatitis elimination goals

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Abstract

The 69th World Health Assembly endorsed the Global Health Sector Strategy for Viral Hepatitis, embracing a goal to eliminate hepatitis infection as a public health threat by 2030. This was followed by the World Health Organization's (WHO) global targets for the care and management of hepatitis B virus (HBV) and hepatitis C virus (HCV) infections. These announcements and targets were important in raising awareness and calling for action, however, tracking countries' progress toward these elimination goals has provided insights to the limitations of these targets. The existing targets compare a country's

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progress relative to its 2015 values, penalizing countries who started their programs prior to 2015, countries with a young population, or countries with a low prevalence.

We recommend that (1) WHO simplify the hepatitis elimination targets, (2) change to absolute targets and (3) allow countries to achieve these disease targets with their own service coverage initiatives that will have the maximum impact. The recommended targets are: reduce HCV new chronic cases to ≤ 5 per 100,000, reduce HBV prevalence among 1-year-olds to $\leq 0.1\%$, reduce HBV & HCV mortality to ≤ 5 per 100,000, and demonstrate HBV & HCV year to year decrease in new HCV and HBV related HCC cases.

The objective of our recommendations is not to lower expectations or diminish the hepatitis elimination standards; but to provide clearer targets that recognize the past and current elimination efforts by countries, help measure progress toward true elimination, and motivate other countries to follow suit.

In 2016, the 69th World Health Assembly endorsed the Global Health Sector Strategy for Viral Hepatitis, embracing a goal to eliminate hepatitis infection as a public health threat by 2030.¹ This was followed by the World Health Organization's (WHO) global targets for the care and management of hepatitis B virus (HBV) and hepatitis C virus (HCV) infections.² These announcements and targets were important in raising awareness and calling for action. Since then, tracking countries' progress toward these elimination goals has provided insights to the limitations of these targets.³ We recognize that the global COVID-19 pandemic has impacted priorities, but we recommend that these targets be updated to better reflect the original goals – clear, measurable targets that better signpost progress toward true viral hepatitis elimination.

Problems: First, the current impact targets for reduction in mortality and incidence are relative to a 2015 baseline (TABLE 1) when hepatitis epidemiology data was not being systematically collected in most countries. The 2015 relative targets also penalize countries that had a low starting point in 2015. Countries with young HCV-infected populations (e.g., Australia and United Kingdom (UK)) will have a difficult time achieving the current mortality targets, even with robust national elimination programs, since their 2015 mortality was already low. Similarly, countries with a low incidence in 2015 (e.g. the Netherlands for HCV; much of Western Europe and the Americas for HBV) will have difficulty reaching an additional 90% incidence reduction by 2030. Second, the current guidelines are ambiguous. A 90% reduction in incidence of chronic HBV infections (compared to 2015 baseline) is inconsistent with a 0.1% prevalence of HBV infection in children five years of age in 2030 as suggested by WHO.⁴ The former favors countries that began universal vaccination between 2015-2020 (e.g., Japan and UK), while the

latter favors countries/regions that have had long-standing vaccination programs prior to 2015 (e.g., China & Taiwan). Finally, the service coverage targets are confusing since they do not include all options available to countries (e.g., antiviral treatment of pregnant women; use of hepatitis B immune globulin).

Recommendation: We recommend that (1) WHO simplify the hepatitis elimination targets, (2) change to absolute targets shown in TABLE 2 and (3) allow countries to achieve these disease targets with their own service coverage initiatives that will have the maximum impact. The recommended targets roughly correspond to the WHO targets but are translated to absolute numbers. TABLE 2 also shows different levels of recommended measures to track progress toward these goals. The reduction in mortality must be coupled with a decrease in new HBV/HCV related hepatocellular carcinoma (HCC) cases: a measurable surrogate for overall liver-related mortality. Countries with a low viral hepatitis prevalence may meet the mortality target and still have an increasing incident number of HBV/HCV related HCC cases. This combination will ensure that steps are taken to reduce HBV/HCV mortality and disease burden.

Using models developed by Polaris Observatory, the projected countries that will achieve the existing 2030 WHO elimination targets and the recommended absolute targets are shown in TABLE 3. The analyses are based on historical treatment and screening data up to 2019 with projections to 2030, not including the impact of the COVID-19 pandemic. There has been a negative impact on hepatitis related services; however, the full impact of COVID-19 is difficult to incorporate at the time of this analysis.

Using existing criteria, only three countries are expected to achieve the 90% reduction in HBV incidence. None will achieve a 65% reduction in mortality relative to 2015, and no country will achieve all of the current HBV elimination targets. Similarly, only four countries are expected to achieve all of the current HCV elimination targets.

HBV surface antigen (HBsAg) prevalence among 5-year-olds reflects the impact of prophylaxis programs instituted 5 years earlier. Table 4 shows that changing the target for prevalence among children from 5-year-olds to 1-year-olds would allow another 20 countries to achieve the absolute target of $\leq 0.1\%$ by 2030. This reflects the benefits of their vaccination programs over the additional 4 years. This measure also correlates well with a low incidence (≤ 5 per 100,000) among the total population. Thus, a separate (relative) target is not needed.

An estimated 76 countries will meet an HBV mortality rate of 5 per 100,000, but only two will also have a year on year reduction of HCC cases (Finland and Japan). This highlights the need for further debate; beyond the scope of this editorial, regarding the current international and national HBV treatment

guidelines that are too narrow and restrictive to sufficiently result in a year to year decrease in HBV related HCC cases.

TABLE 4 also shows that moving from a relative reduction in HCV incidence to an absolute cut-off of ≤ 5 per 100,000 allows 25 additional countries with low HCV prevalence to meet the new targets. It makes little sense to expect a country with a low HCV prevalence and incidence to spend resources to further reduce incidence if HCV is not considered a large public health problem. Similarly, moving to an absolute target of ≤ 5 per 100,000 for HCV mortality allows all countries that started with a low mortality rate in 2015 to achieve the new targets (15 countries). Overall, an additional 11 countries are expected to achieve all new targets relative to the existing WHO elimination targets.

The objective of our recommendations is not to lower expectations or diminish the hepatitis elimination standards; but to provide clearer targets that recognize the past and current elimination efforts by countries, help measure progress toward true elimination, and motivate other countries to follow suit. We also believe that countries are in the best position to select the mix of service coverages that will allow them to meet these revised global targets. This is particularly important during the COVID-19 pandemic that may have led to diversion of resources from the hepatitis programs. After five years of progress and assessment, we strongly recommend that WHO reconsiders and refines the existing elimination targets in 2020.

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TABLE 1. WHO hepatitis elimination targets².

TABLE 2. Simplified hepatitis elimination targets using absolute targets.

TABLE 3. Countries/regions reaching the existing WHO elimination targets by 2030.

TABLE 4. Countries/regions reaching the absolute HBV & HCV elimination targets by 2030.

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TABLE 1. WHO hepatitis elimination targets

Target areas		Baseline 2015	2020 target	2030 target	
Service coverage	1 Three-dose hepatitis B vaccine for infants (coverage %)	82%	90%	90%	
		2 Prevention of mother-to-child transmission of HBV: hepatitis B birth-dose vaccination or other approaches (coverage %)			
	Prevention	Blood safety: donations screened with quality assurance	89%	95%	100%
		3 Blood and injection safety (coverage %)			
		Injection safety: use of engineered devices	5%	50%	90%
		4 Harm reduction (sterile syringe/needle set distributed per person per year for people who inject drugs [PWID])	20	200	300
		5a Diagnosis of HBV and HCV (coverage %)	<5%	30%	90%
	5 Treatment			5 million (HBV)	80% eligible treated
		5b Treatment of HBV and HCV (coverage %)	<1%	3 million (HCV)	
	Impact leading to elimination	Incidence of chronic HBV and HCV infections	6-10 million	30% reduction	90% reduction
Mortality of chronic HBV and HCV infections		1.46 million	10% reduction	65% reduction	

HBV: hepatitis B virus; HCV: hepatitis C virus.

TABLE 2. Simplified hepatitis elimination targets using absolute targets

Primary Objective	Reduce Incidence		Reduce Mortality	
2030 Target	Reduce HCV new chronic cases to ≤ 5 per 100,000 (excluding the new cases from immigration)	Reduce HBsAg prevalence among 1-year-olds to $\leq 0.1\%$	Reduce HBV & HCV mortality to ≤ 5 per 100,000	Demonstrate HBV & HCV year to year decrease in new HCV and HBV related HCC cases
Measure Options	Conduct two national surveys (minimum one year apart) and estimate incidence between the two by age group.	Conduct HBsAg surveys in 1-year-olds in multiple regions in the country and maintain prophylaxis measures.	Establish/use national registry for HCC, decompensated cirrhosis linked to patient and death registries, attributed cause, & adjust for under reporting.	Establish/use national registry for HCC, decompensated cirrhosis linked to patient and death registries, attributed cause, & adjust for under reporting.
	Conduct two surveys (minimum one year apart) in high risk groups accounting for >80% of new infections and estimate incidence rate.	Conduct HBsAg surveys among 1-year-olds in high prevalence regions/ populations and maintain prophylaxis measures.	Establish/use national HCC registry. Estimate annual decompensated cirrhosis to HCC incident ratio in ≥ 1 major center. Use HCC and cirrhosis survival studies to estimate overall mortality by year.	Establish/use national HCC registry. Estimate annual decompensated cirrhosis to HCC incident ratio in ≥ 1 major center. Use HCC and cirrhosis survival studies to estimate overall mortality by year.
	Use modeling to estimate incidence.	Use modeling that considers the impact of prophylaxis to estimate incidence and maintain prophylaxis measures.	Use modeling to estimate HBV and HCV related HCC and cirrhosis mortality.	Use modeling to estimate HBV and HCV related HCC and cirrhosis mortality over time.

HBV: hepatitis B virus; HCV: hepatitis C virus; HCC: hepatocellular carcinoma; HBsAg: HBV surface antigen

TABLE 3. Countries/regions reaching the existing WHO elimination targets by 2030

HBV 90% reduction in incidence	HBV <=0.1% prevalence among 5-year-olds	HBV 65% reduction mortality	Countries/regions meeting all HBV targets	HCV 90% reduction in incidence	HCV 65% reduction in mortality	Countries/regions meeting all HCV targets
Italy	Albania	Korea, Republic of	None	Egypt	Austria	Egypt
Japan	Algeria	Kosovo		France	Canada	France
UK	Argentina	Kuwait		Iceland	Egypt	Iceland
	Armenia	Latvia		Korea, Republic of	France	Spain
	Australia	Lebanon		Spain	Georgia	
	Austria	Lithuania			Iceland	
	Belgium	Macedonia			Italy	
	Brazil	Malaysia			Japan	
	Bulgaria	Mexico			Mongolia	
	Canada	Morocco			Netherlands	
	Chile	Netherlands			Spain	
	China	New Zealand			Sweden	
	Colombia	Nicaragua			Switzerland	
	Costa Rica	Norway			Taiwan	
	Croatia	Oman			United States	
	Cuba	Panama				
	Czechia	Peru				
	Dominican Republic	Poland				
	Ecuador	Portugal				
	Egypt	Qatar				
	El Salvador	Russia				
	Finland	Saudi Arabia				
	France	Serbia				
	Gambia	Singapore				
	Germany	Slovakia				
	Greece	Spain				
	Guatemala	Sweden				
	Hong Kong	Switzerland				
	Hungary	Taiwan				
	Iceland	Thailand				
	Iran	Tunisia				
	Ireland	Turkey				
	Israel	UAE				
	Italy	UK				
	Japan	United States				
	Jordan	Uruguay				
	Kazakhstan	Uzbekistan				
	Kenya					

Notes: Blue countries/regions – those not achieving the absolute targets for a similar category in Table 4; only countries/ regions analyzed by Polaris Observatory are listed; UAE: United Arab Emirates, UK: United Kingdom

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TABLE 4. Countries/regions reaching the absolute HBV & HCV elimination targets by 2030

HBV ≤0.1% HBsAg prevalence among 1-year-olds		HBV reduce mortality to ≤5 per 100,000 & decrease in new HCC cases	Countries/ regions meeting all HBV targets	HCV reduce new chronic infections to ≤5 per 100,000	HCV reduce mortality to ≤5 per 100,000 & decrease in new HCC cases	Countries/ regions meeting all HCV targets
Albania	Kosovo	Finland	Finland	Argentina	Australia	Australia
Algeria	Kuwait	Japan	Japan	Australia	Austria	Austria
Argentina	Kyrgyzstan			Austria	Brazil	Brazil
Armenia	Latvia			Belgium	Cameroon	Canada
Australia	Lebanon			Brazil	Canada	Egypt
Austria	Libya			Canada	CAR	France
Azerbaijan	Lithuania			Chile	Chad	Germany
Bangladesh	Macedonia			Costa Rica	Egypt	Iceland
Belarus	Malaysia			Croatia	France	Italy
Belgium	Mexico			Denmark	Georgia	Japan
Brazil	Moldova			Dominican Republic	Germany	Korea, Republic of
Bulgaria	Mongolia			Egypt	Iceland	Netherlands
Cambodia	Morocco			El Salvador	Italy	Spain
Canada	Nepal			France	Japan	Turkey
Chile	Netherlands			Germany	Korea, Republic of	UK
China	New Zealand			Iceland	Latvia	
Colombia	Nicaragua			Israel	Libya	
Costa Rica	Norway			Italy	Lithuania	
Croatia	Oman			Japan	Madagascar	
Cuba	Panama			Korea, Republic of	Netherlands	
Czechia	Peru			Lebanon	New Zealand	
DPR Korea	Poland			Mexico	Rwanda	
Denmark	Portugal			Netherlands	Spain	
Dominican Republic	Qatar			Portugal	Sweden	
Ecuador	Romania			Saudi Arabia	Switzerland	
Egypt	Russia			Slovenia	Turkey	
El Salvador	Saudi Arabia			Spain	UK	
Finland	Serbia			Tanzania	United States	
France	Singapore			Turkey		
Gambia	Slovakia			UK		
Georgia	Slovenia					
Germany	Spain					
Greece	Sweden					
Guatemala	Switzerland					
Hong Kong	Taiwan					
Hungary	Tajikistan					
Iceland	Thailand					
India	Tunisia					
Iran	Turkey					

Ireland	Turkmenistan
Israel	Ukraine
Italy	UAE
Jamaica	UK
Japan	United States
Jordan	Uruguay
Kazakhstan	Uzbekistan
Kenya	Venezuela
Korea, Republic of	

Notes: Blue countries/regions – those not achieving the current targets for a similar category in Table 3, only countries/regions analyzed by Polaris Observatory are listed; CAR: Central African Republic, DPR Korea: Democratic People's Republic of Korea, UAE: United Arab Emirates, UK: United Kingdom