World Health Organization

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Criteria for validation of elimination of viral hepatitis B and C: report of seven country pilots

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# ABBREVIATIONS

| | |
|---|---|
| **Ab** | antibody |
| **ANC** | antenatal care |
| **CI** | confidence interval |
| **DAA** | direct-acting antiviral (drug) |
| **EASL** | European Association for the Study of the Liver |
| **ECDC** | European Centre for Disease Prevention and Control |
| **EMTCT** | elimination of mother-to-child transmission |
| **EPI** | Expanded Programme on Immunization |
| **GFME** | Global Framework for Multi-disease Elimination |
| **GHSS** | Global health sector strategy on viral hepatitis 2016–2021 |
| **GVAC** | Global Validation Advisory Committee |
| **HBsAg** | hepatitis B surface antigen |
| **HBV** | hepatitis B virus |
| **HCC** | hepatocellular carcinoma |
| **HCV** | hepatitis C virus |
| **HepB-BD** | hepatitis B vaccine birth dose (HepB-BD) |
| **HIV** | human immunodeficiency virus |
| **M&E** | monitoring and evaluation |
| **MTCT** | mother-to-child transmission |
| **OST** | opioid substitution therapy |
| **PMTCT** | prevention of mother-to-child transmission |
| **PTE** | Path to Elimination |
| **PVST** | post-vaccination serology testing |
| **PWID** | people who inject drugs |
| **UAM** | unlinked anonymous monitoring (survey) |
| **UNICEF** | United Nations Children's Fund |
| **WHO** | World Health Organization |

# 1. BACKGROUND

Chronic viral hepatitis B and C are major global public health threats with an estimated 354 million people living with chronic hepatitis B (296 million) and C (58 million), accounting for over 1.1 million deaths in 2019, mainly due to the complications of cirrhosis and hepatocellular cancer *(1)*. In 2016, the World Health Assembly endorsed the Global health sector strategy on viral hepatitis 2016–2021 (GHSS), which proposed the elimination of viral hepatitis as a public health threat by 2030 (defined as a 90% reduction in new chronic infections and a 65% reduction in mortality, compared with the 2015 baseline), and included a roadmap towards elimination by implementing key prevention, diagnosis, treatment and community intervention strategies *(2)*. In May 2022, the World Health Assembly endorsed a new set of integrated Global health sector strategies on HIV, viral hepatitis and sexually transmitted infections for the period of 2022–2030 *(3)*. Based on these strategies, a broad range of Member States have developed comprehensive national hepatitis programmes and elimination strategies guided by the GHSS and have requested WHO's guidance on the establishment of standardized criteria and a process for validation of elimination of viral hepatitis B and/or C.

In response, WHO developed the first *Interim guidance for country validation of viral hepatitis elimination (4)* to provide a framework for countries seeking validation of viral hepatitis elimination as a public health threat with a specific focus on hepatitis B (including elimination of mother-to-child transmission of hepatitis B virus [HBV EMTCT]), and hepatitis C. Overall, the Guidance suggests the use of absolute impact targets to validate elimination at the national level (rather than the relative reduction targets originally defined in the 2016–2021 GHSS on viral hepatitis) to provide a standardized approach across all settings. For validation, attainment of the impact targets will be accompanied by a set of programmatic targets linked to service delivery, which need to be maintained for two years to show consistency in the programmatic response *(4)* (Table 1). Additionally, the validation requires documentation of other implementation considerations, including evidence of the quality of data sources, laboratory processes, and health-care programmes, as well as ensuring adherence to the principles of equity and human rights in access to services. A specific path to elimination (PTE) of HBV EMTCT was included to recognize the significant national effort and importance of implementing interventions for HBV EMTCT in high-burden countries that may not yet be able to achieve the impact targets for elimination. In the Guidance, countries were encouraged to pursue elimination of both viral hepatitis B and C together as a public health problem but may also choose to apply for one of the four validation options in a phased approach (Table 2).

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# TABLE 1 SUMMARY OF IMPACT AND PROGRAMMTIC TARGETS FOR THE COUNTRY VALIDATION OF ELIMINATION FOR THE HBV EMTCT, HCV INCIDENCE AND HBV/HCV MORTALITY

| Elimination targets | Elimination of chronic HBV infection as a public health problem | | Elimination of chronic HCV infection as a public health problem | |
|---|---|---|---|---|
| **2030 GHSS relative reduction reference targets (compared to 2015)** | **Incidence**<br>95% reduction | **Mortality**<br>65% reduction | **Incidence**<br>80% reduction | **Mortality**<br>65% reduction |
| **HBV- and HCV-specific absolute prevalence, incidence and mortality targets** | **HBV EMTCT**<br>≤0.1% HBsAg prevalence in ≤5 year olds[a,b]<br>*Additional target:* ≤2% MTCT rate (where use of targeted HepB-BD)[c] | **Annual mortality**[g] (HBV)<br>≤4/100 000 | **Annual incidence** (HCV)<br>≤5/100 000<br>≤2/100 (PWID) | **Annual mortality**[g] (HCV)<br>≤2/100 000 |
| **Programmatic targets**[d] | **Countries with universal HBV vaccine birth dose (BD)**<br>≥90% HepB3 vaccine coverage<br>≥90% HepB timely hepatitis B BD (HepB-BD) coverage[e]<br><br>**Countries with targeted HBV vaccine birth dose (BD)**<br>≥90% HepB3 vaccine coverage<br>≥90% coverage of those infants at risk with targeted HepB-BD<br>≥90% coverage of maternal antenatal HBsAg testing<br>≥90% coverage with antivirals for those eligible[f] | **Testing and treatment**<br>≥90% of people with HBV diagnosed<br>≥80% of people diagnosed with HBV and eligible for treatment are treated[h]<br><br>**Prevention**<br>≥90% HepB3 vaccine coverage<br>≥90% HepB-BD coverage | **Testing and treatment**<br>≥90% of people with HCV diagnosed<br>≥80% of people diagnosed with HCV are treated[g]<br><br>**Prevention**<br>0% unsafe injections<br>100% blood safety<br>300 needles/syringes/PWID/year | |

*Source:* Interim guidance for country validation of viral hepatitis elimination. Geneva: WHO; 2021 *(4)*

EMTCT: elimination of mother-to-child transmission; HBsAg: hepatitis B surface antigen; HBV: hepatitis B virus; HepB-BD: hepatitis B birth dose vaccine; HepB3: three doses of hepatitis B vaccine; PWID: people who inject drugs

a Childhood prevalence is a proxy for HBV incidence.

b The ≤0.1% HBsAg prevalence can be measured among either 5 year olds, 1 year olds or those aged 1–5 years, according to existing country surveillance and data collection activities. For those regions and countries with a long history of high Hep B vaccination coverage (e.g. WHO Region of the Americas), and that already conduct school-based serosurveys, there could be flexibility to conduct serosurveys in older children >5 years.

c The ≤2% MTCT rate is an additional impact target to the ≤0.1% HBsAg prevalence among ≤5-year-old children in countries that provide targeted HepB-BD.

d All programmatic targets must be achieved and maintained for at least 2 years.

e Timely birth dose (HepB-BD) is defined as within 24 hours of birth.

f In accordance with national policies or WHO 2020 guidelines on use of antiviral prophylaxis on PMTCT of HBV.

g The GHSS defines the reduction of combined mortality for both HBV and HCV to ≤6/100 000/year at a global level. The use of HBV- and HCV-specific mortality target rates will depend on the national epidemiology of viral hepatitis and the relative contributions of HBV and HCV to overall mortality.

h Short-term curative treatment for HCV infection (SVR12), and generally lifelong antiviral therapy for HBV to maintain long-term HBV DNA viral suppression, in accordance with standard guidelines.

## TABLE 2 OPTIONS FOR ELIMINATION OF VIRAL HEPATITIS B AND C AS A PUBLIC HEALTH PROBLEM

| Option | Options for validation of elimination | Impact indicators | Programme indicators |
|---|---|---|---|
| **Option A** | HBV EMTCT (as part of triple elimination of HIV, syphilis and HBV, or HIV/HBV)[a] | Annual HBV incidence[b] and MTCT rate[c] (additional target) in countries with targeted timely HepB-birth dose (BD) | HBV birth dose and infant vaccination coverage for newborns and infants<br>HBV antenatal testing and antiviral prophylaxis coverage |
| **Option B** | HCV as a public health problem | Annual HCV incidence and HCV mortality | Coverage of prevention, testing and treatment |
| **Option C** | HBV as a public health problem (including HBV EMTCT) | Annual HBV incidence (and MTCT rate) and HBV mortality | Coverage of prevention, testing and treatment |
| **Option D** | Elimination of both HBV and HCV as a public health problem (including HBV EMTCT) | A, B and C above | A, B and C above |

*Source:* Interim guidance for country validation of viral hepatitis elimination. Geneva: WHO; 2021 *(4)*

EMTCT: elimination of mother-to-child transmission; Hep B: hepatitis B; MTCT: mother-to-child transmission

a Countries can choose EMTCT of HIV, or HIV and syphilis, or HIV and syphilis and hepatitis B.

b The prevalence of hepatitis B surface antigen (HBsAg) in children aged ≤5 years is used as a surrogate indicator of the cumulative incidence of chronic hepatitis B.

c The ≤2% MTCT rate is an additional impact target to ≤0.1% HBsAg prevalence among ≤5-year-old children in countries that provide targeted timely HepB-BD.

The elimination criteria were developed in partnership with a range of different stakeholders through two global consultation meetings attended by over 50 experts, including representatives of the ministries of health from 15 countries (June and August 2021). Selection of elimination targets and criteria were supported by scientific evidence and comprehensive literature reviews presented at the global consultations. Additionally, a survey of 28 countries across all six WHO regions was commissioned by WHO in 2020 and conducted to assess the availability of data and preparedness for validation of HBV and HCV elimination to gain critical insights for the development of the interim validation guidance.

This document presents the outcomes and lessons learned from a series of seven country pilots, which provided a unique opportunity for in-depth country assessment and feasibility of evaluation of the elimination criteria using representative serosurveys, surveillance, programmatic and modelled data. It also allowed for the identification of surveillance and data gaps, and implementation challenges as well as solutions. Another key benefit of the pilot was the opportunity for countries to provide feedback on the process and indicators being assessed. The country selection for the pilots was based on evidence of country engagement, current progress towards elimination and aimed for full representation of WHO regions. There are potential limitations in the findings from this exercise, including the context-specific nature of the data reported, and methods employed at country level that may be unique to the setting and thus cannot be completely applicable to all Member States.

# 2. OBJECTIVES OF COUNTRY PILOTS OF WHO CRITERIA FOR COUNTRY VALIDATION OF VIRAL HEPATITIS ELIMINATION

A series of country pilots of the elimination criteria across the six WHO regions was undertaken during 2021–2022. The main objective was to conduct a practical assessment and evaluate the feasibility of accurately measuring the impact and programmatic targets for hepatitis elimination as established by the WHO I*nterim guidance for country validation of viral hepatitis elimination (4)*. Specific objectives included the evaluation of national capacity to generate relevant data to measure progress towards elimination, obtain country feedback on the validation tools, assess different measurement approaches and proposed processes, promote country readiness for validation, and explore key validation questions that remain unresolved.

Specific questions that were addressed in the pilot included:

a. the need for an additional "path to elimination" approach to measure and recognize significant progress toward reduction of HCV incidence and HBV/HCV mortality (like the HBV EMTCT PTE as part of Triple Elimination *(5)* for high-burden countries that will not meet the absolute targets despite significant progress);

b. the feasibility of measuring the mother-to-child transmission (MTCT) rate as an additional criterion for validation of EMTCT in settings with targeted timely hepatitis B vaccine birth dose (HepB-BD);

c. validation of programmatic targets of hepatitis B surface antigen (HBsAg) testing and antiviral prophylaxis in pregnant women through the use of modelling to estimate the coverage with these interventions;

d. the optimal age ranges of populations included in HBsAg serosurveys for validation of HBV EMTCT;

e. the ease of measurement of mortality with the use of combined versus HBV-/HCV-specific mortality rates;

f. the validity of using reduction in HCV viraemic prevalence as a proxy for direct measurement of reduction in HCV incidence and mortality.

**This brief report summarizes the key lessons learned from these country pilots, advice for future elimination guidance and next steps. This report includes country profiles to highlight key data inputs and sources and outlines country progress towards elimination (Annex).**

# 3. METHODOLOGY

WHO pilots of the criteria and tools for validation of elimination were conducted between June 2021 and May 2022 in seven countries across the six WHO regions (Brazil, Egypt, Georgia, Mongolia, Rwanda, Thailand, and the United Kingdom[1] (England)). Six countries that participated in the two formal consultations to develop the interim guidance were invited to participate in the pilot process and all accepted. The United Kingdom was added during the pilot process and was the only high-income country represented. It was included to explore the use and advantages of mathematical modelling in some of the additional validation questions that remain unresolved as well as to facilitate comparison of available programme data against existing modelling work. Desk reviews, key informant interviews, virtual and hybrid consultation meetings and field visits were systematically conducted in each of the seven countries using draft standardized WHO hepatitis elimination protocols and tools. The tools included a quantitative data collection instrument for the impact and programme indicators for validation of hepatitis B and C elimination (including HBV EMTCT), a feedback questionnaire to capture

[1] The elimination pilot was conducted in the United Kingdom (England)

information on the feasibility of different approaches to assess and measure the proposed impact and programmatic elimination targets, a qualitative tool for country self-assessment of national capacities, and implementation considerations for validation of hepatitis elimination.

The feedback tool assessed additional questions on MTCT rates and PTE using a four-point Likert scale. In all countries, the pilot was conducted for both HBV and HCV criteria regardless of the stage of the hepatitis response, country progress or preferred validation options using the proposed WHO tools. The elimination pilot review team comprised the core Global Hepatitis Programme team from WHO headquarters, regional technical officers and WHO country office focal points, together with the relevant partners at the ministries of health (MoHs), external and internal partners, and key country consultants.

The Ministry of Health, WHO, partners and relevant stakeholders in each pilot country jointly reviewed all information and data presented by the Ministry of Health. Advice to strengthen country progress and data systems towards validation of elimination and recommendations to WHO for refinement of the validation tools and processes were discussed and agreed. All data are presented in this document as reported by the Ministry of Health during the pilot and have not been further validated by WHO. The pilots are considered a learning process both for WHO and countries and, as such, cannot be considered as a formal pre-validation process.

# 4. KEY FINDINGS AND LESSONS LEARNED FROM THE ELIMINATION PILOTS

The criteria for country validation of elimination of hepatitis B and C by impact and programmatic targets are shown in Table 1. As recommended in the *Interim guidance for country validation of viral hepatitis elimination (4)*, possible data sources include the following: (a) nationally representative viral hepatitis serosurveys and data from routine surveillance (acute and chronic infection); (b) vital statistics or surveillance of cause-specific mortality; and (c) programme data defined as routine data from the Expanded Programme on Immunization (EPI) and programmes for HBV EMTCT, injection and blood safety, harm reduction for people who inject drugs (PWID); surveillance for infections transmitted in health-care settings (e.g. infection prevention and control, transfusion services); and data from patient registers or databases to monitor the cascade of diagnosis and treatment. All participating countries piloted the criteria for both hepatitis B and C, irrespective of the progress of the national hepatitis response or their validation preference.

## 4.1. Criteria for validation of elimination of mother to child transmission of hepatitis B

### 4.1.1. Key findings

#### 4.1.1.1. Direct measurement of HBV prevalence in ≤5 year olds

The impact indicator for validation of EMTCT of hepatitis B is measured by the prevalence estimate based on the collection of empirical data, i.e. a representative national-level biomarker survey of HBsAg seroprevalence in children aged ≤5 years (and also in older children, as appropriate) (Table 3).

## TABLE 3 HBV INCIDENCE: IMPACT TARGET AND MEASUREMENT INDICATORS

| Targets | Preferred measurement indicators | Additional measurement indicator | Data sources and approaches to measurement |
|---|---|---|---|
| ≤0.1% HBsAg prevalence in those aged 5 years or less[1] | % HBV infections in ≤5 year olds[1] | MTCT rate ≤2%[2] | • National serosurvey<br>• Post-vaccination serological testing (PVST) survey for MTCT rate<br>• Programmatic data |

*Source:* Interim guidance for country validation of viral hepatitis elimination. Geneva: WHO; 2021 *(4)*

[1] The ≤0.1% HBsAg prevalence can be measured among either 5 year olds, 1 year olds or those aged 1–5 years, according to existing country surveillance and data collection activities. For those regions and countries with a long history of high Hep B vaccination coverage (e.g. Region of the Americas), and that already conduct school-based serosurveys, there could be flexibility in conducting serosurveys in older children >5 years.

[2] The ≤2% MTCT rate is an additional target to ≤0.1% HBsAg prevalence among ≤5-year-old children in countries that provide targeted timely HepB-BD, where vertical transmission remains in specific populations of pregnant women with high HBsAg.

Representative childhood serosurveys have been conducted in five of the pilot countries: Egypt, Georgia, Mongolia, Rwanda, Thailand, confirming the feasibility of this direct, empirical measurement approach (figure 1). Georgia, Rwanda and Thailand have already attained the 2030 target of ≤0.1% HBsAg prevalence among children less than 5 years of age. For validation, attainment of impact targets must be accompanied by reaching and maintaining the achievement of programmatic targets for 2 years as well as demonstrating the implementation considerations. In Rwanda, the study was conducted among children aged 10–14 years as part of the AIDS impact assessment survey (RPHIA, 2019 *(6)*) while in Georgia, an HBV and HCV survey was conducted among children 5–17 years of age in combination with a COVID-19 serosurvey (7,8). A hepatitis B serosurvey was conducted in Thailand (2014) in children aged 6 months to 5 years as part of the evidence to demonstrate the success of the national EPI programme *(9)*. In Mongolia (2011) and Egypt (2015), the prevalence of HBsAg in children under 5 years was 0.5% and 0.2%, respectively, and there are plans for further assessment and repeat surveys. This may be costly, given the low HBV prevalence.

The MTCT rate is an additional target in countries that provide timely targeted HepB-BD (birth dose vaccination) and for those countries with a low HBsAg prevalence but where it is recognized that there is still continuing vertical transmission due to specific subpopulations of pregnant women with high HBsAg prevalence (e.g. among Indigenous populations or migrant populations from high HBsAg-prevalence countries). Of the 194 WHO Member States. It is noted that 111 (57%) Member States have a universal HepB-BD policy, 32 (16%) have a targeted policy that focuses only on exposed infants and 51 (27%) have no policies *(5)*. Among the 32 countries with targeted policies, 30 are in the WHO European Region and two in the Western Pacific.

Overall, five of the pilot countries offer universal timely BD and therefore did not require MTCT rate assessment for validation. These countries had measurement limitations related to inadequate coverage of systems to capture maternal HBsAg screening or absence of linkage with maternal and child-care programmes for post-vaccination serology testing (PVST) of exposed infants (figure 1). In Rwanda, guidelines for universal HepB-BD are in place and vaccine introduction imminent. As a first step to implementation of this policy, a pilot of targeted BD was under way using the established HIV prevention of mother-to-child transmission (PMTCT) programme as a platform for maternal HBsAg testing and administration of HepB-BD to exposed infants born to HBV-positive mothers.

The United Kingdom (England) was the only pilot country with a targeted BD policy and reported an estimated MTCT rate of <0.5% *(10)*. Data were obtained from the routine monitoring and evaluation systems for neonatal vaccine uptake and the Infectious Diseases in Pregnancy Screening programme (IDPS), which has >99% coverage.

Infants born to HBV-positive mothers identified through universal antenatal screening receive a BD and 4-week dose of hepatitis B vaccine in addition to the universal infant hepatitis B immunizations and are routinely tested for HBsAg at 12 months of age by dried blood spot. Using these data, the prevalence of HBV in children less than 5 years of age and MTCT rates were estimated at ≤0.1% and <0.5%, respectively. The availability of standardized strong monitoring and evaluation (M&E) systems promoted the use of routine data for assessing both impact and programme targets for EMTCT of HBV. Specific country profiles with further details are given in the annex.

#### 4.1.1.2. Measurement of HBV vaccination coverage using programme data

In terms of programme data, surveillance and monitoring systems for assessing universal childhood HBV vaccination coverage are well established in all the pilot countries (UNICEF/WHO), all of whom have a strong EPI and have attained relevant programmatic targets. Figure 1 shows programme highlights from the pilot countries.

**FIGURE 1** Availability of in-country mechanisms to measure impact and programme targets for HBV EMTCT among participating countries

| WHO target | Brazil | Egypt | Georgia | Mongolia | Rwanda | Thailand | United Kingdom (England) |
|---|---|---|---|---|---|---|---|
| **Impact targets** | | | | | | | |
| **WHO preferred measurement** ≤0.1% prevalence of HBsAg in children ≤5 years of age (direct measurement serosurvey) | | | | | | | |
| **Alternative measurements/ available data** | | NA | NA | NA | NA | NA | |
| ≤2% Maternal–child transmission rate | | | | | | | |
| **Programme targets** | | | | | | | |
| ≥90% Hepatitis B vaccination coverage (HepB3) | | | | | | | |
| ≥90% Hepatitis B vaccination coverage (universal HepB-BD) | | | | | NA | | NA |
| ≥80% Coverage of Hep B-BD and HepB3 in all provinces of subnational areas | | | | | | | |
| ≥90% Coverage of HBsAg testing among pregnant women | | | | | | | |
| ≥90% Antiviral therapy coverage among eligible pregnant women | | | | | | | |

Measurement system available
Measurement system available with limitation
Measurement system not available

HepB-BD: hepatitis B vaccine birth dose; HepB3: three doses of hepatitis B vaccine; HBsAg: hepatitis B surface antigen; NA: not applicable

### 4.1.2. Lessons learned: criteria for validation of elimination of mother-to-child transmission of HBV

**Assessment of the EMTCT impact target (HBsAg prevalence in ≤5 year olds) using national serosurveys is feasible but costly and may require innovative methodologies or flexibility to conduct measurement among older children.**

Nationally representative serosurveys in countries with very low prevalence of HBsAg in children under 5 years of age require a large sample size and significant financial costs. To increase efficiencies, some countries have integrated childhood hepatitis B serosurveys into existing national surveys for other disease areas, such as in the AIDS impact survey or COVID-19 survey, as documented by Rwanda and Georgia, respectively. There is a need to further explore flexibilities of age, especially in countries with long-standing HBV childhood vaccination at high coverage. Approaches such as multiphase sampling (as has been demonstrated in Colombia) offer additional insights to minimize the challenges and cost of conducting a serosurvey in the low-prevalence population, especially where there have been decades of HBV vaccine implementation.

**Routinely available programmatic data can be expanded and strengthened for the assessment of both HBV prevalence among children aged ≤5 years of age and MTCT rates.**

This requires the availability of strong programmes and integrated strategic information systems that generate routine and standardized data. The surveillance systems for assessing childhood HBV vaccination coverage were well established in all seven pilot countries (UNICEF/WHO), all of which have already achieved high levels of coverage with three doses of hepatitis B. Lack of systematic and standardized reporting for HBsAg antenatal screening and/or follow-up screening of exposed neonates was an impediment to evaluating the MTCT rate in all pilot countries except in the United Kingdom (England) and Egypt.

Although the MTCT rate will not be required for validation in many countries, good data capture of antenatal care (ANC) testing coverage and follow up of HBsAg-exposed infants can ultimately be beneficial to both the high HBV-prevalence countries that may wish to aim for validation of HBV PTE, and low-prevalence countries that wish to measure the MTCT rate.

In Rwanda, the availability of a strong EMTCT programme that provides routine maternal screening for HIV provided a platform that could be leveraged for HBV EMTCT and may serve as a strategic approach to promoting triple elimination of HIV, HBV and syphilis. This approach can also be combined with the planned HepB-BD introduction.

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## Box 4.1.2

| Key lessons learned from assessment of criteria for validation of elimination of mother-to-child transmission of hepatitis B |
|---|
| Assessment of the EMTCT impact target (HBsAg prevalence in ≤5 year olds) using national serosurveys is feasible but costly and may require innovative methodologies or flexibility to conduct measurement among older children. |
| Routinely available programmatic data can be expanded and strengthened for the assessment of both HBV prevalence among children aged ≤5 years of age and MTCT rates. |

## 4.2. Criteria for assessment of reduction in hepatitis C incidence

### 4.2.1. Key findings

#### 4.2.1.1. Direct measurement of HCV incidence

Direct estimation of HCV incidence is based mainly on data from prospective cohorts (e.g. HCV antibody re-testing of persons who initially tested negative at baseline).

Overall, two of the seven pilot countries have documented direct estimates of HCV incidence based on cohort design in the general adult population or among PWID (see figure 2). Egypt has provided estimates of HCV incidence using cohort approaches in the general population and Georgia has provided estimates of HCV incidence in PWID using such approaches.

In a demonstration project in Egypt, conducted in collaboration with WHO, re-testing of 97% of 20 490 individuals who had previously tested HCV-Ab negative in nine villages during 2015–2016 was done in 2018. There was a substantial reduction in the overall incidence of new HCV infections compared to a previous estimate of incidence in the Nile Delta region in 2006 *(11)*. This study has now been replicated in 2021 using a nationally representative sample of more than 200 000 persons who had previously tested HCV-antibody negative (Ministry of Health and Population, Egypt, unpublished data).

Estimates for incidence among PWID have been available in Georgia – using different methodologies. A prospective study conducted in Georgia's capital city, Tbilisi, from 2018 to 2019 estimated an incidence (anti-HCV conversion) of 0.77 (95% confidence interval [CI]: 0.31–1.59) per 100 person-years *(12)*. Results are also available and published from a reinfection study in 2015–2017, which estimated an HCV incidence of 1.2 per 100 person-years in previously treated PWID *(12)*.

These incidence studies are the optimal approach to generating empirical data on HCV transmission. They also present the opportunity to include nested case–control studies to understand the drivers of ongoing HCV transmission in a specific country and so inform an appropriate response. For example, in Egypt, dental procedures were identified as potential sources of new HCV infections *(13)*.

#### 4.2.1.2. Alternative measurement for HCV incidence

As shown in figure 2, alternative measurements for HCV incidence have been conducted in Brazil, United Kingdom (England), Georgia and Mongolia. These included HCV incidence estimates based on surveillance of acute HCV and on reduction of HCV viraemic prevalence.

## TABLE 4 INDICATORS FOR HCV INCIDENCE MEASUREMENT AND PROPOSED DATA SOURCES

| Targets | Preferred measurement indicators | Alternative (proxy) measurement indicators | Data sources and approaches to measurement |
|---|---|---|---|
| Annual incidence of new HCV infections <5/100,000/general population<br>AND<br><2/100 in people who inject drugs (PWID) | No. of new HCV cases per 100,000 population<br><br>AND<br><br>No. of new HCV cases per 100 PWID | Reduction in HCV viraemic prevalence by 80% from baseline | • Prospective cohort studies<br>• Surveillance for acute hepatitis<br>• Repeat cross-sectional surveys assessing HCV viraemic prevalence<br>• Modelled estimates using serial serosurveys |

*Source:* Interim guidance for country validation of viral hepatitis elimination. Geneva: WHO; 2021 *(4)*

#### 4.2.1.3. Alternative measurement for HCV incidence: surveillance for acute hepatitis

Mongolia, for example, has provided an estimate of HCV incidence through surveillance of acute HCV at the hospital level and has shown decreasing incidence trends from 4.3 per 100 000 people in 2018 to 3.4 per 100 000 people in 2020 (Mongolia, Health indicators 2018–2020, Health Development Center). All new incidence cases of acute HCV are recorded in the AM-2 form (Health Ministerial Order No. 611 of 2019). Recent modelling from the country by the CDA Foundation (CDAF) suggests a much higher incidence rate of around 80 per 100,000 person-years in 2020. This discrepancy needs further exploration but points to the underestimation of HCV transmission through surveillance of acute HCV in the health-care system.

In Brazil, HCV is a notifiable disease and the country reports annual case detection rates (defined as the total number of annual confirmed cases of HCV reported to the Ministry of Health, per total population [per 100 000]). The HCV case detection rate was estimated at 10.1 per 100 000. This indicator includes acute hepatitis, but also all cases of newly diagnosed chronic hepatitis. Cases can be reported by any health facility across the country, including primary health care facilities, specialized services, hospitals, blood banks and may include as well those diagnosed as part of screening campaigns. This measurement is also directly impacted by the availability and coverage of hepatitis screening across the country and thus during a screening campaign, the number of reported cases is expected to increase. This approach is inadequate to measure or estimate HCV incidence.

#### 4.2.1.4. Alternative measurement for HCV incidence: viraemic prevalence

In Georgia, the viraemic prevalence in the adult population was estimated at 5.4% in 2015 and at 1.8% in 2021 *(12, 14)* through high-quality national serosurveys. Subsequent modelling of HCV incidence using viraemic prevalence (Bristol University, March 2022[2]) estimates an HCV incidence of 70 per 100 000 person-years in the general population and of 1.14 (0.08–6.4) per 100 person-years in PWID – indicating a 58% decrease in incidence in both population groups between 2015 and 2021.

In the United Kingdom (England), it is estimated that in 2020, around 81 000 people were living with chronic HCV infection *(15–17)*. This represents a decrease of 37% from the 2015 estimation of 129 000 persons with chronic HCV infection *(15)*. Additionally, a reduction in the prevalence of HCV viraemia of 39.7% from the 2015 baseline by 2020 has been described among PWID *(15, 17)*. The decline in chronic HCV prevalence in PWID is thought to be due largely to a treatment effect. The monitoring of serial HCV viraemia in the United Kingdom (England) is possible because of a well-established (>30 years) unlinked anonymous monitoring (UAM) survey, an annual biobehavioural serosurvey in PWID attending drug and alcohol services, which can measure annual viraemic prevalence in this population in which transmission is occurring.

In Rwanda, the first nationally representative HCV survey has been conducted as part of the HIV population study (RPHIA, 2019) *(6)* and demonstrated an HCV prevalence of 0.8%, highlighting a decline compared to historical cohorts. Country serosurveys – such as this one in Rwanda – can provide an opportunity to establish a system for re-testing previously negative persons to allow direct assessment of incidence (as described in Egypt, for example).

#### 4.2.1.5. Measurement of HCV programme data

In terms of programme targets, coverage of the cascade for testing and treatment was the most precisely documented and available. Some of the pilot countries have made very strong progress in offering testing, diagnosis and treatment to their populations. For example, in terms of treatment coverage of people diagnosed with chronic HCV reported from ministries of health, the 80% target for treatment coverage was achieved in Brazil (92%, 2020), Egypt (94.2%, 2021) Rwanda (97%, 2020), and Georgia (81%, 2020). High treatment coverage rates are also noted in the United Kingdom (England) and Mongolia, at 65% and 68%, respectively. Although assessment of the treatment coverage rate from programmes are relatively straightforward, the estimates for the proportion of people diagnosed with chronic HCV require a baseline assessment of the population estimate at the start of the elimination response to serve as denominator. The evaluation of this indicator was documented using diverse definitions and parameters and was shown to be often overestimated in some pilot countries. No data were provided from Thailand (*see* figure 2).

[2] Presentation by Bristol University at national TAG meeting in March 2022

**FIGURE 2** Availability of in-country mechanisms to measure impact and programme targets for HCV incidence according to participating countries

| WHO target | Brazil | Egypt | Georgia | Mongolia | Rwanda | Thailand | United Kingdom (England) |
|---|---|---|---|---|---|---|---|
| **Impact targets** | | | | | | | |
| **WHO-preferred measurement for incidence**<br><br>≤5 new HCV infections/100 000 in adult population per year | | | | | | | |
| ≤2 new HCV infections/100 in PWID population per year | | | | | | | |
| **Alternative measurements for incidence estimations as per interim guidance** | | NA | | | | NA | |
| **Programme targets** | | | | | | | |
| ≥90% of persons with chronic HCV diagnosed | | | | | | | |
| ≥80% proportion of persons with chronic HCV treated | | | | | | | |
| 0% of unsafe injections administered in health-care settings | | | | | | | |
| 100% of blood units screened for bloodborne diseases | | | | | | | |
| ≥300 syringes and needles distributed /PWID/year | | | | | | | |
| >40% of opioid-dependent people on OST | | | | | | | |

Measurement system available
Measurement system available with limitation
Measurement system not available

NA: not applicable; OST: opioid substitution therapy; PWID: people who inject drugs

Only one country has documented injection safety at the country level (Rwanda) as per the indicator from the *Interim guidance*. In Egypt and United Kingdom (England), the policy and procurement system document the exclusive use of auto-disabled syringes in the health-care system; this was considered as alternative data to affirm injection safety at the country level. All countries were able to demonstrate that screening for HCV and HBV was routinely done by blood transfusion services; the quality of these services was not assessed. We also noted that four out of the seven countries were able to show estimates for coverage of harm reduction indicators in PWID. The remaining countries highlighted problems with criminalization of this population and the absence of a programmatic response and/or systematic data availability; some countries also highlighted the fact that governments did not see this as a public health priority. Several countries have highlighted the need to consider more flexible and alternative measurements of the coverage of needle and syringe programming. The United Kingdom (England) uses a supplementary indicator based on the percentage of PWID reporting adequate coverage for their injecting needs.

To increase the understanding of harm reduction services and to assess coverage more flexibly, we assessed additionally the coverage of opioid substitution therapy (OST) within the piloting exercise. We observed that four out of the seven countries were able to show estimates for coverage of harm reduction indicators.

### 4.2.2. Lessons learned: criteria for assessment of reduction in incidence of hepatitis C infection

**Direct measurement of HCV incidence using serosurvey data at country level is feasible and requires resources and political commitment.** Most pilot countries have not yet established formal processes for measuring and monitoring HCV incidence based on direct, serosurvey data in the general adult population or among PWID. However, there are now examples of the feasibility and affordability of direct measurement of HCV incidence in the general population and PWID. For example, re-testing of previously negative individuals in the context of screening campaigns or national serosurveys may be feasible and requires further evaluation The methodology of these approaches can be further shared and evaluated.

Nevertheless, costs and feasibility will vary substantially by country and will depend on the type of HCV epidemic, estimated sample size and methodology used. It is also important to note that there are limitations to measuring incidence through cohort studies related to representativeness, attrition and sustainability. Other methodologies for HCV incidence estimates based on triangulation of empirical data with other data points, such as prevalence estimates require further evaluation.

**The reduction in viraemic prevalence[3] may not be a fully appropriate substitute for direct measurement of reduction of HCV transmission in all settings and populations but is a valuable additional metric for measuring progress towards elimination and can be a very useful parameter for modelling the reduction of incidence.** In some country datasets such as Georgia, the viraemic prevalence seemed to accurately mirror reduction in incidence. On the other hand, insights obtained from the data in the United Kingdom (England) suggest that the decline in viraemic prevalence is largely due to treatment effect and potentially not yet reflected in the same amount of incidence reduction, notably among PWID. These findings suggest that (a) prevention and harm reduction services will need to be improved to support and maintain the decline in incidence, and (b) use of this metric as a proxy for incidence may be inadequate for measurement of HCV incidence in all populations and contexts. There is a need to further support and refine these finding from other studies.

**Routine case registries and surveillance of acute infection fail to adequately measure HCV incidence.** Estimates of HCV incidence based on routine surveillance of acute HCV infections or from routine HCV case registries have been used in Mongolia and Brazil, respectively. Such routine surveillance that relies on case-based reporting is subject to underestimation of national incidence rates, as acute HCV infection is very rarely clinically symptomatic. Additionally, case registries are based on detection of both acute hepatitis and newly diagnosed chronic hepatitis and are directly impacted by the availability and coverage of hepatitis screening across the country, including during screening campaigns. Neither of these strategies is a suitable proxy for estimating HCV incidence.

**The use of absolute targets for measuring progress and validation of the decline of HCV transmission will be challenging in high-burden countries.** Egypt, for example, was able to demonstrate an over 90% reduction in HCV incidence from a baseline of 220 per 100 000 population/year in 2015 to 19 per 100 000 person-years in 2019 using a nationally representative sample of more than 200 000 persons who had previously tested HCV-antibody negative. Recent evaluation estimates a further reduction to 9/100 000 in 2021 (Egypt Ministry of Health and Population, unpublished data).

To recognize the challenges of achieving significant reduction in HCV incidence in high-burden countries, and the considerable progress made in some countries, there is a demand for establishing a PTE approach to measure progress on reduction of HCV incidence and other criteria (including mortality reduction) – similar to the HBV EMTCT PTE established for validation of triple elimination of HIV, hepatitis B and syphilis.

[3] 80% decline in prevalence of HCV infection as a proxy for an 80% decrease in HCV incidence as per *Interim guidance*

**The proportion (%) of persons with chronic hepatitis C diagnosed in the population was often overestimated.** The most robust and reliable estimates for cascade data can be generated using representative nationwide surveys (for the denominator), combined with robust programmatic data as, for example, collected in Georgia. This indicator was subject to different interpretations by both Ministry of Health and partners, leading to significant overestimation in some cases. Using the number of infected individuals at baseline – before initiation and roll out of a strong national response – may provide the more realistic assessment of this metric. The need for a clear, unambiguous definition and harmonization of the measurement of this indicator is indicated.

**Measuring progress in prevention interventions remains challenging, especially in relation to safe injection practices as well as for needle and syringe programming.** A 0% proportion of unsafe injections in health-care facilities is one of the essential prevention targets for viral hepatitis elimination. Data for this programmatic target are best taken from health facility surveys or can be alternatively derived from population surveys (e.g. Demographic and Health Surveys). Only one country has documented this indicator at the country level (Rwanda).

For example alternative measurement approaches may need to be investigated; the policy and procurement of auto-disabled syringes in the health-care system may be an alternative measurement approach. Similarly, other measurement approaches for the assessment of needle and syringe programme coverage may need to be investigated in the future.

**Box 4.2.2**

| Key lessons learned from the Criteria for assessment of reduction in hepatitis C incidence |
|---|
| Direct measurement of HCV incidence using serosurvey data at country level is feasible and requires resources and political commitment |
| The reduction in viraemic prevalence may not be a fully appropriate substitute for direct measurement of reduction of HCV transmission in all settings and populations but is a valuable additional metric for measuring progress towards elimination and can be a very useful parameter for modelling reduction of incidence. |
| Routine case registries and surveillance of acute infection fail to adequately measure HCV incidence. |
| The use of absolute targets for measuring progress and validation of the decline of HCV transmission will be challenging in high-burden countries. |
| The proportion (%) of persons with chronic hepatitis C diagnosed in the population was often overestimated. |
| Measuring progress in prevention interventions remains challenging, especially in relation to safe injection practices as well as for needle and syringe programming. |

## 4.3. Criteria for HBV - and HCV-specific mortality

### 4.3.1. Key findings

#### 4.3.1.1. Preferred approaches to mortality measurements

Direct measurements of absolute mortality reduction from HBV and HCV may be based on data from vital registration sources such as death certifications, or from cancer registries and sentinel clinics (Table 5). This requires national data systems with the capacity to estimate, monitor and link the number of liver-related deaths (especially liver cancer and cirrhosis) among people with HBV and/or HCV infection.

Vital registration systems that recorded deaths and provided death certificates were available in all countries. Five of the pilot countries highlighted the significant limitations of this data system (figure 3). Further country details are shown in the Annex.

## TABLE 5 INDICATORS FOR MEASUREMENT OF IMPACT TARGETS OF ABSOLUTE MORTALITY REDUCTION FROM HBV/HCV

| Targets | Preferred measurement indicators | Alternative (proxy) measurement indicators | Data sources and approaches to measurement |
|---|---|---|---|
| Annual incidence of HBV-related deaths <4/100 000<br><br>Annual incidence of HCV-related deaths <2/100 000 | No. of deaths caused by HCV and/or HBV infection per 100 000 population / year | Reduction in HCV viraemic prevalence by 80% from baseline | • Data from vital registration of death and cancer registries (HCC reporting)<br>• Surveillance for sequelae (cirrhosis)<br>• Repeat cross-sectional surveys assessing HCV viraemic prevalence |

*Source:* Interim guidance for country validation of viral hepatitis elimination. Geneva: WHO; 2021 *(4)*

In Egypt, direct estimation of annual mortality rate from death registration (2015-2021) shows a significant decline in hepatitis B- and C-related deaths, representing a 44% reduction in mortality (Egypt Ministry of Health and Population, unpublished data). The attributable fraction of mortality from HCV and HBV infection were 90% and 10% respectively. These proportions differ significantly from the global attributable fractions for HCV and HBV (30% and 66%, respectively) which provided the evidence for the establishment of the differential HCV- and HBV-related mortality rates *(18)*. The national epidemiology of viral hepatitis impacts the relative contribution of HBV and HCV to overall mortality. Adaptation of the differential absolute mortality rate or utilization of the combined global mortality of 6 per 100 000 population/year may require further evaluation in countries with widely differing general population prevalence of hepatitis B and C. Egypt also reports the establishment of over 5000 birth/death registration offices all over the country, and formal reports of reviewed and validated data coming from these vital registration centres would enhance country preparedness for elimination.

Data from Brazil's Mortality Information System (SIM) also showed a decline in HBV and HCV mortality, from 0.94 per 100 000 in 2018 to 0.84 per 100 000 in 2019. However, this surveillance system has limited national coverage. Mongolia, Georgia and Rwanda, articulated the challenges of estimating hepatitis mortality using data and the limitations of death certificates to accurately measure liver cancer or cirrhosis mortality due to HBV or HCV. In Georgia, complementary methodologies for mortality estimates based on triangulation of multiple data systems, including a national cancer registry, vital statistics, and comprehensive hepatitis C elimination programme data, are in the process of producing HCV- and HBV-attributable mortality rates and require further evaluation. There were no mortality estimates available from Thailand.

The use of ICD-10 codes for extracting the attributable fraction and mortality from vital registration provided higher coverage estimates from the United Kingdom (England) and Egypt. The United Kingdom (England), with a more robust database and specific codes suggesting end-stage liver disease (ESLD)/ hepatocellular carcinoma (HCC) as the underlying cause (ONS data 2020), estimated that the annual HCV mortality declined from 0.69 per 100 000 in 2015 to 0.47 per 100 000 in 2020 *(16)*. These low levels of HCV-associated mortality are well within the thresholds required for elimination by 2030 and consistent with the low HCV burden, which is predominantly in PWID. For validation, however, attainment of impact targets must be accompanied by reaching HCV prevention and treatment targets, maintaining this achievement for 2 years as well as demonstrating the implementation considerations. Mortality data for hepatitis B was much less readily available.

#### 4.3.1.2. Alternative measurement

For indirect measurement of liver-related mortality due to HBV and /or HCV, there are several different methodologies, including the use of the incidence of HCC as a surrogate for liver-related mortality, as done in Egypt, United Kingdom (England) and Georgia. Cancer registries could provide good empirical data to estimate mortality from primary liver cancer, specifically HCC.

However, the certainty and completeness of these measurements are variable in different countries. In Rwanda, mortality data were obtained from modelling estimates by the Global Burden of Disease project. These data were not from empirical or country-level sources and were unsuitable for validation purposes. There were no data on mortality from liver cirrhosis in any of the pilot countries.

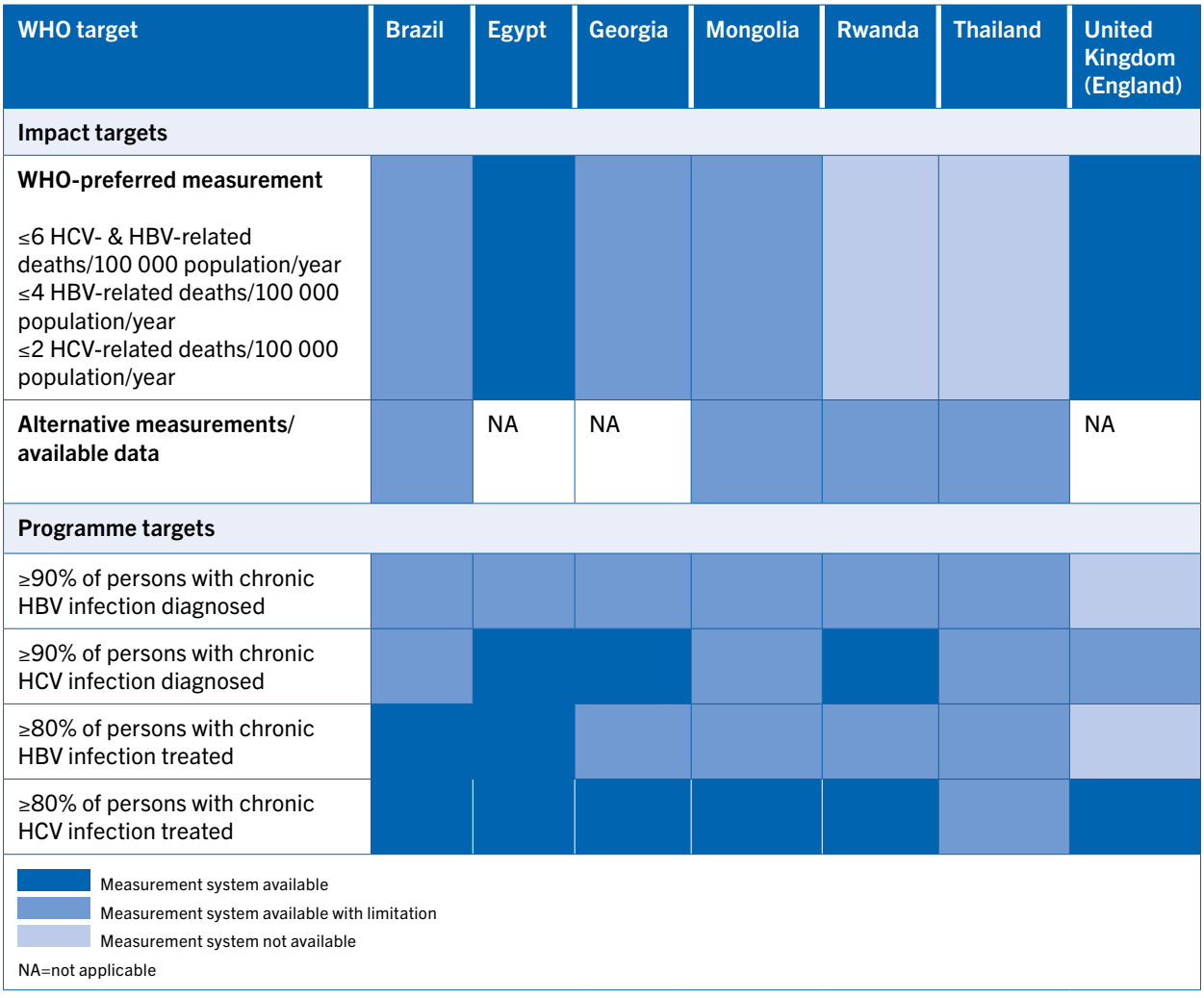
Other WHO-recommended measurement options such as a sentinel network of clinical sites for the estimation of the attributable fraction have not yet been established in any of the pilot countries. However, the feasibility and acceptability of adopting the WHO protocol for sentinel surveillance to assess the attributable fraction has been established in a collaborative study conducted by the European Centre for Disease Prevention and Control (ECDC), European Association for the Study of the Liver (EASL) and the WHO Regional Office for Europe *(19)*.

#### 4.3.1.3. Measurement of programme data

Regarding the measurement of programme targets, the following observations have been made through the piloting process (*see* section 4.2.1.4 for HCV programme data).

The coverage of the cascade of care for testing and treatment for HBV was less precisely documented. Brazil, Egypt, Georgia, Mongolia, Rwanda provided routine data for the proportion of persons with chronic HBV who had been diagnosed, ranging from 3% in Egypt to 85.1% in Rwanda. Georgia tests all individuals chronically infected with HCV for HBsAg, and so has complete data for this subpopulation, but not on a general population scale. Similar variability was noted for the proportion of persons with HBV who are on treatment. The measurement methods for these observations are inadequately standardized and require further assessment.

**FIGURE 3** Availability of in-country mechanisms to measure impact and programme targets for HCV- and HBV-related mortality according to participating country



### 4.3.2. Lessons learned: HBV- and HCV-specific mortality criteria

**Vital registration and cancer registries show declining hepatitis-related mortality but may be inadequate or unreliable as the sole method for measuring mortality towards the 2030 elimination target.** Substantial progress has also been made towards the 2030 target of a 65% reduction in hepatitis-related deaths. Direct estimation of annual mortality from vital registration and cancer registries was a challenge in all the pilot countries. The challenge varied from incomplete vital registration in Rwanda to insufficient subnational coverage in Brazil. Death certificates failed to provide HCC or cirrhosis as an intermediate cause of death and were even less likely to identify HCV or HBV as the underlying cause of death. Most cancer registries do not collect data on the underlying cause of cancer such as viral hepatitis unless additional human resources and funding are specifically provided. This leads to significant underestimation of hepatitis-related deaths from both liver cancer and cirrhosis.

Complementary methods for estimating viral hepatitis mortality based on triangulation of multiple national empirical data systems require further evaluation.

**The national epidemiology of viral hepatitis influences the relative contributions of HBV and HCV to overall mortality.** Current global evidence suggests that up to 96% of deaths due to viral hepatitis are attributable to long-term complications of chronic HBV infection (66%) and chronic HCV infection (30%) *(18)*; namely, decompensated cirrhosis and HCC. The mortality threshold of 2 per 100 000 for HCV and 4 per 100 000 for HBV in the Interim guidance *(4)* is the arbitrary threshold based on application of the global distribution of HCV- and HBV-related mortality. Application of the combined global mortality of 6 per 100 000 persons per year may be better adapted to countries whose national hepatitis epidemiology varies significantly from the estimated global distribution of HBV and HCV.

**Box 4.3.2**

| Key lessons learned from assessment of validation criteria for HBV- and HCV-specific mortality |
|---|
| Vital registration and cancer registries show declining hepatitis-related mortality but may be inadequate or unreliable as the sole method for measuring mortality towards the 2030 elimination target |
| The use of viral hepatitis specific mortality target rates depends on the national epidemiology of viral hepatitis and the relative contributions of HBV and HCV to overall mortality. |

## 4.4. Country feedback on validation criteria, tools and processes

### 4.4.1. Key findings

The various quantitative and qualitative tools were intended to facilitate and standardize the data collection process for countries applying for validation of hepatitis B and C elimination. The tools received wide acceptance from pilot countries and supported the identification of programmatic and surveillance gaps. The pre-assessment tool facilitated a deep self-assessment of countries about the structure of the hepatitis services offered to the population as well as the implementation considerations for validation of hepatitis elimination. The data indicator tool accurately measured programme and impact targets but required clarification and simplification in some specific data fields.

The feedback tool allowed participating countries to provide useful information and feedback on the elimination criteria and highlighted complementary measurement and opportunities for reviewing the elimination tools. The main feedback from countries included the following:

1. The need to utilize routinely available data from national M&E and surveillance information systems as a complementary approach to evaluate the impact targets for elimination;
2. Whilst the global criteria identified PWID as the priority high-risk population for transmission of HCV infection, several countries highlight the need for flexibility to assess other risk populations including persons in prisons and people living with HIV;
3. The need to develop an appropriate criteria for PTE for HCV incidence and HBV and HCV mortality was considered as very important by four of six countries.

### 4.4.2. Lessons learned: country findings and feedback on validation criteria, tools and processes

- The validation tools were robust and acceptable by the countries; however, they need to provide definitions of standardized measures as well as clarification and refinement of data fields.
- There is a need to evaluate key populations according to country context, develop an approach to PTE and establish global and regional governance processes for validation of viral hepatitis elimination.

**Box 4.4.2**

| Country feedback on validation criteria, tools and processes |
|---|
| The validation tools were robust and acceptable by the countries; |
| There is a need to evaluate key populations according to country context, develop an approach to PTE and establish global and regional governance processes for validation of viral hepatitis elimination |

# 5. FIVE KEY CONSIDERATIONS AND NEXT STEPS

The current pilots conducted in seven countries provide an important evidence base for promoting and refining the measurement of the impact and programme criteria as defined in the Interim guidance for country validation of viral hepatitis elimination *(4)*. The findings demonstrate the utility of this framework for measuring and monitoring country progress towards attainment of the targets. The inclusion of the United Kingdom (England) provided a unique opportunity to explore some of the key validation questions as well as facilitate comparison between available empirical data and existing modelling work. The pilots emphasize the need for high-quality national programmes and a comprehensive system for strategic information and surveillance. The five key considerations and next steps are highlighted below.

1. **Establish a set of criteria for the Path to Elimination (PTE) for validation of hepatitis B and C elimination in high-burden countries.** The pilot countries have requested the development of a set of criteria for a PTE approach to recognize countries that have made significant progress but are not yet able to attain the absolute impact targets for hepatitis B and/or C because of the initial high burden of infection. PTE has historically been established for validating the EMTCT of HIV and syphilis and now includes HBV *(5)*; it entails a three-tier system (gold, silver and bronze), which recognizes different stages of progress toward elimination. Each tier is defined by service coverage of key programme interventions. Moving to a higher tier brings a country progressively closer to the ultimate elimination targets. WHO will convene a consultation with experts and key partners to establish a criteria for PTE for both hepatitis B and C elimination as a public health threat.

2. **Strengthening routine national surveillance and programme data to support assessment of validation criteria and provide credible input for mathematical modelling where needed.** Where national surveillance and programmatic data are of sufficient quality and coverage, mathematical models using existing in-country data as well as previously published literature may be useful for assessing the progress of countries towards the achievement of the hepatitis B and/or C impact targets.

3. **Complementary methodologies for measurement of hepatitis B and C impact targets should be assessed.** These would include multistage methodologies for assessing HBsAg prevalence among children; using the WHO protocol for surveillance to estimate mortality from cirrhosis and hepatocellular cancer attributable to viral hepatitis B and C; and, generating direct estimates of HCV incidence in different population groups. Other methodologies for measuring HCV incidence or HBV/HCV mortality based on triangulation of relevant data systems including from serosurveys, vital statistics, national cancer registry and programme data require further evaluation.

4. **Validation assessment tools should provide clear and standardized definitions to better support country self-assessment and data collection.** Further refinement is needed of the pre-assessment and data collection tools, including a standardized definition of the indicators with clearly defined numerators and denominators.

5. **A global and regional governance validation process for viral hepatitis elimination should be established.** Structured global governance for viral hepatitis elimination linked to the current Global Validation Advisory Committee (GVAC) for MTCT of hepatitis B may be augmented with capacity to address viral hepatitis B and C elimination as a public health problem. At the regional level, an interim governance structure leveraged on pre-existing validation committees such as the hepatitis B control verification committee and Validation Committee for Elimination of Mother-to-Child Transmission of HIV and syphilis can be considered.

WHO is currently developing a Global Framework for Multi-disease Elimination (GFME) as an overall framework to facilitate elimination of multiple communicable diseases. This Framework will provide a holistic, comprehensive, and sustainable people-centred approach to future validation within the context of universal health coverage (UHC).

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## Box 5

| Five key considerations and next steps |
|---|
| Establish a set of criteria for the Path to Elimination (PTE) for validation of hepatitis B and C elimination in high-burden countries. |
| Strengthening routine national surveillance and program data to support assessment of validation criteria and provide credible input for mathematical modelling where needed. |
| Complementary methodologies for measurement of hepatitis B and C impact and programme targets should be assessed. |
| Validation assessment tools should provide clear and standardized definitions and measurement to better support country self-assessment and data collection |
| A global and regional governance validation process for viral hepatitis elimination should be established |

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# ANNEX. KEY DATA INPUTS AND HEPATITIS ELIMINATION PROFILES FROM THE SEVEN PARTICIPATING PILOT COUNTRIES

## BRAZIL

| 0.4 | 0.84 |
|---|---|
| Confirmed cases of HBV among children <5 years /100 000 live births (2021) | Number of HCV- and HBV-related deaths/ 100 000 population per year (2019) estimated from ICD-10 codes |

In Brazil, the public health system provides free and universal treatment for all HCV-infected patients, and the surveillance system is based on compulsory notification (case registry) of HCV infection.

**"It is very important and an honor for the National Hepatitis Program to be able to contribute to the development of tools that will be used in the future to certify the elimination of hepatitis B and C in countries. It is also an opportunity to notice the Program's advances in its 20 years and plan the qualification of actions, monitoring and information systems for the coming years."**

**"The tools proposed by the WHO prove to be broad and complete. This characteristic allows a deep self-assessment of countries about their structure and services offered to the population. The tools also make it possible to identify weaknesses and aspects that need more efforts to provide an adequate response on the actions implemented to eliminate viral hepatitis."**

| WHO-preferred elimination indicator | Brazil's progress towards elimination |
|---|---|
| **HBV EMTCT** | |
| ≤0.1% Prevalence of HBsAg in children ≤5 years of age | Complementary data [1] |
| ≤2% Maternal–child transmission rate | No estimates |
| ≥90% Hepatitis B vaccination coverage (HepB3) | 68% (2021) |
| ≥90% Hepatitis B vaccination coverage (HepB-BD) | 60% (2021) |
| ≥90% Coverage of HBsAg testing of pregnant women | No estimates |
| **HCV incidence** | |
| ≤5 new HCV infections/100 000 in adult population per year | Complementary data [2] |
| ≤2 new HCV infections/100 in PWID population per year | No estimates |
| **Mortality** | |
| ≤6 HCV- & HBV-related deaths/100 000 population per year | Complementary data [3] |
| ≤4 HBV-related deaths/100 000 population per year | 0.2 (2019) |
| ≤2 HCV-related deaths/100 000 population per year | 0.7 (2019) |
| **HBV/HCV prevention, testing and treatment programmes** | |
| ≥90% of persons with chronic HCV infection diagnosed | 16.5% (2020) |
| ≥80% of persons with chronic HCV infection treated | ≥80% (2020) |
| 0% of unsafe injections administered in health-care settings | No estimates |
| 100% of blood units screened for bloodborne diseases | No estimates |
| ≥300 syringes and needles distributed per PWID per year | No estimates |
| ≥40% of opioid-dependent people on opioid substitution therapy (OST) | No estimates |

[1] 0.4/100 000 live births (2021) confirmed cases of HBV among children <5 years (HBsAg or anti-HBc IgM serology)
[2] 4.4/100 000 estimated as HCV detection rate from case registries, i.e defined as number of confirmed cases of HCV /100 000 population
[3] 0.84/100 000 (2019) estimated from ICD-10 codes and death registry as death from acute or chronic viral hepatitis

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| EGYPT | | |
|---|---|---|
| **0.2%** | **9** | **8.78** |
| Prevalence of HBsAg in children ≤5 years of age (2015) | HCV incidence rate per 100 000 adult population per year (2021) | HCV- and HBV-related deaths/100 000 population per year (2021) |

In 2018, Egypt launched the "100 million healthy lives" campaign; a nationwide campaign to screen Egyptians for HCV and treat them. Together with this, the Egyptian government made direct-acting antiviral agents (DAAs) widely available at markedly reduced prices. Since then, more than 4 million Egyptians have been treated, with a cure rate exceeding 95%.

| WHO-preferred elimination indicator | Egypt's progress towards elimination |
|---|---|
| **HBV EMTCT** | |
| ≤0.1% Prevalence of HBsAg in children ≤5 years of age | 0.2% (2015) |
| ≤2% Maternal–child transmission rate | 0.6% (2022) |
| ≥90% Hepatitis B vaccination coverage (HepB3) | 95.2% (2018) |
| ≥90% Hepatitis B vaccination coverage (HepB-BD) | 91.2% (2018) |
| ≥90% Coverage of HBsAg testing of pregnant women | 40% (2021) |
| **HCV incidence** | |
| ≤5 new HCV infections/100 000 in adult population per year | 9 (2021) |
| ≤2 new HCV infections/100 in PWID population per year | 0.4 (2021) |
| **Mortality** | |
| ≤6 HCV- & HBV-related deaths/100 000 population per year | 8.78 (2021) |
| ≤4 HBV-related deaths/100 000 population per year | 1.34 (2021) |
| ≤2 HCV-related deaths/100 000 population per year | 7.44 (2021) |
| **HBV/HCV prevention, testing and treatment programmes** | |
| ≥90% of persons with chronic HCV infection diagnosed | 90.2% (2021) |
| ≥80% of persons with chronic HCV infection treated | 94.2% (2021) |
| 0% of unsafe injections administered in health-care settings | 0% |
| 100% of blood units screened for bloodborne diseases | 100% |
| ≥300 syringes and needles distributed per PWID per year | 260 (2022) |
| ≥40% of opioid-dependent people on opioid substitution therapy (OST) | No estimates |

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## GEORGIA

| 0.03% | 0.77 |
|---|---|
| Prevalence of HBsAg in children 5–17 years of age (2021) | HCV incidence per 100 PWID per year (2019) |

Availability of nationwide HCV testing and treatment registries with unique national identifiers allows Georgia to cross-link HCV programmatic data with the cancer registry and death registry data, potentially assessing HCV-related mortality. Conducting serial population serosurveys has enabled the estimation of reductions in HCV viraemic prevalence in Georgia.

**"Path to elimination could be useful to track the progress for those indicators that can be estimated using the routine surveillance data (e.g. testing and treatment coverage). However, it can be feasible only if it includes programmatic indicators, similar to the HBV EMTCT path to elimination. It might not be feasible for indicators that require special studies or other one-time efforts (e.g. nationwide surveys)."**

| WHO-preferred elimination indicator | Georgia's progress towards elimination |
|---|---|
| **HBV EMTCT** | |
| ≤0.1% Prevalence of HBsAg in children ≤5 years of age | 0.03 (2021)[1] |
| ≤2% Maternal–child transmission rate | No estimates |
| ≥90% Hepatitis B vaccination coverage (HepB3) | 92% (2020) |
| ≥90% Hepatitis B vaccination coverage (HepB-BD) | 97% (2020) |
| ≥90% Coverage of HBsAg testing of pregnant women | 94% (2020) |
| **HCV incidence** | |
| ≤5 new HCV infections/100 000 in adult population per year | No estimates |
| ≤2 new HCV infections/100 in PWID population per year | 0.77(2019) |
| **Mortality** | |
| ≤6 HCV- & HBV-related deaths/100 000 population per year | No estimates |
| ≤4 HBV-related deaths/100 000 population per year | No estimates |
| ≤2 HCV-related deaths/100 000 population per year | Complementary data[2] |
| **HBV/HCV prevention, testing and treatment programmes** | |
| ≥90% of persons with chronic HCV infection diagnosed | 60% (2020) |
| ≥80% of persons with chronic HCV infection treated | 81% (2020) |
| 0% of unsafe injections administered in health-care settings | No estimates |
| 100% of blood units screened for bloodborne diseases | 100% |
| ≥300 syringes and needles distributed per PWID per year | 70 (2020) |
| ≥40% of opioid-dependent people on opioid substitution therapy (OST) | 71% |

[1] Estimated from a serosurvey conducted among children aged 5–17 years

[2] Modelling study in 2019 indicated that HCV mortality reduced by 14%.

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## MONGOLIA

| 0.53% | 3.4 |
|---|---|
| Prevalence of HBsAg in children ≤5 years of age (2011) | HCV incidence rate per 100 000 adult population per year (2020) |

The "Healthy Liver" programme in Mongolia has been successfully implemented to accelerate the country's goals in achieving hepatitis elimination. The cost of medical care and services is covered by health insurance, ensuring the sustainability of care. The coverage of health insurance was progressively expanded to include testing and treatment costs for HCV and later on HBV.

| WHO-preferred elimination indicator | Mongolia's progress towards elimination |
|---|---|
| **HBV EMTCT** | |
| ≤0.1% Prevalence of HBsAg in children ≤5 years of age | 0.53% (2011) |
| ≤2% Maternal–child transmission rate | No estimates |
| ≥90% Hepatitis B vaccination coverage (HepB3) | 96.4% (2020) |
| ≥90% Hepatitis B vaccination coverage (HepB-BD) | 98.5% (2020) |
| ≥90% Coverage of HBsAg testing of pregnant women | 98.8% (2020) |
| **HCV incidence** | |
| ≤5 new HCV infections/100 000 in adult population per year | 3.4 (2020)[1] |
| ≤2 new HCV infections/100 in PWID population per year | No estimates |
| **Mortality** | |
| ≤6 HCV- & HBV-related deaths/100 000 population per year | No estimates |
| ≤4 HBV-related deaths/100 000 population per year | No estimates |
| ≤2 HCV-related deaths/100 000 population per year | No estimates |
| **HBV/HCV prevention, testing and treatment programmes** | |
| ≥90% of persons with chronic HBV/HCV infection diagnosed | 53%/25% (2020) |
| ≥80% of persons with chronic HBV/HCV infection treated | 41%/incomplete data (2020) |
| 0% of unsafe injections administered in health-care settings | No estimates |
| 100% of blood units screened for bloodborne diseases | 100% |
| ≥300 syringes and needles distributed per PWID per year | No estimates |
| ≥40% of opioid-dependent people on opioid substitution therapy (OST) | No estimates |

[1] incidence of acute viral hepatitis due to HCV based on hospital records

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| RWANDA | | |
|---|---|---|
| **0.0%** | **0.8%** | **2.2** |
| Prevalence of HBsAg in children 10–14 years of age (2019) | HCV prevalence (2019) | HCV- and HBV-related deaths/100 000 population per year (2019) |

In 2018, the hepatitis programme in Rwanda launched the HCV elimination plan. Over 6 million people have been screened for HCV and 54 518 have been treated. As part of the initiative, the Government of Rwanda introduced rapid diagnostic tests for HCV and negotiated a price reduction for HCV treatment. Programmatic indicators for hepatitis elimination have been included in the District Health Information Software (DHIS)-2 to allow tracking of progress towards elimination.

**"The path to elimination would document achievements of interim programmatic targets for hepatitis prevention, testing and treatment."**

| WHO-preferred elimination indicator | Rwanda's progress towards elimination |
|---|---|
| HBV EMTCT | |
| ≤0.1% Prevalence of HBsAg in children ≤5 years of age | 0.0% (2019)[1] |
| ≤2% Maternal–child transmission rate | No estimates |
| ≥90% Hepatitis B vaccination coverage (HepB3) | 96% (2020) |
| ≥90% Coverage of HBsAg testing of pregnant women | No estimates |
| **HCV incidence** | |
| ≤5 new HCV infections/100 000 in adult population per year | Complementary data[2] |
| ≤2 new HCV infections/100 in PWID population per year | No estimates |
| **Mortality** | |
| ≤6 HCV- & HBV-related deaths/100 000 population per year | 2.2 (2019)[3] |
| ≤4 HBV-related deaths/100 000 population per year | 1.1 (2019)[3] |
| ≤2 HCV-related deaths/100 000 population per year | 1.1 (2019)[3] |
| **HBV/HCV prevention, testing and treatment programmes** | |
| ≥90% of persons with chronic HBV/HCV infection diagnosed | 85.1%/≥90%[4] |
| ≥80% of persons with chronic HCV infection treated | 96.7% (2021) |
| 0% of unsafe injections administered in health-care settings | 0.8% (2010) |
| 100% of blood units screened for bloodborne diseases | 100% |
| ≥300 syringes and needles distributed per PWID per year | No estimates |
| ≥40% of opioid-dependent people on opioid substitution therapy (OST) | No estimates |

[1] Estimated among 10–14 year olds
[2] 0.8% HCV estimated prevalence in 2019
[3] Mortality estimation based on data from the Global Burden of Disease on mortality from HCC attributable to HBV and HCV
[4] Estimates subject to validation

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## THAILAND

| 0.1% | 10% |
|---|---|
| Prevalence of HBsAg in children ≤5 years of age (2014) | HCV incidence among PWID (2020) |

Thailand has a strong HBV PMTCT programme with coverage surpassing the 2030 global targets.

| WHO-preferred elimination indicator | Thailand's progress towards elimination |
|---|---|
| **HBV EMTCT** | |
| ≤0.1% Prevalence of HBsAg in children ≤5 years of age | 0.1% (2014) |
| ≤2% Maternal–child transmission rate | No estimates |
| ≥90% Hepatitis B vaccination coverage (HepB3) | 99% (2019) |
| ≥90% Hepatitis B vaccination coverage (HepB-BD) | 99.9% (2012) |
| ≥90% Coverage of HBsAg testing of pregnant women | 99.9% (2021) |
| **HCV incidence** | |
| ≤5 new HCV infections/100 000 in adult population per year | No estimates |
| ≤2 new HCV infections/100 in PWID population per year | Complementary data[1] |
| **Mortality** | |
| ≤4 HBV-related deaths/100 000 population per year | 0.44 (2020)[2] |
| ≤2 HCV-related deaths/100 000 population per year | 0.47 (2020)[2] |
| **HBV/HCV prevention, testing and treatment programmes** | |
| ≥90% of persons with chronic HCV infection diagnosed | No estimates |
| ≥80% of persons with chronic HBV/HCV infection treated | 39% /18% (2020) |
| 0% of unsafe injections administered in health-care settings | No estimates |
| 100% of blood units screened for bloodborne diseases | 100% |
| ≥300 syringes and needles distributed per PWID per year | 12 (2020) |
| ≥40% of opioid-dependent people on opioid substitution therapy (OST) | 9.1% (2020) |

[1] HCV prevalence in PWID was 42.2% (2019–2020) and 10% in the 2020 Integrated Biological and Behavioural Surveillance (IBBS) survey.

[2] Proxy mortality data estimates of deaths that are consequences of acute or chronic liver disease

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## UNITED KINGDOM (ENGLAND)

| <0.1% | 0.73 |
|---|---|
| Estimate of HBsAg prevalence among infants at risk of HBV MTCT (2018) | HCV- and HBV-related deaths/100 000 population per year (2020) |

The United Kingdom has high-quality data collection systems and serosurveys that allow tracking of the hepatitis impact and programmatic indicators. These include the unlinked anonymous monitoring (UAM) survey, which is an annual, cross-sectional, biobehavioural survey that recruits PWID through drug and alcohol services, COVER (coverage of vaccination evaluated rapidly) for monitoring immunization uptake, infectious diseases in pregnancy screening programme, and a deaths register for mortality rates and causes.

**With regard to HBV PMTCT, the United Kingdom does not offer a universal HepB birth dose. However, the United Kingdom has a universal HBV antenatal screening programme, combined with a selective neonatal immunization programme with birth dose, which has high coverage for both screening, vaccination and postvaccination serological testing/serosurvey of infants born to infected women, at 12 months of age. The United Kingdom has a universal infant immunization programme starting at 8 weeks.**

| WHO-preferred elimination indicator | United Kingdom (England)'s progress towards elimination |
|---|---|
| **HBV EMTCT** | |
| ≤0.1% Prevalence of HBsAg in children ≤5 years of age | Complementary data[1] |
| ≤2% Maternal–child transmission rate | <0.5% (2018) |
| ≥90% Hepatitis B vaccination coverage (HepB3) | 92.1% (2021) |
| ≥90% Hepatitis B vaccination coverage (HepB-BD) | No estimates[2] |
| ≥90% Coverage of HBsAg testing of pregnant women | >99% (2019) |
| **HCV incidence** | |
| ≤5 new HCV infections/100 000 in adult population per year | Complementary data [3] |
| ≤2 new HCV infections/100 in PWID population per year | Complementary data [3] |
| **Mortality** | |
| ≤6 HCV- & HBV-related deaths/100 000 population per year | 0.73 (2020) |
| ≤4 HBV-related deaths/100 000 population per year | 0.17 (2020) |
| ≤2 HCV-related deaths/100 000 population per year | 0.56 (2020) |
| **HBV/HCV prevention, testing and treatment programmes** | |
| ≥90% of persons with chronic HCV infection diagnosed | 40.4% (2020)[4] |
| ≥80% of persons with chronic HCV infection treated | 65.3% (2020) |
| 0% of unsafe injections administered in health-care settings | Complementary data [5] |
| 100% of blood units screened for bloodborne diseases | 100% (2020) |
| ≥300 syringes and needles distributed per PWID per year | Complementary data [6] |
| ≥40% of opioid-dependent people on opioid substitution therapy (OST) | 73% |

[1] No routine seroprevalence studies in place for HBV in children <5 years in the United Kingdom (England) – only those at risk of MTCT are routinely tested at 12 months and the low prevalence in this cohort (<0.5%) is used to estimate a prevalence of <0.1% for the entire birth cohort *(8)*.

2 Universal BD is not offered. Selective neonatal immunization programme with BD is offered to infants of HBsAg-positive mothers.

3 Serial seroprevalence surveys were used to estimate reduction in viraemic prevalence from 2015 (baseline) to end-2020 as a proxy measure for HCV incidence. 37.2% reduction in viraemic prevalence reported among adults and 39.7% reduction among PWID

4 Estimated among PWID – proportion of PWID testing positive for HCV RNA in the UAM survey who are aware of their chronic HCV infection

5 National infection control and prevention policy and procurement of needles/syringes are in place to ensure 0% unsafe injecting.

6 The United Kingdom (England) reports adequate needle and syringe provision for their needs; through the UAM among people injecting psychoactive drugs participating during 2020, 62.7% reported adequate needles and syringes for their needs (66.1% in 2019).

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