NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1 Quality standard title

Hepatitis B

Date of Quality Standards Advisory Committee post-consultation meeting:
1 May 2014

2 Introduction

The draft quality standard for hepatitis B was made available on the NICE website for a 4-week public consultation period between 10 March and 7 April 2014. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 21 organisations, which included service providers, national organisations, professional bodies and others.

This report provides the Quality Standards Advisory Committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the Committee as part of the final meeting where the Committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the Committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include overarching outcomes, thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the Committee should read this summary alongside the full set of consultation comments, which are provided in appendix 1.

3 Questions for consultation

Stakeholders were invited to respond to the following general questions:

1. Does this draft quality standard accurately reflect the key areas for quality improvement?

2. If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?

Stakeholders were also invited to respond to the following statement specific questions:

For draft quality statement 5: For this statement on ‘Monitoring people who do not meet the criteria for hepatitis B antiviral treatment’ – are there any specific groups to prioritise for quality improvement, i.e. are there any groups who are not currently monitored?

4 General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

- Overall the quality standard was supported for its approach and the practice it promotes in regards to the standards of care including testing, management and

prevention of hepatitis B infection which will lead to clearly visible auditable goals in improving care.

- Stakeholders queried what is meant by those who ‘test positive’ and requested a clear definition.
- Stakeholders requested inclusion of hepatitis C testing and monitoring.
- Stakeholders requested inclusion of HIV testing in people who test positive for hepatitis B.
- Stakeholders made suggestions for amending the introductory paragraph to make clear that most of the UK acquired infections have been acquired through sexual transmission.
- A stakeholder highlighted that the quality standard needs to acknowledge the resources and workforce competencies/ expertise required to deliver these statements.

Consultation comments on data collection

- Data are already collected on vaccine uptake in men who have sex with men (MUM) and other GUM clinic attendees (in GUMCAD), as well as among people who inject drugs (NDTMS) so the structures and systems are in place for data collection for these quality measures.
- For statement 4, a stakeholder reported that data systems and structures are in place to collect data but there are data quality issues which have meant that some areas do not submit data or submit data with questionable accuracy.
- A stakeholder highlighted that robust commissioning arrangements will be needed to put in place the systems and structures to allow accurate data collection for the proposed quality measures.
- A stakeholder highlighted that vaccination is not captured in data collection. This was recommended as a useful dataset as it would help to understand the impact of targeting high risk groups for vaccination on infection rates.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

People who are at increased risk of infection are offered testing for hepatitis B.

Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

- Stakeholders responded that the role of vaccination is not clear in relation to this statement on testing.
- Some suggestion for the addition of a new measure or expansion of the statement to include offer of vaccination to
  - (i) high risk groups being tested for hepatitis B
  - (ii) people who test negative for hepatitis B
- Some concern that the statement does not include HIV testing of those with acute or chronic hepatitis B.
- Some suggestion for expanding the list of high risk groups. These include:
  - those who travel abroad who are classified as medium to high risk if not vaccinated
  - those who travel or have lived in intermediate or high prevalence areas
  - unaccompanied and trafficked children
  - foster carers
  - adoptive parents
- Inclusion of Dried Blood Spot Testing (DBSTs).
- Suggestion to amend statement to read 'people at increased risk of hepatitis B infection are offered testing' rather than just 'people at risk of infection'.
- Query raised whether testing strategies for hepatitis B should include termination of pregnancy services?
- Immigration detainees who are found to be HBsAg negative and at increased risk of hepatitis B should be allowed to complete the three doses of hepatitis B vaccine before deportation.

- Further definition is needed on ‘anyone who has had unprotected sex’ as this covers the majority of adult population and also ‘multiple sexual partners’.
- Suggestion that community pharmacies should be included as one of the settings where hepatitis B testing services can be offered.
- Inclusion of screening for looked after older children and young people in the list of people at increased risk of hepatitis B
- Suggestion to expand this statement to include ‘in those at continued risk this [testing] should be repeated at least annually’
- Suggestions to expand structure measures and audience descriptors

5.2 Draft statement 2

People who test positive for hepatitis B infection are referred to specialist care for further assessment.

Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

- Request for inclusion of HIV testing in people who test positive for hepatitis B.
- Suggestion that newly identified cases sent for specialist care should also be initiated to contact tracing and offered vaccination. This would be in line with national policy.
- Suggestion that within the definitions section of specialist care, it should state ‘Infectious Diseases Specialists with an interest in viral hepatitis’ rather than ‘an interest in hepatology’.
- Suggestion to include the word 'paediatric' for 'children are referred to a paediatric hepatologist or to a **paediatric** gastroenterologist'
- Suggestion that immigration detainees who are diagnosed as HBSAg positive should be referred to a hepatologist or similar specialist and that they would be allowed to complete any treatment deemed necessary by that specialist before deportation.
- Request for clarity on the process of referral back to the GP or onwards to a specialist service where the user is found to be HBsAg positive.
- Clear definition required on what is meant by ‘test positive’- the assumption is antigen positive?

- Clarity on referral routes requested where user was found to be hepatitis B positive. For example, would service providers who provide testing services in GUM clinics and in the private sector need to refer back to GP for inward referral to a specialist?
- Suggestion to include hepatitis delta testing in all hepatitis B antigen positive individuals.
- Concern raised on not including reference to additional blood tests (as recommended in the NICE guideline) which could risk these tests being overlooked in primary care and which would need to be done later in the care pathway.

5.3 Draft statement 3

Pregnant women who are identified as being hepatitis B-positive at antenatal screening are assessed by a specialist within 6 weeks of receiving the screening test result.

Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

- Suggestion to expand statement to make it clear that the referral is to a liver specialist and not an obstetrician.
- Further clarification on the timeframe of ‘within 6 weeks of receiving the test result’ and when/where the clock starts.
- Concern raised concern on the term ‘specialist’ and whether women at ‘low risk’ (hep B infectivity) could be seen by an obstetrician and women at ‘high risk’ referred This stakeholder also queried whether 6 weeks may be too long for some women and whether the time to see a specialist would need to be altered to take into account pregnancy duration so that treatment can be as effective as possible.
- Suggestion that women in the ‘at risk’ group should not only be checked for hepatitis B infection at the ‘booking’ appointment but also during pregnancy and at delivery.
- Suggestion to include hepatitis delta testing in all hepatitis B antigen positive individuals.

- Suggestion to add ‘where presentation is in the 3rd trimester or at delivery referral advice should be sought urgently’.
- Suggestion to expand list of complex social needs to include learning difficulties, looked after teenagers and trafficked women.
- Concern raised that vertical transmission rates from mother to child as an outcome is unlikely to be estimable from local data collection as numbers are so small and the denominators are not clear. National data collection and review is required.

5.4 Draft statement 4

Babies born to mothers who have the hepatitis B infection receive a complete course of hepatitis B vaccination and a blood test for hepatitis B at 12 months.

Stakeholders made the following comments in relation to draft statement 4:

- Stakeholders made a number of suggestions to reword statement to read:
  - Babies born to mothers who have the hepatitis B infection receive a complete course of hepatitis B vaccination, followed by a blood test at 12 months for the detection of hepatitis B
  - Babies born to mothers who have the hepatitis B infection receive a complete course of hepatitis B vaccination and a blood test to check that they are not infected with hepatitis B and whether they have achieved good levels of immunity to the hepatitis B virus at 12 months.

Other suggestions to the wording of the statement include:

- adding text to cover those who don’t achieve good HBsAg levels or ‘vaccine failures’ who have become infected with hepatitis B.
- in addition to a complete vaccination course, the statement should state babies born to HBsAg+ mothers should receive first-dose of vaccine within 24hrs of birth as per national guidance
- the first vaccine dose is given at birth: ie “…are given the first dose promptly at birth and the recommended vaccination course is completed at the right time.”

- Suggestion to improve the definition of ‘complete course of hep B vaccination’ in line with Green Book recommendations.
- Suggestion that the blood test should occur in babies aged 14 months which then confirms vaccine response as well as testing for infection.
- Suggestions to improve structure measures to specify arrangements for the provider/commissioning immunisation lead to be informed at an early stage of the pregnant women’s hepatitis B status.
- Suggestions to improve process measure denominators and data source.
- Some concern raising about collecting data at local level because of small numbers.
- Suggestion that this statement could be broader to ensure that all individuals that require vaccination for Hepatitis B receive a full course and not just neonates. A complete vaccination course for those at risk individuals that test negative and those in close contact with hepatitis B positive individuals was also suggested.

5.5 Draft statement 5

People with chronic hepatitis B who do not meet the criteria for antiviral treatment are monitored regularly at intervals determined by infection status and age.

Stakeholders made the following comments in relation to draft statement 5:

- Suggestion to improve clarity on this statement’s intent in terms of how often should the individuals be tested and in which service this should happen?
- Suggestion to include ‘at least annually’
- Role of quantitative surface antigen testing?
- A stakeholder suggested to include socially disadvantaged groups with chronic hepatitis B i.e. those who are homeless or have chaotic lifestyles through substance misuse.

5.6 Draft statement 6

People with chronic hepatitis B, and their family members or carers (if appropriate), are offered a personalised care plan outlining the proposed treatment and long-term management of their hepatitis B.

Stakeholders made the following comments in relation to draft statement 6:

- Suggestion to improve rationale section.
- Suggestion that this statement should address the transition from children's to adult's services.

5.7 Draft statement 7

Adults with chronic hepatitis B with significant liver fibrosis or cirrhosis are offered 6-monthly surveillance testing for hepatocellular carcinoma.

Stakeholders made the following comments in relation to draft statement 7:

- Suggestion that this statement should include children and young people.
- Suggestion to include adults at high risk of hepatocellular carcinoma (African and Asian patients, patients with a family history of hepatocellular carcinoma) in addition to those with advanced fibrosis/cirrhosis are offered 6-monthly surveillance for hepatocellular carcinoma.
- Suggestion to add wording to the statement to include 'and are reviewed with, or are under the joint care of, a hepatologist'
- Suggestion to include reference to the use of transient elastography as it is recommended by CG165 to quantify liver fibrosis and because this technology is new it would be helpful for implementation.

6 Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

- A statement on antiviral treatment. This was suggested because the recommendations in NICE clinical guideline 165 involved a change of practice with regard to HBsAg quantitative assay testing to determine whether a patient should continue with a full course of peginterferon alfa-2a therapy or move onto other antiviral therapy. The stakeholder raised concerns that having no statement on antiviral treatment could mean that these changes to practice will take a longer time to implement.
- Antenatal testing for the hepatitis B virus.
- Occupational screening and processes.
- Vaccination of high risk groups.

Appendix 1: Quality standard consultation comments table

ID	Stakeholder	Statement No	Comments[1]
001	Addaction	General	I certainly feel that these standards will place an emphasis on services ensuring that they remain vigilant and that there is no complacency around screening or monitoring, especially those that are not appropriate/do not meet the criteria for treatment. It highlights the need for babies to have the complete course of vaccinations, something that has previously been missed in some areas of health care. Overall I believe that this document ensures a gold standard approach encompassing equality, diversity and ensuring the patient is empowered and engaged.
002	Roche Products LTD	General	Roche supports the inclusion of measuring the outcomes proposed as demonstrated by the effective implementation of the Scottish Sexual and Blood Borne Virus Framework 2011-2015 in the draft quality standard as an area of improvement for testing for hepatitis B. Data Sources and Supporting Contextual Information of the Scottish Framework with some of the following examples: • Laboratory data blood borne virus avidity testing • Needle exchange surveillance initiative • HIV treatment data • Substance misuse databases • National surveillance systems, test and diagnoses databases for hepatitis B and data linkage The data collection for the UK can be modelled from existing local and national databases and reporting frameworks already in place from the former Health Protection Agency/PCTs. Rationale/Evidence Please refer to the Appendix 2 of The Sexual Health and Blood Borne Virus Framework 2011-2015. www.scotland.gov.uk
003	FRSH	General	I note there is no mention of vaccination of household contacts of index cases. Is this considered beyond the scope of this document?
004	FRSH	General	I think the draft document does highlight the key areas for improvement and the data could be collected if the structures were in place to measure these.
005	RCOG	General	2nd paragraph: Commissioners…and a blood test for the detection of hepatitis B infection at 12 months

[1]PLEASE NOTE: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how quality standards are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its staff or its advisory committees.

ID	Stakeholder	Statement No	Comments[1]
006	BMA	General	We support this draft quality standard, the measures seem sensible and we agree with the key paragraph: "Commissioners ensure that they commission services with local arrangements to offer adults with chronic hepatitis B with significant fibrosis or cirrhosis 6-monthly surveillance testing for primary liver cancer." which is repeated several times throughout.
007	FFLM	General	The Faculty of Forensic and Legal Medicine (FFLM) would support the introduction of Universal vaccination but if not we would support the identification and vaccination of high risk patients.
008	RCP	General	• The RCP is grateful for the opportunity to comment on the Quality Standard. We have received the following comments from our experts in genito-urinary medicine. • A clear definition of what is meant by test positive is required - we assume this to mean antigen positive. • Those individuals tested Hepatitis B positive in Genito-urinary Medicine clinics should have a means of direct referral to care rather than having to be referred back to their GP for onward referral. • Hepatitis Delta testing should be discussed in all Hepatitis B antigen positive individuals. All patients who test positive for hepatitis B, whether Ag or Ab without history of vaccination, should also be screened for HIV infection.
009	CLDF	General	CLDF cannot identify any incorrect information within the Hepatitis B quality standard when referring to the processes of treatment once a clear diagnosis has been established. However, CLDF does feel that when referring to testing and immunisation, there is scope to improve standards to allow for greater opportunities for screening. CLDF calls for a UK Universal vaccination programme as well as a wider reach for immunisation to cover all UK residence, and not just those considered to be 'high risk'. The World Health Organisation has been recommending global immunisation since 1992 and while 179 countries have taken up the recommendation and consequently seen a marked reduction in the rate of chronic infection, as a nation the UK is behind the curve.
010	BAAF	General	Thank you for the opportunity to comment on this guidance. This response is being submitted on behalf of the BAAF Health Group, which is also a special interest group of the Royal College of Paediatrics and Child Health (RCPCH). The Health Group was formed to support health professionals working with children in the care system, through training, the provision of practice guidance and lobbying to promote the health of these children. With over 500 members UK-wide, an elected Health Group Advisory Committee with representation from community paediatricians working as medical advisers for looked after children and adoption panels, specialist nurses for looked after children, psychologists and psychiatrists, the Health Group has considerable expertise and a wide sphere of influence. Our area of concern is the particularly vulnerable group comprised of looked after and adopted children and young people.
011	BAAF	General	While we recognise that the QS is specifically addressing hepatitis B, we are concerned that testing and monitoring for hepatitis C should also be carried out. Our members note that even within the group of pregnant women who are known drug users, testing for hepatitis C is often missed - currently ordering this test depends on the level of awareness and practice of the individual midwife.
012	Paediatric Liver Centre, King's College Hospital	General	Addition of quality statement around ensuring that all pregnant women are offered antenatal testing for the hepatitis B virus

ID	Stakeholder	Statement No	Comments[1]
	NHS Foundation Trust		
013	BHIVA-BASH	General	BHIVA/BASHH Response to the Hep B NICE Quality Standards This is a timely document that defines the standards of care for the testing, management and prevention of HBV infection. This will lead to clearly visible auditable goals in improving care. There are a number of issues that need addressing, which are detailed below.
014	BHIVA-BASH	General	Those tested positive in GU Medicine should have a means of direct referral to care rather than referred back to their General Practitioner
015	BHIVA-BASH	General	All HIV -positive individuals should be tested
016	BHIVA-BASH	General	All patients tested positive for Hepatitis B whether ag or ab without history of vaccination should be tested for HIV
017	BHIVA-BASH	General	Use Infectious Diseases Specialists with an interest in Viral Hepatitis rather than hepatology
018	Public Health England	General	The quality standard is unclear about hepatitis B vaccination. The only group which is specifically recommended to receive a course of vaccination is babies born to mothers with hepatitis B (QS4), but there are other groups which would benefit from a clear steer in the QS on vaccination, such as injecting drug users. NICE QS23 states the need for people who use drug treatment services to be offered tests and if needed, vaccination for hepatitis B. Some attempt must be made to more clearly link the two quality standards, otherwise there is potential for confusion in the intended audience. In addition to 'traditional' injecting drug users, there is an emerging group of people who inject image and performance enhancing drugs (IPEDs). This group don't identify as drug injectors and in some parts of the country they make up a significant proportion of needle exchange clients. It would be helpful if identified as a specific at-risk group.
019	RGCP	General	This draft quality standard is clearly very comprehensive and well researched. There however needs to be a summary page / pages with a summary of the key points and recommendations.
020	RGCP	General	Due to the length of the quality standard it is unlikely to be read in full by the vast majority of healthcare workers.
021	RGCP	General	This makes it imperative to have a couple of summary pages.
022	RGCP	General	The UK's priority is the introduction of Hepatitis B immunisation into the childhood immunisation programme
023	RGCP	General	Next, the UK needs a catch-up programme to immunise all children and Students
024	RGCP	General	In addition, the UK needs to ensure all healthcare professionals are immunised against Hep B.
025	RGCP	General	In the NICE document the groups at risk are mentioned and of course, no one will disagree, they need to be immunised.
026	RGCP	General	It is important to accept that Migration has changed the epidemiology of Hepatitis B virus in the UK and this has happened already years ago and worsening as the carrier migrants can infect others here in the UK.

ID	Stakeholder	Statement No	Comments[1]
027	ANHOPS	General	Where hepatitis B infection is detected as part of occupational immunisation schemes it would be expected that the occupational health provider would retain responsibility for the occupational health aspects of the case but would refer the individual back to primary care services for clinical management. Occupational screening is usual only for health care workers and there may be exceptional cases where a consultant occupational physician working in the NHS may need to refer the individual directly to a specified hepatologist. This should be done in consultation with the patient's GP. Occupational screening processes for health care worker are defined separately by PublicHealth England, are the responsibility of the employer's occupational health provider and may not follow the clinical pathways set out in this document" As we in Occupational Medicine deal with considerable risk to workers acquiring BBV during occupations we feel that it would be valuable at the very least to have this included. Where hepatitis B infection is detected as part of occupational immunisation schemes it would be expected that the occupational health provider would retain responsibility for the occupational health aspects of the case but would refer the individual back to primary care services for clinical management. Occupational screening is usual only for health care workers and there may be exceptional cases where a consultant occupational physician working in the NHS may need to refer the individual directly to a specified hepatologist. This should be done in consultation with the patient's GP. Occupational screening processes for health care worker are defined separately by PublicHealth England, are the responsibility of the employer's occupational health provider and may not follow the clinical pathways set out in this document" As Occupational Medicine deal with considerable risk to workers acquiring BBV during occupations we feel that it would be valuable at the very least to have this included.
028	RCON	General	The boxes detailing the metrics and evidence specifying national outcomes framework that this standard will support is very helpful, and clearly shows joined up thinking and working across a number of areas. This is positive to see.
029	Public Health England	General	Penultimate paragraph. The QS incorrectly states that most of the remaining 5% of people with UK acquired chronic hepatitis B infection is through horizontal transmission or through vertical transmission from mother to child. Please note most of these infections have been acquired through sexual transmission. Please see following reference. 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 2004; 29:211-220
030	GSK	General	This quality standard could be broader and ensure that all individuals that require vaccination for Hepatitis B receive a full course and not just neonates (Quality Standard 4). Further, it might call for a complete course of vaccination for those at risk individuals that test negative and those in close contact with Hepatitis B positive individuals.
031	Public Health England	General	Babies born to mothers who have "the" hepatitis B infection". Delete "the"
032	Public Health England	General	The statements do cover the key areas in testing, diagnosis and treatment. However, I think a quality statement about

ID	Stakeholder	Statement No	Comments[1]
			prevention specific to vaccinating high risk groups is missing. This would be distinct to the neonatal immunisation standard but would remind commissioners and providers that systems are in place to vaccinate close household and sexual contacts of persons with hepatitis B, or people with multiple sexual partners such as those who attend GUM clinics (ie groups mentioned in the Green Book recommendations). Data are already collected on vaccine uptake in MSM and other GUM clinic attendees (in GUMCAD), as well as among people who inject drugs (NDTMS) so the structures and systems are in place for data collection for these quality measures. However, there is no systematic auditing and follow up of vaccination of close household contacts (unless in a family clinic in a tertiary centre). These individuals are frequently missed from vaccination and this is a major equality issue. (See also comments Quality statement 6: personalised care plan – where I have suggested that vaccination of household and sexual contacts be included in the care plan).
033	RCON	General	It may be possible to collect the data proposed for these measures. The substance misuse field has been collecting statistics in this area for many years so it should be a simple process for all providers to build in the ability to record such statistics. This could either be in the form of a requirement of service specifications or as part of quality standards measurements.
034	Public Health England	General	For many of the quality statements e.g. #4 neonatal hepatitis B infection, there are systems and structures in place to collect data but there are data quality issues which have meant that some areas do not submit data or submit data with questionable accuracy. Hopefully having NICE quality standards will help drive for improvements to be made to data collection systems.
035	BAAF	General	It would be helpful to acknowledge 1) the resources and 2) the workforce competencies/expertise required to deliver these standards. Engagement with high risk groups whether for testing, immunisation, treatment or monitoring is challenging and skilled work and often requires additional time. Similarly, it is resource intensive to obtain a comprehensive history in order to determine, for instance, whether a looked after child is at high risk and requires testing or immunisation. There may also be additional considerations relating to consent, confidentiality and information sharing and this also requires additional training, skill and time to carry out to meet the standards. We have attached a Practice Note concerning looked after children, which addresses these issues. Robust commissioning arrangements will be needed to put in place the systems and structures to allow accurate data collection for the proposed quality measures. In addition, a considerable commitment to training and ongoing development of a highly skilled workforce will be required.
036	BHIVA-BASH	General	NICE needs to define what is meant by test positive – BHIVA and BASHH assume this to be “antigen positive”
037	Public Health England	General	This additional quality standard should be entitled:- Referral/offer of hepatitis B vaccination to high risk adults.
038	National AIDs Trust (NAT)	1	NAT is concerned at the failure of the Quality Standard to make a clear element in this Quality Statement the testing for HIV of those with acute or chronic hepatitis B. Currently there is mention of HIV only in Quality Statement 2 on referral to specialist care where it states that such referral is 'so that they can be assessed for the stage of hepatitis B and other infections (such as HIV, hepatitis C and hepatitis D) and liver health'. The UK National Guidelines for HIV Testing (2008) agreed by the three main relevant

ID	Stakeholder	Statement No	Comments[1]
			UK clinical bodies - BHIVA, BASHH and BIS (now BIA) - makes clear that hepatitis B is a clinical indicator condition for HIV and that therefore HIV testing should be offered routinely on an opt-out basis to all people not previously diagnosed with HIV who test positive for hepatitis B (see Table 1 'Clinical Indicator Diseases for Adult HIV Infection' and also para.4.2). The Guidelines also makes clear that testing for HIV comes within the competence of all trained healthcare workers (para.4.1). The UK National Guidelines for HIV Testing (2008) agreed by the three main relevant UK clinical bodies - BHIVA, BASHH and BIS (now BIA) - makes clear that hepatitis B is a clinical indicator condition for HIV and that therefore HIV testing should be offered routinely on an opt-out basis to all people not previously diagnosed with HIV who test positive for hepatitis B (see Table 1 'Clinical Indicator Diseases for Adult HIV Infection' and also para.4.2). The Guidelines also makes clear that testing for HIV comes within the competence of all trained healthcare workers (para.4.1). This clinical guidance has been reiterated at a pan-European level. The HIV in Europe initiative, with support from WHO Europe, ECDC and the EACS (the European AIDS Clinical Society) have developed 'HIV Indicator Conditions: Guidance for Implementing HIV Testing in Adults in Health Care Settings'. This Guidance also recommends routine testing for 'Hepatitis B or C (acute or chronic)' given they are conditions associated with an undiagnosed HIV prevalence of at least 1 per 1,000. The NICE Quality Standard though it speaks of 'assessment' for hepatitis B, falls short of explicitly recommending universal HIV testing for those with hepatitis B. This is a worrying omission and a failure to meet the national ambition to 'make every contact count'. NICE advice needs to be 'joined up' rather than limit itself to 'single condition silos' - recommending HIV testing in all guidance around relevant clinical indicator conditions will be an important public health contribution to the reduction in undiagnosed and late diagnosed HIV. As importantly, for those individuals with these clinical indicator conditions, it is on the basis of clear clinical recommendations optimising those patients' health and health outcomes. We are most concerned to ensure routine HIV testing on an opt-out basis for people with hepatitis B is clearly stated as an essential element in the Quality Statements in the Standard. One option is to include it in Quality Statement 2 - revising the current reference which is just to 'assessment'. However, we think it definitely preferable to include it in Quality Statement 1 on testing. Services testing for hepatitis B can certainly also test for HIV and should be doing so - ensuring the HIV test is offered to all who have hepatitis B on an opt-out basis is an essential element in a testing service of acceptable quality. NAT recommends the Quality Statement 1 is amended in line with national and European guidance to require the universal offer of an opt-out HIV test to all people who test positive for hepatitis B infection.
039	Roche Products LTD	1	Roche position: Roche supports the definition in this Draft Quality Standard which outlines the ethnicities of people

ID	Stakeholder	Statement No	Comments[1]
			that are of high risk including those from South East Asia, Africa, the Middle East and Far East, Southern and Eastern Europe, as well as the Pacific and Amazon Basin. Addition: Roche would like to ask NICE to consider including those who travel abroad who are classified as medium to high risk if not vaccinated according to the British Liver Trust. People that intend to stay in an area where hepatitis B is common, particularly if they are likely to need medical treatment, should get vaccinated. Rationale/Evidence More than 12% of cases in the UK are thought to result from people travelling to and working in countries where there is increased risk of hepatitis B infection. Around 40% of these cases are due to unprotected sexual activities. Vaccination is strongly recommended for all travellers to countries where hepatitis B is common. Being born in a country where hepatitis B is common does not mean natural protection from infection. Lavanchy D. Hepatitis B virus epidemiology, disease burden, treatment, and current and emerging prevention and control measures. Journal of Viral Hepatitis. 2004;11(2):97-107. The British Liver Trust Hepatitis B report, July 2012 with the next update scheduled for July 2014
040	Roche Products LTD	1	**Dried Blood Spot Test (DBST).** Roche Position: Roche requests the inclusion of the DBST in the draft quality standard as an area of improvement for testing for hepatitis B. Addition: As the DBST has been validated by Public Health England, is easy to perform and have shown to be successful in driving diagnosis of high risk population in the community, Roche requests that NICE considers the following process quality measure: Numerator - the number of Dried Blood Spot tests conducted on high risk adult patients Denominator – the number of high risk adults who may be infected with hepatitis B Rationale/Evidence Public Health England has developed a dried blood spot test that has been validated in detecting hepatitis B surface antigen. The DBST involves pricking a finger and squeezing a few drops of blood onto a small card. The test is then sent away and the results are then made available to the individual through their local GP service, usually within two weeks of the prick. If any result is positive, a further, detailed blood test is required and the patient is then referred on to a specialist for treatment and monitoring. These tests have proven to be effective in diagnosing high risk groups such as those with East Asian backgrounds residing in the UK. Please refer to the Leeds hospital best practice example and Outreach programmes targeting Chinese community in Leeds. Both of these examples were led by Consultant Mark Aldersley. http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/HepatitisB/NationalHepatitisBDriedBloodSpotService/ Best practice case study. ‘Reducing the number of hepatitis B patients lost to follow-up: A dedicated hepatitis B clinical specialist nurse’ Dr Mark Aldersley, Leeds Teaching Hospitals NHS Trust Leeds

ID	Stakeholder	Statement No	Comments[1]
			http://www.leedsth.nhs.uk/a-z-of-services/liver-unit/news-events/hepatitis-b-testing-in-the-chinese-communityleeds/ A considerable proportion, possibly around 50%, of infected persons in Scotland remains undiagnosed. Undiagnosed infections present a transmission risk and can lead to further spread of disease. It is vital that undiagnosed infections are reduced to ensure the maximum individual and public health benefit. The Sexual Health and Blood Borne Virus Framework 2011-2015. www.scotland.gov.uk Chronic HBV is on the rise, with almost 8,000 new cases detected each year.
041	FRSH	1	Under rationale, should the “Green Book’ be a website reference?
042	FRSH	1	Under “ what the quality statement means or service providers, health and public health practitioners and commissioners” there should perhaps be an additional statement first stating “ service providers should ensure systems are in place for identifying people at risk”, before the statement about offering Hep B testing to people at increased risk
043	RCOG	1	Needs to be expressed as 'People at increased risk of Hep B infection are offered testing' rather than just 'people at risk of infection' as infection is a broad term.
044	RCOG	1	Should testing strategies for hep B not include termination of pregnancy services also? Please note Hep B is already screened for in (some) fertility clinics
045	GSK	1	People who are at increased risk of Hepatitis B infection and test negative should be offered vaccination to reduce the risk of future infection and onward transmission. This is currently stated within the quality standard rationale and is consistent with Public Health England’s Green Book chapter on Hepatitis B. Therefore we believe this should form part of the quality statement.
046	RCON	1	It seems odd that whereas quality statement 1 states that people at increased risk of infection are offered testing, but none of the headline statements mentions vaccinating people at risk of Hepatitis B. Surely this should be linked in to ensure that vaccination is also offered by way of protection and prevention. This is outlined in the rationale for Quality Statement 1 but it should also be clear in the headline statement as well.
047	RCON	1	Also vaccination is not captured in data collection. This would be a useful data set - as it would indicate if targeting high risk groups for vaccination does reduce rates of infection.
048	FFLM	1	The FFLM proposes that if immigration detainees are found to be HBsAg negative and at increased risk of hepatitis B that they should be allowed to complete the three doses of hepatitis B vaccine before deportation.
049	RCP	1	Anyone who has had unprotected sex’ - This covers the majority of adult population and so requires further definition. • ‘multiple sexual partners’ - Also needs further definition. • ‘people presenting at sexual health and genitourinary medicine clinics’ - This recommendation has been removed from the NICE Hepatitis screening guidelines. All HIV Positive individuals should all be tested.
050	Terrence Higgins Trust	1	We would strongly recommend that this statement also suggests offering other tests including HIV and refers to the BHIVA testing guidelines (2008). As 22 per cent of people living with HIV remain undiagnosed and hepatitis B is a clinical indicator for HIV it is important that those at increased risk of hepatitis B are offered an HIV test as well.
051	Royal Pharmaceutical	1	We support offering testing for hepatitis B to people who are at an increased risk of infection. We would like to

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	Society		highlight that pharmacies are suitable testing venues. Community pharmacies are already involved in harm reduction strategies that impact on the transmission of hepatitis B and C such as needle and exchange programmes and health promotion advice and are therefore ideally placed to offer testing services. Community pharmacies are often centrally located and open for longer hours (including evenings and weekends) and easily accessible offering a viable and convenient option for testing. Community pharmacies have consultation rooms/areas to maintain patient confidentiality and privacy. Pharmacists comply with confidentiality regulations and standards (as set by the General Pharmaceutical Council).
052	BAAF	1	We welcome inclusion of looked after children in the list of people at increased risk of hepatitis B. However, our members note that screening older children and young people who are at risk from vertical transmission is often overlooked. In this group it may be because of the difficulties of obtaining a history which is sufficiently comprehensive to enable detection of their high risk status. It would be helpful if this was noted in the QS. Please be aware that we are not advocating that all looked after children should be screened for blood-borne viruses as this would be discriminatory, but we do believe that it is necessary to raise wider awareness of their high risk.
053	BAAF	1	We would strongly advocate for universal childhood hepatitis B immunisation in keeping with practice carried out in other developed countries. Failing, this, we suggest that all those at increased risk, and in particular children of substance misusing parents, should receive immunisation for hepatitis B.
054	Paediatric Liver Centre, King's College Hospital NHS Foundation Trust	1	Consider adding: • those who travel or have lived in intermediate or high prevalence areas • unaccompanied and trafficked children • foster carers • adoptive parents
055	Paediatric Liver Centre, King's College Hospital NHS Foundation Trust	1	Consider adding: • LAC health review Pre-adoption
056	BHIVA-BASH	1	Multiple sexual partners needs definition – includes majority of population so does not this translate into the UK following every other country and vaccinating the population as by definition those at risk should be protected
057	BHIVA-BASH	1	Add 'in those at continued risk this should be repeated at least annually'
058	BHIVA-BASH	1	In reference to: 'anyone who has had unprotected sex'; this cover 95% of the adult population. Therefore everyone should be tested and/or vaccinated, as the WHO recommends
059	BHIVA-BASH	1	In order for all sexual health patients to have an HBV test, it is suggested that this is not done everywhere yet and would need a change in practice.
060	Halve It Secretariat	1	The Halve It coalition is concerned that Quality Statement 1 does not include a clear recommendation on HIV testing for those newly diagnosed with acute or chronic hepatitis B. Underlying HIV infection is known to increase the chance of hepatitis B chronicity, and as the routes of transmission for HIV and hepatitis B are similar there is a significant rate of coinfection in patients (estimated to be 3–10% in the UK).

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			The UK National Guidelines for HIV Testing (2008) state that hepatitis B is a clinical indicator condition for HIV and that therefore HIV testing should be offered routinely on an opt-out basis to all people not previously diagnosed with HIV who test positive for hepatitis B. NICE public health guidance documents 33 and 34 (2011) on increasing the uptake of HIV testing among black Africans and among men who have sex with men, recommend that all health professionals should 'routinely offer and recommend an HIV test to patients that have symptoms that may indicate HIV or where HIV is part of the differential diagnosis'. This recommendation is based on the list of indicator diseases outlined in the UK National Guidelines for HIV Testing referenced above, which includes hepatitis B. Although Quality Statement 2 does make reference to 'assessment' for HIV after referral to specialist care, it does not advocate universal HIV testing for people diagnosed with hepatitis B in line with the UK National Guidelines for HIV Testing and in line with existing NICE guidance on HIV testing. In order to effectively impact the diagnosis and management of hepatitis B and HIV, it is imperative that NICE aligns its Quality Standard for hepatitis B with existing NICE guidance on HIV testing. **Halve It recommends that Quality Statement 1 is revised in line with national guidance to require the universal offer of an opt-out HIV test to all people who test positive for hepatitis B infection.**
061	Public Health England	1	The QS needs to be much clearer in stating that hepatitis B vaccination should be linked to HBV testing in adults. This could be done by the QS explicitly including the offer of (referral to /access to) hepatitis B vaccination to those being tested for HBV who are at risk of infection (in line with "Immunisation against Infectious Disease" (The Green Book). This may require the addition of another standard (between 1 and 2) on the referral/offer of vaccination to high risk adults. People who have ever injected drugs are one of the groups who are increased risk of hepatitis B, but there is no clear linking the need for them to be tested and their vaccination. QS1 refers to PHE's Green Book which makes clear the need for the priority for injecting drug users to be given hepatitis B vaccination. It would be helpful if the QS could make the point more explicitly clear. At a minimum, it should state that injecting drug users are one of the groups recommended for a vaccination course. This could be done by the QS explicitly including offer/referral/access to vaccination (rather than completion/update) among those being tested who are still at risk.
062	CHIVA	1	The document states that testing of high risk population is done – testing should be implemented in GP practices and sexual health and GU clinics. This are the only testing areas where children/young people will be seen and tested. CHIVA would be concerned that children will not be a focus point and children will lose out on early diagnosis with

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			improved health outcomes. We also know that past hepatitis follow up of pregnant women and children was not complete in most areas around the UK and perhaps a push for diagnosing hepatitis B/C infected children through retrospective audits and testing children of all mothers in hepatitis follow up (similar to the DOH Don't forget the children) would be more successful
063	CHIVA	1	In relation to local data collection, this is very vague description and does not give clear indications who, where and how?
064	Roche Products LTD	2	Roche Position: Roche supports the inclusion of more specific standards relating to treatment in the draft quality standard as an area of improvement for referral to specialist care. Addition: To improve patient outcomes and quality of life, Roche proposes the additional process quality measure below and asks the NICE Committee to consider adopting the measures from the Scottish Framework as mentioned below: Numerator - the number of adults treated (excluding pregnant women) with peg interferon and other antiviral agents as per NICE Clinical Guidelines 165.Denominator - the number of adults (excluding pregnant women) who are referred to a specialist care for further assessment. The inclusion of a quality measure aligned to treatment of hepatitis B is an important addition to ensure that the outcomes of specialist care received following referral is measured. Treatment is a very important element in quality service provision and as such the inclusion of this in the quality standard will reinforce the importance of not just referring to specialist care but also that the specialist care is measured on quality. The Scottish Framework leading outcome 3 which promotes 'People affected with blood borne virus(es) lead longer, healthier lives,' utilises the following measures: • HBV3.3 – Annual number of hepatitis B diagnosed persons hospitalised, or having died with end-stage liver disease; total and within 1 year of diagnosis. • HBV3.4 – Proportion of diagnosed highly infectious (eAntigen positive/high viral load) HBV chronically infected persons, who are receiving antiviral therapy. • HBV3.5 – Proportion of the treated HBV population achieving an 'optimal' treatment response'. Rationale/Evidence An audit of London GP practices found the vast majority (83%) of people with chronic HBV infection diagnosed in primary care were not referred for specialist treatment at a hepatology clinic. Treatment levels in the UK remain low given the fact that 83% of patients diagnosed are not referred to a specialist hepatology clinic. Smith B, Brown I et al. Referral of hepatitis B surface AG positive patients to specialist hepatology care: need for improvement. Gut. 2010;59:A40-A41 doi:10.1136/gut.2010.223362.99 While the UK is classified as a 'low prevalence' country, the infection still poses a significant challenge in terms of potentially preventable mortality and morbidity often due to population migration, in many cases causing serious liver damage and liver cancer.

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			Health Protection Agency. Standards for local surveillance and follow up of hepatitis B and C. Health Protection Agency. 2011. Available from http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1194947376936 [accessed August 2013] In Scotland, during 2009-2010, it is estimated that between 1000 and 1500 chronically infected individuals attended a specialist for hepatitis B infection management/care. Antiviral therapy was being administered to between 10 and 20% of those attending for management and/or care. It should be noted, however, that only a proportion of chronically infected individuals in specialist care would be eligible for antiviral therapy. The Sexual Health and Blood Borne Virus Framework 2011-2015. www.scotland.gov.uk Chronic HBV is on the rise, with almost 8,000 new cases detected each year. Kale AR and Snape MD. Immunisation of adolescents in the UK. Archives of Disease in Childhood. 2011;96:492-495 doi:10.1136/adc.2010.196667 PegIFN-α has higher effectiveness in restoring the host immune control on viral replication, which results, after a finite course of therapy, in a durable suppression of viral replication, leading to sustained disease remission in a significant proportion of patients and a subsequent hepatitis B envelope antigen (HBeAg) and/or hepatitis B surface antigen clearance. If maintained over time, sustained response to PegIFN-α treatment reduces the progression of fibrosis, thereby preventing the development of typical complications of end-stage liver disease and HCC and, ultimately, increases survival Degasperi et al PegIFN-α2a for the treatment of chronic hepatitis B and C: a 10-year history Expert Rev. Anti Infect. Ther. 2013:11(5) 459-474
065	RCOG	2	Suggest to include 'paediatric ' in 'children are referred to a paediatric hepatologist or to a paediatric gastroenterologist'
066	GSK	2	When newly identified cases are sent for specialist care appropriate mechanisms should be initiated to trace contacts and offer vaccination. This is in line with national policy documents used to inform the development of the quality standard.
067	FFLM	2	The FFLM proposes that if immigration detainees are found to be HBSAg positive that they should be referred to a hepatologist or similar specialist and that they would be allowed to complete any treatment deemed necessary by that specialist before deportation.
068	FFLM	2	What is the proposed route of referral for service providers in the private sector who provide screening tests for

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			hepatitis B at the service user's request? There needs to be clarification as to whether the mechanism would be to refer back to the GP or onwards to a specialist if the service user was found to be HBsAg positive.
069	FFLM	2	The FFLM proposes that there should be a robust mechanism of referral by GPs such that all service users needing onward referral should be referred. There should not be a two tier system within primary care and that the decision whether to offer treatment or not should be made by the specialist and not the GP. This comment is made with particular reference to service users with drug and or alcohol problems.
070	Terrence Higgins Trust	2	We fully support the intention of quality statement 2 and believe it is in implicit within the statement that further tests including an HIV test should be carried out routinely. However, we believe that this needs to be explicit within the statement. Given the supporting evidence that people living with HIV are less likely to clear a hepatitis B infection and that 22 per cent of people living with HIV are still undiagnosed, it is crucial that an HIV test is offered as a matter of course when someone is diagnosed with hepatitis B. BHIVA guidelines for testing (2008) states that there should be universal testing for everyone who tests positive for hepatitis B as hepatitis B is listed as a clinical indicator for HIV. We would suggest that the statement is amended to say: "People who test positive for hepatitis B infection are referred to specialist care for further assessment, care and tests to eliminate possible co-infections." As BHIVA is an accredited and NICE approved all relevant guidelines, including the testing guidelines should be referenced as source guidance We would suggest that the statement is amended to say: "People who test positive for hepatitis B infection are referred to specialist care for further assessment, care and tests to eliminate possible co-infections." As BHIVA is an accredited and NICE approved all relevant guidelines, including the testing guidelines should be referenced as source guidance.
071	Paediatric Liver Centre, King's College Hospital NHS Foundation Trust	2	Children and young people who are HBsAg+ should be referred to one of the three supraregional paediatric liver centres as they require specialist liver assessment. The three designated centres are: • Birmingham Children's Hospital • King's College Hospital • Leeds General Infirmary
072	BHIVA-BASH	2	Should discuss delta testing in all antigen positive
073	FRSH	3	Although it is acknowledged that the list of pregnant women with complex social needs is not exhaustive, it should maybe also include those with learning difficulties and "looked after" teenagers.
074	RCOG	3	Statements 3 & 4 are largely consistent with existing KPI's (key performance indicators) currently applied by CCGs. Accordingly they will come as no surprise and will automatically be met by units who achieve the existing KPI's. Neither of the QS's differentiates between women who are "high-risk" or "low-risk" for hep B transmission. I think this reflects a key deficiency. It results in an inappropriate degree of clinical priority being applied to 100% of women whereas in reality the priority only relates to about 5%.
075	RCOG	3	Suggest adding 'liver specialist' to the QS as in 'preg women who are hep B positive are assessed by a liver

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			specialist'. As there are 2 specialist conditions in the QS - preg and Hep B. ' specialist may then refer to either an obstetrician or a hepatologist.
076	RCOG	3	Issues: “Within 6 weeks of receiving the test result” Who do we mean has received the result and started the clock ticking? Is it the laboratory, the maternity team, the woman herself? Should the clock start ticking when the test is taken? What if it takes three months to get the result but then she is seen by a specialist in less than six weeks? Clarification please. “Specialist” What constitutes a relevant specialist? What does the specialist do? If the woman is “low-risk” (in terms of hep B infectivity – about 95% of cases are) then the most vital things are: 1. Inform the woman of the result and its implications. 2. Advise/arrange testing of any existing children of unknown (hep B) status. 3. Advise/arrange/carry out partner testing unless the partner’s hep B status is known. 4. Arrange for the baby (after birth) to be vaccinated. These can all be carried out by an appropriate/competent MW or obstetrician. Typically the woman is seen by a hepatologist (the “specialist”) after these steps have been taken. At the first consultation with the hepatologist the tests carried out may include: • Liver function tests • Hep B viral DNA level • Liver ultrasound Often these tests take some time to arrange/carry out/be reported. In the 5% of women who are “high risk”, the same tests will typically be carried out, though the results are more likely to lead to action. Fundamentally should we not allow the specialist obstetrician/MW to selectively refer urgently the “high-risk” women? The background text explains the rationale: Pregnant women who are identified as being hepatitis B-positive at antenatal screening should be referred to and seen by a gastroenterologist or infectious disease specialist with an interest in hepatology within 6 weeks of receiving the screening test. This is important to allow treatment (tenofovir) in the third trimester if needed to reduce the risk of the baby becoming infected with the hepatitis B virus.

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			The need for antiretroviral therapy is likely to be confined to “high-risk” cases. In order to achieve the desired outcome these women need to be seen (only) before the end of the 2nd trimester. If a woman books at 8 weeks, the current draft QS mandates that ALL POSITIVE WOMEN must be seen by 14 weeks! We also need to bear in mind that antenatal screening for hep B (as with HIV and to a large extent syphilis) largely re-identifies women already known to have been infected and therefore most of these women have previously been seen (and often are already under follow up) by hepatologists. This arises because the vast majority of hep B positive women have acquired the infection before coming to the UK. This cohort tends to have relatively high parity and accordingly cases are repeatedly re-identified with each pregnancy. QS3 really ought to concentrate appropriate clinical priority to high-risk cases and newly identified low-risk cases.
077	RCON	3	If it is important that pregnant women receive treatment in the 3rd trimester to ensure that the baby does not contract Hepatitis B, does this not the mean that depending on the duration of the pregnancy, 6 weeks may be too long? Is there not a need to ensure that the time to see a specialist needs to alter to take into account pregnancy duration so that treatment can be as effective as possible?
078	BAAF	3	It would be helpful to include pregnant women with a history of being in care in the list of women with complex social needs.
079	BAAF	3	Suggesting that an identified person is responsible for co-ordinating the local hepatitis B immunisation programme may be useful, but they must also be supported by sufficient training and resources. For example it may require considerable time to locate children who have moved homes/placements/ boroughs, and success may then depend on a professional who is skilled in engaging with chaotic or drug using families, etc.
080	Paediatric Liver Centre, King’s College Hospital NHS Foundation Trust	3	Consider adding: • trafficked
081	Paediatric Liver Centre, King’s College Hospital NHS Foundation Trust	3	Women in the ‘at risk’ group should not only be checked for HBV infection at ‘booking’ but also during pregnancy and at delivery
082	BHIVA-BASH	3	Should discuss delta testing in all antigen positive
083	BHIVA-BASH	3	The 6-week window may possibly be too long for some patients. As with the HIV standards, patients should be seen and assessed within 2 week
084	BHIVA-BASH	3	Add ‘where presentation is in the 3rd trimester or at delivery referral advice should be sort urgently’
085	Public Health England	3	Outcome vertical transmission rates from mother to child –this is unlikely to be estimable from local data collection as numbers are so small and the denominators are not clear. We need to collate and review the data nationally.
086	Roche Products LTD	4	**Antenatal clinics – vaccination and follow-up of babies** Roche supports the process suggested which is also in line with the Scottish framework clause HBV1.2 for measuring outcome as the proportion of babies born to HBV infected mothers vaccinated and immunised.

ID	Stakeholder	Statement No	Comments[1]
			Rationale/Evidence Despite the World Health Organization recommending universal immunisation to prevent HBV infection, less than ½ of the at-risk groups receive a vaccine in the UK: only 37% of injecting drug users and 49% of infants of infected mothers are vaccinated. In some inner-city areas, where there is a high percentage of people from parts of the world where the virus is common, as many as 1 in 60 pregnant women may be infected with HBV Kale AR and Snape MD. Immunisation of adolescents in the UK. Archives of Disease in Childhood. 2011;96:492-495 doi:10.1136/adc.2010.196667 The Sexual Health and Blood Borne Virus Framework 2011-2015. www.scotland.gov.uk
087	RCOG	4	Statements 3 & 4 are largely consistent with existing KPI's (key performance indicators) currently applied by CCGs. Accordingly they will come as no surprise and will automatically be met by units who achieve the existing KPI's. Neither of the QS's differentiates between women who are "high-risk" or "low-risk" for hep B transmission. I think this reflects a key deficiency. It results in an inappropriate degree of clinical priority being applied to 100% of women whereas in reality the priority only relates to about 5%.
088	RCOG	4	Statement 4 – Babies born to mothers who have the hepatitis B infection receive a complete course of hepatitis B vaccination and a blood test for hepatitis B at 12 months. This has been in the Green Book since ~1996 (I think). I recognise that compliance is often far from 100% nearly two decades later. I'm not convinced that the background to the QS adequately defines the inter-agency working that is required to achieve the result desired. Again as the QS fails to differentiate between low/high risk it fails to adequately define/describe what is a "complete course of hep B vaccination". Babies born to low risk mums need to have a first vaccination within 48/72 hours of birth, then two subsequent vaccinations in line with the Green Book recommendation, then to be tested for infection/immunity at a later date. Babies born to high risk mums need to receive hep B immunoglobulin and to have a first vaccination within 48/72 hours of birth, then two subsequent vaccinations in line with the Green Book recommendation, then to be tested for infection/immunity at a later date. This isn't really adequately covered by "a complete course of hepatitis B vaccination". FURTHER: It is disappointing that the QS's did not cover: • Screening immigrants entering the UK from high risk areas • Any consideration of including hep B in the routine infant vaccination programme for all infants, which at a stroke would much to overcome the failures that continue among at risk mums and which would potentially have major benefits to the rest of the population!
089	RCOG	4	Page 15, first paragraph - Babies born to mothers who have the hepatitis B infection receive a complete course of hepatitis B vaccination, followed by a blood test at 12 months for the detection of hepatitis B
090	RCP	4	Our experts advise that the blood test occurs at age 14 months which then confirms vaccine response as well as testing for infection.
091	BAAF	4	Our members note the considerable difficulties in delivering a full course of immunisation to this group of children.

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			Many of the looked after infants receive the initial dose but fail to receive the complete course. This is labour intensive and skilled work and needs to be resourced as such.
092	Paediatric Liver Centre, King's College Hospital NHS Foundation Trust	4	Change wording from '…receive a complete course of hepatitis B vaccination and a blood test for hepatitis B at 12 months' to '…receive a complete course of hepatitis B vaccination and a blood test to check that they are not infected with hepatitis B and whether they have achieved good levels of immunity to the hepatitis B virus at 12 months'
093	Paediatric Liver Centre, King's College Hospital NHS Foundation Trust	4	Change wording from 'a blood test for hepatitis B surface antigen (HBsAg) should be performed at 12 months…' to 'a blood test for hepatitis B surface antigen (HBsAg) levels should be performed at 12 months…'
094	Paediatric Liver Centre, King's College Hospital NHS Foundation Trust	4	Consider adding something about what happens to: • those who don't achieve good HBsAg levels • those 'vaccine failures' who have become infected with HBV
095	BHIVA	4	In addition to complete vaccination course, babies born to HBsAg+ mothers should receive first-dose of vaccine within 24hrs of birth. Receipt of HBIG as per national guidance.
096	BHIVA	4	With reference to testing babies at 12 months at the same time as the 4th vaccine dose; some practice is to advise the blood test at age 14 months, which then confirms vaccine response as well as testing for infection.
097	Public Health England	4	insert that first dose given at birth: ie "…are given the first dose promptly at birth and the recommended vaccination course is completed at the right time."
098	Public Health England	4	Quality measures, data source: local data collection. Note that COVER (coverage of vaccines evaluated rapidly) is already collected locally by child health record departments and is published as experimental statistics because of the data quality concerns.
099	Public Health England	4	Quality measures, data source: (b) "evidence of local arrangements to ensure that there is an identified person responsible for coordinating the local hepatitis B vaccination programme for babies at risk of hepatitis B infection". As recommended in the NHS Hepatitis B antenatal screening and newborn immunisation programme, best practice guidance (DH 2011), it is important that the provider/commissioning immunisation lead is informed at an early stage of the pregnant woman's hepatitis B positive status. This is the ideal point at which failsafe and follow-up monitoring can be initiated. This should be These guidelines should be added to the "source guidance" for this section and statement #3
100	Public Health England	4	Outcome vertical transmission rates from mother to child –this is unlikely to be estimable from local data collection as numbers are so small and the denominators are not clear. We need to collate and review the data nationally.
101	Public Health England	4	Quality measure denominator: worth ensuring that the definitions for numerator and denominator for vaccination are consistent with that used in COVER: 3 doses of vaccine by 12 months and 4 doses of vaccine at 24 months among eligible infants at birth. If the denominator is the number of babies reaching the age of 1 year born to mother with hepatitis B, many of those in the numerator will not have had an opportunity be vaccinated and so uptake will be low.
102	Roche Products LTD	5	**Specific groups to prioritise for quality improvement** Roche supports the use of quantitative surface antigen testing throughout the patient journey from diagnosis and

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			treatment right through to monitoring of patients. As per NICE Guidelines, the clear stopping rule with peg interferon alfa-2a at 24 weeks allows consultants to personalize therapy for their patients. This means that if a patient is not responding to peg interferon alfa-2a, the consultant can switch to a second-line therapy using a different antiviral agent. The use of quantitative surface antigen testing better defines patient who meet anti-viral criteria and also to provides greater clarity on infection status, including adding specifics to the definition of infection status. Rationale/Evidence Pegasys Summary of Product characteristics Nov 2013, accessed Mar 2014 NICE Clinical Guidelines 165 Decline in HBeAg-positive or HBeAg-negative patients: - Piratvisuth et al. Hepatol Int 2013; 7: 429–436 - Rijckborst et al. Hepatology 2010; 52:454-461 - Marcellin et al. Hepatol Int 2013; 7:88–97 - Sonneveld et al. Hepatology 2013; epub
103	RCP	5	A detailed description of what this means is required ie how often should individuals be tested and in what service should this happen?
104	BAAF	5	This statement should be strengthened by explicitly addressing socially disadvantaged groups including those who are homeless or have chaotic lifestyles through substance misuse, etc.
105	BHIVA-BASH	5	Statement 5 requires detailed description of what this is and where it happens
106	BHIVA-BASH	5	add ‘at least annually’
107	RCOG	6	Noun -verb dysjunction in the last sentence. better rephrased as ' engaging patients helps to ensure that they adhere to treatment and minimises nonattendance, inadequate monitoring and poor patient outcomes.'
108	RCOG	6	Avoid 2 'their' in one sentence. rephrase as 'people with hep B are offered a personalised plan that outlines the proposed treatment and long term mge of their hep B.
109	RCON	6	Suggest that this statement is rephrased for clarity: It should made clear that the person and their family will have a personalised care plan and that that this will be led by the person and their family as far as possible to ensure it is person centred.
110	BAAF	6	This statement should address the transition from children’s to adult’s services. There are well recognised difficulties with all aspects of transition for looked after young people and care leavers, and it is essential that robust arrangements are in place for those individuals with recognised chronic health conditions such as hepatitis B.
111	Paediatric Liver Centre, King’s College Hospital NHS Foundation Trust	6	Second paragraph, line four should read ‘take an active role in ensuring that any required monitoring..’ Any and required are currently around the wrong way
112	BHIVA-BASH	6	May want to include completion of screening and vaccination for partners, family and household contacts (or have this as a separate Quality Statement)
113	BHIVA-BASH	6	There is a conflict in the statement that there is no need to test older people or those from different cultures (Equality

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			and diversity) if they do not want it; this is contrary to the statement to test everyone, on the other NICE is saying that certain groups can be excluded. From experience in HIV and HBV testing in pregnancy, the only way to efficiently test is through universal application.
114	Public Health England	6	Include testing and vaccination of household contacts as a quality measure
115	Paediatric Liver Centre, King's College Hospital NHS Foundation Trust	7	This quality statement should also cover children and young people
116	BHIVA-BASH	7	Adults at high risk of HCC (African and Asian patients, patients with a family history of HCC) in addition to those with advanced fibrosis/cirrhosis to be offered 6-monthly surveillance for HCC
117	BHIVA-BASH	7	Add 'and are reviewed with, or are under the joint care of, a hepatologist'

Stakeholders who submitted comments at consultation

- Addaction
- Association of National Health Occupational Physicians (ANHOPS)
- British Association for Adoption & Fostering (BAAF)
- British HIV association jointly with British Association for Sexual Health and HIV (BHIVA-BASH)
- British Medical Association (BMA)
- The Children's HIV Association (CHIVA)
- Children's Liver Disease Foundation (CLDF)
- Faculty of Forensic and Legal Medicine (FFLM)
- Faculty of Sexual and Reproductive Healthcare (FRSH)
- GlaxoSmithKline (GSK)
- Halve it Secretariat

- National AIDS Trust (NAT)
- Paediatric Liver Centre, King’s College Hospital NHS Foundation Trust
- Public Health England
- Royal College of Obstetricians and Gynaecologists (RCOG)
- Royal College of General Practitioners (RCGP)
- Royal College of Nursing (RCON)
- Royal College of Physicians (RCP)

- Roche Products Ltd
- Royal Pharmaceutical Society
- Terence Higgins Trust