Public Health Programme Guidance

Hepatitis B and C: ways to promote and offer testing to people at risk of infection

Consultation on the Draft Scope: Stakeholder Comments and Response Table
22nd September – 20th October 2010

***Stakeholder* Organisation**	***Evidence submitted***	***Section***	***Comments*** **Please insert each new comment in a new row.**	***Response*** **Please respond to each comment**
Abbott Diagnostics UK		4.2.2a **Activities/ measures that will not be covered** Evaluation of the validity or comparative diagnostic effectiveness of different types of hepatitis B or C test.	The type of testing used to test for HCV will affect the effectiveness of the guidance and should not be excluded from the scope of the guidance. Several comments were made to this effect by other participants in the stakeholder meeting. (1) As a first line test HCV Antibody testing in populations at high risk of HCV transmission (e.g. IVDUs) is likely to miss a significant proportion of individuals who have been recently infected as the seroconversion window for HCV (before antibody can be detected) can be 70 days (or more in immunosupressed individuals e.g. those who may be HIV positive). (2) An HCV Antibody test without follow-up testing for viraemia, e.g. HCV RNA PCR or HCV Antigen, can not determine whether this is a resolved infection or an active infection. Testing with an assay that can detect viraemia e.g. HCV RNA PCR or HCV Antigen testing can pick up those individuals who are not expressing antibody and also determine if the individual is actively infected. As a minimum in the guidance there should be information that only repeat testing for HCV Antibody, at perhaps a 3 month interval, can detect individuals who have been exposed to HCV and that only HCV RNA PCR or an HCV Ag assay can determine whether viraemia and active infection is present. Ideally an alternative testing paradigm using HCV RNA PCR or HCV Antigen (with or without HCV Antibody) should be recommended especially in those at high	Thank you for your comment. The referral received from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. In order to be able to develop guidance on this area within the requisite time, this piece of work will develop recommendations, in line with the currently accepted clinical pathways, up to the point of the first test. We will however discuss the need for guidance in this area with the Centre for Clinical Practice and the Department of Health. Depending upon the outcome of these discussions we will return to stakeholders if an additional referral is sent through, or if not, whether there is a need to extend the current remit.

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			risk of acquiring an HCV infection (e.g. IVDUs).	

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Advisory Group on Hepatitis (AGH)		Section 3 (b)	1. The figure of 38,000 diagnoses of HCV is somewhat out of date (the reference given is 2004). Why not use data from the latest HPA report http://www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb_C/1259152221168	Thank you for your comment. The scope document has been amended appropriately.
Advisory Group on Hepatitis (AGH)		Section 3 (d & e)	1. Need to mention maternal transmission as a risk factor as this is the main mode of transmission in children	Thank you for your comment. The scope document has been amended appropriately.
Advisory Group on Hepatitis (AGH)		Section 4.1.1	1. While it is practical and preferable to target hepatitis C and hepatitis B together, differences in the two populations (where and how they present, risk factors, language and cultural barriers, optimal testing modalities) should be taken into account	Thank you for your comment. When developing the guidance the committee will, where appropriate, take into account the differences.
Advisory Group on Hepatitis (AGH)			2. When assessing risk factors, the following should be acknowledged: I. History of multiple sexual partners - for hepatitis B infection II. High risk sexual practices among homosexual males - for hepatitis C infection III. Vertical transmission prior to arrival in the UK - particularly of hepatitis B IV. Extended travel to country of origin / medical interventions in intermediate/high prevalence countries (e.g., dialysis)	Thank you for your comment. Section 4.1.1 has been amended to state which groups will be the focus of the guidance and where the evidence allows, which groups the committee will also comment upon.
Advisory Group on Hepatitis (AGH)			3. When identifying those at risk it is right to place the emphasis on country of origin rather than ethnicity	Thank you.

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Advisory Group on Hepatitis (AGH)		4.2.1 a), b) and c)	1. Education of the public plays a key role that is rightly emphasised. In relation to this, issues for consideration include: I. How to optimally target those who do not perceive themselves as being at risk due to the fact that risk activities relate to many years back II. Opportunities should be sought to maintain a link with HIV, given that risk factors are shared and significant efforts are currently being made to increase HIV testing in primary care, the community and a variety of clinical settings where undiagnosed patients may present. However, it is important to approach this in a sensitive manner and recognise that stigma continues to be attached to HIV; it may be speculated that combining hepatitis and HIV testing may actually deter some people from testing for hepatitis B and C. Some communities e.g. Pakistan (who are at high risk of hepatitis infection but low risk for HIV) see HIV as a sexual virus that is not relevant to them. Any linkage needs to be done with great care. We hope that NICE will engage with communities at high risk of infection to establish a comprehensive overview of the different testing needs. Perhaps a separate point to be included as 'Assess the current views, customs and needs of diverse ethnic groups prior to considering the activities.' III. Emphasising the fact that the majority of HBV and	Thank you When developing the guidance the committee will take into account any associated barriers to testing. In addition to an assessment of the evidence, community members will be recruited onto the committee and/or being invited to speak at the meetings to relay the concerns of their respective communities. In addition where it is appropriate fieldwork may be commissioned to test feasibility of the recommendations with those working at a grass roots level.

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			HCV is transmitted by unsafe injections - often in a health care setting. This issue has been addressed by the World Health Organisation who host an organisation called SIGN = Safe Injection Global Network. This was set up in 1999 when it was realised that, for the decade 1987-98, 12 billion syringes were sold each year and, on average, they were used between 3 and 10 times before being sterilised or discarded. Clear explanation of the risk factors included in Sections 3 d) and 4.2.1 e) should be considered. IV. Use of the word pre-test and post-test counselling should be avoided as it generates a perception that the process of testing is complex, and therefore creates a barrier. The word discussion should be preferred.	

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Advisory Group on Hepatitis (AGH)		Section 4.2.1 (d)	1. Education of healthcare professionals is pivotal as there is considerable confusion. Issues are not just related to risk factors for infection, but also to how hepatitis C and B exposure and infection status are established diagnostically, the natural history of the infection, the risk of transmission through different routes, and the optimal management strategies for both infected patients and their contacts.	Thank you.
Advisory Group on Hepatitis (AGH)			2. While expanding testing outside of traditional settings, it is important to maintain close links with primary care and avoid disengaging GPs from hepatitis care – it is proving very difficult currently to re-engage GPs with HIV testing and care following the "separation" enforced over many years.	Thank you.
Advisory Group on Hepatitis (AGH)			3. It is helpful to be clear about the difference in chronicity between HBV and HCV and the influence of age of infection. If a neonate gets HBV, either from the mother or from a reused syringe in the hospital where they were born, then they have a >90% chance of going chronic, compared to an adult acquiring HBV sexually, who has <10% chance of going chronic. For HCV more infected patients go chronic but it is not easy to transmit sexually and the majority will acquire the infection from a contaminated syringe or needle.	Thank you. The differences in chronicity have been highlighted within Section 2 of the scope.
Advisory Group on Hepatitis (AGH)		Section 4.2.1 (e)	1. Close contacts include sexual contacts in the case of hepatitis B and these may or not be part of the household	Thank you for your comment we have update the scope appropriately.
Advisory Group on Hepatitis (AGH)			2. Close contacts include sexual partners who have engaged in high risk sexual practices (typically receptive anal intercourse with trauma) in the case of	Thank you for your comment we have updated the scope appropriately.

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Advisory Group on Hepatitis (AGH)		Section 4.2.1 (f)	1. Timely return of results is important and delays are often related to pre-test sample transport and post-test paperwork. Looking at ways of improving communication of results (e.g., through text messaging), avoiding the need to return for negative results, may make testing more acceptable to many.	Thank you.
Advisory Group on Hepatitis (AGH)		Section 4.2.2 a) and b)	1. It is stated that the guidance will not address the relative validity or effectiveness of different types of tests. Yet, this area is potentially complex and issuing guidance around some of its general aspects should be considered. This will provide a direction to those responsible for assay development and service provision. For instance, many believe that point-of care tests can increase uptake. However well validated point-of-care tests for hepatitis B or hepatitis C are not currently available. At the same time it should be acknowledged that point-of-care testing, with the additional burden it imposes on staff whose primary role is generally other than testing, and the reduced sensitivity relative to more conventional forms of testing, is not necessarily the best solution in all settings. In addition, in line with a key outlined requirement, attention should be drawn to the need for solid evidence of cost-effectiveness when selecting one testing approach over the other.	Thank you for your comment. The referral received from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. When developing recommendations on how best to increase the uptake of testing the committee may consider issues pertaining to sensitivity and specificity. We will however discuss the need for guidance in this area with the Centre for Clinical Practice and the Department of Health. Depending upon the outcome of these discussions we will return to stakeholders if an additional referral is sent through, or if not, whether there is a need to extend the current remit.
Advisory Group on Hepatitis (AGH)			2. The potential role of dry blood spots – for some settings - should be addressed although again issues related to sensitivity of testing should be taken into account.	Thank you. Please see previous response
Advisory Group on Hepatitis (AGH)			3. It is stated that the guidance will not address the issue of sequence and type of diagnostic tests used to	Thank you for your comment.

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			confirm whether someone is chronically infected. It is important to use the word "confirmatory" correctly in this setting. This group believes that some of the tests undertaken after an initial reactive screening test are part of the initial diagnostic process and are needed to guide the post-test discussion (e.g., need for referral and possible treatment options), the referral pathway, and the management of contacts. Thus, hepatitis C RNA testing is an essential part of the testing process and cannot be regarded as "confirmatory".	The referral received from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. In order to be able to develop guidance on this area within the requisite time, this piece of work will develop recommendations, in line with the currently accepted clinical pathways, up to the point of the first test. We will however discuss the need for guidance in this area with the Centre for Clinical Practice and the Department of Health. Depending upon the outcome of these discussions we will return to stakeholders if an additional referral is sent through, or if not, whether there is a need to extend the current remit.
Advisory Group on Hepatitis (AGH)			4. The role of repeat testing for those at ongoing risk should be discussed	Thank you for your comment. The scope has been amended appropriately.
Advisory Group on Hepatitis (AGH)			5. Whatever the testing methodology, it is important that those accessing testing are given the correct information and where appropriate the choice about the testing modality and this should be based on evidence (e.g., false positive and false negative rate).	Thank you for your comment.
Advisory Group on Hepatitis (AGH)			6. Hard evidence is needed about the acceptability of different approaches to testing in different patient populations	Thank you. As part of the guidance development approaches a series of evidence reviews will be carried out.
Advisory Group on Hepatitis (AGH)		Section 4.2.2 (c)	1. While it is understandable that the guidance wishes to refrain from addressing the issue of treatment pathways, it should be acknowledged that the	Thank you for your comment. When developing the guidance the committee will consider what

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			availability of a clearly defined pathway of care for those who test positive is an important incentive to testing	the barriers to testing are.

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Advisory Group on Hepatitis (AGH)		Section 4.3	1. When defining the purpose of testing it should be emphasised that antiviral treatment is not the only possible outcome; testing provides an opportunity for a discussion about other important issues including for instance life-style (e.g., ETOH use) and transmission risk	Thank you.
Advisory Group on Hepatitis (AGH)		Section 4.3 Question 2	1. It might be better to have 2 questions one for hepatitis B and one for hepatitis C and this is a very important question to address.	Thank you for your comment. When developing the guidance the committee will, where appropriate, consider the differences for each condition.
Advisory Group on Hepatitis (AGH)		Section 4.3 - Expected Outcomes	1. The expected outcomes should include ensuring defined pathways of care for both infected patients and their contacts are clear	Thank you for your comment. The referral received from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. In order to be able to develop guidance on this area within the requisite time, this piece of work will develop recommendations, in line with the currently accepted clinical pathways, up to the point of the first test. We will however discuss the need for guidance in this area with the Centre for Clinical Practice and the Department of Health. Depending upon the outcome of these discussions we will return to stakeholders if an additional referral is sent through, or if not, whether there is a need to extend the current remit.
Advisory Group on Hepatitis (AGH)		Section 6	1. NICE have now released their latest guidance on PEG/RV in HCV - in NICE technology appraisal	Thank you for your comment the scope has been amended.

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			guidance 200.	
Advisory Group on Hepatitis (AGH)		List of stakeholders registered as of the 28th Sept 2010	1. Involvement of the following is recommended: Royal College of Pathologists, British Viral Hepatitis Group, Clinical Virology Network	Thank you.
Bristol Specialist Drug and Alcohol Service, Avon and Wiltshire Mental Health Partnership Trust		4.3 Q1	Financial incentives work well~ using dry blood spot tests that provide both antibody and PCR tests work, and can be used by all the members of specialist drug and alcohol teams, not just the nurses.	Thank you. As part of the guidance development process a series of evidence reviews will be carried out to determine what is effective and cost effective at increasing the uptake of testing.
Bristol Specialist Drug and Alcohol Service, Avon and Wiltshire Mental Health Partnership Trust		Q2 (a)	People often don't realise that there is a dry blood spot test available, and so are concerned that venepuncture will be painful, and most likely unsuccessful.	Thank you. When developing the guidance the committee will examine the barriers and facilitators to testing.
Bristol Specialist Drug and Alcohol Service, Avon and Wiltshire Mental Health Partnership Trust			People are frightened that they will get a positive result, so prefer not to know	Please see previous comment.
Bristol Specialist Drug and Alcohol Service, Avon and Wiltshire Mental Health Partnership Trust			People think that if they are positive they will not be eligible for treatment for HCV because they are still using street drugs, or sometimes because they are on a methadone/subutex prescription (but they would be).	Please see previous comment.

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Bristol Specialist Drug and Alcohol Service, Avon and Wiltshire Mental Health Partnership Trust			People know that if they get a positive result they should act responsibly re sharing, but may not feel able to do so, so prefer not to know.	Please see previous comment.
Bristol Specialist Drug and Alcohol Service, Avon and Wiltshire Mental Health Partnership Trust			People think they will be stigmatised.	Please see previous comment.
Bristol Specialist Drug and Alcohol Service, Avon and Wiltshire Mental Health Partnership Trust			People have heard horror stories about treatment for HCV, so prefer not to know their status	Please see previous comment.
Bristol Specialist Drug and Alcohol Service, Avon and Wiltshire Mental Health Partnership Trust		(b)	People are more likely to be tested if the process is simplified~ ie one dry blood spot test (rather than dry blood spot then venepuncture to ascertain PCR)	The referral received from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. In order to be able to develop guidance on this area within the requisite time, this piece of work will develop recommendations, in line with the currently accepted clinical pathways, up to the point of the first test. We will however discuss the need for guidance in this area with the Centre for Clinical Practice and the Department of Health. Depending upon

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				the outcome of these discussions we will return to stakeholders if an additional referral is sent through, or if not, whether there is a need to extend the current remit.

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Bristol Specialist Drug and Alcohol Service, Avon and Wiltshire Mental Health Partnership Trust		(b)	People are more likely to seek and accept a test when they trust the person doing the test	Thank you. When developing the guidance the committee will examine the barriers and facilitators to testing.
Bristol Specialist Drug and Alcohol Service, Avon and Wiltshire Mental Health Partnership Trust			Or when they have heard positive reports re testing from peers	Thank you, please see previous comment
Bristol Specialist Drug and Alcohol Service, Avon and Wiltshire Mental Health Partnership Trust			When the test is pain free	Thank you, please see previous comment
Bristol Specialist Drug and Alcohol Service, Avon and Wiltshire Mental Health Partnership Trust		Q3	In my experience, professionals need to be taught, and reminded of something repeatedly over a prolonged period of time, before it becomes the norm for them to do.	Thank you, please see previous comment
Bristol Specialist Drug and Alcohol Service, Avon and Wiltshire Mental Health Partnership Trust		Q4	Service users are most likely to stay engaged with treatment if they are seen by the same person (or small team of people) who offer consistent care, and give consistent messages. For example, if I test someone, and they are HCV positive, I am able to see them with the Hepatology Clinical Nurse Specialist within the months to begin to engage with pre	The referral received from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. In order to be able to develop guidance on this area within the requisite time, this piece of work will develop recommendations, in line with the currently accepted clinical pathways, up

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			treatment tests, and within a couple of months to start treatment. A smooth, uncomplicated carepathway means there are less chances for the service user to disengage.	to the point of the first test. We will however discuss the need for guidance in this area with the Centre for Clinical Practice and the Department of Health. Depending upon the outcome of these discussions we will return to stakeholders if an additional referral is sent through, or if not, whether there is a need to extend the current remit.

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Bristol Specialist Drug and Alcohol Service, Avon and Wiltshire Mental Health Partnership Trust			Drugs workers need to know who to contact, and when. A lot of BBV/ Harm reduction nurses clinical time is used up promoting their service and educating other services about blood borne viruses.	Thank you. When developing the guidance the committee will take into account issues around education and how this affects the retention of individuals within services.
Birmingham Drug and Alcohol Action Team		General comments	• As the screening technologies are very similar, there is a strong argument to include HIV testing at the same time. There is a huge amount of overlap with respect to accessing this hard to reach group.	Thank you for your comment. The referral from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. As such an assessment of the cost effectiveness of simultaneously testing for other blood borne viruses is outside of the scope of this referral. However, when developing the guidance the committee may comment on this issue. Stakeholders can also suggest that guidance is needed in this area via the topic selection process: http://www.nice.org.uk/getinvolved/topicselection/topicselection.jsp
Birmingham Drug and Alcohol Action Team		General comments	• The target audience should include all drug users (not just injecting drug users) as the risks (esp. of Hep B transmission) are still very real in this population.	Thank you for your comment. Section 4.1.1 has been amended to state which groups will be the focus of the guidance and where the evidence allows, which groups the committee will also comment upon.
Birmingham Drug and		General	• Education would be the cornerstone of	Thank you.

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Alcohol Action Team		comments	success, both for services users to combat the anxiety of a positive result and of treatment, and of the healthcare professionals to ensure that accurate, appropriate and myth-free advice is given.	
Birmingham Drug and Alcohol Action Team		General comments	• As well as what has already be suggested, guidance would also need to include; ○ How to interpret the screening results and what to do once the results are known; ○ What harm reduction advice to offer (particularly if the result is negative), including what to do about close contacts; ○ Guidance on follow up, particularly if the test is negative (test again in 3 months) or if the client declines the test; ○ Guidance on interventions that could take place if the screen is positive but before Combi-Rx treatment e.g. delivering a brief intervention for alcohol use (or more intensive work if appropriate) is often relevant and an early (relatively easily achievable) outcome, which may influence disease progression.	The referral received from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. In order to be able to develop guidance on this area within the requisite time, this piece of work will develop recommendations, in line with the currently accepted clinical pathways, up to the point of the first test. We will however discuss the need for guidance in this area with the Centre for Clinical Practice and the Department of Health. Depending upon the outcome of these discussions we will return to stakeholders if an additional referral is sent through, or if not, whether there is a need to extend the current remit.
Birmingham Drug and Alcohol Action Team		General comments	• The guidance should have a strong focus on community-based testing, especially via the	Thank you for your comment.

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			community pharmacy network, which is already highly accessible in terms of opening hours and location. Pharmacies in particular are already being accessed regularly by the target population and see a cohort of potential patients hidden from the rest of the health service. It would be important to emphasize the need for effective communication with the GP once results are known.	
Birmingham Drug and Alcohol Action Team		General comments	• It would seem sensible to have a specific focus on the prison population as the evidence suggestions a disproportionately higher concentration of drug users and migrant populations in these establishments.	Thank you for your comment. The prison setting is included within the scope of the guidance.
Birmingham Drug and Alcohol Action Team		General comments	• If the guidance suggests targets for number of tests performed as an outcome, it should target the number of tests performed on the target populations only.	Thank you for your comment.
Birmingham Drug and Alcohol Action Team		General comments	• Harmonise the terminology. For example, decide on whether it is a "PCR" test or an "RNA" test, the latter being the preferred term for the screening labs.	Thank you for your comment.
Birmingham Drug and Alcohol Action Team		4.3 Q1	As a result of NTA targets around BBV testing, most drug services test for HCV upon a drug users initial presentation for addiction treatment. There is not enough data to suggest that this is the most cost effective approach. Most drug users upon initial	Thank you for your comment. When developing the guidance the committee will assess the best available evidence to determine what is most effective and cost effective at increasing the uptake of testing.

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			presentation at a treatment centre are in a chaotic state with a variety of physical/health and social needs. The potential of having a test which is positive may not help the drug user and may add to their existing problems and may lead to the thinking that their life is hopeless and increase their chaotic lifestyle/drug use and leave the treatment service. Access to testing that takes into account these factors is clearly important. There are a number of advocates for pharmacy-based testing, as this is probably the most easily accessible in terms of location and hours of opening. The additional bonus is where the service user already has a good relationship with the pharmacist from whom (s)he obtains their medication on a daily basis. This becomes even more important where quarterly retesting is advised if risky behaviours are still present. There are other options that could offer additional support. For example, the C Level service in Glasgow offers a peer support service, lead by ex/current HCV positive people, that offers advice/support and buddying for HCV testing and treatment. This type of service was also recently commissioned in Coventry via the HepC Trust. The approach developed by C Level shows that the process required to encourage people into testing (and retesting where risks are still present) is one which is developed over a period of time with drug users and	

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			needs nurturing.	

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Birmingham Drug and Alcohol Action Team		Q2	The C Level service offers the correct level of peer support and mentoring to people who are contemplating testing, yet are deterred from seeking test/treatment either as a result of negative experience in NHS settings by other HCV users, inappropriate testing venues, or are worried that they may test positive. There are users who believe that treatment is ineffective, too difficult to tolerate, and there are no support networks if treatment does become difficult.	Thank you for your comment. When developing the guidance the committee will consider all of the barriers associated with hepatitis testing.
Birmingham Drug and Alcohol Action Team		Q3	There are a number of issues that need to be addressed in order to overcome barriers to testing. These include: Campaigns/training that remove the stigma of HCV, especially with healthcare professionals Awareness campaigns that make people aware that earlier treatment means a better treatment outcome Campaigns that show that HCV treatment does work Campaigns to show that HCV people for whom treatment has failed can live healthy lives Provision of testing and treatment facilities outside of traditional NHS settings/clinics Work with insurance companies to reduce prohibitively expensive life insurance policies/refusal of insurance/mortgages Development of Buddy schemes, like that of those in	Thank you for your comment.

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			Glasgow and Coventry and those previously adopted for people with HIV by the Terrence Higgins Trust Improved counselling for people contemplating testing and post HCV positive result More support for the families of people with HCV, and especially for those in treatment	

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Birmingham Drug and Alcohol Action Team		Q4	More needs to be done to work with people who have tested positive. Peer support and drop in services are required so that anyone who is positive can seek advice/help treatment when they are ready Information should always be communicated that the earlier the treatment, the greater the potential for cure, and provide assurances that they will receive the best possible treatment and support that is close to home, both for the individual and their family	Thank you for your comment.
Bristol-Myers Squibb Pharmaceuticals		General	Bristol-Myers Squibb welcomes the opportunity to participate on the whole process and have no further comments at this stage.	Thank you
British Association for Adoption and Fostering		general	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), in consultation with social care professionals. 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	Thank you

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			comprised of looked after and adopted children and young people.	

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British Association for Adoption and Fostering		4.1.1	It would be useful to specify that the particularly vulnerable population of children who are looked after, including those with a plan for adoption, will be considered. These children not only come from backgrounds which put them at high risk for blood borne infections, but are doubly disadvantaged by lacking committed parental advocacy for high quality health provision. Indeed, for many of them risk of exposure to Hepatitis B and C arises from birth mothers misusing substances during pregnancy (vertical transmission) and early childhood. Furthermore when they become looked after, all too often health and social care agencies which share corporate responsibility fail to identify their risk and offer appropriate interventions. It is also well recognised that young people who are looked after engage in high risk behaviour including substance misuse and sexual activity which places them at high risk of horizontal transmission of hepatitis. The scope and guidance should specifically identify and address this population of children and young people to improve awareness by the diverse professional groups who have the opportunity to engage with them , including general practitioners, sexual health clinics, drug and alcohol services, obstetricians, neonatologists, midwives, as well as medical advisers and specialist nurses for looked after children.	Thank you for your comment. Section 4.1.1 has been amended to state which groups will be the focus of the guidance and where the evidence allows, which groups the committee will also comment upon. Children who are at high risk of HBV and/or HCV infection are within the scope of this guidance either through directly being within an at risk group (e.g. born in a country of high endemicity), or through being the close contact of someone who is within an at risk group. Where appropriate the committee will consider and comment on these issues.

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			It would also be useful to specify that the population of adopted and looked after children also includes asylum seeking refugee children and children adopted from abroad, many of whom were born in countries where the viruses are endemic.	

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British Association for Adoption and Fostering		4.2.2.d	We are confused as to why immunisation is not part of the scope given that this is key intervention for children born to infected mothers and it claims the scope covers all ages. There is a risk that the most vulnerable client group, described above, namely children born to at risk mothers who sometimes DESPITE mother's status being known, still slip through the net. Our medical adviser members regularly see children who have become looked after, who have missed out on neonatal testing and immunisation/treatment, despite their birth mothers' positive hepatitis status being known at delivery.	Thank you for your comment. The referral from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. However, NICE has developed guidance on immunisation: www.nice.org.uk/PH21
British Association for Adoption and Fostering		4.3	The issue of engagement with services must also be addressed. Agreement to undergo testing is only the first step, and innovative services for the most vulnerable may need to be developed so that results are explained and individuals successfully engage in treatment, including immunisation for those not yet infected but continuing high risk behaviour.	Thank you.
Department of Health		Paragraph 2(a)	Could you please consider inserting the words "effective and.." after "..guidance on the most...""..	Thank you for your comment. This section details the wording of the referral received by NICE from the Department of Health. Therefore we are not able to alter this text.
Department of Health		Paragraph 3(b)	This paragraph states that "an estimated 200,000 people in England (0.4%) are chronically infected with the hepatitis C virus. However, only around 38,000 diagnoses have been reported (DH 2004b)." You may wish to be aware that, in the Health Protection Agency's (HPA) 2009 annual report on hepatitis C	Thank you for your comment. The scope document has been amended appropriately.

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			(page 9), there is a more up to date figure: *"By the end of 2008, a cumulative total of 69,865 laboratory-confirmed diagnoses of HCV infection from England had been reported to CfI".*	

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Department of Health		Paragraph 3(e)	We feel that it may be helpful to mention further risk factors for hepatitis C infection, as there are risks other than injecting drug use.	Thank you for your comment. We have amended the scope appropriately.
Department of Health		Paragraph 4.2.1(c)	In this paragraph, we would suggest that NICE mentions increasing access to testing (for example, testing for hepatitis B & C in community settings such as community pharmacies). Pilots around the country have demonstrated a high positivity rate by testing through pharmacies. In our view, this may be related to the fact that some people, who do not access routine NHS services, may access services though community pharmacies based in the heart of communities.	Thank you for your comment. We have amended the scope appropriately.
Department of Health		Paragraph 4.2.1(f)	We consider that it may be helpful to also mention activities, to ensure that people are referred to appropriate services (for example, services to assess and treat hepatitis B or C). In our opinion, one cannot assume that people with positive test results will get "the offer of help".	Thank you for your comment. We have amended the scope appropriately.
Department of Health		Paragraph 4.2.2	We would query whether it is correct to assume that antenatal screening for hepatitis B will not be covered, as there is an established UKNSC screening programme. The UKNSC have not recommended antenatal screening for hepatitis C, although antenatal care may provide the opportunity to test pregnant women at risk of hepatitis C infection.	Thank you for your comment. We have amended the scope appropriately
Department of Health		Paragraph 4.3	Could you please clarify whether there needs to be a question about accessibility of testing, or whether NICE considers this to be implicit in the other questions.	Thank you. Accessibility to testing will be looked at as part of the guidance development process.
Department of Health		General	We would expect the outcome to be a change (that is, an increase) in the numbers of people referred to for specialist care, and treated for hepatitis B and C.	Thank you for your comment the scope has been amended appropriately.

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Department of Health		General **(GROUPS):**	In our view, promotion of testing needs to be conveyed in a wide context, in order not to 'stigmatise' certain groups. However, there is not a 'one size fits all' solution. The principal (but not exclusive) groups, where we believe that promotion needs to be targeted, are: **Intravenous drug users (IVDU):** but recognising that there are at least three distinct groups here where different strategies may need to be adopted, that is, current users, former users who are on a methadone programme, and former users (who may have used these many years in the past, and perhaps even only once).The latter group (often middle aged with significant liver disease) is not an obvious group in primary care. **Ethnic and immigrant minorities:** we feel that this group requires a completely different strategy to the IVDU group, and elements of both vertical (maternal) transmission and horizontal (childhood) factors need to be considered. There are also differences between these groups (e.g. Pakistani & Chinese) and possibly significant cultural issues within some groups that need to be considered (e.g. children & females). Although the focus was on first generation in these groups, we could be storing up problems in the future if we do not consider second generation and contact-family tracing in these groups. **Prison populations:** already have a strategy for vaccination of hepatitis B which has demonstrable	Thank you for your comment. Section 4.1.1 has been amended to state which groups will be the focus of the guidance and where the evidence allows, which groups the committee will also comment upon.

Stakeholder **Organisation**	***Evidence submitted***	***Section***	***Comments*** **Please insert each new comment in a new row.**	***Response*** **Please respond to each comment**
			benefits, but need a coherent plan for testing hepatitis C **Pregnant women and newborns:** need to continue reaching this group, but improve our performance. **People who received blood products before 1991**: although the look-back programme has identified a considerable number of these, they still present de-novo in clinics. We feel that some further effort needs to be made to identify these. **Those who travel abroad for health interventions** (a new group), for which there has been an increasing trend. Unfortunately, one cannot assume that the standard of protection against these viruses is the same in all countries. There are instances of several	

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Department of Health			such individuals being infected abroad. This is partly about awareness, and for the professionals who refer or arrange referral to be aware and test them perhaps before and after. **Sex workers and STD clinics:**	
Department of Health		General **(VIRAL DISEASE)**	Hepatitis B & C are very different viruses, affecting different populations. They have different natural histories and management possibilities. May we therefore suggest that, for the purpose of this guidance, they are considered separately in the first instance. Thereafter, the common elements can be presented. The thrust of the guidance is to identify patients with chronic infection, and one of the points to be emphasised here (which is the stance that the USA has taken) is that this is an important way of prevention primary liver cancer, which is increasing.	Thank you for your comment. When developing the guidance the committee where necessary will consider the two viruses separately.
Department of Health		General **(TESTS)**	There is a very strong feeling that the 'test' should not be the ultimate objective, but that we should focus on the resulting <u>outcome</u> of a positive test. This needs to be considered in two parts, that is, what test is done and how. Also, the action undertaken as a result of the positive test. There is a strong view that this guidance should encompass elements of the advice and referral, resulting from a positive test. In our opinion, commissioners and others should not offer a test without considering what mechanisms and pathways need to be put in place to deal with a positive result. **Hepatitis C**: although an antibody test is the first and least expensive test, we feel that the recommendation should be that the laboratory services automatically check PCR when the antibody is positive (and	The referral received from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. In order to be able to develop guidance on this area within the requisite time, this piece of work will develop recommendations, in line with the currently accepted clinical pathways, up to the point of the first test. We will however discuss the need for guidance in this

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			genotype if feasible), and that the result from the laboratory should include advice on interpretation. This is technically feasible, but not always done. Failure to do this has resulted, and is still resulting in unnecessary referral to secondary care for antibody positive (but PCR negative) patients who have previously been successfully treated, or have spontaneously cleared the virus. Conversely, there are also reports of positive patients being told that there is no treatment available. Clearly, testing needs to be allied to an educational programme for several groups of health professionals. The laboratories could play a major role in this. The 'test' for hepatitis C should therefore be a PCR in combination with an antibody test when positive. **Hepatitis B:** similarly, the 'test' for hepatitis B should include HBsAg and when positive, HBeAg and HBeAb. Most laboratories currently do these, but we feel that NICE could recommend a specific line of advice, as frontline staff in some areas still have difficulty interpreting these.	area with the Centre for Clinical Practice and the Department of Health. Depending upon the outcome of these discussions we will return to stakeholders if an additional referral is sent through, or if not, whether there is a need to extend the current remit.

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Department of Health		General **(OUTCOME/REFERRAL/PATHWAY)**	There is a very strong feeling that 'onward referral' or advice along those lines is insufficient. The RCGP and other groups now produce a wealth of educational material on viral hepatitis, and we feel that there needs to be a strong recommendation to healthcare professionals and organisations, in order to ensure that these are used. There appear to still be some barriers or impediments to the outcome of a positive test (which is not just about treatment) and for this reason, the recommendation should include specific advice for commissioners on the outcome of a positive test. In our view, the figures quoted in (b) are out of date – please see the HPA report 2009 on their website for new figures. Under heading (d), we are surprised at omission of a reference to vertical transmission, though this is inferred in final sentence. Also under this heading there appears to be no reference to national variation or international comparisons, e.g. a recent report on use of expensive medicines (by Mike Richards at the Department of Health) cast hepatitis C treatment in poor light by European comparison. Even Scotland and Wales have invested in "test & treat" strategies. We have previously suggested that under paragraph 4.3, (key questions & outcomes), there should be a Question 5 - *How can commissioners ensure that pathways into testing and from testing to treatment are effective?* Under expected outcomes, could you please consider including the numbers referred to specialist	Thank you for your comment. When developing the guidance the committee will consider all associated barriers and how they affect the uptake of testing, this includes service provision and the education of practitioners. The scope has been amended appropriately

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			centres for treatment (plus outcomes) There appears to be no mention of third sector involvement, e.g., apparently successful pilots in Portsmouth and Blackpool for pharmacies offering testing. We would hope also that NICE can engage the RCGP as a partner in this, as we have identified professional education in primary care as a major issue.	

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Department of Health		General	You may wish to be aware that there is quite a good description of the risks groups for hepatitis C testing in *"Hepatitis C: Essential information for professionals and guidance on testing"* at: http://www.nhs.uk/hepatitisc/hcp/resources-for-you/Pages/information-and-guidance-on-testing.aspx There is also the quick reference guide on hepatitis C for primary care at: http://www.nhs.uk/hepatitisc/hcp/resources-for-you/Pages/a-quick-reference-guide-for-primary-care.aspx	Thank you
Dept of Home Affairs, Isle of Man		4.1	Informed consent is the key essence to any screening because it has to cover communication of risk (relevant Reference: BMJ 2010;341:c4830 doi:10.1136/bmj.c4830)	Thank you
Dept of Home Affairs, Isle of Man		4.2; 4.3	None of the activities actually explain what screening is; this list of "activities" does not represent 'screening tests' and 4.3 is somehow disjointed as none of the listed outcomes are in fact outcomes. What is screening? (the Scoping fails to introduce this in the Background) Screening is not, as sometimes supposed, a new concept. The entry point into a screening programme may differ, whether this is a port of entry into a country, a health facility or a service, or some other type of service where a screening test is applied in accordance with a policy and individuals are then 'filtered' in two broad	Thank you for your comment. Screening programmes are outside the remit of this guidance as they are covered by the National Screening Committee (www.screening.nhs.uk). When developing the guidance the committee are likely to consider the issue of the pre-test discussion, the associated content of such discussions and how they affect the uptake of testing. As part of the development of the guidance there

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			categories: "probably" with disease/condition or "probably" healthy; screening is a continuous process, which if applied in accordance with defined inclusion and exclusion criteria (including interval times), may identify those who "probably" have the condition under study from those who "probably have not" got it. Yet, some who "probably have got" the condition may still slip out the detection process (false negatives) or, some who "probably have not got" it may fall into the category of "probably with condition" (false positives). The implication of "false" results needs to be picked up in the communication of risks involved. These are not risks regarding the impact of "brief counselling", but the real implications of what it means if treatment is not available, available but not affordable, etc. E.g. communicating the risk of death to a patient is a very sensitive matter and for anyone to break that news. The implications are enormous The false positive and false negative results have also a huge implication in how risk (for what's next) is communicated to an individual and their close contacts (see above reference) The principles of screening are, or should be universally applied, and amongst them also aspects of universal ethical principles, and the principles of equity and equality prevail (Wilson and Jungner, 1968 and Cuckle and Wald, 1984); Three of their principles stand out in this case and are most likely not to be fulfilled in practice regarding this Scoping as it stands: "Facilities for diagnosis and treatment should be	will be an assessment of the cost effectiveness of any intervention and the committee will base their recommendations on these findings. In addition when developing the guidance the committee take into account issues related to equity. However, issues relating to treatment are outside the remit of this guidance. The referral received from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. In order to be able to develop guidance on this area within the requisite time, this piece of work will develop recommendations, in line with the currently accepted clinical pathways, up to the point of the first test. We will however discuss the need for guidance in this area with the Centre for Clinical Practice and the Department of Health. Depending upon the outcome of these discussions we will return to stakeholders if an additional referral is sent through, or if not, whether there is a need to extend the current remit.

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			available" "There should be an agreed policy on whom to treat as "patients" – in other words the criteria need to be pre-defined and clearly communicated to those offered the screening along with the offered informed consent "The cost of case finding (including diagnosis and treatment of patients *diagnosed*) should be economically balanced in relation to possible expenditure on medical care as a whole. On a practical level outcomes are: survival, disability and quality of life (individual and/or individual and family)	

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Dept of Home Affairs, Isle of Man		Appendix B	Regardless of who is the target population it is clear that the universal principles for screening should be consulted and applied The critical elements are relevant but not well presented (e.g. 'content and intensity of intervention – what does this mean? whether 'it is effective and cost-effective – again, the context is missing and this is a pure statement; whether the "test" (not intervention) targets specific individuals or populations – this is not clear what it means) etc.	Thank you for your comment. Screening programmes are outside the remit of this guidance as they are covered by the National Screening Committee (www.screening.nhs.uk). The term intervention has been used as it encompasses activities such as community engagement or one to one discussions which can target communities or individuals respectively.
Dept of Home Affairs, Isle of Man		General	The development of this guidance cannot be done without the other PDGs. Treatment availability and affordability is a key ethical aspect along with informed consent and risk communication (cross-border services which have language barriers, too if 'migrants' from endemic areas are to be offered the test) In summary: The draft does not address any of the above and uses the term 'intervention' instead of 'test'; Screening means that a 'disposal' element is engaged after a screening test is applied; disposal means either: diagnostic and treatment + risk communication in those who "probably" have the condition or, allow re-entrance in the screening cycle based on evidence of a temporal efficiency cycle (bi-annually, annually, every 2 years, etc re window of infectivity); Ethical issues: e.g. lost to follow-up (what to do) should not be understated for implications.	Thank you for your comment. While developing this guidance the committee will take into previous and ongoing pieces of relevant NICE guidance. NICE has already produced guidance on the most cost effective treatments for Hepatitis B and C. These are listed within Section 6 of the scope. The term intervention has been used as it encompasses activities such as community engagement which can increase the number of people willing to take a test.

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Dudley DAAT		General	The guidance covers all the areas of activity and need that staff working in the Drugs field have been aware of for many years. Most DAATs have already addressed and implemented a number of the proposed activities and put in place services to address the issue of Hepatitis B and C amongst drug users, their families and friends. Currently in Dudley we have a good practice care pathway that has been developed by our BBV Nurse which includes testing pregnant women and an immunisation programme with public health for neonates, close contacts and family members. Young people have access to screening testing and treatment through the young people's Tier 3 Substance Misuse Service alongside general health assessments.	Thank you.
East Cheshire NHS Trust		3D	Need to include the high risk of vertical transmission (especially if baby does not receive immunoglobulin / commence the vaccination process). It is also recommended that all household contacts of a Hepatitis B positive individual receive the vaccinations.	Thank you for your comment. We have amended the scope appropriately.
East Cheshire NHS Trust		4.1.1	I do not think that this guidance should be aimed at just injecting drug users and first generation ethnic origin. If this happens then misleading messages will be sent to the public and to other health professionals. All health professionals working in this field are trying to de-stigmatise these conditions therefore the guidance needs to be aimed at anyone who could possibly be infected.	Thank you for your comment. Section 4.1.1 has been amended to state which groups will be the focus of the guidance and where the evidence allows, which groups the committee will also comment upon.

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East Cheshire NHS Trust		4.2.1. (a)	Despite two national campaigns there still is a lot to be done to raise awareness. But again if this guidance is aimed at the testing of just two high risk groups mixed messages are going to be sent out and there is a risk of the number being tested not increasing. In my clinic many of those patients who attend have not been infected through these two routes. There need to be guidelines in place to prompt those in both primary and secondary care to consider testing.	Please see previous comment.
East Cheshire NHS Trust		4.2.1 (c)	It is important that a pre-test discussion is still recommended and not omitted in order to increase the number being tested.	Thank you.
East Cheshire NHS Trust		4.2.2	Having experienced false negative antibody results (Hepatitis C) with DBS, I think that this should be examined by the institute.	The referral received from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. In order to be able to develop guidance on this area within the requisite time, this piece of work will develop recommendations, in line with the currently accepted clinical pathways, up to the point of the first test. We will however discuss the need for guidance in this area with the Centre for Clinical Practice and the Department of Health. Depending upon the outcome of these discussions we will return to stakeholders if an additional referral is sent through, or if not, whether there is a need to extend the current remit.
East Cheshire NHS Trust		4.3 (Q2)	Many intravenous drug users are needle phobic, many assume they already have the condition and some are	Thank you for your comment. As part of the guidance development process the committee

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			too scared to be tested.	will consider all of the barriers that are associated with testing.
East Cheshire NHS Trust		4.3 (Q3)	Although pharmacy testing has it's place I have concerns about the advice being given to the individual and the follow up / support post testing.	Thank you.
East Cheshire NHS Trust		4.3 (Q4)	Have a care pathway in place to secondary care Well trained staff Good unambiguous written information.	Thank you.
Firmley Park Hospital		General	Holistic consideration of patient care to include discussion of HIV testing.	Thank you for your comment. The referral from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. However, when developing this guidance the committee may comment upon other risk factors for certain populations.
Firmley Park Hospital		3d	Clear guidelines for assessment of risk factors including prior risk factors.	Thank you.
Firmley Park Hospital		3d	Guidelines should include all drug users.	Thank you for your comment. Section 4.1.1 has been amended to state which groups will be the focus of the guidance and where the evidence allows, which groups the committee will also comment upon.
Firmley Park Hospital		4.2.1. c and d	Algorithm to provide clear guidelines about which test is relevant.	The referral received from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. In order to be able to develop guidance on this area within the requisite time, this piece of work will develop recommendations, in line with the currently accepted clinical pathways, up

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				to the point of the first test. We will however discuss the need for guidance in this area with the Centre for Clinical Practice and the Department of Health. Depending upon the outcome of these discussions we will return to stakeholders if an additional referral is sent through, or if not, whether there is a need to extend the current remit.

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Firmley Park Hospital			Clearer interpretation of results for medical staff and patient.	Please see previous comment.
Firmley Park Hospital			Connection to be made clear regarding next step for medical staff referral process and patient	Thank you for your comment.
Gilead Sciences Limited		4.1.1 Groups that will be covered	People at risk including those born in countries where the viruses are endemic. What level of prevalence will be regarded as endemic? i.e. > 2%, > 5% or > 8%?	Thank you. For the purposes of this guidance we will use the WHO classifications. We will consider those born in countries of intermediate (2 to 8%) and high endemicity (>8%).
Gilead Sciences Limited		4.2.2 Activities that will not be covered.	b) Tests to confirm chronic infection. To prevent further distress and unnecessary worry to the patient the guidance should recommend confirmatory tests for chronic/active infection and linkage into appropriate care pathways.	The referral received from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. In order to be able to develop guidance on this area within the requisite time, this piece of work will develop recommendations, in line with the currently accepted clinical pathways, up to the point of the first test. We will however discuss the need for guidance in this area with the Centre for Clinical Practice and the Department of Health. Depending upon the outcome of these discussions we will return to stakeholders if an additional referral is sent through, or if not, whether there is a need to extend the current remit.
Health Protection Agency		General	1. The epidemiology of hepatitis B and C are different in the UK. Whilst there are some overlaps, there are substantial differences. For example IDU's are at increased risk for hepatitis C in particular (as well as	Thank you for your comment.

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			HBV). However current IDUs are a different population to ex-IDUs, particularly those individuals that may have injected many years ago and who no longer consider themselves to be at risk or to be an IDU. The recommendations need to reflect that different populations may want or need to access testing differently. Therefore awareness raising activities will need to be different to reach these different population groups.	

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Health Protection Agency			2. When considering where testing should take place or be offered, there is a difference with respect to yield (i.e. what proportion of the people tested in that setting were positive) versus absolute numbers. HPA data show that whilst a high yield of positives can be identified by testing individuals attending specialist drug services and prisons, a large absolute number of positive individuals can be identified by General practitioners (although low proportion testing positive).	Thank you for your comment.
Health Protection Agency			3. Ethnicity (and/or country of birth) is important for both HCV and even more so for HBV. Individuals from black and minority ethnic populations may use health services differently to the white-British population. It would be important to consider the role of ethnicity in the recommendations.	Thank you for your comment.
Health Protection Agency			4. Educating GP's about how to identify individuals at higher risk for hepatitis B and C is important – as gate keepers their ability to elicit risk factors and recommend testing may be an important element to improving testing for HBV and HCV.	Thank you for your comment.
Health Protection Agency			5. Sign posts are required in the guidelines to other relevant documents and areas – such as immunisation (Green Book – for contacts), testing of HIV positive individuals (BHIVA), renal patients, antenatal screening for HBV and suggestions about contact tracing for HBV.	Thank you for your comment. Where appropriate the final guidance document will refer to other relevant guidelines.
Health Protection Agency			6. Hepatitis B and C testing currently takes part in many parts of the health and prison services. This contrasts to HIV which tends to be focused among antenatal services and sexual health clinics. It would be important to maintain this diverse range of services	Thank you for your comment.

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			providing HBV and HCV testing, rather than to restrict it.	

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Health Protection Agency		Section 4.1.1	1. For hepatitis B, sexual transmission is an important risk factor, so the groups covered should ideally include those individuals at increased risk of acquiring hepatitis B due to higher risk sexual activities – such as men who have sex with men (MSM) and sex workers.	Thank you for your comment. Section 4.1.1 has been amended to state which groups will be the focus of the guidance and where the evidence allows, which groups the committee will also comment upon.
Health Protection Agency			2. It would be helpful if the document clearly outlines what they define as 'at risk groups' as targeted activities will vary enormously and it will assist in ensuring that groups are not missed.	Please see previous comment.
Health Protection Agency		Section 4.2.1 (b)	1. Thought should go into where services may be based e.g. cultural/minority group centres	Thank you.
Health Protection Agency		Section 4.2.1 (c)	1. It would be useful if the guidance included the acceptability of dried blood spot (DBS) testing to patients and to those undertaking the testing (healthcare workers and others). This is a key question we need to answer in terms of DBS being a new testing modality. However, any answers to the questions would need to be interpreted in the light of the lower sensitivity of DBS samples compared to venous samples.	Thank you for your comment. The referral received from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. When developing recommendations on how best to increase the uptake of testing possibly through the form that any sample takes, the committee may consider issues pertaining to sensitivity and specificity.
Health Protection Agency		Section 4.2.2	1. Education and guidelines about what types of tests should be requested is important. For example, testing for hepatitis C should include both an antibody and an RNA test. For hepatitis B, HBsAg is important to identify current infection.	The referral received from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. In order to be able to develop guidance on this area within the requisite time, this piece of work will develop recommendations,

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				in line with the currently accepted clinical pathways, up to the point of the first test. We will however discuss the need for guidance in this area with the Centre for Clinical Practice and the Department of Health. Depending upon the outcome of these discussions we will return to stakeholders if an additional referral is sent through, or if not, whether there is a need to extend the current remit.

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Health Protection Agency			2. The reason for testing is to ensure that individuals are treated to prevent development of liver disease and/or cancer (and to prevent onward transmission). Some consideration needs to be given on accessing treatment. This should be a consideration of the cost-effectiveness of testing certain populations.	Thank you for your comment. In the process of developing the guidance the cost effectiveness of certain interventions aimed at increasing the numbers through testing will be carried out.
Health Protection Agency		4.2.2 (a) & 4.3 Question 3	1. Will near-patient testing be evaluated?	Thank you for your comment. A range of interventions will be assessed as part of the evidence review process. These reviews will assess the best available evidence and will evaluate near patient testing if it meets the inclusion/exclusion criteria for the evidence reviews.
Health Protection Agency		Section 4.3	1. The HPA currently monitor testing for hepatitis B and C (plus HAV) so changes to testing may be evaluated. However, it would be challenging to attribute increases in testing directly to recommendations, as other bodies (DH and charities) regularly conduct awareness campaigns.	Thank you for comment.
Health Protection Agency		4.3 Question 4	Perhaps this should be encourage rather than ensure. More important to review: what support is required, appropriate communications, referral streams and how to prevent loss to follow up and unnecessary repeat testing.	Thank you for your comment the scope document has been amended appropriately.
National Needle Exchange Forum		2 c)	We feel that this guidance should also support “Models of Care for Treatment of Adult Drug Misusers: Update 2006” by the National Treatment Agency, which offers specific guidance on services providing access to BBV testing (specifically, HBV, HCV and HIV).	Thank you for your comment. The scope has been amended appropriately.
National Needle		4.1.1	We feel that this guidance should specifically mention	Thank you for your comment. Section 4.1.1 has

Stakeholder **Organisation**	***Evidence submitted***	***Section***	***Comments*** **Please insert each new comment in a new row.**	***Response*** **Please respond to each comment**
Exchange Forum			the inclusion former injecting drug users with no recent history of drug use (i.e. not just those who may have recently left treatment services). This might include recalling former HBV infected patients who have never been tested for HCV prior to the virus being isolated in 1989. We feel this guidance should specifically include the children of HCB/HBV positive mothers, (and the pregnant partners of HCV/HCV positive males). There is currently local variation regarding the testing of pregnant mothers for HCV and even if the mother is known to be a current/former IDU, it cannot be assumed that maternity services are routinely offering HCV testing in these cases (to the pregnant mother or the child). We feel that attention should be given to high risk non-injecting drug user groups, particularly: a) Crack cocaine users (due to the risk of blood blood transmission from open mouth wounds/sores from sharing crack pipes). b) Cocaine hydrochloride snorters (due to the risk of blood-blood transmission from nasal passage injuries from sharing shorting tubes). c) There should also be close consideration to how those problematic drug users who are transitioning to injecting drug use from a non-injecting route are targeted. In particular, those who are injected by a peer (this is a common practice for those who initially	been amended to state which groups will be the focus of the guidance and where the evidence allows, which groups the committee will also comment upon.

Stakeholder **Organisation**	***Evidence submitted***	***Section***	***Comments*** **Please insert each new comment in a new row.**	***Response*** **Please respond to each comment**
			transition into injecting) as they may not specifically identify them self as an injecting drug user. d) Commercial sex workers may also benefit from BBV screening as they are may be engaging in high risk sexual practices (particularly in relation to HBV transmission) and may also be injecting drug users/crack cocaine users. Services working with Commercial Sex Workers may need to also be involved with the implementation of this guidance. We feel the guidance should also consider those at risk groups who decline testing when offered and offer guidance on how, and when, these individuals should be followed up and re-offered testing at a later date (in order that they are not "lost in the system").	

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National Needle Exchange Forum		4.1.1 continued	The guidance may also wish to give consideration to other high risk practices including tattooing, body piercing, high risk "BDSM" sexual practices. It is of note that much of the Australian HCV guidance has specifically included risks from clandestine tattooing/body piercing. We are aware that other key at risk groups (e.g. recipients of high risk/unscreened blood products or who have received invasive medical treatment in high risk countries) may need to be included in the guidance. We would ask that the scope also clarifies whether those individuals who are at a high occupational risk of HCV/HBV exposure should be included in the guidance and if not, which other guidance would cover this group. This may include those workers who administer HCV/HBV testing.	Please see previous comment. The Department of Health has released guidance on hepatitis B and C for health workers: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_073132
National Needle Exchange Forum		4.2.1 c)	We feel this should specifically include activities which target workers/services involved in BBV testing/promotion of testing, and not just the target groups for testing.	Thank you for your comment. When developing the guidance the committee will consider activities targeted at workers/services.
National Needle Exchange Forum		4.2.1 f)	We agree with this activity but would advise that it is our knowledge that in some areas of England some services have offered BBV testing, specifically HCV testing, on the condition that the person must sign consent to be referred to a liver specialist unit if the test result is positive and have declined to test those who do not consent to such a referral. Whist we would always like to see good pathways and implementation	Thank you for your comment. The committee will consider the issue of referral into appropriate services.

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			of these to enable HCV positive patients access the correct treatment services, we would not advocate that such coercion is used and would like to see any guidance does not endorse or encourage this practice. We also feel this would be an appropriate place to include in the guidance scope clarity on how the guidance will bridge the "grey area" between this (testing) guidance and existing HCV treatment guidance, e.g. by considering effective care pathways.	

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National Needle Exchange Forum		4.2.1 – general	We feel that the guidance should also specifically explore and ideally identify which types of services and professional groups could be offering HCV/HBV testing and would be keen to see this added as an additional activity/separate bullet point under this section.	Thank you for your comment. It is planned that these aspects will be considered during the guidance development process.
National Needle Exchange Forum		4.2.1 – general	We feel this guidance should also consider recommendations on documentation and reporting tools used in BBV testing, in particular a clear BBV risk assessment tool (identifying whether an individual should be offered testing) and clear guidance on how test results are communicated from the lab to the testing service (i.e. plain English explanation of the meaning of results).	Thank you for your comment.
National Needle Exchange Forum		4.2.2 a)	We accept that this is intervention guidance and not technical guidance and therefore cannot evaluate the validity or effectiveness of different diagnostic tests. However we do feel that this guidance will need to specifically consider and make reference to the range of different available diagnostic methods for HCV/HBV testing and their potential limitations/benefits, as this would have a considerable implication for implementation.	Thank you for your comment. It is likely that the committee will consider these issues when developing the guidance.
National Needle Exchange Forum		4.2.2 b)	We are disappointed that it has been proposed that the sequence and type of diagnostic tests used to confirm whether someone is chronically infected has been specifically excluded in the draft scope. We feel strongly that with regards to HCV testing, this guidance should end at the point of diagnostic confirmation (i.e. should include guidance on offering PCR RNA testing to confirm an active HCV infection). This may be more cost effective (reducing the number of referrals to a	The referral received from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. In order to be able to develop guidance on this area within the requisite time, this piece of work will develop recommendations, in line with the currently accepted clinical pathways, up to the point of the first test.

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			specialist liver team) and is a more humane response (it has been our experience that many injectors have been so unduly concerned or confused about their HCV anti-body positive results that they have disengaged from services before ever knowing their true diagnosis).	We will however discuss the need for guidance in this area with the Centre for Clinical Practice and the Department of Health. Depending upon the outcome of these discussions we will return to stakeholders if an additional referral is sent through, or if not, whether there is a need to extend the current remit.

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National Needle Exchange Forum		General	We feel the guidance should consider the cross-over of this guidance with HIV testing, given that some of the transmission risks are the same. This may also include consideration of the differences and the similarities between HIV risk viral hepatitis risks.	Thank you for your comment. Where appropriate the guidance will refer to other pieces of NICE guidance. NICE is currently two pieces of guidance on HIV testing: Increasing the uptake of HIV testing to reduce undiagnosed infection and prevent transmission among black African communities living in England http://guidance.nice.org.uk/PHG/Wave19/3 Increasing the uptake of HIV testing to reduce undiagnosed infection and prevent transmission among men who have sex with men http://guidance.nice.org.uk/PHG/Wave19/4
National Needle Exchange Forum		General	We feel this guidance should consider the differences between HCV and HBV transmission risk factors and high risk groups and ensure that the guidance does consider the differences (and similarities) with these two infections.	Thank you for your comment. When developing the guidance the committee are likely to consider the differences and similarities between HBV and HCV.
National Needle Exchange Forum		General	We feel that NICE may need to remain watchful of the proposed changes to the UK drug treatment system throughout the guidance development period as this may have an impact for implementation (i.e. the drug treatment system, which is likely to be implementing a fair portion of this guidance, may be a very different treatment system in 2012).	Thank you for your comment.
National Needle		General	We feel that this guidance will need to balance the	Thank you for your comment. Section 4.1.1 has

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Exchange Forum			need to appropriately weight its emphasis on the key high risk HCV transmission groups (injecting drug users) and the risk of stigmatising this virus. Specifically, over-identification of HCV with injecting drug use could be counter-productive to the aims of implementing an expansive testing scheme.	been amended to state which groups will be the focus of the guidance and where the evidence allows, which groups the committee will also comment upon.
National Needle Exchange Forum		General	We feel that the guidance will need to offer specific guidance on the frequency at which individuals who continue to be at risk of transmission should be re-tested after negative test results (including consideration of "window" periods).	Thank you for your comment.
National Needle Exchange Forum		General	We would recommend that the guidance uses the terminology of "pre and post testing discussion" (as per DH guidance) as opposed to counselling. Some services have previously been reluctant to offer testing with "counselling" has inferred the need for qualified/accredited counsellors to provide this service.	Thank you.
National Needle Exchange Forum		General	We feel that this guidance could make clear recommendations for anonymised data collection and reporting on testing uptake and results as this would be extremely useful from both an epidemiological and a service planning/provision point of view.	Thank you for your comment. When developing the guidance the committee will consider those aspects that could have a positive effect on the uptake of testing.
National Needle Exchange Forum		General	We feel that the guidance should also include clarity on best practice regarding issues of confidentiality. In particular we would like to see guidance regarding medical record keeping and the passing on of information relating to testing (whether accepted or declined) and results (whether positive or negative) to third parties (e.g. employers, insurance companies, mortgage providers).	Please see previous comment
National Treatment		General	People who inject anabolic steroids and other	Thank you for your comment. Section 4.1.1 has

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Agency			performance and image enhancing drugs (PIED). A recent report from the Advisory Council on the Misuse of Drugs (Sept 2010) on anabolic steroid users suggested that there may be a significant group of PIED users who do not access needle and syringe programmes (NSPs) because of associated stigma with injecting opioid users. The report also stated that harm reduction interventions such as NSP are the mainstay of treatment provision for this client group. Being at risk of contracting HCV and HBV, access to testing for this group should be considered alongside that for other (opioid/crack) injectors.	been amended to state which groups will be the focus of the guidance and where the evidence allows, which groups the committee will also comment upon.
National Treatment Agency		General	Need for pre and post-test counselling/advice to encourage people, especially injecting drug users at risk of HCV, to be tested and to take appropriate action following their result. This could include successfully completing treatment for their illness.	Thank you for your comment. It is likely that these areas will be considered by the committee.
National Treatment Agency		General	Identification of barriers which may make IDUs less likely to take up the offer of an HCV test, or referral into HBV vaccination or HCV treatment. This could include barriers to testing in a range of different settings, such as structured treatment services, NSPs, or pharmacies. This would be particularly relevant for those who are considered 'treatment naïve' or who have no contact with harm reduction or treatment services.	Thank you for your comment. It is likely that these areas will be considered by the committee.
National Treatment Agency		General	Activities undertaken by primary care providers to identify, test and refer to treatment, those who are at increased risk of HCV or HBV. It could also consider	Please see previous comment.

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			the role of pharmacies which currently run NSPs, and the enhanced role they could play in offering and providing testing and referral to specialist treatment for HCV and HBV.	

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National Treatment Agency		General	Analysis of activity which is most useful at ensuring injecting drug users follow up on referral to treatment, by looking at the systems in place to link between the referral source which carried out testing (e.g. a Tier 2 drug treatment service) and the specialist treatment service (e.g. HCV treatment provider).	Thank you for your comment.
National Treatment Agency		General	Assessment of the effectiveness of interventions which follow testing, for example harm reduction interventions/advice to ensure that people who test positive for HCV or HBV engage in less risky injecting practices.	The referral received from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. In order to be able to develop guidance on this area within the requisite time, this piece of work will develop recommendations, in line with the currently accepted clinical pathways, up to the point of the first test. We will however discuss the need for guidance in this area with the Centre for Clinical Practice and the Department of Health. Depending upon the outcome of these discussions we will return to stakeholders if an additional referral is sent through, or if not, whether there is a need to extend the current remit.
National Treatment Agency		General	We also think that the section outlining the evidence of need would benefit from reference to the Health Protection Agency Shooting Up data on hepatitis B and C infections amongst injecting drug users, since such a high proportion of this group have contracted these viruses.	Thank you for your comment, the scope does include data on hepatitis B and C infection within injecting drug users. These sources have been chosen to allow the epidemiology of infection to be compared across

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				the various at risk groups.

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National Users' Network		3d	The definition of household has caused problems for our members. In that some organisations take it to mean a hostel with shared kitchen and bathroom facilities. This has caused some of our members to be concerned about confidentiality and to thus refuse testing.	Thank you for your comment. When developing the guidance will consider barriers to the uptake of testing, this may include the definitions of certain terms.
National Users' Network		3e	Other groups at risk need to be considered – including non-injecting drug users. There seems to be a higher prevalence amongst this group. Research is unsure as to whether this is due to sharing of paraphernalia (such as tubes/straws) or higher sexual risk taking behaviour (including sex working).	Thank you for your comment. Section 4.1.1 has been amended to state which groups will be the focus of the guidance and where the evidence allows, which groups the committee will also comment upon.
National Users' Network		General	A number of those at risk decline testing because they "assume" that they have it anyway. Or assume that they have been tested in prison or hospital as part of routine testing. Or they have a number of misconceptions about the effectiveness of treatment and/or the severity of side effects.	Thank you for your comment. When developing the guidance the committee will consider the associated barriers and facilitators to increasing the uptake of testing.
National Users' Network		4.2.1f	The manner in which consent for testing is given is a concern for our members. Some individuals have felt that they didn't fully understand all of the tests that they were given when presenting with an un-related health problem (eg abscess from injecting)	Thank you, please see previous comment.
National Users' Network		4.2.1f	Concern was expressed with how test results were communicated. Eg on discharge from prison, or by letters sent to c/o addresses.	Thank you, please see previous comment
National Users' Network		4.3	A consideration of what advice should be given to individuals who decline a test/receive a negative result, that may be continuing with high risk behaviours.	Thank you for your comment. When developing the guidance the committee is likely to consider issues around the pre and post

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				discussion.

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NHS Peterborough PCT		4.1.1	There is a need here to define who is at risk (particularly including Midwives, healthcare workers in this field, and the prison population). Hepatitis B and C needs to be differentiated.	Thank you for your comment. Section 4.1.1 has been amended to state which groups will be the focus of the guidance and where the evidence allows, which groups the committee will also comment upon.
NHS Peterborough PCT		4.1.2	The criteria needs defining	Thank you for your comment. The scope has been clarified.
NHS Peterborough PCT		4.2.1 (b)	Define where it can be done and where the follow up advice will be, (staff should be trained in giving 'bad / sensitive news and access to treatment plan	Thank you for your comment. It is the final guidance document that will state where testing can be carried out and where any discussions should take place.
NHS Peterborough PCT		4.2.1 (C)	Consideration needs to be given to finger prick testing and if the referral pathway would include a liver biopsy which is not necessarily required.	The referral received from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. In order to be able to develop guidance on this area within the requisite time, this piece of work will develop recommendations, in line with the currently accepted clinical pathways, up to the point of the first test. We will however discuss the need for guidance in this area with the Centre for Clinical Practice and the Department of Health. Depending upon the outcome of these discussions we will return to stakeholders if an additional referral is sent through, or if not, whether there is a need to extend the current remit.
NHS Peterborough		4.2.1 (d)	Requirement for regular / access to GP training,	Thank you for your comment.

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PCT			medical student training, nurse training, people working in the field and hospital staff.	
NHS Peterborough PCT		4.2.2 (a)	Evaluation of the validity of relevant test is an effective diagnostic tool. It would be much better if NICE recommended a test or further reading, such as Manchester microbiology partnerships report for the dry blood spot test.	The referral received from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. In order to be able to develop guidance on this area within the requisite time, this piece of work will develop recommendations, in line with the currently accepted clinical pathways, up to the point of the first test. We will however discuss the need for guidance in this area with the Centre for Clinical Practice and the Department of Health. Depending upon the outcome of these discussions we will return to stakeholders if an additional referral is sent through, or if not, whether there is a need to extend the current remit.
NHS Peterborough PCT		4.2.2 (b)	This would be key to assist in commissioning full testing and treatment pathway.	Please see previous comment.
NHS Peterborough PCT		4.3 Question 1	Dr Cartmel recommends having access to dry blood spot testing, which is low intensity and does not involve staff being highly trained. There is also a need to change the attitude and knowledge of: professionals, at risk group, and close contacts. Specific advice about testing of people working with	Thank you for your comment. Guidance on this issue has already been

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			people who are positive or high risk The details would also be required regarding the type of test, the cost, the process and implications of different types of tests and the expected timescales. Direction if someone had previously tested negative – how often do you test?	developed by the Department of Health: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_073132 Please see previous comment regarding the type of test. Thank you

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NHS Peterborough PCT		4.3 Question 2	Information available and counselling once a diagnosis is made- the fact that it is a curable disease and they may not necessarily require a liver biopsy an ultrasound would be preferable.	The referral received from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. In order to be able to develop guidance on this area within the requisite time, this piece of work will develop recommendations, in line with the currently accepted clinical pathways, up to the point of the first test. We will however discuss the need for guidance in this area with the Centre for Clinical Practice and the Department of Health. Depending upon the outcome of these discussions we will return to stakeholders if an additional referral is sent through, or if not, whether there is a need to extend the current remit.
NHS Peterborough PCT		4.3 Question 3	Training staff involved in the care of patients who would require Hepatitis C testing.	Thank you for your comment
NHS Peterborough PCT		4.3 Question 4	Provision of local services (If provision is to many miles away patients will not attend).	Thank you for your comment.
NHS Peterborough PCT		EXPECTED OUTCOMES	It is imperative that a direction is given to a Care Pathway following a diagnosis which is linked to available treatment and any onward referral recommendations Include data with number of patients tested, how many people are positive to B and C	The referral received from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. In order to be able to develop guidance on this area within the requisite time, this piece of work will develop recommendations,

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				in line with the currently accepted clinical pathways. ,

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NTA		4.1.1	Group that will be covered I believe should also include those who work in the sex industry	Thank you for your comment. Section 4.1.1 has been amended to state which groups will be the focus of the guidance and where the evidence allows, which groups the committee will also comment upon.
RCGP Sex Drugs and HIV Group		4.2	Should include indications for suggesting testing to people isuch as abnormal LFTs, chronic fatigue as well as targeting risk groups	Thank you for your comment. When developing the guidance the committee will assess the risk factors which should indicate to a professional that a test should be offered.
RCGP Sex Drugs and HIV Group		4.2	Should also look at outreach testing and testing in innovative ways to reach people at risk of infection ,not relying on traditional testing venues which may not be accessible to those at risk. Testing as an integrated part of the care of drug users and testing in prisons should be part of this.	Thank you for your comment.
RCGP Sex Drugs and HIV Group		4.2	Should consider prevention activities linked to testing activities to ensure those at risk are moved towards not being at risk in the future	Thank you for your comment. The referral from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. As such an assessment of prevention activities is outside of the remit of this guidance. However, while developing this guidance the committee will take into account and where appropriate comment upon relevant prevention activities.
Royal College of Nursing		General	The Royal College of Nursing welcomes proposals to develop this guideline. It is timely.	Thank you
Royal College of		General	It is important to access hard to reach communities by	Thank you for your comment.

***Stakeholder* Organisation**	***Evidence submitted***	***Section***	***Comments*** **Please insert each new comment in a new row.**	***Response*** **Please respond to each comment**
Nursing			training individuals from different cultural backgrounds to raise awareness and offer testing close to that population.	
Royal College of Nursing		4.1	The remit of who to include is clear.	Thank you for your comment. Section 4.1.1 has been amended to state which groups will be the focus of the guidance and where the evidence allows, which groups the committee will also comment upon.
Royal College of Nursing		4.2.1: A,B,C, D & F	We are currently seeing a reduction in the role of the specialist Blood Bourne Virus (BBV) workers within the local authorities as a result of cost pressures. Many of these trained professionals are from the ethnic groups and were born in countries where the virus is endemic and are skilled within the drug population.	Thank you for your comment.
Royal College of Nursing		4.3	The decline in or loss of trained BBV professionals has potential to undermine the implementation of these and future related guidelines. If specialist training is required it may result in significant cost and delay.	Thank you for your comment.
Royal College of Nursing		General	There is evidence that communities who take ownership of their specific health related problems and raise awareness are highly effective. Example 'Jade ribbon' HBV initiative in the USA. We welcome any engagement with community leaders and groups to increase awareness, treatment and improved outcomes and care.	Thank you for your comment.
Royal College of Nursing		General	It is also important to engage with the 'leaders' of different communities so that they can support testing and its implications.	Thank you
Royal College of Paediatrics and Child		Population	The population should include children and the significant sub group of these children who are in	Thank you for your comment. Section 4.1.1 has been amended to state which groups will be the

***Stakeholder* Organisation**	***Evidence submitted***	***Section***	***Comments*** **Please insert each new comment in a new row.**	***Response*** **Please respond to each comment**
Health			care/fostered.	focus of the guidance and where the evidence allows, which groups the committee will also comment upon. Please note that there is no age limit and therefore where appropriate the committee are likely to comment upon children.
Royal College of Paediatrics and Child Health		Key Questions and Outcomes	The College believes that these key questions are suitable but difficult to answer.	Thank you
Royal Pharmaceutical Society		General	The RPS welcomes these guidelines	Thank you
Royal Pharmaceutical Society		General	The RPS and the Hepatitis C Trust have organised a campaign to raise awareness of Hepatitis C through community pharmacies. The Trust is also offering free training for pharmacists to provide pharmacy-based hepatitis testing services (commissioned by PCTs) across England.	Thank you
Royal Pharmaceutical Society		General	Community pharmacists in the Isle of Wight NHS PCT are currently piloting a hepatitis screening and vaccination services developed by the Hepatitis C Trust. The aim of this service is to identify unknown sufferers of Hepatitis B & C. In addition, a separate vaccination service is offered by the pharmacy for Hepatitis B. This is only available where the pharmacy is actively engaged with needle exchange and supervised consumption of methadone services.	Thank you
Sheffield Teaching		General	Two representatives attended the stakeholders	Thank you

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***Stakeholder* Organisation**	***Evidence submitted***	***Section***	***Comments*** **Please insert each new comment in a new row.**	***Response*** **Please respond to each comment**
Hospitals		comment 1:	meeting of 29th September 2010, the guideline is timely and coincides with our experience of outreach screening for populations which are hard to reach.	
Sheffield Teaching Hospitals		General comment 2:	We think that examples of methods used to facilitate education and testing that have been used in this context will be important to allow other centres to try strategies for hard to reach populations. Our experience comprises long term outreach screening using blood samples in Substance Misuse Centres and innovative screening in Asylum Seeker Health General Practice; more recently innovative ethnic group community screening - *Chinese, North African and South East Asian*- with health educator language support using dried blood spots. References Below:	Thank you for your comment
Sheffield Teaching Hospitals		General comment 2 References:	Ray Poll (Nurse Consultant for Viral Hepatitis) program run at substance misuse centres demonstrated an improvement in DNA rate if patients screened and counselled in this setting. Results were presented: at the Consensus Conference on Hepatitis C in April 2004 at the Royal College of Physicians, Edinburgh - Developing Patients Services: Outreach Screening Clinic. The innovative Asylum Seeker Health extended screening program which has run for 5 years will be presented at the Federation of Infection Societies (FIS) on 17th November 2010 by Dr Anne Tunbridge Consultant Physician- (Title/authors TBC)	Thank you for these references

Stakeholder **Organisation**	***Evidence submitted***	***Section***	***Comments*** **Please insert each new comment in a new row.**	***Response*** **Please respond to each comment**
			The ethnic group screening pilot showed that screening including education in ethnic group community settings is effective, well received and reaches people that would not normally be reached by normal health care pathways. Results were presented at the Kings Fund on the Best Practice Event of the Gilead Fellowship Programme on 20th May 2010. Pilot results focused in the Chinese Community will be presented at American Association for the Study of Liver Disease (AASLD) on 31st October 2010 in Boston, USA – (Testing for hepatitis in the community - results of dried blood spot study in Chinese residents in Sheffield, UK. Authors: A.B. Vedio*, H Ellam◆, F Rayner*, R Poll*, G Kudesia◆, MW McKendrick*. *Department of Infection and Tropical Medicine and ◆Department of Virology – Sheffield Teaching Hospitals – Sheffield).	

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Hepatitis B and C: ways to promote and offer testing to people at risk of infection

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Sheffield Teaching Hospitals		**Section 4**	Hepatitis B and Hepatitis C separate sections would more appropriately address different risk groups and recommend different strategies.	Thank you for your comment. As the committee develop the guidance they will, where appropriate, consider HBV and HCV separately.
Sheffield Teaching Hospitals		**Section 4.1.1**	It is necessary to define high endemic countries: see 2008 CDC guidelines for screening: *- persons born in countries with a Hepatitis B prevalence >=2%* *- persons born in the UK, not previously vaccinated, whose parents were born in countries with a prevalence of Hepatitis B >= 8%*	Thank you. The scope document has been amended appropriately.
Sheffield Teaching Hospitals		**Section 4.2.1**	d – Suggestion – Activities to raise awareness amongst high risk groups and knowledge of risk; natural history including complications and potential benefits of testing, monitoring and treatment.	Thank you. Activities to raise awareness amongst at risk groups are detailed in section 4.2.1 a
Sheffield Teaching Hospitals		**Section 4.2.1**	f – Suggestion - change **ensure** to **encourage or facilitate**	Thank you. The scope document has been amended appropriately.
Sheffield Teaching Hospitals		**Section 4.2.2**	b – HCV PCR should be part of routine testing for those who are antibody positive and this has already been established as routine in some national centres.	The referral received from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. In order to be able to develop guidance on this area within the requisite time, this piece of work will develop recommendations, in line with the currently accepted clinical pathways, up to the point of the first test. We will however discuss the need for guidance in this area with the Centre for Clinical Practice and the Department of Health. Depending upon the outcome of

Stakeholder **Organisation**	***Evidence submitted***	***Section***	***Comments*** **Please insert each new comment in a new row.**	***Response*** **Please respond to each comment**
				these discussions we will return to stakeholders if an additional referral is sent through, or if not, whether there is a need to extend the current remit.

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Sheffield Teaching Hospitals		**Section 4.3**	Suggested additional question What is the minimum information to be delivered in gaining full consent?	Thank you for your comment. When developing the guidance the committee will consider issues regarding consent.
Sheffield Teaching Hospitals		**Outcomes**	**- attitudes and knowledge** should specify – populations at risk & add professional groups - **additional outcome** Number of actively infected patients accessing specialist health care.	Thank you for your comment. The scope has been amended appropriately
Terrence Higgins Trust		4.1.1	Groups targeted should include people living with HIV and men who have sex with men	Thank you for your comment. Section 4.1.1 has been amended to state which groups will be the focus of the guidance and where the evidence allows, which groups the committee will also comment upon.
Terrence Higgins Trust		4.3	Key outcomes should include the percentage of positives measured against the number of tests carried out. Would be interested to know how many declined testing and the reasons why	Thank you for your comment. It is hoped that through the assessment of the available evidence base that data on these issues will be uncovered.
Terrence Higgins Trust		General	Although out with the scope of the document the client needs in terms of availability of after testing care including social care support particular around access to treatment and adherance should be considered.	Thank you for your comment.
The Hepatitis C Trust		General	The Hepatitis C Trust welcomes the development of this guidance, and the recognition of the need for a comprehensive approach, increased diagnosis of hepatitis B and C and to identify and disseminate how this can be done most effectively.	Thank you.

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The Hepatitis C Trust		General	At present 'testing' has not been defined for the purposes of this process. Guidance should address the full diagnostic testing process and not solely the identification of antibodies (which indicate just that exposure has occurred at some time and not the presence of ongoing infection). Although guidance relating to pathways and types of diagnostic tests used is largely excluded from this work, consistently identifying and monitoring the presence of current hepatitis B or C infection will be vital if the guidance is to comprehensively address (cost) effective approaches to case detection.	The referral received from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. In order to be able to develop guidance on this area within the requisite time, this piece of work will develop recommendations, in line with the currently accepted clinical pathways, up to the point of the first test. We will however discuss the need for guidance in this area with the Centre for Clinical Practice and the Department of Health. Depending upon the outcome of these discussions we will return to stakeholders if an additional referral is sent through, or if not, whether there is a need to extend the current remit.
The Hepatitis C Trust		General – particularly sections 3d, 3e, 4.1.1, 4.1.2, 4.2 and 4.3	It is slightly unclear whether the guidance will focus only on interventions to increase testing among those most at risk, or if it also aims to increase this among all risk groups. If the former, it would be helpful to specifically identify (and consult upon) the groups included. As a minimum, this should include people who currently inject or have previously injected drugs and people from high prevalence countries (specifically including Eastern Europe as well as South Asia). If the latter, all groups at increased risk should be included in the consultation, for example, people who	Thank you for your comment. Section 4.1.1 has been amended to state which groups will be the focus of the guidance and where the evidence allows, which groups the committee will also comment upon.

Stakeholder **Organisation**	***Evidence submitted***	***Section***	***Comments*** **Please insert each new comment in a new row.**	***Response*** **Please respond to each comment**
			had a blood transfusion / organ transplant / received blood products prior to 1992, and people who've had medical / dental treatment in a high prevalence country.	

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The Hepatitis C Trust		General	It's important to recognise that there is a considerable lack of knowledge and information on incidence and prevalence rates among many sub-populations (people from sub-Saharan Africa, for example, people who inject performance and image enhancing drugs, or people who use cocaine intra-nasally, which a French study has found to involve similar hepatitis C infection risks as the receipt of unscreened blood). Additional research, as well as maintaining and increasing mainstream testing options, is essential to fully understand which populations are at increased risk of hepatitis B and C in the UK and how these groups are most effectively targeted. Any final guidance will need to recognise this and consequent implications for ensuring widespread accessibility of testing and diagnostic services.	Thank you for your comment.
The Hepatitis C Trust		General	A flexible approach to this will be necessary both for the above reasons and due to the ongoing reform within the NHS, which is likely to have a considerable impact on the availability of services through which testing can be accessed.	Thank you for your comment.
The Hepatitis C Trust		4.2, d)	We welcome the breadth of activity included to increase testing and diagnosis, particularly the inclusion of work to increase awareness among professionals. However, although an understanding of the groups most at risk is undoubtedly essential, it is also imperative that this does not encourage (or entrench) attitudes to hepatitis B and/or C as being "drug users'" or "immigrants'" diseases.	Thank you for your comment.

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The Hepatitis C Trust		4.2.2: Activities that will not be covered: b & c)	While, as discussed above, we recognise that the evaluation of and recommendations around treatment pathways are beyond the direct scope of this work, it is important that the guidance relates to the full diagnostic test in identifying active cases of hepatitis B and C and that this is understood and approached as one part of a wider pathway. This will require some consideration as to infrastructural barriers to testing which stem from inadequate onward pathways. During the development phase of our pharmacy-based testing project we have encountered resistance to increased testing from local health services due to insufficient treatment capacity (leading to long waiting lists), concerns over the costs of treatment and directives requiring all new interventions to achieve cost benefits within five years. Onward referral capacity therefore does seem to have a clear impact upon testing provision in some areas and will need to be addressed as a possible barrier to testing. Furthermore, guidance and/or recommendations relating to how, when and to whom referrals can be made most effectively, and monitoring mechanisms for this, should be included (as addressed at section 4.3, question 4). This would ensure that the testing process is effectively integrated into the pathway, and therefore that testing is not viewed as an end in itself but as an essential first step to increasing diagnosis, treatment,	The referral received from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. In order to be able to develop guidance on this area within the requisite time, this piece of work will develop recommendations, in line with the currently accepted clinical pathways, up to the point of the first test. We will however discuss the need for guidance in this area with the Centre for Clinical Practice and the Department of Health. Depending upon the outcome of these discussions we will return to stakeholders if an additional referral is sent through, or if not, whether there is a need to extend the current remit. The committee will consider when developing the guidance how services can be commissioned and run, to encourage people who have tested positive to continue to seek support from the appropriate services

Stakeholder **Organisation**	***Evidence submitted***	***Section***	***Comments*** **Please insert each new comment in a new row.**	***Response*** **Please respond to each comment**
			care and support.	

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The Hepatitis C Trust		4.3	*Question 1: Which interventions are effective and cost effective in getting people from high-risk groups to use services that currently (or potentially could) offer hepatitis testing?* This question might be broadened to examine which services are already engaging high-risk groups and how this existing contact could be leveraged to increase uptake of testing. For example, needle exchange and supervised consumption providers such as community pharmacies often have ongoing contact with large numbers of current and former injectors and therefore offer an effective location for public health interventions such as hepatitis B and C testing. Similarly, rates of hepatitis C in prison populations are thought to be at least 6-7 times that of the general public and consideration should therefore be given to making testing routinely available to people in prison (where this is not done already). Other institutional settings which tend to engage with higher prevalence groups, such as mental health or homelessness services, may also provide effective platforms for raising awareness and offering testing to some groups at higher risk. Religious and cultural centres can also provide opportunities to undertake this with populations from high prevalence countries.	Thank you for your comment. Where the evidence allows interventions to increase testing rates further will be examined.
The Hepatitis C Trust		4.3	*Question 2: What prevents people in high-risk groups from having a hepatitis B and hepatitis C test – and what factors increase the likelihood that they will seek*	Thank you for your comment.

Stakeholder **Organisation**	***Evidence submitted***	***Section***	***Comments*** **Please insert each new comment in a new row.**	***Response*** **Please respond to each comment**
			and accept a test? The factors which increase / decrease the likelihood or someone being tested vary across different risk groups, and need to be addressed accordingly. **Barriers:** - Stigma / embarrassment / fear - Lack of awareness of hepatitis B/C and/or who is at risk - No symptoms (including in some instances misconception that this means infection is doing no damage) - Confidentiality. For example, a pharmacist in Kirklees involved in the testing pilot noted that South Asian people, especially women, were accessing testing through his pharmacy as they may go shopping alone whilst they'd usually be accompanied to the GP or GP is known to family so they're not comfortable requesting a test there. - Convenience. Tests are often only available with an appointment, and/or at a certain time or during working hours - Testing is not offered / recommended or is even refused by practitioners (one study recoded 15 instances of people who had received a blood transfusion prior to 1992 being refused a test by their GP in just one week) - Chaotic lifestyles for some risk groups make	

***Stakeholder* Organisation**	***Evidence submitted***	***Section***	***Comments*** **Please insert each new comment in a new row.**	***Response*** **Please respond to each comment**
			appointments difficult - People may not be registered with a GP and/or be willing to access GUM services - Fragmentation of services and service provision **Facilitators:** - Removal of/ addressing the factors listed above - Integration of testing with other services offered as a package (though allowing selection if preferred) – such as hepatitis B vaccination, STI screening, HIV tests - A long-term approach by practitioners to engaging people – working with them over a period of time until they feel ready. Particularly where there is an existing good relationship. - Testing that goes to the client, particularly where this is linked to a service or location that's already accessed (e.g. community centre, pharmacy offering needle exchange)	

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The Hepatitis C Trust		4.3	*Question 3: Which interventions are effective and cost-effective at overcoming the barriers to hepatitis testing faced by high-risk groups and professionals?* Increased awareness and understanding of hepatitis B and C is of primary importance both for high risk groups and for professionals engaging with all groups at increased risk of hepatitis (including drug or needle exchange workers, for example, or community leaders as well as medical professionals such as GPs). There is significant progress to be made in successfully engaging even the most at risk groups in testing; in 2008/9 just 70% (as opposed to the NTA target of 100%) of injecting drug users presenting at treatment services were even offered a hepatitis C test, and only 47% accepted. Improving professionals' understanding of how to successfully offer testing, as well as increasing the availability of saliva swab tests and dried-blood spot tests, would make testing easier and more accessible (particularly for people with veinous access problems or a fear of needles).	Thank you for your comment.
The Hepatitis C Trust		4.3	*Question 4: How can practitioners ensure people who have tested positive continue to seek support from the appropriate services?* Again this question might be broadened to look beyond the role of professionals to include the system they're working in and the people they're working with. Pathways need to be well planned and appropriate to	Thank you for your comment. Question 4 has been amended appropriately.

Stakeholder **Organisation**	***Evidence submitted***	***Section***	***Comments*** **Please insert each new comment in a new row.**	***Response*** **Please respond to each comment**
			patients' needs, designed in consultation with patients. While practitioners need to be informed of management and treatment options, wider support services, and when and how referrals should be made, the patient should always be fully involved in this process. In addition, mechanisms through which GPs, Blood Borne Virus services or other community or primary care services that provide testing can be kept informed of progress into secondary care would also serve to strengthen the testing and treatment process. All people who test positive for hepatitis B and/or hepatitis C should also be provided with comprehensive information on the patient groups and other support services available to them.	

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The Hepatitis C Trust		4.3	*Outcomes – a change in:* - *Attitudes and knowledge about hepatitis B and C:* among people at increased risk and among professionals working with people who have hepatitis B or C and working with people at increased risk - *Awareness of hepatitis B and C testing facilities*: as above - *The number and types of venues offering tests* - *The number of at-risk people seeking / accepting a test* - *The number of tests carried out* - *The number of positive diagnoses of hepatitis B and C* In addition to the above, monitoring the number of people referred into, and the number actually accessing, secondary care would provide vital information on the effectiveness of testing services as points of entry into the care and treatment pathway.	Thank you for your comment.
The National LGB&T Partnership		3d	This section should be updated to include men who have sex with men as an at-risk group. Estimates prevalence of Hepatitis B infection are around 15-30%. 10% prevalence among men who have sex with men under 35, 35% for those over 35. (Presented by Alan McOwan at the 79th Medical Society for the Study of Venereal Disease Spring meeting, Belfast, May 2001). Also, 16.5% prevalence (6.9% under 25, 19.7% over 25) is	Thank you for your comment. The scope has been amended appropriately.

Stakeholder **Organisation**	***Evidence submitted***	***Section***	***Comments*** **Please insert each new comment in a new row.**	***Response*** **Please respond to each comment**
			cited in Hart G et al. Risk behaviour, anti-HIV and anti-hepatitis B core prevalence in clinic and non-clinic samples of gay men in England, 1991-2. AIDS 1993; 7:863-869.	

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The National LGB&T Partnership		3d	One group that may have a higher than average prevalence of Hepatitis B is the trans community. It is common for members of the trans community to select their sexual partners from members of another community with a higher than average prevalence of Hepatitis B i.e. men who have sex with men. Moreover some trans people are part of the men who have sex with men community. It is therefore highly probable that due to the proximity and sexual mixing of the two communities that Hepatitis B is being transmitted sexually to the trans community. It concerns us that the trans community may have a higher than average prevalence of Hepatitis B and yet there are no systems in place to monitor the prevalence of Hep B for this group. This lack of data ensures that the trans community are not included in reviews such as this and that members of the trans community are not encouraged to test or access vaccination for Hepatitis B.	Thank you for your comment. It was not possible to update this section as no figures could be found for this group.
The National LGB&T Partnership		3e	This section should be updated to include men who have sex with men within the groups with higher prevalence. More specifically, HIV positive men who have sex with men have a higher prevalence of Hep C. However around a third of men who have sex with men have not had their HIV diagnosed, and therefore men who have sex with men would be a better target group for this guidance.	Thank you for your comment. The scope has been updated to include the number of cases of HCV in men who have sex with men.

Stakeholder **Organisation**	***Evidence submitted***	***Section***	***Comments*** **Please insert each new comment in a new row.**	***Response*** **Please respond to each comment**
			7% of HIV positive gay men screened at Chelsea & Westminster Hospital in 2002 had been exposed to HCV. Nelson M et al. Increasing incidence of acute hepatitis C in HIV positive men secondary to sexual transmission, epidemiology and treatment. 9th European AIDS Conference, Warsaw, abstract F12/3; 2003	

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The National LGB&T Partnership		3e	This section should be updated to specifically include the subset of injecting drug users who are homeless. IDUs who had ever been homeless were more like to be infected with HCV than those who had not (45% vs. 28%). Health Protection Agency (2007): Shooting Up - Infections among injecting drug users in the United Kingdom 2006 An update: October 2007	Thank you for your comment the scope has been updated.
The National LGB&T Partnership		4.1.1	Men who have sex with men should be included in the section on “Groups that will be included”	Thank you for your comment. Section 4.1.1 has been amended to state which groups will be the focus of the guidance and where the evidence allows, which groups the committee will also comment upon.
The National LGB&T Partnership		4.2.1	IDUs who are homeless find it difficult to register with GPs, often present at A&E at more advanced stages of illness and discharge is problematic because of lack of secure accommodation. Consequently this section should contain activities that increase partnership working with voluntary and community groups to ensure better prevention, healthcare and after care services.	Thank you for your comment. These areas are likely to be addressed as part of 4.2.1c under associated barriers.
The National LGB&T Partnership		4.2.1	This section should include activities to begin measuring the prevalence of Hepatitis B within the trans community.	Thank you for your comment. The activities listed within section 4.2.1 are concerned with increasing access to testing to those at risk of infection. However, when developing the guidance the

Stakeholder **Organisation**	***Evidence submitted***	***Section***	***Comments*** **Please insert each new comment in a new row.**	***Response*** **Please respond to each comment**
				committee will assess the gaps in the available evidence base and where appropriate make research recommendations.

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The National LGB&T Partnership		4.2.1 c	One barrier to testing is that services are rarely designed to be inclusive of LGBT people. Consequently NICE should also be looking at activities that increase the inclusiveness of services for men who have sex with men.	Thank you for your comment. When developing the guidance the committee will examine any barriers that prevent the testing of those at the greatest risk of infection.
The National LGB&T Partnership		4.2.1 e	"Close contacts" should be updated to include sexual contacts of men who have sex with men. Coutinho R et al. Rise in HCV Incidence in HIV infected Men Who Have Sex with Men in Amsterdam: Sexual Transmission of Difficult to Treat HCV Genotypes 1 and 4. Thirteenth Conference on Retroviruses and Opportunistic Infections, Denver, abstract 87, 2006. Danta M et al. Evidence for Sexual Transmission of HCV in Recent Epidemic in HIV- infected Men in the UK. Thirteenth Conference on Retroviruses and Opportunistic Infections, Denver, abstract 86, 2006. Furthermore, people with HIV often have higher HCV viral loads and HCV is more likely to be detected in semen. A study has shown that 38% of HIV positive men with HCV had HCV in their semen at some time (compared to 18% of HIV negative men) and that the men with HIV had higher levels of HCV in their blood. Briat et al. Hepatitis C virus in the semen of	Thank you, the scope document has been amended appropriately.

Stakeholder **Organisation**	***Evidence submitted***	***Section***	***Comments*** **Please insert each new comment in a new row.**	***Response*** **Please respond to each comment**
			men coinfected with HIV-1: prevalence and origin. AIDS 2005; 19:1827-1853.	

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The National LGB&T Partnership		4.3 Question 1	When the Programme Development Group considers alternative measures and approaches to encouraging men who have sex with men to test, we would urge you to look at the recommendations contained within the NICE "Public Health Draft Guidance: Increasing the uptake of HIV testing to reduce undiagnosed infection and prevent transmission among men who have sex with men". We believe all men who have sex with men who attend GUM services should be offered both Hepatitis B and C tests on an "opt-out" basis.	Thank you. When developing the guidance the PDG will consider any related guidance that NICE has developed.
Torbay Care Trust		1	Should be people at HIGH risk of infection	Thank you for your comment. The scope has been amended appropriately
Torbay Care Trust		4.1.1	Would like to see close personal contacts of those infected or at high risk, for example partners and pregnant injectors/pregnant partners of injectors to have HBV and HCV tests routinely in their antenatal screening	Thank you for your comment. These groups are covered under section 4.2.1 e
Torbay Care Trust		4.2.1	Need a lot of information on what is meant by 'activities' and consideration re:cost implications surrounding this, particularly in current climate of change in all public services	Thank you. The exact detail of the activities is to be determined through the guidance development process. The detail will be provided in the final guidance document.
Torbay Care Trust		4.2.2	I feel strongly that HCV PCR testing must be routinely carried out in all who are antibody positive. Without this a diagnosis is incomplete and the client is left not knowing their status, hence they are unable to definitively say whether they have a virus or not. Whilst the guidance is not meant to cover aftercare for those diagnosed it should at least make some reference to	The referral received from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. In order to be able to develop guidance on this area within the requisite time, this piece of work will develop recommendations, in line with the currently accepted clinical pathways, up

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			care pathways for onward referral and this should be included in the pre/post test discussions.	to the point of the first test.

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Torbay Care Trust		4.3	Consideration needs to be given not only to physical interventions but also to relationships being formed with client groups and service which are already accessed in order to effectively promote testing in a safe and trusted environment. Any approach needs to be flexible, realistic and responsive to client need.	Thank you.
UK Harm Reduction Alliance (UKHRA)		2 c)	We feel that this guidance should also support "Models of Care for Treatment of Adult Drug Misusers: Update 2006" by the National Treatment Agency, which offers specific guidance on services providing access to BBV testing (specifically, HBV, HCV and HIV): 'Drug misuse and dependence: Guidelines on clinical management 2007' (NTA/DH) which offers on BBV testing and screening as part of general healthcare checking of substance users and Royal College of General Practitioners 'Guidance for the prevention, testing, treatment and management of hepatitis C in primary care 2007' that offers guidance around HCV testing in primary care.	Thank you for your comment the scope has been amended appropriately.
UK Harm Reduction Alliance (UKHRA)		4.1.1	We feel that this guidance should specifically include former injecting drug users with no recent history of drug use (i.e. not just those who may have recently left treatment services). This might include recalling former HBV infected patients who have never been tested for HCV prior to the virus being isolated in 1989. We feel this guidance should specifically include the children of HCB/HBV positive mothers. There is currently local variation regarding the testing of pregnant mothers for HCV and even if the mother is known to be a current/former IDU, it cannot be	Thank you for your comment. Section 4.1.1 has been amended to state which groups will be the focus of the guidance and where the evidence allows, which groups the committee will also comment upon. There are no age limits associated with the population groups that are to be included. However, the testing of pregnant women has been addressed previously by the national screening committee and has been included in

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			assumed that maternity services are routinely offering HCV testing in these cases (to the pregnant mother or the child). We feel that attention should be given to non-injecting drug user where the risk of transmission is reduced but where repeated exposure may constitute risk particularly: e) Crack cocaine users (due to the risk of blood-blood transmission from open mouth wounds/sores from sharing crack pipes). f) Cocaine hydrochloride snorters (due to the risk of blood-blood transmission from nasal passage injuries from sharing shorting tubes). We feel there needs to be a focus within the guidance on those or those being initiated into injecting drug use or who are new to injecting practice g) There should also be close consideration to how those problematic drug users who are transitioning to injecting drug use from a non-injecting route are targeted. In particular, those who are injected by a peer (this is a common practice for those who initially transition into injecting) as they may not specifically identify them self as an injecting drug user or indeed be exposed to the risk reduction messages that might be afforded longer term users with more ready access to services and NSPs.	previous NICE guidance (www.nice.org.uk/CG62)

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			Those at rick through both sexual and injecting drug use transmission also warrant to be considered as for targeting for testing: h) Commercial sex workers may also benefit from BBV screening as they are may be engaging in high risk sexual practices (particularly in relation to HBV transmission) and may also be injecting drug users/crack cocaine users.	

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UK Harm Reduction Alliance (UKHRA)		4.1.1 continued	Services working with Commercial Sex Workers may need to also be involved with the implementation of this guidance. We feel the guidance should also consider those at risk groups who decline or face barriers to testing when offered and offer guidance on how, and when, these individuals should be followed up and re-offered testing at a later date (in order that they are not "lost in the system"). The guidance may also wish to give consideration to other high risk practices including tattooing (particularly given its more recent and almost universal acceptance), body piercing, and high risk "BDSM" sexual practices. It is of note that much of the Australian guidance has specifically included risks from clandestine tattooing/body piercing. This is evidently a sensitive issue, but consideration of how migrant populations from Central and Eastern Europe, particularly those who are IDU's and from countries where blood screening isn't universal can be engaged and access testing facilities. We would ask that the scope also clarifies whether those individuals who are at a high occupational risk of HCV/HBV exposure should be included in the guidance and if not, which other guidance would cover this group. This may include those workers who administer	Thank you for your comment. Section 4.1.1 has been amended to state which groups will be the focus of the guidance and where the evidence allows, which groups the committee will also comment upon. The Department of Health has released guidance on hepatitis B and C for health workers: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_073132

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			HCV/HBV testing.	

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UK Harm Reduction Alliance (UKHRA)		4.2.1 c)	We feel this should specifically include activities which target workers/services involved in BBV testing and not just the target groups for testing.	Thank you for your comment. When developing the guidance the committee will consider activities targeted at workers/services.
UK Harm Reduction Alliance (UKHRA)		4.2.1 d)	There should be an emphasis on the significance of how increased awareness of hepatitis B and C, natural history, treatment options and implications is central to informing those at risk or with hepatitis B and/or C and reducing fear and barriers to testing and so, treatment.	Thank you for comment. This document sets out the areas which will be investigated during the guidance development process. The detail will be determined during the guidance development process.
UK Harm Reduction Alliance (UKHRA)		4.2.1 – general	We feel that the guidance should also specifically explore and ideally identify which types of services and professional groups could be offering HCV/HBV testing and would be keen to see this added as an additional activity/separate bullet point under this section.	Thank you for your comment. While developing the guidance the committee are likely to consider issues around which types of services can offer testing.
UK Harm Reduction Alliance (UKHRA)		4.2.1 – general	We feel this guidance should also consider recommendations on documentation and reporting tools used in BBV testing, in particular a clear BBV risk assessment tool (identifying whether an individual should be offered testing) and clear guidance on how test results are communicated from the lab to the testing service (i.e. plain English explanation of the meaning of results). It is recognised that as in comments 4.2.1 d), enhanced professional knowledge and understanding is central.	Thank you for your comment.
UK Harm Reduction Alliance (UKHRA)		4.2.2 a)	We accept that this is intervention guidance and not technical guidance and therefore cannot evaluate the validity or effectiveness of different diagnostic tests. However we do feel that this guidance will need to specifically consider and make reference to the range of different available diagnostic methods for HCV/HBV testing and their potential limitations/benefits, as this would have a considerable implication for	Thank you for your comment. It is likely that the committee will consider these issues when developing the guidance

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			implementation and, potentially, for reducing barriers to testing –various recent UK studies and implementation trials across PCT's of dried bloodspot testing are suggesting increased ease of use and broader opportunity for non-nursing professionals within drug treatment settings to increase testing capacity over more traditional testing. The Hepatitis C Trust has recently run a pharmacy hepatitis B and C testing pilot successfully using dried blood spot testing.	

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UK Harm Reduction Alliance (UKHRA)		4.2.2 b)	We are disappointed that it has been proposed that the sequence and type of diagnostic tests used to confirm whether someone is chronically infected has been specifically excluded in the draft scope. We feel strongly that with regards to HCV testing, this guidance should end at the point of diagnostic confirmation (i.e. should include guidance on offering PCR RNA testing to confirm an active HCV test). This may be more cost effective (reducing the number of referrals to a specialist liver team) and is a more humane response (it has been our experience that many injectors have been so unduly concerned or confused about their HCV anti-body positive results that they have disengaged from services before ever knowing their true diagnosis.	The referral received from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. In order to be able to develop guidance on this area within the requisite time, this piece of work will develop recommendations, in line with the currently accepted clinical pathways, up to the point of the first test. We will however discuss the need for guidance in this area with the Centre for Clinical Practice and the Department of Health. Depending upon the outcome of these discussions we will return to stakeholders if an additional referral is sent through, or if not, whether there is a need to extend the current remit.
UK Harm Reduction Alliance (UKHRA)		General	We feel the guidance should consider the cross-over of this guidance with HIV testing, given that some of the transmission risks are the same. This may also include consideration of the differences and the similarities between HIV risk viral hepatitis risks.	Thank you for your comment. Where appropriate the guidance will refer to other pieces of NICE guidance. NICE is currently two pieces of guidance on HIV testing: Increasing the uptake of HIV testing to reduce undiagnosed infection and prevent transmission among black African communities living in England http://guidance.nice.org.uk/PHG/Wave19/3 Increasing the uptake of HIV testing to reduce undiagnosed infection and prevent transmission

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				among men who have sex with men http://guidance.nice.org.uk/PHG/Wave19/4

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UK Harm Reduction Alliance (UKHRA)		General	We feel this guidance should consider the differences between HCV and HBV transmission risk factors and high risk groups and ensure that the guidance does consider the differences (and similarities) with these two infections.	Thank you for your comment. When developing the guidance the committee are likely to consider the differences and similarities between HBV and HCV.
UK Harm Reduction Alliance (UKHRA)		General	We feel that NICE may need to remain watchful of the proposed changes to the UK drug treatment system throughout the guidance development period as this may have an impact for implementation (i.e. the drug treatment system, which is likely to be implementing a fair portion of this guidance, may be a very different treatment system in 2012).	Thank you for your comment.
UK Harm Reduction Alliance (UKHRA)		General	We feel that this guidance will need to balance the need to appropriately weight its emphasis on the key high risk HCV transmission groups (injecting drug users) and the risk of stigmatising this virus. Specifically, over-identification of HCV with injecting drug use could be counter-productive to the aims of implementing an expansive testing scheme.	Thank you for your comment. Section 4.1.1 has been amended to state which groups will be the focus of the guidance and where the evidence allows, which groups the committee will also comment upon.
UK Harm Reduction Alliance (UKHRA)		General	We feel that the guidance will need to offer specific guidance on the frequency at which individuals who continue to be at risk of transmission should be re-tested after negative test results (including consideration of “window” periods).	Thank you for your comment when developing the guidance the committee is likely to consider these issues.
UK Harm Reduction Alliance (UKHRA)		General	We would recommend that the guidance uses the terminology of “pre and post testing discussion” (as per DH guidance) as opposed to counselling. Some services have previously been reluctant to offer testing with “counselling” has inferred the need for qualified/accredited counsellors to provide this service. More significantly, it is believed that the term	Thank you

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			counselling may actually constitute a barrier to accessing HCV and HBV testing whereas the term discussion is more readily suggestive of a more empowering exchange of information and understanding.	

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UK Harm Reduction Alliance (UKHRA)		General	We feel that this guidance could make clear recommendations for anonymised data collection and reporting on testing uptake and results as this would be extremely useful from both an epidemiological and a service planning/provision point of view.	Thank you for your comment. When developing the guidance the committee will consider those aspects that could have a positive effect on the uptake of testing in those at greatest risk of infection.
UK Harm Reduction Alliance (UKHRA)		General	We feel that the guidance should also include clarity on best practice regarding issues of confidentiality. In particular we would like to see guidance regarding medical record keeping and the passing on of information relating to testing (whether accepted or declined) and results (whether positive or negative) to third parties (e.g. employers, insurance companies, mortgage providers).	Please see previous comment
UK Harm Reduction Alliance (UKHRA)		Key questions 1-4	We feel that the key questions asked can largely be attended to by ensuring that all relevant professionals have a comprehensive understanding of hepatitis B and C testing. We feel that ignorance amongst professionals remains high and that there is a common lack of confidence in testing options, results etc and creating barriers to testing. Further, there is typically a limited contextual understanding of hepatitis B and C, natural history, treatment options, treatment adherence challenges, that further compromises testing engagement opportunities. We strongly suggest that all those involved in testing should be required to have a comprehensive understanding of hepatitis B and C and treatment options – uncertainty in this inevitably lends uncertainty to the guiding the testing process. Practitioners are often insufficiently knowledgeable to effectively engage	Thank you for your comment.

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			often vulnerable and fearful at risk individuals around the benefits of testing and, if necessary, treatment and care. Enhanced knowledge amongst professionals may well be considered a first step in informing and supporting the dissemination of hepatitis B and C information in the broader context of hepatitis B and C prevention, testing, treatment and care and this development of enhanced knowledge for professionals and significantly, those at risk, is seen as crucial in removing barriers to testing and improving engagement to support systems as needed.	

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Worcestershire DAAT/Worcester Royal Hospital		4.2.2 a and b	Evaluation of screening methods should be included in the guidance to compare sensitivity and specificity of venous blood, blood spot and oral swab tests to ascertain cost effectiveness and reliability of the screening tests	The referral received from the Department of Health asked NICE to develop guidance on most cost effective methods of offering hepatitis testing. In order to be able to develop guidance on this area within the requisite time, this piece of work will develop recommendations, in line with the currently accepted clinical pathways, up to the point of the first test. We will however discuss the need for guidance in this area with the Centre for Clinical Practice and the Department of Health. Depending upon the outcome of these discussions we will return to stakeholders if an additional referral is sent through, or if not, whether there is a need to extend the current remit.
Worcestershire DAAT/Worcester Royal Hospital		General	Staff performing screening should have appropriate knowledge and training to deal with questions and interpret results. Overall management should be undertaken by specialist blood borne virus/hepatitis teams so that positive diagnoses are picked up and managed correctly.	Thank you for your comment.
Worcestershire DAAT/Worcester Royal Hospital		General	NICE public health screening programme will only be effective if it is part of an integrated initiative to support treatment of Hepatitis B and in particular Hepatitis C. Hence, the argument for getting support to properly reimburse labs for PCR testing and PCT for PEG interferon/ribavirin and the cost of nurse-led/clinician follow up.	Thank you for your comment. Screening programmes are outside the remit of this guidance as they are covered by the National Screening Committee (www.screening.nhs.uk). This guidance will consider activities that aim to increase the uptake of testing. The final guidance will be accompanied by a costing report which

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				details the costs and potential savings that can be realised through the implementation of the guidance.
Worcestershire DAAT/Worcester Royal Hospital		General	There is a similar situation in obstetrics where there is a debate about testing drug users in pregnancy and the full resource implications of this.	Thank you for your comment.