UK Health Security Agency

Hepatitis B in England – 2023 report

Working to eliminate hepatitis B as a public health threat

Data to end of 2021

Contents

Foreword

I am pleased to introduce the first UKHSA report on England's progress towards the elimination of hepatitis B as a public health threat. With safe and highly effective vaccines and new treatments in the pipeline that hold promise for functional cure, elimination of hepatitis B infection is an extraordinary and achievable opportunity. UKHSA has prioritised, and will continue to prioritise, a programme of work to reduce the harmful impact to health of hepatitis C, hepatitis B and HIV. This report includes available data on hepatitis B up to the end of 2021 and will complement the existing annual reports for hepatitis C and HIV.

For England to achieve the elimination of hepatitis B by 2030, in line with our commitment to the World Health Organization (WHO), we must sustain and renew our collective and concerted efforts to improve the whole care pathway from prevention, to testing and diagnosis, and treatment and care. Services need to be accessible, or even to reach out, to all, recognising that the estimated 200,000 people with chronic infection includes many from underserved and marginalised groups in our society, where hepatitis B infection amplifies the health inequalities that they experience.

We should, however, be encouraged by our success in preventing vertical transmission – we achieve almost 100% uptake of hepatitis B universal antenatal screening and more than 90% coverage of neonatal and infant immunisation. Our world leadership in improving the programmes of screening during pregnancy and infant immunisation has been recognised: we achieved WHO Europe certification of elimination of hepatitis B maternal to child transmission in 2022.

More work needs to be done to improve the implementation and monitoring of targeted vaccination in other higher risk groups, and to ensure that individuals at higher risk of chronic hepatitis B infection are tested, diagnosed, engaged and retained in a treatment and care pathway. A major challenge here is increasing professional and public awareness so that people at high risk seek or are offered testing. Furthermore, the eligibility criteria to receive treatment for chronic hepatitis B are complex, and slowing progression of liver disease may currently require lifelong treatment. Whilst we have met the WHO target of achieving a mortality rate less than 4 per 100,000 deaths per year, this is mainly because the prevalence of chronic infection is very low. Therefore, we cannot be complacent as we not yet seen any sustained reductions in hepatitis B associated liver cancer, end-stage liver disease, transplants and deaths.

Despite these challenges, I am optimistic about future progress. The infrastructure, mechanisms and enthusiasm already exist to improve the levels of awareness, and uptake of prevention and treatment programmes. UKHSA will continue to work with our partners to ensure that information from recent innovations in surveillance, evaluation and research are available to improve policy and practice.

At UKHSA, we are united in our belief that hepatitis B elimination in England is achievable, and in our commitment to working together with partners to make it a reality.

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Summary

This is the first UKHSA national report on the scale of hepatitis B virus (HBV) infection and related disease in England up to the end of 2021. Hepatitis B is a blood-borne virus that damages the liver, and can lead to cirrhosis, cancer, and death. Hepatitis B is vaccine preventable and selective and universal immunisation programmes exist in the UK.

The World Health Organization (WHO) estimates that in 2019, 296 million people (3.8%) globally were living with chronic HBV infection and an estimated 820,000 deaths occurred in that same year (1). In May 2016, the United Kingdom (UK) signed up to the WHO Global Health Sector Strategy on Viral Hepatitis committing to elimination of HBV as a public health threat by 2030. In 2017 the cross-agency multidisciplinary expert advice group: the National Strategic Group on Viral Hepatitis (NSGVH) was established to support achievement of the WHO elimination goal in England.

This report presents disease surveillance and programme data to monitor England's progress towards WHO HBV elimination targets. Recommendations for further work by UKHSA and stakeholders to achieve and sustain elimination post 2030 are made.

An estimated 200,000 people (0.45% of the population) are living with chronic HBV infection in England

Using an indirect method (2), UKHSA estimates that the number of people living with chronic hepatitis B infection in England is ~206,000 (95% CI 157,000 to 274,000), equivalent to a prevalence estimate of 0.45% (95% CI 0.35% to 0.60%).

Most of the disease burden (>95%) in England is amongst migrants who have acquired infection overseas in endemic countries prior to arrival in the UK (3). Other communities at higher risk include people who inject drugs (PWID), gay, bisexual and men who have sex with men (GBMSM), sex workers and people detained in prisons or immigration detention centres.

England has surpassed the WHO absolute impact and coverage targets on eliminating mother to child transmission and impact absolute target on HBV-related mortality

In 2021, the WHO introduced new, absolute impact targets including a <2% mother to child transmission (MTCT) rate, ≤0.1% hepatitis B surface antigen (HBsAg) prevalence in ≤5-year-olds, and an annual HBV-related mortality of ≤4 per 100,000 deaths. These absolute targets are currently met or exceeded in England with <0.1% mother to child transmission rate, an estimated <0.1% prevalence in ≤5-year-olds and 0.15 HBV related deaths per 100,000 deaths in 2021.

England has also exceeded the WHO programmatic (coverage) targets of 90% for screening and immunisation which underpin elimination of MTCT. Over 99% coverage of HBV screening

of pregnant women and administration of a timely dose of birth vaccine in babies born to women with HBV was achieved in 2020 to 2021 (4). In 2017, the UK introduced universal infant immunisation against hepatitis B with a hexavalent (DTaP/IPV/Hib/HBV) vaccine at 8, 12 and 16 weeks of age; 2021 quarterly coverage for these 3 doses was 91% to 92%. Estimating the MTCT rate uses post vaccination serological testing by UKHSA's dried blood spot (DBS) testing service where coverage of eligible infants was 58% in 2020 to 2021.

Monitoring and maintaining high vaccine coverage in adult risk groups remains a challenge

Immunisation is the cornerstone of control of hepatitis B in adult risk group populations. More assurance is needed of adequate vaccine uptake in these populations through improved implementation and monitoring of programmes in prisons, sexual health services for GBMSM, and drug services.

Levels of testing and diagnosis are recovering post-coronavirus (COVID-19), but the undiagnosed burden remains unknown

Test positivity for HBsAg in the general population, primary care and sexual health services has remained stable at 0.8% to 1.0% between 2019 and 2021. The number of laboratory reports of new diagnoses of HBV peaked at 11,440 in 2016 and declined to 8,399 in 2019. The size of the population still undiagnosed will be estimated through statistical models.

Testing and diagnosis levels in most settings are recovering following sharp reductions during the COVID-19 pandemic, but pre-pandemic levels have not yet been reached with 6358 new diagnoses in 2021 which is 22.2% lower than in 2019.

The number of people who are diagnosed and on HBV treatment is unknown

Treatment coverage of 80% among those diagnosed is a WHO programmatic target. While in England this is currently unknown, work is in progress to estimate the number of diagnosed people on treatment and to describe the cascade of care by inequality characteristics.

Interventions need to be directed at improving case finding and engagement in care among migrant and minority ethnic groups

As the majority of people with chronic HBV in England are from migrant communities and minority ethnic groups, these likely constitute the majority of the undiagnosed and untreated population. Interventions that are culturally sensitive and aim to improve case-finding and retention in care of migrant populations and minority ethnic groups have been developed with partners and are being evaluated.

Recommendations

The following recommended areas of work have been identified after review of the monitoring data on progress towards WHO elimination programmatic and impact targets presented in this report and have been endorsed by the NSGVH. These areas of work encompass monitoring and evaluation, surveillance, research, advocacy and consensus building, communications and programme improvement.

Current work at UKHSA

UKHSA is leading on work in partnership with the NSGVH, the NHS Antenatal and Newborn Screening Programme, and National Institute for Health Research (NIHR) Health Protection Research Unit (HPRU) in Blood Borne and Sexually Transmitted Infections at University College London and the NIHR HPRU in Behavioural Science and Evaluation at University of Bristol to:

- define national and local indicators for monitoring elimination progress
- generate modelled estimates of incidence and prevalence of chronic HBV infection
- monitor the cascade of care from testing, diagnosis to treatment
- perform serosurveys in key population groups to inform prevalence estimations, including in under 5-year-olds to demonstrate elimination of MTCT
- increase the coverage of post vaccination serology using Dried Blood Spot (DBS) testing in infants born to women with HBV to provide ongoing assurance of elimination of MTCT from 58% (2020 to 2021) to 75%
- establish national antiviral treatment surveillance, including for pregnant women with HBV
- use sequencing, including whole genome sequencing (WGS), where appropriate, to investigate transmission networks and clusters and monitor vaccine escape and antiviral resistance
- design and deliver HBV resources for public and professionals in multiple formats to primary care

New work at UKHSA

UKHSA, in agreement with the NSGVH, will commence work with clinical and public health academic partners including the NIHR HPRUs to:

- undertake evidence reviews and public health and economic evaluations of interventions to improve case-finding, engagement and retention in care, for example for opt-out testing in emergency departments and primary care

- use behavioural insights to develop and optimise implementation of case-finding and retention in care interventions
- develop data dashboards linked to care pathways to monitor performance and guide elimination activities at national and local level
- demonstrate the public health and economic impacts of scaling up testing and treatment interventions and eliminating hepatitis B on disease burden (including cancers, transplants, end-stage liver disease, and deaths prevented)
- monitor characteristics of people tested, diagnosed and on treatment to identify inequities in access and outcome
- establish NSGVH subgroups and organise roundtable discussions with stakeholders to focus on themes, for example treatment surveillance, in-depth review of care pathways

Areas of work that require further discussion and co-design with stakeholders

Prevention, testing, diagnosis, treatment and care services for people at risk of or affected by HBV are mainly funded, commissioned and delivered by external stakeholders, and often devolved to local level. There are therefore multiple stakeholders involved in service configuration and delivery across the care pathway, including:

- Department of Health and Social Care (DHSC) including Office of Health Improvement and Disparities (OHID)
- NHS England
- England local authority commissioners
- Integrated Care Boards (ICBs)
- NHS trusts
- general practice and local medical committees
- NHS screening and immunisation teams
- NHS Antenatal and Newborn Screening: Infectious Diseases in Pregnancy Screening Programme
- NHS Prevention Programme
- NHS Healthcare Inequalities Improvement Programme
- professional clinical networks, for example British Viral Hepatitis Group (BVHG)

UKHSA will collaborate with these stakeholders, as well as academia (HPRU) and patient and third-sector organisations to support actions that improve services for people affected by HBV and contribute to overarching public health aims of preventing new infection and reducing morbidity and mortality from HBV.

Through consensus building among NSGVH members and UKHSA Viral Hepatitis Leads Group, and informed by the data presented in this report, the following areas of work have been identified for further development and prioritisation with relevant partners:

- increasing vaccination offer and uptake, reducing variation and improving monitoring systems in groups at higher risk of HBV including gay, bisexual and other men who have sex with men (GBMSM) in sexual health services, PWID in all settings, prisoners and immigration detainees
- improving primary care testing and vaccination of close household contacts of cases
- optimising harm reduction in community drug services to prevent HBV infection
- strengthening engagement and role of patient and community representative organisations to help raise awareness, develop public resources and improve patient experience
- simplifying national clinical guidance on HBV treatment eligibility to increase treatment coverage and retention in care
- scoping feasibility of health promotion campaigns that are culturally sensitive and targeted towards ethnic minority communities
- determining the optimum workforce and clinic capacity to manage newly diagnosed patients as a result of increased case-finding
- working with organisations to develop a person and place-based approach to improve the integration of care delivery for blood-borne viruses, detection of latent infectious diseases and vaccination uptake in populations with higher risk profiles

Introduction

HBV is a bloodborne virus that infects and damages the liver. Persistent infection over time can lead to cirrhosis, liver failure, cancer and deaths.

HBV can cause an acute or chronic infection; the risk of developing chronic hepatitis B infection depends on age at acquisition. Young infants are at highest risk of acquiring chronic infection. Most healthy adults who have an acute symptomatic infection will clear the infection. However, around 5% of these individuals will develop a chronic infection (hepatitis B surface antigen (HBsAg) in the blood for 6 months or longer (5). These individuals have a greatly increased risk of developing cirrhosis and/or hepatocellular carcinoma (HCC, primary liver cancer) in later life (6).

Viral hepatitis (HBV and HCV) has been on the rise globally becoming a leading cause of death associated with infections, reaching 1.45 million deaths globally in 2013, similar to deaths from HIV and tuberculosis (7, 8). In 2019, it was estimated that globally 296 million people were living with chronic HBV infection; leading to an estimated 820,000 deaths in that same year (1).

Despite the significant burden it places on communities across all global regions, hepatitis has historically not received the same attention as other health and development priorities. In May 2016, the UK signed up to the WHO Global Health Sector Strategy on Viral Hepatitis committing to meet targets of a 90% reduction in incidence of HBV infection and a 65% reduction in mortality from HBV by 2030 from a 2015 baseline (see Appendix 1 WHO targets) (5, 9). More recently, in 2021, WHO introduced absolute impact targets for incidence focusing on elimination of mother to child transmission (MTCT) (including a <2% mother to child transmission rate, ≤0.1% hepatitis B surface antigen (HBsAg) prevalence in children ≤5 years), and an annual mortality of ≤4 per 100,000 deaths (see Appendix 1 WHO targets) (9). In May 2022, the World Health Assembly updated its global strategy for viral hepatitis for the period, 2022 to 2030 renewing the ambitions of the 2016 to 2021 strategy with a focus on absolute targets and system integration (10).

Over 95% of people with newly diagnosed chronic hepatitis B infection in the UK are migrants. Most acquired the infection in their country of origin, either at birth or in early childhood (11). Migrant populations are therefore the main focus for hepatitis B case-finding. The remaining 5% likely acquired chronic hepatitis B in the UK, either through MTCT or through transmission associated with adult risk behaviours such as unprotected sexual intercourse and injecting drug use (12).

Safe and effective vaccines to prevent and control HBV infection have been available since 1982, and the WHO recommended that all countries implement universal immunisation programmes by 1997 (5). Until 2017, the UK HBV immunisation programme was selective immunisation targeting those at highest risk of infection or complications of infection, including post-exposure immunisation of babies born to women with HBV infection, identified through universal screening during pregnancy (13). In 2017, the UK introduced a hexavalent

hepatitis B-containing vaccine into the routine infant immunisation programme. Given that immunisation is the most effective strategy for prevention against HBV infection, this represented a major step change in the control of the HBV in the UK born population.

Current HBV treatments aim to suppress viral replication and reduce liver disease progression as inducing complete viral clearance is rarely possible. Optimal treatment duration is unknown and individual response and treatment may vary from months to years. However, new treatments offering functional cure are on the horizon, including drugs inhibiting viral replication through targeting novel virus targets and therapeutic (as opposed to preventative) HBV vaccines.

Vision and scope

The collective vision for HBV in England developed by the NSGVH is that:

“All people at risk of HBV infection should have access to vaccination and testing. If positive, they should be advised on prevention of onward transmission and placed on a treatment pathway. If negative, action should be taken to reduce subsequent risk of infection.”

This report summarises surveillance data on HBV in the UK, shows progress against the WHO 2030 targets up to 2021 set out in the viral hepatitis strategy for 2016 to 2021 and recommended areas of work for UKHSA and other stakeholders to consider.

While data on hepatitis delta co-infection is not in scope for this report, it may be considered in future reports as a care quality metric since new treatments are becoming available.

Monitoring metrics

To track progress, the following outcomes which include WHO impact targets for incidence and mortality are monitored:

- reduce transmission and the number of new (incident) HBV infections
- prevent mother to child transmission (WHO impact target)
- reduce morbidity due to HBV such as end-stage liver disease (ESLD), hepatocellular carcinoma (HCC) and transplants
- reduce mortality due to HBV and its complications – death by ESLD/HCC (WHO impact target)

Process measures including coverage of services and programmes that are critical in driving down the levels of HBV infection and HBV-related mortality are also monitored. WHO expects programmatic targets to be achieved and maintained for validation of impact targets (see Appendix 1 WHO targets).

Given that infection control measures (legislation, policy and practice) are already in place to prevent transmission in healthcare settings and the blood supply is routinely screened for HBV, the main programmatic or service coverage targets of interest are:

- coverage of antenatal screening in pregnant women
- proportion of eligible pregnant women with HBV infection receiving antiviral therapy
- vaccine coverage of selective neonatal immunisation programme (including birth dose and hepatitis B immunoglobulin (HBIG) if indicated)
- vaccine coverage of universal infant immunisation programme (3 doses at 8, 12, 16 weeks)
- vaccine uptake in high-risk groups (migrants, GBMSM, prisoners and detainees, PWID)
- adequacy of harm reduction provision (captured by several metrics monitoring needle and syringe programmes and coverage of opiate agonist therapy)
- testing uptake in high-risk groups (migrants, GBMSM, prisoners and detainees, PWID)
- numbers and proportion of people with chronic HBV infection diagnosed
- numbers and proportion of people diagnosed with HBV on treatment

In addition to WHO targets, potential England monitoring and evaluation indicators are considered in Appendix table 2 and marked as a placeholder if further development is needed, and so are subject to change. Where relevant and possible, breakdown by key sociodemographic characteristics such as age, sex, sexual preference, ethnicity, world region of birth will be provided in future reports to monitor equity.

Prevalence of HBV infection

Using a previously published method by Schnier et al (2) which uses laboratory surveillance data, UKHSA estimates that the number of people with chronic hepatitis B in England is ~206,000 (95% CI 157,000 to 274,000), equivalent to a prevalence estimate of 0.45% (95% CI 0.35% to 0.60%). The UKHSA estimate for England is roughly consistent with other prevalence estimates by the National Institute for Health and Care Excellence (NICE) (326,000 in the UK in 2008) (14) and the Department of Health and Social Care (DHSC) (180,000 in 2002 in the UK) (11, 15).

Monitoring WHO impact targets for HBV incidence

The WHO absolute impact targets for incidence focus on elimination of MTCT in addition to a relative target to reduce chronic HBV incidence across the population (table 1). Data to monitor progress towards elimination of MTCT impact targets is derived from the selective neonatal and infant immunisation programmes. These immunisation programmes are detailed further in Immunisation against Infectious Disease: Green Book Chapter 18: Hepatitis B (13).

Table 1. WHO proposed impact targets for incidence

Impact target area	WHO 2030 absolute impact target (9)	WHO 2030 relative impact target to 2015 baseline (5)	England status 2020/21
Elimination of mother to child transmission metrics			
HBsAg prevalence in children ≤5 years old	<0.1%		Serosurveillance data available in 2023 Q4
MTCT rate (where countries use a targeted birth dose programme)	≤2%		Target met 0.1%
Relative reduction in chronic HBV incidence metrics			
Reduction in incidence of chronic HBV infection		>95%	Modelled estimates: by Q4 2024

Elimination of mother to child transmission (MTCT)

England has universal antenatal screening offer for HBV and targeted neonatal birth dose as part of the selective neonatal immunisation programme, alongside a universal hepatitis B containing infant immunisation schedule. All pregnant women are offered antenatal screening and tested for HBsAg and infectivity markers (where relevant). Infants born to women testing positive for HBsAg receive a targeted hepatitis B vaccine within 24 hours of birth, with a second dose at 4 weeks followed by a further 3 doses as part of the universal routine childhood vaccines (DTaP/IPV/Hib/HepB) and a final dose at 12 months. Hepatitis B immunoglobulin (HBIG) is also given at birth if the woman has a high infectivity risk, for which the criteria are outlined in the Green Book criteria. Post vaccination serological testing (PVST) for HBsAg, at 12 months, is recommended to check transmission was prevented and to identify infected infants for specialist referral.

In 2022, UKHSA have commenced a series of serosurveillance surveys, using residual blood samples, to monitor the prevalence of HBsAg in children under 5 years old. PVST of babies born to women with HBV provides the MTCT rate. In addition, enhanced surveillance of hepatitis B in children (now part of the Hepatitis Infection Paediatric Surveillance Network (HIPSNet)) monitors the likely route of transmission in children who have been newly diagnosed and investigates whether this was preventable by the England infant immunisation programmes.

Post Vaccination Serology testing (PVST) in infants born to women with HBV

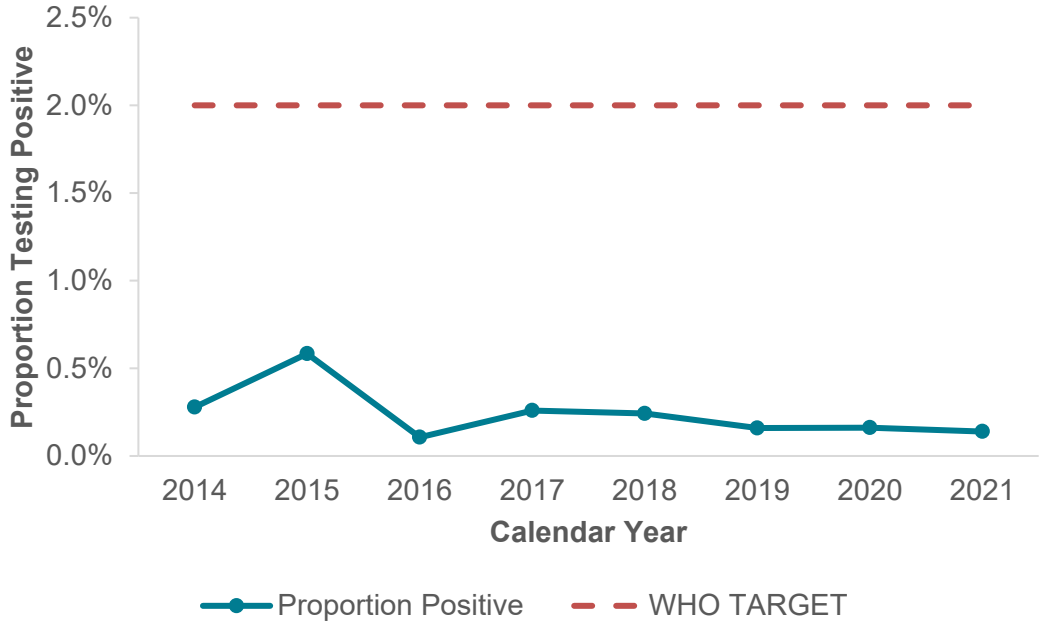
A free national Dried Blood Spot (DBS) testing service was launched in 2014, to monitor PVST and improve testing uptake as the sample can be taken in a GP practice or home visit at the same time as the infant receives their final hepatitis B vaccine dose at 12 months old.

Between 2014 and 2021, 8,893 infants were tested, with a year-on-year increase from 359 in 2014 to 1430 in 2021. This increase represents more units using the service rather than increases in the total number of children born to hepatitis B positive mothers nationally which are collated by the NHS Infectious Diseases in Pregnancy Screening (IDPS) programme. Comparing IDPS reported births with DBS samples received, in 2020 to 2021, an estimated 58.0% (1,197 out of 2,065) of eligible children were tested through this service. Testing outside of the DBS service also occurs but is not consistently reported to UKHSA.

The estimated MTCT rate by year can be seen in Figure 1. This has consistently been below the 2% WHO target having reduced from 0.6% in 2015 to 0.1% in 2021. Of the 8,893 samples tested to date, 1,122 (12.6%) of infants were reported to be born to mothers with high infectivity risk as per the Green Book criteria. The service has identified 19 (0.21%) children with confirmed HBV infection all of whom were born to women with high infectivity risk where risk status was available.

Increased coverage of PVST in infants at 12 months old to 75%, combined with a nationally representative serosurvey will provide assurance that England is maintaining WHO targets to keep MTCT below 2%. Investigation of variation in screening and vaccine coverage by demographics will also identify inequalities that should be addressed in programme implementation. UKHSA are collaborating with IDPS to improve the surveillance of infants to capture the PVST of those not tested by the national DBS service.

Figure 1: MTCT rate from England DBS testing of infants born to women with HBV infection 2014 to 2021



Reduction in incidence of chronic HBV

The WHO impact target for incidence in 2016 was a 95% reduction in new cases of chronic HBV. In 2021 WHO clarified that elimination of MTCT was the main goal and defined the absolute impact targets for EMTCT. Monitoring incidence of chronic HBV infection will be done through statistical modelling.

Trends in incidence of acute HBV

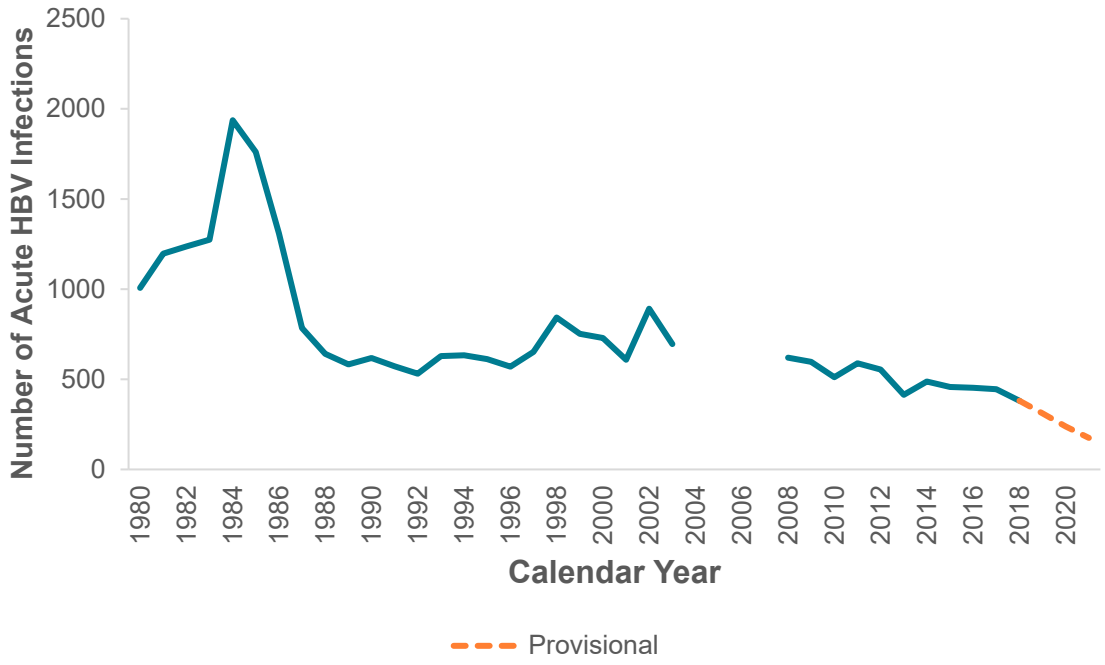
Acute hepatitis is a notifiable condition. Data on incidence of reported acute HBV infection is available from 1980 based on laboratory reports and reconciliation with clinician reporting of acute viral hepatitis (Figure 2). The number of laboratory-reported acute HBV cases can be used as an indicator of national trends.

Acute HBV infection is defined as a person who is hepatitis B surface antigen (HBsAg) positive and anti-hepatitis B core (anti-HBc) Immunoglobulin M (IgM) positive and has abnormal liver function tests with a clinical pattern consistent with acute viral hepatitis. As part of enhanced molecular surveillance of acute HBV, diagnostic laboratories submit all

samples of acute HBV to UKHSA Virus Reference Department for confirmation and sequencing.

Figure 2 shows the number of acute hepatitis B infections in England since 1980. Between 2015 and 2021 an average of 350 acute HBV infections were reported annually to UKHSA (range 175 to 457) (Figure 2). Since 2015, cases of acute hepatitis B in England have continued to decrease. Where information was provided, the most likely route of transmission was heterosexual then GBMSM.

Figure 2: Number of Acute Hepatitis B infections: England 1980 to 2021*



Data source: Acute Hepatitis B Surveillance

* Data from 2004 to 2008 not available due to change in reporting and surveillance system. Laboratory and clinical reporting systems reinstated in 2008

Between 2012 and 2015, a number of acute HBV clusters were reported across England, and through sequencing done at UKHSA Virus Reference Department, were found to be associated with a particular strain of the virus (A2) (16). These clusters involved men who engage in higher risk sexual behavior, such as having unprotected, anonymous sex with multiple male partners but do not necessarily consider themselves as being gay or bisexual. As they do not engage with routine sexual health services, they miss out on opportunities for immunisation against HBV, hepatitis A virus (HAV) and human papilloma virus (HPV), assessment for HIV pre-exposure prophylaxis (PrEP), sexual health advice, and regular screening for sexually transmitted infections (STIs) including HIV. In response to the clusters, targeted health promotional materials were developed and outreach services began to operate at sites frequented by these men.

UKHSA provides guidance on the public health management of acute hepatitis B including use of post exposure prophylaxis with vaccine +/- hepatitis B specific immunoglobulin (see also the Green Book Chapter 18: Hepatitis B).

Monitoring WHO impact targets for HBV-related mortality

Data to monitor trends in HBV-related mortality is available from the Office of National Statistics (ONS) deaths data (see Appendix 2).

Table 2: WHO proposed targets for reductions in HBV-related mortality (see Appendix 1)

Impact target area	WHO interim absolute target (9)	WHO GHSS 2030 targets relative to 2015 baseline (5)	WHO GHSS 2020 target relative to 2015 baseline (5)	England status 2020/21
HBV Mortality (rate or reduction)	≤4 per 100,000	65% reduction	10% reduction	0.15 per 100,000 population 3.3%% decrease in number of deaths since 2015

Deaths from HBV-related end stage liver disease (ESLD) or hepatocellular carcinoma (HCC)

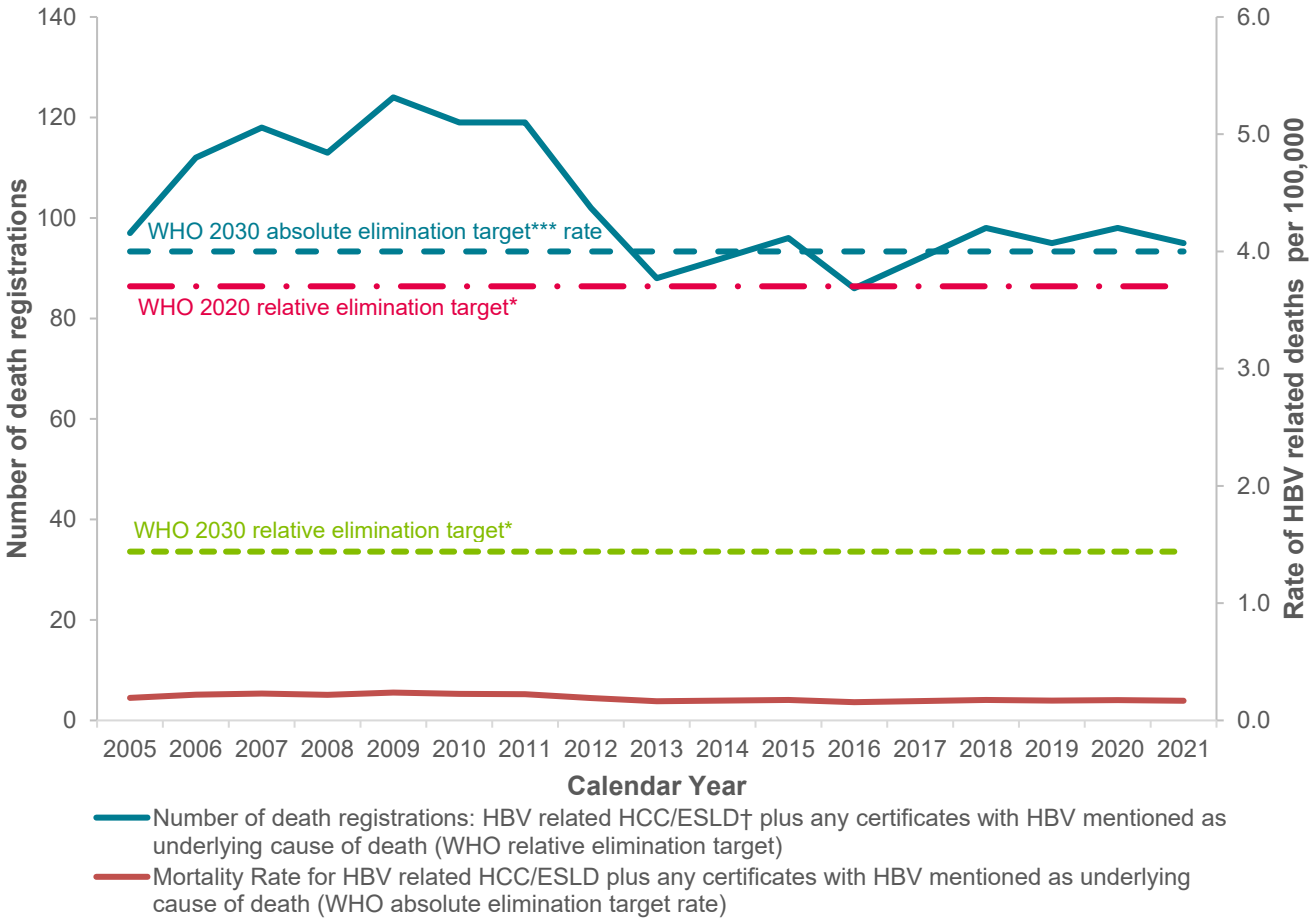
England has a low HBV-related annual mortality rate, already less than 5% of the 2030 WHO absolute mortality target of less than or equal to 4 per 100,000 persons. The annual HBV-HCC/ESLD mortality rate in 2015 WHO baseline year was 0.16 per 100,000 population and remains at a similar level in 2021 (0.15 per 100,000 population).

HBV-related HCC/ESLD deaths, rather than just deaths associated with HBV infection, are monitored since HCC/ESLD presents clinically so the full spectrum of deaths from this indication should be captured.

When deaths, where HBV is coded as the underlying cause of death without any mention of HCC/ESLD, are also included, trends were similar, with a slight fall in the death rate from 0.18 in 2015 to 0.17 per 100,000 in 2021 (Figure 3), but this is not used for monitoring the global metric (see Appendix 3: technical notes, Section 1).

When numbers of deaths are considered, there were 87 death registrations for HBV-related HCC/ESLD in 2021, a decrease of 3.3% from 90 in the 2015 WHO baseline year. When deaths where HBV is coded as the underlying cause of death without any mention of HCC/ESLD are also included, overall numbers were similar, with a slight decrease in deaths (1.0%) from 96 in 2015 to 95 in 2021 (Figure 3), so significant reductions in numbers of deaths have not been observed. The 2030 target of a 65% reduction in HBV-related deaths, would be represented by a fall in HBV deaths to 32 (31.5) in 2030. If HBV-related deaths without a mention of HCC/ESLD are also included, a 65% reduction would be represented by 34 deaths in 2030 (Figure 3).

Figure 3: Death registrations for HBV related ESLD or HCC and those with HBV coded as underlying cause on their death certificate in England, 2005 to 2021



Data source: Office for National Statistics (17).

† Defined by codes or text entries for ascites, bleeding oesophageal varices, hepato-renal syndrome, hepatic encephalopathy, or hepatic failure.

¶ Excluding deaths registered in England when the deceased's usual residence is outside England.

* 10% reduction on 2015 level; **65% reduction on 2015 level; ***Less than or equal to 4 per 100,000 persons. For further information on methodology see Appendix 3: technical notes, Section 1

Monitoring morbidity from HBV-related advanced liver disease

Data to monitor trends in HBV-related morbidity is available from the Healthcare Episode Statistics (HES) for data on severe HBV-related liver disease, and NHS Blood and Transplant (NHSBT) for registrations and liver transplants undertaken, where post-HBV cirrhosis is the indication for transplant (see Appendix 3: technical notes, Section 2).

HBV infection can take decades before cirrhosis develops and a liver transplant is clinically indicated. Increased global coverage of HBV vaccine in past decades amongst people migrating to the UK, more effective antiviral treatments, and wider access to these

treatments in the UK and globally should eventually lead to reductions in liver disease progression and therefore ESLD and transplant registration.

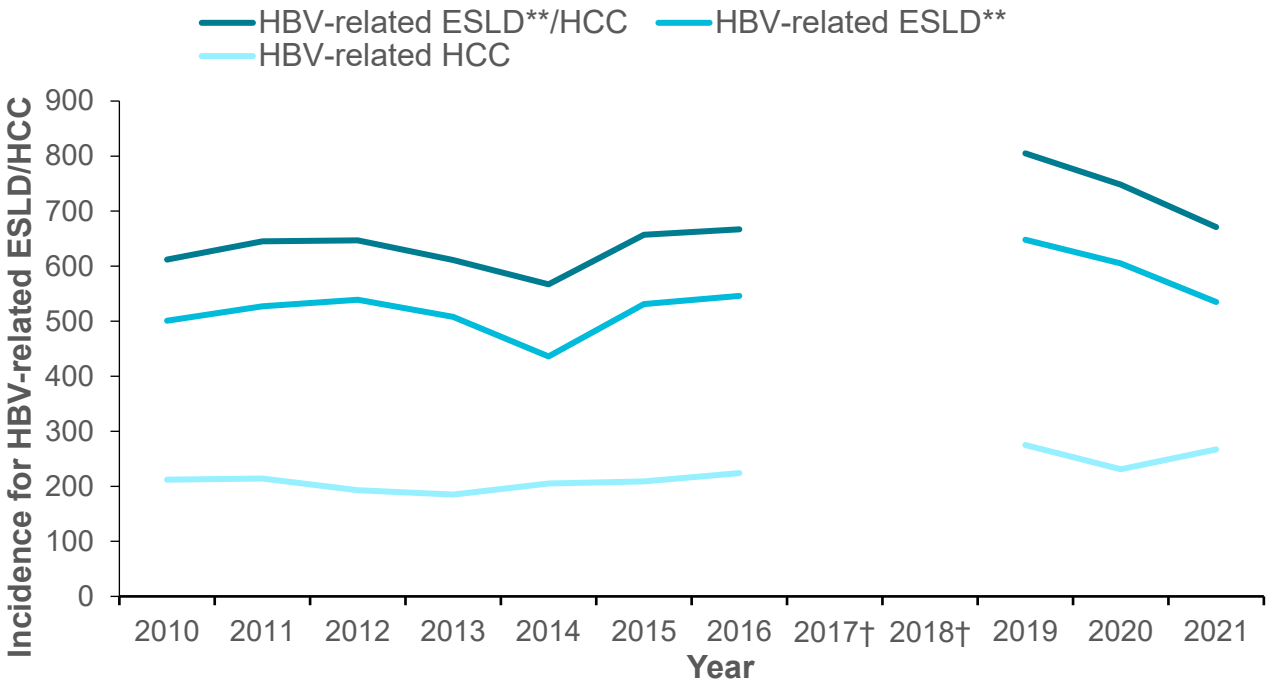
Hospital admissions from HBV-related end stage liver disease or hepatocellular carcinoma

HBV-related morbidity can be estimated by monitoring the number of new cases (incidence) of HBV-related HCC/ESLD in England using HES (see Appendix 3: technical notes, Section 2).

In 2021, HES analysis identified 267 and 535 first presentations of HBV-related HCC and HBV-related ESLD respectively (671 people with either or both HCC/ESLD) (Figure 4). The 2021 HBV-related HCC/ESLD combined Figure is 2.1% higher than the 2015 WHO baseline year (209 for HBV-related HCC and 531 for HBV-related ESLD). Whilst numbers of first presentations for HBV-related ESLD have decreased (17.3%) since 2019, a slight increase in HBV-related HCC between 2020 and 2021 was observed.

Estimates of incidence of HBV-related ESLD/HCC are not available for 2017 and 2018 due to an interruption in the supply of identifiers by NHS Trusts in the HES year April 2017 to March 2018.

Figure 4: Preliminary estimates of incidence of HBV-related ESLD/HCC in England, 2010 to 2021*



Data source: Hospital Episode Statistics (HES), NHS Digital for England. Produced by UKHSA.

*Data based on Hospital Episode Statistics as of January 2023

†Estimates of incidence of HBV-related ESLD

**/HCC are not available for 2017 and 2018. This is due to an interruption in the supply of identifiers by NHS Trusts in the HES year April 2017 to March 2018.

For further information on methodology see Appendix 3: technical notes, section 2.

Registrations and liver transplant for HBV-related disease given as the indication for transplant

HBV-related morbidity can also be monitored by reviewing the number of English residents with post-cirrhosis (recorded as either primary, secondary, or tertiary indication for transplant) registered with NHSBT for a liver transplant, as well as the number and proportion of transplants undertaken in those with HBV infection (see Appendix 3: technical notes, Section 2).

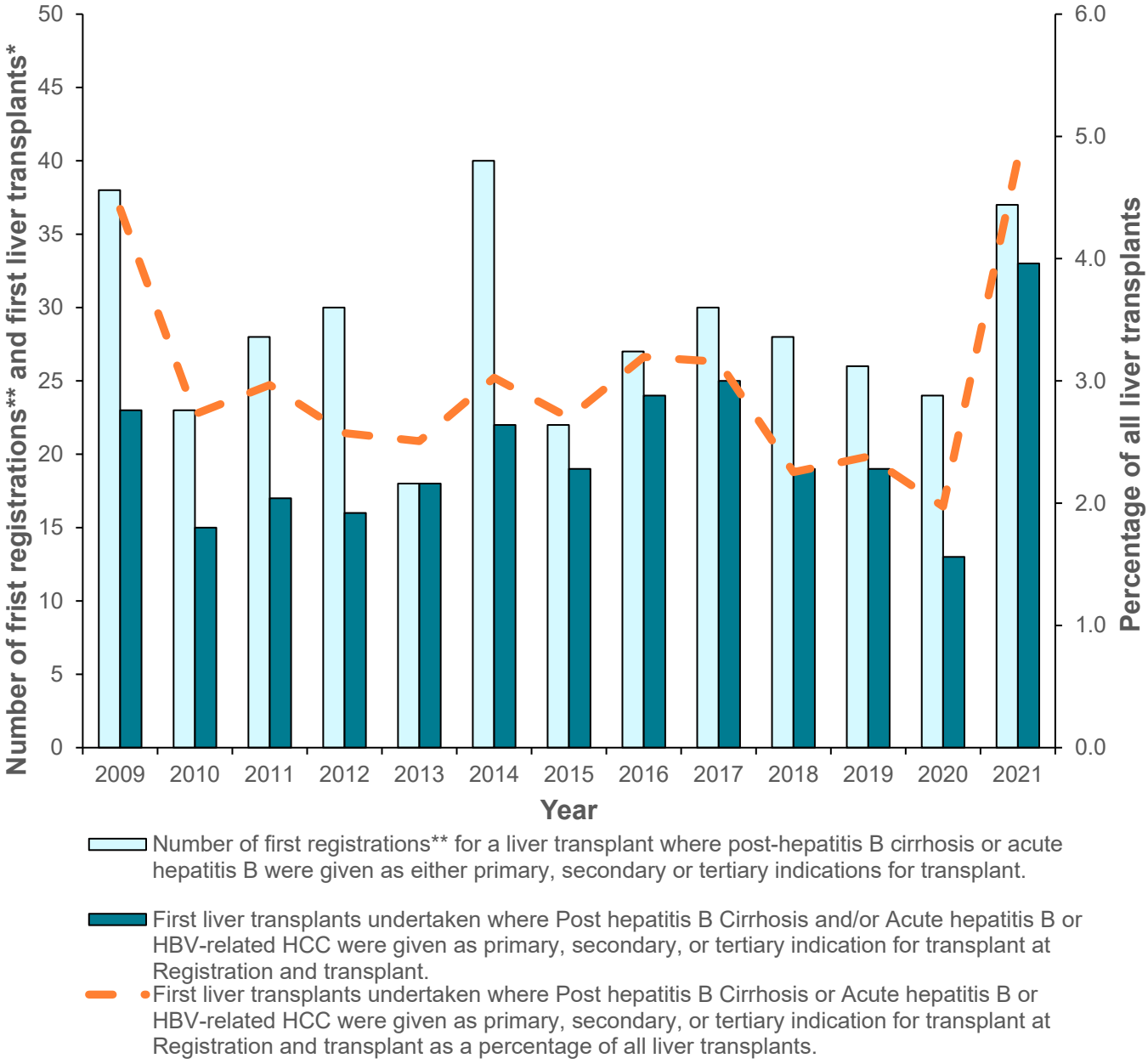
Between 2009 and 2021, registrations and transplants for post-HBV cirrhosis or acute HBV have fluctuated. In this time period 371 patients had post-HBV cirrhosis or acute HBV reported as either the primary, secondary, or tertiary indication for a transplant. These registrations saw a decrease of 20% between 2017 and 2020, but not if compared to the 2015 baseline (Figure 5). An increase of 23.3% was seen in these registrations between 2017 and 2021. Similarly, the number of HBV-related first liver transplants saw a decrease of

48% between 2017 and 2020 but not if compared to the 2015 baseline. In 2021 HBV-related transplants increased by almost 3-fold. It is important to note that the number of registrations and transplants recorded in the same year cannot be compared as not all registrations receive a transplant in the same year.

The number of first liver transplants undertaken in individuals with HBV where post-HBV cirrhosis, acute HBV and/or HBV-related hepatocellular carcinoma (HCC) were reported as an indication for transplant as a percentage of all liver transplants decreased from 4.4% in 2009 to 2.0% in 2020; however, these increased to 4.8% in 2021.

Caution is needed in over-interpreting single data point changes in transplants, particularly the increase in transplants in 2021; data quality issues need to be excluded and the increase may be due to random fluctuations as single year peaks have been noted in previous years.

Figure 5: Number of first patient registrations in England* where post-HBV cirrhosis was given as either the primary, secondary, or tertiary indication for transplant and the number of first liver transplants undertaken in patients who were HBV positive at transplant, 2009 to 2021



Data source: NHS Blood and Transplant UK Transplant Registry.

*These figures are based on registry data as of July 2022 and include both elective and urgent registrations.

††Hepatitis B status was ascertained by interpreting results for the following HBV markers HBV DNA, HBsAg and HBeAg.

Monitoring WHO programme and service coverage indicators for incidence

Elimination of MTCT

Service coverage targets for elimination of MTCT are monitored through routinely collected antenatal screening and infant immunisation programme data.

IDPS Screening Standards collect quality metrics of the antenatal screening programme, including coverage of HBsAg screening of pregnant women, timely birth dose (BD) vaccine coverage in infants at risk (born to HBsAg pregnant woman) and HBIG coverage in babies if mother is of high infectivity (of example high viral load).

Vaccine coverage with 3 doses of hepatitis B containing vaccine (Hep B3) by 12 months of age in the universal infant programme (which does not include a BD) is monitored through Cover of Vaccination Evaluated Rapidly (COVER) surveillance.

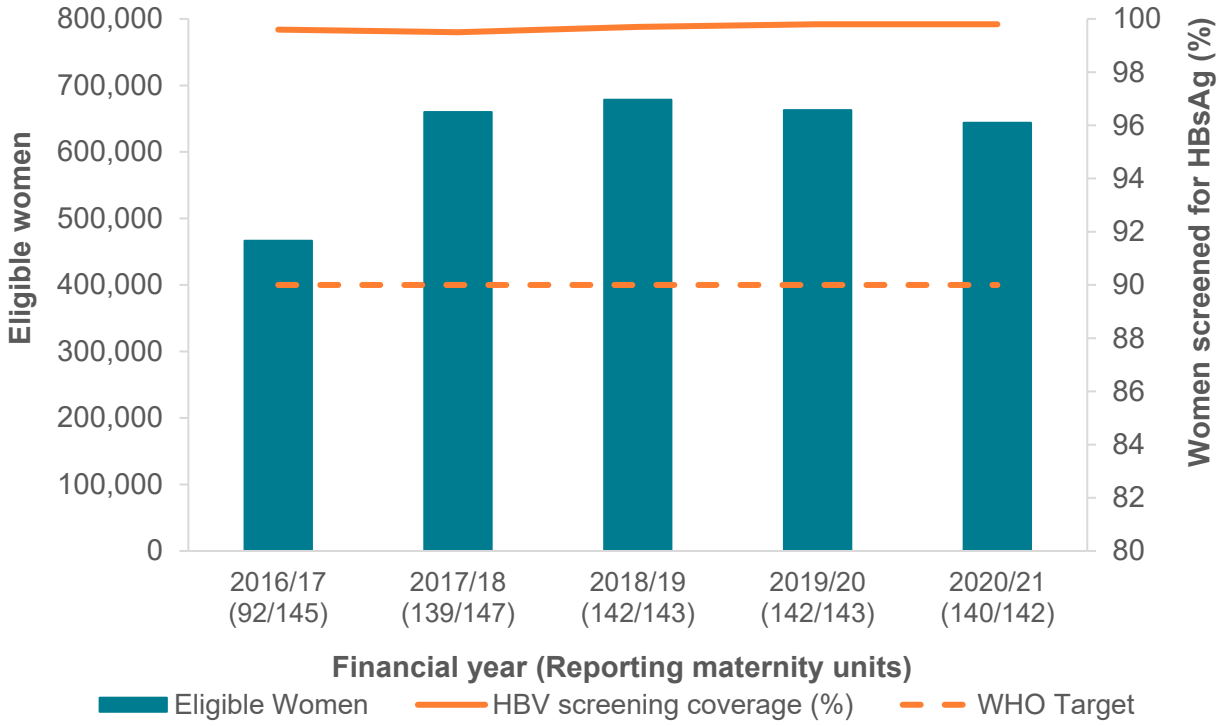
Table 3: WHO proposed programmatic targets to eliminate MTCT

Programmatic target	WHO 2030 target (5, 9)	England status 2020/21
Coverage of antenatal HBsAg testing among pregnant women	≥90%	Target met ≥99%
Coverage with antivirals for those eligible HBsAg pregnant women with high viral loads (plus coverage of HBV-exposed babies with HBIG)	≥90%	Available Q4 2023 through IDPS/ISOSS HBIG coverage target met 97.6%
Coverage of infants at risk targeted with timely birth dose (BD)	≥90%	Target met 99.2%
HepB3 coverage (universal)	≥90%	Target met 92.0%

Coverage of maternal HBsAg testing

Coverage is calculated as the proportion of pregnant females eligible for screening for which a confirmed screening result is available at the day of report (further details in Appendix 3: technical notes, Section 3). The annual cohort of pregnant women is around 650,000. The uptake of antenatal screening for HBV is stable and consistently over 99 % from financial year 2016/17 to 2020/21 (Figure 6).

Figure 6: Coverage for hepatitis B antenatal screening, England – Screening Standard IDPS-S02



Data source: Infectious Disease in pregnancy screening standard reports

Coverage of antiviral treatment in pregnant women

Antiviral treatment of pregnant women is recommended in the third trimester to those with hepatitis B infection and an HBV deoxyribonucleic acid (DNA) level ≥200,000 IU/ml, (9, 18).

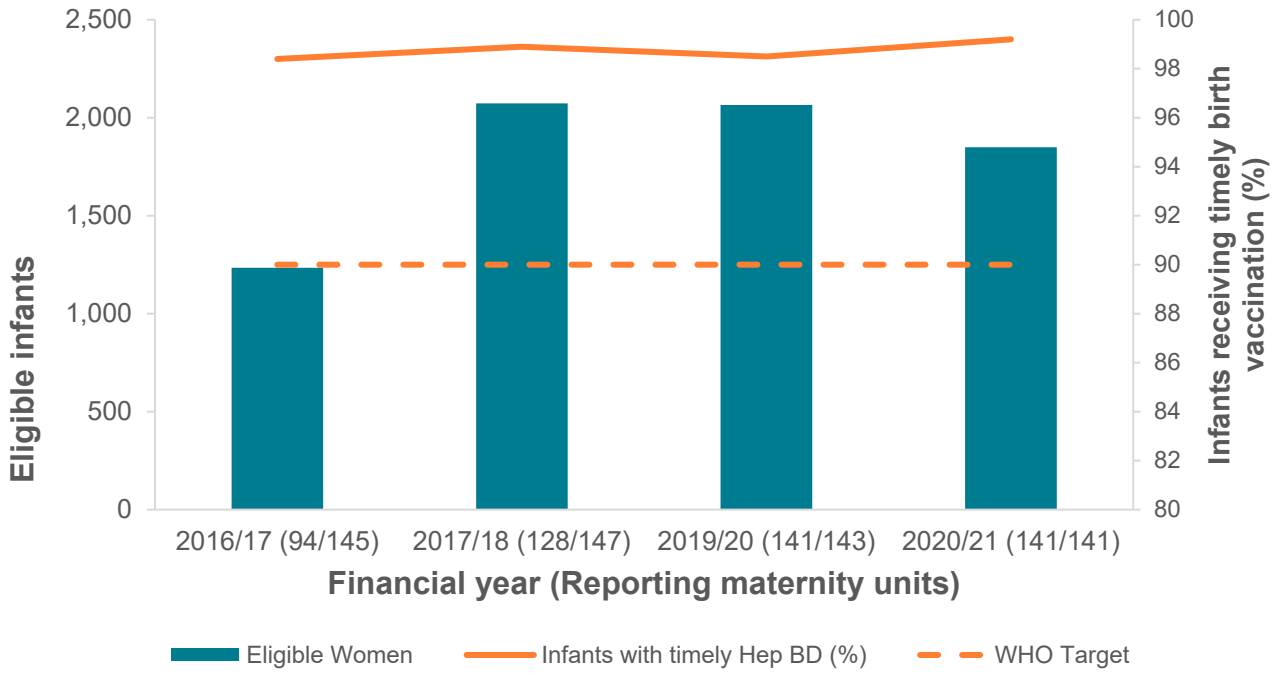
Robust data collection will commence in 2023 as part of IDPS following a pathway quality improvement project launched in 2021.

Coverage of a timely hepatitis B birth dose and HBIG in selective programme

Timely hepatitis B birth dose (HepB BD) is defined as vaccination within 24 hours of birth for babies born to women with hepatitis B. For the last 5 years, over 98% of eligible infants were vaccinated in 24 hours (Figure 7).

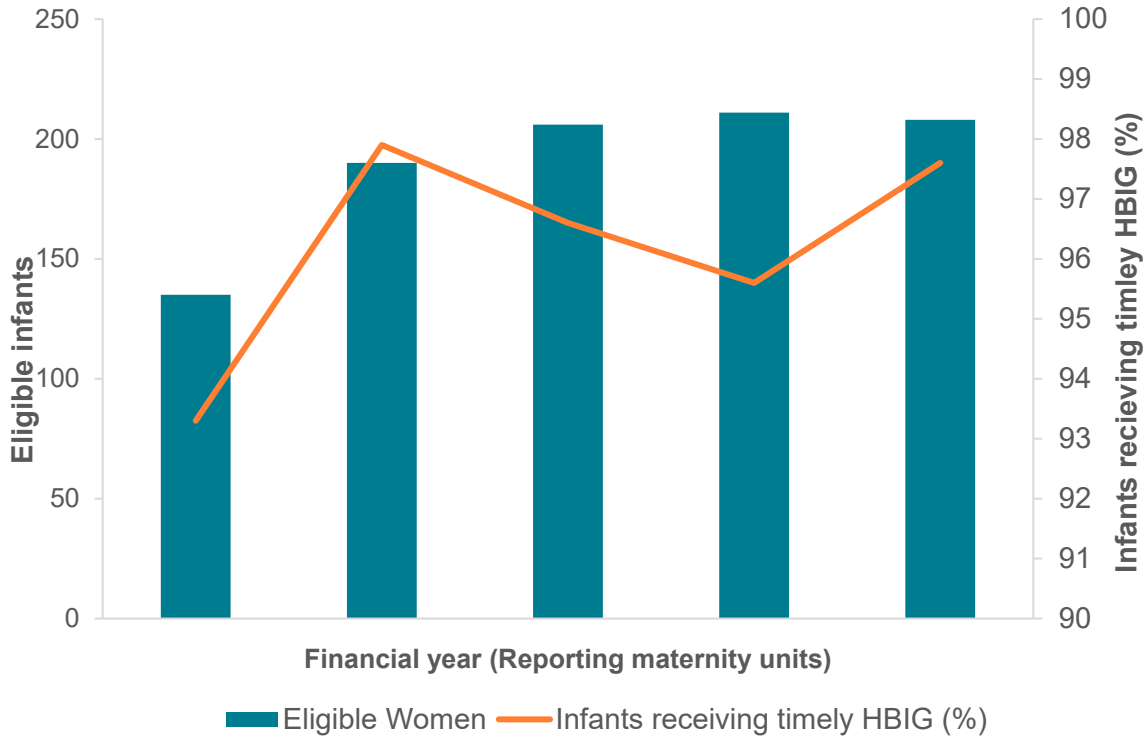
Coverage of higher infectivity risk births receiving HBIG within 24 hours is shown in Figure 8. This has remained above 90% since 2016 to 2017 and has reached 97.6% in 2020 to 2021. Any infants not vaccinated or receiving HBIG on time are raised as screening safety incidents and investigated to improve programme delivery.

Figure 7: Coverage for timely neonatal hepatitis B vaccination, England – Screening Standard IDPS-S07a



Data source: Infectious Disease in pregnancy screening standard reports

Figure 8: Coverage for hepatitis B immunoglobulin at birth, England – Screening Standard IDPS-S07b



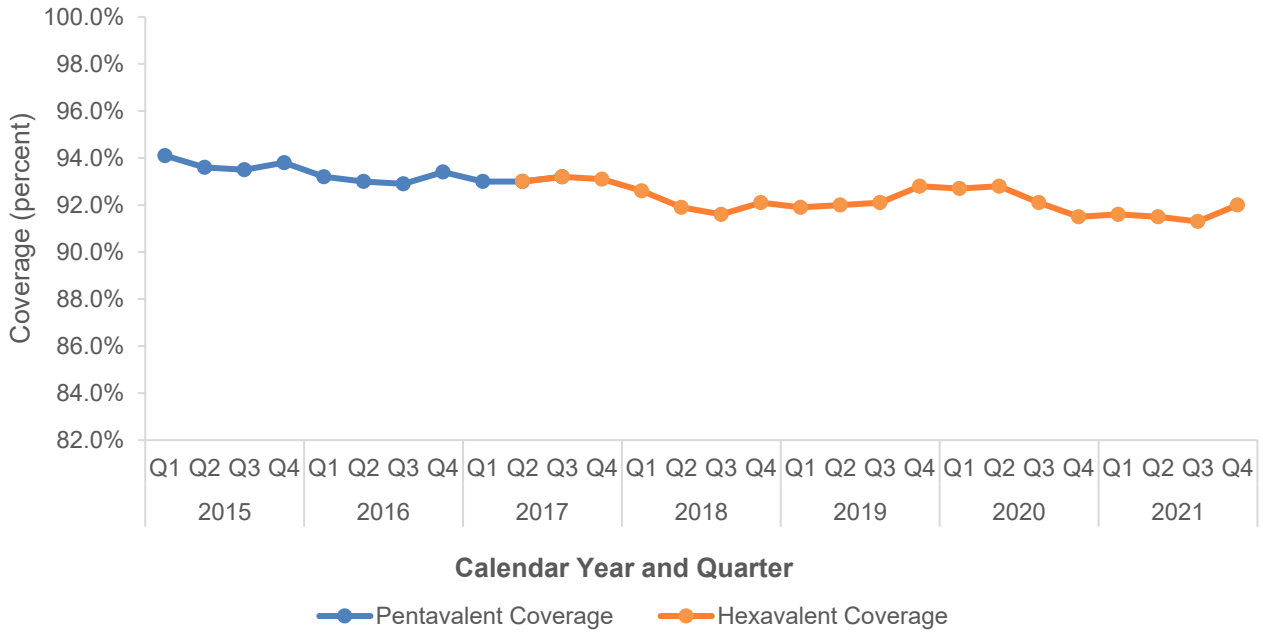
Data source: Infectious Disease in pregnancy screening standard reports

Coverage of hepatitis B 3 doses (HepB3) in universal programme

UKHSA monitors vaccine coverage for all 3 doses of the universal HBV hexavalent programme, (and other childhood immunisation programmes) through Cover of Vaccination Evaluated Rapidly (COVER). Details on the COVER programme and methodology are at COVER reports.

In 2017, England introduced the hexavalent (6 in 1) DTaP/IPV/Hib/HepB vaccine, replacing the pentavalent (5 in 1) which did not protect against HBV. England has consistently maintained over 90% coverage of children receiving DTP3 or HepB3 by their first birthday between 2015 and 2021, exceeding the WHO target. However, similar to other infant immunisation programmes in UK, a general decline in coverage has been occurring, further impacted by the COVID-19 pandemic (Figure 9).

Figure 9: Coverage for DTP containing vaccine at 12 months of age, England, 2015 to 2021



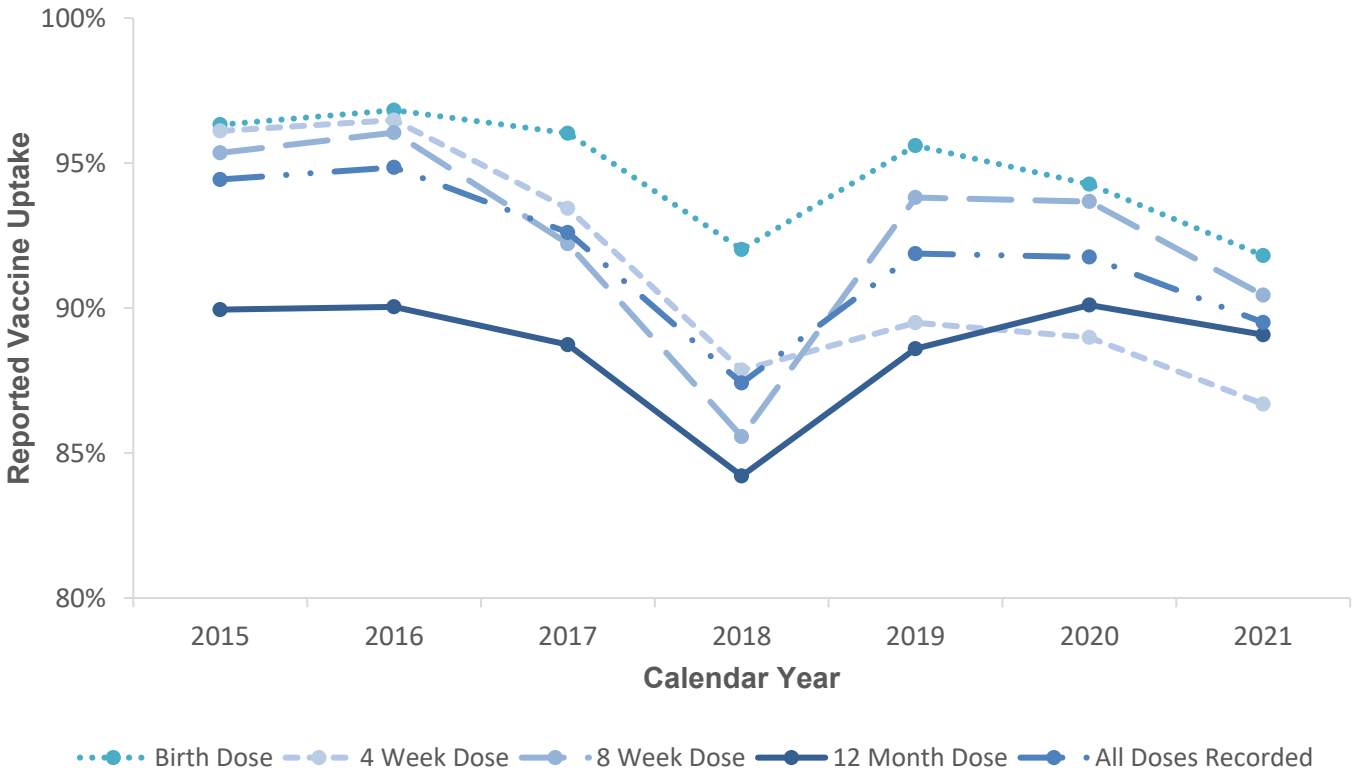
Data source: Cover of Vaccination Evaluated Rapidly (COVER) reports

Coverage of hepatitis B 4 doses in selective neonatal programme

Vaccine history is collected in primary care on infants born to a woman with hepatitis B when they have post vaccination serology testing (PVST) by DBS at 12 months of age. In 2020 to 2021, an estimated 58.0% (1,197 out of 2,065) of eligible infants had PVST by DBS.

Data completeness and quality is an issue here; however, where vaccination status was known, vaccine uptake for all of the 4 recorded doses in the selective programme (birth, 4 weeks, 8 weeks and 12 months) has remained above 90% for all years, except 2018 when there was disruption to the surveillance process, and 2021 (Figure 10). Importantly, birth dose uptake has remained over 90% throughout. Overall, reported uptake of the earlier doses was higher than 12-month dose uptake in all except 2021 where uptake of the 4-week dose decreased from 93.4% in 2017 to 86.7% in 2021.

Figure 10: Reported vaccine uptake at time of 12-month DBS test in at risk infants (born to woman with HBV infection)*



*Reporting year 2018 saw a significant drop in coverage across all doses, which was due to quality issues in the surveillance process and follow-up of newly recruited regions that year.

Characteristics of HBV screen-positive pregnant women

In 2020 to 21 2,170 of 642,621 women screened positive for HBV antenatally (4, 19). The prevalence has remained very low and stable at 0.3% to 0.4% each year, although there is regional variation. Around 10% to 12% of women who screen-positive are classified as of higher infectivity based on HBeAg status, high viral load, or acute hepatitis B in pregnancy (see Green Book criteria).

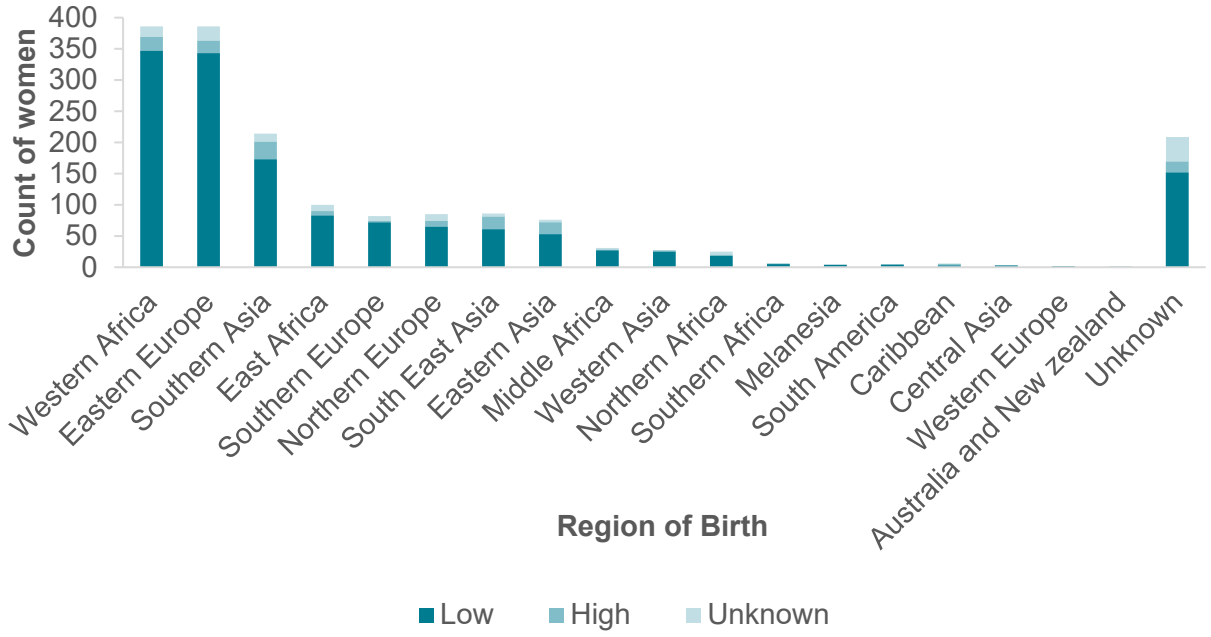
Some antenatal testing is captured in sentinel surveillance of blood borne viruses (SSBBV) where test positivity between 2015 and 2021 remained stable at 0.2%. The HBeAg test (a marker of higher infectivity) was available for the majority of women (ranging from 98% in 2015 to 85.4% in 2020). Of women tested for HBeAg in 2021, 8.8% were positive, ranging from 7.1% in 2017 and 12.8% in 2016.

Region of birth in screen positive antenatal population

Following the launch of an antenatal screening and immunisation pathway quality improvement in 2021, an extended set of surveillance samples are being collected nationally from women with HBV and their children. These include a blood sample from all HBV screen positive women in early pregnancy. Antenatal blood samples were collected from 94% (141 of 150) maternity units across England in the tax year 2021 to 2022. Most samples came from maternity units in London (35.8%). Of the 1,733 samples, 184 (10.6%) were classified as higher infectivity risk according to Green Book criteria.

The majority of HBV infected pregnant women were born in Western Africa and Eastern Europe (Figure 11), which both saw similar proportions of high infectivity risk cases (5.7% versus 5.2%). The regions with the highest proportion of high infectivity risk women came from the Caribbean, Eastern Asia, and South-East Asia (33.3%, 25.0% and 23.3% respectively).

Figure 11: Number of antenatal samples by women's geographic region of birth and infectivity risk (as per Green Book criteria)



Prevention of infection by immunisation in other risk groups

In addition to the infant immunisation programmes, targeted vaccination of people at increased risk of infection or complications of HBV is recommended as this is the cornerstone of preventing transmission in the general population. These are outlined in the Green Book and include PWIDs, GBMSM, those who change sexual partners frequently, those travelling to or from countries of high prevalence, those in custodial institutions, and close household contacts of people living with HBV infection.

Vaccine uptake in GBMSM in sexual health services

British Association for Sexual Health and HIV (BASHH) guidelines recommend that all services commissioned to manage sexually transmitted infections (STIs) should provide appropriate hepatitis B vaccination to non-immune GBMSM. While vaccination coverage in GBMSM was as high as 95% in 2008, coverage of first dose HBV vaccination in non-immune first time attendees in 2019 was estimated to be below 20% (ranging from 0% to 67% by clinic) based on data reported by specialist sexual health services to UKHSA's GUMCAD STI surveillance system (further details in Appendix 3: technical notes, Section 4 and Section 5). In 2020, during the first year of the COVID-19 pandemic, first dose vaccination coverage in GBMSM attendees decreased to 4.3% reflecting the reconfiguration of sexual health services to increasingly remote service provision either online or by telephone. Vaccination coverage remained below 5% in 2021 – while this may reflect reduced offer or uptake of vaccination, hepatitis B vaccination coverage is underestimated when using GUMCAD data because of the underreporting of immunity to hepatitis B (the latter leads to an overestimate of the denominator of people assumed to be eligible for vaccination, leading to artefactually low estimates of vaccination coverage).

Hepatitis B vaccination is also available to other attendees at sexual health services who are at risk of exposure to HBV.

As accurate vaccine coverage is not yet available, trends in counts of hepatitis B doses in GBMSM delivered in sexual health services since 2017 are shown in table 4. Number of first doses administered increased 32% from 11,080 in 2017 to 14,645 in 2019, with similar increases seen across all other doses. In 2020 there was almost a halving in number of doses given compared to 2019 across each dose. These all rebounded in 2021 however have not reached their 2019 levels.

Table 4: Hepatitis B vaccination in GBMSM: counts of first, second, third, fourth and booster doses, England sexual health services 2017 to 2021

Hepatitis B vaccination dose	2017	2018	2019	2020 [†]	2021 [†, ‡]
First dose	11,080	11,808	14,645	6,761	9,014
Second dose	7,659	7,624	11,063	5,049	7,200
Third dose	6,053	4,619	7,945	3,941	4,726
Fourth dose	857	813	893	453	491
Booster	2,702	3,286	4,310	2,202	2,816

Data source: STI diagnoses and services by gender and sexual orientation

† Data reported in 2020 and 2021 are notably lower than previous years due to the reconfiguration of SHSs during the national response to the COVID-19 pandemic.

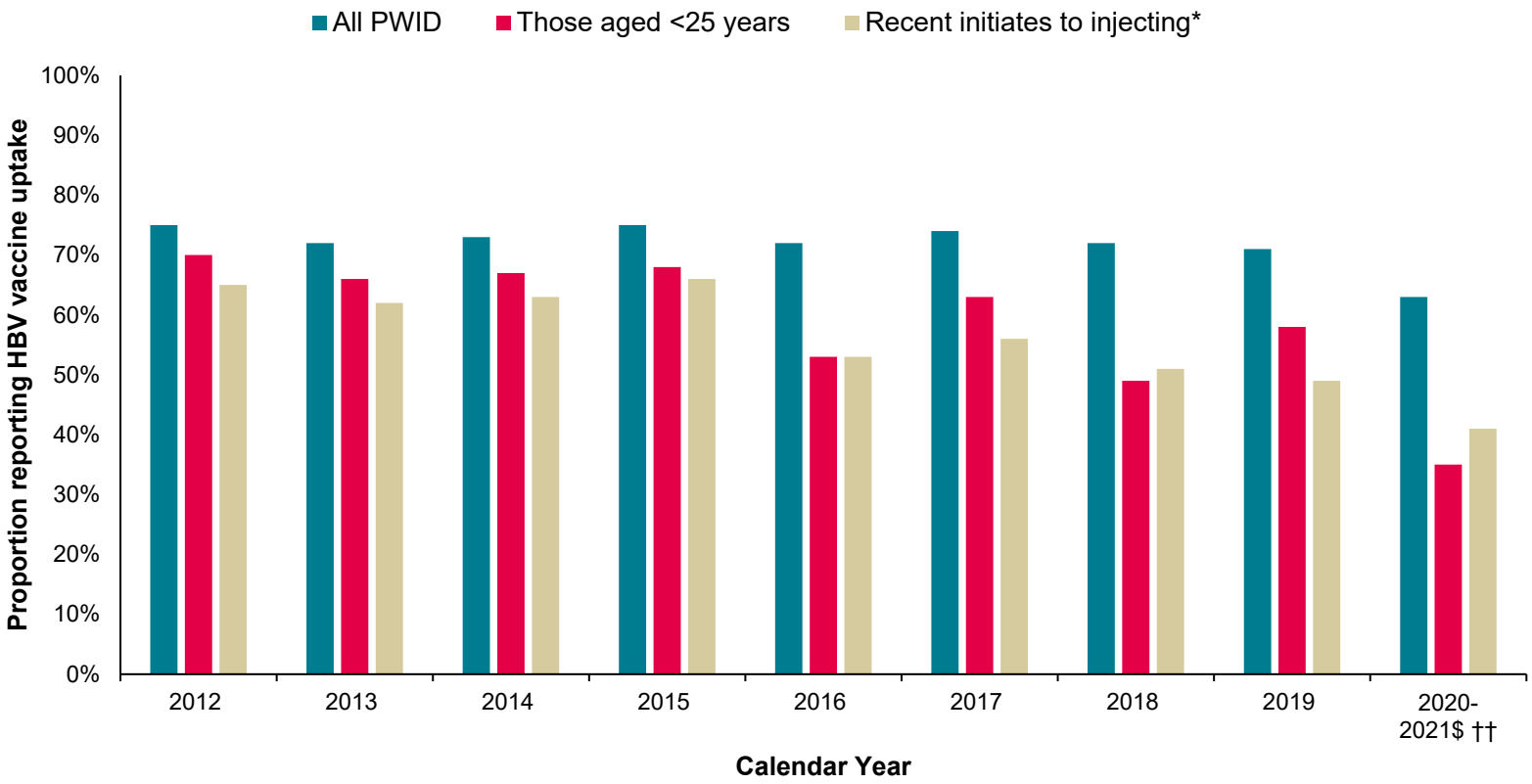
‡ Data for GBMSM is under-reported in London for 2021.

Vaccine uptake in people who inject drugs

PWID are at increased risk of acquiring HBV and vaccination is recommended for those currently or intermittently injecting, those likely to 'progress' to injecting, and close contacts. Data from the Unlinked Anonymous Monitoring (UAM) Survey of PWID in England, Wales and Northern Ireland indicates that self-reported uptake of at least one dose of HBV vaccine has decreased over the past decade with 61% uptake in 2021 versus 75% uptake in 2012 (Figure 12) across all age groups (20).

For the period 2020 to 2021, HBV vaccination uptake was particularly low among those aged under 25 years as well as recent initiates to injecting drug use (those who first injected during the preceding 3 years) where vaccine uptake was 35% and 41% respectively. UAM Survey data indicates that these individuals report recent contact with other services, such as general practice, prison health services and drug treatment, highlighting missed opportunities for HBV vaccination (21).

Figure 12: Proportion of PWID self-reporting at least one hepatitis B vaccination dose, 2012 to 2021



*Recent initiates are defined as people who first injected drugs during the preceding 3 years.

††UAM Survey data is provided for combined years due to limited recruitment due to the COVID-19 pandemic.

$ During 2020 and 2021, recruitment to the UAM Survey was impacted by COVID-19 pandemic. As a result, there were changes in the geographic and demographic profile of those taking part. This should be taken into account when interpreting data for these years. For more information, please see the UAM annual data tables report at People who inject drugs: HIV and viral hepatitis monitoring.

Data source: UAM Survey of PWID reported in Shooting Up: infections among people who inject drugs in the UK

Data from National Treatment Monitoring System (NDTMS) in England also shows a similar trajectory in the proportion of those at risk who are offered and accept a HBV vaccine, declining from 58% in 2011 to 42% in 2020 (Table 5).

Table 5: HBV vaccine offer and uptake in PWID from NDTMS (England), 2011 to 2020

Proportion offered and accepting an HBV vaccine (those at risk only) (NDTMS)										
Financial year		**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
England	People who have ever injected drugs attending specialist drug services‡	58%	57%	54%	52%	50%	50%	46%	48%	48%	42%^

‡ Excludes those previously vaccinated, with acquired immunity, deferred due to clinical reasons or assessed as inappropriate to offer. Includes those with 'missing' data.

^NDTMS data on the proportion offered and accepting an HBV vaccine for the 2020 to 2021 tax year is not comparable to previous years. Data for the 2020 to 2021 tax year represent people newly presenting for drug treatment, instead of all PWID presenting for drug treatment.

Data source: NDTMS reported in Shooting Up: infections among people who inject drugs in the UK

Vaccine uptake in prisons and detained settings

People in prison are at a higher risk of BBVs than the general population due to the overlapping risk factors of imprisonment and injecting drug use (22, 23), and so immunisation against HBV is recommended for all sentenced prisoners and all new inmates entering prison in the UK. Health and Justice indicators of performance (HJIPs) monitored uptake in prisons between 2014 to 2019 (see Appendix 3: technical notes, Section 6). Currently Health and Justice Strategic Reporting Unit's (H&J SRU) provide vaccine coverage in this setting. On average 54% of prisoners were identified as having had at least one dose of HBV vaccine in financial year 2021 to 2022. However, it is not possible to ascertain from the way data is collected if the prison inmate was vaccinated in prison or elsewhere.

Due to current prison capacity and health resources in prisons, testing, treatment, and vaccination coverage rates have remained low in many prison settings (22, 23).

Vaccine uptake in migrants

Vaccination is recommended in the Green Book for individuals travelling to or residing in areas of high or intermediate prevalence of HBV infection (≥2%). The Office for Health Improvement and Disparities (OHID) Migrant Health Guide for hepatitis B includes advice on immunisation of migrants.

Some migrants to the UK who emigrate from endemic countries are at higher risk of hepatitis B infection than the UK-born population. NICE recommends HBV testing to anyone remaining at higher risk of infection and vaccination to those testing negative to HBV. As migrants settled in the UK are likely to maintain community links and continue to travel back to a higher prevalence country, vaccination is recommended.

Vulnerable migrants such as those who are undocumented (those living in the UK with no legal status), asylum seekers and refugees, unaccompanied minors, and low paid migrant workers may have additional health needs and be at increased risk of blood borne virus infection because of their experiences either before, during or after migration. They should be offered testing and vaccination commencing pre-departure or on arrival in England.

Currently there is limited data on vaccination in migrants and improvements are needed in monitoring of testing and vaccination uptake in these groups, but research and surveillance in these vulnerable groups is underway.

Prevention of infection by harm reduction

Harm reduction interventions for PWID include access to needle and syringe programmes (NSP) opiate agonist therapy (OAT), as well as information, BBV testing, and hepatitis B immunisation. Data on harm reduction metrics is collected via the biobehavioral UAM survey in PWID; (for vaccine uptake in PWID see earlier section).

Table 6: WHO proposed programmatic targets to eliminate HBV through harm reduction

Programmatic target	WHO 2030 target (5, 9)	England status 2020/21
Harm reduction: A comprehensive package of harm reduction services to all PWID including:	At least 300 sterile needles and syringes provided per person who injects drugs per year	Not directly collected, however 60% of users reported adequate needle and syringe provision.
	At least 40% of opioid dependent PWID receive OAT	55% in 2011 to 2012: updated estimates underway

As these are critical services for elimination of hepatitis C virus infection too, full information and data are available in Hepatitis C in England report and Shooting Up report.

Monitoring WHO programmatic or service coverage targets for diagnosis

The WHO service coverage target for diagnosis aims to contribute to prevention of HBV infection by diagnosed people being more aware of risks to others and prompting management of close contacts. Diagnosis should also lead to treatment and care, contributing to reductions in morbidity and mortality from HBV-associated liver disease.

Table 7: WHO proposed programmatic targets for HBV diagnosis

Programmatic target	WHO 2030 target (5, 9)	England status 2020/21
Percentage of people with chronic HBV infection are diagnosed	90%	Modelled estimates by Q4 2025

The proportion of those diagnosed cannot yet be estimated in England, but modelling work is underway to estimate the size of the infected population and incorporate laboratory reports of new chronic infections to derive the diagnoses proportion.

Trends in HBV testing and diagnosis in the general population and risk groups

Trends in HBV diagnosis and testing are useful for monitoring the impact of awareness-raising initiatives and prevention activity; monitoring testing and diagnosis is important at both a population level, as well as in sub-groups that are at increased risk of infection so that potential inequalities can be identified and addressed.

NICE public health guidance on improving offer and uptake of testing for HBV and HCV was published in 2012 to increase awareness in the general population and those at risk, improve knowledge and skills in health professionals and make recommendations on testing to increase diagnosis in those at risk of HBV (and HCV) infection. Recommendations include testing in primary care, prisons and immigration removal centres, drug services, sexual health services and contacts of cases.

Monitoring data on testing and diagnosis in risk groups and settings is available from several surveillance systems (see Appendix 2) which are:

- laboratory reporting of new diagnoses (via Second Generation Surveillance System (SGSS) or predecessor systems)

- sentinel Surveillance of BBV testing (SSBBV)
- the Health and Justice Strategic Reporting Units (H&J SRU)
- the UAM survey of PWID
- the NHSBT and UKHSA Epidemiology Unit Blood Donor Surveillance Scheme

Multiple local audits have indicated that there is variable implementation of NICE guidance on management (testing and vaccination) of household and sexual contacts, and contact tracing is largely incomplete (24, 25).

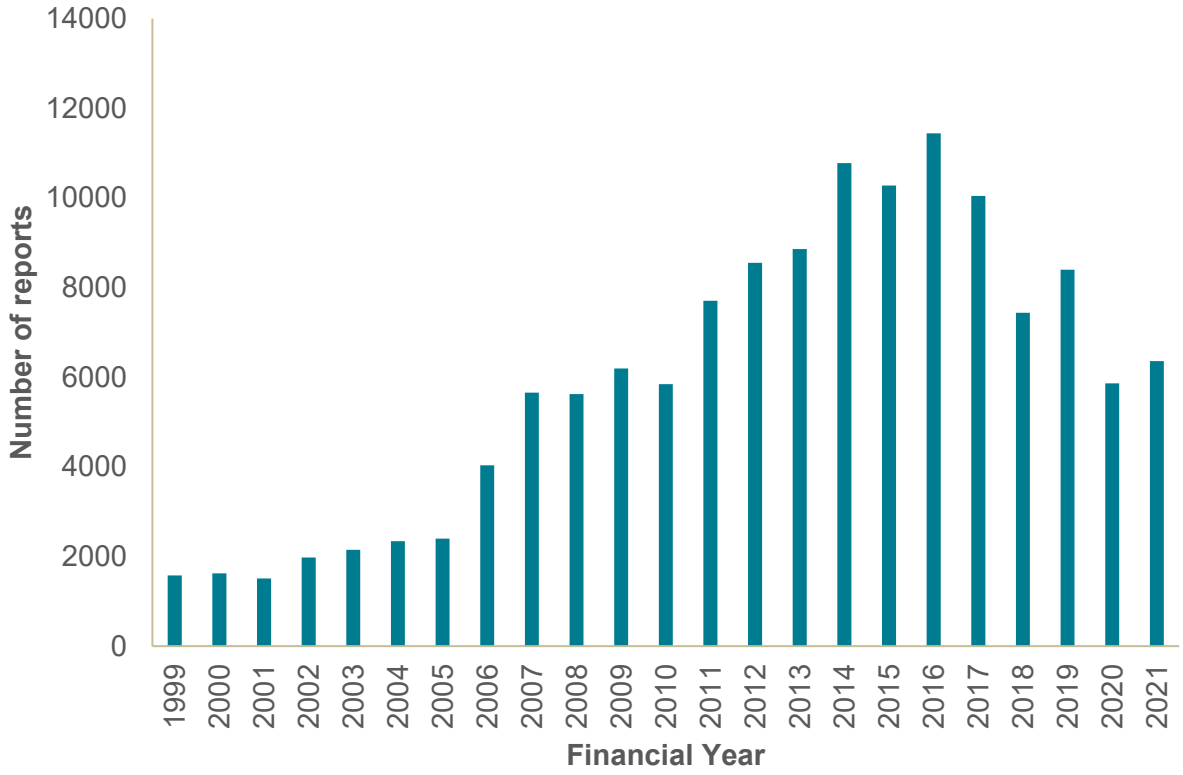
Testing and diagnosis in emergency departments (ED) will be included in future reports since in April 2022 the NHS has launched a 3-year programme of BBV opt-out testing. While primarily driven by the HIV Action Plan for England 2022 to 2025 which recommends HIV testing in higher prevalence areas for HIV, many sites are currently or planning to expand to hepatitis B and C. UKHSA is leading on the programme monitoring of this case-finding initiative in EDs.

New laboratory confirmed diagnoses of HBV in England

Over more than 2 decades, because of improvements in professional and public awareness, diagnostics, targeted testing, reporting by laboratories and surveillance systems as well as hepatitis B becoming a notifiable organism, there has been a steady increase in the number of new laboratory-confirmed reports of HBV in England. There was a more than 6-fold increase between 2000 and 2016, peaking at over 11,440 new diagnoses in 2016, followed by a decrease of 26.6% to around 8,399 reports in 2019 (Figure 13). Reports of new diagnoses has decreased further through the COVID-19 pandemic years (2020 to 2021) with a 44.4% reduction in 2021 compared to 2016 and 22.2% reduction compared to 2019.

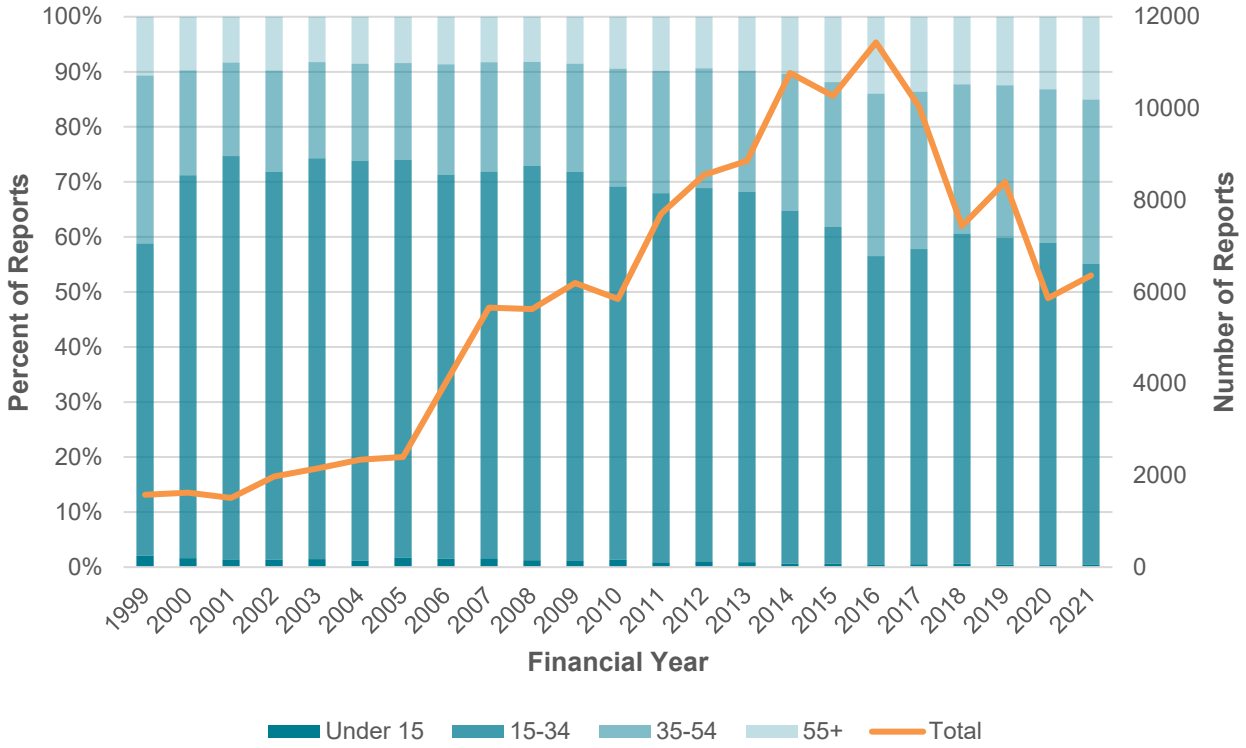
Between 1999 and 2021, of all laboratory reports where sex was reported (97.5%), 57.0% were in men, with little change over time (range 51.2% to 62.5%). Age was available for 99% of laboratory reports, the distribution of age at diagnosis over time suggests an ageing cohort (Figure 14), with 58.3% of laboratory reports in 1999 among those aged 34 years and under, decreasing to 36.3% in 2021, whereas the proportion aged 35 to 54 years surpassed those aged 34 years and under in 2015, increasing from 30.4% in 1999 to 46.0% in 2021. The proportion aged 55 years and over at diagnosis have also increased, albeit slower, from 10.7% in 1999 to 17.7% in 2021. In 2021, 63.7% of individuals newly diagnosed with HBV were aged 34 years and over, compared with 41.2% in 1999.

Figure 13: Number of laboratory reports of HBV from England, 2000 to 2021



Data source: CoSurv/SGSS (for further details see Appendix 3: technical notes, Section 7)

Figure 14: Age distribution of laboratory reports of HBV from England, 1999 to 2021



Data source: CoSurv/SGSS (for further details see Appendix 3: technical notes, Section 7)

HBV testing in primary care and the wider population

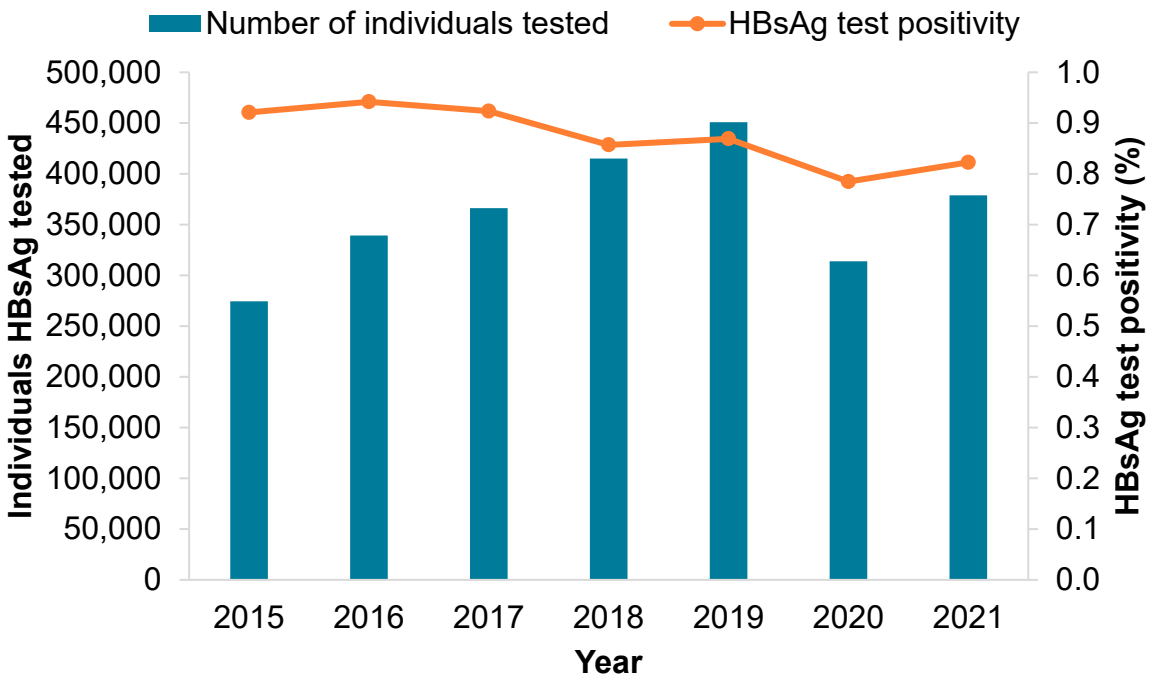
Data on HBV testing in primary care and the wider population is available from SSBBV testing (see Appendix 2).

Trends in testing were analysed using data from the 23 sentinel laboratories (further details in Appendix 3: technical notes Section 7), where complete and consistent data has been available from January 2015 to December 2021 (Figure 15). Overall, data shows that the number of individuals tested for HBsAg in primary care and the wider population, excluding antenatal screening, rose by 64.3% between 2015 to 2019, but fell by 30.2% between 2019 and 2020, likely due to the response to the COVID-19 pandemic. The proportion of persons testing HBsAg positive has remained relatively stable over the same period with 0.9% between 2015 and 2019 and 0.8% in 2020 and 2021 (Figure 15), suggesting that the proportion of individuals at high-risk of infection that are being tested is remaining stable and constant.

Overall, a hepatitis B e-antigen (HBeAg) test was available for 80.7% individuals testing HBsAg positive; however, the proportion decreased from 94.9% in 2015 to 68.5% in 2021. Of those tested, 12.6% were HBeAg positive, ranging from 11.0% in 2018 and 15.4% in 2015.

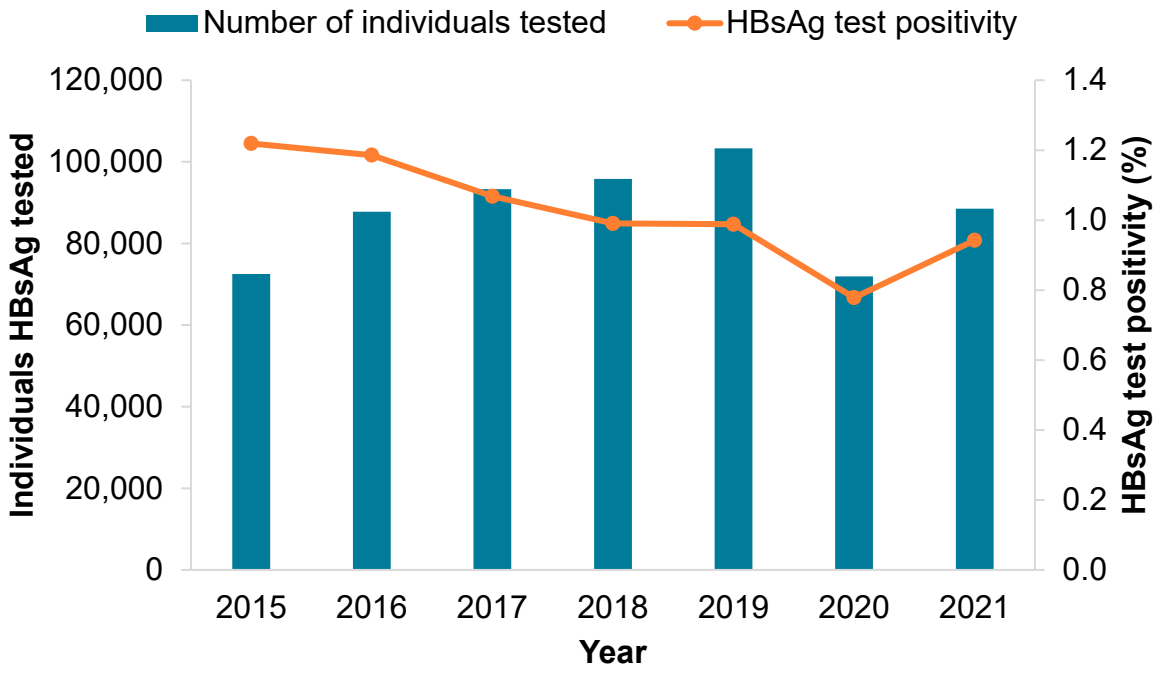
Testing in GP services is important as it is the first point of access for many to healthcare services, it is also an opportunity to find those with undiagnosed infection who are not in contact with other services, like sexual health. The trends in testing in GP services was similar to testing in the general population (excluding antenatal testing) with tests increasing by 42.5% between 2015 and 2019 (Figure 16), followed by a decrease between 2019 and 2020 likely due to the response to the COVID-19 pandemic. The proportion of persons testing HBsAg positive has remained stable with an average test positivity of 1.0% between 2015 and 2021 (Figure 16).

Figure 15: Number of individuals tested for HBsAg by year (excluding antenatal testing), and proportion positive, in 23 sentinel laboratories, 2015 to 2021



Data source: Sentinel Surveillance of Bloodborne Virus Testing (for further details see Appendix 3: technical notes, Section 8)

Figure 16: Number of individuals tested for HBsAg by year (excluding antenatal testing), and proportion positive, through GP surgeries in 23 sentinel laboratories, 2015 to 2021



Data source: Sentinel Surveillance of Bloodborne Virus Testing (for further details see Appendix 3: technical notes, Section 8)

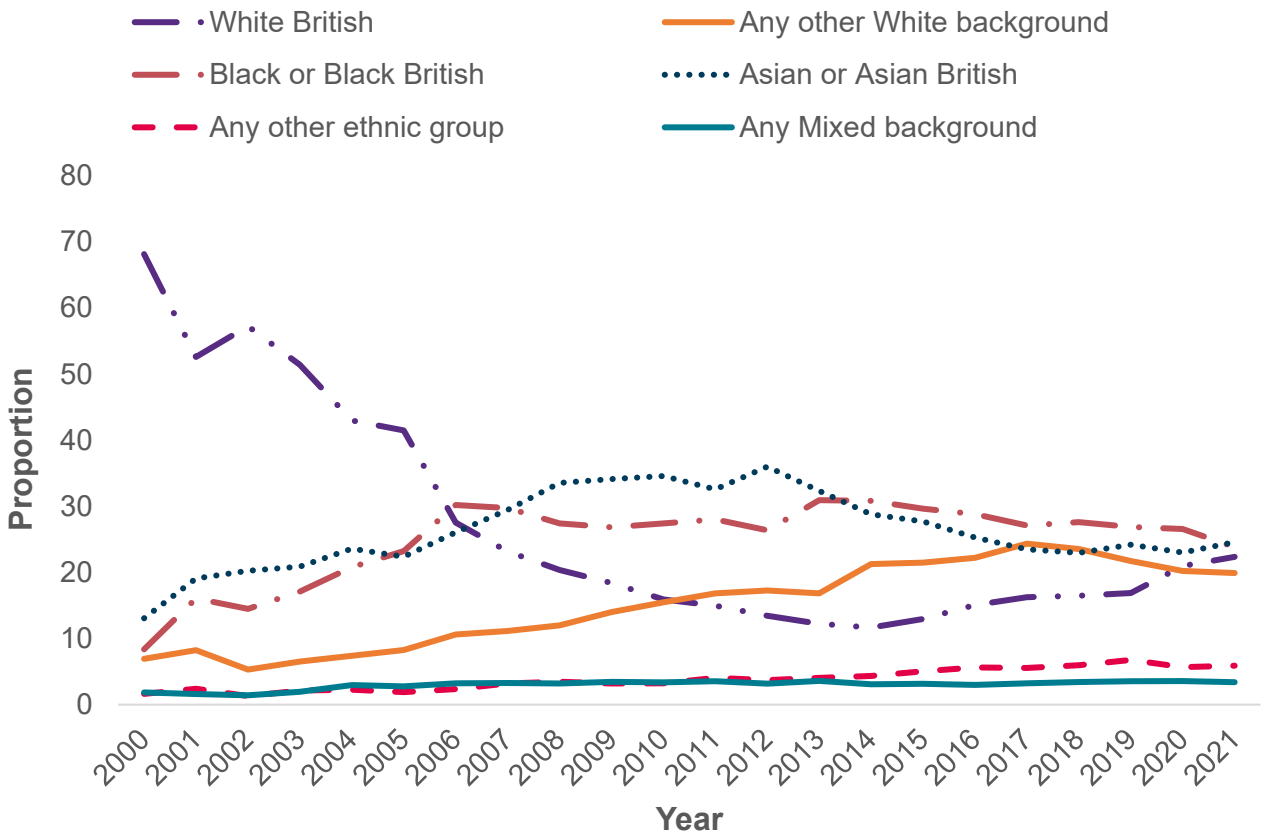
HBV testing and diagnosis in minority ethnic populations

An estimated 95% of new chronic hepatitis B infections in the UK are in migrants, who acquired their infection overseas in endemic countries, most often perinatally or horizontally in childhood (3).

Data on HBV testing and diagnosis in minority ethnic populations is available from Laboratory reporting (via SGSS) and SSBBV testing. In SSBBV testing, ethnicity is assigned by linking to the Emergency Care Dataset, and HES which contains this information. For SSBBV ethnicity was available for 64% of individuals tested outside of antenatal services and 85.8% of those tested in antenatal care. Data on ethnicity was available for 57.3% of laboratory reports of new diagnoses. Most individuals of unknown ethnic origin were tested in sexual health and drug and alcohol services where only minimal demographic data is available for linking.

Between 1999 and 2021 of all laboratory reports where ethnicity was available, 28% were among individuals of Asian or Asian British ethnicity, followed by 27.5% of individuals of Black or Black British ethnicity. Over time the ethnicity breakdown has changed (Figure 17), with the proportion of laboratory reports among individuals of White British ethnicity decreasing and the proportion among any Other White ethnic background increasing. The proportion of laboratory reports assigned to all other ethnic groups remained relatively stable over time.

Figure 17: Ethnicity distribution of laboratory reports of new diagnoses of HBV from England, 1999 to 2021



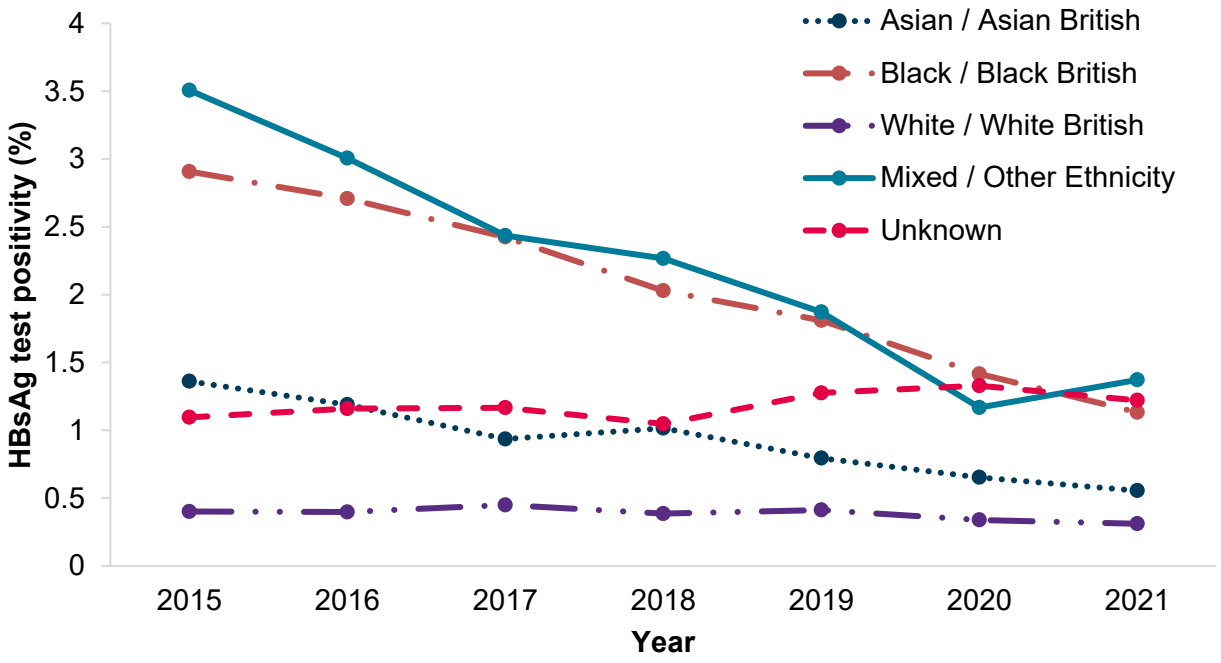
Data source: CoSurv/SGSS (for further details see Appendix 3: technical notes, Section 7)

Data from SSBBV on the number of individuals testing for HBV by ethnic group, where reported, showed most non-antenatal tests were among those of White or White British ethnicity (75.0%), followed by Asian or Asian British (10.4%), Black or Black British (9.6%) and Mixed or Other ethnicity (5.0%). This distribution has not changed over time. Overall, HBsAg test positivity was 2.2% among those of Mixed or Other ethnicity, 2.1% among those of Black or Black British, followed by Asian or Asian British (0.9%) and White or White British (0.4%). Test positivity has decreased markedly across all ethnic groups between 2015 and 2021, except in White ethnicity (figures 18 and 19). This was a similar picture for those testing in antenatal settings.

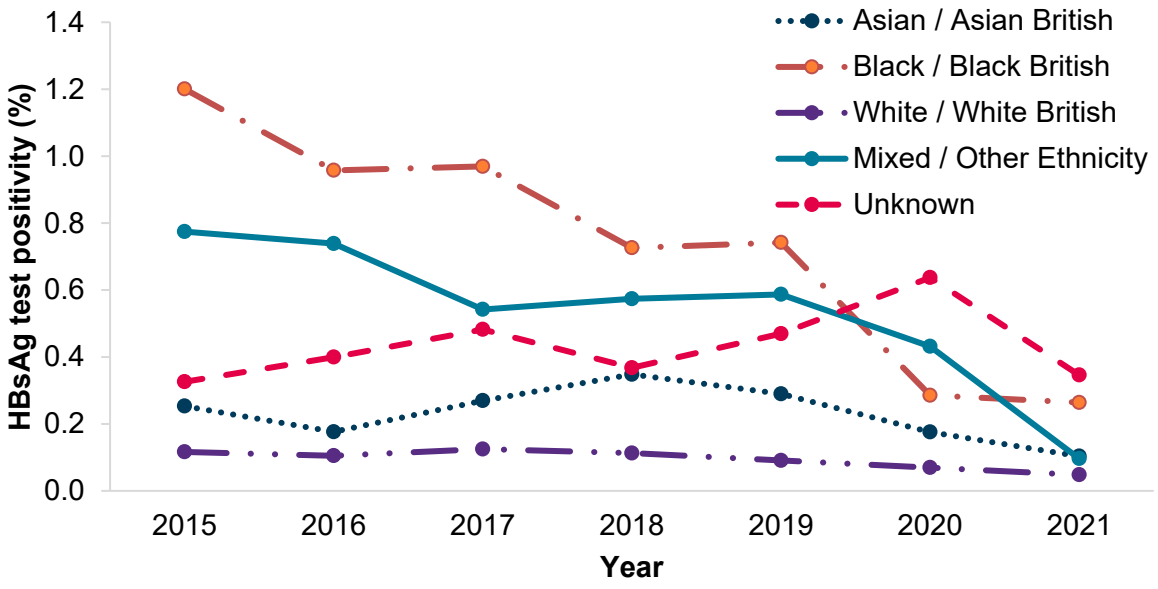
Among those testing HBsAg positive, HBeAg positivity was highest (15.2% and 14.4%) in those of Mixed or Other and Black or Black British ethnic groups for both antenatal and non-antenatal tested persons.

Figures 18 and 19: HBsAg test positivity by year and ethnic group, 2015 to 2021
a. Non-antenatal testing in 23 sentinel laboratories, b. Antenatal testing in 18 sentinel laboratories

a.



b.



Data source: Sentinel Surveillance of Bloodborne Virus Testing (for further details see Appendix 3: technical notes, Section 8)

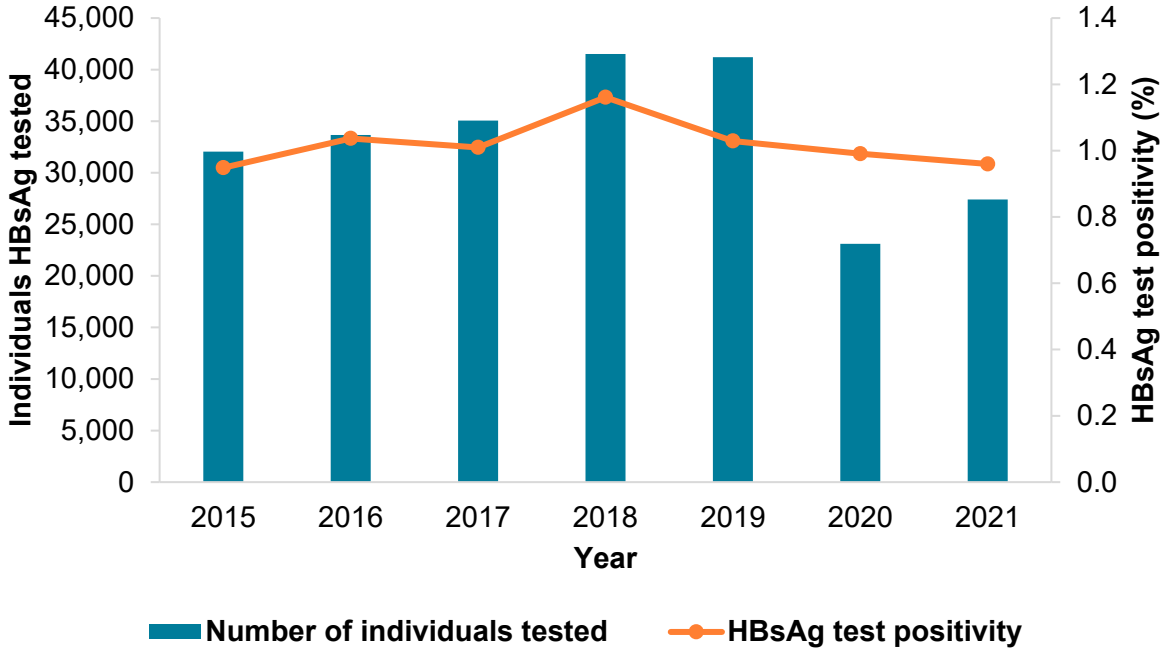
Testing and diagnosis in sexual health services

NICE and BASHH guidance recommend that sexual health services (SHSs) should offer hepatitis B testing to all service users at increased risk of infection.

Data on HBV testing and diagnoses is available from sentinel laboratories serving SHSs (SSBBV testing).

Data from SSBBV on the number of individuals testing for HBV in sentinel sexual health services shows an increase of 29.5% in HBsAg testing between 2015 and 2018, however, a 44.3% decrease seen between 2018 and 2020. Falls in testing between 2018 and 2020 are partly explained by the scale up of online self-sampling services for BBV, STI, and HIV testing since 2018, and the fact that this activity is not currently captured by SSBBV testing (Figure 20). The fall from 2020 is also likely due in part to the response to COVID-19 pandemic with restrictions and service reconfigurations. HBsAg test positivity shows little change between 2015 and 2021, at around 1.0% (range: 0.9 to 1.2%, see Figure 20).

Figure 20: Number of individuals tested for HBsAg by year, and proportion positive, through SHS in 23 sentinel laboratories, 2015 to 2021



Data source: Sentinel Surveillance of Bloodborne Virus Testing (for further details see Appendix 3: technical notes, Section 8)

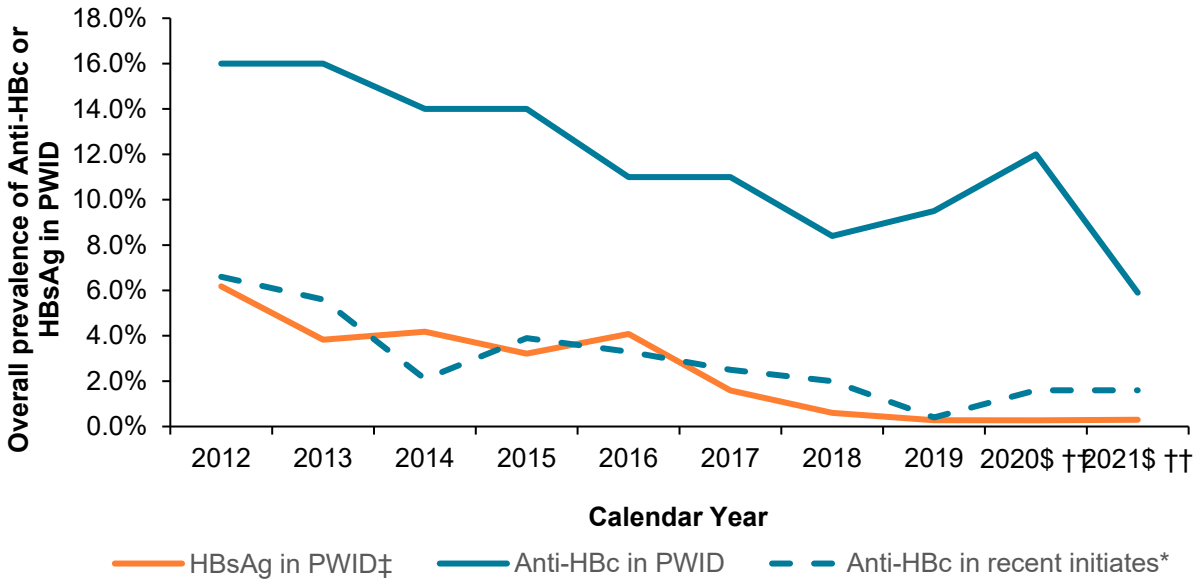
Testing and diagnosis in people who inject drugs and/or attend drug services

Data on HBV testing in people who inject drugs is available from the UAM Survey and SSBBV testing.

Data collected through the UAM Survey has shown a decline in the proportion of PWID who have ever been had HBV (anti-HBc) over the last decade, from 16% (95% CI: 15% to 17%) in 2012 to 5.9% (95% CI: 4.7% to 7.3%) in 2021. The prevalence of ever having a HBV infection is lower among recent initiates to injecting than seen among PWID overall, with proportion of recent initiates anti-HBc positive also decreasing over the past decade (6.6% (95% CI: 4.3% to 9.5%) in 2012 to 1.6% (95% CI: 0.2% to 5.5%) during 2020 to 2021) (Figure 21).

Of samples tested for HBsAg (a marker of current HBV infection), 0.3% of tested samples were HBsAg positive during 2020 to 2021, a significant decline from that seen a decade ago (6.2% in 2012), as seen in Figure 21.

Figure 21: HBsAg and Anti-HBc prevalence among people who have ever injected drugs and recent initiates to injecting*



Data source: UAM survey

$ During 2020 and 2021, recruitment to the UAM Survey was impacted by COVID-19 pandemic. As a result, there were changes in the geographic and demographic profile of those taking part. This should be taken into account when interpreting data for these years. For more information please see the UAM annual data tables report.

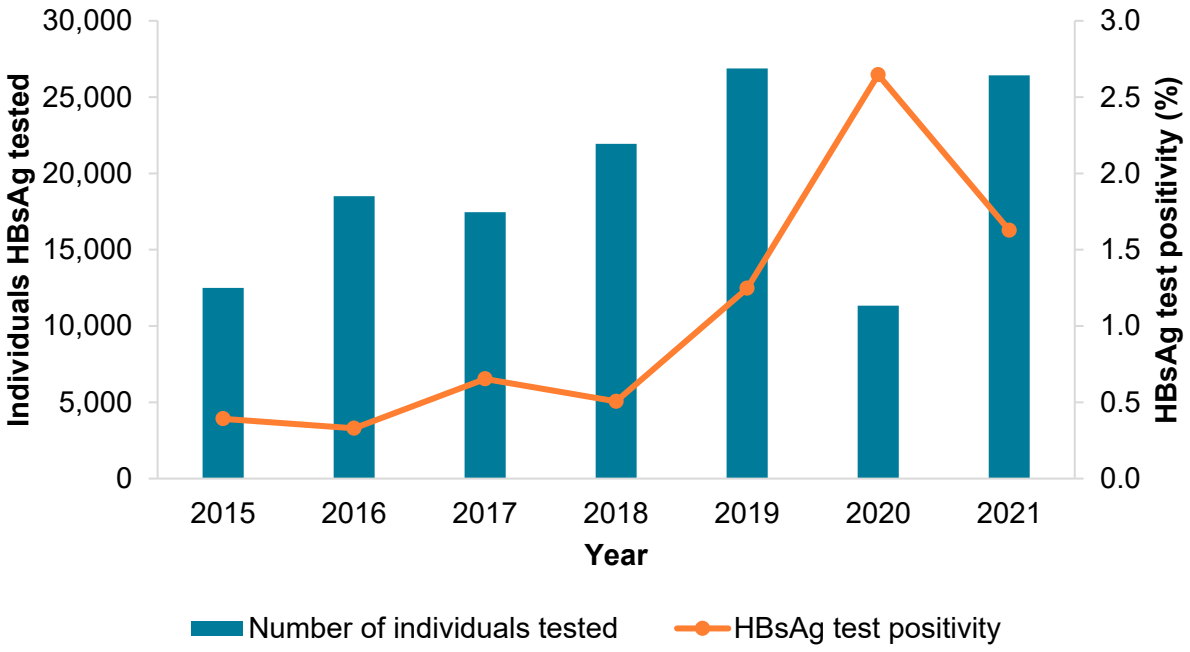
*Among those who began injecting in the last 3 years (recent initiates).

†† UAM Survey data for HBsAg prevalence and recent initiates is provided for combined years 2020 to 2021 due to limited recruitment due to the COVID-19 pandemic.

‡ of those tested for HBsAg (presented differently to UAM data tables).

SSBBV suggests that the number of individuals tested for HBsAg within drug services more than doubled between 2015 and 2019 from 12,497 to 26,875 (115.1% increase) (Figure 22). Test positivity has been increasing steadily between 2015 and 2021, rising to 1.6% in 2021 from 0.4% in 2015. Although numbers tested in 2020 were considerably lower due to the COVID-19 restrictions (11,335), the positivity peaked in this year at 2.6% suggesting targeted testing of the very high risk. Among those HBsAg positive, where sex was reported (96.4%), 76.5% were in men, with little change over time (range 69.0% to 85.7%).

Figure 22: Number of individuals tested for HBsAg by year, and proportion positive, through drug services in 23 sentinel laboratories, 2015 to 2021



Data source: Sentinel Surveillance of Bloodborne Virus Testing (for further details see Appendix 3: technical notes, Section 8)

Testing and diagnosis among people in secure and detained settings

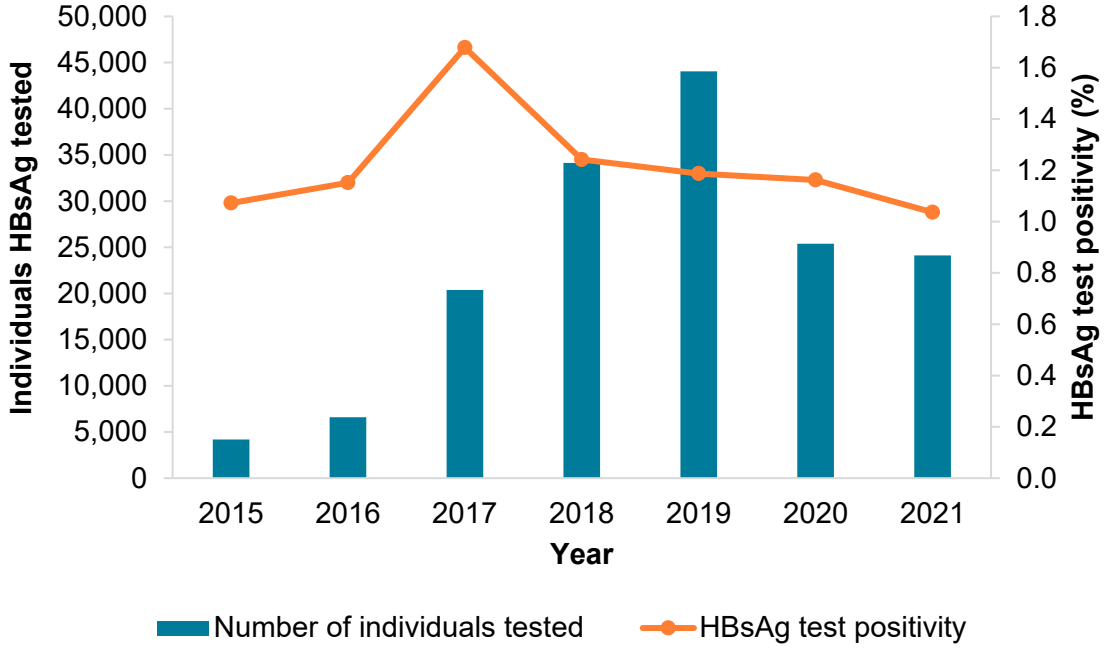
People in prison are at a higher risk of hepatitis B infection than the general population due to the overlapping risk factors of imprisonment and injecting drug use. In 2003 the hepatitis B vaccination programme was introduced into prisons and detention centres in England and Wales. Through a national partnership agreement between Public Health England (PHE), NHS England and HM Prison and Probation Service (HMPPS), opt-out testing for BBVs (HIV, HBV and hepatitis C) was rolled out across the entire adult prison estate in 2014. The challenge has been in programme implementation and monitoring, including the recording of offer and uptake of testing.

Data on HBV testing among people in secure and detained settings (including prisons, immigration removal centres, secure training centres, secure children's homes and young offenders' institutes) is collected by NHSE and laboratories serving prisons and reporting to UKHSA's SSBBV testing.

The tax year 2014 to 2015 saw the introduction of the Health and Justice Indicators of Performance (HJIPs), which were superseded by the NHSE Strategic Reporting Unit (SRU) in tax year 2020 to 2021. According to the most recent data from NHSE SRU, 140,386 receptions (including new admissions and transfers) were received during tax year 2020 to 2021. Of these, 81,997 were eligible for testing and 83.3% (68,297) were offered HBV testing within 7 days of reception. Of those who were offered and accepted testing, 46.7% (28,957 out of 61,962) were tested within 28 days of reception. In total, the number of patients with a positive HBsAg test in tax year 2020 to 2021 was 704 and of these, 13.1% (92) were referred to a specialist service withing 14 days of their positive result. These figures have shown a decline compared to previous years which is likely to be due to the response to COVID-19 including restrictions.

Data from SSBBV testing suggests that the number of individuals tested via prison services rose dramatically by 949.9% between 2015 and 2019, in line with roll out of the national policy for opt-out testing for BBVs in adult prisons. Like all other services numbers testing in 2020 were lower due to COVID-19, however, unlike other services the number of tests for 2021 have failed to increase. The proportion of individuals tested via prison services identified as HBsAg positive has remained relatively stable at 1.2%, with an increase to 1.7% in 2017 and a decrease to 1.0% in 2021 (Figure 23).

Figure 23: Number of individuals tested for HBsAg by year, and proportion positive, through prisons in 23 sentinel laboratories, 2015 to 2021



Data source: Sentinel Surveillance of Bloodborne Virus Testing (for further details see Appendix 3: technical notes, Section 8)

Testing of the blood donor (low-risk) population

Blood donors are a cohort with a lower risk of BBV infection. Monitoring infections is important as observations in this group can signal issues in the wider population. NHSBT currently collects blood donations from donors in England; all donations are screened for HBsAg and DNA while repeat reactive donations and donors undergo confirmatory testing (26). Donors with a confirmed positive donation testing result are referred for follow up and notified to the local Health Protection Team.

There were approximately 800,000 donors in England in 2021 giving around 1,500,000 donations, of which approximately 130,000 donations or 9% were given by new donors. The rate of HBV in new NHSBT blood donors increased significantly in 2021 to 57.8 per 100,000 donations, the highest rate since surveillance began in 1996 (Figure 24). Prior to 2021 the average rate for 1996 to 2020 was 34.7 per 100,000 donations (Figure 24).

HBV in new donors mainly reflects chronic undiagnosed infection in people born in or to parents from areas with higher prevalence than the UK. Although country of birth is only collected for donors with confirmed positive donations, all donors are asked to report their ethnic group. In 2021, 10.7% of new whole blood donors in England were of Asian or Black ethnicity compared to 7.5% in 2020 and may account for the increase in the rate of HBV in new donors.

In 2021, a total of 95 donors (78, of which 75 were new-blood donors, 15 convalescent plasma donors and 2 plasma for medicine donors) were screen positive for HBsAg with or without HBV DNA (n=91) or HBV DNA only (n=4) and confirmed HBV positive in England; 90 were assigned as chronic infection, 2 as acute HBV and 3 as occult HBV (HBsAg undetectable, DNA positive).

In 2021, ethnicity was known for 74 out of 75 new donors who were screen positive with 40.5% (30 out of 74) of Asian ethnicity, 23 born in Asia, 28.4% (21 out of 74) of white ethnicity with 16 born outside the UK in Europe and 24.3% (18 out of 74) of Black ethnicity with 15 born in Africa. Country of birth was not known in 7 donors, while the top 10 most common countries of birth in new donors with chronic HBV in 2021 were Romania (10), UK (7), India (5), Nigeria (5), Pakistan (5), and 15 from Ghana, Philippines, Thailand, Vietnam, and Afghanistan reflecting the diversity of people coming forward to give blood. Of those 7 born in the UK, 4 were of Chinese ethnicity. Only 2 donors had occult HBV infection, both born abroad. In the 17 plasma donors, country of birth was not known for one while 1.2% were UK-born.

The number and rate of HBV in repeat NHSBT donors is low (compared to new donors) and variable ranging from 0.1 per 100,000 donations to 0.6 per 100,000 donations (Figure 25). The peak in 2018 was due to 9 donors; 3 males with occult HBV and 5 males and one female with acute HBV.

Figure 24: Rate of HBV among donations from new blood donors in England per 100,000 donations, 1996 to 2021

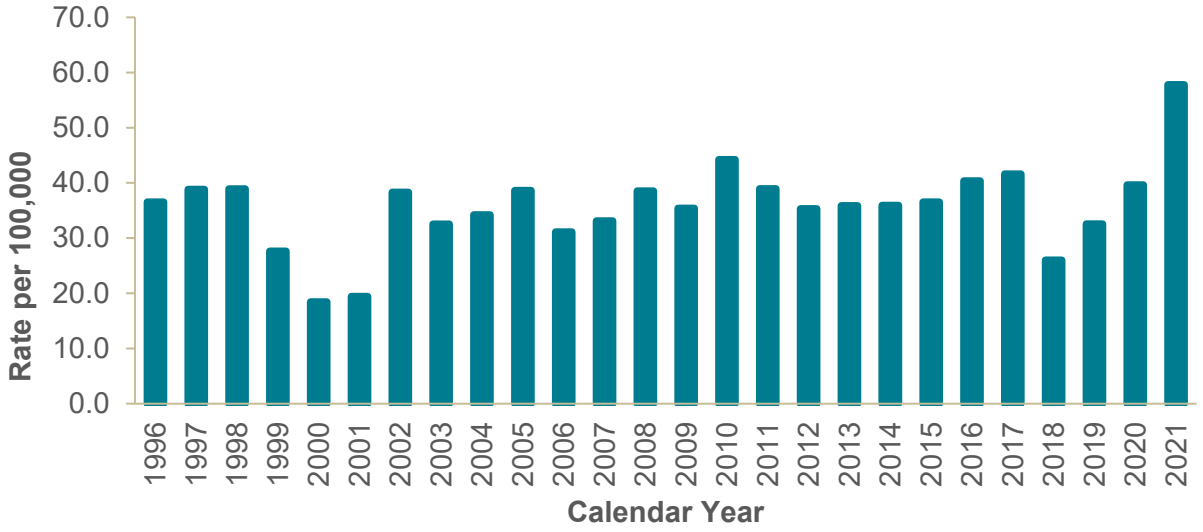
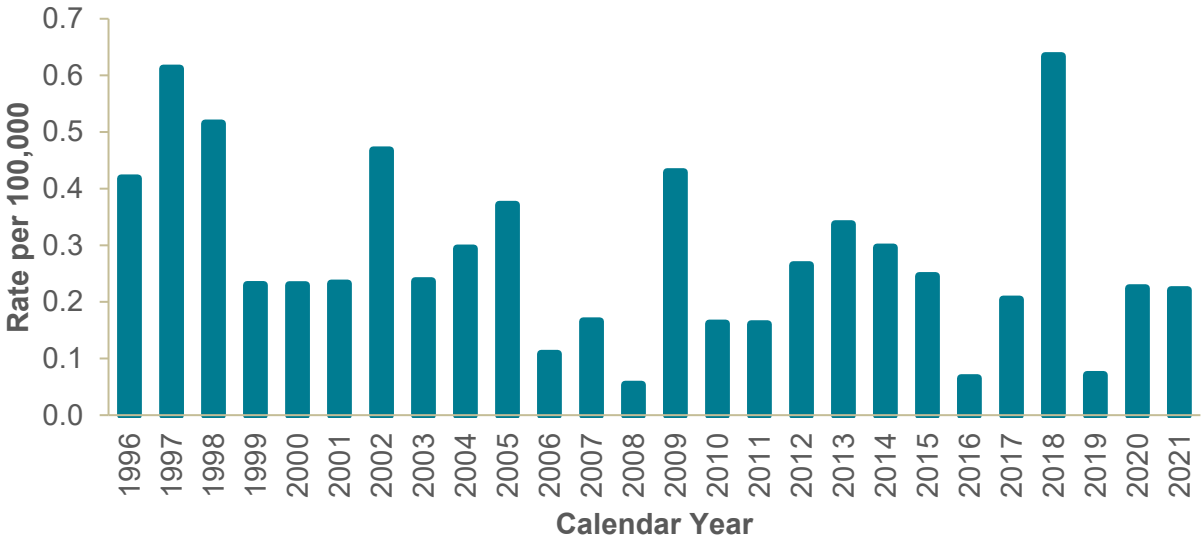


Figure 25: Rate of HBV among donations from repeat blood donors in England per 100,000 donations, 1996 to 2021



Between 1996 and 2021 of 1750 chronic HBV cases in blood donors, country of birth was known in 84.5% of cases and where known, 36.3% were of Asian ethnicity while 32.8% were born in Asia, 22.6% were of African ethnicity with 21.9% African-born and 36.1% were of White ethnicity with 18.7% born in Europe (excluding the UK). Possible exposure was identified in 69.3% with the most common exposure being born in or to parents from an HBV-endemic country (70.8%).

Overall, 32 occult infections (defined as detectable HBV DNA in blood without detectable HBsAg) have been identified to the end of 2021; country of birth was known in 90.6% with 24.1% born in the UK. In the 128 acute cases, 82% were of White ethnicity. Country of birth was known in 76.6% of cases and, where known, 79.6% were born in the UK. Possible exposure was identified in 50% of acute cases with heterosexual contact the most common reported

exposure in 56.2% or 36 cases while 19 reported possible blood contact, 8 reported sex between men and one reported injecting drug use. Male donors accounted for 62.5% of acute cases.

Screening of donations does not completely prevent HBV TTI (transfusion transmitted infection) due to the long window period of HBV where assays will not detect very recently acquired infections, or occult infections, with low levels of DNA which may be below the level of detection of current tests (27). With a low HBV incidence in the general and donor populations, it is estimated that there is less than one in a million chance of not detecting and releasing a potentially infectious window period donation or up to 2 released per year which may go on to transmit if an infectious dose is transfused to a susceptible patient (28). Since 1995 there have been 12 reported confirmed HBV TTI incidents and 5 reports of an HBV infection in recipients who had received components from donors with occult HBV in England; transmission could not be confirmed because of a lack of sequencing information (29). A working group has looked at the risk of transmission of occult HBV from blood or blood component transfusion, strategies to reduce this risk and the cost/benefit of changing the current screening strategy (30). Hepatitis B core antibody screening has been introduced for blood donations in 2022.

Further data on donors with HBV is also available from the NHSBT/UKHSA Epidemiology Unit Annual review, Safe Supplies.

Monitoring WHO programme and service coverage indicators for treatment

The WHO target for treatment coverage is that 80% of people diagnosed and eligible are on antiviral treatments.

Table 8: WHO programmatic targets for HBV treatment coverage

Programmatic target	WHO 2030 target (5, 9)	England status
Percentage of diagnosed people on antiviral treatment who are eligible	80%	Estimates by Q4 2023

A national comprehensive treatment monitoring system has not yet been established but is a priority area for development with clinical, commissioning, and public health stakeholders. Different methodological approaches and data sources are being scoped including triangulating national pharmacy prescribing data, clinical databases and patient management tools. This is an important development area, not only to monitor WHO metrics but also to monitor equity in

access and outcome from treatments, particularly with the new drugs on the horizon that have potential for ‘functional cure’.

The main endpoint of current treatment strategies is long-term suppression of HBV replication while HBsAg loss is an optimal endpoint. The typical indication for treatment requires HBV DNA >2,000IU/ml, elevated alanine aminotransferase (ALT) and/or at least moderate histological lesions, while all cirrhotic patients with detectable HBV DNA should be treated. Other indications include the prevention of MTCT in pregnant women with high viremia and prevention of HBV reactivation in patients requiring immunosuppression or chemotherapy. Nucleos(t)ide analogues with high barrier to resistance, for example entecavir, tenofovir, represent the treatment of choice. Treated patients should be monitored for therapy response and adherence. All patients should be monitored for risk of disease progression and HCC.

As treatment eligibility is complex and can change over a person’s life course, with many people being monitored but not on treatment for years, attrition in retention in care can occur. Simplified treatment guidelines may improve patient engagement, require less specialist follow up, and expedite achievement of public health programme goals.

Raising awareness and supporting case finding

NICE guidelines highlight the importance of up-to-date information being available and accessible to communities and professionals on hepatitis B and its consequences, vaccination, benefits of early diagnosis and treatment.

As HBV is usually asymptomatic in the early years, many individuals remain unaware of their infection. As a result, raising both professional and public awareness remains critical to reduce the undiagnosed burden of HBV and encourage those diagnosed to engage with specialist care and adhere to treatment in order to reduce long term complications of cirrhosis and cancer. Engagement in care is undermined by stigma, noting that underserved communities, already experiencing intersectional inequalities, are disproportionately affected by HBV.

Raising awareness among healthcare professionals

Local audits have shown that there is variation in primary care management of cases and close household contacts, with some cases not being referred to specialist care and family or household contacts not being offered testing and immunisation. Effective interventions have been developed to support primary care in identifying and managing cases and contacts but need to be more widely implemented. These include nurse-led enhanced management of cases and contacts (31), electronic flagging or risk-based search tools on GP systems (32), and remote or home-based sampling with non-invasive test kits (33).

NICE published its public health guidance HBV and C: ways to promote and offer testing to people at increased risk of infection in 2012 (34, 35).

Resources for the antenatal screening and selective neonatal immunisation programmes are available for health professionals online.

A drugs commissioning support pack for adults is available which outlines principles that local areas might consider when developing plans for integrated alcohol and drugs prevention, treatment and recovery systems. The principles are backed up by tailored annual data packs provided to local areas.

PHE produced COVID-19 guidance for commissioners and providers of services for people who use drugs or alcohol (36) as the availability and accessibility of services, including NSP, reduced in England during the COVID-19 pandemic.

Local authorities continue to play a central role in testing for viral hepatitis in people accessing community drug treatment services with HBV testing recommended for those with a history, risks (including current or past injecting), symptoms, or findings from physical examinations that signify testing is indicated.

An RCGP Course on Hepatitis B and C is available to help raise awareness in primary care and among other professionals working with groups at high risk of viral hepatitis infection (12). By 12 April 2021 more than 3,200 individuals had completed the e-learning module (29). Other downloadable resources are available, like those accessible via the International Network on Hepatitis in Substance Users

PHE in partnership with NHS England and HM Prison and Probation Service (HMPPS) oversaw the rollout of opt-out BBV testing in adult prisons, primarily at reception. The challenge moving forward is increasing and sustaining BBV testing levels to within the upper NHS England performance standard.

Emergency department opt-out testing for HIV, hepatitis B and hepatitis C which was launched in April 2022 in London, Brighton, Manchester and Blackpool has raised awareness among healthcare professionals of the unmet burden of hepatitis B infection: the provisional data in the NHSE report on the first 100 days showed that HBV constituted the largest number and proportion of diagnoses.

Raising awareness among communities at risk of infection

A suite of resources are available to help encourage people at risk of infection to seek an HBV test. These include posters, videos and banners for social media in multiple languages, co-branded by the World Hepatitis Alliance and the British Liver Trust.

An evidence review conducted by Liverpool John Moores University entitled 'A practice survey of activities and interventions that aim to raise awareness among, and/or engage with, groups who are at an increased risk of HBV and C infection' describes services and interventions

implemented to raise awareness in the UK among those at increased of HBV and HCV (37). Commonly reported interventions for raising awareness were providing advice and information through leaflets and posters. For South Asian migrant populations, regional specific interventions included outreach in mosques, providing information to South Asian males, and 'on the spot testing'.

NHS England have funded community vans to support safe community working across operational delivery networks (ODNs, clinical networks established by NHSE, which are responsible for delivering hepatitis C treatment) in England. These and other independently funded vans focus on areas of high health inequality and offer hepatitis C testing (and treatment) to patients from various backgrounds such as those who sleep rough, asylum seekers, sex workers, MSM and PWID. Providers operating the vans also engage with other local professionals to include addiction service workers, needle exchange and access to testing for other conditions as a part of van delivery, including hepatitis B, HIV, STIs and occasionally tuberculosis.

The impact of COVID-19 on HBV elimination

This report comes at a critical moment when the COVID-19 pandemic has placed an enormous strain on health systems in the UK, and worldwide, exposing system weaknesses and structural inequalities faced by underserved communities. As such, the COVID-19 pandemic poses a serious threat to the UK's ability to (i) meet, and (ii) demonstrate that we have met, WHO HBV elimination goals. This includes the impact on service delivery and access for key populations, plus the quality and timeliness of surveillance data that allows us to monitor changes in service capacity and effectiveness, and our ability to monitor progress to elimination.

Previous analyses from UKHSA have already highlighted a reduction in testing and diagnosis for viral hepatitis in drug services, prisons, general practice and SHSs. Between January and April 2020, the number of tests for HBsAg carried out as part of the sentinel surveillance of blood borne virus testing declined by 61%. Between January and August 2020, PHE reported that there was a 34% reduction in new diagnoses of HBV reported through their laboratory surveillance system compared to the same period in 2019 (38). In 2021, following easing of restrictions levels have not returned to pre-pandemic levels for many services as the data in this report shows (24). A reduction in testing, diagnosis, immunisation and treatment initiations during COVID-19 was also observed in Europe (39).

Whilst there has been a loss of capacity across all UK Public Health agencies as staff have been diverted to the COVID-19 response, (25) COVID-19 has also accelerated the development of innovations in service delivery, including telemedicine, expanded community outreach testing and linkage into care, and postal medications delivery. However, caution is required, as new digital solutions may amplify existing inequalities since digital literacy may be lower in some of the most vulnerable populations affected by HBV. Close monitoring is therefore needed as the full impact of the COVID-19 pandemic and response on inequalities, infection transmission, longer-term health outcomes, and HBV elimination will take time to emerge.

Appendix 1. WHO HBV elimination targets

WHO GHSS targets (5) for viral hepatitis, relevant to HBV in the UK context, with proposed interim targets from the WHO interim guidance for country validation of hepatitis elimination (9).

Impact target area	**WHO GHSS 2020 target relative to 2015 baseline (5)**	**WHO GHSS 2030 target relative to 2015 baseline (5)**	**WHO Interim guidance on elimination validation 2030 target (9)**	**England 2020/21**
Incidence: New cases of chronic HBV infection	30% reduction (Equivalent to 1% prevalence of HBsAg among children)	95% reduction (Equivalent to 0.1% prevalence of HBsAg among children)	Equal to or less than 0.1% HBsAg prevalence in those aged 5 years or less Equal to or less than 2% MTCT rate	Seroprevalence survey data available Q4 2023 Target met: 0.1%
Mortality: HBV deaths	10% reduction	65% reduction	Equal to or less than 4 per 100,000 persons	Target met: 0.15/100,000 3.3% decrease in number of deaths since 2015
Service coverage or programme target area	**WHO GHSS 2020 target (5)**	**WHO GHSS 2030 target (5)**	**WHO interim guidance on elimination validation 2030 target (9)**	**England 2020/21**
Prevention of MTCT: Coverage with antenatal HBsAg testing		90%	Equal to or greater than 90% coverage of maternal antenatal HBsAg testing	Target met: greater than 99%

Coverage with antiviral therapy in eligible pregnant women	50%	90%	Equal to or greater than 90% coverage with antivirals for those eligible	Available Q4 2023 through IDPS/ISOSS
HBV birth-dose vaccination coverage or other approach to prevent mother-to-child transmission	90%	90%	Equal to or greater than 90% coverage of those infants at risk with targeted HepB-BD	Target met 99.2%
HBV universal HepB3 vaccination coverage		90%	Equal to or greater than 90% HepB3 vaccine coverage	Target met: 92.0%
Blood safety: *Proportion of donations screened in a quality-assured manner	100%	100%	100%	Target met*: 100 %
Safe injections: **Percentage of injections administered with safety engineered devices in and out of health facilities Unsafe injections	50%	90%	90%	Target met**
Harm reduction: A comprehensive package of harm	At least 200 sterile needles and syringes provided per person who	At least 300 sterile needles and syringes provided per person who	At least 300 sterile needles and syringes provided per person who injects drugs per year	Not directly

reduction services to all PWID including:	injects drugs per year At least 40 % of opioid dependent PWID receive OAT	injects drugs per year		55% in 2011 to 2012: updates underway
Testing and Treatment: Proportion of people with chronic HBV diagnosed and aware of their infection	50 % [75 % of estimated number of patients at late stage of viral hepatitis-related liver disease (cirrhosis or HCC) diagnosed]	90 %	Equal to or greater than 90% of people with HBV diagnosed	Modelled estimates by Q4 2025
Treatment coverage of people diagnosed with chronic HBV who are eligible for treatment	75 % [90 % of diagnosed patients with chronic HBV are linked to care and adequately monitored]	80 %	Equal to or greater than 80% of people diagnosed with HBV and eligible for treatment are treated	Provisional estimates by Q4 2023

* In England, 2020 and 2030 targets are already met as all donors and donations are screened.

** In England, 2020 and 2030 targets are already met in the healthcare setting as the UK follows the EU Directive for the prevention of sharps injuries in the healthcare setting by using safety engineered devices.

Appendix 2. Indicators to monitor HBV elimination in England

[W] refers to a WHO indicator, [P] refers to a provisional placeholder for a national indicator. Some indicators are both WHO indicators and placeholders. Data sources (and links for more information) for indicators are provided where possible.

	Impact and service coverage or programmatic indicators	Data source
Prevalence of HBV infection	**Prevalence of HBV infection**	
	Estimated chronic prevalence of HBV infection in general population [W] [P]	Modelled estimates
	Estimated chronic prevalence of HBV infection among minority populations [P]	Modelled estimates
Monitoring programme target for proportion diagnosed and aware of their infection	**Proportion of people with chronic HBV, diagnosed and aware of their infection**	
	Proportion of antenatally screen positive women reported as newly diagnosed [P]	IDPS
	Proportion of people with late stage of HBV-related liver disease (ESLD/HCC) that are diagnosed [W] [P]	Modelled estimates
Monitoring impact target for reducing incidence of HBV infection	**Elimination of mother to child transmission**	
	Estimated HBsAg prevalence in children ≤5 years old	Serosurveillance Survey
	Mother to child transmission rate	IDPS and PVST
	Prevention of infection in other risk groups	
	Prevalence of anti-HBcore/HBsAg among ever injected and recent initiates to drug use	UAM Survey
	Incidence of acute HBV per 100,000 people	SGSS; HPZone
Monitoring impact target for reducing HBV-related mortality	**Reducing HBV-related morbidity and mortality**	
	Annual HBV-related mortality rate per 100,000 population, and number of death registrations for HBV and HBV-related HCC/ESLD [W]	ONS
	Incidence of HBV-related HCC/ESLD admissions	HES
	Number of registrations for liver transplant and transplants undertaken, where post-HBV cirrhosis /HCC/acute liver failure is given as the indication for transplant	NHSBT
	Elimination of mother to child transmission	

Monitoring programme and service coverage indicators for incidence	Coverage of antenatal HBsAg screening among pregnant women [W]	IDPS
	Proportion of pregnant females who are HBV positive attending for specialist assessment within 6 weeks of the positive result being reported to maternity services [P]	IDPS
	Coverage of antivirals for those eligible HBsAg pregnant women with high viral load [P]	IDPS
	Coverage of HBIG at birth in at risk babies in selective programme [W]	IDPS
	Coverage of timely birth dose (BD) in at risk babies in selective programme [W]	IDPS
	Coverage of 3 doses (HepB3) universal programme by 12 months [W]	COVER
	Coverage of 3 doses by 12 months old for at-risk infants in selective programme [P]	IMMFORM
	Coverage of 3 doses (HepB3) universal programme by 24 months [P]	COVER
	Prevention of infection by other risk groups through immunisation	
	Vaccine update in gay, bisexual and other men who have sex with men in sexual health services [P]	GUMCAD
	Vaccine uptake in people who inject drugs [P]	UAM Survey; NDTMS
	Vaccine uptake in prisons and detained settings [P]	H&J SRU
	Vaccine uptake in migrants [P]	TBC
Monitoring programme targets for prevention of infection by ensuring adequate harm reduction for PWID	**Harm reduction in PWID/drug services**	
	Proportion of opioid dependent PWID receiving OAT* [W][P]	NDTMS; Modelled estimate [W]
	Number of people in drug treatment who currently, previously, or ever injected drugs	NDTMS
	Number of sterile needles and syringes provided per PWID per year [W]	UAM survey
	Estimated adequacy of NSP coverage among PWID	UAM survey
	Provision of LDSS through drug services	UAM survey
	Sharing of infecting equipment and associated paraphernalia among PWID	UAM survey
Monitoring trends in HBV diagnosis and	**In the primary care and the wider population**	
	Laboratory reports of new HBV diagnosis in England (by age and sex)	SGSS

testing in the general population and risk groups	Number of individuals HBV tested and proportion HBsAg positive in the general population	SSBBV
	Proportion of individuals with additional hepatitis B markers / viral load	SSBBV
	Number of individuals tested and proportion HBsAg positive in primary care	SSBBV
	Proportion of those newly diagnosed with late disease stage (HCC/ESLD) [P]	TBC
	In opt-out testing in emergency departments	
	Number of individuals HBV tested and proportion HBsAg positive in ED [P]	SSBBV
	Number and proportion of individuals newly diagnosed in ED [P]	SSBBV
	In people who report ever injecting drugs attending drug services	
	Number of people recorded as having been offered and received an HBV test (all, and those newly presenting to drug services) [P]	NDTMS/UAM
	In all attendees of drug and alcohol services, whether or not they report injecting drugs	
	Number of people recorded as having been offered and received an HBV test (all, and those newly presenting to services) [P]	NDTMS
	Number of individuals tested for HBsAg by year, and proportion positive, through drug services	SSBBV
	Proportion of individuals with additional hepatitis B markers / viral load	SSBBV
	Among people in secure and detained settings	
	Proportion of new receptions to prison offered and tested for HBV	H&J SRU
	Number of individuals tested for HBsAg by year, and proportion positive, through prison services	SSBBV
	Proportion of individuals with additional hepatitis B markers / viral load	SSBBV
	Among minority ethnic populations	
	Laboratory reports of HBV new diagnoses in England by ethnicity	SGSS
	Number of individuals tested for HBsAg by year, and proportion positive by ethnicity	SSBBV
	Rates of HBV infection among blood donors by ethnicity	NHSBT UKHSA Epidemiology Unit donor testing data

	Proportion of individuals with additional hepatitis B markers / viral load by ethnicity	SSBBV
	In sexual health services	
	Number of individuals tested for HBsAg by year and proportion positive through SHS	SSBBV/GUMCAD
	Number co-infected with HCV and/or HIV [P]	GUMCAD/HARS/SSBBV
	In the blood donor (low risk) population	
	Rate of HBV infection in the blood donor population (new and repeat donors)	NHSBT UKHSA Epidemiology Unit donor testing data
Monitoring programme targets for access to HBV treatment	**Engaged on a care pathway and on HBV treatment**	
	Proportion of diagnosed population linked into care and monitored [P]	To be confirmed (TBC)
	Proportion of diagnosed individuals from ED opt-out testing linked into care and monitored [P]	TBC
	Number and proportion of diagnosed people originating from, or born in, endemic countries linked into care and monitored [P]	TBC
	Proportion of those diagnosed who are eligible for treatment who are on treatment [P]	TBC
	Estimated number on HBV treatment [P]	TBC
	Proportion of those initiating treatment with late disease stage (HCC/ESLD) [P]	TBC
	Proportion achieving viral suppression in those on long-term treatment [P]	TBC

Notes: Placeholders are for indicators that are not currently available or in development with stakeholders and are subject to change.
* Available up until tax year 2011 to 2021; analysis of injecting drug use prevalence is under development to provide updated, robust estimates of the number of PWID and the proportion on OAT.

Appendix 3. Technical notes

Section 1 – Monitoring HBV-related mortality

ESLD is defined by codes or text entries for ascites, bleeding oesophageal varices, hepato-renal syndrome, hepatic encephalopathy, or hepatic failure. Deaths registered in England when the deceased's usual residence is outside England are excluded.

ICD10 codes used for HCC/ESLD

Comparison of ICD10 codes used by UKHSA and WHO and European Centre for Disease Prevention and Control (ECDC) for monitoring annual HBV-related mortality rates and death registrations for HBV and HBV-related HCC/ESLD.

	UKHSA	WHO/ECDC
B160, B161, B162, B169 – Acute hepatitis B	✓	
B181, B180 – Chronic viral hepatitis B	✓	✓
C220 – HCC	✓	✓
R18 – Ascites (ESLD)	✓	
I850 – Oesophageal varices with bleeding (ESLD)	✓	
I98.3 – Oesophageal varices with bleeding in diseases classified elsewhere (ESLD)	✓	
K704 – Alcoholic hepatic failure (ESLD)	✓	
K720 – Acute and subacute hepatic failure (ESLD)	✓	✓
K721 – Chronic hepatic failure (ESLD)	✓	✓
K729 – Hepatic failure, unspecified (ESLD)	✓	✓
K73* – Chronic hepatitis, not elsewhere classified (CLD)		✓
K74.0 – Hepatic fibrosis (CLD)		✓
K74.1 – Hepatic sclerosis (CLD)		✓
K74.2 – Hepatic fibrosis with hepatic sclerosis (CLD)		✓
K74.3 – Primary biliary cirrhosis (CIRRHOSIS) (CLD)		✓
K74.4 – Secondary biliary cirrhosis (CIRRHOSIS) (CLD)		✓
K74.5 – Biliary cirrhosis, unspecified (CIRRHOSIS) (CLD)		✓
K74.6 – Other and unspecified cirrhosis of liver (CIRRHOSIS) (CLD)		✓
K75* – Other inflammatory liver diseases (CLD)		✓
K767 – Hepatorenal syndrome (ESLD)	✓	

Section 2 – Monitoring HBV-related morbidity associated with HCC/ESLD

Hospital admissions from HBV-related HCC/ESLD

ESLD is defined by codes or text entries for ascites, bleeding oesophageal varices, hepato-renal syndrome, hepatic encephalopathy or hepatic failure.

In England, new cases of HBV-related HCC/ESLD are monitored using HES. This analysis enables the production of preliminary estimates of new cases (incidence) of HBV-related HCC/ESLD. However, it is important to recognise the limitations of these estimates; HBV may be unreported in HES, and patient episodes can only successfully be linked when identifiers exist in HES to allow this. New cases are identified by first linking all episodes of ESLD or HCC for an individual using their unique patient identifier and then linking these to hospital records with a diagnosis of HBV since 2004. Once these are linked, a case of HBV-related ESLD or HCC is classified as 'new' if no previous episodes of ESLD or HCC for that individual are found in at least the previous 5 years (less than 1% of HCC/ESLD episodes are estimated to have had a previous episode more than 5 years earlier).

The loss of identifiers in HES data for 2017 (described previously (40)) meant that it was not possible to distinguish repeat hospital episodes for the same person, and thus determine the number of incident or prevalent cases of HBV-related HCC/ESLD in 2017. This had a further effect on 2018, as although the issue was rectified, attendees may appear as incident cases in 2018 due to a failure to link to previous records in 2017, thus over-counting incident cases. To rectify this, NHS Digital facilitated a resubmission of around 54% of HES data for 2017. The scaling factor used was the historic proportion of HBV-related HCC/ESLD from resubmitting providers of the national total. However, exploration of more recent data suggests that this proportion may not be constant over time, which would lead to bias in estimates scaled up from the subset of resubmitted provider data. Further, it has been suggested that resubmitted data is not guaranteed to be complete for all providers. In this report, data for 2017 and 2018 is therefore omitted. By 2019, however, the residual impact of the loss of identifiers in 2017 is small. Misclassification of an incident case would require a first attendance in 2017, no attendance in 2018, then attendance in 2019. Analysis of pre-2017 HES data shows that the proportion of HBV-related HCC/ESLD cases with such an attendance pattern is less than 5%, and for a 2-year gap (2020) less than 3%, indicating that observed incidence in 2019, and certainly 2020, are unlikely to overcount incidence by more than a small degree. This is also supported by further comparisons of corrected and uncorrected data sets for these years. It is unfortunate that there is now a gap in the time trend, which is likely to remain.

Registrations and liver transplant for HBV-related disease given as the indication for transplant

A total of 371 first registrations in England between 2009 and 2021 had either post-hepatitis B cirrhosis or acute hepatitis B given as the primary, secondary or tertiary indication for a liver transplant. These cases may have also had other indications for a liver transplant including primary biliary cirrhosis, alcoholic cirrhosis, post hepatitis C cirrhosis, hepatocellular carcinoma non-cirrhotic, hepatocellular carcinoma cirrhotic, autoimmune cirrhosis, non-alcoholic fatty liver disease, haemochromatosis, primary liver sarcoma, and other. HBV test markers[1] were not available for registrations.

There were a total of 115 first liver transplants in England between 2009 and 2021 that had a code for post hepatitis B cirrhosis and acute hepatitis B given as the primary, secondary, or tertiary indication at Registration and/or transplant. These had no other indicators for a transplant. A number of these cases also had a positive result for the HBV[1]. In addition, there were a total of 148 first liver transplants that had codes for hepatocellular carcinoma non-cirrhotic or hepatocellular carcinoma cirrhotic. These also had a positive result for HBV[1] and/or post hepatitis B cirrhosis or acute hepatitis B as a transplant indicator. A small number of these cases had additional indicators for transplant, which included, autoimmune cirrhosis, secondary biliary cirrhosis, alcoholic cirrhosis, post hepatitis C cirrhosis, other indicator not described. Of those that had post hepatitis C cirrhosis, all had a negative or unknown result for HCV RNA.

NHSBT transplant indicator codes are:

- post-hepatitis B cirrhosis (413)
- acute hepatitis B (436)
- primary biliary cirrhosis (411)
- alcoholic cirrhosis (419)
- post hepatitis c cirrhosis (424)
- hepatocellular carcinoma non-cirrhotic (441)
- hepatocellular carcinoma cirrhotic (442)
- autoimmune cirrhosis (412)
- non-alcoholic fatty liver disease (426)
- haemochromatosis (461)
- primary liver sarcoma (444)
- secondary biliary cirrhosis (418)
- other (498)

[1] A positive HBV result was described as a positive result for HBV surface antigen and/or HBV DNA and/or HBV E-antigen.

Section 3 – Monitoring screening coverage in antenatal population

For IDPS HBsAg coverage, eligible women are the total number of pregnant females booked for antenatal care during the reporting period, or presenting in labour without previously having booked for antenatal care, excluding women who:

- miscarry between booking and testing
- opt for termination between booking and testing
- transfer out between booking and testing (do not have a result)
- transfer in who have a result from a screening test performed elsewhere in the NHS in this pregnancy

Section 4 – Historical MSM vaccination coverage monitoring

In 2001, the Department of Health's Strategy for Sexual Health and HIV introduced specific vaccination standards for MSM in order to improve vaccination coverage in this group. A standalone enhanced surveillance system called HBV3 was introduced across all genitourinary medicine (GUM) clinics in England in 2003 which collected data on first dose and complete (3 dose) courses of vaccine among new MSM attendees. The survey ran from January 2003 to June 2008. Since then, vaccine data has been collected in GUMCAD.

Section 5 – Current MSM HBV vaccination monitoring

Current data on HBV vaccination coverage in MSM is collected through the GUM Clinic Activity Dataset (GUMCADv2) which collects pseudo-anonymised patient level data on all STI diagnoses and services provided by all GUM services in England.

Section 6 – Monitoring vaccination in detained settings

The Health and Justice Indicators of Performance (HJIPs) released on 1st April 2014 include an HBV vaccine indicator, where the HBV vaccine coverage for completed course (3 doses) for all eligible patients should be installed into the establishment within 4 weeks of reception. From 2019, H&J SRU Health and Justice Information System reported on uptake. This data capture which prisoners have been vaccinated for HBV, but do not show whether this was in

prison or in another setting. These do not specify a fully vaccinated individual and will include those with a full course or who have only received one dose.

Section 7 – Testing and diagnosis SGSS/CoSurv

Laboratory reports of new diagnoses of HBV include positive test results for HBV surface antigen (HBsAg) are submitted to UKHSA or predecessor organisations via SGSS/CoSurv. Mandatory reporting by laboratories of notifiable organisms started in 2010. 2021 data is provisional and figures for previous years are subject to change as a result of late reporting and the associated de-duplication procedure. Patient identifiable data submitted by NHS laboratories is variable, particularly from sexual health and drug and alcohol services, which limits the ability to deduplicate. Results for children under one year of age are excluded to rule out detecting maternal antibody.

Section 8 – Testing and diagnosis: sentinel surveillance of BBV testing

Sentinel surveillance data is from 19 laboratories and are based on complete and consistent reporting for a 5-year period. This means that the numbers of laboratories included for trend data may change each year depending on their reporting history. Sentinel Surveillance covers approximately 45% of all testing in the GP registered population. As sentinel surveillance includes the 2 laboratories processing DBS tests for the major drug services in England, it is likely that sentinel surveillance covers most tests coming from drug services, where DBS is the main method of testing.

Sentinel Surveillance excludes samples collected outside routine testing such as look back studies, reference testing, and children aged <1 year. Patient identifiable data submitted by laboratories is variable, particularly from sexual health and drug and alcohol services, which limits the ability to de-duplicate. Data is de-duplicated subject to availability of date of birth, Soundex, NHS number and first initial. The proportion positive is calculated using number of individuals tested. For antenatal testing only women aged 12 to 49 years old are included. Test request location and free text clinical field accompanying the test request are used to identify antenatal testing, not all women will have been correctly classified. Ethnicity is identified through linking to hospital episode statistics and is dependent on an individual having their NHS Number reported as part of the test request. Trend data does not reflect cumulative data as only locations that have consistently reported during the 5 years presented are included in trend data to remove any artificial changes in testing. The positive result is the first reported by participating laboratories and may not reflect an individual’s first diagnosis

Glossary of abbreviations

Abbreviation	Meaning
Anti-HBc	Antibodies to Hepatitis B core antigen
Anti-HCV	Antibodies to Hepatitis C
BASHH	British Association for Sexual Health and HIV
BBV	Blood Borne Virus
CI	Confidence Interval
COVID-19	Coronavirus 19 disease
DBS	Dried Blood Spot
DHSC	Department of Health and Social Care
DNA	Deoxyribonucleic acid
DTaP/IPV/Hib/HepB	Diphtheria, Tetanus, Pertussis, Polio, Haemophilus influenzae type b and Hepatitis B vaccine
ECDC	European Centre for Disease Prevention and Control
ESLD	End-stage liver disease
GBMSM	Gay, bisexual or other men who have sex with men
GHSS	Global Health Sector Strategy
GP	General Practitioner
GUM	Genitourinary Medicine
GUMCAD	GUM Clinic Activity Dataset
HARS	HIV and Aids Reporting System
HBeAg	Hepatitis B e antigen
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B Virus
HCC	Hepatocellular carcinoma
HCV	Hepatitis C Virus
HES	Hospital Episode Statistics
HIV	Human Immunodeficiency Virus
HJIP	Health and Justice Indicators of Performance

Abbreviation	Meaning
HJIS	Health and Justice Information System
H&J SRU	Health and Justice Strategic Reporting Unit
HMPPS	Her Majesty's Prison and Probation Service
IgM	Immunoglobulin M
ICB	Integrated Care Board
LDSS	Low dead space syringe
MTCT	Mother to child transmission
NDTMS	National Drug Treatment Monitoring System
NHS	National Health Service
NHSBT	NHS Blood and Transplant
NICE	National Institute of Health and Care Excellence
NIHR	National Institute for Health Research
NSGVH	National Strategic Group for Viral Hepatitis
NSP	Needle and syringe programme
OAT	Opiate Agonist Therapy
OR	Odds Ratio
ODN	Operational Delivery Network
OHID	Office for Health Improvement and Disparities
ONS	Office for National Statistics
PHE	Public Health England
PVST	Post Vaccination Serology Testing
PWID	Persons who inject drugs
RCGP	Royal College of General Practitioners
SGSS	Second Generation Surveillance System
SSBBV	Sentinel Surveillance of Bloodborne Viruses
STI	Sexually Transmitted Infections
SHS	Sexual Health Services
UAM	Unlinked Anonymous Monitoring
UK	United Kingdom

Abbreviation	Meaning
UKHSA	United Kingdom Health Security Agency
WGS	Whole Genome Sequencing
WHO	World Health Organization

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Acknowledgements

Editor: Sema Mandal

Contributors from UKHSA (including previous PHE staff):

Elisa Allen, Koye Balogun, Simon Burton, Toni Benson, Maciej Cazachorowski, Eleanor Clarke, Shirley Cole, Selene Corsini, Annastella Costella, Sara Croxford, Katy Davison, Monica Desai, Chantal Edge, Claire Edmundson, Gabriel Gurmail-Kaufmann, Iain Hayden, Ellen Heinsbroek, Susan Hopkins, Samreen Ijaz, Georgina Ireland, Nalini Iyanger, Katri Jalava, Emma Keeley, David Leeman, Sema Mandal, Madeleine McMahon, Priya Meghani, Stephanie Migchelsen, Holly Mitchell, Sophie Mitra, Hamish Mohammed, Eamonn O'Moore, Celia Penman, James Plunkett, Rajani Raghu, Mary Ramsay, Claire Reynolds, Reisha Simmonds, Ruth Simmons, Tracey Smeulders, Ines Ushiro-Lumb, Bhavita Vishram, Sharon Webb, Joanne White, Ruth Zwizwai.

We would also like to thank the clinicians, microbiologists, scientists, data analysts, public health practitioners, academics, commissioners, third sector organisations and other colleagues who have contributed insights and/or data to the surveillance and monitoring systems presented in this report, in particular:

- National Strategic Group on Viral Hepatitis (NSGVH)
- National Institute for Health Research (NIHR) Health Protection Research Unit (HPRU) in Blood Borne and Sexually Transmitted Infections at University College London
- NIHR HPRU in Behavioural Science and Evaluation at University of Bristol
- NHS community, primary and secondary care services
- NHS Screening and Immunisation Teams
- community drug service staff and service users who support, and participate in, the Unlinked Anonymous Monitoring (UAM) survey of people who inject drugs
- National Health Service (NHS) Blood and Transplant
- Hospital Episode Statistics (HES) (Copyright © 2023, re-used with the permission of NHS Digital, all rights reserved)
- Office for National Statistics (ONS carried out the original collection and collation of the data but bears no responsibility for their future analysis or interpretation)
- Office of Health Improvement and Disparities
- National Drugs Treatment Monitoring System team
- staff who work in the laboratories and contribute to the laboratory surveillance of new diagnoses of hepatitis B (SGSS) and Sentinel surveillance of bloodborne Virus Testing (SSBBV)
- NHS Infectious Diseases in Pregnancy Screening (IDPS) Programme team, (part of NHS Antenatal and Newborn Screening Programmes)

- Integrated Screening Outcomes Surveillance Service (ISOSS)
- NHSE Health and Justice Strategic Reporting Unit
- NHSE Public Health Commissioning
- Royal College of General Practitioners (RCGP)
- WHO Global HIV, Hepatitis and Sexually Transmitted Infections (STI) Programmes

We are extremely grateful to all the NHS and non-NHS teams involved in delivering the services and programmes outlined in this report.

Suggested citation:

UK Health Security Agency. ‘Hepatitis B in England: Working to eliminate hepatitis B as a public health threat’ 2023

About the UK Health Security Agency

UKHSA is responsible for protecting every member of every community from the impact of infectious diseases, chemical, biological, radiological and nuclear incidents and other health threats. We provide intellectual, scientific and operational leadership at national and local level, as well as on the global stage, to make the nation health secure.

UKHSA is an executive agency, sponsored by the Department of Health and Social Care.

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Published: February 2023
Publishing reference: GOV-14029