

Hepatitis C Screening Guideline Development Group Background to recommendation 7 and 8: Prisoners

The purpose of this document is to provide the background information to the formulation of recommendations by the Guideline Development group.

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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History of development of the recommendation

Date	Process	Outcome
02/06/2015	Recommendations from quality appraised national and international guidelines reviewed	Agreed to adopt/ adapt recommendations
20/12/2016	GDG subgroup meeting to undertake considered judgement process	Formulation of recommendation
24/01/2017	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: 20 December 2016

Attendees: Margaret Bourke, Austin O'Carroll, Lar Murphy, Ursula Norton (by phone), Sinead Donohue, Eve Robinson, Lelia Thornton

Table 1: Considered judgement form

1. What is the question being addressed? Present PICO if relevant
<p>Q2. Who should be offered screening for Hepatitis C? b. Should the following specified groups be offered screening? <u>ii. Prisoners</u></p>
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)
Relevant guidelines – quality appraised (Section 3)
3. What is the body of evidence?
<p>Source of evidence: (tick all that apply) Guidelines ✓ Primary literature Other ✓ ; specify: Cost effectiveness literature; Irish literature</p>
<p>Current Guidelines</p> <p>WHO, 2017 In all epidemic settings, it is recommended ...(that screening) ...be offered with linkage to prevention, care and treatment service to the following individuals: Adults and adolescents from populations most affected by HCV infection (ie. who are either part of a population with high HCV seroprevalence or who have a history of HCV risk exposure and/or behaviour). This includes PWID (strong recommendation, low quality of evidence) (WHO 2017 Guidelines on hepatitis B and C testing (1))</p> <p>WHO, 2016 It is recommended that HCV serology testing be offered to individuals who are part of a population with high HCV seroprevalence or who have a history of HCV risk exposure / behaviour including prisoners and previously incarcerated persons. (WHO Guidelines for the screening, care and treatment of persons with hepatitis C infection (2), <i>HIQA quality score 148</i>)</p> <p>NICE, 2013 Prisoners, including young offenders, should be offered screening for HCV. All prisoners and immigration detainees are offered access to confidential testing for hepatitis B and C when entering prison or an immigration removal centre and during their detention. (National Institute for Health and Care Excellence, Hepatitis B and C: Ways to Promote and Offer Testing to People at Increased Risk of Infection (3) <i>HIQA Quality Score 148</i>)</p> <p>AASLD, 2016 One-time testing should be performed for all persons with behaviours, exposures, and conditions associated with an increased risk of HCV infection: this includes persons who were ever incarcerated.</p>

<p>(American Association for the Study of Liver Diseases, Recommendations for Testing, Managing, and Treating Hepatitis C (4) <i>HIQA Quality Score 134.5</i>)</p> <p>US Preventive Services Taskforce, 2013 All persons who have ever been incarcerated should be offered screening for HCV. (United States Preventive Services Taskforce, Screening for Hepatitis C Virus Infection in Adults (5) <i>HIQA Quality Score 117</i>)</p> <p>BASHH, 2015 Ex-prisoners should be tested for HCV. (British Association for Sexual Health and HIV, United Kingdom. National Guideline on the Management of the Viral Hepatitides A, B & C 2015 (6) <i>HIQA Quality Score 97</i>)</p> <p>IUSTI/WHO Euro, 2010 Other groups to be considered for HCV testing include ex-prisoners. (International Union Against Sexually Transmitted Infections/WHO Europe. European Guideline for the Management of Hepatitis B and C Virus Infections (7) <i>HIQA Quality Score 66.3</i>)</p>
<p>4. What is the quality of the evidence? To be considered if primary literature was reviewed (also apply where appropriate to guidelines)</p>
<p>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.</p>
<p>A number of high quality guidelines addressed this question</p>
<p>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</p>
<p>Current guidelines are consistent in recommending that prisoners be offered screening for HCV. Many guidelines also recommend screening for HCV for ex-prisoners. The optimum time during incarceration for testing is not addressed by most guidelines. One guideline recommends screening on entry. The frequency of testing is not addressed in the guidelines.</p>
<p>4.3. Generalisability . are the patients in the studies similar to our target population for this guideline? is it reasonable to generalise</p>
<p>Yes, the prison population covered in these guidelines are considered similar to the prison population in Ireland.</p>
<p>4.4. Applicability - Is the evidence applicable to Ireland? Is the intervention/ action implementable in Ireland?</p>
<p>The recommendations of current guidelines are applicable to the Irish prison population.</p>

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
Not relevant
5. Additional information for consideration
5.1. Additional literature if applicable e.g. Irish literature
<p>Allwright et al carried out a cross-sectional study in 1998 of prisoners in high and medium risk prisons in Ireland (8). The 88% study response rate represented 45% of the total Irish prison population at that time. Forty three per cent of respondents reported ever injecting drugs. A total of 1,193 oral fluid samples were tested for antibodies to HCV (modified Ortho HCV 3.0 SAvE ELISA) and a prevalence of 37% (95% CI 34.3-39.9%) was found in total. The prevalence in those who reported IDU was 81%. Amongst those prisoners who reported not injecting drugs the anti-HCV prevalence was 4%.</p> <p>Allwright et al also reported that a fifth (104) of 501 injecting drug users reported first injecting in prison, and 347 (71%) users reported sharing needles in prison. However, self-reporting of hepatitis status was found to be unreliable - 5% of those who reported being hepatitis C positive tested negative on oral fluid assay, and 37% who reported a previous negative hepatitis C test had a positive anti-HCV result on oral fluid assay (9).</p> <p>Long et al carried out a cross-sectional study in 1999 of prisoners entering the Irish prison system (prisoners committed within the previous 48 hours) (10). The 97% study response rate represented 85% of the total population committed to the prison system within the study period and 6% of the estimated annual number of committals. Twenty nine per cent of respondents reported ever injecting drugs. A total of 596 oral fluid samples were tested for antibodies to HCV (modified Ortho HCV 3.0 SAvE ELISA) and a prevalence of 22% (95% CI 18.6-25.4%) was found. The prevalence was significantly lower ($p < 0.0001$) in respondents who had never been in prison before.</p> <p>Drummond et al carried out a cross-sectional study in 2011 targeting a random sample of all inmates (sentenced and remand) in prison in the Republic of Ireland (11). Eight hundred and twenty four (824) prisoners took part in the study, giving an overall response rate of 49.5%, with response rates in the different participating prisons ranging from 33.3% to 100%. Twenty six per cent of respondents reported ever injecting drugs. A total of 777 oral fluid samples were tested for antibodies to HCV (modified Ortho HCV 3.0 ELISA) and a prevalence of 13% (95% CI 10.9-15.2%) was found. Among those with a history of injecting drug use, 41.5% were anti-HCV positive. Prisoners' self-reported HCV status was lower at 8.6%. Ninety five per cent of those who self-reported that they were positive had a positive oral fluid sample test result and 91% of those who self-reported that they were negative had a negative test result. Two prisoners who did not know their status tested positive.</p>
5.2. Relevant national policy / strategy / practice
<p>National HCV Strategy Ireland, 2011 (12) (HIQA quality score 98) Recommendation 24 of the National HCV Strategy recommends that every prisoner on committal is provided with a hepatitis C risk assessment, including details of previous virological tests, and offered screening for blood-borne viruses, including hepatitis C, if required.</p> <p>Irish Prison Service Health Care Standards, 2011 (13) In view of the long-standing association between I/V drug use, infection with communicable diseases (in particular Hepatitis B,C, and HIV), and criminality with the risk of incarceration it has been long-standing healthcare policy and practice to regard the prison population as being at high risk for such</p>

conditions. In view of the requirement on healthcare staff to do all possible to safeguard the health of those in their care appropriate screening, immunisation, and referral to specialist services has been undertaken over a considerable time.

In this context it is recommended that all persons entering prison who volunteer a background history with risk factors for any infectious disease should be offered any available screening for that condition.

Health Care Standard 6: Hepatitis C

Hepatitis C testing will be offered where clinically appropriate. Testing will be undertaken only when requested by a prisoner or where, following consultation, a prisoner gives informed consent to a test on the clinical recommendation of the doctor involved

Current practice in relation to this policy:

On committal, entrants attend a standard healthcare interview with a nurse. At this they are asked about previous hepatitis C testing and risk factors for infection. They are still offered screening even if they report no risk factors, however it is acknowledged that those who report a risk factor are likely to receive more encouragement towards testing. They are also reviewed by a GP within 24 hours of committal. There is no arrangement for repeat testing for prisoners who continue to engage in risk behaviours while in prison.

Uptake data is not available. However, while uptake is reported to have improved it is still reported to be low. The appointment of nursing unit managers has improved uptake.

When a prisoner agrees to be screened they are then entered onto the waiting list for phlebotomy.

Currently there is no arrangement for offering HCV testing for ex-prisoners in Ireland.

5.3. Epidemiology in Ireland if available and applicable

See section 5.1

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
- There is a potential for transmission within prisons. Identification of cases early in sentence may reduce the risk of transmission to others through education of the infected person. Linkage to care and treatment will also reduce risk of transmission
- While in prison, it may be a reasonably stable period for the prisoner, thus providing an opportunity to treat people who would otherwise not avail of or be retained in treatment

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.

- Detection of cases who may not yet be eligible for treatment, or who cannot access care while in prison may lead to frustration and anxiety.
- Opportunity cost. Prisoners can suffer from many other health problems which also may need resources to adequately address.
- May lead to stigma within the prison setting
- Confidentiality may be difficult to maintain in the prison setting
- A prisoner may be released from prison before the test result is received and in the absence of any arrangement for follow-up or continuity of care

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

Cost effectiveness literature

Three studies of screening in the prison setting were identified. All studies were UK based.

Castelnuovo et al examined the impact of two different case finding strategies in the prison setting (14). In one strategy new entrants received a general lecture on BBVs during induction. Prisoners were then offered an opportunity to make an appointment for individual discussion and confidential testing. It was assumed that 8.5% would be tested with 16% of these testing anti-HCV positive. This strategy had an ICER of £20,083. In the second scenario the lecture focused on intravenous drug use as a risk factor for HCV. Here it was assumed that 12% would be tested and 42% of these would be anti-HCV positive. The ICER in this scenario was £16,484.

Martin et al performed a cost utility analysis of introducing dried blood spot (DBS) testing for current or former PWID in the prison setting (15). They assumed a 2.6 fold increase in the uptake of testing with the availability of DBS testing. They estimated an ICER of £59,400 per QALY gained. DBS testing in prison was not cost effective without continuity of treatment between prison and the community. If continuity of care of >40% was ensured, the ICER would fall to below £20,000.

Sutton et al (2006) compared the cost per chronic case detected of a range of testing scenarios based on verbal screening (16). They found that testing based on a negative response to verbal screen on having a past positive test, and positive response to a verbal screen on ever having injected illicit drugs was the most cost effective strategy with an incremental cost of £2,102 per chronic case detected. The verbal screen based on ever having injected illicit drugs had in an incremental cost of £16,625, while no verbal screening had an incremental cost of £6,338. Offering screening based on a negative response to a verbal question on past positive test was dominated.

Sutton et al (2008) determined that offering screening to all prisoners at reception was not cost effective with an ICER of £54,852 per QALY gained (17).

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

In general, discussion and the offer of screening is considered likely to be acceptable to prisoners. It was noted that sometimes a prison officer will be present during the consultation and the prisoner may not disclose risk factors or accept or request testing due to this.

Committal to prison is a stressful time for a prisoner, who may have many other concerns. Hepatitis C screening may not be a priority at that time. It may be more acceptable to offer at a different time.

In general, screening is likely to be acceptable to prison health staff, particularly those who have designated responsibility for health assessment of prisoners. The balance between ensuring privacy and confidentiality on the one hand, versus ensuring safety and security on the other hand, may impact on acceptability in some situations.

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

Given the current low uptake of HCV screening, successful implementation of a recommendation to offer HCV screening to all prisoners would require additional support and resources. Timing is considered to be a barrier to the initial uptake of screening at present. Alternative approaches to offering screening may be needed to improve uptake. Repeat testing of those who initially test negative will require additional mechanisms. Prison health services have limited healthcare staffing. It is not likely to be feasible for the prison health service to implement these recommendations without additional resourcing.

If ex-prisoners are to be offered one time screening for HCV this may be logistically difficult to implement as they are likely to be a hard-to-reach group.

There are likely to be difficulties in relation to HCV results which are not available until after the prisoner has left prison, unless a clear pathway for continuity of care has been established. There will be difficulties for those who do not have a designated GP, and particularly for homeless people. If the ex-prisoner is attending the addiction services or psychiatric clinic, linkage to care through these services may be an option.

6.5. What would be the impact on health equity?

If the principle of proportionate universalism¹ underpins the implementation of the recommendations then there will be a positive impact on health equity.

In general, prisoners are from marginalised groups who are otherwise poorly reached by healthcare services. Their time in prison may offer a unique opportunity for the diagnosis, assessment and treatment of hepatitis C infection.

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

Recent advances in treatment options for hepatitis C make treatment more acceptable and more successful. Treatment with the new DAAs which are now available results in cure in the majority of patients with shorter duration of treatment and less side effects than previous treatments. However at present the cost of these treatments is high.

Screening enables early detection, referral for assessment and treatment where indicated. Without

¹ Proportionate universalism is the resourcing and delivering of universal services at a scale and intensity proportionate to the degree of need.

screening cases may go undetected for a considerable length of time due to the asymptomatic nature of HCV infection. Individuals often do not present until symptomatic, which is usually indicative of severe liver damage. Early treatment and cure will confer personal, social, and economic benefits. Early treatment and cure will also reduce the risk of transmission to others. A treatment programme exists in Ireland allowing detected cases access treatment.

The benefit of detecting and treating cases while in prison is considered important as this population may be difficult to reach otherwise.

Detection of cases early in a sentence is considered very important to minimise transmission within the prison setting.

Also, for those initially testing HCV negative, there is a recognised transmission risk within prisons and repeat testing is considered important.

8. Final Recommendations

Strong recommendation

Conditional/ weak recommendation

Text:

- Screening should be offered to all prisoners on entry to prison. Screening should be offered at a time at which it is most likely to be accepted by the prisoner, but also minimising the risk of transmission to others by delaying identification of infections.
- Those found to have infection should be linked into specialist care and treatment facilitated
- Prisoners who initial test HCV negative should be offered annual / six monthly repeat screening while in prison. Screening should also be offered at any time if a risk exposure (e.g. tattooing, needle-sharing) is known to have occurred.
- Prisoners should be able to easily access testing on request at any stage of their sentence.
- One-off testing of ex-prisoners is recommended, although implementation may be difficult.

Good practice points:

- Education on the risk of hepatitis C should be provided upon entry into prison
- At the time of committal, the interviewing nurse or GP is best placed to identify the optimal time to carry out HCV screening on an individual prisoner.
- Continuity of care and/or treatment on discharge or entry to prison should be ensured. This should be considered as part of discharge planning.
- Communication between the prison health services and the prisoner's GP, or other services attended by the prisoner such as Addiction Services or psychiatric services, about test results or treatment should occur.
- Confidentiality at the time of screening offer and results should be ensured as far as possible while still ensuring a safe environment for healthcare staff

9. Justification

There is a high prevalence of current or past drug use amongst the prisoner population, and prevalence of hepatitis C amongst prisoners in Ireland has been shown to be high. Also transmission can occur in prison through various mechanisms. Screening should be undertaken early during committal to enable an opportunity to link into care, and to minimise the risk of transmission to others within the prison setting.

10. Implementation considerations

Uptake of screening is currently low and initiatives to improve this are needed. Adequate resourcing of prison health services is needed.

Implementation would be facilitated by the availability of a designated nurse within each IPS complex, and regional nurses within the stand alone prisons, to systematically screen, follow up, record results and refer for assessment and treatment.

Peer support within prisons may help. The Irish Red Cross prison programme provides peer-led education and promotion of health, including uptake of screening: <https://www.redcross.ie/CBHFA>.

Availability of different test types such as DBS may improve uptake.

Screening of former prisoners may be difficult to implement. The probation services may be able to facilitate this. The Irish Red Cross is commencing a peer support group for former prisoners which may be an avenue for education and promotion of HCV screening.

Subgroup members suggested that it would be beneficial to have a computerised system by which both prison health staff and GPs or addiction services could more easily check previous testing history, given the discrepancy known to exist between self-reported status and actual status.

At present hepatology inreach clinics are taking place in some prisons. This will facilitate implementation.

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.

It is recommended that HCV screening uptake rates and linkage to care be monitored.

Research is recommended into successful initiatives to improve uptake of screening and attendance at specialist care.

New initiatives to improve uptake should be evaluated.

Review by GDG

Date: 24/01/2017

It was suggested that the interval between repeat testing should be shorter than the proposed 12 months. The recommendation is to be amended to reflect this. Otherwise the recommendation was accepted as proposed.

Consultation feedback and review by GDG

Please see [Report of the consultation process](#) for feedback received.

No material change to recommendation.

Final recommendation

Recommendation 5

- 5.1. All those who have ever injected unprescribed or illicit drugs should be offered screening for HCV. This includes those who only injected once, and those who injected any type of drug which was not prescribed, including performance enhancing drugs like steroids, and novel psychoactive substances.
- 5.2. Re-testing of those who test HCV negative should be offered on an annual basis, or six monthly if deemed clinically appropriate*, for those who remain at ongoing risk of infection.
- 5.3. Testing should be available during this interval if a risk exposure is known to have occurred.
- 5.4. Re-testing for those who have been previously infected, but have cleared infection spontaneously or through treatment, should be done by HCV-RNA testing, as anti-HCV antibody remains positive after the first infection.

*More frequent testing may be considered in circumstances such as: if a risk exposure is known to have occurred; an unexplained rise in alanine aminotransferase (ALT); a diagnosis of another bloodborne virus (BBV).

Quality/level of evidence: high; good consistency between existing high quality guidelines

Strength of recommendation: strong

Recommendation 6

- 6.1. Screening should be offered to all those who have used unprescribed or illicit drugs by a route other than injecting (i.e. non-injecting drug use (NIDU)), if there is a possibility of transmission of HCV by the route of administration. This includes those who 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 (e.g. smoking crack pipes).

Quality/level of evidence: low

Strength of recommendation: strong

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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

The following grey literature identified by expert members of the GDG was included for review:

- Irish Prison Healthcare Standards
- Study on the prevalence of drug use, including intravenous drug use, and blood-borne viruses among the Irish prisoner population

Primary literature

Literature on HCV in prisons identified by expert members of the GDG was included for review.