# Public Health Programme Guidance

## Hepatitis B and C – Ways to Promote and Offer Testing - Consultation on Draft Guidance
## Stakeholder Comments Table

## 13th June – 8th August 2012

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| **Addaction** | 3.25 | | Further research needed | Thank you for your comment; the guidance recommends, in section 5, further research into cost effective interventions to ensure continuity of care for prisoners who are diagnosed with chronic hepatitis B or C in prison. |
| **Addaction** | 3.39 | | Further research needed | Thank you for your comment; the guidance recommends, in section 5, further research into cost effective interventions to increase hepatitis B case-finding among migrant population in primary and secondary care. |
| **Addaction** | 3.44 | | Guidance required for vaccination course for babies born to infected mothers | Recommendation 9 includes a hyperlink to the Department of Health's Green book: immunisation against infectious disease, which details the vaccination course for babies born to mothers infected with hepatitis B. In addition, reference is made at the start of section 1 of the guidance to NICE public health guidance 21, 'Reducing the differences in the uptake of immunisations' which includes a focus on improving uptake of the hepatitis B immunisation for babies born to mothers infected with hepatitis B. |
| **Addaction** | general | | Steroid users to be included | Recommendation 4, testing for hepatitis B and C in primary care, now states that 'GPs and practice nurses should ask newly registered adults if they have ever injected drugs, including image and performance enhancement substances at their first consultation'.<br>In section 3, considerations, the PDG note the potential risk |

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| | | | | of hepatitis C transmission among people that inject performance and image-enhancing drugs (PIEDs) such as anabolic steroids (for non-medical reasons). However, they noted that there is a lack of published evidence on the extent of risk in this group or on their contribution to overall hepatitis C prevalence. |
| **BASHH** | 1 | 7 | Hepatitis B and C should not necessarily be used interchangeable. In saying that household contacts will benefit from advice re hep c suggests they are at risk | The 'Whose health will benefit' section of the guidance has been amended to make it clear which groups are at increased risk of hepatitis B and which are at increased risk of hepatitis C. |
| **BASHH** | 3.27 | 30 | No evidence testing HIV negative MSM for hepatitis C routinely is indicated. Nil to suggest at sig increased risk | The 'Whose health will benefit' section of the guidance now specifies that it is HIV-positive men who have sex with men who are at increased risk of hepatitis C.<br><br>While the PDG acknowledged that different populations are at increased risk of hepatitis B and C they felt there is some overlap between them, and it would simplify delivery, if testing was recommended for both hepatitis B and C at the same time in those who are at increased risk of either. |
| **BASHH** | 3.39 | 32 | Increasing evidence published about hepatitis C risk of HIV positive MSM including Browne et al, Danta et al | The 'Whose health will benefit' section of the guidance now lists HIV-positive men who have sex with men as one of the groups at increased risk of hepatitis C. |
| **BASHH** | general | | Would be helpful to include reference to what the state of | Reference is made in the introduction of section 1 of |

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| | | | the art policy for testing is (good example is NICE guidance on promoting HIV testing which quotes HIV guidelines | the guidance to the European Association for the Study of the Liver best practice guidelines and to the national standards for local surveillance. |
| **BASHH** | general | | Quite a lot of the document seems out of scope eg vaccination and commissioning of hepatitis treatment services | The PDG did not consider evidence in relation to vaccination and treatment; as such the guidance does not provide detail on these areas but signposts to existing NICE and Department of health guidance:<br>• The PDG emphasised existing hepatitis B vaccination recommendations (as detailed in the Department of health's Green book) because, although hepatitis B vaccination was beyond the scope of this guidance, case-finding may identify people who should be offered vaccination.<br>• Given the need for integrated services the PDG worked closely with the NICE group developing the clinical guideline, on the diagnosis and management of hepatitis B, to ensure there was not a gap in relation to progress from testing into treatment.<br>• For treatment recommendations readers are directed to section 7 of the guidance which lists other relevant NICE guidance that is either published or in development. |
| **BASHH** | general | | Section on training should include messages on how to prevent hepatitis B and C infection | Consideration 3.6 details what the PDG felt education programmes might cover, depending on the role of the health and social care professional; one of the areas listed is harm reduction interventions for people who remain at |

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| | | | | increased risk of hepatitis B and C infection, including hepatitis B vaccination. |
| **BASHH** | general | | A lot of evidence of benefit of POC testing in dropping barriers and increasing update in HIV testing. Would be good to include a summary of data re testing methodologies for hepatitis | The PDG note in section 3 of the guidance that :<br>• while venepuncture samples remain the gold standard, dried blood spot testing for hepatitis have a high test sensitivity and specificity and can be very useful in certain settings for people with poor venous access, as samples are less invasive to obtain. (Hickman et al 2008, Judd et al 2003)<br>• the use of dried blood-spot testing for diagnosis may be more acceptable to some of the target populations than taking a blood sample from a vein, especially if there is poor venous access (for example, this may occur in a person who has injected drugs due to the damage done to their veins) or the patient is needle-phobic. In addition, more staff would probably be able to carry out such tests, so helping to increase the number of people who are tested. For this reason, the PDG felt that the provision of both dried blood-spot testing and access to specialist phlebotomy services would be an important aid in increasing testing and treatment uptake.<br>• oral fluid testing may be more acceptable to some people because it is less invasive than taking blood from a vein, but oral fluid testing has a lower sensitivity and specificity than tests for hepatitis B and C performed on blood. If an oral fluid sample was used, a blood sample would then be needed to confirm the |

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| | | | | initial positive results, and for PCR testing to diagnose chronic hepatitis C. |
| **Bristol-Myers Squibb Pharmaceuticals** | introduction | 1 | BMS suggests the inclusion of secondary care as a testing setting. | As noted in section 3, the PDG felt there may be merit in commissioners considering a range of venues for hepatitis B and C testing in order to improve accessibility. In addition, the guidance now has a recommendation on testing in GUM and sexual health clinics. |
| **Bristol-Myers Squibb Pharmaceuticals** | Introduction: Who is this guidance for | 2 | BMS suggests reconsidering the wording of the phrase "The guidance may also be of interest to groups at increased risk of viral hepatitis..." to "The guidance is also of interest to groups of increased risk of viral hepatitis... and including it as a sub-bullet of the above. | Thank you for commenting, we have fed these ideas back to the editors to be considered when the guidance template is next updated. |
| **Bristol-Myers Squibb Pharmaceuticals** | Introduction: Whose health will benefit | 7 | BMS suggests including not only people born or brought up in a country of intermediate or high prevalence, but also those who currently reside in such areas. | The 'Whose health will benefit' section has been updated. |
| **Bristol-Myers Squibb Pharmaceuticals** | Introduction: Whose health will benefit | 7 | BMS suggests rewording the phrase "people who have injected recreational drugs or who share drugs paraphernalia" to "people who have injected recreational drugs, who have shared or who share drugs paraphernalia" in order to include all individuals with a history of any kind of drug misuse i.e. ex and current IDDU and non-IDDU groups. | As noted in consideration 3.36 the PDG recognised and understood the potential risks associated with the transmission of hepatitis C via sharing straws to snort drugs but there was a lack of strong biological evidence on which to base recommendations. The key risk was considered to be through sharing injecting equipment; as such this section of the guidance was amended to: 'People who have ever |

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| | | | | injected drugs.' |
| **Bristol-Myers Squibb Pharmaceuticals** | Introduction: Whose health will benefit | 7 | BMS suggests reconsidering the wording the phrase "Men who have sex with men, commercial sex workers and anyone who has unprotected sex and frequently changes partner" to "Anyone who has had and has unprotected sex frequently changes partner".<br>This suggestion for rewording includes all the above and more sub-groups. | Guidance has been amended to:<br>'Anyone who has had unprotected sex, particularly:<br>• people who have had multiple sexual partners<br>• people reporting unprotected sexual contact in areas of intermediate and high prevalence)<br>• people presenting at sexual health and genitourinary medicine clinics<br>• people diagnosed with a sexually transmitted disease<br>• commercial sex workers.'<br><br>Men who have sex with men are now in a separate bullet. |
| **Bristol-Myers Squibb Pharmaceuticals** | Introduction: Whose health will benefit | 7 | BMS suggests including the following subgroups:<br>• Persons reporting unprotected sexual contact in areas of intermediate and high prevalence (abroad and in the UK)<br>• All persons presenting at STD clinics<br>• Persons diagnosed with a sexual transmitted disease<br>• Persons diagnosed with HIV. | Guidance has been amended accordingly. |
| **Bristol-Myers Squibb Pharmaceuticals** | General | | BMS recommends performing the sub typing test on those individuals diagnosed with HCV.<br>The future hepatitis C agents to be introduced in the coming years will most certainly be offering sub genotype | While the guidance does not make reference to sub-type testing, section 1 does state that the recommendations assume that hepatitis B and C tests are provided according to current best practice and that testing facilities |

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| | | | specific treatment. Therefore, the identification of the sub genotype at the point of diagnosis will be critical for the allocation of the patients to the most appropriate treatment, in line with the principles of targeted treatment. | follow advice on appropriate testing methods. |
| **Bristol-Myers Squibb Pharmaceuticals** | General | | According to the EASL guidelines, in HBsAg-positive patients receiving chemotherapy or immunosuppressive therapy including the established and emerging range of biological response modifiers, the risk of reactivation is high, particularly if rituximab is given alone or in combination with steroids. Therefore, EASL recommends all candidates for chemotherapy and immunosuppressive therapy to be screened for HBsAg and anti-HBc prior to initiation of treatment.<br>BMS strongly supports the reference of this sub group as one of the high risk sub groups. | Section 1 of the guidance, under pre-requisites, references the EASL best practice guidelines on managing hepatitis B and C. In addition, section 3 of the guidance now refers, in consideration 3.56, to the need to test candidates for chemotherapy or immunosuppressive therapy for hepatitis B prior to treatment given that in people with hepatitis B, chemotherapy or immunosuppressive therapy can result in a flare-up of liver disease and death by fulminant liver failure. |
| **Bristol-Myers Squibb Pharmaceuticals** | Recommendation 1; What actions should they take | 8 | BMS recommends including HIV campaigns in the existing campaign messages and resources on hepatitis B and C. | Recommendation 1 does state that it should be ensured messages to raise awareness of hepatitis B and C are coordinated and integrated within other health promotion campaigns, where possible or appropriate. However, as noted in consideration 3.12, in section 3 of the guidance, the PDG note that combining awareness-raising campaigns for hepatitis B and C with other health promotion campaigns, such as those for HIV, may risk alienating some populations at increased risk. For example, the PDG was made aware that some migrant populations are unlikely to engage with a campaign that associates hepatitis B with sexually transmitted infection. The need to target awareness-raising |

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| | | | | campaigns to different audiences was felt to be of considerable importance to the PDG. |
| **Bristol-Myers Squibb Pharmaceuticals** | Recommendation 3 | 11 | BMS recommends including education institutions in the local organisations engaging in the local programmes of awareness-raising. | Education institutions are felt to come under the broader terms of 'local organisations providing services for children and adults at increased risk of hepatitis B or C infection.' |
| **Bristol-Myers Squibb Pharmaceuticals** | Recommendation 4 | 12 | BMS recommends incorporating the same comments as in the section "Whose health will benefit". | Recommendation 4 refers back to the section "Whose health will benefit", which has been amended according to your earlier comment. |
| **Bristol-Myers Squibb Pharmaceuticals** | Recommendation 5 | 13 | BMS recommends universal screening upon entry into a prison | Recommendation 5 now recommends that 'all prisoners and immigration detainees are offered access to confidential testing for hepatitis B and C when entering prison or an immigration removal centre and during their detention.' |
| **Bristol-Myers Squibb Pharmaceuticals** | Recommendation 7 | 16 | BMS recommends contract tracing for hepatitis B and C instead of only B | In section 3 of the guidance, consideration 3.30, the PDG note that active contact tracing for people testing positive for hepatitis C is not recommended, given low transmission rates to both sexual and household contacts. The PDG acknowledge that it would be sensible to discuss with individuals, on receipt of a positive test outcome, whether any of their contacts may have been exposed to infection. The testing of identified contacts would be at clinical discretion. In addition, recommendation 8 now states that primary care practitioners should promote the importance of hepatitis C testing for children who may have been exposed to hepatitis C at birth or during childhood. |

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| **British Association for Adoption and Fostering (BAAF** | | | This response is being submitted on behalf of the BAAF Health Group, which is also a special interest group of the Royal College of Paediatrics and Child Health (RCPCH). The Health Group was formed to support health professionals working with children in the care system, through training, the provision of practice guidance and lobbying to promote the health of these children. With over 500 members UK-wide, an elected Health Group Advisory Committee with representation from community paediatricians working as medical advisers for looked after children and adoption panels, specialist nurses for looked after children, psychologists and psychiatrists, the Health Group has considerable expertise and a wide sphere of influence.<br><br>Our area of concern is the particularly vulnerable group comprised of looked after and adopted children and young people, many of whom are at high risk for blood borne infections due to parents who misuse and inject substances. These children are also at risk of sexual abuse and sexually transmitted infections. | Thank you for your comments. |
| **British Association for Adoption and Fostering (BAAF** | general | | Raising the profile of testing for individuals at risk of HCV infection is very welcome. | Thank you. |
| **British Association for Adoption and Fostering (BAAF** | prerequisite | 6 | We do not think the assumption that all front line staff involved in testing are trained in diversity issues is accurate. While ideally this should be true, our members frequently comment on the continuing stigma associated | Recommendation 3 now notes the need for professionals providing health and social care services for people at increased risk of hepatitis B or C to be trained in overcoming social and cultural |

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| | | | with these infections and testing, including among health care professionals. It should be made explicit that this training is required. | barriers and improving access to testing and treatment for people at risk of hepatitis B and C infection. |
| **British Association for Adoption and Fostering (BAAF** | testing | 6 | We do not think the assumption that pre- and post- test discussions will occur is always accurate, or that if they occur they are sufficiently detailed, informative, sensitive and non-stigmatising, so welcome the specific points here which should facilitate improved uptake of testing.<br><br>The guidance should highlight the importance of training in values, communication skills and information needed. | Thank you. In section 3 of the guidance, consideration 3.6, the PDG note that education programmes should typically support, health and other care professionals, depending on role, to be able to list the factors to consider in a pre- and post test discussion and identify how these discussions should be conducted, offering additional advice and support as needed. |
| **British Association for Adoption and Fostering (BAAF** | Whose health will benefit | 7 | We are concerned that in many areas although routine prenatal screening is carried out for hepatitis B, and HIV, it is not offered for hepatitis C, which means significant numbers of hepatitis C infected women and their infants will be missed. We advocate routine prenatal screening for hepatitis C but in its absence prenatal services should routinely ask about risk behaviour, and continue to do so throughout pregnancy for improved identification of all infections due to continued risky behaviour after initial screening. Our members note significant instances where looked after children have later been found to have acquired hepatitis B and C from their mothers, yet the mothers had not been asked about past risk behaviour by maternity services and declined testing at booking appointments. | Screening programmes are beyond the remit of this guidance. In addition, NICE clinical guideline 62, Antenatal Care, does not recommend routine screening for hepatitis C.<br><br>However, recommendation 4 of this guidance states that staff providing antenatal services, including midwives, obstetricians, practice nurses and GPs, should ask about risk factors for hepatitis C during pregnancy and offer testing for hepatitis C to women at increased risk. In addition, recommendation 8 now states that primary care practitioners should promote the importance of hepatitis C testing for children who may have been exposed to hepatitis C at birth or during childhood. |

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| | | | It is not just children living in care homes who may benefit but any looked after child (LAC) as many of their parents have risk factors for hepatitis B and C. | The 'whose health will benefit' section now states 'Looked-after children and young people, including those living in care homes'. |
| **British Association for Adoption and Fostering (BAAF** | Recommendation 2 | 9 | Suggest include 'all health professionals providing services for LAC' in the list of staff needing education | Guidance has been amended; it now refers to 'statutory and non-statutory staff working with looked after children. |
| **British Association for Adoption and Fostering (BAAF** | Recommendation 2 | 10 | In list of what training should cover, it should specify that consent and confidentiality can be particularly complex in situations involving LAC and when testing any child at risk of prenatal exposure, as the mother's status is also being tested. | The pre-requisites set out in section 1 of the guidance states that the recommendations are based on the assumption that hepatitis B and C tests are provided according to current best practice. The recommendations assume that people being tested for hepatitis B and C are offered pre- and post-test discussions, areas listed for consideration include addressing issues of confidentiality and anxiety. |
| **British Association for Adoption and Fostering (BAAF** | Recommendation 6 | 15 - bullet point 6 | We know that often drug and alcohol services fail to take into account the welfare of children of substance misusing parents, and that health services for children may not be aware that these children are at high risk. It is therefore essential to add to this list that drug services staff should routinely consider the needs of the children of their clients who have hepatitis B and C risk factors so that appropriate action re testing, referral and support can be offered. | Recommendation 6 has been amended and now states that drug services should:<br>• provide information to women with hepatitis C about the importance of testing in babies and children born after the woman acquired infection<br>• provide information to injecting drug users about the importance of hepatitis B vaccination for sexual partners and children (see the Green book).<br><br>In addition, recommendation 4 states that Staff providing antenatal services, including midwives, obstetricians, |

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| | | | | practice nurses and GPs, should ask about risk factors for hepatitis C during pregnancy and offer testing for hepatitis C to women at increased risk; while recommendation 8, contact tracing, states that primary care practitioners should promote the importance of hepatitis C testing for children who may have been exposed to hepatitis C at birth or during childhood. |
| **British Association for Adoption and Fostering (BAAF** | Recommendation 7 | 16 | Is there certainty that notification occurs for all cases of hepatitis B, or does this need to be addressed in this guidance to ensure contacts at risk are offered testing ? | Acute hepatitis B is a notifiable disease in the UK. Doctors in England and Wales have a statutory duty to notify a 'Proper Officer' of the Local Authority or local Health Protection Unit/ Public Health England centre.<br><br>Recommendation 8, contact tracing, states that:<br>• Public Health England centres should:<br>○ take overall responsibility for tracing the close contacts of people with confirmed acute and chronic hepatitis B infection<br>○ advise and oversee the activities of other local organisations undertaking contact tracing, such as GP surgeries and genitourinary medicine clinics, to ensure the national standards for local surveillance and follow-up of hepatitis B and C are met. For example, GPs may need to offer close contacts hepatitis B vaccination and refer for treatment |
| **British Association for Adoption and Fostering** | Recommendation 8 | 16 | We welcome this recommendation as our members note that infants who become looked after, are children in | Recommendation 9 now states that 'Public Health England should audit the hepatitis B vaccination programme for |

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| **(BAAF** | | | need or who experience chaotic family life due to substance misusing mothers are at particularly high risk of incomplete immunisation for hepatitis B. It would be very helpful to note these groups here. | babies. The audit should note how many children received vaccines, whether vaccinated children were given all doses and if not how many doses they received, whether doses were given on schedule, whether babies were tested after completing the vaccination course and the rate of vaccination failure. This audit should be carried out annually and deficiencies addressed.'<br><br>In addition, recommendation 4 states that GPs and practice nurses should offer testing for hepatitis B and C to children at increased risk of infection. Looked after children and young people, including those living in care homes are listed at the start of section 1 as a group at increased risk whose health will benefit from the implementation of this guidance. Consideration 3.54 in section 3, notes that it may not always be easy to identify people from groups at increased risk of hepatitis B or C infection. Examples given include: children born to parents who inject drugs, and who may later be placed in care or adopted, or children who have been adopted from a country with medium or high background prevalence. |
| **British Association for Adoption and Fostering (BAAF** | Recommendation 10 | 18 | Under 'audit the uptake...' there should be an analysis of people who test positive who are not referred to a specialist, or are referred but do not attend, so that any patterns can be identified and further work on engagement carried out to improve outcomes. | The guidance has been amended accordingly |

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| **British Association for Adoption and Fostering (BAAF** | Recommendation 10 | 18 – last bullet point | Given the significant numbers of LAC at high risk, they should be identified here along with 'those who are in prison' | The guidance has been amended and no longer refers to 'those in prison'. |
| **British Association for Adoption and Fostering (BAAF** | 3.41 | 33 | **All** children born to parents who inject drugs are at risk, not just those who may later be placed in care or adopted - all of these risk groups should be specified in the guidance wherever possible to raise awareness and make it more obvious. If they remain with their families they are much less likely to be tested than if they go into care, hence the comment re Recommendation 6. | Consideration 3.54 concerns groups at increased risk but where it may not be obvious such as children born to parents who inject drugs who are later placed in care or adopted. The PDG felt the increased risk of children born to parents who are known to inject drugs would be more apparent. |
| **British Association for Adoption and Fostering (BAAF** | General | | The guidance would be strengthened by more specific acknowledgment of:<br>• the need to develop a highly skilled and competent work force with expertise in recognising those at high risk, and with knowledge and skills to maximise uptake of testing<br>• the training requirements to develop this workforce | Recommendation 2 notes the need to ensure there is an ongoing education programme for professionals providing any health and social care services that are for those at increased risk of hepatitis B or C. In section 3 of the guidance, the PDG specify what the training should typically support, this includes being able to identify the risk factors for hepatitis B and C and population groups most at risk of infection of hepatitis B and C; and awareness of the social and cultural barriers to testing and treatment (for example, people's fear of stigma and staff attitudes towards hepatitis B and C) |
| **British Infection Association** | General | | We welcome strategies to improve the take-up of appropriate testing for BBV and have no specific comments on the document | Thank you for your comment. |
| **BHIVA** | **Treatment**<br>Current best practice guidelines on managing | Page 7 | W e would suggest that best practice guidelines for treating HIV/Hepatitis are additionally added. | Guidance has been amended accordingly. |

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| | hepatitis B and C are available from the European Association for the Study of the Liver (EASL). | | For guidelines on managing patients with HIV and hepatitis B or HIV and hepatitis C co infection, please refer to:<br>**British HIV Association guidelines for the management of co infection with HIV-1 and hepatitis B or C virus 2010**<br>G Brook, J Main, M Nelson, S Bhagani, E Wilkins, C Leen, M Fisher, Y Gilleece, R Gilson, A Freedman, R Kulasegaram, K Agarwal, C Sabin and C Deacon-Adams on behalf of the BHIVA Viral Hepatitis Working Group*<br>British HIV Association (BHIVA), BHIVA Secretariat, Mediscript Ltd, London, UK<br>Keywords: HIV, hepatitis B, hepatitis C, guidelines, treatment<br>Accepted 27 August 2009<br>These are in the process of being updated | |
| **BHIVA** | | Page 8 | All patients with Hepatitis B and C should be tested for HIV<br><br>Reasons<br>• Shared mode of transmission<br>• Impact of hepatitis B and C on HIV<br>• Impact of HIV on hepatitis B and C<br>• Treatment guideline differs in HIV co infected population<br><br>**British HIV Association guidelines for the** | Guidance has been amended accordingly. |

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| | | | **<u>management of co infection with HIV-1 and hepatitis B or C virus 2010</u>**<br><br>In addition, awareness programmes should target hepatitis B and hepatitis C and HIV. These awareness programmes should be inclusive and linked**.** | |
| **BHIVA** | 3.39 Snorting drugs and sex have been recently recognised as routes for hepatitis C infection about which there is little data. | Page 32 | **<u>Acute HCV infections in HIV positive men who have sex with men</u>**<br><br>There is little data outside HIV cohorts and this should be appropriately referenced:<br><br>van de Laar T, Pybus O, Bruisten S et al. Evidence of a large,<br>international network of HCV transmission in HIV-positive men who have sex with men. Gastroenterology 2009; 136:<br>1609–1617<br><br>Danta M, Brown D, Bhagani S et al. Recent epidemic of acute<br>hepatitis C Virus in HIV-positive men who have sex with men linked to high-risk sexual behaviours. AIDS 2007; 21:<br>983–991.<br><br>Low E, Vogel M, Rockstroh J, Nelson M. Acute hepatitis | Guidance has been amended accordingly. |

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| | | | C in<br>HIV-positive individuals. AIDS Rev 2008; 10: 245–253<br><br>Ghosn J, Deveau C, Gouiard C et al. Increase in hepatitis C<br>virus incidence in HIV-1 infected patients followed up since primary infection. Sex Transm Infect 2006; 82: 458–460<br><br>Browne R, Asboe D, Gilleece Y et al. Increased numbers of<br>acute hepatitis C infections in HIV positive homosexual men;<br>is sexual transmission feeding the increase? Sex Transm Infect<br>2004; 80: 326–327<br><br>Gotz HM, van Doornum G, Niesters HG et al. A cluster of acute hepatitis C among men who have sex with men: results<br>from contact tracing and public health implications. AIDS 2005; 19: 969–974 | |
| **BHIVA** | **Testing / screening**<br><br>**HCV** | | No mention is given to the frequency of screening for hepatitis C if the test is negative. These are available for HIV infected patients. In addition, HIV infected antibody may take up to a year to become positive, so we recommended performing a pcr test, if the patient presents with abnormal LFT with negative serology and | The guidance has been amended accordingly; the guidance recommends that individuals testing negative for hepatitis C but who remain at risk be re-tested annually. |

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| | | | there is no other explanation.<br><br>**<u>British HIV Association guidelines for the management of co infection with HIV-1 and hepatitis B or C virus 2010</u>**<br><br><u>Recommendations</u><br><br>All HIV-positive patients with unexplained transaminitis should be evaluated for acute HCV infection (with HCV antibody and RNA testing).<br><br>HIV-infected MSM should be tested for HCV antibody on an annual basis.<br><br>HIV-infected MSM should be informed about current understanding of acute HCV infection and possible transmission risks. | |
| **Chinese Health Information Centre(CHIC)** | General | |  <br>Hepatitis B survey in Manchester.doc | Thank you for submitting this survey. This has been passed to the implementation team at NICE. |
| **Department of Health (blood-borne viruses, health inequalities and inclusion policy teams)** | Introduction (testing) | 1 | Please could the Programme Development Group (PDG) consider including under testing *'within homeless hostels and outreach'*, as the populations served will include individuals at risk of infection from past or current | Those working in homeless hostels and providing outreach are now listed in recommendation 3 as professionals providing health and social care services that are for those at increased risk of hepatitis B or C. In addition, |

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| | | | injecting drug use. | recommendation 2 includes homeless hostels as an example of a venue where awareness-raising sessions to promote hepatitis B and C testing could take place. |
| **Department of Health (blood-borne viruses, health inequalities and inclusion policy teams)** | 1 (treatment) | 7 | It might be helpful to refer here to the NICE hepatitis B clinical guidelines that are in development. | Guidance has been amended accordingly. |
| **Department of Health (blood-borne viruses, health inequalities and inclusion policy teams)** | 1 (whose health will benefit?) | 7 | Could you please consider including *'people living in homeless hostels and those sleeping on the streets'*. | Guidance has been amended accordingly. |
| **Department of Health (blood-borne viruses, health inequalities and inclusion policy teams)** | 1 (whose health will benefit?) | 7 | Could you please clarify whether needles and other drug injecting equipment should be mentioned before straws (because of the higher risk involved and evidence base). It may be helpful to expand on what "paraphernalia" includes. | As noted in consideration 3.36 the PDG recognised and understood the potential risks associated with the transmission of hepatitis C via sharing straws to snort drugs but there was a lack of strong biological evidence on which to base recommendations. The key risk was considered to be through sharing injecting equipment; as such this section of the guidance was amended to: 'People who have ever injected drugs.' |
| **Department of Health (blood-borne viruses, health inequalities and inclusion policy teams)** | 1 (whose health will benefit?) | 7 | Could you please consider whether the recent US Centres for Disease Control and Prevention recommendations on one-off hepatitis C testing for people born between 1945-1965 have any relevance in | At its final meeting, the PDG discussed the possibility of testing all people between the ages of 40 and 65 or 70 for hepatitis C infection. They concluded that a birth cohort testing programme is unlikely to be cost effective if it were |

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| | | | this country –<br><br>www.regulations.gov/#!documentDetail;D=CDC-2012-0005-0001 | carried out independently of other programmes. |
| **Department of Health (blood-borne viruses, health inequalities and inclusion policy teams)** | 1 (whose health will benefit?) | 7 | Could you please confirm whether NICE has considered making recommendations in relation to patients presenting with jaundice or with abnormal unexplained liver functions tests. | The PDG noted in section 3, consideration 3.55, other smaller groups who are at increased risk of hepatitis B and C infection including people who present with jaundice or with abnormal liver function tests. It was also noted, in consideration 3.30, that abnormal liver function tests, such as raised ALT (alanine aminotransferase) can occur for a variety of reasons (for example, as a consequence of alcohol consumption and fatty liver, or use of statins). In primary care there is a requirement to investigate the cause of an abnormal liver function test, including testing for hepatitis. In secondary care, however, hepatitis tests should only be conducted if the cause of an abnormal liver function test is not known. |
| **Department of Health (blood-borne viruses, health inequalities and inclusion policy teams)** | 1 | 7 | Could you please clarify whether NICE has considered making recommendations about testing of patients in other risk groups, for example:<br><br>- those who have received transfused blood in the UK before September 1991 or blood products before 1986 (hepatitis C);<br>- patients on renal dialysis (hepatitis B and hepatitis C); | Section 1, whose health will benefit, now lists:<br>– People who received a blood transfusion before 1991 or blood products before 1986, when screening of blood donors for hepatitis C infection, or heat treatment for inactivation of viruses were introduced.<br>– HIV-positive men who have sex with men (in relation to risk of hepatitis C infection) |

# Public Health Programme Guidance

## Hepatitis B and C – Ways to Promote and Offer Testing - Consultation on Draft Guidance
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| | | | - patients with HIV, and;<br>- recipients of organ or tissue transplants in the UK before November 1991.<br><br>Whilst paragraph 3.41 refers to other risk groups, the PDG may wish to consider whether this is prominent enough. | Consideration 3.55 (previously 3.41) lists smaller groups who the PDG felt were at increased risk of hepatitis B and C infection, for example, those who have received renal dialysis in countries where infection control maybe inadequate. |
| **Department of Health (blood-borne viruses, health inequalities and inclusion policy teams)** | Rec 1 | 8 | Could you please consider including: *"ensure awareness-raising messages take into account the needs of those with low literacy level"*. | Guidance has been amended accordingly. |
| **Department of Health (blood-borne viruses, health inequalities and inclusion policy teams)** | Rec 1 | 8 | Could you please consider including the following in the bullet point list: *'ensure messages reach those who make only chaotic interactions with statutory services through innovative awareness raising campaigns'* . | Guidance has been amended accordingly. |
| **Department of Health (blood-borne viruses, health inequalities and inclusion policy teams)** | Rec 2 | 9 | Could you please consider including in the list: *'those working in homeless hostels and providing outreach services'*. | Guidance has been amended accordingly. |
| **Department of Health (blood-borne viruses, health inequalities and inclusion policy teams)** | Rec 2 | 11 | An additional suggested point is to address the needs of those with literacy problems. | Guidance has been amended accordingly. |
| **Department of Health (blood-borne viruses, health inequalities and inclusion policy teams)** | Rec 2 | 12 | In the first bullet point, could you please consider adding *'homeless hostels'* to the list of examples of possible venues. | Guidance has been amended accordingly. |
| **Department of Health** | Rec 4 | 12 | Could you please clarify whether NICE has considered | Recommendation 10 notes that commissioners, working |

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| **(blood-borne viruses, health inequalities and inclusion policy teams)** | | | whether there is a role for community pharmacy based or mobile outreach testing. | with services that provide hepatitis B and C tests and treatment in both primary and secondary care, should develop and commission a fully integrated care pathway. This should consider all venues where testing and treatment services are, or could be offered, to ensure continuity of care and onward referral to specialist treatment for people who test positive (such as pharmacy testing and outreach testing and treatment). |
| **Department of Health (blood-borne viruses, health inequalities and inclusion policy teams)** | Rec 4 | 12 | Could you please clarify whether there is a role for directors of Public Health in promoting hepatitis B and C testing locally in primary care. | Recommendation 4 has been amended to make it clear that the actions in this recommendation are to be undertaken by GPs and practice nurses, antenatal services and local community services serving migrant populations. Directors of public health are listed in recommendation 2 as needing to take action to raise awareness in people at increased risk of hepatitis B or C infection specifically to promote local testing and hepatitis B vaccination services. |
| **Department of Health (blood-borne viruses, health inequalities and inclusion policy teams)** | Rec 6 | 14 | Could you please clarify whether directors of Public Health or Local Authorities should be mentioned under *"who should take action?"*, as they will commission drug services locally. | Guidance has been amended accordingly. |
| **Department of Health (blood-borne viruses, health inequalities and inclusion policy teams)** | Rec 7 | 16 | Who should take action? – will there not be others who may need to take action e.g. general practitioners may need to deliver hepatitis B vaccine? | This recommendation has been amended to make it clear that it relates to the implementation and auditing of the existing recommendations on neo-natal hepatitis B vaccination, rather than the actual delivery of the |

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| | | | | vaccination. |
| **Department of Health (blood-borne viruses, health inequalities and inclusion policy teams)** | Rec 7 | 16 | Could you please clarify whether there needs to be some mention of hepatitis B contact tracing in the GUM clinic context. | Guidance has been amended accordingly, please refer to recommendation 8. |
| **Department of Health (blood-borne viruses, health inequalities and inclusion policy teams)** | Rec 10 | 18 | Under "Who should take action?", we feel that it might be helpful to have a reference to providers of hepatitis C testing and treatment services. | The actions listed in recommendation 11 (previously recommendation 10) specifically relate to commissioners of laboratory services for hepatitis b and c testing. Recommendation 10 (previously recommendation 11) states that commissioners should develop and commission a fully integrated care pathway, working with services that provide hepatitis B and C testing and treatment in primary and secondary care . |
| **Department of Health (blood-borne viruses, health inequalities and inclusion policy teams)** | 2 (Public Health need and practice) | 20 | 95,555 hepatitis C infections were diagnosed by the end of 2011 (see the latest Health Protection Agency annual report on Hepatitis C in the UK -<br><br>www.hpa.org.uk/webw/HPAweb&HPAwebStandard/HPAweb_C/1317135237627 | Section 2 has been updated. |
| **Department of Health (blood-borne viruses, health inequalities and inclusion policy teams)** | 2 (Public Health need and practice) | 21 | In our view, it may be helpful to reference the 360,000 estimate. Could you please confirm which DH study is being referred to. | Section 2 has been updated. |
| **Department of Health** | 2 (Public Health need | 23 | Antenatal screening for hepatitis B has been a national | Guidance has been amended accordingly. |

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| **(blood-borne viruses, health inequalities and inclusion policy teams)** | and practice) | | screening programme since April 2000 -<br><br>www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecirculars/DH_4004295 | |
| **Department of Health (blood-borne viruses, health inequalities and inclusion policy teams)** | 3 (barriers and facilitators) | 26 | Could you please consider adding to bullet points *'lack of awareness because of the lack of access to statutory services'.* | Guidance has been amended accordingly. |
| **Department of Health (blood-borne viruses, health inequalities and inclusion policy teams)** | 3 (testing 3.19) | 29 | As part of NIHR-funded research, we understand that the London 'Find &Treat' TB mobile outreach service is offering blood-borne virus testing alongside TB screening. | Thank you for providing this information. |
| **Department of Health (blood-borne viruses, health inequalities and inclusion policy teams)** | 3 (testing 3.20) | 29 | Could you please consider adding homeless hostels and sexual health drop-in centres as other possible venues for testing. | Guidance has been amended accordingly:<br>• Recommendation 2 states that local organisations should run awareness-raising sessions to promote hepatitis B and C testing in venues and at events popular among groups at increased risk; hostels for the homeless are given as an example. Testing should be offered at these awareness-raising sessions, where this is not possible, information on where and how to access testing locally should be provided.<br>• Recommendation 7 addresses testing for hepatitis B and C in sexual health and genitourinary medicine clinics |
| **Department of Health** | 3 (prisons 3.29) | 31 | Could you please consider whether the PDG has | The guidance now states, in recommendation 2, that |

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| **(blood-borne viruses, health inequalities and inclusion policy teams)** | | | considered whether there is evidence suggesting that homeless hostels may be an appropriate venue for offering hepatitis B and C testing. | local organisations should run awareness-raising sessions to promote hepatitis B and C testing in venues and at events popular among groups at increased risk; hostels for the homeless are given as an example. Testing should be offered at these awareness-raising sessions, where this is not possible, information on where and how to access testing locally should be provided. |
| **Gilead Sciences Limited** | GENERAL | N/A | In creating the guidance the PDG have highlight the lack of data that is currently available to adequately asses testing, diagnosis, awareness and treatment commissioning. However as utilized by the PDG, personal experience and small data sets offer insights that can aid critiquing and assessing intervention methods. In the considerations outlined below reference has been made to a unique data set that exists which specifically was created by Gilead Sciences through the Gilead Fellowship Programme to generate and promote best practice in the delivery of patient-centred care through innovative and reproducible models in HBV testing. These projects have been supported since 2009 and similar projects in HIV testing have generated data to shape public health policy (either at local or national level) in the UK and Ireland, and to generate new studies or joint ventures to shape clinical care pathways. Most recently the HIV data set was cited in the Health | Thank you for this information. |

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| | | | Protection Agency (HPA) guidance document ;' Evidence and resources to commission expanded HIV testing in priority medical services in high prevalence areas, April 2012'. Since 2009 over half a million pounds have been invested through the Gilead Fellowship Programme in HBV testing initiatives in specialized care, community, primary care and in prisons. Further details of the Gilead Fellowship HBV testing programmes can be found in the appendix of this response and by going to the Fellowship website at http://www.ukifellowshipprogramme.com/hepatitis-b-section | |
| **Gilead Sciences Limited** | 1 | 8 | The guidance that commissioners and providers of national public health services should work in partnership with other allied organizations both commercial and no-profit making is prudent and has been proven to be a model of success in other therapeutic areas, such as HIV. However there should be a requirement for these various parties to co-ordinate their awareness activities and pool all available resources, this is suggested by the recommendation but is not implicit, as this would create a consistent awareness message and potentially will have great reach into high risk communities both at a regional and national level. Furthermore consistent messaging could and can lead to reducing the stigma associated with both HBV and HCV amongst the general population if handled in a sensitive manner. | The guidance has been amended accordingly, recommendation 1 states that messages to raise awareness of hepatitis B and c should be coordinated. |

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| **Gilead Sciences Limited** | 1 | 8 | Any awareness campaign as well as being consistent, clear and culturally appropriate must be sustainable for a given length of time to ensure the longevity of the messaging and cross generation cultural acceptance. | To aid sustainability, the guidance refers to the need to ensure messages to raise awareness of hepatitis B and C are integrated within other health promotion campaigns, where possible or appropriate |
| **Gilead Sciences Limited** | 1 | 9 | Whilst the recommendation is pragmatic in its approach and focuses on health care professionals who were likely to be providing services for those at increased risk of hepatitis B or C and consideration was given to educating all health professionals, there should be a general awareness amongst healthcare providers of the risk factors for HBV or HCV and the potential clinical complications In the case of chronic HBV infection the risk of reactivation due to immunosuppressant /modulation medicines (such as a chemotherapy regimen) carries significant morbidities and mortality outcomes. Hence within this recommendation it would be prudent to define the services referred to or otherwise define the services as 'any clinical service provision that maybe accessed by a high proportion of individuals that maybe at risk of being infected with HBV or HCV' | The guidance has been amended accordingly; it now states that an ongoing education programme should be provided 'for professionals providing health and social care services for people at increased risk of hepatitis B or C infection. This includes:<br>– clinical and non-clinical staff in primary and secondary care including nurses, health visitors, midwives, healthcare assistants and support workers as well as staff in sexual health, genitourinary medicine and HIV clinics<br>– people working in drugs services<br>– staff in community-based criminal justice services<br>– social workers working with people at increased risk of hepatitis B or C infection<br>– statutory and non-statutory staff working with looked-after children<br>– prison, youth offender and immigration removal centre staff<br>– staff in voluntary and community organisations that care for or support migrant populations, people who inject drugs, people with HIV, or men who have sex with men<br>– people working in hostels for the homeless and providing outreach services to homeless people. |

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| **Gilead Sciences Limited** | 1 | 9 | To aid cohesive and widespread development of awareness in health and social care staff professional bodies such as the Royal College of Physicians could be named alongside NHS deaneries, the current statement implies this but drawing out key professional bodies beyond deaneries may increase implementation of the recommendation | The guidance has been amended and now lists the following organisations as needing to take action:<br>• Health Education England.<br>• Public Health England.<br>• Royal medical and nursing colleges.<br>• Local authorities, in particular directors of public health.<br>• Clinical commissioning groups.<br>• Local education and training boards. |
| **Gilead Sciences Limited** | 1 | 11 | As with recommendation 1, encouragement should be given for the organisations named to seek partnerships with the commercial sector, not-for-profit and NGOs. Again this maybe implied but it should be explicit. | The recommendation has been amended; It now states that Public Health England, the NHS Commissioning Board and directors of public health should facilitate partnership working, between those listed to take action, to ensure there is a coordinated national and local programme of awareness-raising about hepatitis B and C among groups at increased risk. |
| **Gilead Sciences Limited** | 1 | 12 | Primary Care practitioners must also have a care pathway in place and should be encouraged to develop this with their local specialist centre for viral hepatitis, commissioners and public health directors. | Recommendation 10 states that 'commissioners should develop and commission a fully integrated care pathway, working with services that provide hepatitis B and C testing and treatment in primary and secondary care (in the community or specialist services in hospital).' |
| **Gilead Sciences Limited** | 1 | 12 | There must be a tracking method in place, potentially implemented by public health directors to monitor testing | Recommendation 10 states that commissioners should audit the uptake of testing and outcomes, including: |

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| | | | offering and uptake and then linkage to care and contact tracing. If not on a national basis, it should be a requirement in areas with potentially a high prevalence of HBV or HCV based on population demographics | • the number of people tested for hepatitis B and C<br>• the number of people diagnosed with hepatitis B and C<br>• the number of people with chronic infection who:<br>o are referred to a treatment service<br>o attend a treatment service<br>o are receiving treatment in accordance with treatment guidelines<br>• the number of people with hepatitis C who obtain a sustained virological response on antiviral therapy.<br><br>The PDG also noted, in section 3, consideration 3.53 the need for a comprehensive hepatitis B and C database holding details on people who have been tested and treated and on those who are at increased risk but have chosen not to be tested. They noted the importance of collecting data on treatment uptake and the need for this data collection to be built into the pathway at every point was noted. However, it was felt that there needed to be a balance between the burden of collecting data and the value of those data. |
| **Gilead Sciences Limited** | 1 | 12 | If a high risk individual has tested negative for HBV, but remain at risk of acquiring the infection at a later date, general practitioners should offer vaccination to the individual. | The guidance has been amended accordingly. |
| **Gilead Sciences Limited** | 1 | 12 | General practitioners should be made aware through public health directors of awareness campaigns in their region and be granted access to materials (especially in | The guidance has been amended accordingly; recommendation 2 now states that directors of public health should facilitate partnership working to ensure |

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| | | | foreign languages) to give to individuals that test negative for the infections but may continue to be at risk. | there is a coordinated local programme of awareness-raising about hepatitis B and C among groups at increased risk. |
| **Gilead Sciences Limited** | 1 | 12 | There should be a recommendation that the Royal College of General Practitioners and deaneries to also take action and provide support in the form of education, development of testing and care pathways on a national level specifically for GPs, outside of the guidance in recommendation 2, based on the fact that this particular group of physicians will have access to more individuals at risk than any other professional healthcare group. | The PDG note in section 3, consideration 3.5 that targeted education programmes for health and social care professionals was considered key, such as that produced by the Royal College of General Practitioners. This programme is aimed at generalist clinicians such as GPs and nurses working in primary care, and covers detection, diagnosis and management of hepatitis B and C in primary care. |
| **Gilead Sciences Limited** | 1 | 12 | It would be prudent to encourage GPs to audit the notes of high risk individuals that may have been diagnosed in the past and ensure they are still linked to appropriate specialist care, previous audits conducted in GP practices have uncovered many individuals 'lost to follow-up', either due confusion on the patient's behalf or misinterpretation of HCV/HBV test results by the GP | Recommendation 4 states that GPs should ensure people diagnosed with hepatitis B or C are referred to specialist care, this would include those who had been diagnosed in the past but who were no longer linked with specialist care services. |
| **Gilead Sciences Limited** | 3 | 27 | Stigma of being diagnosed with HBV and HCV as the PDG comment is a key barrier to uptake of testing, however when testing and treatment services are presented in a culturally sensitive manner uptake is very high, this was a key finding amongst the Fellowship projects, of consideration, the projects seemed to reveal the root cause was a lack of awareness and not a fear of being stigmatized. A key facilitator to uptake was | Thank you for providing this information. The PDG discussed the need to raise awareness and for awareness-raising activities to take into account cultural, religious and group norms and needs, in terms of message format, the medium and the language used. This is reflected in recommendations 1-3. |

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| | | | ensuring appropriately translated and accessible materials were available both as text and in a multi media format. | |
| **The Hepatitis C Trust** | General | | Overall we are very happy with these guidelines and look forward to the benefits they will bring to people at increased risk of hepatitis B & C. To facilitate the use of – and reporting against – them it might be helpful though to number them in slightly more detail (especially the recommendations – so we can refer to recommendation 6a, for example). | Thank you for your comments. |
| **The Hepatitis C Trust** | General | | We very much welcome the emphasis on the importance of the whole pathway to encouraging greater levels of testing.<br><br>We are very concerned, however, by recent reports of local areas refusing to increase hepatitis C testing services because their treatment facilities might not meet an increased demand (we've heard this for hep C but that may simply reflect our focus being predominantly on C, it may also be the case for hep B). The rationale for this is that it's immoral to test someone if you can't offer them immediate treatment, so much so that people can be | The guidance has been amended accordingly, recommendation 10 states that commissioners should regularly undertake a health needs assessment, health equity audit and an audit of hepatitis B and C services as part of the agreed local care pathway and commission testing and treatment services accordingly. |

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| | | | denied the right to diagnosis and control over their own health.<br><br>We feel that given this 'whole pathway' approach it's important to explicitly state that testing should not be commissioned according to treatment services but according to the needs of local people. | |
| **The Hepatitis C Trust** | General | | Particularly when working with harder to reach populations – as we are here – placing Peer support/ mentors/ workers front and centre to interventions (especially those focused on education and support with diagnosis & treatment) can make a huge difference.<br><br>This approach should be explicitly included in the recommendations, especially in numbers 2 (when educating healthcare staff) 3, 4, 5 and 6. | As detailed in section 3, consideration 3.10, the PDG recognised a role for the peers of people at increased risk in promoting hepatitis B and C testing and supporting people who are diagnosed positive. In consideration 3.37, the PDG noted the lack of evidence specific to the role of peer support in promoting the uptake of testing and treatment for hepatitis B and C. Evidence of its positive effect on attitudes, knowledge and behavioural practices relating to prisoners' sexual health was considered. Based on this evidence, the PDG considered it logical that peer support could be beneficial for the groups of interest identified in the guidance and made reference to it in recommendations 5 and 6. |
| **The Hepatitis C Trust** | 1 | 6 | **Draft recommendations, Pre-requisites, testing**<br><br>People being tested should be provided with information about what will happen if the result is positive – including what the result will mean (especially, for hepatitis C, whether they're being tested for antibodies or PCR). They should also be offered details of support available, | Section 1 now details areas to consider when offering a test for hepatitis B or C, these include information to enable people to make informed choices about their care should they test positive as well as details of support available for clinical and non-clinical needs both while waiting for test results and following diagnosis. |

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| | | | including while they are waiting for their result (e.g. Hep C Trust helpline) | |
| **The Hepatitis C Trust** | 1 | 7 | **Draft recommendations, Whose health will benefit?**<br><br>There seems to be some lack of clarity as to whether this guidance promoted testing for people from countries where hepatitis B alone is of intermediate/high prevalence, as stated here, or where it's aimed at people from countries where 'hepatitis' is of intermediate/high prevalence (p.12).<br><br>This is perhaps referred to in the Considerations section (section 3, Limitations point 3.21) but the current lack of evidence should not deter this group bring considered at increased risk.<br><br>We would strongly recommend that this guidance promote testing for any person from a country in which hepatitis B or hepatitis C or both viruses are of intermediate or high prevalence.<br><br>Not only is this vital because there is a significant overlap between the populations affected by hepatitis B & C and between transmission routes (i.e. largely 9 billion unsafe injections worldwide each year) but also because we are still at a very early stage in understanding hepatitis C | This section of the guidance has been amended to clarify the groups at increased risk of hepatitis B and C. |

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| | | | prevalence in migrant communities and excluding this from these guidelines for 'people at increased risk' is likely to undermine future efforts to address this. Given the findings from initial studies, such as those in the British Pakistani population (from Uddin et al) this burden could be significant. | |
| **The Hepatitis C Trust** | 1 | 7 | **Draft recommendations, Whose health will benefit?**<br><br>Recent years have seen a massive increase in the distribution of needles for injecting Performance and Image Enhancing Drugs (PIEDs); overwhelmingly steroids but also in some areas tanning agents, for example. We've received reports from many areas and services that half or more than half of their exchanges are now for injecting PIEDs.<br><br>Although evidence that transmission is occurring in these populations is not comprehensive, there are increasing reports of transmission and given the likelihood that prevalence will increase as the viruses become more common among this population this would seem the ideal time to begin to target testing at this population and normalise it as a basic and routine health measure. | In section 3 the PDG note the potential risk of hepatitis C transmission among people that inject performance and image-enhancing drugs (PIEDs) such as anabolic steroids (for non-medical reasons). However, there is a lack of published evidence on the extent of risk in this group or on their contribution to overall hepatitis C prevalence. People who inject PIEDs are of course included in the group 'People who have ever injected drugs' who are noted in the guidance as a group at increased risk. In addition, recommendation 4 of the guidance states that GPs and practice nurses should ask newly registered adults if they have injected drugs, including image and performance enhancement substances at their first consultation. |

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| **The Hepatitis C Trust** | 1 | 8 | **Recommendation 1, Who should take action, point 4**<br><br>This would be applicable to the local as well as the national voluntary sector | Guidance has been amended accordingly. |
| **The Hepatitis C Trust** | 1 | 11 | **Recommendation 3, What action should they take, bullet 2**<br><br>We'd suggest an additional bullet under 'Local organisations should provide...this should:<br>- Be written in an appropriate way for the target population(s), including those with limited literacy<br><br>It may also be helpful to rephrase the final bullet to 'be appropriate for the target age group(s)' as effective educational material can't be appropriate to all ages – something for a 50 year old would not be the same as that for a 15 year old. | Guidance has been amended accordingly. |
| **The Hepatitis C Trust** | 1 | 12 | **Recommendation 3, What action should they take**<br><br>We'd suggest an additional bullet that provision of testing should be incorporated into awareness wherever possible. Offering screening alongside education can be effective in some settings, capitalising on people's motivation at the time and also on the presence of people with personal experience and trained staff to answer questions and provide testing. | Guidance has been amended accordingly. |

# Public Health Programme Guidance

## Hepatitis B and C – Ways to Promote and Offer Testing - Consultation on Draft Guidance
## Stakeholder Comments Table

## 13th June – 8th August 2012

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| | | | If not possible on site, information on where and how to access testing locally should be provided as a minimum at all awareness events. | |
| **The Hepatitis C Trust** | 1 | 13 | **Recommendation 4, What Action Should they take, bullet 4 point 1:**<br><br>The definition of 'prisoners at increased risk' would benefit from some clarification. In 2010 & 2011, no more than 7% of new receptions per quarter were tested for hepatitis C (Parliamentary Question response from Paul Burstow to Paul Goggins, 8th March 2012 http://www.publications.parliament.uk/pa/cm201212/cmhansrd/cm120308/text/120308w0002.htm), and yet all prisons are currently monitored against the PHPQI 1.29 on Hepatitis C to evidence that *All those at risk are offered confidential screening for Hepatitis C*. Clearly a risk-based approach is not working.<br><br>The HPA Commissioning toolkit uses estimates of 7% anti-HCV prevalence for sentenced and 20% for remand prisoners; this is clearly a very high prevalence population, around least 14 times the UK average.<br><br>We would therefore posit that all prisoners are at increased risk of infection, as indeed is recognised with the inclusion of *Prisoners and young offenders* on the 'Whose Health Will Benefit' list on page 7 of this guidance. | The guidance has been amended accordingly and now states that all prisoners and immigration detainees are offered access to confidential testing for hepatitis B and C when entering custody and during their detention. |

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| | | | In addition, opportunities for transmitting BBVs such as through tattooing, sharing hair clippers or razors, needles, unprotected sex and so forth are higher In the prison setting. As such a universal offer of a test for hepatitis B and C (and HIV) would seem entirely appropriate for this population. | |
| **The Hepatitis C Trust** | 1 | 13/14 | **Recommendation 4, What action should they take, bullet 4**<br><br>Given the prevalence of hepatitis B and C in the prison population it's important that all staff have a basic level of understanding of these viruses. We would therefore suggest an additional point specifying that mandatory basic BBV training is provided to all prison staff in all prisons.<br><br>This is vital both so they can treat prisoners who have hepatitis appropriately, and also for their own peace of mind (e.g. when having to clean up blood, intervening in fights, worried about transmission through spitting etc). | The guidance has been amended accordingly; recommendation 5 now states that all prison and immigration removal centre staff are trained to promote hepatitis B and C testing and treatment and hepatitis B vaccination. The detail of what this training should cover is listed in recommendation 3. |
| **The Hepatitis C Trust** | 1 | 15 | **Recommendation 6, What Action Should they take, bullet 6 point 3:**<br><br>It would be very helpful to define 'routinely' in this context. | The guidance has been amended, the recommendation now states that people who test negative for hepatitis C but who remain at increased risk of infection should be offered testing annually. |

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| | | | We've received a number enquiries from staff working with people at ongoing risk – particularly those in drug services – as to how often their clients should be offered testing.<br><br>Setting a standard for this (nurses we work with tend to suggest every six months) is vital to helping services structure their screening in a way that will:<br>- make testing genuinely routine and normal for this population,<br>- Help staff respond to 'I've already been tested for that' response and thus encourage regular routine, and<br>- identify cases early enough to minimise the risk of onward transmission and optimise the chances for effective treatment. | |
| **The Hepatitis C Trust** | 1 | 17 | **Recommendation 9, What Action Should they take, bullet 1 point 5:**<br><br>We'd suggest labs always run an RNA test if possible when a sample is antibody positive. Since this can't be done with some (e.g. oral fluid) we'd suggest this be rephrased as:<br>Whenever possible, automatically perform an assay for detection of hepatitis C virus in the sample if the sample is antibody positive (for example, the polymerase chain | Recommendation 11 has been amended accordingly and now states that laboratories should automatically test samples that are positive for hepatitis C antibody for the presence of hepatitis C virus (for example, using a polymerase chain reaction [PCR] assay), or refer the sample to a laboratory which can perform this test. |

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| | | | reaction assay). This should be the default (opt-out) procedure for all appropriate samples.<br><br>This is all too often not done (for example the recent HPA prisons survey found that just 40% (44/110) of blood samples taken in prison are routinely tested for PCR if they have a positive antibody test result, http://www.dh.gov.uk/health/files/2012/07/Hep-C-Prison-Survey.pdf) is. | |
| **The Hepatitis C Trust** | 1 | 17 | **Recommendation 9, What Action Should they take, bullet 3:**<br><br>Since at the present time some primary care practitioners' knowledge of hepatitis is inadequate or out of date, we would suggest laboratory results automatically include some basic information on where to direct patients for further information and patient support (eg national help lines, websites).<br><br>We'd recommend an additional bullet under the third bullet in this section which states:<br>- Provide the organisation or person requesting a test with details of where the patient can find further information and support | Recommendation 11 has been amended and now states that laboratories should provide the organisation or professional requesting a test with an accurate interpretation of the laboratory results and guidance on future management of confirmed cases, such as onward referral to specialist care. |
| **HEALTH PROTECTION AGENCY (HPA)** | Recommendation 2 Awareness raising | 9 | PHE and CCGs should be added to the list<br>More specifically, PHE will provide "health improvement | Guidance has been amended accordingly. |

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| | amongst health professionals and others providing services for those at increased risk of hepatitis B or C: Who should take action | | support for local authorities and NHS CB, and social marketing and behaviour change campaigns including campaigns to prompt early diagnosis via awareness of symptoms", whilst CCGs will be responsible for commissioning "Promoting early diagnosis as part of community health services and outpatient services". (from "Commissioning fact sheet for clinical commissioning groups") | |
| **HEALTH PROTECTION AGENCY (HPA)** | Recommendation 3: Who should take action? | 11 | As per above | Guidance has been amended accordingly. |
| **HEALTH PROTECTION AGENCY (HPA)** | Recommendation 5: What action should they take | 13 | Perhaps there should be a bullet point reminder that prison health care staff needs to notify Hepatitis C and Hepatitis B cases to local HPU | The pre-requisites to the recommendations state that the recommendations are based on the assumption that Standards for local surveillance are followed, including laboratory reporting to Public Health England centres and follow-up of hepatitis B and C. |
| **HEALTH PROTECTION AGENCY (HPA)** | Recommendation 6: What action should they take? | 15 | Bullet point: "Medical staff should use their clinical judgment to determine who is suitable for hep B or C treatment in a community setting" Should it better to specify which medical staff here? I think it should be up to specialist secondary care staff to determine who is suitable for treatment, while other medical staff in the community should simply encourage referral to specialist staff. Once the hepatitis C module for GPs has had some up-take from GPs, then those who will have been certified as "GPs with special interest" would be able to | Guidance has been amended and now states: 'Commissioners of hepatitis testing and treatment services should agree local care pathways for people with hepatitis B and C who use drugs services. If possible, the pathway should include provision of hepatitis C treatment services in the community. ' |

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| | | | make themselves the above decision | |
| **HEALTH PROTECTION AGENCY (HPA)** | Recommendation 6: What action should they take? | 15 | Again a reminder to drug users services that they should be notifying cases of hepatitis to local HPUs. Often DUs use private laboratories to test their clients and the samples they send to the laboratories are even anonymous, therefore the labs cannot report (even if they wished so) positive tests to local HPUs. In our region (Y&H) the HPA has been working closely with the NTA to agree reporting systems to local HPUs | The pre-requisites to the recommendations state that the recommendations are based on the assumption that Standards for local surveillance are followed, including laboratory reporting to Public Health England centres and follow-up of hepatitis B and C. |
| **HEALTH PROTECTION AGENCY (HPA)** | Recommendation 9: What action should they take? | 17 | - "can automatically perform an assay for detection of hep C virus in the sample if the sample is Ab positive (for example, the PCR)"<br>Not all labs are able to do PCR, so the recommendation should be amended by adding:"….perform an assay **or refer the sample to a lab which can perform an assay….** | The guidance has been amended accordingly. |
| **HEALTH PROTECTION AGENCY (HPA)** | Recommendation 10 What action should they take? | 18 | Audit the up-take of testing and outcomes, including the number of :<br>Add - :**people who were assessed by a specialist but for whom treatment was not deemed appropriate at the moment and longer term follow up is in place for** | The guidance has been amended to:<br>'Commissioners should audit the uptake of testing and outcomes, including:<br>• the number of people tested for hepatitis B and C<br>• the number of people diagnosed with hepatitis B and C<br>• the number of people with chronic infection who:<br>  ○ are referred to a treatment service<br>  ○ attend a treatment service<br>  ○ are receiving treatment in accordance with treatment guidelines |

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| | | | | • the number of people with hepatitis C who obtain a sustained virological response on antiviral therapy.' |
| **HEALTH PROTECTION AGENCY (HPA)** | Hepatitis B | 22 | More recent data on incidence of acute Hepatitis B are available from the HPA. The incidence has reached a historical low in 2010 and this should be appropriately reflected in this important NICE paper. | Section 2 has been updated. |
| **HEALTH PROTECTION AGENCY (HPA)** | Testing | 29 | " ….people had repeatedly been vaccinated against hep b but not tested for infection…."<br>The hepatitis B vaccination program in prisons does not require pre-testing. This key Public Health decision was taken on the epidemiological evidence that the incidence and prevalence of Hepatitis B in this country amongst the autochthonous population is very low. The main objective of the programme was to vaccinate and protect against hepatitis B as many as possible individual at risk; having pre test would have slowed down the whole process and seriously hampered the success of this programme. As it stands the programme in prisons has been extremely successful with the greatest proportion of DUs surveyed annually indicating that if they are vaccinated, they have indeed been vaccinated while in prisons. Furthermore: the large outbreaks of hepatitis B amongst DUs which took place in the late '90s early '00s, have not been repeated providing further evidence of the efficacy of this programme, together with the very current incidence of the disease. | The guidance has been amended to:<br><br>'Prison and immigration removal centre healthcare services should ensure that:<br>• all prisoners and immigration detainees are offered hepatitis B vaccination when entering prison or an immigration removal centre (for the vaccination schedule, refer to the Green book)<br>• all prisoners and immigration detainees are offered access to confidential testing for hepatitis B and C when entering prison or an immigration removal centre and during their detention.'<br><br>In section 3, consideration 3.45 notes the importance of testing being offered in prisons after vaccination, so as not to hamper the success of the established hepatitis B vaccination programme. |

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| | | | There is however an issue when prisoners are not from the autochthonous population , but come from prevalence areas. A re-think of the vaccination programme in prisons will have to be done at some point to take into account the ethnic changes in the prison population. | |
| **HEALTH PROTECTION AGENCY (HPA)** | Data: 3.37 | 32 | Totally agree with idea of data bases (I personally have a quite comprehensive one in my unit and I am just embarking in a programme of exchange of information with local specialist provider to identify individuals ho where tested incompletely and not referred and so on). I am aware, however, that they are people very concerned about data bases and Caldicott issues; it would be of great help to have clear indications from NICE dispelling some of the myths about confidentiality and legality of data bases! | The pre-requisites to the recommendations list issues concerning confidentiality and anxiety as areas to cover when offering a text for hepatitis B or C. |
| **HEALTH PROTECTION AGENCY (HPA)** | Recommendation 9 What action should they take? | 17 | Perhaps it would be worthwhile add something general such as "…other tests has they become available and established" to the examples within the brackets, as there are methods being developed, such as near patient testing, capillary tube testing and so on , which might become more and more relevant | Recommendation 11 now states commissioners should ensure 'service specifications specify that laboratory services providing hepatitis B and C testing can support the range of samples used for hepatitis B and C testing (for example, dried blood-spot or venepuncture samples) or can refer the sample to a laboratory which can perform these tests'. This was felt to cover both existing tests and other tests as they become established. |
| **HEALTH PROTECTION** | General | | A very useful paper indeed! Just needs a few refinements | Thank you for your comments. |

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| **AGENCY (HPA)** | | | | |
| **HEALTH PROTECTION AGENCY (HPA)** | ***Recommendation 7 Contact tracing for hepatitis B*** | 16 | Public Health England units should be directly accountable for tracing the close contacts of all notified cases of hepatitis B. This is appropriate for all acute cases of hepatitis B. The national standards recommend contact tracing for chronic hep B but currently HPUs will not usually do this themselves but will advise GP(or other) to undertake contact identification and screening. HPUs/PHECs cannot be directly responsible for the actions of GPs/other clinicians – they can be responsible for advising it is done. | The guidance has been amended accordingly. |
| **HEALTH PROTECTION AGENCY (HPA)** | ***Recommendation 9 Laboratory services for hepatitis B and C tests*** | 17 | Commissioners of laboratory services offering hepatitis B and C tests should ensure laboratory services offering hepatitis B and C tests:<br>- can support the range of samples used for hepatitis B and C tests (for example, dried blood-spot or venipuncture samples) – not all labs need to be able to do DBS samples – e.g. those doing GP and hospital specimens. It should only be done by labs who do it frequently<br>- can provide the full spectrum of tests needed to determine infection – not all labs need to be able to do this – many refer specimens positive on a screening test to another lab for more specialist tests which is appropriate<br>- can automatically perform an assay for detection of hepatitis C virus in the sample if the | The guidance has been amended accordingly. |

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| | | | sample is antibody positive (for example, the polymerase chain reaction assay) – not all labs need to be able to do this – many refer on to another specialist lab. | |
| **HEALTH PROTECTION AGENCY (HPA)** | General | | Seems to consider DBS and venepuncture samples tested as identical in terms of sensitivity and specificity. Venepuncture is gold standard and DBS is not – it is silver and very useful in some settings but the results are not identical. | The guidance has been amended accordingly. Consideration 3.21, in section 3 of the guidance states: 'While venepuncture samples remain the gold standard, the PDG noted that dried blood spot tests for hepatitis B and C have a high test sensitivity and specificity and can be useful in certain settings for people with poor venous access and where there may be no facilities or expertise to take venous blood samples (for example, in specialist drug treatment services or prisons)..' |
| **HEALTH PROTECTION AGENCY (HPA)** | introduction | 1 | 'and' rather than 'including' young offenders…under 'Testing- | Guidance has been amended accordingly. |
| **HEALTH PROTECTION AGENCY (HPA)** | Introduction | 1 | Add 'at risk ethnic groups' under Testing- | The bullets listed under testing now refers to settings rather than groups considered to be at increased risk. |
| **HEALTH PROTECTION AGENCY (HPA)** | Section 1 | 10 | Add '- availability and need for vaccination against hepatitis A in those with chronic hepatitis' | Hepatitis A was beyond the remit of this guidance, however, section1 states that the recommendations are based on the assumption that hepatitis B and C tests are provided according to current best practice and are offered as part of a care pathway covering diagnosis, treatment and |

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| | | | | immunisation. In relation to immunisation the guidance refers to the Department of Health's Green book – Immunisation against infectious disease, which of course details the need to consider vaccination against hepatitis A for those with chronic hepatitis B or C. NICE clinical guidelines on hepatitis B and hepatitis C are currently under development. |
| **HEALTH PROTECTION AGENCY (HPA)** | | 24 | After postexposure immunisation add '(which may include hepatitis B immunoglobulin as well as vaccine)' | Guidance has been amended accordingly |
| **HEALTH PROTECTION AGENCY (HPA)** | | 15 | 'Be trained to undertake dried blood spot testing' – add (and oral fluid collection) | No recommendations were made on the use of oral fluid for hepatitis B or C testing. The PDG recognised that this method may be more acceptable to some people because it is less invasive than taking blood from a vein. However, if an oral fluid sample was used, a blood sample would then be required to confirm the initial positive results, and for PCR testing to diagnose chronic hepatitis C. |
| **HEALTH PROTECTION AGENCY (HPA)** | 3.41 | 33 | 'Received medical or dental procedures abroad'- add specifically 'including renal dialysis' | The guidance has been amended accordingly. |
| **HEALTH PROTECTION AGENCY (HPA)** | 3.44 | 34 | 'have their immunity confirmed' – testing for immunity in babies after the vaccination course is not current UK policy which advises testing for HBsAg at 12 months to exclude infection | The guidance has been amended accordingly. |
| **HEALTH PROTECTION** | 3.58 | 36 | Contact tracing following a new notification – need to | Recommendation 8 states that Public Health England |

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| **AGENCY (HPA)** | | | clearly state whether contact tracing is expected after every case both acute and chronic | centres should take overall responsibility for tracing the close contacts of people with confirmed acute and chronic hepatitis B infection. No recommendations were made for active contact tracing for people who test positive for hepatitis C given low transmission rates to both sexual and household contacts. The PDG acknowledged that it would be sensible to discuss with people who test positive whether any of their contacts may have been exposed to infection, including the children of mothers with hepatitis C infection. Testing of identified contacts would be offered at clinical discretion. |
| **HEALTH PROTECTION AGENCY (HPA)** | general | | No mention of delta testing | This was beyond the remit of this guidance. |
| **HEALTH PROTECTION AGENCY (HPA)** | | Page 15 | I wonder if the encouragement to use DBS testing should be accompanied by some caveat with respect to infection control. For example, a specific mention of the need to ensure facilities are adequately equipped with sharps bins and take advice on infection control – particularly if testing is to be done outside of healthcare settings in a group at high risk of bloodborne viruses. | The guidance has been amended accordingly. |
| **HEALTH PROTECTION AGENCY (HPA)** | | Page 20 | The estimates of the proportion diagnosed are extremely low and out of date. The numbers diagnosed and reported are already > 95000 (Hep C 2012 but also over 80,000 in 2011) and allowing for under-reporting this suggests the number diagnosed is substantially higher than 30%. In addition, a higher figure is supported by the | Section 2 of the guidance has been updated. |

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| | | | survey quoted on page 21 that over 55% of positive IDUs have been tested. | |
| **HEALTH PROTECTION AGENCY (HPA)** | | Page 21 | The DH prevalence estimates were obtained from WHO estimates. The "DH study of laboratory reports" was actually an HPA study which estimated incidence of hepatitis B from laboratory reports – this was used to inform the DH decision on cost-effectiveness of universal vaccination. | The guidance has been amended accordingly. |
| **HEALTH PROTECTION AGENCY (HPA)** | | Page 23 | You may wish to refer to the new publication in Eurosurveillance. Differences in hepatitis B infection rate between ethnic groups in antenatal women in Birmingham, United Kingdom, May 2004 to December 2008. http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=20228 | Section 2 of the guidance now references the sentinel surveillance programme, detailing the percentage of women tested in the antenatal programme who tested positive and their ethnicity. |
| **HEALTH PROTECTION AGENCY (HPA)** | | Page 16-17 | Annual audit of infant hepatitis B is totally inadequate to prevent infection – if you wait a year and then audit you are potentially missing an opportunity to use a cost-saving interevention to prevent a life-threatening disease.<br><br>When universal screening was recommended in 2000 it was recommended that all DHAs (now PCTs) should have a name coordinator and that this individual should coordinate the programme. In addition, supplying quarterly coverage data has been a ROCR requirement | The PDG emphasised existing hepatitis B vaccination recommendations (as detailed in the Green book) because although hepatitis B vaccination was beyond the scope of this guidance, case-finding may identify contacts of infected individuals who should be offered vaccination. As such, recommendation 9 states that directors of public health should ensure existing recommendations on hepatitis B prophylaxis for babies born to mothers with chronic hepatitis B infection are implemented locally by general practitioners, as described in the Green book. |

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| | | | since 2006 and yet around 30% of PCTs do not supply coverage data. This is a major failure of basic care – without an active call recall system and regular monitoring of coverage (which comes from the former) children will miss out on this intervention.<br><br>This was recently a subject of further recommendations by NICE PH21 and most of these recommendations need to be referred to in this document. (see below table in yellow) | |
| **HEALTH PROTECTION AGENCY (HPA)** | | Page 17 continued | PCTs should have an identified person responsible for coordinating the local hepatitis B vaccination programme for babies at risk of hepatitis B infection. The person should also be responsible for scheduling and follow-up to ensure babies at risk are vaccinated at the right time. This may involve working within and across several PCT areas.<br>A clear process for the local infant hepatitis B vaccination programme should be developed and implemented. Antenatal, postnatal, neonatal, paediatric, primary care and community support teams should communicate effectively and share information so that the children and families affected can be contacted and followed up.<br>Babies born to hepatitis B-positive mothers should be given the first dose of the vaccine promptly, whether they are delivered in hospital or at home. They should then receive all other recommended doses, a blood test to | The pre-requisites set out in section 1 state that the recommendations in the guidance are based on the assumption that hepatitis B and C tests are provided according to current best practice and are offered as part of a care pathway covering diagnosis, treatment and immunisation. In relation to hepatitis B vaccination the guidance references the Green book: immunisation against infectious disease and the Hepatitis B antenatal screening and newborn immunisation programme, both published by the Department of Health, and in the NICE guidance on Reducing the differences in the uptake of immunisations. |

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| | | | check for infection and, where appropriate, hepatitis B immunoglobulin, in line with the 'Green book | |
| **HEALTH PROTECTION AGENCY (HPA)** | | Page 17 continued | Health professionals should record the mother's hepatitis B status in the personal child health record as soon as possible after birth, before the midwife hands over care of the baby to the health visitor. The mother's hepatitis B status should also be entered on the child's record in the local Child Health Information System. '.<br>Health professionals should provide parents with information, advice and support on how to prevent the transmission of hepatitis B. They should emphasise the importance of ensuring babies complete the recommended vaccination course at the right time. In addition, they should assess whether or not the baby's siblings need to be immunised against hepatitis B or tested for infection and should offer them vaccinations and blood tests if necessary.<br>Health professionals should ensure administered doses of hepatitis B vaccination are recorded in the patient records and the personal child health record.<br>All the above actions should be integrated into the local care pathway for infant hepatitis B. (See also NICE clinical guideline 62 on antenatal care at www.nice.org.uk/CG62). | The pre-requisites set out in section 1 state that the recommendations in the guidance are based on the assumption that hepatitis B and C tests are provided according to current best practice and are offered as part of a care pathway covering diagnosis, treatment and immunisation. In relation to hepatitis B vaccination the guidance references the Green book: immunisation against infectious disease and the Hepatitis B antenatal screening and newborn immunisation programme, both published by the Department of Health, and in the NICE guidance on Reducing the differences in the uptake of immunisations and antenatal care. |
| **HEALTH PROTECTION AGENCY (HPA)** | 1 | 7 | Whose health will benefit: HIV positive individuals should also be included. | Guidance has been amended accordingly.<br>Reference is now made in section 1, under pre- |

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| | | | The BHIVA guidelines for the management of coinfection with HIV-1 and hepatitis B or C recommend annual screening of HIV infected individuals, and more regular testing among those at increased risk – MSM/IDU etc. This document should probably echo recommendations from elsewhere. It is touched upon on page 19, but it would also be useful to reference them here, and appear in the references. | requisites, to the British HIV Association guidance on managing co-infection with HIV-1 and hepatitis B or C. |
| **HEALTH PROTECTION AGENCY (HPA)** | 1 | 9 | In recommendation 2, there are specific comments about linking awareness raising activities with existing education for health and social care professionals and Deaneries to ensure HBV/HCV are included as part of CPD. Likewise, consideration should be given to raising awareness among young adults through appropriate existing educational initiatives including Personal Social Health & Economic education (PHSE) among school aged children which focuses on issues which affect children and young people, their families and their communities. In addition, opportunities for increasing awareness among university students should also be explored. This should be carried out in partnership with organisations such as the Drug Education Forum. Also, what about prison inmates at reception and induction – developing a standardised education and peer education programme would be of benefit. | Recommendation 2 (previously recommendation 3) states that local organisations should run awareness-raising sessions to promote hepatitis B and C testing in venues and at events popular among groups at increased risk. Examples of possible venues include: faith and cultural centres, NHS and non-NHS drugs services, GP surgeries, sexual health and genitourinary medicine services, immigration centres, hostels for the homeless, prisons and youth offender institutions.<br><br>As detailed in section 3, consideration 3.10, the PDG recognised a role for the peers of people at increased risk in promoting hepatitis B and C testing and supporting people who are diagnosed positive. In consideration 3.37, the PDG noted the lack of evidence specific to the role of peer support in promoting the uptake of testing and treatment for hepatitis B and C. Evidence of its positive effect on attitudes, |

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| | | | | knowledge and behavioural practices relating to prisoners' sexual health was considered. Based on this evidence, the PDG considered it logical that peer support could be beneficial for the groups of interest identified in the guidance and made reference to it in recommendations 5 and 6. |
| **HEALTH PROTECTION AGENCY (HPA)** | 1 | 9 | Ensuring there is an education programme for professionals providing health and social care services for those at greatest risk of HBV/HCV should also include fertility services. In 2010, among sentinel surveillance laboratories, 7% of individuals undertaking an anti-HCV test through front-line services were tested through fertility services, of which 1% tested positive. | The PDG felt that despite the focus of this guidance on primary and secondary care, tertiary clinical services (such as fertility services) should offer routine testing for hepatitis B and C, have access to appropriate training and a role in awareness raising. The PDG was aware that evidence regarding the effectiveness of routine testing in tertiary clinical services has not been adequately considered in the development of this guidance, but felt this area should be acknowledged. |
| **HEALTH PROTECTION AGENCY (HPA)** | 1 | 11 | How to access and raise awareness among previous drug users? | The PDG note in section 3, consideration 3.33 their concern about people who have previously injected drugs but are no longer doing so, and other groups at increased risk, because there was limited evidence on how to reach them effectively. This includes, for example, commercial sex workers and men who have sex with men. The group felt that the principles of the recommendations may apply to these groups. |
| **HEALTH PROTECTION AGENCY (HPA)** | 1 | 12 | Identifying prisoners at increased risk of HBV/HCV relies on self-reporting injection drug use, and requires inmates to disclose illegal and potentially stigmatising behaviours. | The guidance has been amended to:<br><br>'Prison and immigration removal centre healthcare services |

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| | | | As a result, there is the potential that many HCV-infected individuals will not be tested according risk-based HCV testing. I'm not sure what the evidence is on universal screening, but the CDC have repeatedly suggested it. This may, if other recommendations are in place, allow for clinical care and treatment to begin in prison and continue in the community. In fact the treatment estimated from sentinel surveillance suggests the prison service is actually a good place to get tested and start/complete treatment. Also, the July 2012 National survey of hepatitis C services in prisons in England reported that among the 110/128 prison services that provide information on hepatitis C services, only 10% provided DBS testing. Clearly this should increase in line with drug services and recommendation 9 that laboratories should offer HBV/HCV tests for the full range of samples, including DBS. | should ensure that:<br>• all prisoners and immigration detainees are offered hepatitis B vaccination when entering prison or an immigration removal centre (for the vaccination schedule, refer to the Green book)<br>• all prisoners and immigration detainees are offered access to confidential testing for hepatitis B and C when entering prison or an immigration removal centre and during their detention.' |
| **HEALTH PROTECTION AGENCY (HPA)** | 1 | 17 | Is this suggesting that all laboratories should be offering DBS, and that all anti-HCV positive samples are immediately followed by a PCR test? Or that labs who offer anti-HCV screening have the capacity to offer a PCR test – barrier to PCR testing? Surely this reflects commissioning practices? | Recommendation 11 now states that commissioners of laboratory services for hepatitis B and c testing should ensure service specifications specify that laboratory services providing hepatitis B and C testing:<br>• can support the range of samples used for hepatitis B and C testing (for example, dried blood-spot or venepuncture samples) or can refer the sample to a laboratory which can perform these tests<br>• automatically test samples that are positive for hepatitis C antibody for the presence of hepatitis C virus (for |

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| | | | | example, using a polymerase chain reaction [PCR] assay), or refer the sample to a laboratory which can perform this test. |
| **HEALTH PROTECTION AGENCY (HPA)** | 1 | 17 | Instead of suggesting that laboratories 'can' provide information including the number of tests performed etc, it should be 'do' provide. I'm sure they all can do these things, but most do not. In fact outside sentinel surveillance, these data are not centrally collected by anyone else.<br><br>Also, among infections diagnosed within prisons, where does the responsibility for reporting reside – do prisons have an obligation report to prison surveillance? Or via HPU etc? Maybe this should form a part of the recommendation | Recommendation 11 has been amended accordingly.<br><br>The recommendations assume, as stated in the pre-requisites in section 1, that standards for local surveillance are followed, including laboratory reporting to Public Health England centres. In addition, recommendation 3 states that education programmes for prison staff should incorporate the recommendations in national guidance to improve identification and testing of people at increased risk of hepatitis B and C infection. This would include the national standards for local surveillance. |
| **HEALTH PROTECTION AGENCY (HPA)** | 1 | 18 | Recommendation 10:<br>Is there an opportunity for us to feed into this pathway using our HCVcube estimates?<br><br>Clearly we'll miss any notion of 'offer', and reading their 'epidemiology' section, I'm not convinced they actually understand what sources of information exits for HBV/HCV, so suggestions of this sort probably won't inform the process. | NICE welcomes all comments. |
| **HEALTH PROTECTION** | 1 | 18 | Fully integrated care pathways – I was interested to read | Thank you for providing this information. |

# Public Health Programme Guidance

## Hepatitis B and C – Ways to Promote and Offer Testing - Consultation on Draft Guidance
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| **AGENCY (HPA)** | | | that in New Zealand they put together a standardised national electronic referral pathway which has been adopted across NZ. Apparently its been a success. It might be a model worth considering – allows for a far higher degree of scrutiny... | |
| **HEALTH PROTECTION AGENCY (HPA)** | 3 (3.37 + 3.36) | 32 | A comprehensive hepatitis B and C database holding details on people who have been tested and treated would be ideal. Do we take from this that there is an appetite for such a national database, and therefore some cash to support it's development? I think collecting information on those identified as being at increased risk but who have refused to be tested would be an even greater challenge – negative reporting? | This guidance reflects what the PDG consider to be cost effective in promoting and offering testing to people at increased risk of hepatitis B and C infection; it is not accompanied by funding but those with a responsibility to commission such services should take note of the recommendations in this guidance. |
| **HEALTH PROTECTION AGENCY (HPA)** | Section | 7 | There is no specific reference to individuals who inject drugs to enhance the body (eg anabolic steroids -body building drugs, eg botulinum, change cosmetic appearance of the skin) . targeting this group will be through different channels to those who inject illicit recreational drugs. | In section 3 the PDG note the potential risk of hepatitis C transmission among people that inject performance and image-enhancing drugs (PIEDs) such as anabolic steroids (for non-medical reasons). However, there is a lack of published evidence on the extent of risk in this group or on their contribution to overall hepatitis C prevalence.<br><br>This group is of course included in the group 'People who have ever injected drugs' who are noted in the guidance as a group at increased risk. The guidance also now recommends that GPs should offer testing for hepatitis B and C to people if they have ever injected drugs, including image and performance enhancement substances. |

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| **HEALTH PROTECTION AGENCY (HPA)** | General | 6 | Recommendation 1: Awareness raising for general public<br>Frontline staff should promote the fact that better outcome for individuals if disease identified early when treatment indicated. | The guidance has been amended accordingly. |
| **HEALTH PROTECTION AGENCY (HPA)** | General | 21 | This section on page 21 (top of page) is misleading and contains errors:<br>'The prevalence of chronic disease varies by region. It is highest in London and the North West and increases with an increasingly aged population (Harris et al. 2011b). This is confirmed by data from the 2010 Unlinked Anonymous Monitoring (UAM) survey of people who inject drugs and attend specialist services (Harris et al. 2011b). The UAM survey suggests that more of this group are being tested (83% reported having a voluntary test for hepatitis C, compared to 40% in 2000). However, the numbers being tested is still low. Only 55% of those who tested positive were aware they were infected before they had the test.'<br>It should be rephrased so as to read.<br>'The prevalence of chronic disease varies by region. It is highest in London and the North West and increases with an increasingly aged population (Harris et al. 2011a). This is supported by data from the 2010 Unlinked Anonymous Monitoring (UAM) survey of people who inject drugs who attend specialist services; which indicates an overall prevalence of hepatitis C antibodies | Section 2 of the guidance has been updated. |

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| | | | among people who inject drugs of 43%, but with marked local variation ranging from 14% to 82% (Harris et al. 2011b). The UAM survey also indicates that more of this group are being tested (83% reported having a voluntary test for hepatitis C, compared to 40% in 2000). However, the numbers of people who inject drugs being tested regularly is still low, and among this group around half of those with hepatitis C remain unaware of their infection (Health Protection Agency 2011b).' | |
| **HEALTH PROTECTION AGENCY (HPA)** | | 22 | This section on page 22 (middle of page) is misleading and contains errors:<br>'Since 2000, transmission routes of acute infection have followed a similar trend. For 2010, risk factor information (only available for 47% of acute cases) suggests the number of cases attributable to injecting drug use has continued to decline (Health Protection Agency 2011a). This is confirmed by the 2010 UAM survey, which reports a fall from 28% to 16% cases (Health Protection Agency 2011c). This decrease might be associated with an increase in the self-reported uptake of hepatitis B vaccine, from 35% in 2000 to 74% in 2010, among the people injecting drugs who were cited by the UAM survey (Health Protection Agency 2011c).'<br>It should be rephrased so as to read.<br>'Since 2000, transmission routes of acute infection have followed a similar trend. For 2010, risk factor information (only available for 47% of acute cases) suggests the | Section 2 of the guidance has been updated. |

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| | | | number of cases attributable to injecting drug use has continued to decline (Health Protection Agency 2011a). This is confirmed by the 2010 UAM survey, which reports a fall from 28% to 16% in the proportion of people who inject drugs that have ever been infected with hepatitis B (Health Protection Agency 2011c). This decrease is probably associated with an increase in the self-reported uptake of hepatitis B vaccine, from 35% in 2000 to 74% in 2010, among the people who inject drugs participating in the UAM survey (Health Protection Agency 2011c).' | |
| **LASS (Leicestershire AIDS Support Services)** | General | | It is really good to see such a wealth of information, research and evidence in one document, as well as clear identification of the gaps. | Thank you for commenting. |
| **LASS (Leicestershire AIDS Support Services)** | General | | It would be helpful to have more numbering in the recommendations – to facilitate feedback but also to add focus and linking actions to these recommendations. | Thank you for commenting, we have fed these ideas back to the editors to be considered when the guidance template is next updated. |
| **LASS (Leicestershire AIDS Support Services)** | General | | Recommendations should include using peer support and peer mentors in many roles – to raise awareness and to support people who have been diagnosed. Peer support provides great benefits. | As detailed in section 3, consideration 3.10, the PDG recognised a role for the peers of people at increased risk in promoting hepatitis B and C testing and supporting people who are diagnosed positive. In consideration 3.37, the PDG noted the lack of evidence specific to the role of peer support in promoting the uptake of testing and treatment for hepatitis B and C. Evidence of its positive effect on attitudes, knowledge and behavioural practices relating to prisoners' sexual health was considered. Based on this evidence, the PDG considered it logical that peer support could be |

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| | | | | beneficial for the groups of interest identified in the guidance and made reference to it in recommendations 5 and 6. |
| **LASS (Leicestershire AIDS Support Services)** | General | | It would be beneficial to add guidelines for how frequently people should test, depending on setting and risk. | The guidance now states that people who test negative for hepatitis C but remain at increased risk of infection should be offered annual testing for hepatitis C. Those who test negative for hepatitis B but who remain at increased risk of infection should be offered hepatitis B vaccination. |
| **LASS (Leicestershire AIDS Support Services)** | Section 1 | 6 | Under 'Testing' heading add<br>• Pathway and support available for clinical and non-clinical needs following diagnosis | The guidance has been amended accordingly. |
| **LASS (Leicestershire AIDS Support Services)** | Section 1<br>Recommendation 1 | 8 | Under 'Who should take action'<br>Last bullet point should include national and local voluntary sector, not-for-profit…… | Guidance has been amended accordingly. |
| **LASS (Leicestershire AIDS Support Services)** | Section 1<br>Recommendation 1 | 8 | Under 'What action should they take'<br>1st main bullet starting – Identify and make use of……<br>Add – what diagnosis means re lifestyle, diet, and family life<br><br>Last main bullet should start:<br>Ensure national and local awareness raising……. | Guidance has been amended accordingly, recommendation 2 now states that awareness raising material should 'explain how a positive diagnosis can affect lifestyle'; lifestyle is felt to cover 'diet and family life'. |
| **LASS (Leicestershire AIDS Support Services)** | Section 1<br>Recommendation 2 | 9 | Under 'What action should they take'<br>1st bullet point<br>Add – HIV voluntary sector | Guidance has been amended accordingly. |

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| **LASS (Leicestershire AIDS Support Services)** | Section 1<br>Recommendation 2 | 10 | Under 'What action should they take'<br>Penultimate bullet point<br>'Deaneries in each region should ensure doctors and nurses and community workers involved in testing……. | The guidance has been amended and now states 'local education and training boards in each region should ensure that people involved in testing for hepatitis B and C take part in a programme of continuing professional development.' |
| **LASS (Leicestershire AIDS Support Services)** | Section 1<br>Recommendation 2 | 10 | Under 'What action should they take'<br>Also add another bullet<br>'Deaneries in each region should ensure there are adequate clinical staff available to provide treatment support'. | Recommendation 10 now states that commissioners should regularly undertake a health needs assessment, health equity audit and an audit of hepatitis B and C services as part of the agreed local care pathway and commission testing and treatment services accordingly. |
| **LASS (Leicestershire AIDS Support Services)** | Section 1<br>Recommendation 2 | 11 | Under 'What action should they take'<br>Final bullet point<br>'Directors of Public Health should ensure that all managers in health, in collaboration…….' | Guidance has been amended accordingly. |
| **LASS (Leicestershire AIDS Support Services)** | Section 1<br>Recommendation 3 | 11 | Under 'What action should they take'<br>Second main bullet point<br>Add<br>- audio / visual resources for those groups with oral tradition<br>- ensure that materials are culturally appropriate and are delivered so that people can understand and access the information. | Guidance has been amended. |
| **LASS (Leicestershire AIDS Support Services)** | Section 1<br>Recommendation 3 | 12 | Final bullet:<br>Consider offering testing at these sessions. | Guidance has been amended accordingly. |

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| | | | (we have found that people take HIV testing at sessions like this as it is accessible and available). | |
| **LASS (Leicestershire AIDS Support Services)** | Section 1<br>Recommendation 5 | 13 | Under 'what action should they take'<br>2nd main bullet<br>Add – Hepatitis lead should recruit and train peer mentors and champions among the prisoners to promote testing and vaccinations. | The guidance has been amended and now states that 'Consideration should be given to training peer mentors and health champions from the prison and immigration removal centre populations to support this work.'<br><br>Consideration 3.37, in section 3 of the guidance, points out that the PDG noted a lack of evidence specific to the role of peer support in promoting the uptake of testing and treatment for hepatitis B and C. Evidence of its positive effect on attitudes, knowledge and behavioural practices relating to prisoners' sexual health was considered. Based on this evidence, the PDG considered it logical that peer support could be beneficial for the groups of interest identified in the guidance. |
| **LASS (Leicestershire AIDS Support Services)** | Section 1<br>Recommendation 5 | 13 | Under 'what action should they take'<br>Prison staff (all, not just carats & healthcare) need to have regular BBV training to ensure that have appropriate knowledge and can provide supportive messages if necessary. | The guidance has been amended accordingly; recommendation 5 now states that all prison and immigration removal centre staff are trained to promote hepatitis B and C testing and treatment and hepatitis B vaccination. The detail of what this training should cover is listed in recommendation 3. |
| **LASS (Leicestershire AIDS Support Services)** | Section 1<br>Recommendation 5 | 13 | Under 'what action should they take'<br>All prisoners should be encouraged to get tested – regardless of their own perceived risk. Many people do not understand (or remember) what risks they have | Recommendation 5 now recommends that 'all prisoners and immigration detainees are offered access to confidential testing for hepatitis B and C when entering prison or an immigration removal centre and during their detention.' |

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| | | | taken. | |
| **LASS (Leicestershire AIDS Support Services)** | Section 1<br>Recommendation 6 | 15 | Under 'what action should they take' 3rd main bullet<br>Drugs services and other appropriate community organisations should have access to suitable testing technologies and kits to offer testing in a range of settings and services. | Guidance has been amended accordingly. |
| **LASS (Leicestershire AIDS Support Services)** | Section 1<br>Recommendation 10 | 19 | Add "commissioners need to ensure adequate community nurse provision for treatment and treatment support' | Recommendation 10 now states that commissioners should regularly undertake a health needs assessment, health equity audit and an audit of hepatitis B and C services as part of the agreed local care pathway and commission testing and treatment services accordingly. |
| **LASS (Leicestershire AIDS Support Services)** | Section 3.21<br>Considerations | 29 | LASS have undertaken research with AHPN looking at HIV testing interventions in the African communities and the effect of a) community champions<br>b) taking testing to community events and meetings.<br>People are very responsive to both these elements and the (LASS) community testing increased significantly.<br>Many people in the communities ask for information and testing for Hep B but it is not available.<br>We can provide a copy of the research report on request. | Thank you for providing this reference. |
| **The National LGB & T Partnership** | Generally | | Conflating hepatitis B and C into a single strategy for promoting and offering testing is unhelpful and at times misleading (see later comments). This is particularly true in relation to target groups and effective methods for | The 'Whose health will benefit' section of the guidance has been amended to make it clear which groups are at increased risk of hepatitis B and which are at increased risk of hepatitis C. |

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| | | | reaching these target groups. For example gay men are generally at risk of Hep B while the majority of infections of Hep C in gay men are in people with HIV[i]. The best way of reaching gay men with Hep C is via HIV clinics while gay men generally should not be a target of Hep C interventions as unhelpfully suggested in this guidance. Considering the complexity of how different forms of Hepatitis effect the general population of gay men and a subset of that population, the guidance did little to provide helpful information for people of this target group or indeed healthcare professionals or voluntary sector organisations that work with this groups. Rather at times the guidance was misleading. | |
| **The National LGB & T Partnership** | Generally | | Furthermore the guidance generally did not address the needs of gay men in any meaningful way. We note that in 3.46 under "Other Issues" Page 34 you state " The PDG focused on people who inject drugs and migrants from medium and high endemicity countries. The Group noted that effective testing has already been implemented for other groups at increased risk, including men who have sex with men and people with multiple partners".<br>We believe this is an assertion rather than fact. In 2007 Sigma Research, as part of their annual gay men's sex survey, asked gay men about their Hepatitis B vaccination history. They found that 47.6% of gay men were vulnerable to Hep B infection. | The guidance notes in section 3, consideration 3.33, that there was limited evidence on how to effectively reach certain groups at increased risk. This includes men who have sex with men. The group felt that the principles of the recommendations may apply to this group.<br>Recommendation 4, testing in primary care, states that GPs and practice nurses should offer hepatitis B testing and vaccination to men who have sex with men who are offered a test for HIV and have not previously tested positive for hepatitis B antibodies (see NICE guidance on Increasing the uptake of HIV testing among men who have sex with men).<br>In addition, a recommendation has been added to the guidance on testing for hepatitis B and C in sexual health and genitourinary medicine clinics. |

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| | | | | |
| **The National LGB & T Partnership** | Generally | | Hepatitis B within gay men had a substantial impact on SaBTO's recommendation to defer gay men from donating blood for a year after their last sexual experience. The political sensitivities around this decision merits a more thoughtful and nuanced response in tackling hepatitis B within the gay male population and this guidance fails to do this. We would therefore request that you meaningfully address how testing for Hepatitis B is promoted and offered to gay men and include it in this guidance before the final draft. | Please see above response. |
| **The National LGB & T Partnership** | In What is this guidance about | Page 1 | Include contact tracing for Hepatitis C | The PDG note in consideration 3.31, section 3 of the guidance, that active contact tracing for people who test positive for hepatitis C is not recommended, given low transmission rates to both sexual and household contacts. The PDG acknowledged that it would be sensible to discuss with people who test positive test whether any of their contacts have been exposed to infection. Testing of identified contacts would be offered at clinical discretion.<br><br>In addition, recommendation 6 now states that information should be provided by drug services to women with hepatitis C about the importance of testing in babies and children born after the woman acquired infection. |

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| **The National LGB & T Partnership** | Whose health will benefit | Page 6 | 3.4 of your considerations stated "When defining those at increased risk of hepatitis B and C the PDG was mindful not to further stigmatise these groups". We would suggest that putting "Men who have sex with men, commercial sex workers and anyone who has unprotected sex and frequently changes sexual partners" as a single category fails to meet your aspiration not to stigmatise and this grouping of people should be disaggregated. | Guidance has been amended accordingly. |
| **The National LGB & T Partnership** | Section 1 Recommendation 1 | Page 8 | Change "national voluntary sector" to national and local voluntary sector" | Guidance has been amended accordingly. |
| **The National LGB & T Partnership** | Section 1 Recommendation 2 | Page 8 | Include "staff in voluntary and community organisations that care for or support gay men and people with HIV" under What action should they take? | Guidance has been amended accordingly. |
| **The National LGB & T Partnership** | | Page 12 | This is an example of where conflating Hep B and Hep C causes problems "Local organisations should run awareness-raising sessions to promote Hepatitis B and C testing in venues and events frequented by groups at increased risk" | The 'Whose health will benefit' section of the guidance has been amended to make it clear which groups are at increased risk of hepatitis B and which are at increased risk of hepatitis C. |
| **The National LGB & T Partnership** | Section 1 Recommendation 4 | Page 8 | Again, conflating Hep B & C is not helpful. It would make sense for GPs to test for Hep B in gay men but only Hep C in gay men with HIV. | The 'Whose health will benefit' section of the guidance has been amended to make it clear which groups are at increased risk of hepatitis B and which are at increased risk of hepatitis C. |

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| **The National LGB & T Partnership** | | | We believe there should be a recommendation on testing for Hepatitis B in GUM service (to reach gay men)<br><br>We believe there should be a recommendation on testing for Hepatitis B and C in HIV services (for gay men with HIV).<br><br>One report found links between homelessness, injecting drug use and Hepatitis C[ii]. We believe there should be a recommendation on testing for Hep B & C around services for the homeless. | A new recommendation has been included in the guidance, on testing in sexual health and GUM clinics.<br><br>The pre-requisites to the recommendations note that the guidance is based on the assumption that hepatitis B and C tests are provided according to current best practice and are offered as part of a care pathway covering immunisation, diagnosis and treatment. Reference is made to guidance on managing co-infection with HIV-1 and hepatitis B or C, available from the British HIV Association.<br><br>Recommendation 2 now states that local organisations should run awareness-raising sessions to promote hepatitis B and C testing in venues and at events popular among groups at increased risk. Examples of possible venues include hostels for the homeless. |
| **The National LGB & T Partnership** | Section 1<br>Recommendation 7 | Page 16 | We belie that the guidance should be recommending that staff at GUM clinics do contact tracing for Hepatitis B. | Recommendation 8, contact tracing, has been amended and now makes reference to GUM clinics. |
| **The National LGB & T Partnership** | Section 1<br>Recommendation 10 | Page 18 | We believe that all NHS organisations should be monitoring sexuality and gender identity and that this should be included in any audits to ensure that the duty of care towards all people are met.<br><br>In the last bullet point, rather than state “Ensure men who | Recommendation 10 states that commissioners should regularly undertake a health needs assessment, health equity audit and an audit of hepatitis B and C services as part of the agreed local care pathway and commission testing and treatment services accordingly. |

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| | | | have sex with men are tested for Hepatitis B and C, especially those who are HIV-positive." Put "Ensure men who have sex with men are tested for hepatitis B and men who have sex with men who are HIV-positive are also tested for hepatitis C." | This bullet has been deleted from this recommendation. However, the 'Whose health will benefit' section of the guidance has been amended to make it clear which groups are at increased risk of hepatitis B and which are at increased risk of hepatitis C. |
| **The National LGB & T Partnership** | Section 2 Risk factors | Page 22 | "Homosexual contact was the second most frequently reported risk factor." This phrase is both vague and open to misinterpretation. We would suggest "Sex between men" as a minimum. However even this phrase is vague and we would suggest that you be more specific as not all sexual acts that lead to Hepatitis B transmission. | Section 2 has been updated. In addition a definition of sexual contact has been added to the glossary in section 8. |
| **The National LGB & T Partnership** | Section 3 Barriers and facilitators | Page 26 | In the section of fear and stigma you should add sexual partners to the list of people[iii]. | Guidance has been amended accordingly. |
| **The National LGB & T Partnership** | Section 3 Data | Page 32 | 3.37 If a database was to be created it should record people's sexuality and gender identity. | The PDG considered you your suggestion but decided not to add more detail to this consideration. |
| **London Joint Working Group (LJWG) on Hepatitis C and Substance Misuse** | **Recommendation 3** | 11 | **What action should they take:** We suggested an additional bullet that provision of testing should be incorporated into awareness wherever possible. | Guidance has been amended accordingly. |
| **London Joint Working Group (LJWG) on Hepatitis C and Substance Misuse** | **Recommendation 4** | 12 | **What Action Should they take, bullet 4 point 1:** We propose ALL prisoners should be considered at increased risk and as such testing should be offered universally. | The guidance has been amended to:<br><br>'Prison and immigration removal centre healthcare services should ensure that:<br>• all prisoners and immigration detainees are offered hepatitis B vaccination when entering prison or an |

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| | | | | immigration removal centre (for the vaccination schedule, refer to the Green book)<br>• all prisoners and immigration detainees are offered access to confidential testing for hepatitis B and C when entering prison or an immigration removal centre and during their detention.' |
| **London Joint Working Group (LJWG) on Hepatitis C and Substance Misuse** | **Recommendation 4** | 12 | **What action should they take, bullet 4:** We suggest adding a point specifying that mandatory basic BBV training is provided to all prison staff in all prisons. | The guidance has been amended accordingly; recommendation 5 now states that all prison and immigration removal centre staff are trained to promote hepatitis B and C testing and treatment and hepatitis B vaccination. The detail of what this training should cover is listed in recommendation 3. |
| **London Joint Working Group (LJWG) on Hepatitis C and Substance Misuse** | **Recommendation 4** | 12 | **Testing for hepatitis B and C in primary care**<br>Screening "opt out" for every patient in a practice: we would see higher statistics with positive diagnosis within groups of patients who have previously injected drugs and ethnic populations. | Recommendation 4 now states that GPs and practice nurses should offer testing for hepatitis B and C to adults and children at increased risk of infection, particularly migrants from medium- or high-prevalence countries and people who inject or have injected drugs. In addition, local community services serving migrant populations should work in partnership with primary care practitioners to promote testing of adults and children at increased risk of infection. This should include raising awareness of hepatitis B and C, promoting the availability of primary care testing facilities and providing support to access these services. Section 3, consideration 3.8, notes that people who have injected drugs in the past may not want to disclose drug- |

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| | | | | using history. This may be a barrier to hepatitis B and C testing and treatment. The PDG felt that positive messages about the effectiveness of treatment and attempts to 'normalise' testing might help reach these people. |
| **London Joint Working Group (LJWG) on Hepatitis C and Substance Misuse** | **Recommendation 6** | 14 | **What Action Should they take, bullet 6 point 3:** Please could there be a definition of 'routinely' in terms of testing drug users – nurses tend to say every 6 months but there's no clear guidance at the moment which would be really really helpful in getting more people tested! | The guidance has been amended accordingly; the guidance recommends that individuals testing negative for hepatitis C but who remain at risk be re-tested annually. |
| **London Joint Working Group (LJWG) on Hepatitis C and Substance Misuse** | Antenatal Screening | 23 | We would like to see more information specific to hepatitis C - midwives should be proactive in screening for hepatitis C. Children should also be tested. Education programmes would be needed. | Recommendation 4 now states that 'staff providing antenatal services, including midwives, obstetricians and GPs, should ask about risk factors for hepatitis C during pregnancy and offer testing for hepatitis C.' Additionally, recommendation 3 includes midwives in the list of professionals for who there should be an ongoing hepatitis B and C education programme. |

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| **London Joint Working Group (LJWG) on Hepatitis C and Substance Misuse** | **General** | 3, 4, 5 and 6 | We suggest more focus on Peer Support / mentors, particularly in recommendations 2 (when educating healthcare staff). | The Group recognised a role for the peers of people at increased risk in promoting hepatitis B and C testing and supporting people who are diagnosed positive. Peer support is now mentioned in recommendations 5 and 6 (testing in prisons/immigration removal centres and drug services). The PDG noted a lack of evidence specific to the role of peer support in promoting the uptake of testing and treatment for hepatitis B and C. Evidence of its positive effect on attitudes, knowledge and behavioural practices relating to prisoners' sexual health was considered. Based on this evidence, the PDG considered it logical that peer support could be beneficial for the groups of interest identified in the guidance. |
| **London Joint Working Group (LJWG) on Hepatitis C and Substance Misuse** | **General** | | Evidence base: there is a consensus document regarding patients with hepatitis c who have a history of misusing drugs. This is authored by the LJWG as an outcome from their conference in October 2010 and consultation with over 300 stakeholders.<br><br>**Tackling the Problem of Hepatitis C, Substance Misuse and Health Inequalities: A Consensus for London**.<br><br>The London Joint Working Group for Substance Misuse and Hepatitis C (LJWG)<br>Published in the Health Service Journal:<br>A blue print for improving hepatitis c services in London; | Thank you for this information. |

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| | | | Published<br>15th November 2011. By Kosh Agarwal, Ashley Brown, David Badcock, David Nutt, Charles Gore, Owen Bowden Jones. | |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | Assessing the cost-effectiveness of interventions aimed at promoting and offering hepatitis C testing to IDUs: an economic modelling report | P6 and elsewhere | 1. Cost-effectiveness of GPs' offering HCV testing to ex-IDUs aged 30-54 years or to ever-IDUs whose last HCV –ve test predated their cessation from injecting **refers only** to Cullen et al (2011) but surprisingly failed to locate the earlier reference (with HCV test in its title!) which did not involve specific GP-reimbursement of £100 per testee:<br>BIRD SM, Robertson R, Beresford H, Hutchinson SJ. Targets for Hepatitis C virus test uptake and case-finding among injecting drug users: in prisons and general practice. *Addiction Research and Theory* 2010; 18: 421 - 432.(doi:10.3109/16066350903267520).<br>This paper by BIRD et al, besides demonstrating the yield from targeted testing, corrects Castelnuovo's previous incorrect interpretations of HCV test uptake by injector-prisoners and untargeted in general practice, which were used in previous assessments for NICE (as referred to in Discussion section of this Assessment report). Perhaps systematic reviewers should revise their search procedures?<br>Targeted testing of ex-IDUs in the birth-cohort 1956-1970 or 75 was first proposed, I believe, in Discussion by Hutchinson SJ, BIRD SM, Goldberg DJ. Modelling the | In the system that the commentator suggests, the patient will be asked on an opportunistic basis whether they have ever injected drugs and if they say yes they will be offered a test but that is only within certain age cohorts; the guidance covers all of those age groups but also covers cohorts outside of those age groups. |

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| | | | current and future disease burden of Hepatitis C among injecting drug users in Scotland. *Hepatology* 2005; 42: 711 – 723. **And is a specific objective** in Scotland's HCV Action Plan Phase 2 (2008-11). | |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | Guidance, Appendix A & Assessing the cost-effectiveness of interventions aimed at promoting and offering hepatitis C testing to IDUs: an economic modelling report | P63 | 2. Appendix A of Guidance indicates that R Grieve is member of PDG: RG is also co-author of a submitted paper with White and Bird which demonstrates impact on CE **when non-drug-related death-rates for IDUs (and former IDUs) are increased** (as they should be – by factor of 2 to 5) from general population rates. That paper also cites, and references, the criticisms by Bird, Robertson et al.of Castelnuovo's interpretation of prisoners' HCV test rates. Hence, surprising that PDG remained unsighted. | This paper was not picked up by the authors of the modelling report as it is not in the public domain, the PDG appeared not to be aware of it. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | Guidance, Appendix A & Assessing the cost-effectiveness of interventions aimed at promoting and offering hepatitis C testing to IDUs: an economic modelling report | P64 | **Academic in confidence data from Scotland**, to which Chair has access because a collaborator with Taylor in Scotland's no-names surveillance of inmates via blood-spot & BBV risk-factor-Q, are used to inform %s for England by age-group of inmates who are IDUs. First, there is no reason for these data to be academic in confidence because IDUs' HCV prevalence and LOW incidence are the key issues (not % IDUs).<br><br>Second, comparison between Weild et al (for E&W circa 1998) and the series of papers by Bird/Gore et al on WASH surveillance in Scottish prisons in 1991-1996 clearly shows that % of inmates who have ever injected is **higher** in Scottish prisons than in E&W counterparts. | The data was obtained on a confidential basis at the authors request.<br><br>All economic models contain assumptions and this was one assumption the modellers made on the basis of the best information that was available to them at them time. From the sensitivity analysis it is unlikely that this assumption is a crucial one for cost effectiveness. |

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| | | | Hence, the unseen academic in confidence %s are likely to be over-estimates for E&W. For that reason, it is essential that they be public-domain, lest NICE veer to over-estimation. | |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | Guidance | General | 4. PDG has considered a too-limited set of issues re HCV testing and HBV immunization/testing [see 6] and does not set out clearly from the off the main features of the respective viruses (transmission routes and at-risk cadres [see 7]) that healthcare workers and others should know. Thus, there is talk about education but no specifics on the key messages [see 5]. | Thank you for your comments, please see responses below. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | General | 5. **KEY MESSAGES:**<br><br>a) HBV is 10 times more infectious than HCV; HCV is 10 times more infectious than HIV (based on needle-stick transmissions). **HCV incidence among susceptible current IDUs remains high** – how high in the range 5% to 20% should be specified & referenced; and may differ between Scotland and E&W.<br><br>b) there is **vaccine to protect against HBV** (also vaccine against HAV) which, in UK, is supposed to be offered to all who may be at risk.<br><br>c) **current HBV risk groups in UK to whom HBV vaccine should be offered** include possible recipients of unscreened blood (eg soldiers); drug users (whether or not they have yet injected), MSM, sex workers, prisoners, | a) Thank you for providing this information; the PDG noted that while true, given the focus of the guidance this level of detail was not necessary.<br><br>b) Although hepatitis B vaccination was beyond the remit of this guidance, the PDG decided to signpost to hepatitis B vaccination in several places in the guidance.<br><br>c) The guidance notes that hepatitis B vaccination should be offered in line with the Department of Health's Green Book: immunisation against infectious disease. |

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| | | | detainees [who are NOT prisoners but may include asylum seekers]; other occupational health groups (healthcare workers, drugs workers, prison staff, prisoner escort staff, police, etc – NOT all of these have their HBV immunisation paid for, an issue - see [7]); newborns to HBV carrier mothers; persons immigrating to UK from countries where HBV is endemic & there is no universal vaccination of newborns or at age 12 years. UK prisons [?not detention centres] offer 1 month HBV immunization to all inmates;<br><br>d) due to HBV's high infectiousness & because of high viraemia in some carriers, HBV **transmissible thro other fluids** than blood, including – semen, saliva, sweat.<br><br>e) There is currently no vaccine to protect against HCV, and – due to HCV's infectiousness and its high prevalence in IDUs (over 30%) – **unless IDUs scrupulously use clean needles,** annually they risk encountering HCV carriers among those with whom they share needles and works – and so IDUs should test annually for HCV (or as often as they have accumulated 20-30 shared injections). Hence, off-injecting is best protection against HCV.<br><br>f) other current **but lesser** HCV transmission routes in UK include HCV-carrier-mother-to-newborn (6% | d) The PDG agreed; the guidance highlights other groups at increased risk of acquiring infection through fluids other than blood. Reference is also made to other bodily fluids in the glossary section, under 'close contact' and 'sexual contact'.<br><br>e) The guidance recommends annual testing for hepatitis C for those who remain at increased risk. |

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| | | | transmission rate), sexual, tattooing, blood-to-blood exchange in shaving, fights, bites etc. Also, HCV transmission risk may be aggravated in presence of recipient's co-infection by HIV or HBV. Persons who have come to UK from (or regularly visit) countries where HCV is endemic. **Anderson et al. (Scottish study in GP practice** in deprived area of Glasgow with high IDU prevalence) set out to find nosocomial transmission but showed it to be elusive/rare. | f) Reference is made in section 3 to other smaller groups at increased risk of hepatitis B and C infection. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | General | 6. **TOO LIMITED SET of ISSUES** has been considered. Missing is consideration of the following:<br><br>a) **WHO recommendations** of long-standing on equity of healthcare provision re BBVs for prisoners – no need for CE re dried blood spot provision in prisons: if available for IDUs on outside, so should it be on the inside.<br><br>b) **solid argument FOR dried blood spot HBV testing in prisons that is NOT made** is that UK prisons successfully offer short-course HBV immunisation BUT are probably less successful at getting inmates to accept venepuncture to check on antibody levels 12 months after short-course. Dried blood-spot testing is brilliant solution . . . | a) Thank you for your comment. The PDG decided that this was one of the scenarios they wished to model. The decision to provide dried blood spot testing is strengthened given that it has been found to be cost effective in prisons, rather than relying on social value judgments alone.<br><br>b) It was noted by the PDG that while DBS is not able to detect HBV markers of immunity; it can test whether a person has been infected. |

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| | | | c) **Waiting time of 2 weeks for BBV test results** is ridiculous – especially in light of 4 week short-course HBV immunization: can NICE sort it? | c) The PDG felt that 2 weeks was feasible in terms of the laboratories delivering the results. |
| | | | d) PDG & Guidance are **UNCLEAR about whether test is ordered for HCV, for HBV, for hepatitis screen** (A,B,C,? etc): for risk-groups in common combined 1st-testing might make sense but the frequency of subsequent BBV testing depends on exposure group: eg annual or 2-yearly for HCV for IDUs [CE might be a determinant here, & is driven basically by IDUs' HCV prevalence and number of shared/muddled injections per annum [cfTaylor on coloured syringes to assist IDU to pick up own]. Whereas, if first HBV test is antibody negative, then HBV immunization should be offered. | d) Guidance has been amended accordingly. |
| | | | e) **testing re HCV that is PCR-based,** as for blood-donors, to ensure that recent seroconverters are picked up. UK's recent HCV seroconversions are mainly in IDUs (who are deferred as blood-donors) and so it would be much more sensible – even on a pilot basis – that HCV testing of declared CURRENT IDUs be on PCR-basis first (with follow-up antibody test of those who are PCR-positive). Reversed–order testing, as above, will be **more expensive** (eg 100 PCRs when previously only 30-50 depending on IDUs' HCV carriage) **BUT** offers the potential for | e) The PDG felt this was an interesting hypothesis but had not been modelled. The PDG noted, in section 3, the importance of all blood samples that test positive for hepatitis C antibody being routinely tested for hepatitis C virus, for example, by PCR. In addition, further consideration of and research on the use of PCR for initial testing in current injecting drug users, with follow-up antibody testing for people who test PCR positive, may be warranted to enable rapid diagnosis of recent infections. |

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| | | | stronger public health messages that make IDUs aware of RECENT TRANSMISSIONS and, therefore, their need to protect themselves & others (by not sharing & ultimately by off-injecting). | |
| | | | f) **major epidemiological issue** [both in Scotland & in E&W] is that, even when IDU risk is declared, test-request form **does not even seek to** differentiate current IDU from former IDU and so audit of HCV testing of former IDUs is not easily done. Likewise, alternative-order testing would be cheaper if limited to current IDUs because former IDUs are unlikely seroconverters. **It would be wonderful if NICE could sort HCV test request form.** | f) Thank you for your comment; it has been passed to the NICE implementation team |
| | | | g) Although I know prisons well, but I know less about healthcare set-up for detainees – except that I'd wager that provision is less good and that healthcare problems are probably even more complex: traumatic injury, TB, HIV as well as HBV and HCV; children as well as adults. Thus, re BBVs, PDG needs to compare formally what is i) done & ii) 'said to be done' for detainees vs for prisoners. HM Chief Inspector of Prisons for England inspects (or used to) Dungavel Detention Centre in Scotland because Scotland's former HMCIP Clive Fairweather CBE refused to – on the basis that detainees were not prisoners, and he needed a different remit. Consult | g) Recommendation 5 now refers to detainees in Immigration Removal Centres. |

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| | | | inspection reports by HMCIP, E&W.<br><br>h) Surprisingly, NO DISCUSSION/CE modelling of when UK should reconsider its HBV vaccine policy (those at risk) to be immunization of new-borns or at 12 years of age – RECONSIDER because or when immigration from/visiting to endemic countries increases UK-carriage prevalence to XX% . . . | h) HBV vaccine policy is outside the remit of NICE, responsibility for this lies with JCVI. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | General | 7 WHO IS AT-RISK<br><br>a) Prisoners re HBV: prisons immunize 1st, test later - for good pragmatic reasons. PDG seems to be blind to this VERY SUCCESSFUL intervention - first by Scottish prison in 1999, later by Scottish drug treatment centres & GPs, but still not by Scottish liver clinics – eg sent back to GP; and only later by English prisons & community teams. BUT, hugely successful with HBV immunization of IDUs up from 5% in 1996 (see Bird/Gore in BMJ: BIRD AG, GORE SM, HUTCHINSON SJ, LEWIS SC, CAMERON S and BURNS S on behalf of the European Commission Network on HIV infection and hepatitis in prison. Harm reduction measures and injecting inside prison versus mandatory drugs tests: results of a cross sectional anonymous questionnaire survey. *British Medical Journal* 1997; 315: 21 - 24.<br>& for later post 1999 impact, see Hutchinson SJ, Wadd S, Taylor A, BIRD SM, Mitchell A, Morrison DS, Ahmed | a)The guidance has been amended to:<br>'Prison and immigration removal centre healthcare services should ensure that:<br>• all prisoners and immigration detainees are offered hepatitis B vaccination when entering prison or an immigration removal centre (for the vaccination schedule, refer to the Green book)<br>• all prisoners and immigration detainees are offered access to confidential testing for hepatitis B and C when entering prison or an immigration removal centre and during their detention.' |

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| | | | S, Goldberg DJ. Sudden rise in uptake of Hepatitis B among injecting drug users associated with a universal vaccine programme in prisons. *Vaccine* 2004; 23: 210 - 214. PDG - do not risk throwing out baby with bath water; do not delay start of short-course HBV vaccine by suggesting preHBV test; instead, ADD post blood-spot!<br><br>b) current IDUs re HCV transmission: ever HCV-tested does not cut the mustard, testing needs to be annual.<br><br>c) ex-IDUs born in 1956-75 (even if rarely injected), because former IDUs are at high risk if HCV carriage and of an age to be into their second decade of HCV infection and at risk of treatable liver progression: need HCV test if never previously tested & need repeat HCV test if most recent HCV negative test pre-dated their cessation of injecting . . .<br><br>d) GUM clinics attendees: universal offering of HBV vaccine & HCV screen (because of higher susceptibility if co-infected by HBV or HIV & some may also inject).<br><br>e) as above, occupational groups who need to have HBV vaccination encouraged (ie by being paid-for): | <br><br>b) The guidance has been amended accordingly; the guidance recommends that individuals testing negative for hepatitis C but who remain at risk be re-tested annually.<br><br>c) The guidance recommends testing for people who have ever injected drugs, no matter how rarely.<br><br>d) The guidance now has a recommendation on testing in sexual health and GUM clinics. The recommendation states that sexual health and genitourinary medicine clinics should offer hepatitis B vaccination to all service users in line with the Green book and offer and promote hepatitis B and C testing to all service users at increased risk of infection, including people younger than 18.<br><br>e) The guidance emphasises, in several recommendations, existing hepatitis B vaccination recommendations (as |

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| | | | check police forces, prison escort staff (mainly privatized security & so ?? done), prison staff (done), drugs workers (should have – do they??) . . .<br><br>f) new to GP practice from/visitor to endemic countries: HBV test before HBV immunization makes sense here because carriage rate of 5%+ implies contact/family testing then immunization/treatment according to result.<br><br>g) detention/immigration centres: an opportunity to offer BBVs checks . . . | detailed in the Green book) because although hepatitis B vaccination was beyond the scope of this guidance, case-finding may identify contacts of infected individuals who should be offered vaccination.<br>The introduction of section 1<br><br>f) Thank you.<br><br>g) Recommendation 5 now includes testing detainees in immigration removal centres. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | | Hereafter, I make some specific editing comments but my advice is that a major re-structuring and more radical thinking is needed that goes well beyond editing of the current draft guidance. | Thank you for your comments. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | Guidance | P3 | Recommendations for future research are wish-list, not priority-list, see later. | Section 5 has been updated. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P7 | People who have **injected heroin/opiates** or recreational drugs and who share needles or drugs paraphernalia;<br><br>Separate line for sharing of straws for snorting of drugs – a much lesser risk re HCV . . . | The 'Whose health will benefit' section of the guidance has been amended to make it clear which groups are at increased risk of hepatitis B and which are at increased risk of hepatitis C. |

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| | | | this section needs to CONSIDER separately HCV and HBV: thus, re HBV especially, MSM . . . (HCV also a risk but lesser for reasons explained above)<br><br>WHY are children and people living in care homes at risk of HBV (sexually) and HCV (from carrier mother or if they inject or . . . historically from iatrogenic reuse of needles & syringes: EXPLAIN)<br><br>Close contact of someone injected with HCV . . . do you mean nosocomial transmission (very low) or sexual (also low . . . eg we don't recommend condoms in HCV discordant marriages).<br><br>Babies born to HCV carrier mothers should be much higher up the HCV list – we know their risk if mum was not treated! | |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P8 | NO MENTION of HBV vaccine as ACTION to TAKE & already p8! | Guidance has been amended accordingly. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P9 | NO MENTION of need for HBV & HAV vaccine (eg combined) for HCV antibody persons! VACCINATION is more protective than education!! | Hepatitis A was beyond the remit of this guidance, however, section1 states that the recommendations are based on the assumption that hepatitis B and C tests are provided according to current best practice and are offered as part of a care pathway covering diagnosis, treatment and immunisation. In relation to immunisation the guidance refers to the Department of Health's Green book – Immunisation against infectious disease, which of course |

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| | | | | details the need to consider vaccination against hepatitis A for those with chronic hepatitis B or C. NICE clinical guidelines on hepatitis B and hepatitis C are currently under development. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P9 | As above, list should be much longer than prison staff; consider also children's care home staff?? | Guidance has been amended. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P10 | Hep B vaccine should be 1st on list, not LAST! | Guidance has been amended. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P11 | ONE TEST or TWO , TYPE and FREQUENCY: Clarify, as above, what PDG means by "a (ungrammatical) Hepatitis test" – for HCV or HBV or single test but hepatitis screen (A, B, C etc)<br><br>Re HCV TEST – discuss whether PCR-1st for current IDUs and how laboratory will know which samples are from current IDUs.<br><br>NOTHING about need for ANNUAL HCV testing by current/lapsed IDUs but HBV immunization for HBV negatives etc. | Guidance has been amended. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P12 | Awareness-raising should not overlook liver clinics (re HBV vaccination), GUM clinics (to be consistent with earlier guidance, occupational groups) | Guidance has been amended accordingly. |

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| | | | Offer a hepatitis B and C test to everyone who is newly registered, and who [DELETE comma which alters sense to test everyone new to practice] | |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P13 | 2nd bullet: prisons' 1st priority is HBV vaccination, then offering of HCV test to those with history of injection drug use (self or mother)<br><br>3rd bullet: only hepatitis carriage (chronic infection) is treated<br><br>Notice that if escort-costs are paid centrally, as in Scotland, then they don't come off governor's budget and so s/he may be more inclined to have HCV-carrier treated in local hospital than in jail where governor pays for staff costs but does not pay for prisoner-escort. I agree that PDG's approach is preferable for prisoner-patients, especially if there is prison-nurse who has specialist training for HCV management [nurse-specialism not mentioned]. | Guidance has been amended accordingly. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P13 | WRONG – on entry to prison, ALL prisoners are offered HBV immunization and HCV testing, although open to all (as in outside community), is targeted for IDUs & should be offered, for example, to prisoners who receive methadone maintenance, many of whom will have injected in recent past [not mentioned]. | The guidance now recommends that prison and immigration removal centre healthcare services should ensure that:<br>• all prisoners and immigration detainees are offered hepatitis B vaccination when entering prison or an immigration removal centre (for the vaccination schedule, refer to the Green book) |

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| | | | Confidential HCV testing has been on offer in prisons (at least in Scotland) since HCV testing was available . . . And, I believe, is so also in E&W. | • all prisoners and immigration detainees are offered access to confidential testing for hepatitis B and C when entering prison or an immigration removal centre and during their detention |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P14 | Best 'mechanism' is for test results to be got in less than 2 weeks!<br><br>Prison healthcare staff have a duty of medical confidentiality to prisoners as to any other patient. Better to phrase in these terms. | Guidance has been amended. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P14 | Medical-hold on prisoner transfer is mentioned more explicitly later but could be explicit here too. Detainees are not prisoners.<br><br>If hospital doctor is responsible for HCV treatment, s/he may not be informed about prisoner-transfer and so the agreement with prison's healthcare staff has to be set up ab initio – practicalities need more work here. | Guidance has been amended. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P15 | For UK-born persons, every acute Hep B case is a public health failure (to have immunized) - this clear message does not come thro.<br><br>TOO LITTLE re HBV immunization vs HBV testing: depends on risk group. | The focus of this guidance is on promoting the uptake of testing, however, the pre-requisites state that the recommendations are based on the assumption that hepatitis B and C tests are provided according to current best practice and are offered as part of a care pathway covering immunisation, diagnosis and treatment. Reference is made to guidance on hepatitis B vaccination [Green book: immunisation against infectious disease; Hepatitis B antenatal screening and newborn immunisation programme, |

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| | | | | and Reducing the differences in the uptake of immunisations.] |
| | | | Last sentence re HCV/HBV test: barrier is venepuncture & blood-spot helps to assuage that. | Consideration 3.21, in section 3 of the guidance, notes that while venepuncture samples remain the gold standard, the PDG noted that dried blood spot tests for hepatitis B and C have a high test sensitivity and specificity and can be useful in certain settings for people with poor venous access. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P16 | Hep b vaccine at last . . . but, 1st bullet, summarise what NICE says | Hyperlinks are included in the guidance to enable the reader to easily view other related NICE guidance. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P17 | 2 week wait for test result is TOO LONG.<br>No discussion of PCR before HCV antibody testing | The PDG felt that 2 weeks was feasible in terms of the laboratories delivering the results. The PDG noted, in section 3, the importance of all blood samples that test positive for hepatitis C antibody being routinely tested for hepatitis C virus, for example, by PCR. In addition, further consideration of and research on the use of PCR for initial testing in current injecting drug users, with follow-up antibody testing for people who test PCR positive, may be warranted to enable rapid diagnosis of recent infections. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P17 | National legislation: mandatory reporting is widely honoured in breach & does NOT serve well public health. BE CLEAR that master index (initial of 1st name, soundex | The PDG felt that this level of detail in the guidance was unnecessary. |

# Public Health Programme Guidance

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| | | | of surname, sex, d.o.b), not name, is needed for confidential HCV diagnosis register.<br><br>Separately discuss contact tracing wrt acute hep B. | |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P17 | Laboratory need new national HCV (or hep) test request form which allows current vs former IDU risk to be differentiated. | Thank you for your comment; it has been passed to the NICE implementation team |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P18 | Given the absence of decent test request form, how does PDG think its audit requirement can be competently met? | Thank you for your comment; it has been passed to the NICE implementation team. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P18 | Not even liver clinics routinely offer HBV & HAV vaccine to their HCV carrier patients . . . | Thank you for your comment. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P21 | Cannot be correct that HCV prevalence increases with an increasingly aged population [unless ever-IDUs are being referred to?] | Section 2 has been updated. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P21 | UAM survey should ask about HCV-testing in past year or past 2-years as well as ever-HCV tested as REGULAR testing not once-off is needed by current IDUs. Wrong survey questions send wrong public health messages! | Thank you for your comment. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P22 | What else than HBV immunization could have accounted for magnitude & timing of fall . . . ? | Section 2 has been updated. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | 3.9, p27 | Each HBV transmission is public health failure (not just patient responsibility) | Noted. |
| **MRC Biostatistics Unit,** | | 3.14 | Probably be able to carry out . . . | Guidance has been amended accordingly. |

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| **Robinson Way, CAMBRIDGE CB2 0SR** | | | | |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | 3.16 | Mouth swabs – no mention of false negative, another problem | Consideration 3.21, in section 3, notes that no recommendations were made on the use of oral fluid for hepatitis B or C testing. The PDG recognised that this method may be more acceptable to some people because it is less invasive than taking blood from a vein. However, if an oral fluid sample was used, a blood sample would then be required to confirm the initial positive results, and for PCR testing to diagnose chronic hepatitis C. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | 3.17 | STRONGLY disagree re overlap between populations as reason to test for both – HBV immunize, HCV test in iDUs; different strategy for imported HCV/HBV | The PDG acknowledge that different populations are at increased risk of hepatitis B and C. However, there is some overlap between them and it would simplify delivery if testing for both infections at the same time was recommended in people who are at risk of either. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | 3.18 | Don't make best the enemy of the good – we've gone from 5% IDUs HBV immunized to nearer 70% . . . you risk undoing massive good. | Guidance has been amended. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | 3.19 | Waffle | Guidance has been amended. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | 3.20 | No phlebotomist at pharmacy, not immunization . . . | Consideration 3.29, section 3, has been amended to clarify that the evidence related to community pharmacist providing dried blood spot testing for hepatitis. |

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| | | | | |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | 3.21+3.22 | Immunize | As noted in section 3, the PDG emphasised existing hepatitis B vaccination recommendations (as detailed in the Green Book) because although hepatitis B vaccination was beyond the scope of the guidance, case-finding may identify individuals who should be offered vaccination. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | 3.24 | How do you know that 90% of IDU's HCV infections are by shared injecting & what accounts for the other 10%?<br><br>Only 5% of migrant adult-to-adult transmissions become chronic hepB – is that lower than more usual 10% or ??? (and if so, why) | Evidence is from HPA (2011c) mentioned in section 2 of the guidance.<br><br>Changed to 5% to 10% adult to adult transmissions become chronic (WHO http://www.who.int/csr/disease/hepatitis/whocdscsrlyo20022/en/index3.html |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | 3.25 | Equity for prisoners trumps cost-effectiveness | This section considers the cost effectiveness. The equity was considered separately. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | 3.26 | No mention of detainees | This section is not about detainees as such. Detainees will be part of the groups mentioned. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | 3.27 | Primary care needs to promote HBV vaccine, not just HBV testing | HBV vaccination is being considered elsewhere in this guidance and does not require further emphasis in 3.27, which is about the cost effectiveness of testing. |
| **MRC Biostatistics Unit, Robinson Way,** | | 3.28 | There is very good evidence for impact of prisons' HBV immunization & currently in Scotland for prisons' issue of | Guidance has been amended to clarify that this lack of evidence is related to testing not immunisation. |

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| **CAMBRIDGE CB2 0SR** | | | Naloxone kits. | |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | 3.30 | HBV vaccine is 1st requirement in prisons, HBV testing 2nd. | Guidance has been amended accordingly. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | 3.32 | NO-ONE surely is suggesting that HCV testing should not be open to prisoners who want to check-out their HCV status, confidential HCV testing in prisons is by prisoners' request and/or is offered to prisoners - it is not something that is done to prisoners except by their informed consent, as with all patients! | Guidance has been amended. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | 3.33 | Scottish prisons initially prioritized HCV carrier prisoners who were sentenced to 1 year or more as those to be referred for HCV treatment (for continuity reasons) | Thank you for providing this information. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | 3.37 & 3.42 | Rephrase to emphasise no-names confidential database that uses master index and probabilistic linkage. BUT, 1st sort out proper registration of HBV positive tests – walk before you run.<br><br>Those data . . . plural.<br><br>Which country – not even Scotland has HCV denominator study outside of Glasgow. | The PDG felt that this level of detail in the guidance was not necessary.<br><br>The guidance has been amended.<br><br>This consideration has been amended. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | 3.39 as there are few data | What about tattoos etc | This is addressed in consideration 3.55. |
| **MRC Biostatistics Unit,** | | 3.40 | Coronary heart disease is odd comparator because NOT | Guidance has been amended accordingly. |

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| **Robinson Way, CAMBRIDGE CB2 0SR** | | | a transmissible disease. | |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | 3.43 | Which vaccines? Also against Hep A | The guidance has been amended to state hepatitis B vaccine. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | 3.45 & 3.46 | Be vaccinated or test . . . re HBV | Guidance has been amended accordingly. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P39 | Several references are incomplete | Guidance has been amended accordingly. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | Appendices C & D | Other than to remark as at outset above on missed reference on targeted HCV testing by Bird et al (eg p66), I have not commented on these appendices but instead comment in detail below on CE modelling report. If time allows, I shall return to Appendices C & D. Other than to say . . .<br><br>Appendix C: PDG does nothing to dispel the confusion refered to in Evidence statement Q5 re HBV vaccine.<br><br>Evidence statement Q9 = Q10;<br><br>Q11-13 missing.<br><br>Q18: one-stop shop on HCV is not possible with 2 week wait for test results**!** | <br><br>The guidance has been amended.<br><br>Typo amended<br><br>These evidence statements do not support any of the recommendations hence not listed. |

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| | | | **E4: why don't state laboratories consider providing DBS test kits?** | Laboratories do provide DBS test kits. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | Assessing the cost-effectiveness of interventions aimed at promoting and offering hepatitis C testing to IDUs: an economic modelling report | P11 | Summary does not state that payment to GP is £100 when average of test-costs is £93 – so that GP-extra more than doubles costs. NO SENSITIVITY ANALYSIS on this, whereas Bird et al reported not only successful, unpaid implementation by (admittedly highly committed academic) GP but also successful auditing in Lothian region of practices with special interest in drug treatment wherein focus was to establish IDU-history of all clients & - if ever-IDU – to increase HCV test uptake & document extent of new diagnoses . . . | *The response supplied by the authors of that report:*<br>We were following trial protocol by including the £100 reimbursement, and our base-case analysis shows this intervention is cost-effective. Without the additional £100 payment, provided that the intervention effect stays constant, the intervention would be even more cost-effective. We have added this comment to the discussion, and also noted the payment in the summary as requested. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P11 | HCV testing of current IDUs needs to be regular – eg annual or 2-yearly. CE may help to determine regularity which also depends on current IDUs' HCV incidence (which in turn depends on HCV prevalence, deliberate or inadvertent (cf colour-coded syringes) needle-sharing frequency with IDUs whose HCV status in positive/unknown, and IDUs' looking-out for each other by responsible-disclosure of HCV status – as previously was done re HIV, including by prisoners). Such responsibility, which IDUs do embrace, is of itself de-stigmatizing & should be promoted/lauded. | *The response supplied by the authors of that report:*<br>We acknowledge that regularity of testing was not examined in our model, but we agree that frequency of testing is an important point which we will include as a discussion point. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P13 & p14 | 'More research is needed to establish cost-effectiveness of prison interventions' . . . as with HBV immunization in prisons such 'research' delayed for several years | *The response supplied by the authors of that report:*<br>We believe that HBV and HCV testing should not interfere with HBV vaccination. As we understand it, the NICE PDG is |

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| | | | universal offering of HBV vaccine to prisoners in E&W when it had already been established by Hall et al in early 1990s that HBV vaccination of those at risk was highly cost-effective. In other contexts, as here re HCV testing by blood spot, equity of provision for prisoners & outside community – unless there are potential counter-harms in jails (cf needle exchange vs methadone maintenance) – means that same healthcare provision should be made for inmates. Hence decision problem 2 is answered by equity if decision problem 1 is affirmative. | recommending that same policy of case finding among higher risk groups is followed in prison as in community, but also believe that the modelling raises important issues regarding treatment continuity in prison. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P14 | As modelled cost-effectiveness seems to derive from treatment-impact but we are here dealing with largely-silent infectious transmissible disease, diagnosis of which requires HCV test. It seems odd to consider that diagnosis should be prevented if treatments are not sufficiently cost-effective because if 'education' means anything it means patients being aware of their HCV status and empowered thereby to try to reduce onward transmission. Reduction in viraemia by HCV treatment is not the only way of limiting IDU's HCV incidence: off-injecting, particularly by HCV carriers, is another! | *The response supplied by the authors of that report:* As the systematic review did not identify conclusive qualitative or quantitative evidence that positive or negative diagnosis is associated with behaviour change, and evidence from elsewhere is weak, we felt it conservative to exclude this from the analysis. However, we have added a statement noting that if behaviour change were to result from diagnosis, the interventions would be more cost-effective. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P16 | Rate of entry of never-IDUs in youngest age-group (15-19 years?) was fitted to a total population size of 1000 – however, I cannot find the estimated IDU-incidence rates by age-group in the Tables at end of report - I find only the age-distribution of newly-initiated IDUs, | *The responses supplied by the authors of that report:* The reviewer is correct in noting that we fitted the IDU initiation rate to ensure a population of 1000 IDU. The incidence rate varied for each of the 1000 simulations, depending on the sampled cessation rate, death rate, and |

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| | | | | HCV prevalence (due to HCV related death). As this parameter was fitted and not sampled, it was not included in the tables. The cessation rate and initiation rate are highly correlated. The fitted median initiation rate is 0.004 per year (95% interval 0.0031-0.0059), the report has been amended to include this detail along with a plot showing this correlation. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P17 | Inclusion of societal costs make a substantial difference to CE in respect of IDUs because their criminality makes their cost-per-quality-adjusted-life year around £38K to £45K (as per previous CE assessments for NICE). | *The response supplied by the authors of that report:* We acknowledge that in other IDU interventions (such as NSP or OST), the inclusion of societal costs makes a substantial difference in the c/e. However, we are unaware of any evidence surrounding the impact of HCV diagnosis on offending (over and above effect of OST), and therefore did not include this in our analysis. We have included a sentence in the discussion noting this. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P18 | How were cessation rates from injecting modelled and did sensitivity analysis explore implications for higher cessation rate for recently diagnosed HCV carriers . .. ? [into HCV treatment, off-injecting are dual public health goals] | *The response supplied by the authors of that report:* The cessation rate from injecting was estimated from Sweeting et al. Stats Meth Med Res 2009 (as noted in Table 12), but sampled from a range of values (from 6.2 to 15.8 years) for the 1000 simulations, and was assumed constant. Unfortunately, we were not able to model differential cessation rates for recently diagnosed carriers with our model structure, but have included this as a limitation in our discussion. |
| **MRC Biostatistics Unit,** | | P20 | Prisons aim to smooth transition from prison-based to | *The response supplied by the authors of that report:* |

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| **Robinson Way, CAMBRIDGE CB2 0SR** | | | community-based addiction services – they don't always succeed but nor do they uniformly fail!<br>Hospital-based HCV testing of current & ex-IDUs is likely to be highly selective -eg those closer to cirrhosis because referrals to liver clinic are outcome-dependent (ie more likely the closer the individual is to late sequelae of HCV carriage), see Fu et al (2007, 2009). | We deal with the issue of continuity in our sensitivity analysis, where we vary the % continuity between prison and the community from 0% (base-case) to 100%, to determine the impact on cost-effectiveness. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P21 | Irrespective of what is written re meta-analysis, I am sceptical because relative risk of HCV-progression depends on co-morbidities (heavy drinking; HIV) and is age-dependent: in general these covariates differ for IDU-related and other-exposure patients. Perhaps text means that covariate-adjusted rates are similar, which is probably correct. | *The response supplied by the authors of that report:*<br>The meta-analysis we referenced shows that HCV progression rates are similar between IDU and non-IDU, both in the unadjusted and co-variate adjusted analyses. We have clarified this in the text. We understand the commentator is sceptical of the results from the cited meta-analysis on HCV progression in IDU (Jean-Baptiste J Hep 2010). We note there has not been an updated meta-analysis and therefore used the most recent available data regarding this. However, a line has been added in the discussion regarding this point and the need for additional research on HCV progression in this population. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P22 | Highly unlikely that utility values for ex-IDUs are same as for non-IDUs because of differences in intrinsic deprivation which is also why (see White et al, under review by RSSA) IDUs' and ex-IDUs' non-DRD death-rates are higher than for general population, see Merrall et al (2011) re mortality of Scottish Drug Misuse(SDMD) | *The responses supplied by the authors of that report:*<br>As we assume that ex-IDUs have no risk of infection/transmission, the only utilities which determine c/e of intervention targeting ex-IDUS are the incremental values associated with SVR, or decrements associated with liver disease progression. Therefore, alterations of baseline |

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| | | | Cohort over nearly 70,000 clients, 1996-2006. See Merrall ELC, BIRD SM, Hutchinson SJ. Mortality of those who attended drug services in Scotland 1996-2006: record linkage study. *International Journal of Drug Policy* 2011 [29 June 2011 Epub ahead of print]. | uninfected values would not alter our conclusions. As it is likely that most of those involved in the UK studies determining improvement of QoL associated with SVR were ex-IDU, we believe these data are comparable. We agree, however, that more research is needed surrounding IDU/ex-IDU utility values and note this in the discussion.<br><br>We agree that non drug related (nonDRD) death rates could be elevated for IDU due to intrinsic deprivation, but reliable estimates of ex-IDU non DRD rates are unavailable as very few studies record information on injecting status over time. We note that an elevated non-DRD mortality for IDU would be swamped by DRD mortality, and therefore would not substantially alter impact of interventions for this population An elevated mortality for ex-IDU would make interventions for this subgroup slightly less cost-effective. To examine this, we therefore have performed an additional sensitivity analysis for the GP intervention (targeting only ex-IDU), and find that doubling ex-IDU death rates only increases the ICER by 15% (from an estimated £13,900 to £16,000 per QALY gained), and the intervention is still estimated to be cost-effective. The impact on the ICER for the addiction services and prisons intervention will be less than the GP intervention, as more of the cost-effectiveness is determined by IDU instead of ex-IDU (and DRD as modelled will far outweigh any increase in nonDRD for current IDUs). Therefore, none of the base-case conclusions change with elevated non-DRD death rates. We now include mention of |

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| | | | | this extra sensitivity in the results and discussion. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P22/23 & Table 2 on utilities | There is evidence, I believe, that HCV diagnosis is associated with lower utility and Taylor et al in Scotland's no-names Needle Exchange Surveillance Initiative (NESI) have elicited IDUs' EQ-5D and also know whether respondent has correctly identified his/her HCV status (which NESI obtained biological sample to establish). Thus, I suspect that the academic confidential data are from NESI (and from Scotland) whereas the reference utilities for ex-IDUs are apparently for UK. However, heavy drinking is likely to exact a different toll on EQ-5D in Scotland versus in E&W, an issue that should at least be mentioned. Moreover, Table 2, proposed that the age-specific IDU-disutility is constant, which I doubt, because of the progressive damage that prolonged injecting-careers constitute. Sensitivity analysis on this issue could be important. Here, the academic in confidence data are a primary goal of a NESI-publication and so confidentiality is understandable. | *The responses supplied by the authors of that report:*<br>We agree that the alcohol consumption among IDU in Scotland is likely higher than in England, but do not believe that this should have an impact on the presence or magnitude of a disutility attached with diagnosis, especially given the cross-sectional design of the Scottish study. Unfortunately, the data in Scotland was not sufficiently powered with higher age groups to explore whether a disutility changes with age—other studies which have included an age disutility (cite Clin Infec Dis birth cohort) use an age-constant disutility. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P24 & Table 5 vs p35 [addiction services: 14.7%, 29.4%, 44.4%?] | Are the % referred to in middle of main paragraph (re IDU-risk tests by location) those in the bottom rows of Table 5? If so, why do they not add to 100% - see 38.4%, 11.5%, 29.4%, 20.7%? AND, what consideration has been given to ascertainment bias – some services being more likely to report IDU-risk ?? | *The response supplied by the authors of that report:*<br>Yes, the IDU risk tests by location are in the bottom row of Table 5, and they do add to 100%. We explore the impact of ascertainment bias in the sensitivity analysis where we change the proportion of tests by location to be +/-50% in a given setting (keeping the total at 100%). |

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| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P26 | Referral & treatment rates for Muirhouse Practice's former IDUs are available in Bird et al. | *The response supplied by the authors of that report:*<br>We attempted to use England specific data wherever possible, and therefore have used English referral rates (Irving et al) and estimated treatment rates. We agree that a Scotland-specific analysis could use those from Muirhouse Practice (Edinburgh). We note, however, that Muirhouse's 73% referral rate, and 21% treatment of those in referral equates to an effective treatment rate of 15.3% of those diagnosed, similar to our effective rate of 17.5% treated within 2 years (given 35% referred, and 50% treated in referral) |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P29 | It is odd that when part of reason for diagnosis of transmissible infection is to inform host so that s/he can take steps to limit onward transmission that HCV transmission should be neglected in CE modelling. Or, have I misread this? | *The responses supplied by the authors of that report:*<br>As stated above, the systematic review did not find convincing evidence that positive or negative diagnosis resulted in behaviour change, and therefore we felt it conservative to assume no behaviour change in the model. We agree that if behaviour change were to occur it would increase the cost-effectiveness, and have included a sentence in the discussion. We note that we did include the impact of testing and treatment of onward HCV transmission. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P29 | Scottish % (by age-group) of prisoners who are IDUs are likely to be over-estimates for E&W. | *The response supplied by the authors of that report:*<br><br>Unfortunately, we were not able to obtain estimates of the % (by age-group) of prisoners with IDU history from England |

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| | | | | as previous data (Weild et al 2000) defined current IDU as those who have injected within 4 weeks of prison entry, while we define current IDU as those with an ongoing infection risk and who have not permanently ceased injecting. Therefore, the estimate used by Weild would likely underestimate the number of injectors we define as 'current', who may not have injected in the past 4 weeks but are at risk of relapse and who have not permanently ceased injecting. We also note that the Weild data is now relatively old, and the distribution of IDU and age of IDU in prison is likely to have changed. Additionally, the Scottish prison data was collected from all Scottish prisons, and therefore is likely to be less biased than the Weild study (which surveyed 8/135 [6%] of prisons in England in 2000). |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P29 | What does MPES by De Angelis et al suggest re HCV prevalence in ex-IDUs? How do model outputs compare with outputs from MPES on HCV prevalence in England by exposure route. | *The response supplied by the authors of that report:* We compare our model estimates of prevalence among ex-IDU to those of the MPES by Harris and DeAngelis on page 29 (study 12 is an update of original work by DeAngelis). As stated, the model estimates a 28% chronic prevalence among ex-IDUs, falling in line with the upper uncertainty estimate (25-35% antibody prevalence) from Harris et al. As we do not model other exposure routes (such as immigrants), we did not compare to the other MPES estimates. |

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| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P48 | No sensitivity analyses on GP payment of £100?? | *The response supplied by the authors of that report:*<br>As stated before, excluding the £100 would make the GP intervention more cost-effective, although it was already cost-effective in the base-case. We now note this in the discussion. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | P48 & Table 10 | Comparability with Castelnuovo is misleading – in that study GPs were not incentivised by £100 per test & a single high-IDU prevalence GP practice was studied (to find out about nosocomial transmission) & Castelnuovo misinterpreted IDUs' HCV test uptake rates in prisons & GP practice, see Bird et al (2011). | *The response supplied by the authors of that report:*<br>We agree the Castelnuovo study (and all the other case-finding intervention studies in prison or addiction services) explored slightly different interventions from those we studied. We have mentioned this in the discussion and added a line citing the Bird study as a limitation of the Castelnuovo study. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | Table 12 | Non-DRD death-rates do not appear to have been at least doubled compared to age-specific general population rates. | *The response supplied by the authors of that report:*<br>As mentioned above, we agree that non drug related (nonDRD) death rates could be elevated for IDU due to intrinsic deprivation, but reliable estimates of ex-IDU non DRD rates are unavailable, as very few studies record information on injecting status over time. We note that an elevated non-DRD mortality for IDU would be swamped by DRD mortality, and therefore would not substantially alter impact of interventions for this population An elevated mortality for ex-IDU would make interventions for this subgroup slightly less cost-effective. To examine this, we therefore have performed an additional sensitivity analysis for the GP intervention (targeting only ex-IDU), and find that doubling ex-IDU death rates only increases the ICER by |

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| | | | | 15% (from an estimated £13,900 to £16,000 per QALY gained), and the intervention is still cost-effective. The impact on the ICER for the addiction services and prisons intervention will be less than the GP intervention, as more of the cost-effectiveness is determined by IDU instead of ex-IDU (and DRD as modelled will far outweigh any increase in nonDRD for current IDUs). Therefore, none of the base-case conclusions change with elevated non-DRD death rates. We now include mention of this extra sensitivity in the results and discussion. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | Table 15 | Without addition of £100 per test, ICER could be nearer £7,000. | *The responses supplied by the authors of that report:* As stated before, excluding the £100 would make the GP intervention more cost-effective, although it was already cost-effective in the base-case. We now note this in the discussion. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | Table 16 | All modelling seems to have been done on a life-time basis, rather than curtailed at 20 years hence, say, which would potentially increase ICERs. | *The responses supplied by the authors of that report:* NICE's terms of reference to those who provided the report were for a lifetime time horizon, although we do perform a sensitivity analysis where we shorten the time horizon to 50 years, and show it reduces c/e, but does not change the main results. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | Table 19 | No sensitivity on £100 payout per GP-test | *The responses supplied by the authors of that report:* As stated before, excluding the £100 would make the GP intervention more cost-effective, although it was already |

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| | | | | cost-effective in the base-case. We now note this in the discussion. The aim of the analysis was to determine the cost-effectiveness of the case-finding interventions based on the primary study data on cost and impact. Therefore, as the original study included £100 remuneration for the GP, we included this cost in the analysis. As detailed before, we felt it was inappropriate to perform a sensitivity analysis without this £100 remuneration for two reasons: 1) it is unclear whether the impact of the intervention would be maintained without the £100 payment, and 2) if the impact is sustained and the £100 excluded, the intervention would come in as more cost-effective than in our base-case analysis which already fell under the willingness-to-pay threshold (and our priorities for sensitivity analyses were those which could change the policy-decision). However, we note that because an elevated mortality rate for IDU could make interventions targeting them less cost-effective, this was performed as an additional sensitivity analysis as previously suggested. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | Gaps in Evidence | Appendix D | 1d &e) 1st HBV vaccinate in prisons & communities so that IDU is NOT HBV-transmission route! (see Scotland). | The guidance has been amended accordingly. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | | 2c) Normalise (if not already routine) offering of HBV vaccination for MSM & regular HCV testing if HIV co-infected or ever-IDU | The guidance has been amended accordingly. |
| **MRC Biostatistics Unit, Robinson Way,** | | | 2d) maternal testing during pregnancy . . . | Appendix D relates to gaps in the evidence based on an assessment of the evidence. The group made 12 |

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| **CAMBRIDGE CB2 0SR** | | | 2f) Normalise as important actionable health check & necessary because of high HCV carriage rate in older former IDUs<br><br>2i) neither prisoners not their treating doctors like HCV patients to double-cuffed when escorted to hospital to see hepatologist! {pretty obviously}<br><br>2k) liver biopsy is not necessarily part of routine care . . .<br><br>2m) why do GPs refer for test, rather than test & refer carriers? | recommendations for research into areas that it believes will be a priority for developing future guidance. |
| **MRC Biostatistics Unit, Robinson Way, CAMBRIDGE CB2 0SR** | | | 5. Non-invasive testing is better than no test in high risk individuals BUT beware false negative rate.<br>6. Attributable HCV testing needs subject's informed CONSENT – make this clear. | See response above. |
| **National Treatment Agency for Substance Misuse** | General | | We think the guidance overall is very good, and it has the right aspirations for hepatitis B and C testing. It will be valuable in helping promote testing, as well as helping ensure treatment options are available, and building a more accurate picture of what happens after testing. We have some specific comments which are below. | Thank you for your comments. |
| **National Treatment Agency for Substance Misuse** | Recommendation 4 | 13 | Prisoners have the right to refuse their information being shared, so we suggest amending the third bullet point, first sub-bullet point to "subject to consent, any confirmed cases should be reported to, and managed by, the local hepatitis treatment services, in liaison with prison | The recommendations are based on the assumption that hepatitis B and C tests are provided according to current best practice and are offered as part of a care pathway covering diagnosis, treatment and immunisation. The |

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| | | | healthcare services" | recommendations assume testing is undertaken with the person's consent and that people are offered pre- and post-test discussions covering issues such as confidentiality and provision of information to enable people to make informed choices about their care should they test positive. The recommendation makes clear that the results from hepatitis B and C testing should only be provided to the prisoner's community-based GP if consent is given. |
| **National Treatment Agency for Substance Misuse** | Recommendation 10 | 18 | The data audit recommended in the second bullet point may put an unnecessary burden on commissioners (including substance misuse commissioners who will have a role in commissioning testing in drug treatment services).<br><br>While we think would be useful for local areas to have this information, it shouldn't be the responsibility of commissioners of testing and treatment services. Data on people in drug treatment who have been offered and have accepted or refused a hepatitis C test is readily available from the National Drug Treatment Monitoring System, but the other data may be more difficult to acquire.<br><br>We suggest making this bullet point read like less of a requirement, for instance "Audit the uptake and testing of outcomes, using available local data, which may include…" | The PDG considered this at some length and felt it prudent that commissioners of services be in receipt of data to assess how successful services are and as such kept the recommendation as it was**.** |

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| **Substance Misuse, Public Health, NHS Blackpool** | Pre-requisites | Page 6 | Mandatory training delivered by the Hepatitis nurse offering background to the virus, risk factors, dispelling myths, results and treatment and testing including dry blood spot testing for all substance misuse workers. | Recommendation 3 concerns developing the knowledge and skills of healthcare professionals and others providing services for people at increased risk of hepatitis B or C infection; those working in drug services are listed. The recommendation states that an ongoing education programme should be provided and that the training programme content should be accurate and up-to-date, reflecting advances in testing, diagnosis and treatment of hepatitis B and C. In addition, recommendation 6 states that it should be ensured that staff have the knowledge and skills to promote hepatitis B and C testing and treatment and that staff who undertake pre- and post-test discussions and dried blood spot testing are trained and competent to do so. |
| **Substance Misuse, Public Health, NHS Blackpool** | Recommendation 1 | Page 8 | Delivering Hep B & C testing from local pharmacies offering pre and post test discussion, dry blood spot testing and direct referral to treatment services | Recommendation 10 states that commissioners of hepatitis testing and treatment services should consider all venues where testing and treatment services are, or could be offered that can also ensure continuity of care and onward referral to specialist treatment for people who test positive (such as pharmacy testing and outreach testing and treatment).<br>The guidance now notes, in section 3, that the PDG felt that there may be merit in commissioners considering a range of venues for hepatitis B and C testing in order to improve accessibility. Mechanisms would need to be in place to ensure access to laboratory testing services, delivery of results and referral of people who test positive into the care |

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| | | | | pathway. In addition, venues would need to ensure adequate measures were taken to ensure infection control and privacy. The PDG acknowledged that there is encouraging evidence from pilot schemes where community pharmacists provide dried blood spot testing for hepatitis. Although the evidence is not strong enough to uniformly recommend that all community pharmacists provide this service, the PDG felt that it would be worthwhile considering extending pilot programmes. This extension could be considered for pharmacists already engaged with people at increased risk of hepatitis B and C, such as pharmacists providing needle exchange and NHS health checks. |
| **Substance Misuse, Public Health, NHS Blackpool** | | | Outreach by volunteers/peers and professionals using targeting campaigns aimed at dispelling myths and offering testing. Ensuring the testing environment is non judgemental, friendly and welcoming whilst making this accessible to all. | The Group recognised a role for the peers of people at increased risk in promoting hepatitis B and C testing and supporting people who are diagnosed positive. Peer support is now mentioned in recommendations 5 and 6 (testing in prisons/immigration removal centres and drug services). The PDG noted a lack of evidence specific to the role of peer support in promoting the uptake of testing and treatment for hepatitis B and C. Evidence of its positive effect on attitudes, knowledge and behavioural practices relating to prisoners' sexual health was considered. Based on this evidence, the PDG considered it logical that peer support could be beneficial for the groups of interest identified in the guidance. |

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| **Substance Misuse, Public Health, NHS Blackpool** | Recommendation 2 | Page 9 | To ensure all health professionals are in receipt of mandatory training delivered by the Hepatitis nurse offering background to the virus, risk factors, dispelling myths, results and treatment and testing including dry blood spot testing for all substance misuse workers. | Recommendation 3 concerns developing the knowledge and skills of healthcare professionals and others providing services for people at increased risk of hepatitis B or C infection; those working in drug services are listed. The recommendation states that an ongoing education programme should be provided and that the training programme content should be accurate and up-to-date, reflecting advances in testing, diagnosis and treatment of hepatitis B and C. In addition, recommendation 6 states that it should be ensured that staff have the knowledge and skills to promote hepatitis B and C testing and treatment and that staff who undertake pre- and post-test discussions and dried blood spot testing are trained and competent to do so. |
| **Substance Misuse, Public Health, NHS Blackpool** | Recommendation 3 | Page 11 | Involve local pharmacies and peer groups to extend the message to those groups who are marginalised i.e. injecting drug users whose only contact with services is through their local pharmacy needle exchange programme. | Recommendation 2 (previously 3) states that local organisations should encourage and support people from groups at increased risk who have been diagnosed with hepatitis B or C to contribute to awareness-raising activities (for further information see NICE guidance on Community engagement). In addition it states that local organisations should run awareness-raising sessions to promote hepatitis B and C testing in venues and at events popular among groups at increased risk. Examples of possible venues include: faith and cultural centres, NHS and non-NHS drugs services, GP surgeries, sexual health and genitourinary medicine services, immigration centres, hostels for the homeless, prisons and youth offender institutions. |

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| **Substance Misuse, Public Health, NHS Blackpool** | | | Blackpool has a peer mentor programme of which a harm reduction training programme is offered. The aim is to attract treatment naïve or hard to reach groups especially those at risk of Hep B & C into treatment services. | Thank you for this example; the NICE implementation team were notified. |
| **Substance Misuse, Public Health, NHS Blackpool** | Recommendation 6 | Page 14 | Although a harm reduction nurse is in place across the partnership providing screening and vaccinations for Hep A, B and C and HIV. We are currently training all front line staff to deliver dry blood spot test for those entering and in treatment. The training also covers risk factors, cirrhosis of the liver, why it's important to test, dispelling myths associated with hepatitis and exploring reasons why someone would not want to be tested and ways in which to discuss testing. Once this training is complete, the pathway for Hepatitis will ensure testing is available at all substance misuse sites across the locality. | Recommendation 3 concerns developing the knowledge and skills of healthcare professionals and others providing services for people at increased risk of hepatitis B or C infection; those working in drug services are listed. The recommendation states that an ongoing education programme should be provided and that the training programme content should be accurate and up-to-date, reflecting advances in testing, diagnosis and treatment of hepatitis B and C. In addition, recommendation 6 states that it should be ensured that staff have the knowledge and skills to promote hepatitis B and C testing and treatment and that staff who undertake pre- and post-test discussions and dried blood spot testing are trained and competent to do so. |
| **Substance Misuse, Public Health, NHS Blackpool** | General Comments | | Dried Blood Spot Testing is both user and client friendly as it does not require veins and the sharp used is a lancet which reduces the risk of needle stick injuries.<br>Cost – for those who do not have a virology lab locally the cost of DBST is significantly lower than whole blood volume however those who have virology labs on site may find them more costly.<br>Following introducing DBST in Blackburn in 2008 the numbers attending increased by 400% in the first 2 | Thank you for providing this information. Recommendation 6 states that drugs services should have access to:<br>dried blood spot testing for hepatitis B and C for people for whom venous access is difficult. |

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| | | | years.<br>Feedback from clients is that they often would not access testing if it was via a vein and relief when they know it is only a finger prick.<br>Prevention of accessing testing;<br>The result. Getting blood from veins. Other priorities such as their substance use. Peer influence (their friends look well and have hep B/C so it is no big problem).<br>Myths – "dormant disease" "treatment like Chemo" "telling partners/children". | |
| **Substance Misuse, Public Health, NHS Blackpool** | | | PIED users – do not see themselves as at risk although on further discussion with them they often share tubes for cocaine, have unprotected sex etc. They are less likely to access testing – stigma of a "druggie disease" and they do not see themselves as using "drugs"<br>Factors that have increased their likelihood of testing – Displays on the diseases/treatments,<br>Testing method as mentioned above,<br>Vouchers/reward for testing (although ethically problematic). Having a family often makes them want to live longer so may look into testing/treatment. | Recommendation 4 now states that GPs and practice nurses should offer testing for hepatitis B and C to people if they have ever injected drugs, including image and performance enhancement substances. In section 3 of the guidance the PDG note the potential risk of hepatitis C transmission among people that inject performance and image-enhancing drugs (PIEDs) such as anabolic steroids (for non-medical reasons). However, there is a lack of published evidence on the extent of risk in this group or on their contribution to overall hepatitis C prevalence. |
| **Public Health Wales** | Recommendation 7 – Contact tracing for hepatitis B | 16 | Regarding 'Who should take action?', in Wales this would be Public Health Wales.<br>Regarding 'What action should they take?', Public Health Wales works with other organisations that undertake contact tracing and supports them in following national | Thank you for your comment, NICE public health guidance applies to England only, although other parts of the United Kingdom may choose to review and adapt it to their own circumstances. |

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| | | | standards. | |
| **Public Health Wales** | Recommendation 8 – Delivering and auditing hepatitis B vaccination | 16 | 'Who should take action?' – In Wales this would be the Health Boards Directors of Public Health (HB DPH). Public Health Wales supports the Health Boards in ensuring existing recommendations are implemented locally and audits of activity take place regularly. | Thank you for your comment, NICE public health guidance applies to England only, although other parts of the United Kingdom may choose to review and adapt it to their own circumstances. |
| **Royal College of General Practitioners** | General | - | I have not identified anything that should be changed. I remember commenting extensively on this some time ago. The document now is good and comprehensive. | Thank you for your comment. |
| **Royal College of Nursing** | General | General | The Royal College of Nursing welcomes proposals to develop this guidance. It is timely. | Thank you for your comments. |
| **Royal College of Nursing** | Recommendation 1 | 8 | This action should not be limited to simply public health commissioning, as this is work that should cut across a range of commissioning areas many of which are not covered by public health. For example primary care and also acute settings are ideal to use as an opportunity for testing and advice giving. As are sexual health /GUM clinics. | Recommendation 1 concerns raising awareness about hepatitis B and C among the general population; it was felt that this action should be led by commissioners and providers of national public health services but in partnership with others, for example, primary and secondary care including GUM and sexual health clinics. |
| **Royal College of Nursing** | Recommendation 2 | 9 | Again to get this message across to all healthcare staff, there is a need to widen the areas of engagement. Deaneries will only target new staff; there is a need for existing staff to be given such information. This again needs to be collaborative working driven by commissioners including Clinical Commissioning Groups to move forward.<br>Local education & Training Boards and ultimately Health Education England and the devolved administrations | Guidance has been amended accordingly. |

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| | | | should also be included. | |
| **Royal College of Nursing** | Recommendation 4 | 12 | "Who should take action?". A glossary of terms should expand on the membership of this category.<br><br>Under Primary Care Practitioners - It might be good to add that GP Practices providing a Travel Health Service are well placed to offer testing to the non-UK born population returning to their home country to visit friends and relatives – AKA VFRs.<br><br>Community pharmacists also need to be included. | This recommendation has been amended to clarify which primary care practitioners are expected to take action. The guidance now notes in section 3, consideration 3.29, that the PDG felt that there may be merit in commissioners considering a range of venues for hepatitis B and C testing in order to improve accessibility. Mechanisms would need to be in place to ensure access to laboratory testing services, delivery of results and referral of people who test positive into the care pathway. In addition, venues would need to ensure adequate measures were taken to ensure infection control and privacy. The PDG acknowledged that there is encouraging evidence from pilot schemes where community pharmacists provide dried blood spot testing for hepatitis. Although the evidence is not strong enough to uniformly recommend that all community pharmacists provide this service, the PDG felt that it would be worthwhile considering extending pilot programmes. This extension could be considered for pharmacists already engaged with people at increased risk of hepatitis B and C, such as pharmacists providing needle exchange and NHS health checks. |
| **Royal College of Nursing** | Recommendation 4 | 12 | "Who should take action?"<br><br>Travel Clinics may also be included here – some are NHS and some are independent. | See response above. |
| **Royal College of Nursing** | Recommendation 4 | 12 | In addition to the testing of all newly registered patients to | At its final meeting, the PDG discussed the possibility of |

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| | | | the surgery, the addition of testing all patients registered between the age of 40 and 60 within the surgery would identify those who have been exposed through transient drug use in the past who are difficult to identify.<br><br>This would in addition identify a significant burden of disease approaching cirrhosis who comprise the current mortality age of 59 years.<br><br>Allowing possible treatment and reduction of future cost to the NHS of cirrhosis, HCC and transplant. | testing all people between the ages of 40 and 65 or 70 for HCV infection. They concluded that a birth cohort testing programme in England is unlikely to be cost effective if it were carried out independently of other programmes. |
| **Royal College of Nursing** | Recommendation 7 | 16 | GPs are also responsible for tracing their own registered patients who are close contacts of a Hepatitis B case. | Recommendation 7 has been amended and now states:<br><br>'Public Health England centres should:<br>• take overall responsibility for tracing the close contacts of people with confirmed acute and chronic hepatitis B infection<br>• advise and oversee the activities of other local organisations undertaking contact tracing, such as GP surgeries and genitourinary medicine clinics, to ensure the national standards for local surveillance and follow-up of hepatitis B and C are met. For example, GPs may need to offer close contacts hepatitis B vaccination and refer for treatment.' |
| **Royal College of Nursing** | Recommendation 8 | 18 | 2nd bullet point: 'local public health services' needs to be clarified. It should include Public Health England Centres. | Guidance has been amended. |

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| **Royal College of Nursing** | 2<br>National Recommendations | 24/24 | "Post exposure immunisation is also recommended for babies born to chronically infected mothers".<br><br>We know that many of these babies are lost to follow-up and courses are incomplete, so again the opportunity arises within a travel health consultation, especially if the parents are seeking yellow fever vaccination (or malaria prophylaxis) prior to a trip to visit family in an endemic area where vaccination and certification is a requirement for entry to the country. | Recommendation 9 has been amended and now states: 'Public Health England should audit the hepatitis B vaccination programme for babies. The audit should note how many children received vaccines, whether vaccinated children were given all doses and if not how many doses they received, whether doses were given on schedule, whether babies were tested after completing the vaccination course and the rate of vaccination failure. This audit should be carried out annually and deficiencies addressed.'<br><br>In addition, the guidance now notes in section 3, consideration 3.29, that the PDG felt that there may be merit in commissioners considering a range of venues for hepatitis B and C testing in order to improve accessibility. Mechanisms would need to be in place to ensure access to laboratory testing services, delivery of results and referral of people who test positive into the care pathway. In addition, venues would need to ensure adequate measures were taken to ensure infection control and privacy. The PDG acknowledged that there is encouraging evidence from pilot schemes where community pharmacists provide dried blood spot testing for hepatitis. Although the evidence is not strong enough to uniformly recommend that all community pharmacists provide this service, the PDG felt that it would be worthwhile considering extending pilot programmes. This extension could be considered for pharmacists already engaged with people at increased risk of hepatitis B and C, such as pharmacists providing needle exchange and NHS |

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| | | | | health checks. |
| **Royal College of Nursing** | 3.10 | 27 | Regarding Stigma – It is important for employees to know that Hepatitis B transmission within households is possible and therefore children who become infected through a household contact can in turn pass on the virus through playground injury. | The guidance notes in section 3, consideration 3.7, a general lack of knowledge about hepatitis B and C including awareness in relation to the transmission of infection. Members felt that this contributed to the stigma surrounding these infections. Recommendations 1 and 2 attempt to address the lack of knowledge of the general population and groups at increased risk by raising awareness of hepatitis B and C, including the main routes of infection and transmission. |
| **Royal College of Nursing** | 3.14 | 28 | Dried blood spot testing may be preferable but stringent training would be essential as the HBV can exist outside the body for up to a week. | The recommendations are based on the assumption that hepatitis B and C tests are provided according to current best practice. Recommendation 6 states that it should be ensured that staff [in drug services] who undertake dried blood spot testing are trained and competent to do so. In addition recommendation 10 states that commissioners should ensure primary and secondary care staff are educated and trained in hepatitis B and C testing. |
| **Royal College of Nursing** | 3.20 | 29 | Mention of no evidence to support pharmacists testing but pharmacists are now providing travel health services so would be likely to see VFRs as per our comments on recommendation 4. | The guidance now notes in section 3, consideration 3.29, that the PDG felt that there may be merit in commissioners considering a range of venues for hepatitis B and C testing in order to improve accessibility. Mechanisms would need to be in place to ensure access to laboratory testing services, delivery of results and referral of people who test positive into the care pathway. In addition, venues would need to |

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| | | | | ensure adequate measures were taken to ensure infection control and privacy. The PDG acknowledged that there is encouraging evidence from pilot schemes where community pharmacists provide dried blood spot testing for hepatitis. Although the evidence is not strong enough to uniformly recommend that all community pharmacists provide this service, the PDG felt that it would be worthwhile considering extending pilot programmes. This extension could be considered for pharmacists already engaged with people at increased risk of hepatitis B and C, such as pharmacists providing needle exchange and NHS health checks. |
| **Royal College of Nursing** | 3.20 | 29 | With high numbers of people who initiate addiction to opiate substitution treatment (OST) relieving supervised consumption at a pharmacy this would seem to be an ideal opportunity to do some BBV work. Not least as this is one appointment that is very likely that this population will attend to. | Please see response above. |
| **Royal College of Nursing** | 3.41 | 33 | Each of these bullet points can be related to travel abroad. Health tourism for medical and dental procedures is on the increase and not all establishments offering treatment are regulated. | Please see response above. |
| **Royal College of Physicians** | General | | The RCP is grateful for the opportunity to respond to the draft guidance. Overall we welcome and support the guidance but would like to make the following comments | Thank you for your comments. |
| **Royal College of** | Recommmendation | 11 | In addition to prisons sexual health services should be | The guidance now includes a recommendation on |

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| **Physicians** | 4,5, 6 | | included. Hep B and C should be recommended for all attending patients as a routine screen.<br>There are higher rates of risk factors in those attending such services including MSMs, IDUs , ethnic minorities and sex workers | testing in sexual health and GUM clinics stating:<br><br>'Sexual health and genitourinary medicine clinics should:<br>• offer hepatitis B vaccination to all service users in line with the Green book<br>• offer and promote hepatitis B and C testing to all service users at increased risk of infection, including people younger than 18' |
| **Royal College of Physicians** | General | | This document only covers the testing of higher risk people. We know from data from antenatal clinics and blood transfusion services that a substantial number of people who test positive have no recognised risk factors. Universal testing would overcome this. | It is quite clear at universal testing is most effective as it will find more than targeted testing but it is estimated not to be cost effective. The cost effectiveness of universal testing depends on the prevalence of hepatitis B or C in the population; the modelling estimates that the prevalence in England is too low to warrant universal testing. |
| **Royal College of Physicians** | general | | All people found to be Hep B or C positive should be offered HIV testing as this is a indicator disease for HIV. – The BHIVA guidelines should be referenced. | Reference is made in the pre-requisites section to the British HIV Association guidance on managing co-infection with HIV-1 and hepatitis B or C. |
| **Royal College of Physicians** | 10 | 19 | ALL HIV patients should be tested for HEP B and C – not just MSMs | The 'Whose health will benefit' section of the guidance has been amended to make it clear which groups are at increased risk of hepatitis B and which are at increased risk of hepatitis C. |
| **Royal College of Physicians** | 10 | 19 | Regarding commissioning of services 'ensure msm are tested for Hep B and C, especially those who are HIV | The 'Whose health will benefit' section of the guidance has been amended to make it clear which groups are at |

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| | | | positive. Our experts believe that there should be commissioning for testing all MSMs regardless of HIV status. | increased risk of hepatitis B and which are at increased risk of hepatitis C. |
| **Royal College of Physicians** | | 17 | Typo venepuncture | Guidance has been amended accordingly. |
| **Royal College of Physicians** | 3.11 | 27 | Noted that some stigma might be attached but unclear of the evidence. Virtually all IDU's have shared on some occasion – especially the first time they inject. | Evidence statement Q29 in Appendix C notes:<br><br>The experience of stigma prevented IDUs from seeking hepatitis C testing because of fear of disclosure, and prevented IDUs from disclosing a positive hepatitis C status because of fear of a negative reaction, isolation and social exclusion (eight [++], three [+], one [-] and one [NR])[1,2,3,4,5,6,7,8,9,10,11,12,13]. Stigma also prevented engagement with further prevention education, investigations and treatment and resulted in IDUs receiving inadequate and judgemental care by healthcare professionals (seven [++], six [+], one [-] and two [NR])[5,6,7,9,12,14,15,16,17,18,19,20,21,22,23,24.]<br><br>[1] Craine et al. 2004.<br>[2] Ellard 2007.<br>[3] Harris 2009b.<br>[4] Khaw et al. 2007.<br>[5] Lally et al. 2008.<br>[6] McCreaddie et al. 2011.<br>[7] Roy et al. 2007.<br>[8] Sosman et al. 2005. |

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| | | | | [9] Strauss et al. 2008.<br>[10] Sutton and Treloar 2007. |
| **Royal College of Psychiatrists.** | General | | Whilst the frequency with which people with a Learning Disability (especially those with Severe Learning Disability) engage in IV drug use or similar activities may be lower than the general population, they are a vulnerable population who may indeed be liable to a number of the other identified risk factors. It is important that clinicians do not automatically assume that such patients are not at risk. These guidelines are therefore equally applicable to individuals with a Learning Disability. This will, of course, necessitate the application of "reasonable adjustments" especially in relation to communication, i.e. adaptation of educational materials, careful consideration of capacity to consent to investigation and treatment and, most importantly, adaptation of any consultation to take into account barriers relating to intellectual function, concentration, sensory deficits etc. If the individual is incapable of consenting then assessment and treatment should be carried out in accordance with the Mental Capacity Act 2005. | Guidance has been amended accordingly. |
| **Roche Products Ltd.** | General | 1 | In addition to testing in primary care, prisons, including youth offender institutions, and within drugs services; we believe that this guidance should also cover testing in ante-natal services. | A national antenatal screening programme for hepatitis B surface antigen (HBsAg) began in 2000, uptake of screening during pregnancy has increased over time to 97% in 2011. In addition, testing in antenatal services is covered in NICE guideline 62 |

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| | | | According to the Department of Health (DH) Hepatitis B infection transmitted from the mother to child during birth accounts for 21% of all new persistently infected cases. It is important to detect active hepatitis B infections in pregnant women because newborns are especially vulnerable to developing chronic infection; up to 90% of those who become infected with hepatitis B *in utero* will become carriers. We request NICE makes reference to DH, Best practice guidance (2011): Hepatitis B antenatal screening and newborn immunisation programme. | (2008).<br><br>Reference has been in section 1 of this guidance to guidance on hepatitis B vaccination available in the Green book: immunisation against infectious disease and the Hepatitis B antenatal screening and newborn immunisation programme, both published by the Department of Health, and in the NICE guidance on Reducing the differences in the uptake of immunisations. |
| **Roche Products Ltd.** | 1 | 8 | 'who should take action' - It may be worth mentioning Health and Wellbeing Boards by name under local public health services in | Guidance has been amended accordingly. |
| **Roche Products Ltd.** | 1 | 8 | 'what action should they take' – under the following bullet point we suggest the following addition:<br>benefits of testing and treatment, including the fact that earlier diagnosis and treatment **can lead to a cure** ("HCV screening and early treatment have the potential to improve average life-expectancy" / European journal of public health (Jun 2009) Long-term effectiveness and cost-effectiveness of screening for hepatitis C virus infection. Sroczynski) and can help prevent complications and serious illness such as liver disease. | Recommendation 1 now states that the benefits of early testing and treatment should be conveyed, including the role of earlier treatment in preventing serious illness such as chronic liver disease and liver cancer. In addition, recommendation 10 states that commissioners of hepatitis testing and treatment services should audit the number of people with hepatitis C who obtain a sustained virological response on antiviral therapy. |
| **Roche Products Ltd.** | 2 | 10 | Within recommendation 2 'Consider linking awareness-raising activities with existing education for health and social care professionals' we request that reference is | Guidance has been amended accordingly. |

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| | | | made to the RCGP training module:<br><br>http://www.rcgp.org.uk/substance_misuse/hepatitis_b_and_c.aspx | |
| **Roche Products Ltd.** | 5 | 13 | In addition to offering a test for prisoners at increased risk of hepatitis B or C infection on entry into a prison we suggest this is also offered on release from a prison. | Recommendation 5 now states that it should be ensured that all prisoners and immigration detainees are offered access to confidential testing for hepatitis B and C when entering prison or an immigration removal centre and during their detention. |
| **Roche Products Ltd.** | 7 | 16 | We suggest that contact tracing data collected by local organisations are held on a national database in order for organisations such as Public Health England or the NHS Information Centre for Health and Social Care to analyse the data and identify root causes of transmission. | As noted in section 3 of the guidance, the PDG acknowledged the limitations and challenges of current surveillance systems for hepatitis B and C (for example, data on the number of people completing treatment successfully are not available). The Group considered that the collection and collation of robust, service-level data on testing and treatment services was important for both monitoring and developing services. |
| **Roche Products Ltd.** | 10 | 18 | We suggest that audit data on uptake of testing and outcomes is stored on a national database ideally hosted by Public Health England. | As noted in section 3, the PDG discussed the need for hepatitis B and C databases holding details on people who have been tested and treated. The importance of collecting data on treatment uptake and the need for this data collection to be built into the pathway at every point was noted. It considered that an integrated system, bridging different healthcare providers and capturing a range of data, was the ideal. However, it was felt that |

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| | | | | there needed to be a balance between the burden of collecting data and the value of those data. The Group acknowledged that it would be resource-intensive. |
| **Roche Products Ltd.** | 10 | 18 | Commissioners should ensure providers of Hepatitis B and C testing consider the following:<br>• existing routes through which at-risk patients can be identified (for example simple checklist of vital risk factors to be added on to those already carried out i.e. Liver function tests to be included in Annual Health Check)<br>• A pre - test discussion of the implications of the test should accompany the test. Following a history and examination, testing should be offered to family members who may have been at risk.<br>• Give the person support and information regarding the:<br>○ likely progression of the infection<br>○ need for specialist management<br>○ treatments now available for hepatitis B and C | Recommendation 3 aims to develop the knowledge and skills of healthcare professionals and others providing services for people at increased risk of hepatitis B or C infection. Areas the PDG felt might be covered in education programmes, depending on the role of the health and social care professional, included risk factors for hepatitis B and C and population groups at increased risk of infection, detection and diagnosis of hepatitis B and C factors to consider in a pre- and post-test discussion and how these discussions should be conducted. Areas to consider in such discussions are listed in section 1 of the guidance, they include providing details of support available for clinical and non-clinical needs, enabling people to make an informed choice about their care should they test positive, and reduce their risk of infection should they test negative. |
| **The Royal College of Midwives** | General | | The RCM welcomes the publication of this useful guideline, which despite the lack of evidence on effective interventions to promote testing, offers important statistical information and recommendations on approaching this issue in a sensitive and unstigmatising way. | Thank you for your comments. |

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| **The Royal College of Midwives** | General | | It has a helpful focus on awareness raising among the general population and health professionals. | Thank you. |
| **The Royal College of Midwives** | Recommendation 2 | 10 | Midwives need to be included in the group of health professionals encouraged to take part in continuing professional development on this subject. | Guidance has been amended accordingly. |
| **The Royal College of Midwives** | Recommendation 2 | 9 | The health care assistants and support workers who work in the relevant areas, also need to be included in the groups that receive an ongoing education on this subject. | Guidance has been amended accordingly. |
| **The Royal College of Midwives** | Recommendation 7 | 16 | It is unclear how Public Health England units can provide accountability for tracing close contacts. | Recommendation 8 has been amended and now states:<br>'Public Health England centres should:<br>• take overall responsibility for tracing the close contacts of people with confirmed acute and chronic hepatitis B infection<br>• advise and oversee the activities of other local organisations undertaking contact tracing, such as GP surgeries and genitourinary medicine clinics, to ensure the national standards for local surveillance and follow-up of hepatitis B and C are met. For example, GPs may need to offer close contacts hepatitis B vaccination and refer for treatment.' |
| **The Royal College of Midwives** | Recommendation 8 | 16 | Annual auditing of the uptake of hepatitis B vaccination programme for babies will be of great value but it is | Recommendation 9 now states:<br>'Public Health England should audit the hepatitis B |

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| | | | unclear how this will be carried out, and which health professionals will be involved. | vaccination programme for babies. The audit should note how many children received vaccines, whether vaccinated children were given all doses and if not how many doses they received, whether doses were given on schedule, whether babies were tested after completing the vaccination course and the rate of vaccination failure. This audit should be carried out annually and deficiencies addressed.' |
| **Royal Pharmaceutical Society** | Recommendation 10 | 18 | We support the proposal to include pharmacies as suitable testing venues, a view we have supported through our campaign work with the Hepatitis C trust by calling for pharmacy commissioners to introduce testing in pharmacies, to ensure the early diagnosis of the disease. Community pharmacies are already involved in harm reduction strategies that impact on transmission of Hepatitis B and C such as needle and syringe exchange programmes and health promotion advice and are therefore ideally placed to offer testing services. In addition community pharmacies with their informal settings, longer opening hours, often central location and easy access offer a viable and convenient option for testing. | Thank you. |
| **Sheffield Teaching Hospitals NHS Foundation Trust** | General | | Generally it is felt that this guidance is timely, well-received, and look forward to seeing the next draft/final version to support services in this area. However, the general consensus from the group is that the guidance needs to be more explicit in the cohorts that it covers, | The introduction section of the guidance states:<br>'The guidance is for:<br>• Commissioners and providers of public health services, hepatitis testing and treatment services and laboratory services for hepatitis B and C testing. |

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| | | | with particular emphasis on those groups that it does not cover. For example, the guidance mentions applicability to people attending hospital services, but does not explicitly mention people presenting to Acute Medicine Departments, A&E etc. It is felt that this could lead to missed opportunities for potential testing. At the start of the guidance it would be useful to list all those services / cohorts that the guidance is for, and not for. | • Local organisations providing services for children and adults at increased risk of hepatitis B and C infection, including those in the NHS, local authorities, prisons, immigration removal centres and drugs services. It is also for voluntary sector and community organisations working with people at increased risk.<br>The guidance may also be of interest to groups at increased risk of viral hepatitis, for example, migrant populations from countries with an intermediate or high prevalence of hepatitis B or hepatitis C infection or people who inject drugs and their families. In addition, other members of the public may have an interest in this guidance.' |
| **Sheffield Teaching Hospitals NHS Foundation Trust** | General | | Although there are commonalities between hepatitis B & C, again the general consensus was to split the guidance (where appropriate) into two, one arm of the guidance specifically dealing with hep B and the other hep C. The rationale behind this is that the two infections have different prevalence, different risk factors, and different epidemiology. Trying to amalgamate the two infections, can at times lead to confusion and potentially neglect identifying relevant interventions appropriate to each individual infection type. | As noted in section 3 of the guidance, consideration 3.24, the PDG acknowledged that different populations are at increased risk of hepatitis B and C. However, there is some overlap between them, and it would simplify delivery if testing for both infections at the same time was recommended in people who are at increased risk of either. The 'Whose health will benefit' section of the guidance has been amended to make it clear which groups are at increased risk of hepatitis B and which are at increased risk of hepatitis C. |
| **Sheffield Teaching Hospitals NHS Foundation Trust** | General | | Change hep B and C to hep B and C infection. | Guidance has been amended accordingly. |
| **Sheffield Teaching** | General | | The use of bullets in each of the sections does not make | Thank you for commenting, we have fed these ideas back to |

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| **Hospitals NHS Foundation Trust** | | | it clear to the reader that they are linked to those that follow – perhaps should have used a numbering index. | the editors to be considered when the guidance template is next updated. |
| **Sheffield Teaching Hospitals NHS Foundation Trust** | General | | There is no reference to the window period for hep C antibodies and when it is appropriate to test for HCV RNA i.e. in immunocompromised patients. | The PDG felt it important to test for chronic infections rather than acute; people who are HCV antibody negative (or HCV antibody positive and PCR negative) but still at ongoing risk should be regularly tested. Section 3 of the guidance has been amended; consideration 3.56 now notes that the PDG was aware of the need to test candidates for chemotherapy or immunosuppressive therapy for hepatitis B prior to treatment. In people with hepatitis B, chemotherapy or immunosuppressive therapy can result in flare-up of liver disease and death by fulminant liver failure. |
| **Sheffield Teaching Hospitals NHS Foundation Trust** | General | | It was felt that there needs to be a statement about screening the contacts of persons with active HBV infection. Also, is there any evidence of cost-effectiveness in relation to the verification of contacts having been screened and immunised if non-immune? | Screening programmes are beyond the remit of this guidance [http://www.nice.org.uk/nicemedia/live/11957/52314/52314.pdf ]; recommendation 8 does however state that Public Health England centres should take overall responsibility for tracing the close contacts of people with confirmed acute and chronic hepatitis B infection. |
| **Sheffield Teaching Hospitals NHS Foundation Trust** | Testing (first bullet point) | Page 6 | The group felt that this was a good recommendation, and in full agreement that a "mechanism" needed to be in place. However, it was felt that issues of confidentiality and addressing / minimising anxiety and distress also needed to be tackled. | Guidance has been amended accordingly. |

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| **Sheffield Teaching Hospitals NHS Foundation Trust** | Whose health will benefit? | Page 7 | It was felt that the following groups should also be included:<br>• offspring from high prevalent areas where the parent status is unknown,<br>• renal dialysis patients,<br>• those patients receiving blood transfusions, and<br>• potentially consider testing all patients. | The PDG note in section 3 of the guidance other smaller groups at increased risk of hepatitis B and C infection including people who:<br>• have received medical or dental procedures, including renal dialysis, in countries where infection control may be inadequate<br>• have been exposed to unsterile needles (for example, by having non-professional tattoos, body or ear piercing, or acupuncture, or through vaccination in a developing country)<br>• are jaundiced or have abnormal liver function tests. |
| **Sheffield Teaching Hospitals NHS Foundation Trust** | Recommendation 1 – what action should they take? (bullet point 1) | Page 8 | …. 'serious illness such as liver disease' add including liver cancer. | Guidance has been amended accordingly. |
| **Sheffield Teaching Hospitals NHS Foundation Trust** | Recommendation 1 – what action should they take? | Page 8 | It should be made clear in patient communications that it is possible to cure hep C (for some people); this should be made explicit, as the majority of people will not have this information. In addition, although hep B is non-curative, the infection is treatable; again this information should be offered and made explicit. | Recommendation 1 states that awareness raising campaigns should:<br>• cover the benefits of early testing and treatment, including the role of earlier treatment in preventing serious illness such as chronic liver disease and liver cancer<br>• address misconceptions such as the belief that treatments are not effective, or that treatment is not needed until the illness is advanced. |

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| **Sheffield Teaching Hospitals NHS Foundation Trust** | Recommendation 2 – who should take action? | Page 9 | The recommendation refers to "NHS deaneries", should the terminology be changed in light of recent changes to the NHS landscape i.e., Medical Education England / Health Education England - this would incorporate all health care professionals (not just medical staff). | Guidance has been amended accordingly. |
| **Sheffield Teaching Hospitals NHS Foundation Trust** | Recommendation 4 – what action should they take (second bullet point)? | Page 12 | It was discussed that primary care practitioners should offer testing to all patients newly registered; whilst those currently registered with GPs should follow-up on those patients considered to be in the 'at-risk' groups as part of their regular check ups.<br><br>In addition, it was considered that the definition of 'at risk' groups needed to be clarified e.g., how do you define | The PDG recommended that GPs and practice nurses should offer testing for hepatitis B and C to adults and children at increased risk of infection, particularly migrants from medium- or high-prevalence countries and people who inject or have injected drugs. In addition GPs and practice nurses should offer testing for hepatitis B and C to people who are newly registered with the practice and belong to a group at increased risk of infection. The PDG did discuss the possibility of linking a cohort testing programme for hepatitis C to the Health Check programme currently being introduced for people between 40 and 70 years in England. However, given that a potential extension of the Health Check programme had not been mentioned in the draft guidance sent for consultation, and that there was uncertainty about whether cohort testing offered as part of the Health Check programme would be cost effective, the PDG believed that it would be preferable to wait for more information before making a substantive recommendation in this area.<br><br>Groups at increased risk of hepatitis B or C compared with the general UK population include people born or brought |

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| | | | those patients from high prevalent countries are they 1st generation, 2nd generation or 3rd generation? | up in a country with an intermediate or high prevalence (2% or greater) of chronic hepatitis B. This includes all countries in Africa, Asia, the Caribbean, Central and South America, Eastern and Southern Europe, the Middle East and the Pacific islands. |
| **Sheffield Teaching Hospitals NHS Foundation Trust** | Recommendation 5 – what action should they take (bullet point 3)? | Page 13 | Remove suspected, and make reference to any active Hep B or Hep C infection. Also, need to include reference to acute and chronic Hep B / C infection. | The recommendation has been amended. |
| **Sheffield Teaching Hospitals NHS Foundation Trust** | Recommendation 5 – what action should they take (bullet point 4)? | Page 13 | Need to recommend that prison health care staff should be empowered to deliver treatment under supervision following shared care protocols. | Recommendation 5 states that all prison and immigration removal centre staff should be trained to promote hepatitis B and C testing and treatment and hepatitis B vaccination. In addition, prison and immigration removal centre healthcare services should designate a member of staff as the hepatitis lead in every prison, young offender service and immigration removal centre. The lead should have the knowledge and skills to promote hepatitis B and C testing and treatment and hepatitis B vaccination. Consideration should be given to training peer mentors and health champions from the prison and immigration removal centre populations to support this work. Prisoners and immigration detainees with hepatitis B and C should be treated in the prison or immigration removal centre, using in-reach services involving local specialist secondary care providers or the prison or immigration removal centre healthcare team. |

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| **Sheffield Teaching Hospitals NHS Foundation Trust** | Recommendation 5 – what action should they take (extra recommendation suggested)? | Page 13 | All prisoners should be tested and screened for vaccine status, not just those at increased risk. | Recommendation 5 now recommends that 'all prisoners and immigration detainees are offered access to confidential testing for hepatitis B and C when entering prison or an immigration removal centre and during their detention.' |
| **Sheffield Teaching Hospitals NHS Foundation Trust** | Recommendation 5 – what action should they take (extra recommendation suggested)? | Page 14 | All efforts should be made to copy results to GP, if they have one. Again, be mindful of issues of confidentiality, timely return of results and communication of results in a patient sensitive manner. | Guidance has been amended accordingly. |
| **Sheffield Teaching Hospitals NHS Foundation Trust** | Recommendation 6 – Who should take action (bullet point 2)? | Page 14 | Should Hepatology service commissioners read Hepatitis service commissioners? | Guidance has been amended accordingly. |
| **Sheffield Teaching Hospitals NHS Foundation Trust** | Recommendation 6 – who should take action (bullet point 6)? | Page 15 | Should testing not be offered to 'all clients', not just those at high risk? Those attending drug services could be considered to be all 'at risk', must be mindful that not all people declare risk factors. Testing all people attending these services would create a culture of routine testing from all services for hep B and C infection. | Guidance has been amended accordingly. |
| **Sheffield Teaching Hospitals NHS Foundation Trust** | Recommendation 6 – who should take action (bullet point 6)? | Page 16 | If you changed the above bullet point to coincide with the above comments, then this recommendation would become redundant. | Guidance has been amended accordingly. |
| **Sheffield Teaching Hospitals NHS Foundation Trust** | Recommendation 7 – Contact tracing for hepatitis B | Page 16 | What is the rationale for including only Hep B patients and not Hep C patients? There is a need to include a separate section for Hep C patients, as this would be different recommendations from Hep B patients. Also, it | In section 3 of the guidance, consideration 3.30, the PDG note that active contact tracing for people testing positive for hepatitis C is not recommended, given low transmission rates to both sexual and household contacts. The PDG |

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| | | | would be sagacious to include testing of regular partners and children and injecting drug user contacts where feasible. | acknowledge that it would be sensible to discuss with individuals, on receipt of a positive test outcome, whether any of their contacts may have been exposed to infection. The testing of identified contacts would be at clinical discretion. In addition, recommendation 8 now states that primary care practitioners should promote the importance of hepatitis C testing for children who may have been exposed to hepatitis C at birth or during childhood. |
| **Sheffield Teaching Hospitals NHS Foundation Trust** | Recommendation 7 – What action should they take (bullet point 1) | Page 16 | Suggest make explicit for both acute and chronic cases. | Guidance has been amended accordingly. |
| **Sheffield Teaching Hospitals NHS Foundation Trust** | Recommendation 8 – what action should they take? | Page 16 | Should be a separate bullet point which links to microbiological screening in pregnancy. | This recommendation has been amended and now states:<br>• Directors of public health should ensure existing recommendations on hepatitis B prophylaxis for babies born to mothers with chronic hepatitis B infection are implemented locally by general practitioners, as described in the Green book.<br>• Public Health England should audit the hepatitis B vaccination programme for babies. The audit should note how many children received vaccines, whether vaccinated children were given all doses and if not how many doses they received, whether doses were given on schedule, whether babies were tested after completing the vaccination course and the rate of vaccination failure. This audit should be carried out annually and deficiencies addressed. |

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| **Sheffield Teaching Hospitals NHS Foundation Trust** | Recommendation 9 – | Page 17 | There needs to be a distinction between screening and diagnostic laboratory services i.e. DGH versus central laboratory services. There is a need to commission for both. | The PDG felt that 'laboratory services for hepatitis B and C testing' covered both screening and diagnostic. |
| **Sheffield Teaching Hospitals NHS Foundation Trust** | Recommendation 9 – what action should they take | Page 17 | This appears to be misquoted. It should read results reported to the HPU within 1 day of the result being available. | Guidance has been amended accordingly. |
| **Sheffield Teaching Hospitals NHS Foundation Trust** | Recommendation 9 – what action should they take (bullet point 4) | Page 17 | It is not possible to provide exposure category data as this is not recorded or stored. Also, the recommendation for 'number of positive tests', this should be re-phrased to read 'number of positive patients', as there is a lot of repeat testing. Is it worth splitting this down further to acute, chronic or past infection? | Guidance has been amended accordingly. |
| **Sheffield Teaching Hospitals NHS Foundation Trust** | Recommendation 10 – What action should they take (bullet point 2)? | Page 18 | Replace 'hep B and C tests performed' with 'number of people tested for hep B and C'. Replace 'positive tests' with 'positive patients'. Replace 'people who test positive who are referred to a specialist' with 'number of people with active infection referred to a specialist'.<br><br>Generally it was felt the term 'test positive' should be replaced with 'active infection'. | Guidance has been amended accordingly.<br><br>The recommendation now states 'the number of people testing positive:<br>• for hepatitis B, this should include acute, chronic and past infection<br>• for hepatitis C, this should include PCR positive/current |

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| | | | | and PCR negative/resolved' |
| **Sheffield Teaching Hospitals NHS Foundation Trust** | Recommendation 10 – What action should they take (bullet point 3)? | Page 18 | The recommendation on 'consider the broader health and psychological needs ….' should have included in the examples explicit reference to mental health or psychological needs. | Recommendation 10 now states that the needs of people who test positive for hepatitis B or C infection and are assessed for treatment, should be taken into account, including their broader health and psychosocial needs. |
| **Sheffield Teaching Hospitals NHS Foundation Trust** | Section 2 – Hepatitis C background information | Page 20 | The opening sentence is deemed to be too narrow, it should be expanded to include 'or using contaminated medical equipment', also it was felt that reference to 'bodily fluids' could be misconstrued, it would be better to change this to 'other blood contaminated bodily fluids'. | Section 2 has been updated. |
| **Sheffield Teaching Hospitals NHS Foundation Trust** | 3.16 | Page 28 | 'Mouth swab' should be changed to 'oral fluid'. | Guidance has been amended accordingly. |
| **Sheffield Teaching Hospitals NHS Foundation Trust** | 3.16 | Page 28 | Testing oral fluids should have more of a "presence" in the main sections of the document. Taking oral fluids would allow for home-testing or in other non-medical settings, be easier to undertake, whilst being safer (minimise cross infection), easier to transport and screen out negative persons. | No recommendations were made on the use of oral fluid for hepatitis B or C testing. The PDG recognised that this method may be more acceptable to some people because it is less invasive than taking blood from a vein. However, if an oral fluid sample was used, a blood sample would then be required to confirm the initial positive results, and for PCR testing to diagnose chronic hepatitis C. |
| **Society for General Microbiology** | Pg 7 Section "Men who have sex with men, commercial sex workers and anyone | 7 | Agree that men who have sex with men and those having unprotected sex with commercial sex workers should be tested. However, does this also mean that heterosexuals should be tested for HCV? Sexual transmission of the | This section of the guidance has been amended to clarify the groups at increased risk of hepatitis B and C. |

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| | who has unprotected sex and frequently changes sexual partners." | | disease in heterosexual couples is very uncommon. | |
| **Society for General Microbiology** | Pg 15 "Medical staff should use their clinical judgement to determine who is suitable for treatment in a community setting." | 15 | Could the document provide some factors to consider in making this judgement? | The guidance has been amended; recommendation 6 now states that drugs services should ensure people diagnosed with hepatitis B and C are referred for specialist care; for hepatitis C this may involve offering hepatitis C treatment in the community for people who are unwilling or unlikely to attend hospital appointments, and whose hepatitis C treatment could be integrated with ongoing drug treatment (such as opiate substitution treatment). |
| **Society for General Microbiology** | Pg 18 "Commissioning hepatitis B and C testing and treatment services" | 18 | Data gathering can be arduous for laboratories (and hepatologists) and some of these data regarding the number of positive tests are already gathered by the Health Protection Agency. Perhaps audits should be applied to determine if enhanced testing is cost-effective and if not, what is required to ensure that it is.<br><br>It could also be made explicit that data gathering to inform commissioners about such services should be paid for *by the commissioners.* | The PDG felt it important that commissioners audit the uptake of testing and outcomes, including:<br>• the number of people tested for hepatitis B and C<br>• the number of people diagnosed with hepatitis B and C<br>• the number of people with chronic infection who:<br>  ○ are referred to a treatment service<br>  ○ attend a treatment service<br>  ○ are receiving treatment in accordance with treatment guidelines<br>• the number of people with hepatitis C who obtain a sustained virological response on antiviral therapy.<br><br>The collection and collation of robust, service-level data on testing and treatment services was felt to be important for both monitoring and developing services. |

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| **Society for General Microbiology** | 3.5 & 3.6 | 26 / 27 | This is a thoughtful treatment of the complex societal issues in relation to how chronic hepatitis infection or the fear of it affects lives. | Thank you for your comment. |
| **Society for General Microbiology** | 3.12 | 27 | Mention could be made of needle-phobia as a barrier to obtaining venous as opposed to capillary (dried blood-spot) samples. | Guidance has been amended accordingly. |
| **Society for General Microbiology** | 3.37 | 32 | Generating accurate information in a database is likely to be resource-intensive. Further attention may need to be paid to compliance with data gathering and database requirements. | As noted in section 3 of the guidance, the PDG discussed the need for hepatitis B and C databases holding details on people who have been tested and treated. The importance of collecting data on treatment uptake and the need for this data collection to be built into the pathway at every point was noted. It considered that an integrated system, bridging different healthcare providers and capturing a range of data, was the ideal. However, it was felt that there needed to be a balance between the burden of collecting data and the value of those data. The Group acknowledged that it would be resource-intensive. |
| **Society for General Microbiology** | Q9 & 10 | 56 | Q 9 and Q10. Are these duplicated? | Guidance has been amended accordingly. |
| **Society for General Microbiology** | Evidence statement E5/E6/E9 | 66 & 68 | General comments:<br>(1) Does the treatment of HCV infection lead to lower admission rates, hospital costs and longer life expectancy for injecting drug users who are also alcoholic?<br>(2) Clinical experience suggests that trying to | Thank you for your comments. They are interesting questions.<br><br>1) this is a special case of your point 3.<br>2) the committee was aware of this difficulty.<br>3) this been allowed for in the economic model. |

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| | | | increase access to hepatitis C testing in a methadone maintenance clinic leads to the successful treatment of those who were already very highly motivated. However, with insufficient resources, others who test HCV positive may attend poorly at the liver clinic.<br>(3) It is worth bearing in mind that patients may die for a range of reasons completely unrelated to chronic HCV infection, e.g., a drug overdose. | |
| **Terrence Higgins Trust** | General | | Terrence Higgins Trust (THT) is the UK's largest HIV and sexual health charity, with 30 service centres across England, Scotland and Wales. THT is a membership and campaigning organisation which works with and advocates on behalf of people living with or affected by HIV and poor sexual health. We provide a range of services which aim to promote Hepatitis vaccination and testing to a number of at risk groups. We also have significant experience of promoting HIV testing to MSM and BME communities. | Thanks for your comments. |
| **Terrence Higgins Trust** | General | | THT supports this guidance and considers that it is vitally important that more is done in the UK to increase Hepatitis testing in at risk groups. | Thank you. |

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| **Terrence Higgins Trust** | Section 1 | 6 | We would recommend that the section entitled 'pre requisites' include a further sentence at the end which directs people to the characteristics of effective hepatitis training as detailed in recommendation 2. | Thank you for this suggestion; reference to the recommendation on developing the knowledge and skills of healthcare professionals and others providing services for people at increased risk of hepatitis B or C infection is made in the introduction section of the guidance. |
| **Terrence Higgins Trust** | Recommendation 1 | 8 | We would welcome consideration as to whether this recommendation should include a suggestion that Local Authorities consider including Hepatitis B& C in their Joint Strategic Needs Assessments. Hepatitis does not feature in the Public Health Outcomes Framework and could therefore be overlooked in many JSNAs. Hepatitis therefore could suffer from a very low profile within the new public health structure. | Guidance has been amended accordingly, recommendation 10 now states that 'Local authorities, in particular directors of public health and clinical commissioning groups should ensure the inclusion of hepatitis B and C in the health and wellbeing board's joint strategic needs assessment.' |
| **Terrence Higgins Trust** | Recommendation 2 | 10 | We would suggest that education programmes should also explore ways in which to make an offer of a test. We are concerned that health professionals often feel uncomfortable with targeted testing where the risk characteristic is based on ethnicity or sexuality. Health professionals may feel vulnerable to accusations of racism or homophobia. Good education programmes should explore and address these concerns. | As detailed in section 3, one of the areas the PDG felt education programmes might cover, depending on the role of the health and social care professional, factors to consider in a pre- and post-test discussion and how these discussions should be conducted. The PDG noted that it was important to ensure people are not stigmatised by the way information on hepatitis B and C is delivered. |
| **Terrence Higgins Trust** | Recommendation 2 | 10 | We would suggest that it might be worth detailing in this section that it is not enough to rely on existing BBV training on occupational exposure and that training | Guidance has been amended. |

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| | | | packages have to be patient centred. | |
| **Terrence Higgins Trust** | Recommendation 3 | 11 | We understand that it is not technically within the scope of this guidance to explore vaccination policy. However, we think that best it is a lost opportunity and at worst remiss not to include references to signposting to vaccination services at relevant points. | Guidance has been amended |
| **Terrence Higgins Trust** | Recommendation 4 | 12 | This section should also contain a reference to signposting to vaccination for those at increased risk. | Guidance has been amended |
| **Terrence Higgins Trust** | Recommendation 4 | 12 | Men who have sex with men should be included in the list of at risk groups in this section. | Guidance has been amended, the recommendation now refers back to the section 'Whose health will benefit' where men who have sex with men are listed. |
| **Terrence Higgins Trust** | Recommendation 5 | 13 | We would query the 7 day recommendation for information provision to people arriving in prison. We would suggest that prisoners with a history of injecting drug use should be given advice earlier than 7 days into their prison term. | Guidance has been amended<br>. |
| **Terrence Higgins Trust** | Recommendation 5 | 14 | A reference could be made in this section which directs people to the characteristics of effective hepatitis training as detailed in recommendation 2. | Guidance has been amended |
| **Terrence Higgins Trust** | Recommendation 5 | 15 | This recommendation should reference referral for Hepatitis B vaccination. | Guidance has been amended |
| **Terrence Higgins Trust** | Recommendation 9 | 17 | A reference could be made in this section to the dearth in surveillance on Hepatitis B and C in the UK and the need to support the development of a strong data set. | The PDG discussed the lack of surveillance on Hepatitis B and C in the UK and the need to support the development of a strong data, reference is made |

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| | | | | to this in consideration 3.52 and 3.53. Recommendation 10 and 11 support the development of a strong data set. |
| **Terrence Higgins Trust** | 'Risk Factors' | 22 | Change 'homosexual contact' to 'sex between men' | Section 2 has been updated. |
| **Terrence Higgins Trust** | 'Risk Factors' | 22 | It may also be worthwhile including a reference in this section to levels of co-infection with HIV. | Section 2 has been updated. References is now made to evidence that HIV-positive men who have sex with men are at increased risk of hepatitis C infection, and that British HIV Association guidelines recommend regular hepatitis C testing in this group. |
| **Terrence Higgins Trust** | Barriers and Facilitators | 26 | We would welcome a reference here to sensitivities of discussing people's sexuality and/or potential sexual exposure to Hepatitis B or C. | The guidance has been amended accordingly; section 3 now states 'the PDG were mindful of the sensitivities of discussing people's sexuality and potential sexual exposure to hepatitis B or C.' |
| **Terrence Higgins Trust** | 3.18 | 28 | This point underlines the very close interactions between testing and vaccination interventions for hepatitis. This is the main reason why we think that the guidance should make more references to vaccination programmes and signposting where relevant. We do not consider that this means that the Guidance will be significantly altering how vaccination programmes operate and can therefore remain within its immediate remit. | The guidance emphasises, in several recommendations, existing hepatitis B vaccination recommendations (as detailed in the Green book) because although hepatitis B vaccination was beyond the scope of this guidance, case-finding may identify contacts of infected individuals who should be offered vaccination.<br>The introduction of section 1 signposts to hepatitis B vaccination guidance available in the Green book: immunisation against infectious disease and the Hepatitis B antenatal screening and newborn immunisation programme, both published by the |

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| | | | | Department of Health, as well as the NICE guidance on Reducing the differences in the uptake of immunisations. |
| **Terrence Higgins Trust** | 3.20/ 3.27 | 29/3076 | There is significant evidence of the benefit of delivering HIV testing in community settings which offers learning for hepatitis. The following link provides further details. http://www.hpa.org.uk/Publications/InfectiousDiseases/HIVAndSTIs/1011TimetotestHIVtesting/ | Thank you for providing this information. Recommendation 2 states that local organisations should run awareness-raising sessions to promote hepatitis B and C testing in venues and at events popular among groups at increased risk. Consideration should be given to offering testing for hepatitis B and C at these awareness-raising sessions. If this is not possible, information on where and how to access testing locally should be provided. |
| **UKHRA** | ***1. Whose health will benefit?*** | 7 | Replace<br><br>'People who have injected recreational drugs (no matter how rarely) or who share drugs paraphernalia, such as straws (used for snorting drugs) or needles'.<br><br>With<br><br>People who have ever injected drugs, both current and former drug users (including performance and image enhancing drug users), or where drug using paraphernalia, such as straws to snort drugs, are shared. | Guidance has been amended and now states 'people who have ever injected drugs'.<br><br>As noted in section 3:<br>• the PDG recognised and understood the potential risks associated with the transmission of hepatitis C via sharing straws to snort drugs (in theory, if nasal passages were bleeding a straw could transfer infected blood to others using the same straw), but there was a lack of strong biological evidence on which to base recommendations. The key risk was considered to be through sharing injecting equipment<br><br>• the PDG recognised the potential risk of hepatitis |

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| | | | | C transmission among people who inject performance and image-enhancing drugs (PIEDs) such as anabolic steroids (for non-medical reasons). However, there is a lack of published evidence on the extent of risk in this group or on their contribution to overall hepatitis C prevalence. |
| **UKHRA** | ***Recommendation 4 Testing for hepatitis B and C in primary care*** **What action should they take?** | 12 | Offer a hepatitis B and C test to everyone who has newly registered, and who is part of an at-risk group. This includes both adults and children from countries with an intermediate or high prevalence of hepatitis. It also includes adults who are newly registered with the practice who have injected drugs. (Ask all adults whether or not they have ever injected drugs once they have registered with the practice.).<br><br>This should be extended to include also performance and image enhancing drug users and non-injecting drug use where 'straws' maybe shared when snorting drugs | Guidance has been amended accordingly. |
| **UKHRA** | ***Recommendation 6 Testing for hepatitis B and C within drugs services***<br><br>**What action should they take?** | 15 | 'Be trained to undertake dried blood-spot testing if carrying out hepatitis B and C testing'.<br><br>There needs to be reference to training/competency in pre and post test discussion<br><br>'Routinely check all clients, including those aged under 18, for hepatitis B and C risk factors' | Recommendation 6 now states that drug services should:<br>• ensure staff who undertake pre- and post-test discussions and dried blood spot testing are trained and competent to do so.<br>• offer annual testing for hepatitis C to people who test negative for hepatitis C but remain at risk of infection |

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| | | | Need to clarify routine. Checks should be done regularly – and when in drug treatment, as part of three monthly care plan reviews -. Perhaps include guidance on how often people at ongoing risk should be screened | |
| **UKHRA** | ***Barriers and facilitators 3.5*** | 26 | People who may have injected drugs in the past may not want to revisit that part of their lives.<br><br>Replace with<br><br>People who may have injected drugs in the past may not want to disclose drug using history. | Guidance has been amended accordingly. |
| **UKHRA** | 3.12 | 27 | Replace - for injecting drug users<br><br>With - For people who inject drugs<br><br>Replace -<br>(It can be difficult to take blood from someone whose veins have been damaged and can lead to multiple attempts which can prove embarrassing, not to mention painful.)<br><br>With<br><br>(In situations where individuals have poor vascular access – typically associated with long term injecting | Guidance has been amended accordingly. |

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| | | | and/or poor injecting technique - it can be difficult to obtain blood samples without causing pain and embarrassment and this can present as a barrier to testing) | |
| **UKHRA** | Testing 3.13 | 27 | 'It recognised that a barrier to the implementation of such training was time constraints'<br><br>This is unhelpful and undermines the significance of basic – and readily learnt - required clinical practice | This consideration has been deleted. |
| **UKHRA** | Testing 3.14 and General | 28 | Some guidance needed that outlines the pros and cons of both DBS and venapuncture | The guidance notes in section 3 that:<br>• While venepuncture samples remain the gold standard, the PDG noted that dried blood spot tests for hepatitis B and C have a high test sensitivity and specificity and can be useful in certain settings for people with poor venous access and where there may be no facilities or expertise to take venous blood samples (for example, in specialist drug treatment services or prisons).<br>• The PDG recognised that the use of dried blood spot testing for diagnosis may be more acceptable to some of the target populations than taking a blood sample from a vein, especially if there is poor venous access or the person is needle phobic. In addition, more staff would probably be able to carry out such tests, so helping to increase the number of people who are tested. The PDG noted the success of the Scottish Hepatitis C Action Plan in place since 2008 (Scottish Executive 2006, 2008). Preliminary evidence from this programme suggests that hepatitis C testing in specialist |

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| | | | | drug clinics increased after the introduction of dried blood spot testing and wide-scale training of healthcare workers in hepatitis C.<br>• The PDG recognised that oral fluid testing may be more acceptable to some people because it is less invasive than taking blood from a vein, but that oral fluid testing has a lower sensitivity and specificity than tests for hepatitis B and C performed on blood. If an oral fluid sample was used, a blood sample would then be needed to confirm the initial positive results, and for PCR testing to diagnose chronic hepatitis C. |

[i] Giraudon I, Ruf M et al. *Increase in diagnosed newly acquired hepatitis C in HIV-positive men who have sex with men across London and Brighton, 2002-2006: is this an outbreak?* Sexually Transmitted Infections 2008; 84: 111-115.

[ii] *Health Protection Agency 'Shooting Up: Infections Among Injecting Drug Users in the United Kingdom 2006. An update: 2007 HPA, October 2007.*

[iii] *G. Owen. An 'elephant in the room'? Stigma and hepatitis transmission among HIV-positive 'serosorting' gay men. Culture, Health and Sexuality 10: 601 – 610, 2008.*