Report on the consultation process and outcomes

National Clinical Guideline - Hepatitis C Screening

July 2017

Background

This document outlines the consultation process undertaken as part of the development of the National Clinic Guideline on Hepatitis C Screening.

The National Clinical Guideline is available from: http://health.gov.ie/national-patient-safety-office/ncec/national-clinical-guidelines/

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Contents

Methodology used in the consultation process

The consultation process involved three strands – consultation with key stakeholders, expert external review, and an open public consultation process.

Key stakeholders

Individuals or organisations identified as stakeholders in the health and social care of those who are infected with hepatitis C virus (HCV) or at risk of HCV infection were invited to review the guideline and provide feedback. They were invited via email distribution lists held by the HSE Health Protection Surveillance Centre (HSE HPSC). In some circumstances, where a distribution email list was not available, a key person was asked to disseminate the invitation within their organisation or network. Those invited to provide feedback are listed in Appendix 1. The letter of invitation is presented in Appendix 2.

Excluding those to whom the invitation was disseminated to, the invitation to provide feedback was directly emailed to approximately 1,000 persons.

Public

In addition, a public consultation process was undertaken. The consultation was advertised on the HSE HPSC website, Epi-Insight (a monthly on-line bulletin published by the HSE HPSC), and via the HSe HPSC and HSE social media platforms.

For both the key stakeholder and the public consultation process, the guideline was available online. The webpage was visited over 600 times during the consultation period.

Feedback was requested to be submitted via a template based on that recommended by the National Clinical Effectiveness Committee (NCEC) (see Appendix 3) (1). The template asked for comments on the questions outlined in Box 1 with an option for additional feedback if required.

Box 1: Questions reviewers were asked to comment on

1. User friendliness
   a) Is the draft guideline easy to read?
   b) Do you think the guideline will be easy to use in practice?
2. Content

a) Do the recommendations cover the scope of the draft guideline?
b) Do the recommendations clearly link to the evidence presented?
c) Does the draft guideline consider the views and needs of specific population groups?
d) Does the draft guideline consider gaps in the current evidence?

3. Implementation

a) Do any recommendations change current practice substantially? If so, do you consider that the reasons given in the draft guideline explain why the change is necessary?
b) Which areas do you think may be difficult to put into practice? Please explain why.
c) What would help users to implement the guideline? (For example, useful checklists, patient information leaflets etc.)

The consultation period ran between 31 March and 20 April 2017.

External review

International external review of the guideline was undertaken by two experts in the epidemiology and public health management of HCV. Dr Susan Hahné is a Senior Epidemiologist and Head of Department for Early Warning and Surveillance in the Netherlands National Institute for Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieu (RIVM)). Dr Hahné was chair of the European Centre for Disease Prevention and Control (ECDC) Hepatitis Coordination Committee from 2014 to 2016. Dr Magdalena Rosińska (M.D., Ph.D) is an epidemiologist a National Institute of Public Health - National Institute of Hygiene (Narodowy Instytut Zdrowia Publicznego - Państwowy Zakład Higieny) in Poland and chair of the ECDC Hepatitis Coordination Committee from 2017.

International external reviewers were asked to provide feedback based on questions recommended by National Quality Assurance Criteria for Clinical Guidelines Version 2 (see Box 2) (2). The external reviewers were also asked to provide any additional feedback they had.

Box 2: Questions asked of the international external reviewers

1. Has the appropriate evidence been identified and reviewed in line with the scope and clinical questions posed by this guideline?
2. Are there specific links between decisions and the available scientific evidence?
3. Have the risks and potential harms of recommendations been fully considered in the context of clinical practice?
4. Is the guideline clearly written, user friendly and allow for individual clinician decisions?
5. Is the guideline suitable for routine use as intended (in so far as you are able to comment on the Irish situation)?
6. Are there relevant international or well referenced guidelines (recommendations) on the same topic that these guidelines are in conflict with, and if yes are the reasons for this justified in the guidelines?

Review of feedback

Feedback received was reviewed by the GDG and the guideline was amended where appropriate.

The proceeding sections summarise the feedback received and the action or response of the GDG. Feedback is grouped by recommendation or section of the guideline. The feedback of the external reviewers to the questions in Box 2 is presented separately. More specific feedback from the external reviewers relating to particular recommendations or sections is incorporated with the feedback from the stakeholder and public consultation process.

Comments are presented as received as far as possible. However, in some instances comments have been altered e.g. only the relevant part of a sentence or paragraph is presented, or it has been edited to maintain anonymity or confidentiality.

Feedback received and response of the Guideline Development Group

General comments

Theme of comment	Comments[1]	GDG Response
Size of document	…it is a huge document …	Summary version of the guideline will be available
No major change in practice; difficulty in implementing for some risk groups	The draft is user friendly and should be easy to use in practice Recommendations cover the scope of the draft guidelines Recommendations are clearly linked to evidence presented In most cases specific groups are considered but the guideline does not consider gaps in current evidence(comment 5) Current practice will not change substantially and all changes been implemented are in good practice. Areas of difficulty will be: engaging the homeless they will need to be linked into services or groups which are willing and have the knowledge to engage with them on this issue Non Injecting Drug Users: this is a major problem in this country and it will be hard to pick up those that do not directly link in with drug support services or clinics e.g. ARC.	It has been acknowledged in the guideline that implementation will be difficult in certain risk groups.
Query over impact on health insurance	There is a catch all question on all insurance forms asking about any testing in the previous five years.	GDG confirmed with insurance companies that they no longer ask about BBV testing history. They only ask if a person has a history of a positive test.
Suggest to integrate with screening of other bloodborne	I am happy with guidelines, would be good to integrate across BBV spectrum inc HIV where there is another working Group under Sexual Health Well laid out and easy to read, long document. Very comprehensive, specific. Clear	It was not within the scope of this guideline to consider other BBVs. Currently national guidelines on screening for other BBVs do not exist. It

[1] Comments are presented as received as far as possible. However, in some instances comments have been altered e.g. only the relevant part of a sentence or paragraph is presented, or it has been edited to maintain anonymity or confidentiality)

viruses (BBVs) Length of document		has been recommended to consider screening for other BBV at the same time as HCV screening.
Support the focus on marginalised groups and on linkage to care.	The guidelines are well laid-out and user-friendly and will be particularly useful given the recent developments in efficacy and access to HCV assessment and treatment. The implementation plan and suggested audit and monitoring criteria should prove helpful to ensuring their uptake. We are pleased to see the attention paid in the guidelines to vulnerable and marginalised groups who bear the greatest burden of HCV infection, such as people who use and/or inject drugs, people who are homeless, prisoners, and migrants. We are also pleased to see the attention paid to the importance of linkage to care and treatment. This is particularly challenging amongst underserved groups such as the aforementioned.	No action required.
Need to highlight prevention. Support that linkage to care is highlighted	We are pleased to see the attention paid to linkage to HCV care and treatment, particularly amongst vulnerable groups, and also the mention of the need to support and evaluate such initiatives. In order for Ireland to meet its goal of elimination by 2030, another important aspect in the continuum of care is prevention. There is no mention here of prevention. Some reference to the importance of prevention and the need to support harm reduction initiatives in this regard would be of value.	While the guideline has highlighted the importance of work across the continuum of care which would include prevention, a section stressing the importance of prevention will be added.
Size of document	The document is robust in measuring weak/strong evidence base for making clear and rational guideline recommendations. It is a comprehensive document in terms of Hep C screening. I felt there was a large volume of text to work through and a more condensed version would be very welcome for busy clinicians	A summary version will be available.
Supports that vulnerable populations are highlighted	It's a very clear comprehensive document and a lot of detail. I think the document sets out the evidence about vulnerability and the need to support services which work with the homeless population and those vulnerable to homelessness. IVDU and prisoners are among the most vulnerable and this is explicitly stated here.	No action required.
Support of guideline	In conclusion we believe this draft to be comprehensive and thorough and very applicable to the needs of our service users, and we would be very happy to be invited for further discussions on this topic.	No action required.

	Very clear, well presented, really helpful to have the evidence set out, and the value judements.	No action required.
	Clear layout. Accessible. Organised. Useful format for feedback.	No action required.
Ensure consistency in terminology/ phrasing	Recommendation 12 (refers also to Annex 1) There should be consistency between the recommendation 12.1 and Annex 1 with respect to the criteria of increased risk (tattoo in high prevalence country is missing form Annex 1). This is for consistence as it does not affect the recommended measure.	Text amended.
Suggestion to include consideration for testing for those with raised ALT	Page 56 Rec 15.1 The second to the last – in other places in the guideline usually the increased ALT is mentioned – it could be also added here. Explicit referral to the Annex 1 could be considered in the last bullet. For the consistency of this guideline this should refer explicitly to the Annex 1 unless something else was meant here. All the other bullet points are in the Annex as well, but I understand that these could be underlined in the STI settings.	To add testing in the case of an unexplained rise in ALT as a good practice point.
Suggestion to highlight that testing should be offered on an opportunistic basis for any risk group presenting to a healthcare service for any reason	Page 67 Recommendation 20 Should there be an explicit recommendation for (opportunistic) screening of people with a risk factor outline in the Annex 1? The lack of sufficient evidence for not recommending the birth-cohort screening at the present time (due to financial impact) is well documented. In several places in the guidelines opportunistic screening due to risk factors (Annex 1) is recommended (e.g. antenatal, STI clinics, prison). While reading these recommendations my impression was that the intention was to screen people who do have a risk factor in any health setting they may present to. In some cases additional outreach may be necessary, but for some (e.g. people with tattoos / ex-prisoners) this is mainly on the opportunistic basis. This would than perhaps make a clear statement to summarize in one recommendation for all practitioners that they should refer to annex 1 for indications for offering the test.	A statement on opportunistic screening for anyone with a risk factor has been made as a good practice point.

Background information

Theme of comment	Comments[1]	GDG Response
Suggest to include references to EU policy	Page 22 Para International Policy There is no reference to European HCV policy in this section. As Ireland is part of Europe, we would suggest also referencing EU policy here, e.g. the Hepatitis C Elimination in Europe Manifesto (http://www.hcvbrusselssummit.eu/elimination-manifesto)	A reference to EU policy was added.
Omission of information	Page 16: the antigen test for diagnosis of HCV should be mentioned here.	Information added on antigen testing.
Case definition for HCV infection	Paragraph 2.3: If there is a case definition for HCV, it would be good to mention it here. Perhaps good to clarify that the majority of notified cases are chronic HCV. E.g. In the Netherlands, only acute HCV is notifiable.	Case definition used is only for surveillance purposes Link to surveillance case definition to be added. There is not an agreed case definition for clinical diagnostic purposes for acute infection.
Query over content	Box 1: Wilson & Jungner: Criterion number 10 I don't recognise - is this perhaps and adapted list of criteria? And, in the discussion of the criteria: Number 9 is met for treatment of chronic HCV but not for all scenario's/target groups of screening.	Text of original Wilson and Jungner report reviewed to confirm that this criterion is present. Reference added to original Wilson and Jungner report.
Omission of reference	It would be good to include a reference for Appendix 2 (prevalence by country)	Reference added.

Antenatal screening

Theme of comment	Comments[1]	GDG Response
Difficulty in risk assessing in antenatal setting	the biggest single thing that strikes me is that the recommendations on screening are probably unimplementable - no one will ever systematically record and consider all the various sub-groups for screening I would have a concern about this in particular in relation to ante-natal…the only safe way that an ante-natal clinic/hospital could ensure compliance with those recommendations is to screen everyone - no one is ever going to successfully implement a system to ask women at the ante-natal clinical about all those risk factors and if they did the time it would take to ask the questions and record the answers would cost more than doing the test I am pretty sure (particularly as you are taking the blood already) -not to mention the almost inevitable legal action that will follow when people find that they were not screened in accordance with national guideline and the diagnosis was made X years later - so I suggest either universal screen or don't nothing else is really implementable	The current practice in all but one maternity unit is to offer targeted screening. This may not be undertaken in a standardised format using a standardised criteria at present. Therefore introduction of such a standardised method as recommended by the guideline may increase the time taken to risk assess. Tools will be developed to aid risk assessment. Implementation of this recommendation should be evaluated by maternity units and may be amended in the future.

Query if prevalence of risk factors amongst antenatal population is changing? Difficulty in risk assessing	Page 30 Recommendation 1 Epidemiological evidence on the possible outcomes of the different screening strategies is presented to decide between universal or targeted screening. The following clarifications could be considered: • Was the list of risk factors (leading to screening) considered by the studies cited comparable to the proposed standardized approach? • Is there any argument that the epidemiological situation among females is stable? • Is there any evidence that risk factor interview will be acceptable both to the practitioners and the patients? The guideline proposes that standardization will improve testing efficacy. A number of studies are cited for which the estimates of how many pregnant women would be eligible for testing based on presence of a risk factor. It would be good to know if the currently proposed list of risk factors would extend or limit the number of indications. The available evidence refers to selected cities/ clinics and to the time period 10-20 years ago. As the current epidemiological situation may differ in the younger age cohorts likely to be pregnant currently, this should be at least noted and the performance of this recommendation should be closely monitored. The routine use may be compromised if the risk factors screening is too time consuming/ unacceptable for the providers or the patients do not disclosed the risk factors. While screening of the risk groups in specialised services serving e.g. PWID has been demonstrated to be acceptable (evidence provided in section 4.1.4) it may be more difficult in the general medical settings.	The GDG recommend that the recommendation should be monitored and evaluated by maternity units. The recommendation may need to be reviewed based on this evaluation.
Should state at what stage of pregnancy testing undertaken	Page 30 Rec 1 An indication of timing of the test in pregnancy could be provided This would facilitate the routine use by the antenatal programs. Alternately, it could be mentioned that the test could take place at any time during pregnancy and this is up to the particular antenatal program to decide.	Text amended to indicate this should be at the booking visit when other booking bloods are taken.

No one is responsible for supporting mothers to follow up with Rainbow clinic Query over testing of mothers who develop low level viraemia in pregnancy	- Expectant mothers on methadone are linked to the liaison midwife for support during pregnancy. They are supported by the midwife for a limited period of time post-partum, but no one has specific responsibility to support these new mothers in relation to follow-up of children at the Rainbow clinic. If the child goes into care, the new carers may not know if the mother was viraemic and if the children remain with the mother, she may need support to ensure that the child is brought to the Rainbow clinic. In order for the child to access the Rainbow Clinic, support and access protocols need to be available in a way which is appropriate to the location of the child. If the child is with the mother, this could be through her methadone prescribing clinic and if the child is in care, it might be through the child's new GP who would need to know the Hep C status of the mother. For this to happen, responsibility has to be defined. - Some Hep C Ab positive mothers on methadone develop low-level Hep C viraemia during the course of their pregnancy, which returns to being PCR negative post-partum. Possibly related to immunosuppressive effect of pregnancy. Should their children be screened according to the Rainbow Clinic protocol or not?	The GDG has acknowledged the potential loss to follow up of children born to HCV infected mothers. It has been proposed in the implementation plan that the proporsed national hepatitis B perinatal programme may also govern the follow up of these children.

Tattoos, healthcare workers, household contacts, dialysis

Comment on	Theme of comment	Comments[1]	GDG Response
Tattoos	Cost-effectiveness	Page 49 Recommendation number 12- very little evidence that screening of those with tattoo is cost effective	Literature on the cost effectiveness of screening of those with tattoos was not identified. This was the case for a number of the risk groups for whom screening was considered. The evidence showed a clear risk between tattooing and HCV. The risk relating to tattoos in Ireland is not known. In the absence of better evidence the GDG believe this to be an appropriate recommendation.
HCWs	Clarify who should be tested	The recommendation 21 regarding the testing of staff that will perform exposure prone tasks may need further definition in order to be clear as to who in service provision should be tested.	A definition of EPPs was added.
HCWs	Clarify where testing can be accessed	HCWs who perform EPPs might also be informed about where they can access phlebotomy. Should it be their own clinic, Occupation Health Dept. or other.	Text amended.
Tattoos	Unclear, rephrasing suggested	Page 10 Para 12 It is not clear what “a long time ago” means. Suggest clarify this. This is discussed in more detail in the section, but still no definition of what this means	The literature does not suggest a clear timeframe for when the risk was highest. The risk was likely highest a number of decades ago. Text amended to reflect this.

Household contacts	Query if cases be told to inform their household contacts; Rephrasing/ clarification	Page 30 Rec 4.1 Evidence for the factors mentioned in second part of the recommendations, i.e. "Screening may be considered based on (…) a risk assessment factors such as …" should be more clearly presented. Evidence is presented pointing to the very limited horizontal transmission in the household settings. Since the horizontal transmission may occur and given the possible anxiety among the family members there is a clear link between the evidence and the general recommendation not to actively screen the household contacts but to test on request. Evidence for the assessment of the risk factors could be more underlined. Although this is not the main focus of the recommendation, but should the person diagnosed with HCV be advised to inform their household members of their infection?	Risk factors within household formatted to bullet points to make clearer. It is not in keeping with recommended practice/ acceptability to require disclosure of HCV status. Information on how to prevent household transmission should be provided and this has been included as a good practice point..
Dialysis	Rephrasing/ clarification	Page 57 Value Judgement The sentence "Detection of cases prior to commencing haemodialysis will ensure the appropriate procedures are followed to prevent transmission" should be rephrased. This sentence right now suggests that otherwise the procedures to prevent transmission are not in place.	Text amended.
Homeless	Query over why limited to certain homeless people and not all	Page 42 Rec 9 Limiting the screening of the homeless to those with additional risks should be better explained. Limiting the screening to those currently homeless (as opposed to those who have been homeless in the past) could be address as well. Recommendation 9 limits screening of the homeless to those with additional risks. This should be better justified as the situation is very similar to the prisoners (excluding the implementation issues) and for the prisoners the recommendation is to screen all. Moreover the quoted UK guideline does not make this exclusion either. Following on that and also looking at the similarity to the prison guideline, there could be some explanation, why it is not necessary to test the people with the history of homelessness? Implementation issues apply here as well, but as part of opportunistic screening (by risks defined in the Annex 1)	There has been an increase in homelessness in Ireland resulting in a shift in the reasons for homelessness. There is a greater proportion of people homeless due to financial reasons rather than addiction, which was previously a common reason. The recommendation was restricted to those with risk factors to reflect the changing face of homelessness in Ireland.

Migrants

Theme of comment	Comments[1]	GDG Response
Query over how it will be implemented	Page 44 The current guideline differs from 2015 guidelines where migrants from countries >3% +Anti HCV are recommended. For these guidelines to be adopted in practice there needs to be screening offered to all migrants from intermediate/ endemic countries not just those in designated health screening centres. How will this happen and will this be adequately resourced?	It has been acknowledged that this recommendation will be difficult to implement.
Suggestion to reference EU policy	Page 43 Para Evidence Summary There is no reference to European policy/guidance, or lack thereof, in relation to HCV screening of migrants. As Ireland is part of Europe, we would suggest also mentioning EU policy, or lack thereof, here. We could not find any EU level policy re HCV screening of migrants. However, there is the HepScreen project which may be worth referencing: http://hepscreen.eu/about-the-project/objectives/	No relevant EU policy was identified.
Recommendation to define migrant more explicitly and to consider migrants at risk of infection within Ireland.	Page 45 Rec 10 If feasible the recommendation could be made more precise by specifying if it applies only to the resident migrants or also to circular and undocumented migrants. Also is the one-off test recommended or re-testing should be considered. Ideally the screening is then followed by linkage to care and treatment. I am not fully aware if there are possibilities to offer treatment for undocumented migrants and circular migrants (e.g. seasonal workers). And if this could result in people migrating to Ireland in order to get treatment? Further there might be an increased risk in the migrant communities also due to transmission in the country of destination, which could substantiate repeat testing. This has been recently described in case of HIV but I am not aware of any evidence that would point to similar situation in case of HCV and perhaps the situation is different	Definition of migrant amended to be more inclusive. Text amended to consider other risk factors amongst migrants and to offer repeat screening if indicated.
Implementation - antenatal services to be included	Page 45 Rec 10 The list of those responsible for the implementation could be supplemented with antenatal services. This is for consistency with other recommendations - as is also part of the Recommendation 1.	Text amended

Substances of human origin

Theme of comment	Comments[1]	GDG Response
Query over year of exposure to contaminated products	Page 98 Appendix 5.2 Xii Recipients of blood and blood products up to the end of 1992	The GDG confirmed with the IBTS commenced screening for HCV in October 1991. Text was amended to indicate that it refers to recipients of products donated pre Oct 1991
Suggesting rephrasing	Page 59 Para 4.1.14 Due to the number of infectious or potentially infectious vials of anti-D it would be sensible to say that there are more people out there infected through blood or blood products. Our organisation has come across people that were never contacted during the first look back nor any subsequent tracings but still were eventually diagnosed with serious disease many years later and were subsequently deemed to be state infected with Hepatitis C.	The independent audit commissioned by the IBTS found that less than 1% remained untested.
Inaccuracy/ clarification required	Page 62 Para 3 Where it is stated "Donors of organs, tissues and cells (other than reproductive cells) must be tested for anti-HCV,……", this is not correct as the exemption for testing in the context of reproductive cells relates only to where the cells are for direct partner use and not subject to storage. It is noted this is somewhat clarified further on in the next paragraph.	Text amended
Inaccuracy/ clarification required	Page 62 Para 4 It is stated that "Third party donors require careful donor selection and testing for anti- HCV." The term 'third party' is not generally used in this context. The term 'non-partner' would be more relevant.	Text amended
Suggested other references/ policies to include	Page 62/63 In the context of the evidence summary there is reference to the UK's Advisory Committee on the Safety of Blood Tissues and Organs (SaBTO) and The Guidelines for the Blood Transfusion Services in the UK published by the Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC). While all such sources of established guidance are acknowledged as having relevance, it is of concern that the following guidelines developed by the European Directorate for the Quality of Medicines & HealthCare (EDQM), have not been referenced as a more primary source of guidance for best practice guidelines in relation to Substances of Human Origin:	EDQM guideline reviewed and included in the text.

	• Guide to the quality and safety of organs for transplantation • Guide to the quality and safety of tissues and cells for human application • Guide to the preparation, use and quality assurance of blood components	
Inaccuracy/ clarification required	Page 63 Para 5 Where it is stated that "Practice in other licensed tissue establishments is not known, this may be taken to infer that the HPRA, as the relevant competent authority, does also not know the practices, which would not be the case.	Text amended
	Page 64 Recommendation 19.2 states: NAT testing of donors of blood, organs, tissues and cells, including reproductive cells (except for partner donation for direct use), should be performed and the results available prior to donation. Further to this, results cannot always be available prior to donation. Samples may only be taken 'at the time of donation' in some cases. In any case, it is already indicated on Page 63 that "Legislation requirements regarding the timing of the screening of blood, organs, tissues and cells, and any re-testing or quarantine periods required are outlined in the respective legislation and relevant amendments and these should be consulted directly." So a similar reference within the recommendation would be more appropriate	Text amended to indicate that for some SoHO the result should be available prior to use of the donation. For deceased donors the text amended to take account of the fact that results may not be available prior to the transplantation.
	Page 64 Recommendation 19.3 states: "For deceased donors of solid organs: soon as possible* but the results are not required prior to transplantation." These recommendations do not constitute agreed provisions in the context of the Framework for Quality and Safety of Human Organs Intended for Transplantation. Notwithstanding this, Recommendation 19.3 is not consistent with Recommendation 19.2. The indication that "NAT testing should also be done as soon as possible* but the results are not required prior to transplantation" and that "NAT testing should be done on the next working day if the donation arises out of hours" is also not considered appropriate in the context of recommendations for best practice.	Text amended and agreed by key stakeholders.

Inaccuracy/ clarification required	Page 64 Recommendation 19.4 states: "Any laboratories undertaking microbiological screening of donors should be accredited by the Irish National Accreditation Board (INAB) to undertake testing in compliance with the International Standard ISO 15189 or the appropriate regulatory authority" It is not appropriate to solely reference INAB in the context of ISO 15189 accreditation, as laboratories outside the State may also be utilised for serological / NAT testing of SoHO donors.	Recommendation amended.
Inaccuracy/ clarification required	The footnotes do not reference all relevant legislation relating to SoHO and the reference to tissues and cells does not include the context of human application	References reviewed.

Testing

Comment on	Theme of comment	Comments[1]	GDG Response
Point of care tests (PoCTs)	Other tests available no mentioned	Page 79 Paragraph 6 Please be aware that OraQuick® HCV Rapid Antibody Test is not the only approved PoCT available in Ireland, which can use finger-prick blood. nal von minden also supplies INFO® anti-HCV (HCVab) Test Cassettes, with CE marking CE1434, for use with Whole Blood, Serum or Plasma collected via venipuncture or finger prick.	Text amended to reflect this.
PoCTs	Suggest being more supportive of the use of PoCTs	Page 80 Recommendation 25- re POC testing- It would be good if more explicit recommendation re use in difficult situations – to enable treatment compliance, engagement in care etc.	The Guideline has not recommended against PoCTs. The GDG acknowledges the benefit of PoCTs in certain circumstances/ populations. However, venous blood is preferred as antigen and RNA testing can be performed. It may be possible to be more supportive of PoCTs in the future.
Testing sequence	Add the need for genotyping into testing algorithm	Page 74 figure 4 Regarding the Flowchart outlining the testing sequence for HCV infection. As many health care providers may refer only to this flowchart for guidance on the recommended testing sequence, we would suggest also specifying the need for HCV genotyping in or after the following box: “Consistent with active HCV infection. Confirm diagnosis on a second sample and test for HCV RNA if not previously done”. This would be commensurate with Recommendation 22.3 on p.14	Diagram amended.

PoCTs	Recommends being more supportive of PoC testing	The document does not recommend POC testing using oral fluids and gives a cautious approval to testing using POCT dried blood spots. Perhaps extending this method of testing to field situations could be tried to see if this captures those most resistant to blood tests.	As above
PoCTs		In line with this perhaps, as aforementioned by xx looking at POC testing, and the extension of POC/ POCT to field situations would be ideal for screening the hard to reach clients that exist in our services.	As above
Testing sequence	Inaccuracy	Page 71 Statement "As anti-HCV remain positive for life" should be rephrased. The anti-HCV antibodies do sometimes drop to undetectable levels after some (long) time following viral clearance. (e.g. Vanhommerig JW et al. Hepatitis C virus (HCV) antibody dynamics following acute HCV infection and reinfection among HIV infected men who have sex with men. Clin Infect Dis. 2014 Dec 15;59(12):1678-85. doi: 10.1093/cid/ciu695. Epub 2014 Sep 3. PubMed PMID: 25186590. Tsai PS, Chang CJ, Chen KT, Chang KC, Hung SF, Wang JH, Hung CH, Chen CH, Tseng PL, Kee KM, Yen YH, Tsai CC, Lu SN. Acquirement and disappearance of HBsAg and anti-HCV in an aged population: a follow-up study in an endemic township. Liver Int. 2011 Aug;31(7):971-9. doi: 10.1111/j.1478-3231.2010.02363.x. Epub 2010 Nov 4. PubMed PMID: 21054768.)	Text amended to reflect that anti-HCV antibodies can sometimes become undetectable

Sexual contacts, MSM

Comment on	Theme of comment	Comments[1]	GDG Response
Sexual health screening	Suggesting it should be routine for all having sexual health screen	Page 11 Para 15 If getting a routine sexual health screening Hepatitis C should automatically be part of it	Universal HCV screening for STI clinic attendees has an associated cost. Given the low risk of HCV transmission through sexual contact, the evidence, including economic evidence, does not support universal screening in this setting.
Sexual contacts	Unclear, rephrasing suggested	Page 11 Para 13.2 Regarding the recommendation to consider offering screening to the sexual partners of known HCV cases in certain situations, we found the wording of the following recommendation unclear: "If the HCV infected case is an injecting drug user (caution: the case may not have disclosed this to the partner). Partners of HCV infected injecting drug user (sic) may be at increased risk as they may themselves have a history of IDU, or due to environmental exposure to discarded needles, or they may have been involved in commercial sex work." We suggest rephrasing this so that the recommendation is clearer.	
MSM	Clarify what is meant by chemsex	Page 11 Para 14.1, 14.2 Regarding the recommendation to offer screening to MSM who engage in chemsex. Many health care providers will be unfamiliar with the term "chemsex." We suggest adding a brief explanation / definition in brackets. Definitions of chemsex are available in the following documents: • Bourne A, Reid D, Hickson F, et al. Sex Transm Infect 2015;91:564–568. Bourne A, Reid D, Hickson F, et al. (2014) The Chemsex study: drug use in sexual settings among gay and bisexual men in Lambeth, Southwark & Lewisham. London: Sigma Research, London School of Hygiene & Tropical Medicine. www.sigmaresearch.org.uk/chemsex	Definition of chemsex is available in the glossary. A footnote with a definition was added to the main text. Of note, there is not a universally agreed definition of chemsex.

MSM - HIV negative	Query over why only those attending sexual health clinics are recommended	Page 55 Recommendation 14 The Recommendation 14.2 includes only the HIV (-) MSM who attend sexual health checkups. Depending on the how the health care system functions it may be of use to explain this selection criterion I am not aware how the system works it may be just the implementation strategy (where they should be tested, in case there is a good coverage of the sexual health check-ups) or a selection criterion (if only a high risk subgroup attends). In the latter case it could be considered to explain. Also Annex 1 mentions MSM without exclusions – for opportunistic testing(?	The recommendation intended that HCV screening should be part of the annual sexual health check-up which is recommended for MSM.

Repeat testing

Theme of comment	Comments[1]	GDG Response
Clarification of "clinically appropriate"	Page 9/10 Para 5.2, 7.3, 9.2 Regarding the recommendation to offer re-testing to those who test HCV negative, on an annual basis, or 6 monthly if deemed clinically appropriate, where there is an ongoing risk of infection. It would be useful to clarify what is meant by “clinically appropriate” in these contexts in order to help health care providers to decide whether to test 6 monthly or annually. The “clinical indications” for more frequent testing of Men who have sex with men (MSM) are specified in Recommendation 14 on p. 11 and a similar clarification would be helpful in Recommendations 5.2, 7.3 and 9.2.	The term “clinically appropriate” was agreed to allow HCWs autonomy in determining the frequency of repeat testing for individual patients. Some examples of when more frequent testing should be considered will be added.

Budget impact/ resources

Theme of comment	Comments	GDG Response
Lab resources	Is there discussion of laboratory resources to implement ?	It is acknowledged that increased screening will impact on laboratory services. The implementation plan stresses that laboratories should be resourced appropriately.
Additional resources required to offer retesting to those at ongoing risk	The document stresses the need for repeat tests on those antibody negative or non PCR positive. However such services would require extra resources in order to flag those who should be tested on 6 months basis'.	It is acknowledged that repeat testing will result in additional resource use. These have been considered in the Budget Impact Assessment.

Recommends a phased and prioritised implementation given the potential budget impact	The XX considered this report and find it to be evidence-based and best practice with some very good recommendations. We were somewhat surprised to note the early comment on page 14 that a previous report of 2004 sent to ERHA was not implemented, especially as this was produced at a time of considerable resources of money and staff. By way of a general comment, we estimate that the total cost of implementing all the recommendations in the report comes to very roughly, and applying ballpark figures to the screening costs, €1.1m, which is a sizeable chunk in any budget. In view of the high cost of the recommendations, we feel the report will be implemented at best on a phased and prioritised basis, and indeed we see that the HSE has committed itself to just such an approach. Thanks again for sight of the report. The XX while aware of HSE budgetary constraints, feel this is an important area requiring attention and development, and we will endeavour to support implementation of the recommendations where we can.	The budget impact assessment estimated a cost of 1.03 million a year over five years. While it is acknowledged that this is a sizeable amount, a commitment of 30 million has been made for HCV drugs.
Suggest calculating for a range of uptakes	Budget impact Rec 6.1 I think that depending on how widely these guidelines are disseminated to the general public, and how actively screening is promoted, there may well be more people coming forward following lifetime cocaine use than has been estimated. Would it be good to look at ranges of rates of presentation, from 5% to perhaps 20%	The uptake of screening for different groups is not known. It could be complicated to put ranges on all estimates. It is stressed in the BIA that this is an estimate only and the budget impact will depend on uptake.
	I did wonder why the economic impact report (appendix 10) is not included in the main body of evidence for each target group. I find it an excellent piece of work, and would have thought it to be an integral part of the evidence. Maybe there is specific Irish guidelines to consider economic evidence separately?	Economic evidence was considered during the considered judgement process. Given that much of it is now redundant

		it wasn't included in the main text.

Implementation

Theme of comment	Comments[1]	GDG Response
Give further detail on this organisation	Page 129 Appendix 12 Should read there are a number of organisations providing support. XX might not be as widely known as the other two organisations. We would suggest a description of our organisation be inserted.	Description of service to be added.
Missing part of implementation plan	Page 117 Table A5 There appears to be an oversight in the section on people who have ever injected drugs. In the section regarding people who have used unprescribed or illicit drugs but not by injecting, possible actions to facilitate screening include "Referral pathways to care for detected cases; Care Co-ordinator and/or peer support (e.g. HepFriend) to support retention in care; Community treatment services" and specific action required by the GDG includes "Develop promotional and educational materials." Should these same suggestions not also appear in the section above for people who have ever injected drugs?	The implementation plan will be amended.
NGOs which can support implementation should be resourced/ supported	Page 26 recommends testing/screening of all drug users especially those who injected or shared including prisoners, to do this requires NGOs involved to have adequate resources to support patient compliance and carry out patient audits. Therefore encouraging patients to engage with methadone clinics is important. Agencies working with IDU client group could use the guidelines to support setting up a separate screening programs although I am not sure this is warranted at present? A lot of problems seem to be about keeping IVDU/ Homeless person engaged with frontline services including GP/ Methadone and needle exchange.	The GDG agree that NGOs play a vital role in and have advocated within the implementation plan that they be supported.
They can offer testing to clients of their service	In relation to addiction and homelessness it would be good to monitor patients and HCV status at time of admission to BBV-Respite/Stabilisation Unit.	No action required. This organisation was added to services list.

Their service can facilitate implementation	The XX as an organization working with the aforementioned client groups including IVDU Clients, clients who have been in prison, who have a history of using and sharing drug paraphernalia, including sharps and indeed clients who are homeless and at risk of homelessness and clients who are living with other BBVs including HIV; in relation to screening for Hepatitis C we would be in a prime position to facilitate same. In terms of wrap around services the nature of XX as it stands allows for clients to be supported holistically as they navigate across our services. …so a coordinated Hepatitis C screening program could allow us to keep track of clients post initial screening. Regular screening of this client group will mitigate against the high medical costs associated with end stage liver disease secondary to Chronic Hepatitis C. Whether or not XX provide a facility for testing (in our treatment services; of which 3 are nurse led) or facilitate / maintain pathways to screening our services are front line and involve one to one engagement with our clients from our XX to the support staff in our residential services. This is in line with the draft papers stipulation on Linkage to care on pg. 83 (175).	No action required.
Access to testing history would facilitate implementation of repeat testing	In relation to re testing those who have spontaneously cleared infection, (recommendation 5) the collection and retention of service data / audits would be vital in facilitating this process across the organization/organizations in general.	The MedLIS system may facilitate access to testing history.

Audit

Theme of comment	Comments[1]	GDG Response
Set targets at 100%	Page 132 Table A6 Regarding the suggestion that the Target for the following process audit criteria is "To be determined by individual services as will vary by risk group": • Percentage of those tested for anti-HCV who are informed of their test result; • Percentage of those who are anti-HCV positive who have a subsequent HCV-RNA or HCV-Ag test; • Percentage of those tested for HCV-RNA or HCV-Ag who are informed of their test result; • Percentage of infants born to HCV-RNA positive women who are referred for follow-up screening; • Percentage of infants born to HCV-RNA positive women who have follow-up HCV RNA at 6 weeks of age; • Percentage of infants born to HCV-RNA positive women who have follow-up HCV-RNA at 6 months of age; Should not the targets for the above be 100%?	The GDG decided not to set a universal target as services will differ in what is an appropriate target. Some services may have particularly chaotic clients and in such services a lower target would be acceptable.

Drug users

Theme of comment	Comments[1]	GDG Response
Suggestion to highlight smoking crack pipes as a risk factor	Page 9 Para 6.1 Regarding the recommendation to offer screening to those who have used unprescribed or illicit drugs, but not by injecting, where the route of adminstration involves a possibility of transmission of infection. The guidelines highlight the use of intranasal drugs (i.e. snort or sniff) as a risk in this regard. We would suggest also adding the smoking of crack pipes as the sharing of pipes is not uncommon and may entail risk of transmission.	The GDG recognise that smoking crack pipes poses a potential risk for HCV transmission as it can cause burning and bleeding of lips.
Outside Dublin access to testing may not be optimal	Page 83 Para 8 The largest cohort of HCV +ve people in Ireland is currently within the drug use cohort. Addiction Services in the Geater Dublin Area have robust policies in place for viral screening and vaccination against Hep A&B. However, outside of Dublin, services that address drug-use are less well resourced and screening and referral may not be optimum. I feel it is important to work with these services to enhance their testing and follow-up	Acknowledged that outside Dublin services may not be as well resourced. Implementation plan aims to address education of all

	services.	HCWs providing services to risk groups.
Consider novel methods of accessing people e.g. outreach testing	Page 117 Those who do not consider themselves at risk of HCV (because they inject steroids etc) are a vulnerable cohort for HCV acquisition. They are some of the undiagnosed we seek to identify. However, the possible actions to facilitate screening are focused mostly on Addiction Services where many of this cohort do not attend. We need to look at more 'creative' ways of providing screening and education to this cohort and I believe it needs to be outside of traditional addiction-related environments, such as gyms, ports centres etc. This is hypothetically where people are procuring steroid-based drugs or sharing information about injecting steroids for performance enhancement. Many of this cohort will never present at Addiction Services, so we need to think how we can reach them otherwise and also consider information in other languages and other formats for immigrant population.	The GDG acknowledge that non traditional drug users who do not attend addiction services will be hard to reach. There will be promotion of guideline to general public to try and reach such persons. The guideline supports outreach initiatives.
Availability of testing in methadone clinics	..phlebotomy for Hepatitis C screening should be universally available in all methadone prescribing units.	Acknowledged that venous access can be a problem in some settings. The use of DBS on cappillary blood is supported in such situations.
Unclear, rephrasing suggested	Page 9 Rec 6.1 As phrased, took me some time to understand this. Perhaps amend as follows Screening should be offered to all those who have used unprescribed or illicit drugs but not by injecting, (remove .if there is a possibility of transmission of infection by the route of administration. This includes those who) if they currently use intranasal drugs (i.e. snort or sniff), or have done so in the past, or share other equipment or drugs where there is a risk of contamination with the blood of others.	

Promotion of testing

Theme of comment	Comments[1]	GDG Response
Suggests having a questionnaire HCWs can use to assess patients	The following may help users implement these guidelines : questionnaire that medics can use when dealing with patients	A quick access card with risk groups will be developed for healthcare workers to assist in risk assessment.
Suggested methods of communicating with GPs re screening of MSM	The second point there, that all MSM should have annual hep C test is new and very significant for GPs doing testing. Up to now, the guidelines for GPs would have been to test for Hep C in asymptomatic men , only if history of drug use or sexual contact with an IV drug user	GDG will link with the ICGP to prepare materials for GPs on the guidelines.
Outreach support for testing should be considered	We know that leaflets and public campaigns are less good at improving screening. We also know that providing assistance with screening at appropriate venues is beneficial.	Implementation plan supports outreach initiatives.
Assistance to GPs to promote testing. Outreach programmes	Within GP practices (outside of Addiction Service) I feel that targeted assistance with testing and patient education would greatly enhance identification of HCV+ve cases. We see that targeted programmes of clinical outreach are proving fruitful in improving HCV screening. This should be factored into service approach. GPs are addressing multi health needs and as such do not always have the time or resources to stay vigilant to HCV testing and certainly less time to provide comprehensive patient education, but with targeted assistance, this could improve substantially	A care coordinator has been recommended in the implementation plan.
Have information in different languages	…and also consider information in other languages and other formats for immigrant population.	The GDG plan on developing material in various languages.

Use social media to educate and promote testing	Page 54 The MISI of 2015 produced a good response rate from MSM cohort. This suggests that social media is used regularly by the MSM cohort. Chemsex drug-use is on the rise in Ireland and with it a possible increase in BBVs. The use of social media is particularly required in accessing sexual partners in terms of 'Grinder' and Chemsex parties. I feel health services should be targeting social media to promote information about transmission and where to go for testing. The Irish Health Service is still in its infancy in utilising social media for health gain, but it needs to adapt and change to the lifestyles of our target cohorts	GDG agree that social media is a method to reach certain target groups. Promotion of the guideline will involve a social media campaign.
Educational campaign should be considered	Education on the risk factors of contracting the virus as younger people that may be at risk but have no symptoms will not feel the need to get tested.	An educational campaign is planned.

Linkage to care

Access to fibroscanning to identify and support linkage to care for those most at risk of severe disease	The purpose of screening is linkage to care and reduction in transmission of Hepatitis C infection. However, uptake of referrals to hospital has often been low and thus patients remain viraemic, with all the personal and societal consequences which follow. These include early death for the patient and transmission of Hep C infection within society. The significance of viraemia is not the same for all patients on methadone. **It is possible to accurately individualise the significance of Hep C viraemia at the point of testing** and we have done so in the Shared Care Programme with St Vincent's Hospital and Patrick Street Clinic. The method is an accurate predictor of premature death and this allows the patient on methadone to make an informed choice about accessing treatment and preventing his own premature death. It allows clinical support to be concentrated on patients who need treatment most, so that they are prioritised for treatment and supported to attend it or receive it at the point of methadone treatment. It has been an effective clinical strategy and a good use of existing clinical and financial resources. We have been utilising this approach in the **Shared Care Hepatitis C Programme between St Vincent's Hospital and Patrick Street Treatment Centre**. I am pasting a current poster presentation to the British/Irish Gastroenterological Society, which is relevant to this. The figure shows how risk is concentrated in a minority of patients and how these patients are readily identifiable by Fibroscan in the methadone clinic. The presentation outlines the clinical sequellae between 2008 and 2016, based on Fibroscan readings.. It presents a strong case for deploying this method nationally and I am also attaching a document on how this method can be applied across Ireland in 60 to 65 weeks, for little cost. It also **identifies a large subgroup who require urgent treatment to prevent premature death from liver failure.** A further city-wide programme of Fibroscanning was carried out under Dr Stewart and others. We were a component of this large study which **scanned 618 consecutive patients** in methadone clinics. **One third of the total cohort had a reading of 8.5kPa or greater, 9% were greater than 25kPa and 5% were greater than 35kPa.** This confirms that there is **a large untreated group of patients in the methadone clinics who need to be prioritised for urgent treatment**. Otherwise they will meet the fate of the 2008 patients in Patrick Street Clinic i.e. **premature death**.. I will be presenting this study on behalf of the many people who were involved at the Irish Gastroenterological Society meeting in May 2017. * We have used the approach in methadone clinics where there has not been universal availability of phlebotomy and we have identified candidates for urgent Hepatitis C treatment, and as a result they have received urgent Hep C treatment. There may be patients like this in many parts of the country and this method may help them in a similar way.	Comment is more related to models of care which is not within scope of the guideline.

Identifying those most at risk	I wonder if we should take care not to conflate the urgent clinical requirement of patients who are developing fibrosis with our universal wish that the prevalence of Hepatitis C to a level which will reduce its incidence in Ireland. The former will definitely happen. People who are developing silent fibrosis will definitely die as a result of this. All of the people who had Fibroscan readings>13.3 kPa in 2008 had died by 2016 and liver failure was the overwhelming cause of death. There is a clinical imperative to identify these people, which we have done and to direct clinical and other resources towards them. The latter is something which we all hope will happen. It is based on mathematical models which no real-world outcome to witness. The models themselves stipulate that they are less reliable in societies which have higher prevalence of Hepatitis C viraemia. They give separate projections in cases where viraemic prevalence of 20%, 40% and 60%. Based on our own studies, quoted above, we think that the prevalence of Hep C viraemia among Hep C Ab positive people in the Addiction service is about 50% - i.e. about 70% of the patients are Hep C Ab positive and about 70% of these are PCR positive, so about 50% of the entire patient population is viraemic. We hope that we will be able to reach all of the viraemic people in Ireland and we hope that further introduction of Hep C infection into Ireland will be limited. There is no Hep C vaccine. The prevalence of HIV among methadone patients has not fallen, although almost everyone on methadone who has HIV gets treated and the prevalence of HIV is much lower than the prevalence of Hep C viraemia among patients on methadone. . In fact there was an outbreak of fresh HIV infection about a year ago among homeless methadone patients on methadone. We experienced this in Patrick Street Clinic. Perhaps we should consider reflecting these realities as a specified target for our National Hepatitis C Programme. **Patients on methadone, who are silently developing fibrosis, need to be identified and treated urgently, because they will die in the short- term unless they receive it.** This can be done by combining Fibroscan with serology at the point of contact for the patient i.e. in their methadone clinic. By contrast if we concentrate on hoped-for reductions in prevalence we risk diverting clinical and financial resources to the 80% of patients who will never develop liver failure, at the expense of those identifiable patients who will definitely die from it.	The guideline has attempted to highlight the need for proportionate universalism and that vulnerable groups may need additional support. We have also highlight the need for support to link to care.

Expert external review

Questions	Comment of external reviewer 1[1]	Comment of external reviewer 2[1]	GDG Response
Has the appropriate evidence been identified and reviewed in line with the scope and clinical questions posed by this guideline?	The available evidence was collected basing on existing and newly performed literature reviews, existing guidelines and exploration of the surveillance data to tackle clinical the questions in the guideline. It has to be acknowledged that the available evidence for some of the clinical questions may be limited in terms of geographic coverage, number and quality of the studies available as well as the time when the studies were performed. However, this is clearly discussed in the guidelines and there is a plan to update the guidelines in the 3 years' time which will allow to include new developments in this fast moving field. Specific comments are included below, they include limited evidence provided for the clinical and risk factors mentioned as part of clinical judgement ("soft recommendations"). These are also phrased differently in different recommendations and this is not clear if this is has been considered and decided this way or if there would be some value of harmonising them.	Yes, the search seems comprehensive to me, and I have not noticed any gaps. The use of GRADE for grading the evidence is appropriate and well carried out.	Recommendations reviewed to ensure consistency. In appendix 1 they are phrase differently to make them more accessible.
Are there specific links between the decisions and the available scientific evidence?	The links between the decisions and the available scientific evidence are clearly explained in the value judgment sections. Scientific evidence is supplemented with the current practice experience and expert judgement as in many situations there is no clear indications available regarding the best solution.	This is well described in the paragraphs 'value judgement'. I would have preferred if the economic evidence was integrated in this, since it is an important part of the assessment (and as such included in the Wilson & Jungner criteria).	A paragraph on economic evidence added to opening section. While the economic evidence was considered in the CJFs, much of it is now redundant given new treatments.

Have the risks and potential harms of recommendations been fully considered in the context of clinical practices?	There are few risks or potential harms associated with the implementation of the guidelines in the clinical practice, which could be related to patient distress and possible stigmatization due to being a member of a risk group, such as people who inject drugs (PWID) (I am not aware of the Irish situation in this respect) and to diverting resources from other health needs. The later have been carefully considered not to include the groups where it is likely to be ineffective. The potential psychological harms to patient were considered specifically for the prisoners ("Good practice points"), which is essential, but possibly they are also relevant for other vulnerable populations, e.g. homeless people? Employmeny implications for the health workers who might be found positive are also important, which are referred to other medical policies.	Harms are considered (e.g. P 34, for screening of household contacts), but I did not see this in every section	Harms were considered in each CJF but not repeated for every recommendation in the body of the guideline. A section on good practice points has been added which highlights the importance of minimising potential harms when offering screening.
Is the guideline clearly written, user friendly and allow for individual clinical decisions?	The guideline is very clear. I especially appreciate that it is organised in a way to allow easy access to all the recommendations in one place and than to the background and justification of each of them in clear chapters. Whenever the clinical judgement is required this is clearly stated and the background information is available on what to consider when taking the clinical decision.	The guidelines is very comprehensive and this resulted in a large document. I think that the use of the guideline could be facilitated by a summary stratified by professional group responsible for implementation (e.g. GPs, maternity units, etc).	Summary version is planned.

Is the guideline suitable for routine use as intended?	The guideline is suitable for routine use in many instances it relies on already existing services, offering standardisation of targeting the testing. As many recommendations refer to the marginalised groups, possibly uninsured (?) funds outlined in the budget impact are crucial for routine implementation of the guideline as is acceptance from the side of those who will implement it. Additional effort will be needed to disseminate the guideline to those responsible for its implementation, but since the key stakeholders were involved from the beginning of the process this should follow naturally.	Yes, these guidelines are suitable for routine use. This is particularly the case for target groups for which there is a clear recommendation for screening. The recommendations for groups where the evidence is less clear (e.g. People with a tattoo) are somewhat difficult to implement: 'screening should be considered for all those with a tattoo'. It will be difficult for clinicians to identify which people with a tattoo should be screened. But, given the lack of evidence, it is difficult to make more explicit guidelines.	Plans in place for dissemination and promotion of the guideline.
Are there relevant international or well referenced guidelines (recommendations) on the same topic that these guidelines are in conflict with and if yes are there reasons for this justified in the guidelines?	There is a number of good clinical guidelines available on the topic. In case of some clinical questions the existing guidelines are in conflict. This may be due to differences in epidemiological situation in different regions, and thus represents the necessary variation in the screening practice. Alternatively, the guidelines tend to conflict, whenever the evidence is insufficient. In these cases the draft guidelines provide sufficient arguments for selection of a specific approach. The small exception concerns the screening of homeless people (roofless, visibly homeless), where the UK guideline proposed screening of all such people and the draft guideline – limiting it to those with additional risks	I have not noticed any conflicts with international guidelines.	The homeless situation in Ireland has changed in recent years, with more people homeless due to economic reasons. To avoid stigmatization the recommendation was restricted to those with risk factors.

References

1. National Clinical Effectiveness Committee. Guidance for Guideline Development Groups for the consultation process for clinical guidelines; Template Version 2. Dublin: Department of Health; 2016.
2. Health Information and Quality Authority and National Clinical Effectiveness Committee. National Quality Assurance Criteria for Clinical Guidelines Version 2. Dublin: HIQA; 2015

Appendices

Appendix 1: List of individuals and organisations who were invited to participate in the consultation process

Groups or representative bodies	
Academy of Clinical Science and Laboratory Medicine	Irish College of Psychiatrists
Addiction service pharmacists	Irish Dental Association
Balseskin Centre doctors and nurses	Irish Faculty of Primary Dental Care
Chrysalis Drugs Project	Irish Haemophilia Society
Community Response	Irish Kidney Association
Consultants in Emergency Medicine	Irish National Accreditation Board (INAB)
Consultant Hepatologists/Gastroenterologists	Irish Patient's Association
Consultant Microbiologists	Irish Penal Reform Trust
Consultant Obstetricians	Red Cross (prison liaison)
Consultant Paediatricians	Irish Prison Service
Consultative Council on Hepatitis C	Irish Prison Doctors group
Cork University Dental School and Hospital	Irish Society of Clinical Microbiologists
Crosscare	Irish Society of Community and Public Health Medicine
Department of Health and Children, Chief Medical Officer	Irish Society of Gastroenterology
Department of Health Drugs Policy Unit	Level 1&2 GPs in addiction services Merchants Quay Project
Directors of Public Health	Migrant Rights Centre Ireland
Directors of Public Health Nursing	National Addiction Advisory and Governance Group National
Dublin Dental University Hospital	Bloodborne Virus Committee (healthcare setting)
Focus Ireland	National Centre for Pharmacoeconomics
Garda National Drugs Unit	National Drug Advisory and Treatment Centre
Gay Mens Health Service	National Hepatitis C Strategy Implementation Committee
GUM Physicians	National Virus Reference Laboratory
Health Information and Quality Authority	Nursing and Midwifery Board of Ireland
Health and Safety Authority	Occupational Health Nurses Association of Ireland
Hepatitis C liaison nurses	Occupational Medicine Consultants
Hepatitis C Partnership	Organ Donation and Transplant Ireland
Hospital Pharmacists Association of Ireland	Office of the Nursing and Midwifery Services Director, HSE
Health Products Regulatory Agency	Pavee Point
HPSC	Peter McVerry Trust
HPSC Scientific Advisory Committee	Principal Medical Officers, HSE
Health Research Board (HRB), Drugs and Alcohol Section	Probation Officers (prisons)
HSE Clinical Strategy and Programmes Division	Rainbow Clinic
HSE Drug Treatment Services – clinics	Reception and Integration Agency
HSE drugs/HIV helpline	Royal College of Physicians of Ireland (RCPI)
HSE Health and Wellbeing	RCPI Faculty of Occupational Medicine
HSE Health Promotion	RCPI Faculty of Paediatrics
HSE Hepatitis C Treatment Programme	RCPI Faculty of Pathology
HSE Infection Prevention and Control Nurses	RCPI Faculty of Public Health Medicine
HSE Integrated Services Directorate	Royal College of Surgeons in Ireland (RCSI)
HSE National Lead for Primary Care	RCSI Faculty of Dentistry
HSE National Lead for Neonatology	SafetyNet
HSE National Lead for Obstetrics	SAOL Project
HSE Occupational Health	Sexual Assault Treatment Units
HSE Quality Improvement Division	Sexual Health and Crisis Pregnancy Programme
HSE Social Inclusion	Simon Community
Infection Prevention Society	Specialists in Public Health Medicine
Infectious Diseases Physicians	Society for the Study of Sexually Transmitted Diseases in Ireland (SSSTDI)
Infectious Disease Society of Ireland	Transfusion Positive
Institute of Obstetrics and Gynaecology	Union for Improved Services Communication and Training (UISCE)
Irish Blood Transfusion Service	
Irish College of General Practitioners	

Individuals:	
Dr Susan Hahné (External reviewer) Dr Magda Rozinska (External reviewer) Dr Kevin Kelleher, Assistant National Director Public Health and Child Health, HSE Health and Wellbeing Dr Stephanie O'Keeffe, Director, HSE Health and Wellbeing Mr John Hennessy, HSE Director Primary Care Professor Joe Barry, HSE Consultant in Public Health Medicine and Professor of Population Health, Trinity College Dublin Dr Jean Long, HRB Professor Declan Devane, School of nursing and midwifery, NUIG Dr Francesca Wuytack, School of nursing and midwifery, NUIG Dr Jennifer Kieran, Consultant in Infectious diseases, St. James's Hospital Ms Michelle O'Neill, HIQA	Dr Mairin Ryan, HIQA Ms Helen Clark, Librarian, HSE Ms Lucia Mullen Dr Lynda Sisson, HR Lead - Staff Health and Wellbeing and Occupational Health, Office of the National Director of HR, HSE Mr Niall Mulligan, HIV Ireland Ms Erin Nugent, HIV Ireland Dr Cliona Ni Cheallaigh, Inclusion Medicine Service, St. James's Hospital Mr Tim Bingham, Irish Needle Exchange Forum Dr Erika Duffell, ECDC Dr Lara Tavoschi, ECDC

Appendix 2: Letter inviting stakeholders to provide feedback

Re: Consultation document - National Hepatitis C Screening Guidelines

Dear Colleague,

I am writing to you to seek your views on the draft document *National Hepatitis C Screening Guidelines* that is now available for consultation.

Hepatitis C virus infection is an important cause of chronic liver disease, including cirrhosis and liver cancer. There have been major advances in treatments for hepatitis C within recent years, with cure now possible for most patients. People with chronic infection may have no symptoms for several decades, thus many of those infected with hepatitis C are unaware of their infection. This means that they will not access available treatment and also present a risk of transmission to others. Testing is the first step in linking to care and treatment. The National Hepatitis C Strategy 2011-2014 identified gaps in current guidance on screening for hepatitis C in Ireland.

The aim of the guidelines is to make recommendations on who should be offered screening for hepatitis C virus infection and how screening should be undertaken, based on international best practice and evidence. The National Clinical Effectiveness Committee (NCEC) prioritised this guideline in February 2016.

The consultation period is from 31/03/2017 to 21/04/2017. The consultation document and the template form for feedback are available on the HPSC website at http://www.hpsc.ie/A-Z/Hepatitis/HepatitisC/Consultation/ . If you have difficulty downloading the document, please contact us and we will send it to you by email attachment.

We would welcome any comments or suggestions you may have, not only in relation to content of the recommendations, but also layout and ease of use of the document, and implementation of the recommendations. We appreciate that not all areas covered by the guidelines would be relevant to your area of expertise and interest so you may wish to concentrate on specific parts of the document such as those related to the risk group you work with. All comments received from organisations and individuals will be reviewed by the Guideline Development Group and used to inform the final guidelines.

The draft budget impact analysis related to the guidelines will be available on the same website page from 13/04/2017.

Please submit your comments by completing the feedback form electronically and returning it by email to **eve.robinson@hpsc.ie**. **The final date for submission of comments is 21/04/2017.**

Thank you for your assistance in this work.

Yours faithfully,

Dr Lelia Thornton

Chair, Guideline Development Group

Appendix 3: External consultation feedback form

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

hpsc

The National Clinical Effectiveness Committee (NCEC) prioritised this guideline in February 2016

The National Hepatitis C Screening Guideline Development Group has been developing this guideline and now invites your feedback on the draft document:

National Hepatitis C Screening Guidelines

Consultation feedback form

Consultation opening date: **This consultation opens on** 31/03/2017

Consultation closing date: The deadline for comments is **21/04/2017**

During the consultation period the draft guideline and the feedback form will be available from: http://www.hpsc.ie/A-Z/Hepatitis/HepatitisC/Consultation/

Comments via email should be sent to: eve.robinson@hpsc.ie

Introduction

We would like to hear your views on the draft guideline ***National Hepatitis C Screening Guideline***s. All comments received on this form by the deadline will be considered and used to inform the final guideline.

Irish National Clinical Guidelines are defined as "*systematically developed statements, based on a thorough evaluation of the evidence, to assist practitioner and service users' decisions about appropriate healthcare for specific clinical circumstances across the entire clinical system*".

The implementation of guidelines can improve health outcomes for patients, reduce variation in practice and improve the quality of clinical decisions that patients and healthcare staff have to make. National Clinical Guidelines will inform patients about the care they should be receiving and assist them to make healthcare choices based on best available information.

The draft guideline contains a number of recommendations, each with a statement of the evidence used by the Guideline Development Group when they formed the recommendation.

Further information on the NCEC and National Clinical Guidelines is available from http://health.gov.ie/national-patient-safety-office/ncec/

Notes:

1. Feedback received may be edited and/or summarised.
2. This consultation is conducted in line with requirements of the Freedom of Information (FOI) Act.
3. Submissions which are unsigned (see below) will not be considered.

Scope of draft guideline

Hepatitis C virus infection is an important cause of chronic liver disease, including cirrhosis and liver cancer. There have been major advances in treatments for hepatitis C within recent years, with cure now possible for most patients. People with chronic infection may have no symptoms for several decades, thus many of those infected with hepatitis C are unaware of their infection. This means that they will not access available treatment and also present a risk of transmission to others. Testing is the first step in linking to care and treatment.

The aim of the guidelines is to make recommendations on who should be offered screening for hepatitis C virus infection and how screening should be undertaken, based on international best practice and evidence.

How to submit your feedback

How to submit your feedback:

- All feedback must be submitted on this form if it is to be considered
- Ensure you have completed your details
- Identify clearly the section feedback relates to by using the page, section and /or paragraph number
- Each comment should be in a separate box
- Add in extra boxes as needed
- Specifically you must explain the rationale for your comment, which should be written clearly and concisely.
- Submit the form as a word document via email.
- Organisations should submit one collated response
- Use full terms for abbreviations on first use
- If you refer to sources of evidence, please detail the reference (with weblink if available)
- Sign your form. This can be done by:
  - inserting your electronic signature ***or***
  - signing in writing and scanning your form in ***or***
  - submission of the form as an attachment from your email address where an email signature is set up.

Consultation questions

This consultation focuses on how user friendly the document is, the content (evidence statements and recommendations) and the implementation of the draft guideline.

1. ***User friendliness***

a) Is the draft guideline easy to read?
b) Do you think the guideline will be easy to use in practice?

2. ***Content***

a) Do the recommendations cover the scope of the draft guideline?
b) Do the recommendations clearly link to the evidence presented?
c) Does the draft guideline consider the views and needs of specific population groups?
d) Does the draft guideline consider gaps in the current evidence?

3. ***Implementation***

a) Do any recommendations change current practice substantially? If so, do you consider that the reasons given in the draft guideline explain why the change is necessary?
b) Which areas do you think may be difficult to put into practice? Please explain why.
c) What would help users to implement the guideline? (For example, useful checklists, patient information leaflets etc.)

Your details

Name of person completing form	
Are you commenting ….? (tick box)	As an individual ☐ On behalf of an organisation ☐
Organisation Name (if relevant)	
Contact Name (if different to above)	
Contact Telephone Number	
Contact Email Address	
Date of feedback	
Signature	

Feedback

General comments e.g. overall layout, usefulness, ease of use of guidelines

General comment	

Specific comments

Page no		Paragraph no	
Comment 1			
Supporting information			

Page no		Paragraph no	
Comment 2			
Supporting information			

Page no		Paragraph no	
Comment 3			
Supporting information			

Page no		Paragraph no	
Comment 4			
Supporting information			