

## ORIGINAL PAPER

# Impact of a nurse-led enhanced monitoring, management and contact tracing intervention for chronic hepatitis B in England, 2015-2017

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## Abstract

Around 200,000 people live with chronic hepatitis B in England. Despite national guidance on identification and management of cases and their close contacts, testing rates of close contacts is as low as 43% in high prevalence areas of London. Our study aimed to determine whether a nurse-led enhanced management and contact tracing of chronically infected individuals improved testing uptake, vaccination and onward referral of close contacts. The study was conducted across Greater Manchester and East of England regions between October 2015 and July 2017. All HBV chronically infected individuals registered with a GP and their close contacts were eligible for recruitment. The proportion of contacts who were tested, vaccinated and referred where appropriate were compared before and after the nurse-led intervention. Baseline and outcome information was collected using questionnaires. The intervention improved case referral rates by an additional 14% (from 86% (88/102 cases) to 99.7%; 648/650 cases). The proportion of contacts tested increased from 34% to 72%-94% with 18 new cases of HBV diagnosed. Amongst close contacts tested, vaccination rates of at least three doses increased from 77% (43/56) to 93% (452/491) during the study. Our study has shown that nurse-led enhanced management greatly improves identification, testing and vaccination of close contacts. The identification of new acute and chronic cases is likely to make the intervention cost effective and local health commissioners should consider providing a nurse-led service as part of hepatitis B care pathways.

## KEYWORDS

hepatitis b, immunization

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## 1 | INTRODUCTION

Hepatitis B is a vaccine-preventable disease caused by the blood-borne hepatitis B virus (HBV). It can cause a liver infection leading to both acute and chronic disease, cirrhosis and liver cancer.<sup>1</sup> Approximately 257 million people suffer from chronic HBV infection (CHB) worldwide and around 600,000 die annually because of associated liver disease.<sup>2,3</sup> In the UK, approximately 0.3% of the population have CHB,<sup>4</sup> mostly among ethnic minority groups and in large cities<sup>5-7</sup> where migrants, who acquired the infection as children in their birth country, mainly contribute to the burden.<sup>8</sup>

The risk of CHB following acute infection is age-dependent. Most adults (90%) clear infection and develop immunity, but <5% develop CHB. In contrast, without intervention, up to 90% of infected infants will develop CHB.<sup>9</sup> Around 25% of chronically infected individuals will develop liver cirrhosis or liver cancer.<sup>10</sup> Effective prevention strategies are therefore of paramount importance. These include birth vaccination of babies born of mothers with CHB and identifying and testing contacts of individuals infected with HBV, with subsequent vaccination or referral.

Until 2017, the UK selectively immunized individuals at increased risk of infection against HBV, including babies born to infected mothers and sexual partners or close contacts of infected persons. In 2017, a universal programme was also introduced with all babies born from August 2017 offered three doses of hepatitis B-containing hexavalent vaccine.<sup>1</sup>

Identifying contacts of CHB cases can prevent transmission through vaccinating those at risk and mitigate the impact of infection through early detection and treatment. The National Institute for Health and Care Excellence (NICE) recommends identification, testing, vaccination and follow-up as necessary for contacts of Hepatitis B (HepB) cases.<sup>11</sup> Contact tracing is included in national HBV surveillance standards and is a key public health response to HepB.<sup>12</sup> Close contacts testing has conventionally been performed on serum or dried blood spot (DBS). Oral fluid (OF) detection of anti-HBc and HBsAg has also been validated and is often a more convenient and less invasive analyte for sampling cases and has the added advantage that it can be undertaken at home by the patients themselves.<sup>11</sup> In England, the public health management of cases of infectious diseases and their contacts (including for Hepatitis B) is coordinated by Public Health England (PHE) health protection teams (HPTs). PHE routinely receives laboratory notifications of all acute and CHB tests across England. Despite national recommendations, contact tracing and subsequent close contact management is not systematic. A 2006 London audit reported only 7% of identified sexual partners were tested, with many not subsequently vaccinated.<sup>13</sup> Another audit conducted in Bristol in 2012 showed that only 12% of migrants for whom HBV serology testing was recommended had been tested.<sup>14</sup>

A pilot study in two London hospitals demonstrated that nurse-led enhanced follow-up of pregnant women with CHB, including home sampling by DBS, increased testing uptake among their partners from 43% to 90%.<sup>15</sup> Nurse-led enhanced contact tracing and

management of CHB cases therefore has the potential to improve testing and management outcomes among contacts. This study aimed to determine whether a nurse-led intervention including enhanced management of cases and contacts of chronically infected individuals improves case referral and testing uptake, vaccination and onward referral of close contacts. The intervention consisted of an intervention nurse (IN) carrying out three key public health tasks: (a) tracing all close contacts of individuals diagnosed with HBV, (b) regular follow-up of contacts to ensure they are getting tested and vaccinated, and (c) appropriate referral and attendance to specialist services for contacts who test positive for HBV.

## 2 | METHODS

### 2.1 | Study design

The intervention was evaluated using a self-controlled before and after study design across two Health Protection Teams (HPTs): Greater Manchester and East of England. The INs in each HPT were in place between 1 October 2015 and 1 July 2017.

In summary, the study entailed recruiting into the baseline individuals who had a laboratory diagnosis prior to the study time period (October 2015 to July 2017) and their contacts. The outcome for baseline cases and their contacts were described retrospectively at the time of recruitment (ie prior to the intervention). Because these individuals were now prospectively being managed by the intervention nurses (giving them a 'second chance' of being followed up), they were counted in the intervention group (with an 'updated' outcome following the nurse intervention), in addition to any individuals who were first notified between 1 October 2015 and 1 July 2017.

### 2.2 | Recruitment

All adults registered with a GP identified as CHB cases during the study period and their close contacts were eligible for recruitment into the study as summarized in Box 1. We excluded cases below the age of one and their contacts because these cases are largely babies born to HBV-infected mothers, and are managed through a different care pathway and nationally commissioned immunization programme which is not the focus of this study.

### 2.3 | Intervention group

After ensuring that each case was aware of their HBV infection, the INs contacted cases to explain study objectives, invite them to participate and ask permission to communicate with their close contacts. Where this permission was declined, cases were asked for a reason and the number, ages and countries of birth of their close contacts. Phone translation services were used to consent non-English speakers. Consent for under 16 years old was obtained from

a parent or legal guardian and appropriate assent from the young person.

Following case recruitment, the IN collected information on diagnosis, testing, close contacts' details, previous referrals and attendance using a patient questionnaire and confirming with the case's GP where necessary. The IN referred cases not already referred or who had missed appointments. The IN obtained GP registration details of close contacts using the NHS personal demographic system (PDS).<sup>16</sup> Following close contact recruitment, information on testing, number of reminders and relevant vaccination (number and dates of doses) or referral were collected using a questionnaire. The IN liaised with GPs to obtain or confirm details of previous tests, vaccinations or referrals and to arrange HBV serology testing.

Eligible contacts were offered HBsAg and anti-HBc testing either as a blood test or as a home OF test kit (Figure 1). Individuals who did not return their OF sample were reminded one week after dispatch. The IN liaised with GP surgeries and contacts to follow-up all individuals to the conclusion of their clinical care, either vaccination or onward referral, recording the outcomes of their interaction using study questionnaires.

## 2.4 | Baseline population

Recruited cases who were diagnosed with CHB before October 2015 through antenatal or primary care services were eligible for inclusion in the baseline study population. Cases without complete GP records were excluded. The outcome for baseline cases and their contacts were described at the time of recruitment (ie prior to the intervention). As described above, baseline cases and their contacts were then offered the intervention and included again in the intervention group with a revised outcome following the nurse intervention (Figure 2).

Contacts who tested negative for HBV serology were contacted by the IN to ensure appointments were booked at their GP to start or complete a HepB vaccination course. Contacts were reminded of vaccination appointments through SMS. In instances where the study ended before a vaccination course could be completed, the IN ensured appointments were booked for the remaining doses. The IN referred contacts with serology suggestive of HBV infection and followed up to attendance at the specialist service.

## 2.5 | Study power

The study sample size was constrained by the number of HBV cases in the study regions in the study timeframe. To ascertain the number of individuals needed in the baseline and intervention contact groups to detect a difference in testing rate, we ran several scenarios with different testing rates for contacts in the baseline and intervention groups that represented the range of what was deemed to be realistic by the intervention team. The biggest difference that was deemed realistic was 30% testing in the baseline and 85% testing in the intervention group. With a significance level of 0.05 and a power of 0.8, this difference could be detected with 6 contacts in the baseline and 17 in the intervention. The smallest expected difference was baseline testing of 45% and intervention testing of 70%, which would require identification and recruitment of 32 contacts in the baseline and 92 in the intervention group.

## 2.6 | Data management and Analysis

Questionnaire information from patients, contacts and GP practices was entered, managed and cleaned using Access 2010 and Excel 2010 (Microsoft). We described cases in terms of age, gender and

### Box 1 Case and contact definitions

#### Definitions:

Case	Intervention: An individual diagnosed with chronic hepatitis B in Greater Manchester or East of England between October 2015 and July 2017 Baseline: An individual diagnosed with chronic hepatitis B in Greater Manchester or East of England before October 2015
Close contact	A current and/or recent sexual partner of a case OR individual sharing the same household as case over the age of 1.
Close contact trace	A close contact that had been tested and/ or started a course of vaccination within 60 days of the index case's date of diagnosis.
Exclusion criteria	
Prisons or other places of detention	CHB cases are not followed up through normal PHE HPT mechanisms.
Sexual health clinics	Cases identified through sexual health clinics anonymised and unable to follow-up.
Specialist services	Case already undergoing treatment for CHB as part of specialist care.
Not registered with GP	No follow-up mechanisms

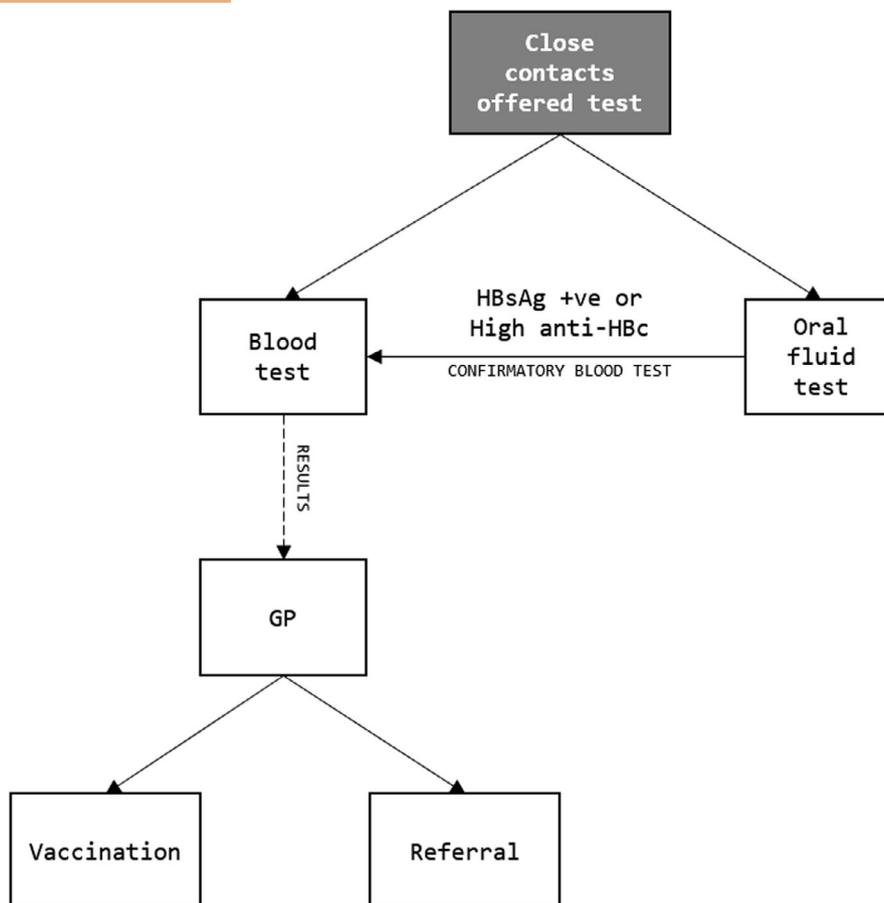


FIGURE 1 Testing of close contacts

region of birth and compared the baseline with the entire study population using chi-square tests, to assess any significant differences in the populations. To assess the impact of the intervention on cases, we compared the proportion of cases who were referred and attended their referral appointment before and after the intervention using chi-square tests. To assess the impact of the intervention on testing and subsequent management of close contacts, the proportion of contacts of cases who were contacted, tested, and appropriately referred or vaccinated (as defined in Box 1) were compared before and after the intervention, using chi-square tests. All statistical analyses were performed using Stata 14 (StataCorp, USA). NHS Ethical approval was obtained from NRES Committee South East Coast and management permission ('R&D approval') was obtained from the relevant NHS organizations.

### 3 | RESULTS

#### 3.1 | Referral of cases

We identified 1,123 eligible cases to be recruited over the study period. INs made telephone contact with 725 (65%) cases (Figure 2). Of these, 650 (90%) consented to participate in the study. Of the 650 recruited cases, 363 had a CHB diagnosis prior to the intervention

period. Of these, 102 (28%) had GP data available and were therefore included in the baseline population (Figure 2). Compared with all cases, baseline cases were of similar age (median 33 vs 34 years), more likely to be female (77% vs 58%,  $P = .003$ ) and comparable in terms of region of birth ( $P = .9$ ) (Table 1). Of the 102 baseline cases, 88 (86%) had been referred to a specialist service at the time of diagnosis (Table 1).

Among the 650 recruited cases, following the intervention, 648 (99.7%) had been referred to specialist services compared with 86% among individuals managed prior to the intervention ( $P < .001$ ).

The INs checked whether referred individuals had attended their appointments and identified 53 who had not. Of these, 42 (79%) were re-referred (the others declined or could not be contacted). Amongst those, 64% (27/42) attended their appointment. Ten cases did not attend despite two reminders from INs, a further five cases were uncontactable.

#### 3.2 | Contact tracing

There were 183 contacts over one year of age identified for the 102 baseline cases, of which 62 (34%) had already been tested prior to the intervention. Of those 62 who were tested, 6 (10%) had evidence of CHB, of which 5 (83%) were referred to a specialist service by the GP.

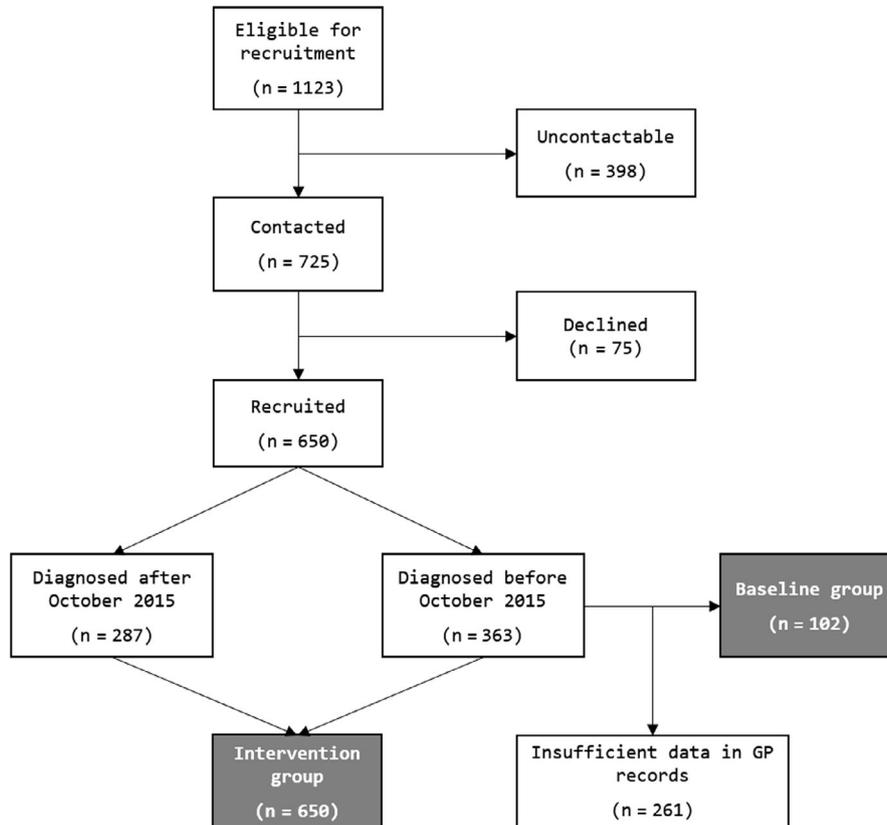


FIGURE 2 Recruitment of baseline and intervention cases

Amongst the 56 close contacts who tested negative, 10 (18%) were completely unvaccinated and 43 (77%) had received three or more doses of hepatitis B vaccine (Table 1). Because the proportion of nontested contacts who are vaccinated is unknown, it is not possible to determine the overall proportion of contacts who were vaccinated at baseline. However, assuming that all of the nontested contacts were unvaccinated, the proportion of contacts who had received at least three doses of vaccine could be as low as 43/183 (23%) at baseline.

A total of 1,402 close contacts were identified for the 650 cases (Table 1). Of these, 830 (59%) consented to testing and follow-up. Amongst those that did not consent, 25% (353/572) reported that they were already fully vaccinated, 13% (187/572) did not provide a reason, 1% (12/572) had moved abroad and one case was already undergoing treatment for CHB. Of the 830 consenting contacts, 641 were over the age of one year old and seven of those were already known to be CHB positive and undergoing treatment. There were therefore 634 eligible for HBV serology testing. Of those, 593/634 (94%) were tested for HBV serology, 60 percentage points higher than in the baseline ( $P < .001$ ). Of the 41 that were not tested, 27 (66%) were uncontactable after consent despite at least three attempts and 14 (44%) did not attend their test. Including those close contacts who did not consent and did not provide a reason (187), a worst-case scenario testing rate of 72% (593/821) was achieved.

Of the 593 contacts tested during the study, 531 (90%) tested negative (HBsAg negative and anti-HBcore negative) and 42 were

found to have had a resolved past infection (HBsAg negative and anti-HBcore positive). There were 18 new cases detected: 2 cases with evidence of acute infection or chronic flare-up and 16 newly detected CHB cases. Laboratory results for two cases were unable to be confirmed due to case complications (Table 1).

Of the 531 negative contacts, 491 (92%) were eligible to be fully vaccinated during the study period. The others were either affected by a vaccine shortage where completion of the full course was deferred (6, 1%) or had vaccine courses finishing outside the study period (34, 6%). All 34 cases whose vaccine course finished outside the study had appointments booked for vaccination following the end of the study. All six cases affected by the vaccine shortage were followed up post-study and vaccinated.

Of the 491 eligible to be vaccinated, 215 (44%) were already vaccinated with at least three doses of vaccine, increasing to 452 (93%), by the end of the study (Table 1).

## 4 | DISCUSSION

Providing nurse-based enhanced support for CHB management greatly improves the identification and testing of contacts (from 34% of contacts before the intervention to 72%-94% during the intervention), as well as contact vaccination (from potentially as low as 23% to 93%). The intervention also identified 18 new diagnoses of HBV who were referred to specialist services. The success of the

TABLE 1 Baseline vs. intervention population demographics and outcomes

	Baseline			Intervention			P-value
	n	Denominator	%	n	Denominator	%	
Recruited	102			650			
Sex							
Male	23	102	23%	270	650	42%	0.003
Female	79	102	77%	380	650	58%	
Median age (range)	33 (20-67)			34 (18-83)			
Continent of birth							
Latin America and the Caribbean	0	102	0%	3	650	0.5%	0.9
Northern Europe	6	102	6%	47	650	7%	
Western Europe	0	102	0%	2	650	0%	
Eastern Europe	15	102	15%	108	650	17%	
Southern Europe	3	102	3%	26	650	4%	
Northern Africa	4	102	4%	10	650	2%	
Sub-Saharan Africa	34	102	33%	225	650	35%	
Eastern Asia	15	102	15%	91	650	14%	
South-eastern Asia	6	102	6%	31	650	5%	
Southern Asia	16	102	16%	93	650	14%	
Western Asia	3	102	3%	12	650	2%	
Unknown	0	102	0%	2	650	0.3%	
Referred to specialist service							
Yes	88	102	86%	648	650	99.7%	<0.001
No	14	102	14%	2	650	0.3%	
Contact tracing							
Close contacts per case/total	2.1	213		2.2	1402		
Consenting Close contacts							
Babies born to HBV+ mothers/over the age of 1	30	213	14%	189	830	15%	
Other	183	213	86%	641	830	85%	
Eligible for testing	183			634			
Tested							
Yes	62	183	34%	593	634	94%	<0.001
No	121	183	66%	41	634	6%	
Results							
Negative	56	62	90%	531	593	90%	
Acute	0	62	0%	2	593	0%	
Chronic	6	62	10%	16	593	3%	
Resolved infection	0	62	0%	42	593	7%	
Not confirmed (case complication)	0	62	0%	2	593	0%	
Vaccination status							
Unvaccinated	10	56	18%	24	491	5%	<0.001
1 Dose	2	56	4%	6	491	1%	
2 Doses	1	56	2%	9	491	2%	
3 Doses	39	56	70%	219	491	45%	
4 Doses	4	56	7%	233	491	47%	

intervention is likely to reflect the nurses providing ongoing support along the care pathway and a bridge between the community, general practice and specialist services to organise referrals, tests and vaccination appointments. The intervention had a limited impact on improving referral rates of CHB cases, which were already high, and suggested that improvements in referral systems may have occurred in recent years. Attendance rates at specialist services, however, improved in the intervention period from 80% to 97% and 80.1% (581/634) of these had recorded appointment attendance. The INs referred the additional 16 patients, of which 14 accepted and attended and two declined, increasing the overall referral rate from 97.5% prior to the study to 99.7%.

Our findings show that the greatest benefit is with improving testing rates. Once a close contact is identified, vaccination and referral rates were high but only once a contact was identified and tested. During the intervention, nurses were responsible for ensuring all close contacts were followed up. These successful outcomes are likely due to three key aspects of the intervention. Firstly, nurses communicated at length with cases and contacts in their own language, explaining the purpose of the referral, testing or vaccination and highlighting that chronic hepatitis B had serious long-term liver complications but was a treatable disease, which may not be possible during a standard short GP appointment. Secondly, the nurses made multiple text and phone call reminders at different times of day (including evenings) prior to appointments. Thirdly, nurses were able to act as a liaison between GPs and patients or contacts to ensure referrals, testing and vaccination took place. Our intervention shows that as a minimum, providing information to cases in their own language on their diagnosis and treatment options and being persistent in follow-up can improve referral and attendance rates, possibly by demonstrating to the patient that CHB was important to diagnose and treat, and their health and care mattered.

Although it is difficult to estimate vaccine uptake among contacts prior to the intervention, the proportion of contacts receiving at least three doses of HepB vaccine increased by up to 70 percentage points following the intervention. Amongst the close contacts tested, vaccination rates of at least three doses of vaccine were high, suggesting vaccination was largely taking place once a close contact had been identified. Even among those tested, the proportion of vaccinated contacts increased significantly after the intervention.

A key limitation to our findings is reflected in the difficulty in determining the number of instances a case may have been previously identified as CHB positive. Year of diagnosis was only available for over half of cases and were estimated based on past case management and laboratory records. It is plausible that cases may have been diagnosed and entered into the HBV care system at multiple times in their lives with mixed healthcare utilization and outcomes, but this information is unlikely to be transferred from GP to GP.

Furthermore, cases with laboratory tests that were requested from services other than general practice were excluded from eligibility in both regions. Because testing occurs in other primary care and secondary care settings,<sup>17</sup> our study population may only be representative of individuals who would be diagnosed and managed

through GPs. However, even if a case is diagnosed in secondary care, for the most part, management of contacts would be mainly undertaken by GPs (in liaison with public health), and the intervention outcome on contacts may therefore be relevant to all cases regardless of the setting of their diagnosis.

Our study has highlighted the challenges in implementing public health interventions for a complex, heterogeneous and mobile population at risk of HBV and the need to be flexible and pragmatic in designing and delivering interventions. Despite these challenges, this study demonstrated the positive impact of a nurse-led patient support intervention on hepatitis B case referral and attendance in specialist care, and most notably in the management of close contacts. The identification of additional acute and chronic cases is likely to make the intervention cost effective, but a formal economic evaluation is underway.

In essence, this was a nudge-type intervention with a focus on prompts reminders to support both patient and GP staff to navigate the system. Nudging has been shown to potentially change behaviour of patients and professionals, for example, lowering nonattendance, and therefore reducing healthcare wastage and inefficiencies.<sup>18</sup>

Local health services should consider commissioning such a nurse-delivered intervention as part of their Hepatitis B care pathways. While the study did not seek to determine the best setting for embedding the nurse service, secondary care liver or infectious disease units or Health Protection Teams in regional PHE Centres, linked into primary care, are options that could be considered. There may therefore be opportunities for adapting or combining with other care models that serve more marginalised communities affected by blood-borne viruses or tuberculosis. For example, a recent study has demonstrated the value of GP based testing using automated flagging of GP systems to identify and test migrant populations at high risk of hepatitis B (and C).<sup>19</sup> While results are encouraging on their own, with some tweaks to maximise yield, this intervention could be combined with our nurse-led intervention to deliver a comprehensive package of care along the whole care pathway from diagnosis to treatment of cases and management of close contacts. Integrated and innovative care pathways are needed to ensure the UK can deliver on its commitment to contributing to the World Health Organisation global strategy to eliminate viral hepatitis as a major public health concern.

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