National Institute for Health and Care Excellence

4-year surveillance (2017) – Hepatitis B and C testing (2012) NICE guideline PH43

Appendix B: stakeholder consultation comments table

Consultation dates: 29 September to 13 October 2017

Do you agree with the proposal not to update the guideline?

Stakeholder	Overall response	Comments	NICE response
Brighton and Sussex University Hospital	No	**This refers to recommendation 10: Commissioning locally appropriate integrated services for hepatitis B and C testing. The recommendation suggests that Commissioners should develop and commission integrated community models** On principle this is a very appropriate recommendation as the majority of people with HCV in England are people who inject drugs (PWID), a cohort with poor engagement with hospital services. Additionally, the WHO mandate to eliminate HCV by 2030 will be impossible without engaging PWID. However this recommendation does not reflect the limited published evidence on community based integrated HCV treatment models in England. Without scientific evidence it will be very challenging for local commissioners to develop effective local commissioning business cases. We would appreciate if this 'chicken and egg' situation could be addressed in recommendation 10. With this conundrum in mind we have written a business case for such a community based integrated model of care. This is due to be presented to our trust financial managers this month. We have a particular interest and expertise in integrated and multidisciplinary community models for liver disease including HCV. In 2013 we set up Project ITTREAT (**I**ntegrated Community based **T**est – stage –**TREAT**) HCV service for PWID. This is based at a large substance misuse service in Brighton (1). In 2015 we set up the VALID (**V**ulnerable	Thank you for your comment. It is appreciated that there is limited evidence in the area of community based integrated hepatitis C care. NICE bases its guidance on the best available evidence, which at the time of guideline development indicated that targeted case finding for high risk groups in primary care was an effective intervention for increasing the number of people receiving a hepatitis C test. The evidence highlighted has been considered. For the following reasons, these studies will not be included in the summary of new evidence (Appendix A): • O'Sullivan et al., 2016 – *excluded as this is not a relevant study type (conference abstract)* • Hashim et al., 2017 - *excluded as this is not a relevant study type (conference abstract)* Although this highlights that there is research activity in this area, there is currently insufficient evidence to suggest an impact on the guideline. Any new evidence published in this area will be considered at the next surveillance time point, alongside the concerns raised here, to determine the impact on the guideline.

		Adults **LI**ver **D**isease) study (2) at two homeless hostels and affiliated GP practices in Brighton. Both provide a “one-stop”HCV clinic in the community with all aspects of care delivered at one site to include blood borne virus screening, liver fibrosis assessment (fibroscan), HCV treatment, social and peer mentor support and psychiatric input. Service evaluation is on going with collection of clinical, patient reported and health economic outcomes. Interim clinical outcome data has been presented at multiple local, regional, national and international meetings and conferences. Till date we have screened about 600 individuals with over a 100 commencing HCV treatment in the community. Service uptake (98%) and treatment compliance (93%) have been excellent with treatment outcomes comparable to secondary care (1,2). **References** 1. O’Sullivan M, Williams H, Jones AM**,** Verma S. Project ITTREAT (**I**ntegrated community based **T**est – stage **T**reat) HCV service for People who Inject Drugs (PWID). Hepatol 2016; 64 Suppl 1; Abstract 781 2. Hashim A, Worthley T, Macken L, Aithal GP, Verma S. Enhancing detection and treatment of chronic hepatitis C related liver disease in vulnerable adults through a dedicated homeless hostel-based liver service: Vulnerable Adults Liver Disease Study. EASL 2017 J Hepatol 2017;66:Suppl1:S267	
British Society Of Gastroenterology	Yes	See comment in 2	Thank you for your response.
Hepatitis B Foundation Trust	No	**We are testing too little to note the boom in undiagnosed infections....** Undiagnosed infections are booming our cirrhosis and liver cancer therefore. As ever can we please notice that since 2000 our mothers in maternity have tested in Sentinel Surveillance 0.5% HBV positive.	Thank you for your response. It is appreciated that the prevalence of hepatitis B is a public health concern. Within the ‘public health need and practice’ section of PH43, this concern is discussed, and it is recognised that at the time of publication, there was considerable uncertainty about the number of people with chronic hepatitis B in the UK. However, despite uncertainties regarding prevalence, the recommendations made in PH43 aim to increase the rate of hepatitis B testing. Therefore, it is felt that the current guideline acts to

		Adjusting that men are 80% more infected and that elders are more infected than youngers we have a minimum of **450,000 people** out there with mainly undiagnosed HBV. A national prevalence figure of 0.75% HBV positive is not a guess it is based on some hundreds of thousands of maternity tests. Nearly triple the dream guess propagated of 180,000 and publicised since 1995 in spite of all our demographic changes. Testing is simply not finding or even prevalencing the existence of huge pools of undiagnosed HBV in our BME communities. The longer we ignore this epidemic the greater the cost in Liver Disease. This is visibly booming in a period of falling alcohol use. **We are diagnosing and causing vast unnecessary suffering through poor patient educations** We also note a total failure to design and offer patients education with their diagnosis after the testing process Patients are still not asked key questions namely. Do you know if you can have children? Do you know if you can have a partner? Do you know how to vaccinate a partner? Have you felt suicidal? Have you felt depressed? Have you given up your job? Do you know what common toxins can kill you? Do you know what common diet actions can help you? Do you know how to kill HBV in blood? Do you know your prognosis? Do you know if you are going to die soon? Huge numbers of the diagnosed have simply poor or wrong facts related to all the above questions. The social and emotional costs are huge. Yet we still leave this poor people without access to real education about their condition, its management and its affect on their health today and in their futures. There is still no quality patient centred booklet to help.. nor any budget to counsel. Huge numbers of lives, careers, relationships, emotional well beings are therefore lost. We cannot expect the current system of rushed meeting with long other agendas with liver units who tend to present different staff at annual meetings to counsel the above. If each patient caller on the helpline feels a need for an average of 60 minutes to address the key questions, we	respond to the concerns regarding the number of undiagnosed cases of hepatitis B. The remit for PH43 exclusively includes the testing of hepatitis B and C, and therefore the management of hepatitis B, including the provision of education for people diagnosed, is not covered by this guideline. However, NICE has produced related guidance on the diagnosis and management of hepatitis B (CG165), which includes recommendations on the provision of information. A number of the individual areas raised, including information on diet, family planning and prognosis are included in recommendation 1.1.1 in CG165. The 2017 surveillance review of CG165 did not identify any new evidence related to this area, and therefore, no impact on this recommendation was anticipated. The remit provided by the Department of Health to NICE for the development of PH43 refers to an at risk population. Through a search for relevant evidence as well as topic expert correspondence, no evidence was identified which addressed how many children in the UK are infected with chronic hepatitis B and C (research recommendation 5.9). As no evidence has been identified to address this area, there is no indication that the groups defined as 'at increased risk' should be altered. Therefore, the 'at increased risk' population determined during guideline development is unlikely to be impacted to include children at this time. The concern raised regarding a lack of equipment and commissioning guides for testing the black and ethnic minority population is an issue with the implementation of the recommendations in PH43 and is not likely to be able to be addressed by an update of this guideline. In addition, there is an implementation aid which can be found in the tools and resources section of the guideline, which aims to provide information about overcoming 3 main barriers to hepatitis B and C testing. Recommendation 3 aims to provide recommendations to develop the knowledge and skills of healthcare professionals and others providing services for people at increased risk of hepatitis B or C infection. This includes ensuring that an education programme is provided for clinical staff in primary care (such as GPs). Therefore, the concern raised regarding a lack of educational materials for GPs

		need to budget £100 per patient for counselling alongside diagnosis. This can avoid the 80% depression/confusion we noticed with our last 1000 patient audit. **We are failing at child care....** To date our HBV testing has failed to diagnose those at greatest risk of catching incurable HBV ...our children. Having left 2 generations of children to catch HBV en masse from their endemic communities, we have rolled HBV vaccination without explaining that the children are testing in Sentinel Surveillence far more infected than anywhere else in the developed world since 2000.... Sentinel has noted 0.6% to 0.4% levels. With so few children able to access testing or diagnosis, we need to think that these numbers could be pointing to an actual prevalence level.. How can we roll hbv universal vaccination and yet fail to find the 35,000 children infected chronically in our midst. Ultimately we have heard over and over from families with infected children, have talked to experts who point out that maternity testing simply delays rather than stops endemic communities infecting their children, yet we are missing both the opportunity to alongside universal vaccination upgrade our catch up vaccinations to the lost generation and the crucial testing this generation deserve. **Current Testing is skewed to acute not chronic patients** Our testing for HBV is fundamentally dead in the water. It is so poor it has not been able to note 20 years of 2 to 3% positive migrants boom the national level. How on earth can we not improve this most broken area of UK healthcare? There are no equipments or commissioning guides at CCG level to mass screen our BME communities, there are no educational materials for GP's. To date our testing for HBV is entirely accidental (at maternity mainly) or after (liver disease emerges). To date instead of focussing on the reality that 1 in 4 humans caught HBV we are seeing the problem as belonging to rare and disadvantaged groups....the homeless.....the drug user.....the gay community.....yet 1 in 4 humans need a test globally and some 1 in 4 of our children are now from high risk communities. This reality has been totally overlooked in our test planning and we are about to rubber stamp years more of the same. Acute reports CANNOT be allowed to dictate who to test.	is an implementation issue which is unlikely to be able to be addressed by an update of this guideline.
Imperial College Healthcare NHS Trust	No	Area for consideration: In addition to existing initiatives for opportunistic testing, we believe that the Emergency Department (ED) could provide a useful healthcare setting for hepatitis B (HBV) and C (HCV) screening.	Thank you for your comment. As part of this surveillance review, a search for all study types conducted in the UK relevant to PH43 was conducted. No evidence was identified regarding the effectiveness of

			testing for hepatitis B or C in emergency departments. Therefore, it is not likely that there would be any impact in this area at this time and no update is proposed. We will monitor ongoing research by Public Health England, as well as outputs from Gilead funded projects on hepatitis B and C testing, and consider their impact on recommendations following publication. It is appreciated that this is an important area for consideration, therefore, this will be recorded as an area for specific evaluation at the next surveillance time point, when any new evidence will be considered alongside the concerns raised during consultation.
British Association for Sexual Health and HIV	No	We would like the review team to consider the benefits of testing for hepatitis B virus (HBV) and hepatitis C virus (HCV) in other secondary care settings, in particular Emergency Departments (EDs) in higher prevalence areas.	Thank you for your comment. As part of this surveillance review, a search for all study types published in the UK relevant to PH43 was conducted. No evidence was identified regarding the effectiveness of testing for hepatitis B or C in emergency departments. Therefore, it is not likely that there would be any impact in this area at this time and no update is proposed. We will monitor ongoing research by Public Health England, as well as outputs from Gilead funded projects on hepatitis B and C testing, and consider their impact on recommendations following publication. It is appreciated that this is an important area for consideration, therefore, this will be recorded as an area for specific evaluation at the next surveillance time point, when any new evidence will be considered alongside the concerns raised during consultation.
Guys and St. Thomas' NHSFT	No	Please see below: Healthcare setting	Thank you for your response.
Public Health England	Yes	Public Health England (PHE) does agree overall with the proposal not to update the guideline. However, it is clear that the viral hepatitis landscape is changing rapidly and that there are a number of studies in the pipeline, some of which will produce results that will be available in the next 18 months that will provide sufficient impetus and evidence to update the current guidance in the next two years. This will include studies from the National Institute for Health Research (NIHR) Health Protection Research Unit in Blood Borne Infections looking at reducing the burden of under-diagnosis of hepatitis C and improving the diagnosis and management of those with hepatitis B and C infection.	Thank you for your comment. It is recognised that there is research activity in the area of hepatitis B and C testing. Any relevant ongoing trials which were identified during the surveillance review will be monitored, with the results evaluated for potential impact on the guideline upon publication.

		NIHR PRP studies on increasing case finding in primary care and drug agencies. Also further studies in the pipeline include a number of Gilead Fellowships on hepatitis B and C testing in Accident and Emergency departments, hepatitis C antenatal testing and non-hospital based settings such as prisons, and prevalence studies in United Kingdom Armed Forces personnel.	

Do you have any comments on areas excluded from the scope of the guideline?

Stakeholder	Overall response	Comments	NICE response
Brighton and Sussex University Hospital	No answers	No comments provided	Thank you for your response.
British Society Of Gastroenterology	Yes	While the bsg supports the proposal not to update the guideline we would like to note the potential shortfall in implementation. Recent data gathered for the lancet commission 2017, the phe annual report on hepatitis c and the atlas of variation for liver disease, all suggest there is still the need for improvements in the identification of individuals at risk and deliverting effective programmes for screening and diagnosis. Public health england has committeed to the who global strategy for the elimination of hepatitis b and c as public health threats by 2030 and some significant upscaling of screening and diagnosis is going to be necessary to achieve this. We would strongly recommend that the guideline comes with a strong recommendation to local authorities, public health bodies, primary care, the prison system and other relevant organisations TO IMPROVE IMPLEMENTATION OF THE GUIDELINE.	Thank you for your comment. It is acknowledged that there is an issue regarding the implementation of the recommendations in PH43 and this information will be communicated with the NICE implementation team. However, as this concern is not likely to be able to be addressed through an update of the guideline, this information is not anticipated to have an impact on PH43. In addition, there is an implementation aid which can be found in the tools and resources section of the guideline, which aims to provide information about overcoming 3 main barriers to hepatitis B and C testing.
Hepatitis B Foundation Trust	Yes	The UK is still alone in failing to border test our 2 to 3% positive migrants (this needs to be done after granting status as care not as an exclusion process) and ignoring child catch up vaccinations. (they are catching HBV in their endemic communities as we have stopped them getting their WHO ordained protection for 18 years)	Thank you for your comment. The recommendations in PH43 aim to increase hepatitis B and C testing in high risk groups, which includes 'people born or brought up in a country with an intermediate or high prevalence of chronic hepatitis B', as detailed in the 'Whose health will benefit?' section of the guideline. In particular, recommendation 4 promotes offering tests for hepatitis B and C to adults and children who are within this population group, as part of the healthcare received in primary care.

			It is outside the remit provided to NICE for the development of this guideline on hepatitis B and C testing to make recommendations concerning childhood hepatitis vaccinations, further than signposting to information provided by the Green book as in recommendation 9.
Imperial College Healthcare NHS Trust	Yes	**Suggested recommendation:** In light of emerging new evidence we would like to encourage a more systematic review of all existing and forthcoming literature related to ED HBV/HCV seroprevalence and blood borne virus (BBV) screening. Further exercises in measuring the ED BBV prevalence across a number of commissioning authorities may broaden the evidence-base and help to shape any future policy on testing in this setting. **Rationale:** Case finding remains a significant threat to achieving the WHO 2030 Hepatitis elimination goals in England. As highlighted by Public Health England (PHE) in their 2017 report on Hepatitis C in England, <50% of HCV positive individuals are aware of their status (1). HCV is commonly associated with past history of active intravenous drug use, whilst >95% of chronic HBV cases can be found in migrant communities (1, 2). Both represent marginalised and underserved populations who have poorer access to healthcare (3). In addition to increased case finding through the ED, diagnoses tend to be coincidental and thus increase the potential for early intervention and prevention of future complication and transmission. Finally, untargeted opt-out testing provides an opportunity address the stigma related to BBVs. **Supporting Evidence:** • *Lessons learnt from HIV testing* The NG60 guidelines highlight that offering testing in the ED setting is a potential resource for identifying undiagnosed cases. Thus, measuring the potential benefit of similar initiatives for HBV and HCV could potentially be of use (4). • *Overview of emerging ED BBV seroprevalence data; ENABLE projects: Multicentre Urban ED unlinked BBV seroprevalence (in process for submission to International European Liver Congress)* ○ In partnership with Public Health England, we conducted a multicentre unlinked anonymous BBV seroprevalence survey. Between May and July 2017 6,000 (4x1,500) residual serum samples from unique patients aged 16-65 years sent for routine biochemistry from the ED at Imperial College NHS Trust (ICHNT) (Charing Cross and St Mary's Hospital), Blackpool, Fylde and Wyre Hospitals NHS Foundation Trust (BFWH) and the Royal Liverpool and Broadgreen University NHS Trust (RLBUNT). Prior	Thank you for your comments. PH43 aims to provide recommendations for the population most at risk of Hepatitis B and C infection. As described in the 'Whose health will benefit? section of the guideline, groups at increased risk (and therefore within the target population for this guideline) include 'people who have ever injected drugs' and 'people born or brought up in a country with an intermediate or high prevalence of chronic hepatitis B/C'. The recommendations made in PH43 aim to increase the testing rate in these populations. While the evidence highlighted indicates there is research activity concerning the measurement of prevalence rates in emergency departments, the following studies have not been considered in the summary of new evidence (Appendix A) for consideration of impact on the guideline, for the reasons described: • England PH. Hepatitis C in England 2017 report. 2017. – *excluded as this is not a relevant study type (not an intervention based effectiveness study)* • Hahne S, Ramsay M, Bolagun K, Edmunds WJ, Mortimer P. Incidence and routes of transmission of hepatitis B virus in England and Wales, 1995-2000: implications for immunization policy. Journal of clinical virology: the official publication of the Pan American Society for Clinical Virology. 2004; 29(4):211-20 - *excluded as this is not a relevant study type (not an intervention based effectiveness study)* • NG60 HIV testing: increasing uptake among people who may have undiagnosed HIV – *related NICE guidance has been evaluated during the surveillance review (including NG60) to evaluate for example if cross referrals are necessary, however, other guidance is not discussed within the summary of new evidence.*

to unlinking and testing, demographic details were recorded and records of previous BBV diagnosis were checked against local laboratory IT systems. Preliminary analysis (Table 1): at the two London sites (n=3,000) combined, the overall prevalence of BBVs was 3.5% (HBV; 1.5%, HCV RNA; 0.8%, HIV; 1.2%). In comparison the seroprevalence for BFNT 1.07% (HBV; 0.47%, HCV; 0.47%, HIV 0.13%) and 3.16% (HBV; 0.4%, HCV RNA; 2.7%, HIV; 0.06%) at RLBUNT.Local BBV prevalence varied widely, although London results are in line with a recent HCV only seroprevalence study of adult ED attendees in East London, which found a HCV seroprevalence of 2·6% (26/997) with 1·2% (12/997) HCV RNA positive (5).

Pilot practical application of BBV testing and linkage to care in urban ED settings

- O'Connell et al have demonstrated that >50% uptake of opt-out BBV testing in an urban ED in Dublin was feasible. This study reported an overall BBV prevalence of 6.63% (HBV; 0.49%, HCV 5.05%, HIV 1.09%) (6).
- During the "Going Viral" campaign (13-19 October 2014), nine UK EDs in areas of high HIV prevalence offered routine tests for HIV, HBV and HCV to adults having blood taken as part of routine care. Results: A total of 7807 patients had blood taken during their ED visit; of these, 2118 (27%) were tested for BBVs (range 9-65%). Seventy-one BBV tests were positive (3.4%) with 32 (45.1%) new diagnoses. There were 39 HCV infections (15 newly diagnosed), 17 HIV infections (six newly diagnosed), and 15 HBV infections (11 newly diagnosed). Those aged 25-54 years had the highest prevalence: 2.46% for HCV, 1.36% for HIV and 1.09% for HBV (7).
- The VirA+EmiC study (combining ED opt-out testing and linkage to care for HBV and HCV) at St Thomas' Hospital, found similar seroprevalence through opt-out testing (74% uptake) and highlights that linkage to care among contactable newly diagnosed patients with active HCV is good (71%) (8).

Table 1. Summary of preliminary BBV seroprevalence from ENABLE sites

	ICHNT (n=2x1,500)	**RLUHT (n=1,598)**	**BFWH (n= 1,499)**
Active BBV	**3.5%**	**3.19%**	**1.07%**
HIV	1.2%	0.06%	0.47%
HBV	1.5%	0.44%	0.13%
HCV RNA	0.8%	2.69%	0.47%

- Orkin C, Leach E, Flanagan S, Wallis E, Ruf M, Foster GR, et al. High prevalence of hepatitis C (HCV) in the emergency department (ED) of a London based hospital: should we be screening for HCV in ED attendees? Epidemiology and infection. 2015; 143(13):2837-40 - *excluded as this is not a relevant study type (not an intervention based effectiveness study)*
- Orkin C, Flanagan S, Wallis E, Ireland G, Dhairyawan R, Fox J, et al. Incorporating HIV/hepatitis B virus/hepatitis C virus combined testing into routine blood tests in nine UK Emergency Departments: the "Going Viral" campaign. HIV medicine. 2016;17(3):222-30 – *excluded as the outcome of interest (hepatitis B and/or C testing rate) cannot be ascertained individually from the abstract (uptake rates include HIV testing also, which is not relevant to this guideline). This study also does not provide comparative evidence of effectiveness for emergency department hepatitis testing.*
- O'Connell S, Lillis D, Cotter A, O'Dea S, Tuite H, Fleming C, et al. Opt-Out Panel Testing for HIV, Hepatitis B and Hepatitis C in an Urban Emergency Department: A Pilot Study. PLoS One. 2016;11(3):e0150546. - *excluded as this is a feasibility study, also measuring prevalence rates. This study does not provide comparative evidence of effectiveness for emergency department hepatitis testing.*
- VirA+Emic G. To be presented at AASLD (20th Oct 2017) and ESCAIDE (4th Nov 2017). 2017. – *excluded as not a relevant study type (conference abstract)*

The following evidence has been included in the summary of new evidence (Appendix A) as it describes the barriers and enablers to hepatitis B testing in a relevant high risk population:

Vedio A, Liu EZH, Lee ACK, Salway S. Improving access to health care for chronic hepatitis B among migrant Chinese populations: A systematic mixed methods review of barriers and enablers. J Viral Hepat. 2017;24(7):526-40.

			No relevant effectiveness evidence was identified regarding the testing for hepatitis B or C in emergency departments. Therefore, it is not likely that there would be any impact in this area at this time and no update is proposed. However, it is appreciated that this is an important area for consideration. As highlighted, NICE guidance on HIV testing (NG60) recommends that tests for HIV are offered to at risk groups in emergency departments. However, this recommendation was based on evidence of effectiveness for this intervention for the specific outcome of HIV testing rates. Similar evidence of effectiveness for hepatitis B or C testing in emergency departments has not been identified and therefore an impact on the guideline is not likely at this time. We will monitor ongoing research by Public Health England, as well as outputs from Gilead funded projects on hepatitis B and C testing, and consider their impact on recommendations following publication. It is appreciated that this is an important area for consideration, therefore, this will be recorded as an area for specific evaluation at the next surveillance time point, when any new evidence will be considered alongside the concerns raised during consultation.
British Association for Sexual Health and HIV	Yes	An unlinked anonymised seroprevalence study showed HCV RNA prevalence of 1.2% in 997 samples in an East London Emergency Department[1]. In addition, prospective opt-out testing for HIV, HBV and HCV in 9 EDs for one week across the UK identified 71/2118 (3.4%) positive HIV or HBV or HCV tests, both new and currently unlinked diagnoses[2]. Testing alone for HIV would have missed 54 HBV or HCV diagnoses (26 new)[2]. For the central London hospital EDs, the HBV (0.79%) and HCV (1.77%) rates were similar to those of the whole cohort. Emergency Departments in inner city Glasgow and in London's Whitechapel had the highest HCV prevalences of 3% (1.67% new diagnoses) and 3.13% (0.63% new diagnoses), respectively. Lambeth ED in South London had the highest prevalence of HBV (1.33%; all new diagnoses) and the HCV prevalence was 1.33% (0.5% new diagnoses). The lowest prevalence was in a hospital in outer London (Essex) with the lowest testing uptake of 9%, where no BBV diagnoses were found in 90 tests[2]. These studies suggest that opt-out screening for HBV and HCV in emergency departments should be offered to patients in areas of known high seroprevalence, rather than solely to those patients deemed to be in a high-risk group.	Thank you for your comments. As part of this surveillance review, a search for all study types published in the UK relevant to PH43 was conducted. No relevant evidence was identified regarding the effectiveness of testing for hepatitis B or C in emergency departments. While the evidence highlighted indicates there is research activity in this area concerning the measurement of prevalence rates, the highlighted studies have not been considered in the summary of new evidence (Appendix A) for consideration of impact on the guideline, for the reasons described: • Orkin C, Leach E, Flanagan S, Wallis E, Ruf M, Foster GR, et al. High prevalence of hepatitis C (HCV) in the emergency department (ED) of a London based hospital: should we be screening for HCV in ED attendees? Epidemiology and infection. 2015; 143(13):2837-40 - *excluded as this is not a*

		Further study of UK Emergency Department screening for Blood borne viruses (BBV) over a twelve month period is currently is in peer review and due to be published soon. We hope these comments will be of use and would be happy to consider any further queries if they should arise. **References:** 1. High prevalence of hepatitis C (HCV) in the emergency department (ED) of a London hospital: should we be screening for HCV in ED attendees? Orkin et al Epidemiol Infect. 2015 Oct;143(13):2837-40. 2. Incorporating HIV/hepatitis B virus/hepatitis C virus combined testing into routine blood tests in nine UK Emergency Departments: the "Going Viral" campaign. Orkin et al HIV Med. 2016 Mar;17(3):222-30.	*relevant study type (not an intervention based effectiveness study).* • Orkin C, Flanagan S, Wallis E, Ireland G, Dhairyawan R, Fox J, et al. Incorporating HIV/hepatitis B virus/hepatitis C virus combined testing into routine blood tests in nine UK Emergency Departments: the "Going Viral" campaign. HIV medicine. 2016;17(3):222-30 - *excluded as the outcome of interest (hepatitis B and/or C testing rate) cannot be ascertained individually from the abstract (uptake rates include HIV testing also, which is not relevant to this guideline). This study also does not provide comparative evidence of effectiveness for emergency department hepatitis testing.* No new evidence specifically regarding the effectiveness of hepatitis B or C testing in emergency departments has been identified. Therefore, it is not likely that there would be any impact in this area at this time and no update is proposed. We will monitor ongoing research by Public Health England, as well as outputs from Gilead funded projects on hepatitis B and C testing, and consider their impact on recommendations following publication. It is appreciated that this is an important area for consideration, therefore, this will be recorded as an area for specific evaluation at the next surveillance time point, when any new evidence will be considered alongside the concerns raised during consultation.
Guys and St. Thomas' NHSFT	Yes	Healthcare settings considered for HBV and HCV testing in the current guideline include primary care, prisons, immigration removal centres, sexual health and GUM clinics. **Recommendation:** We argue that in light of emerging, rapidly evolving evidence from multiple seroprevalence and opt-out testing projects in various stages of publication, HBV/HCV or BBV opt-out testing in urban accident and emergency departments (A&E) serving deprived populations, similar to NICE guidance on HIV testing (1) should be considered for systematic review. **Rationale:** • There is increasing evidence in various stages of publication on both significant population level HBV/HCV prevalence in urban	Thank you for your comment. As part of this surveillance review, a search for all study types conducted in the UK relevant to PH43 was conducted. No relevant evidence regarding the effectiveness of hepatitis B and C testing in emergency departments was identified. However, it is appreciated that this is an active research area, as highlighted by the references provided. All evidence highlighted was considered for inclusion in the summary of new evidence (Appendix A), however, the following references were not included and considered further for their impact on the guideline, for the reasons described: • NG60 HIV testing: increasing uptake among people who may have undiagnosed HIV – *related NICE guidance has been*

		A&E settings and feasibility, acceptability and effectiveness of offering universal opt-out testing to adult A&E attendees. (2-5) • PHE sentinel surveillance data suggests that there is currently only very limited HBV/HCV testing in A&E(6). • In absence of testing guidance for A&E, risk based testing only appears to be undertaken, as shown by the very limited numbers of tests reported through PHE sentinel surveillance. As screening positivity in this setting is not dissimilar from that reported in universal seroprevalence surveys and opt-out- testing projects, a risk based approach is clearly a missed opportunity **VirA+EmiC project** • St Thomas Hospital has successfully implemented sustainable HIV A&E opt-out testing programme since July 2015.(7) • The VirA+EmiC project aims to evaluate universal adult HBV/HCV opt-out testing in A&E combined with enhanced linkage to care). The interim results of this ongoing study will be presented late October at the annual conference of the American Association for Study of the Liver (AASLD) and early November at European Scientific Conference of Applied Infectious Disease Epidemiology (ESCAIDE). Additionally there will be a formal cost-effectiveness analysis carried out by the University of Bristol/London School of Hygiene. • **Interim results** (to date largest UK dataset**)**: in phase 1 we were able to conduct 11,465 HBV/HCV tests in unique adult attendees having blood tests in 4 months between mid-October 2016 to mid-February 2017) at 74% test uptake. Prevalence of HCV Ab: 2.38% of which HCV cAg: 1.55% and HBsAg: 0.5%. 81%. 67% of diagnosed HCV patients were not contactable (either missing or incorrect phone or address details). However 81% (38/47) of contactable patients with active HCV required linkage to care (defined as new or not in care) with 71% being successfully linked to care. • **Conclusion**: The VirA+EmiC project demonstrated: 1. Universal HBV/HCV opt out testing in A&E is effective in diagnosing a high number of active viral hepatitis diagnoses that require linkage to care. The project also highlights relevant deficits in pathways integrating community and specialists clinics in linking identified patients References 1. https://www.nice.org.uk/guidance/ng60	*evaluated during the surveillance review (including NG60) to evaluate for example if cross referrals are necessary, however, other guidance is not discussed within the summary of new evidence.* • The feasibility of blood borne virus testing in inner city emergency departments; L. Cieply, S. Ijaz, E. Kara, A. et al.; Journal of Hepatology 2016 vol. 64 | S183–S212. PS140. Barcelona, Spain – *excluded as not a relevant study type (conference abstract)* • High prevalence of hepatitis C (HCV) in the emergency department (ED) of a London hospital: should we be screening for HCV in ED attendees? Orkin C, Leach E, Flanagan S, et al. Epidemiol Infect. 2015 Oct;143(13):2837-40. - *excluded as this is not a relevant study type (not an intervention based effectiveness study)* • Incorporating HIV/hepatitis B virus/hepatitis C virus combined testing into routine blood tests in nine UK Emergency Departments: the "Going Viral" campaign. Orkin C, Flanagan S, Wallis E, et al HIV Med. 2016 Mar;17(3):222-30. - *excluded as the outcome of interest (hepatitis B and/or C testing rate) cannot be ascertained individually from the abstract (uptake rates include HIV testing also, which is not relevant to this guideline). This study also does not provide comparative evidence of effectiveness for emergency department hepatitis testing.* • Routine blood borne virus testing for HIV, hepatitis B and hepatitis C in the emergency department: the 'new normal'? Parry, S Ullah, G Foster, et al HIV Medicine, 2017 Volume 18, Issue Supplement S1 - *excluded as not a relevant study type (conference abstract)* • https://www.gov.uk/government/publications/sentinel-surveillance-of-blood-borne-virus-testing-in-england-2015 - *excluded as this is not a relevant study type (not an intervention based effectiveness study)* • Reducing the barriers to HIV testing – a simplified consent pathway increases the uptake of HIV testing in a high-prevalence population; Paparello J, Hunter L, Betourney R, et al; HIV Medicine 2016, Volume 17, Issue Supplement S1 -

		2. The feasibility of blood borne virus testing in inner city emergency departments; L. Cieply, S. Ijaz, E. Kara, A. et al.; Journal of Hepatology 2016 vol. 64 | S183–S212. PS140. Barcelona, Spain 3. High prevalence of hepatitis C (HCV) in the emergency department (ED) of a London hospital: should we be screening for HCV in ED attendees? Orkin C, Leach E, Flanagan S, et al. Epidemiol Infect. 2015 Oct;143(13):2837-40. 4. Incorporating HIV/hepatitis B virus/hepatitis C virus combined testing into routine blood tests in nine UK Emergency Departments: the "Going Viral" campaign. Orkin C, Flanagan S, Wallis E, et al HIV Med. 2016 Mar;17(3):222-30. 5. Routine blood borne virus testing for HIV, hepatitis B and hepatitis C in the emergency department: the 'new normal'? Parry, S Ullah, G Foster, et al ; HIV Medicine, 2017 Volume 18, Issue Supplement S1 6. https://www.gov.uk/government/publications/sentinel-surveillance-of-blood-borne-virus-testing-in-england-2015 7. Reducing the barriers to HIV testing – a simplified consent pathway increases the uptake of HIV testing in a high-prevalence population; Paparello J, Hunter L, Betourney R, et al; HIV Medicine 2016, Volume 17, Issue Supplement S1	*excluded as this is not a relevant intervention (intervention to increase HIV testing, not hepatitis B or C)* While it is currently anticipated that the evidence available would not have an impact on the guideline, it is appreciated that this is an important area for consideration. As highlighted, NICE guidance on HIV testing (NG60) recommends that tests for HIV are offered to at risk groups in emergency departments. However, this recommendation was based on evidence of effectiveness for this intervention for the specific outcome of HIV testing rates. Similar evidence of effectiveness for hepatitis B or C testing has not been identified and therefore an impact on the guideline is not likely at this time. Projects funded by Gilead on testing for hepatitis B and C will be monitored, as well as research by Public Health England in this area. This will also be recorded as an area for specific evaluation at the next surveillance time point, when any new evidence will be considered alongside the concerns raised during consultation. NICE monitors relevant ongoing trials that are identified through surveillance, in order to assess the impact new evidence may have on relevant guidance when it is published. However, details of the VirA+EmiC project could not be identified, and therefore this specific study will not be possible to monitor. As results have not yet been published for this project, this does not provide a prompt to update the guideline at this time.
Public Health England	Yes	There are issues around the cost effectiveness of hepatitis C antenatal testing; PHE would like to understand if these will be considered as part of the updated testing guidance.	Thank you for your comment. Through a search for relevant evidence, including cost effectiveness studies, no new evidence was identified regarding hepatitis C antenatal testing. It is also beyond the remit of NICE to make recommendations on population level screening programmes, including antenatal testing. Therefore, it is not anticipated that there would be an impact in this area at this time, and an update is not proposed.

Do you have any comments on equalities issues?

Stakeholder	Overall response	Comments	NICE response
Brighton and Sussex University Hospital	No answers	No comments provided	Thank you for your response.

British Society Of Gastroenterology	No	No comments provided	Thank you for your response.
Hepatitis B Foundation Trust	Yes	**Children and BME** communities are being disproportionately left to die. Without best practice as advised by WHO for 30 years, namely border testing and child vaccinating	Thank you for your comment. It is outside the remit provided to NICE for the development of this guideline on hepatitis B and C testing to make recommendations concerning childhood hepatitis vaccinations. Recommendations are made in PH43 which aim to increase the rate of testing in people born or brought up in a country with an intermediate of high prevalence of chronic hepatitis B and/or C. However, during this surveillance review, no new evidence has been identified regarding border testing as a specific intervention for this population. Therefore, there is unlikely to be an impact on the guideline at this time.
Imperial College Healthcare NHS Trust	Yes	As highlighted above, viral hepatitis disproportionately affects marginalised and disadvantaged communities, whose only interaction with the healthcare system may be through the local ED. We believe that ED based testing initiatives will enhance the interaction between the healthcare services and otherwise difficult to engage populations. **REFERENCES** 1. England PH. Hepatits C in England 2017 report. 2017. 2. Hahne S, Ramsay M, Balogun K, Edmunds WJ, Mortimer P. Incidence and routes of transmission of hepatitis B virus in England and Wales, 1995-2000: implications for immunisation policy. Journal of clinical virology : the official publication of the Pan American Society for Clinical Virology. 2004;29(4):211-20. 3. Vedio A, Liu EZH, Lee ACK, Salway S. Improving access to health care for chronic hepatitis B among migrant Chinese populations: A systematic mixed methods review of barriers and enablers. J Viral Hepat. 2017;24(7):526-40. 4. (NG60) N. HIV testing: increasing uptake among people who may have undiagnosed HIV 2016 [Available from: https://www.nice.org.uk/guidance/ng60. 5. Orkin C, Leach E, Flanagan S, Wallis E, Ruf M, Foster GR, et al. High prevalence of hepatitis C (HCV) in the emergency department (ED) of a London hospital: should we be screening for HCV in ED attendees? Epidemiology and infection. 2015;143(13):2837-40.	Thank you for your comment. PH43 aims to provide recommendations for increasing the hepatitis B and C testing rates in the groups at high risk of infection, as outlined in the 'Whose health will benefit?' section of the guideline. As part of this surveillance review, a search for all study types conducted in the UK relevant to PH43 was conducted. No evidence was identified regarding the effectiveness of testing for hepatitis B or C in emergency departments. Therefore, it is not likely that there would be any impact in this area and no update is proposed. While the evidence highlighted indicates there is research activity in measuring the hepatitis B and C test rates in emergency departments, the following studies have not been considered in the summary of new evidence (Appendix A) for consideration of impact on the guideline, for the reasons described: • England PH. Hepatitis C in England 2017 report. 2017. – *excluded as this is not a relevant study type (not an intervention based effectiveness study)* • Hahne S, Ramsay M, Bolagun K, Edmunds WJ, Mortimer P. Incidence and routes of transmission of hepatitis B virus in England and Wales, 1995-2000: implications for immunization policy. Journal of clinical virology: the official publication of the Pan American Society for Clinical Virology.

		6. O'Connell S, Lillis D, Cotter A, O'Dea S, Tuite H, Fleming C, et al. Opt-Out Panel Testing for HIV, Hepatitis B and Hepatitis C in an Urban Emergency Department: A Pilot Study. PLoS One. 2016;11(3):e0150546. 7. Orkin C, Flanagan S, Wallis E, Ireland G, Dhairyawan R, Fox J, et al. Incorporating HIV/hepatitis B virus/hepatitis C virus combined testing into routine blood tests in nine UK Emergency Departments: the "Going Viral" campaign. HIV medicine. 2016;17(3):222-30. 8. VirA+Emic G. To be presented at AASLD (20th Oct 2017) and ESCAIDE (4th Nov 2017). 2017.	2004; 29(4):211-20 - *excluded as this is not a relevant study type (not an intervention based effectiveness study)* • NG60 HIV testing: increasing uptake among people who may have undiagnosed HIV – *related NICE guidance has been evaluated during the surveillance review (including NG60) to evaluate for example if cross referrals are necessary, however, other guidance is not discussed within the summary of new evidence.* • Orkin C, Leach E, Flanagan S, Wallis E, Ruf M, Foster GR, et al. High prevalence of hepatitis C (HCV) in the emergency department (ED) of a London based hospital: should we be screening for HCV in ED attendees? Epidemiology and infection. 2015; 143(13):2837-40 - *excluded as this is not a relevant study type (not an intervention based effectiveness study)* • Orkin C, Flanagan S, Wallis E, Ireland G, Dhairyawan R, Fox J, et al. Incorporating HIV/hepatitis B virus/hepatitis C virus combined testing into routine blood tests in nine UK Emergency Departments: the "Going Viral" campaign. HIV medicine. 2016;17(3):222-30 – *excluded as the outcome of interest (hepatitis B and/or C testing rate) cannot be ascertained individually from the abstract (uptake rates include HIV testing also, which is not relevant to this guideline). This study also does not provide comparative evidence of effectiveness for emergency department hepatitis testing.* • O'Connell S, Lillis D, Cotter A, O'Dea S, Tuite H, Fleming C, et al. Opt-Out Panel Testing for HIV, Hepatitis B and Hepatitis C in an Urban Emergency Department: A Pilot Study. PLoS One. 2016;11(3):e0150546. - *excluded as this is a feasibility study, also measuring prevalence rates. This study does not provide comparative evidence of effectiveness for emergency department hepatitis testing.* • VirA+Emic G. To be presented at AASLD (20th Oct 2017) and ESCAIDE (4th Nov 2017). 2017. – *excluded as not a relevant study type (conference abstract)*

			The following evidence has been included in the summary of new evidence (Appendix A) as it describes the barriers and enablers to hepatitis B testing in a relevant high risk population: Vedio A, Liu EZH, Lee ACK, Salway S. Improving access to health care for chronic hepatitis B among migrant Chinese populations: A systematic mixed methods review of barriers and enablers. J Viral Hepat. 2017;24(7):526-40. It is appreciated that testing for hepatitis B and C in emergency departments is an important area for consideration. We will monitor ongoing research by Public Health England, as well as outputs from Gilead funded projects in this area, and consider their impact on recommendations following publication. This will be recorded as an area for specific evaluation at the next surveillance time point, when any new evidence will be considered alongside the concerns raised during consultation.
British Association for Sexual Health and HIV	No	No comments provided	Thank you for your response.
Guys and St. Thomas' NHSFT	No answers	No comments provided	Thank you for your response.
Public Health England	Yes	The Equality Act 2010 requires considering whether there is any disproportionate negative impact on specific groups with protected characteristics when making decisions. As long as this is taken into consideration in the final proposal, this will ensure the equality issues are addressed and mitigated against.	Thank you for your comment. NICE considers any potential impact on equalities as part of the surveillance decision. PH43 aims to increase hepatitis B and C testing rates in groups with a high risk of infection, which includes a number of groups with protected characteristics. The recommendations are based on the best available evidence to ensure that the interventions described are effective and cost-effective, as well as consideration of the impact on reducing inequalities. As no new evidence has been identified that is likely to impact the guideline at this point, the current recommendations are likely to represent the most effective interventions available for increasing the testing rates in the population targeted.

COMMENTS:

The RCP would like to endorse the response submitted by the British Society of Gastroenterology (BSG).

The Royal College of Nursing have no comments to submit to inform on the PH43 surveillance review at this time.