Hepatitis C Screening Guideline Development Group
Background to recommendation 15: People attending for a sexual health screen

The purpose of this document is to provide the background information to the formulation of recommendations by the Guideline Development Group (GDG).

Not all evidence in this document is presented in the National Clinical Guideline.

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

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Contents

History of development of the recommendation

Date	Process	Outcome
02/06/2015	Recommendations from quality appraised national and international guidelines reviewed	Agreed to augment evidence from existing guidelines with further literature
02/02/2017	GDG subgroup meeting to undertake considered judgement process	Formulation of recommendation
23/02/2017	Review of subgroup recommendation by GDG	Recommendation accepted
25/04/2017	Consultation feedback reviewed by GDG	No changes to recommendation
June – July 2017	Editing	Recommendation reworded in final editing process

Considered judgement process

The considered judgment form completed by the GDG subgroup in formulating the recommendations is presented below. Please note the final wording of the recommendation may have changed after review of the GDG, after the consultation process, or during the editing process.

Date:2/2/2017
Attendees: LT, PF, ER, SK, OE, CB

Table 1: Considered judgement form

1. What is the question being addressed? Present PICO if relevant
Q2. Who should be offered screening for Hepatitis C? b. Should the following specified groups be offered screening? ix **<u>People having an STI screen/test</u>**
2. What evidence is being considered to address this question and why? (This section will explain the approach taken to address this question and what GDG members are being asked to consider)
Recommendations and evidence from other guidelines. Screening of MSM is addressed in a separate CJF which should be cross referenced. The risk of sexual transmission among heterosexuals, and factors which are associated with an increased risk of sexual transmission of HCV are considered in a separate CJF and should also be considered when formulating the recommendation on STI clinic attendees.
3. What is the body of evidence? Source of evidence: (tick all that apply) Guidelines √ Primary literature √ Other √; specify: economic literature
Current guidelines **CDC 2015 (1)** **HCV screening recommended for:** • Men and women born between 1945-1965 • Other men or women If risk factors are present • MSM born between 1945-1965 • Other MSM if risk factors are present • Annual HCV testing in MSM with HIV infection • People with HIV - serologic testing at initial evaluation • Annual HCV testing in MSM with HIV infection *(CDC Sexually Transmitted Diseases Treatment Guidelines, 2015*) **BASHH CEG, 2014 (2)** It is recommend that persons should be screening for HCV regardless of being asymptomatic or symptomatic if they are IDU, HIV infected MSM, sex partner of HIV infected MSM, exposed to potentially contaminated needles, born to a mother infected with HCV. (*British Association for Sexual Health and HIV Clinical Effectiveness Group, BASHH CEG Guidance on Tests for Sexually Transmitted Infections*) **NICE, 2013 (3)**

It is recommend sexual health and genitourinary medicine clinics should offer and promote hepatitis B and C testing to all service users at increased risk of infection, including people younger than 18. (*The National Institute for Health and Care Excellence, Hepatitis B and C: Ways to Promote and Offer Testing to People at Increased Risk of Infection*) HIQA Quality Score of 148

SIGN, 2013 (4)
In populations where prevalence is low (eg GUM clinic attendees), economic modelling indicates that universal testing does not convey cost-effective clinical benefit. (*Scottish Intercollegiate Guidelines Network, Management of Hepatitis C A National Clinical Guideline*). HIQA Quality Score of 127.7

BAASH, 2006 (5)
Screening of asymptomatic STD clinic attendees is recommended if they fall into one of the groups at increased risk which includes intravenous drug users, recipients of blood/blood products, needle stick recipients, HIV-positive people and sexual partners of HCV-positive people. (*British Association for Sexual Health and HIV, BASHH Sexually Transmitted Infections: UK National Screening and Testing Guidelines*) HIQA Quality Score of 121.5

Economic literature

Two studies examining the cost effectiveness of screening for hepatitis C in the STI/ GUM setting were identified. The applicability of these however is limited as one was conducted in 2003 and was modelled on different management and treatment strategies than are current practice. The second only considered the cost of detecting anti-HCV positive cases.

Stein et al (2003)(6) undertook a cost utility analysis of screening for HCV in people attending GUM clinics in the UK. They compared universal screening, screening of former or current IDU, and selective screening of 'at risk' groups. A health service perspective was taken. Screening was with ELISA followed by PCR if positive. Costs were discounted at 6% and benefits at 1.5% a year. Universal screening (assuming a prevalence of 1.5%) had an ICER of £85,000 per quality adjusted life year (QALY) and a total cost of £4,808,373. Screening only IDUs (assuming 3% of attendees were IDU and a prevalence of 48.6% in this group) had an ICER of £32,138/QALY and a total cost of £982,832. Selective screening was based on criteria such as IDU, sexual behaviours and contacts. If 10% of attendees were screened (assuming a prevalence of 9.9%) an ICER of £34,288 /QALY was estimated and a total cost of £1,530,547 in addition to no screening. Selective screening of 20% who present (with prevalence of 6.2%) had an ICER of £39,647 /QALY and a total cost of £2,168,860 in addition to no screening. When treatment was with pegylated interferon the ICER of universal screening decreased to £46,389. The ICER was sensitive to prevalence, increasing once prevalence decreased below 3%. It was also influenced by acceptance rates, but remained above £60,000 even with 100% acceptance. It was also sensitive to acceptance of treatment, and eligibility for treatment. The IDU and selective screening strategies were also sensitive to acceptance of screening and treatment.

Honeycutt et al estimated the cost and cost effectiveness ratio of testing STD clinic attendees for hepatitis C (7). The cost per anti-HCV positive tester returning for results was estimated. No further costs or utilities were considered. Testing was with EIA followed by RIBA for those with a low positive EIA. In the baseline scenario only IDUs were offered screening. This was compared with testing of other subpopulations: non-IDU males aged over 40 with more than 100 sex partners; non-IDU males over 40 with less than 100 sex partners; and non-IDU females over 40 years. The prevalence of anti-HCV in these groups was taken from the National Health and Nutrition Examination Survey and was 57%, 16%, 2% and 0.9% respectively. The CER of testing these subpopulations compared to testing IDUs only was $179, $1,386 and $2,986 respectively.

4. What is the quality of the evidence? To be considered if primary literature was reviewed.
4.1. How reliable are the studies in the body of evidence? If there is insufficient evidence to answer the key question go to section 11. Comment here on any issues concerning the quantity of evidence available on this topic and its methodological quality.
A number of good quality guidelines considered
4.2. Are the studies consistent in their conclusions – comment on the degree of consistency within the available evidence. Highlight specific outcomes if appropriate. If there are conflicting results highlight how the group formed a judgement as to the overall direction of the evidence
Consistency across guidelines in only recommending screening for risk groups.
4.3. Generalisability – are the patients in the studies similar to our target population for this guideline? is it reasonable to generalise
Likely similar populations
4.4. Applicability - Is the evidence applicable to Ireland? Is the intervention/ action implementable in Ireland?
Yes
4.5. Are there concerns about publication bias? Comment here on concerns about all studies coming from the same research group, funded by industry etc
n/a
5. Additional information for consideration
5.1. Additional literature if applicable e.g. Irish literature
nil
5.2. Relevant national policy
National STI testing guidelines not yet available
5.3. Epidemiology in Ireland if available and applicable
nil
6. Potential impact of recommendation
6.1. Benefit versus harm What factors influence the balance between benefit versus harm? Take into account the likelihood of doing harm or good. Do the desirable effects outweigh the undesirable effects?

Benefits:

- Linkage to care and treatment will result in improved quality of life for detected cases.
- The offer of screening also provides an opportunity to raise awareness and educate on hepatitis C.
- Promotion and further normalisation of testing may improve uptake and reduce stigma around hepatitis C.
- Detection and treatment of undiagnosed cases will reduce the risk of transmission to others.
- Removes barrier of having to ask about or admit to risk behaviours

Harms:

- False positives. The rate of false positive screening results depends on the population being screened. In high risk populations false positive rates are acceptable. However, in low risk populations the positive predictive value of the screening test decreases and may not be acceptable. False-positive test results incur costs and can also cause psychological harm. Confirmatory testing reduces the false-positive rate but increases the cost.
- Regular screening may detect acute cases which would otherwise spontaneously resolve
- Detection of cases who may not yet be eligible for treatment may lead to frustration and anxiety.
- Detected cases may suffer from stigmatisation.
- Opportunity cost. Diversion of resource from other risk groups where greater support is needed for testing and linkage to care. Increase operating cost of STI clinics which are already stretched

6.2. What are the likely resource implications and how large are the resource requirements? Consider cost effectiveness, financial, human and other resource implications

Not expected to have resource implications as recommendations do not differ significantly from current practice.

6.3. Acceptability – Is the intervention/ option acceptable to key stakeholders?

Likely to be acceptable

6.4. Feasibility - Is the intervention/action implementable in the Irish context?

No difficulties expected as not differing from current practice.

6.5. What would be the impact on health equity?

The principle of proportionate universalism[1] should underpin the recommendations and the implementation of the guideline in order to have a positive impact on health equity.

7. What is the value judgement? How certain is the relative importance of the desirable and undesirable outcomes? Are the desirable effects larger relative to undesirable

[1] Proportionate universalism is the resourcing and delivering of universal services at a scale and intensity proportionate to the degree of need.
http://www.healthscotland.com/documents/24296.aspx

The risk of sexual transmission of hepatitis C is generally low amongst heterosexuals and there is limited evidence on particular high risk behaviours which increase the risk. A sexual health screen is an opportunity to screen those with other identified risk factors for hepatitis C infection.

8. Final Recommendations

□ Strong recommenda□on
√ Conditional/ weak recommendation

Text:
Hepatitis C testing should be considered part of routine sexual health screening in the following circumstances:

- MSM
- People who are HIV positive
- Commercial sex workers
- History of IDU
- Female partners of MSM
- If indicated by the clinical history e.g unexplained jaundice
- When other risk factors for hepatitis C as outlined in this guideline are present

9. Justification

The risk of sexual transmission of hepatitis C is generally low amongst heterosexuals and there is limited evidence on particular high risk behaviours which increase the risk. A sexual health screen is an opportunity to screen those with other identified risk factors for hepatitis C infection.

10. Implementation considerations

11. Recommendations for research
List any aspects of the question that have not been answered and should therefore be highlighted as an area in need of further research.

Review by GDG

Date: 23/02/2017

The group questioned the rationale behind screening female partners of MSM. If the risk of heterosexual sexual transmission is low than the risk of sexual transmission to female partners of MSM should not be any different to the risk to sexual partners of cases with other modes of acquisition. The rationale may be related to the increased likelihood of coinfection with other ulcerative STIs in MSM which may increase the risk of transmission to a female partner.

The rationale for screening of commercial sex workers was also discussed. This is mainly due to the high rate of IDU amongst sex workers.

Recommendation amended.

Consultation feedback and review by GDG

Please see *Report of the consultation process* for feedback received.

No material change to recommendation.

Final recommendation

Recommendation 15

See Recommendation 14 for MSM attending for sexual health screening.

15.1. HCV testing should be considered part of routine sexual health screening in the following circumstances:

- People who are HIV positive
- Commercial sex workers
- PWID
- If indicated by the clinical history e.g. unexplained jaundice
- When other risk factors for HCV as outlined in this guideline are present*

*See Appendix 1 for a list of risk populations.

Quality/level of evidence: low

Strength of recommendation: conditional/weak

References List

1. Workowski KA, Bolan GA. Sexually transmitted diseases treatment guidelines, 2015. MMWR Recomm Rep. 2015;64(Rr-03):1-137.
2. BASHH Clinical Effectiveness Group. 2014 BASHH CEG guidance on tests for Sexually Transmitted Infections
British Association of Sexual Health and HIV; 2014.
3. National Institute for Health and Care Excellence. Hepatitis B and C: ways to promote and offer testing to people at increased risk of infection. NICE Public Health Guidance 43. NICE; 2012. Available from: https://www.nice.org.uk/guidance/ph43.
4. Scottish Intercollegiate Guidelines Network. Management of hepatitis C; A national clinical guidance. Edinburgh: SIGN; 2013. Available from: http://www.sign.ac.uk/assets/sign133.pdf.
5. British Association of Sexual Health and HIV. Sexually transmitted infections: UK national screening and testing guidelines. BASHH; 2006. Available from: https://www.bashh.org/documents/59/59.pdf.
6. Stein K, Dalziel K, Walker A, Jenkins B, Round A, Royle P. Screening for hepatitis C in genito-urinary medicine clinics: a cost utility analysis. J Hepatol. 2003;39(5):814-25.
7. Honeycutt AA, Harris JL, Khavjou O, Buffington J, Jones TS, Rein DB. The costs and impacts of testing for hepatitis C virus antibody in public STD clinics. Public Health Rep. 2007;122 Suppl 2:55-62.

Appendices

Evidence search and results

International and national guidelines

HCV guidelines identified, reviewed, and quality appraised as described in the National Clinical Guideline.

Grey literature

Nil used.

Primary literature

As for recommendation 13.