

## Budget Impact Analysis

### National Clinical Guideline - Hepatitis C Screening

July 2017

#### **Purpose of this document**

This document outlines the budget impact analysis undertaken as part of the development of the National Clinical 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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## Background

Hepatitis C virus (HCV) was first identified in 1989 and is a major cause of liver disease worldwide. Transmission occurs through contact with blood of an infected person. Acute infection is asymptomatic in most people. About 55-85% of those infected will become chronically infected. Chronic infection can lead to cirrhosis, liver cancer, liver failure and death, typically occurring several decades after infection (1).

The major risk group for HCV infection in Ireland is people who inject drugs (PWID) (2). Other groups with increased prevalence of infection include people born in an endemic country and those who received unscreened blood or blood products in the past. Less commonly, HCV may be transmitted from an infected mother to her baby, and through sexual exposure, typically in HIV infected men who have sex with men (MSM).

There have been major advances in the treatment of HCV infection in the past few years. The new direct acting antivirals (DAAs) can cure infection in over 90% of cases (3). In 2016 HSE established the National Hepatitis C Treatment Programme (HSE NHCTP) to implement a multi-annual DAA treatment plan based on clinical prioritisation. Diagnosis of infection is the first step in linking to care and treatment. However, it is likely that a large proportion of those with chronic infection are unaware of their infection status as it can take many years for symptoms to develop.

The burden of undiagnosed HCV infection in Ireland is unknown. It is estimated that 20,000 to 42,000 people in Ireland are chronically infected with HCV with approximately 60% not yet diagnosed (4, 5). Screening for HCV is essential in identifying those who may benefit from care and treatment.

Screening for HCV in Ireland is currently undertaken in several different settings and services. However, to date there has been no comprehensive national screening guideline to guide which population groups should be offered testing, and how it should be done.

The new National Clinical Guideline on Hepatitis C Screening makes recommendations on the specific population groups to whom HCV testing should be offered, the frequency with which testing should be offered, the specimen and test method to be used, the setting for testing and the suggested approach to encourage uptake of screening and linkage to care.

This budget impact analysis (BIA) considers the additional resources that will be required to implement the recommendations outlined in the National Clinical Guideline. Many of the recommendations are budget neutral as they mainly involve specifying and standardising practices that are largely already in place. However, there are some anticipated additional resource requirements in order for some of the recommendations to be implemented.

Four key types of additional resources have been identified:

1. Additional testing
  - a. Extra HCV testing, through both improved coverage of population groups for whom screening was previously recommended, increased frequency of testing for some population groups for whom screening was previously recommended, and screening of

population groups for whom screening was not previously recommended. The resource implications of this extra testing include staff time, consumables and laboratory costs.

2. Additional services to enable risk groups access testing.
3. Communicable disease nurse in the Department of Public Health in the greater Dublin area to undertake risk assessments for contacts of identified cases.
4. Information and promotion
  - a. Amongst health professionals.
  - b. Amongst the public.
    - i. A public information campaign among the general population.
    - ii. Specific information campaigns targeting individual risk populations.

## Methodology

The recommendations having a resource impact were considered and then the additional resources quantified under the type of resource. Potential cost savings were also be described. Finally, the additional resources required for all recommendations were combined and costed. A five year time horizon was taken, with annual costs over the five year period estimated.

## Limitations

Of note, there are a number of significant limitations to the BIA which should be kept in mind. One of the main limitations is in estimating the number of additional tests which will result from the guideline implementation. The change in resource use due to additional testing is difficult to estimate for a number of the recommendations. The size of the eligible population is not known for certain risk groups, the number of undiagnosed cases within certain populations is not known, and the amount of screening currently taking place within certain risk groups is not known. The amount of additional testing will also depend on the uptake of screening, which is not known. An attempt has been made, in consultation with key stakeholders working in the relevant areas, to estimate the amount of additional testing by risk group. However, some estimates are still very uncertain. Such estimates are in italics and shaded (*like this*) to highlight the uncertainty around them.

There will also be overlap between risk groups (i.e. a number of people will fall into multiple risk groups). It is not possible to quantify this, and therefore the estimated number of additional tests may be an overestimate.

There will be variability in how screening is implemented for different risk groups and in different settings, which will result in different costs. It is not possible to take into account all of these variations within the scope of this BIA.

## Budget impact

### Recommendations with a resource impact

Table 1 summarises the estimated resource change for each recommendation.

**Table 1: Change in resources for each recommendation.**

<b>Recommendation</b>	<b>Change in resources</b>	<b>Annual budget impact</b>
<b>Recommendation 1 Women who are pregnant</b>		
<p>1.1. Standardised targeted risk based HCV screening of antenatal women is recommended.</p> <p>1.2. Universal HCV screening of antenatal women is not recommended.</p> <p>1.3. Universal antenatal HCV screening may be reconsidered in the future if HCV treatment during pregnancy becomes possible. Also, if national policy progresses to to a policy of birth cohort or total population screening, antenatal screening offers an opportunistic method to reach this particular population cohort.</p>	<p>There will be no change in the majority of maternity units. The standardisation of criteria for screening may result in an increased number of tests. One large Dublin maternity hospital (&gt;8,000 births per year) currently offers universal HCV testing to all women. Therefore, if this unit changes to targeted screening, there may be a net decrease in the number of tests in the antenatal population.</p> <p>Information and promotional material.</p>	See later for information and promotional material.
<b>Recommendation 2 Children born to mothers with HCV infection</b>		
<p>2.1. Infants of HCV-RNA positive women should have HCV-RNA checked at six weeks and six months of age and, if both are negative, HCV anti-HCV at ≥18 months of age.</p> <p>2.2. Infants who are HCV-RNA positive at any time, or who are anti-HCV positive at or after 18 months of age should be referred to the Rainbow Clinic.</p> <p>2.3. Infants of anti-HCV positive but HCV-RNA negative women, where eradication of infection, either spontaneously or by treatment is not assured (i.e. by serial negative HCV-RNA tests) should be tested for anti-HCV at ≥18 months of age.</p> <p>2.4. Infants of anti-HCV positive but HCV-RNA negative women where eradication of infection, spontaneously or by treatment is assured (i.e. persistent negative HCV-RNA tests and no ongoing risk for reinfection), should be managed as infants of uninfected women and do not require HCV follow-up.</p>	<p>Nil additional resources anticipated as current practice (6).</p> <p>Information leaflets for parents explaining follow-up.</p>	See later for information and promotional material.
<b>Recommendation 3</b>		
<p>3.1. If a woman is found to have current or resolved HCV infection, any previous children she has given birth to should be tested for HCV, unless the woman was known to be HCV-RNA negative at the time of their delivery.</p>	<p>Unlikely to result in substantial numbers of additional tests.</p>	Nil
<b>Recommendation 4 Household contacts of a person with HCV infection</b>		
<p>4.1. In general screening of household contacts (with no sexual or vertical exposure to HCV positive household member) is not necessary due to the low risk of horizontal household transmission. However, there may be circumstances where household transmission is more likely to have occurred. Screening may be considered based on clinical judgement or a risk assessment for factors such as: HIV co-infection or high HCV viral load in HCV positive household member; a history of current injecting drug use in HCV positive household</p>	<p>May result in some additional testing. The number of those eligible for screening or who will present for screening is not known.</p> <p><i>if 10% of PWID cases which are notified per year were assessed to be at higher risk of transmitting infection to their household contacts, and each of these has two household contacts which present for testing an estimated 100 additional tests would be carried out each year (75% of 660 notifications in 2016 were amongst PWID=495 (source:</i></p>	<p>100X€55.12 = <b>€5,512</b></p>

<p>member; if there has been a potential exposure to blood of the HCV positive household member e.g. sharing razors; if the HCV positive household member is on dialysis in the home; if there are environmental risks within the household such as discarded needles.</p> <p>4.2. Where a household contact requests testing for reassurance, this should not be denied.</p>	<p><i>Computerised Infectious Disease Reporting system (CIDR), Health Protection Surveillance Centre (HSE HPSC)); 10% of these=50; 50 x 2 household contacts=100).</i></p> <p>Additional staff in Departments of Public Health to carry out risk assessment and follow up contacts. As the majority of cases occur in HSE East this resource should be placed in HSE East.</p> <p>Information and promotional material</p>	<p>0.5 WTE communicable disease control nurse = €33,897/year based on general nurse CNM 2, point 1 salary scale including PRSI, pension and overheads.</p> <p>See later for information and promotional material.</p>
<b>Recommendation 5 People who use unprescribed or illicit drugs</b>		
<p>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.</p> <p>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.</p> <p>5.3. Testing should be available during this interval if a risk exposure is known to have occurred.</p> <p>5.4. Re-testing for those who have been previously infected, but have cleared infection spontaneously or through treatment, should be by HCV-RNA testing, as anti-HCV antibody remains positive after the first infection.</p>	<p>Current practice for those attending addiction services (7, 8). There may be some additional testing among people who use illicit drugs but do not attend addiction treatment centres and those who may have used illicit drugs in the past.</p> <p><i>It has been estimated that between 1991 and 2014, approximately 2,062 PWID never attended drug treatment (9). If 50% of these presented for screening over 5 years then an additional 1,000 tests would be carried out, or 200/year.</i></p> <p>Repeat testing for those at ongoing risk is currently recommended within addiction services but it is not known to what extent it is implemented so it is possible that this recommendation may result in some increase in the level of testing.</p> <p><i>Approximately 10,000 attend addiction treatment services (Personal communication Eamon Keenan, HSE Addiction Services). An estimated one third of these are anti-HCV negative and should be re-tested annually if still risk-taking. It is estimated that 50% of these may still be engaging in risk taking behaviour (n=1,650). If re-testing is currently being carried out in only 50% of these, then implementation of the guidelines would result in an additional 825 tests per year.</i></p>	<p>1,025X€55.12 = €56,498</p>
<b>Recommendation 6</b>		
<p>6.1. Screening should be offered to all those who have used unprescribed or illicit drugs by a route other than injecting, 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.</p>	<p>This is current practice for those attending addiction services. There may be some additional testing among people who do not attend addiction treatment centres and those who may have used illicit drugs in the past. The number of people who will be eligible for screening or who will present for screening is not known.</p> <p><i>The National Advisory Committee on Drugs and Alcohol (NACDA) 2016 drug prevalence study reports on the lifetime prevalence of different drugs in the adult population (10). While it doesn't</i></p>	<p>2,000X€55.12 = €110,240</p>

	<p>report on route of administration, the non IDU drug with the highest prevalence, which also has a biologically plausible transmission potential for HCV, was cocaine with a lifetime prevalence of 6.6%. Applying age specific prevalence of use to 2016 Census data, it can be estimated that 226,935 persons have used cocaine in their lifetime.</p> <p>Between 2004 and 2014 there were approximately 7,000 new entrants to drug treatment services where cocaine was the main problem drug. Of note polydrug use is common in Ireland. If it is assumed that the majority of PWID are also included in this prevalence estimate, then excluding PWID and those who have entered treatment for cocaine results in approximately 200,000 being eligible for screening. This is likely an overestimate as a number may have attended addiction services with other drug problems and have been tested. If 5% of the 200,000 present for screening over 5 years then 10,000 additional tests would be performed, or approximately <b>2,000 per year</b>.</p>	
<b>Recommendation 7 Prisoners or former prisoners</b>		
<p>7.1. Screening for HCV 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, while also ensuring the early identification of infections in order to minimise the risk of transmission to others.</p> <p>7.2. Those found to have HCV infection should be linked into specialist care and treatment should be facilitated while in prison.</p> <p>7.3. Prisoners who initially test HCV negative should be offered repeat testing on an annual basis, or six monthly if deemed clinically appropriate, 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.</p> <p>7.4. Prisoners should be able to easily access testing on request at any stage of their sentence.</p>	<p>Additional testing. The exact number of additional tests is not known.</p> <p>It is estimated that current uptake of screening is 5%-10% (Personal communication Ursula Norton, Irish Prison Service). This equates to 650-1,300 of the approximately 13,000 people committed to prison each year being tested currently.</p> <p><i>If 80% of prisoners with a history of IDU were tested on committal, and 20% of those without a history of IDU were tested, this would result in approximately <b>2,470-3,120 additional tests per year</b>. These figures are based on the following:</i></p> <p><i>15% have a history of IDU: 1,950 x 80% = 1,560</i></p> <p><i>85% without a history of IDU: 11,050 x 20% = 2,210</i></p> <p><i>(26% in 2011 prison study had a history of IDU (11), however the proportion of committals having a history of IDU is likely to be lower given that, in 2015, 9,883 committals were for the non-payment of court ordered fines (12).</i></p> <p>Information and promotional material.</p>	<p>3,120x€55.12 = <b>€171,974</b></p> <p>See later for information and promotional material.</p>
<b>Recommendation 8</b>		
<p>8.1. One-off testing of ex-prisoners should be considered, although implementation may be difficult.</p>	<p>The size of this population is unknown, but the expected number of additional tests is expected to be low. It is likely that many will already have been tested through the prison service or through other services such as addiction services.</p> <p>The rate of reoffending, or recidivism, for prisoners released in 2010 was 45.1% (defined as an individual committing a criminal offence within a three year period following their release from prison and being subsequently convicted for that offence) (13), thus some will be offered testing in the future on committal to prison.</p>	<p>Nil</p>
<b>Recommendation 9 People who are homeless</b>		
<p>9.1. Homeless people who have a history of engaging in risk behaviours associated with HCV transmission, or who have had a potential HCV risk exposure, should be offered screening.</p> <p>9.2. Those who initially test HCV negative should be offered repeat testing on an annual basis, or six</p>	<p>Implementation of the guideline may result in additional testing. The exact number of additional tests is not known. It is estimated that the majority of at risk people in homeless hostels and emergency accommodation in Dublin are offered screening for HCV currently as HCV testing is part of the usual</p>	<p>292x€55.12 = <b>€16,095</b></p>

<p>monthly if deemed clinically appropriate, if there is an ongoing risk of transmission.</p>	<p>health needs assessment in these services (Personal communication Joe Doyle, HSE Social Inclusion). Uptake is not known.</p> <p><i>In February 2017, the number of homeless adults in temporary emergency accommodation and supported temporary accommodation was 2,604 (14). If it is estimated that 50% are at risk of HCV infection (1,300) and current uptake of HCV testing is 60%, and raising awareness increases this to 80%, then an additional 260 tests would be carried out over 5 years on the existing cohort of homeless people, or <b>52 per year</b>. There are approximately 4,500 new presentations per year to homeless accommodation services (15) Assuming that 53% are to temporary emergency accommodation and supported temporary accommodation (2,400), and 50% are at risk of HCV infection (1,200) and current uptake of HCV testing is 60%, and raising awareness increases this to 80%, then an additional <b>240 tests</b> would be carried out per year on the new cohort of homeless people.</i></p> <p>In order to improve the availability and accessibility of screening for homeless people at risk of HCV infection, current services to homeless people (e.g. HSE services, SafetyNet and HepCare Europe) should continue to be supported and may need to be expanded.</p> <p>Information and promotional material.</p>	<p>See later for information and promotional material.</p>
<b>Recommendation 10 Migrants</b>		
<p>10.1. Migrants from a country with an intermediate to high prevalence of HCV (anti-HCV<math>\geq</math>2%) should be offered one-off HCV screening.</p>	<p>Although it has already been recommended that those from a country with a prevalence &gt;3% be offered testing it is not known and how many of these people have been tested. The guideline will result in additional testing.</p> <p><i>According to the 2011 census there were 164,820 residents in Ireland from countries with an anti-HCV prevalence greater than 2%. If 10% of these present for testing over five years, this would result in approximately <b>3,296 tests per year</b>.</i></p> <p><i>There will be new migrants each year to Ireland from high prevalence countries. Based on PRSI allocations, there were approximately 26,000 new entrants from countries with a prevalence of 2% or greater in 2016. This number will include children who are less likely to be at risk as in a number of countries the increased risk is due to historically poor infection prevention and control practices. If it is assumed that 60% are eligible for screening, and 10% of this present for screening then there could be an additional <b>1,560 tests per year</b>.</i></p> <p>Culturally appropriate information and promotional material</p>	<p><math>4,856 \times €55.12 =</math> <b>€267,663</b></p> <p>See later for information and promotional material.</p>
<b>Recommendation 11 People who received medical or dental treatment abroad</b>		

11.1. Screening for HCV should be considered in people who have received medical or dental treatment in countries where HCV is common (anti-HCV prevalence $\geq 2\%$ ) and where infection control may be poor.	There may be some additional testing but the numbers are likely to be low.  Information and promotional material.	See later for information and promotional material.
<b>Recommendation 12 People with tattoos or body piercings</b>		
12.1. Screening for HCV should be considered for all those with a tattoo. Those most at risk of having acquired HCV through tattooing are those who received tattoos a number of decades ago, in non-professional settings, in prison in high prevalence countries or in other circumstances where infection control was poor.  12.2. There is insufficient evidence to support screening of recipients of body piercings (including ear piercings).	The recommendation will result in additional number of people tested.  The number of people eligible for screening or who will present for screening is not known.  <i>If it is estimated that 20% of the adult population aged 20 to 50 years have a tattoo, and 60% of females have been tested as part of antenatal screening, and 10% of the remainder have been screened through other services, then approximately 253,265 persons would be eligible for screening. If 5% of these present for screening then 12,663 would be screened over five years, or 2,533 per year</i>  Information and promotional material.	2,533X€55.12 = <b>€139,619</b>  See later for information and promotional material
<b>Recommendation 13 Heterosexual partners of a person with HCV infection or a person at risk of HCV infection</b>		
13.1. In general, screening of sexual partners of known HCV cases is not recommended in heterosexual couples who are both HIV negative.  13.2. Sexual partners of known HCV cases should be considered for screening in the following situations: a) If the HCV infected case is a PWID. b) If the case or contact is also HIV positive.  13.3. Sexual contacts of PWID, but whose HCV status is unknown or where there is evidence of resolved infection, should be considered for screening.  13.4. If testing of a sexual partner of a HCV infected case is requested for reassurance, then this should not be denied.	Current practice and therefore any change in the number of those tested is likely to be small.  Where required, contact tracing could be undertaken by Departments of Public Health. The additional resources required are listed under Recommendation 4.  Information and promotional material	Costed under Recommendation 4.  See later for information and promotional material.
<b>Recommendation 14 Men who have sex with men</b>		
14.1. HIV positive MSM should be offered screening at least annually for HCV. More frequent testing may be required if clinically indicated e.g. an unexplained rise in ALT, a diagnosis of a new STI, or if a risk exposure has occurred such as contact with a known case of HCV, or other risk behaviours including chemsex.	Nil additional anticipated as current practice.	Nil
14.2. HIV negative MSM should be offered testing annually for HCV as part of an overall STI screen. More frequent testing may be required if clinically indicated eg. an unexplained rise in ALT, a diagnosis of a new STI, or if a risk exposure has occurred such a contact with a known case of HCV, or other risk behaviours including chemsex.	This may result in some additional testing as not current practice in all centres. However, as testing is only undertaken annually rather than at each visit as is being done in some high volume centres there would be a saving so there will not be a net increase in resources  Information and promotional material.	See later for information and promotional material
<b>Recommendation 15 People attending for a sexual health screen</b>		
15.1. HCV testing should be considered part of routine sexual health screening in the following circumstances: <ul style="list-style-type: none"><li>• People who are HIV positive</li><li>• Commercial sex workers</li><li>• PWID</li><li>• If indicated by the clinical history e.g. unexplained jaundice</li></ul>	Nil additional anticipated as current practice.	Nil



<ul style="list-style-type: none"> <li>When other risk factors for HCV as outlined in this guideline are present</li> </ul>		
<b>Recommendation 16 People on renal dialysis or who have had a kidney transplant</b>		
16.1. Patients commencing, or on maintenance, haemodialysis or peritoneal dialysis should be screened according to the current recommendations of the National Standing Advisory Committee on the Prevention of Transmission of Blood-Borne Diseases in the Health-Care Setting and any ensuing updates from this committee.	Nil additional anticipated as current practice (16).	Nil
16.2. All patients having a kidney transplant should be tested for HCV by a combined antigen-antibody test, or anti-HCV test AND HCV-RNA at three months post-transplant.	Although this is currently recommended, adherence to the existing recommendation is not known. This guideline may reinforce practice resulting in some additional testing. Between 2011 and 2015 the average annual number of kidney transplants was 169. If at present only 50% are tested post-transplant, and implementation of this guideline increases this to 100%, this would result in an additional <b>85 tests per year</b> . The laboratory costs are the only additional resources as these patients are already attending services and having regular blood samples taken.	85X€41 = <b>€3,485</b>
16.3. Patients transplanted before the introduction of the above, unless already known to be HCV positive, should be tested on a one-off basis by a combined antigen-antibody test, or anti-HCV test AND HCV-RNA to out rule the possible acquisition of HCV infection through past treatment for renal failure.	May result in some additional testing. The number eligible for testing and that will come forward is not known. <i>At the end of 2014 there were 2,300 recipients of kidney transplants alive. If it is estimated that 80% of the 1,149 people who had a transplant between 2008 and 2014 were still alive, then approximately 1,380 of the 2,300 alive in 2014 were transplanted before 2008 and the issuing of the recommendation on post-transplant screening. Also, if only half of those transplanted since 2008 had post-transplant screening then 460 of this group would require screening. In total there may be 1,840 eligible for screening under this recommendation. If 50% presented for screening over 5 years then 920 additional tests would be performed or approximately <b>184 per year</b>.</i>	184X€14 = <b>€2,576</b>
<b>Recommendation 17 Recipients of substances of human origin</b>		
17.1. Recipients of blood or blood components in Ireland prior to October 1991 who have not yet been tested should be offered screening. 17.2. All recipients of anti-D immunoglobulin in Ireland between 1st May 1977 and the end of July 1979, and 1st March 1991 to 18th February 1994 who have not yet been tested should be offered screening. 17.3. Recipients of plasma derived clotting factor concentrates in Ireland prior to 1992 who have not yet been tested should be offered screening.	Nil additional anticipated as the majority of those affected have already been screened. The number of any additional people coming forward for testing is likely to be very low.	Nil
17.4. Recipients of blood components and blood products overseas in any country where a quality assured blood donor screening programme may not have been in place should be offered screening.	May result in additional testing but the numbers are likely to be low.	Nil
<b>Recommendation 18</b>		
18.1. Screening for HCV should be considered in recipients of solid organ transplants in Ireland who have not yet been tested.	It is estimated that approximately 2,000 solid organ transplants other than kidney transplants have taken place in Ireland since 1964. Approximately 1,300 of these have been since 2010 when screening practices will have been adequate. Given the survival rates post-transplant in previous years, the number	Nil

	of historical transplant recipients from a time before screening was adequate who are still alive is likely to be low.	
<b>Recommendation 19 Donors of substances of human origin</b>		
19.1. Screening of donors of blood, organ, tissue and cells, including reproductive cells, should at a minimum comply with legislative requirements.	Nil additional anticipated as current practice.	Nil
19.2. Nucleic acid testing (NAT) for HCV-RNA of donors of blood should be performed and the results available prior to the use of the donation. The test must be designed and approved for screening of blood donations. 19.3. NAT for HCV-RNA of donors of tissues and cells, including reproductive cells, and living solid organ donors, should be performed in addition to current legislative requirements.	<u>Blood</u> Nil additional anticipated as current practice.  <u>Living organ donors</u> Anti-HCV/Antigen testing is current practice. NAT will be additional. Between 2012 and 2015 the average annual number of living solid organ donors was 34 (source: ODTI) . As this group is already having microbiological testing undertaken, the laboratory cost is the only additional resource.  <u>Other tissues and cells</u> It is not known if NAT is current practice in other services that process tissues and cells. Also the number of donors is not known. Donations within the fertility sector are likely to be the largest group.  Of note, most tissues and cells for use in Ireland, including reproductive cells are imported.	34X€55 = €1,870
19.4. For deceased donors of solid organs: 19.4.1. Anti-HCV and HCV-antigen testing should be done and the results available prior to donation. 19.4.2. NAT should be considered where feasible. NAT results may not be available prior to transplantation but NAT should still be performed to ensure the rapid identification of the recipients of potentially infectious organs.	Combined antigen-antibody testing is current practice. NAT will be additional. No additional staff time or consumables will be required as microbiological testing is already being undertaken for this cohort.  Between 2013 and 2015 the average annual number of deceased organ donors was 77 (source:ODTI).	77X €55 = €4,235
19.5. Any external laboratories used for microbiological screening of donors should be accredited and comply with the standards of the appropriate regulatory authority. Laboratories in Ireland should be accredited by the Irish National Accreditation Board (INAB) to undertake testing in compliance with the International Standard ISO 15189.	Current regulatory requirement. No additional resources required.	Nil
19.6. A national advisory committee on the safety of blood, organs and tissues should be established to advise on best practice in relation to donor selection, and testing of potential donors.	The resources required for this is not within the remit of implementation of this guideline.	Nil
<b>Recommendation 20 General population or birth cohort</b>		
20.1. Birth cohort screening cannot be recommended at present due to the likely substantial cost implications and uncertain benefit. Such a programme would require a full health technology assessment (HTA) and approval of funding prior to being considered. 20.2. Birth cohort screening should be considered if a HTA shows it to be cost effective and affordable in the Irish context.	No action at present pending a HTA	No action at present pending a HTA.
<b>Recommendation 21 Healthcare workers</b>		

21.1. All new healthcare workers (HCWs) should be offered HCV screening on a voluntary basis.	<p>Additional testing as it is not current practice to offer to HCW who will not perform exposure prone procedures (EPPs).</p> <p><i>There are approximately 16,000 new appointments to the HSE each year. However, a significant number of these will not be new employees. If it is estimated that half of new appointments are new employees, and half of these are healthcare workers, there would be approximately 4,000 new staff eligible for screening. It is known that there are approximately 1,000 new entrant NCHDs each year who are all screened at present. A number of other new employees will be involved in EPPs and are screened under existing practice. If this number is assumed to be 500, then there would remain 2,500 newly eligible for screening. As these groups will likely be having blood tests as part of their occupational health screening anyway, uptake is likely to be reasonable. If 25% of these accept screening this would result in an additional <b>625 tests</b> per year. As bloods are already been taken for offer testing, the laboratory cost is the only additional cost.</i></p>	625X€14= <b>€8,750</b>
21.2. Mandatory HCV screening of all new HCWs who will perform exposure prone procedures (EPPs) is recommended.	Nil additional anticipated as current practice (17).	Nil.
21.3. Existing healthcare workers who perform EPPs and have not yet been screened should be offered HCV screening.	<p>May result in additional testing.</p> <p><i>It is estimated that there are approximately 4,000 HCWs (2,000 doctors and 2,000 nurses) who perform EPPs and were appointed prior to the commencement of screening. If 10% of doctors accept an offer of screening, and 50% of nurses this would result in 1,200 additional tests on a once off basis. If these occur over a five year period, this would result in <b>240 additional tests</b> per year. Staff time and consumables are included in the cost for this group.</i></p>	240X€55.12 = <b>€13,229</b>
21.4. Mandatory screening of all new healthcare students is recommended.	<p>This will result in additional number of tests. As this group are already being tested for other bloodborne viruses (BBVs) the additional resource is only the cost of HCV laboratory testing.</p> <p>There are approximately 2,500 new entrants to medicine, nursing or dental courses each year (18).</p>	2,500X€14 = <b>€35,000</b>
21.5. Interval testing of HCWs who perform EPPs is not recommended. However, HCWs should be informed of their professional responsibility to seek appropriate assessment if any possible risk exposure has occurred.	Nil	Nil
<b>Recommendation 22 Testing sequence and frequency</b>		
<p>22.1. Individuals being investigated for evidence of HCV infection should be screened with an anti-HCV antibody or combined HCV antigen/antibody EIA screening assay.</p> <p>22.2. If the initial HCV EIA is reactive (positive), then the sample should be tested for the presence of HCV antigen, or HCV-RNA, to test for current infection.</p> <p>22.3. Current infection should be confirmed on a second sample and HCV-RNA should be performed (if not already performed) and HCV genotyping should be carried out.</p> <p>22.4. Those individuals with evidence of a resolved HCV</p>	Nil additional anticipated as current practice.	Nil

<p>infection (i.e. anti-HCV positive and antigen/RNA negative) should have a further sample drawn after six to 12 months for HCV-RNA testing to confirm their resolved infection status.</p> <p><b>Recommendation 23</b></p> <p>23.1. Individuals who initially test HCV negative but who remain at risk of HCV infection should be offered repeat testing on an annual basis, or six monthly if deemed clinically appropriate.</p>		
<b>Recommendation 24 What specimen type should be used for HCV screening?</b>		
<p>24.1. Serum or plasma are the preferred specimen types for screening and diagnostic testing for HCV infection, using quality assured assays.</p> <p>24.2. Screening and diagnostic testing for HCV infection should not be performed on oral fluid samples due to the low sensitivity and low positive predictive value.</p> <p>24.3. Dried blood spot testing can be considered for screening for HCV in special circumstances, such as mass screening initiatives e.g. in prisons.</p>	<p>Nil additional anticipated as current practice in clinical settings.</p>	<p>Nil</p>
<b>Recommendation 25 What is the role of rapid diagnostic tests or point of care tests in HCV screening?</b>		
<p>25.1. Where concerns exist about hard-to-reach populations or linkage to care then consideration could be given to using approved (e.g. CE marked) rapid diagnostic tests/ point of care tests (RDTs/PoCTs) on blood specimens.</p> <p>25.2. If RDTs/PoCTs are introduced into standard clinical practice then a quality assurance programme should be established that addresses internal quality control and external quality assurance.</p>	<p>If introduced, RDTs/PoCTs are unlikely to have a significant resource implication.</p>	<p>Nil</p>
<b>Recommendation 26 Screening for other BBVs</b>		
<p>26.1. When offering screening for HCV, consideration should be given to the need for screening for other BBVs also.</p>	<p>Not costed</p>	
<b>Recommendation 27 Interventions to increase uptake of HCV screening and subsequent linkage to care</b>		
<p>27.1. Interventions to increase uptake of screening and linkage to care, particularly amongst vulnerable groups, should be supported and evaluated.</p>	<p>Continue to support</p>	<p>Nil</p>
<p>27.2. A national HCV programme with a mandate spanning the entire HCV continuum of care to include full implementation of the <i>National Hepatitis C Strategy</i> and the NHCTP should be established.</p>	<p>Not costed</p>	

## Additional resources and costs

In this section the cost of the additional resources identified are considered.

### 1. Additional testing

The cost of additional testing will vary by risk group and setting. For some, the additional laboratory test will be the only additional cost as the patient will already be attending a healthcare service and having a blood sample taken. For others there will be additional costs from any pre- and post-test counselling required, staff time for taking blood, and consumables.

Of note, there will be overlap between risk groups. The extent of this is not known. Therefore the estimated number of additional tests is likely to be an overestimate.

#### **Laboratory tests**

The cost of the additional HCV testing includes the cost of the initial screening assay and the cost of any subsequent confirmatory tests required. The initial anti-HCV test costs €11 per test (personal communication; Cillian De Gascun, National Virus Reference Laboratory (NVRL)). An antigen test is needed on approximately 10% of those who have an antibody test and costs €30 per test (personal communication; Cillian De Gascun, NVRL). Taking this into account the average cost of the initial screening tests is €14.

In those with resolved infection screening should be by HCV-RNA, at a cost of €55 per test (personal communication; Cillian De Gascun, NVRL). This will increase the cost of screening. The number this will apply to is not known. In most settings it is likely to be low.

Those who are anti-HCV positive will have HCV-RNA testing on the same sample to confirm current infection at a cost of €55 per test. The number who will require this is not known and will likely vary by source of referral. It is assumed that 10% of anti-HCV tests will be positive and will have a HCV-RNA test on the same sample.

For those who are anti-HCV positive, repeat HCV-RNA testing is also recommended after six months to confirm chronic or resolved infection.

#### **Laboratory capacity**

As of 2013, there were 13 laboratories nationally carrying out HCV testing on behalf of the HSE, with the NVRL carrying out over 50% of total tests annually (19). The total number of HCV tests carried out nationally in 2013 was estimated at 135,112 anti-HCV tests, 21,251 antigen tests and 10,881 HCV-RNA tests. Extra laboratory capacity may be required but this would not be a new service.

It is estimated that the new guideline could result in an increase of approximately 20,000 anti-HCV tests and 2,000 HCV-RNA tests annually.

#### **Blood sampling - consumables**

The cost of materials of €1.19 per blood sample was assumed (based on a HTA undertaken by HIQA (20)). This cost includes gloves, cotton wool balls, swabs, needles, blood bottles and tape.

**Staff time – Assessment, blood sampling, communication of results, counselling, referral**

The exact funding mechanism for screening is not decided and will differ by setting and method of presentation of the patient. For the purpose of the BIA the human resource costs were estimated based on the opportunity cost of staff time.

Staff time for assessment, counselling, and taking the blood samples may differ by setting and population group e.g. taking blood may take longer in PWID with difficult venous access. It will also differ depending on the type of staff that undertake the work. The time taken to communicate results and counsel will also depend on the result, being longer when positive. It is not possible to account for all these variations at this stage.

Counselling and testing will likely be performed by a range of staff. In some services, it will be mainly nurse-led and in others it may be doctor-led. To calculate an average staff time it was assumed that half of staff time will be nurse time and half will be GP time. GP time was costed at €4.50 per minute and nurse time at €0.33 per minute giving an average cost of €2.42 per minute (21).

Assessing a patient's risk, taking of blood, and communicating a negative test result were assumed to take five minutes each. Communicating a positive result and arranging follow-up was assumed to take 20 minutes. If it is assumed that 10% of anti-HCV tests will be positive, then the average staff time used from assessment to referral will be 16.5 minutes.

**Table 2: Costs of screening process**

Resource	Cost
Staff time	€39.93
Consumables	€1.19
Laboratory costs	
Anti-HCV	€11
HCV-Ag	€30
Anti-HCV + HCV-Ag in 10%	€14
HCV-RNA/ NAT	€55
Total testing cost	
Initial screen with anti-HCV (anti-HCV test+ Ag for 10% + staff time+ consumables)	€55.12
Confirmatory repeat HCV-RNA six months later (staff time (20 mins), consumables, laboratory costs)	€96.12

## 2. Additional services to provide testing for risk groups

For many population groups a service already exists through which they can be screened. However, for others, there may not be a service or they may be poorly accessed by existing services. A new service or a new approach will be needed. There are some existing initiatives currently funded to improve access for marginalised risk groups. There may be a need in the future to expand these initiatives or develop new ones to, which will be new resources. However, these are not costed at the minute as it isn't within the scope of the guideline or current structures to implement these.

### **3. Communicable disease nurse**

A communicable disease nurse in the Department of Public Health in the greater Dublin area will be required to undertake risk assessments for contacts of identified cases. It is estimated that this would be 0.5 WTE position. A cost of €33,897/year is used based on a general nurse CNM 2 position at point 1 of the salary scale, including PRSI, pension and overheads.

### **4. Information and promotional material**

The publication of the guidelines should be accompanied by awareness-raising among relevant health professionals and services. This will be done by email communication direct from HSE HPSC to well defined health professional groups; and also through HSE Health Matters bulletin and by HSE Broadcast mail. This will be budget neutral and will not be considered further here.

A public information campaign to raise awareness among the general population will be required, in particular to reach those people who may have had a risk exposure in the past but who are not currently engaged in services where HCV testing would be offered. The purpose would be to raise awareness of HCV and risks of transmission. This campaign would be supported by HSE Communications and would include advertising, social media and digital support, using HSE owned assets.

For defined populations there will be a requirement for the development of a targeted information campaign. This would involve the development of information leaflets and posters. Translation of leaflets and posters into different languages will be a necessity. The content of the leaflets and posters will be developed by HSE HPSC, with support from HSE Communications. There would be no additional costs attached to this, as it is within the current function of HSE to undertake such tasks. There would be additional costs involved in the design and layout, translation and printing of the leaflets and posters. Posters and leaflets will be distributed to key healthcare and other settings where risk groups congregate. Promotion of testing will also occur digitally via existing HSE communication channels.

The estimated costs of the information and promotional campaign are outlined in Table 3.

**Table 3: Costs of information and promotion campaigns**

Resource	Cost (including VAT at 23%)	Source of cost data
Design of posters (6 at €529 each)	€3,174 in total or €635 per year over five years	Quotation received by HSE HPSC for similar campaign (personal communication; Kirsty MacKenzie, HSE HPSC)
Design of double sided A4 leaflets (10 different designs at €554 each)	€5,535 or €1,107 per year over five years	Quotation received by HSE HPSC for similar campaign
Translation of leaflets into different languages (9 different leaflets at €2,793 each; HCW leaflets not translated)	€25,137 or €5,027 per year over five years	Quotation received by HSE HPSC for similar campaign
Printing of information leaflets: Generic leaflets – 10,000 Prisoners – 14,000 Migrants – 10,000 Antenatal women – 10,000 Parents of children born to infected mothers - 250 MSM – 10,000 Healthcare workers - 1000 For cases on sexual and household transmission - 1000 Homeless people - 2000 People who use drugs - 2000	Annual cost: €1,138 €1,593 €1,138 €1,138 €134 €1,138 €178 €178 €683 €683	Quotation received by HSE HPSC for similar campaign
Printing of posters: Generic posters – 2000 Prisoners – 1000 Migrants – 1000 Antenatal women – 500 MSM – 1000 People who use drugs - 1000	€228 €178 €178 €154 €178 €178	
Social media and internet information and promotional material	Neutral – cost of leaflets and posters above includes digital friendly versions. Other material will be generated by HSE staff. Promotion will be by HSE communications.	
Total (annual)	€ 15,864	

Table 4 summarises the anticipated annual additional resources and costs for implementation of this guideline over a five year period. The annual cost is estimated to be €1.1 million. The main cost is due to the increased testing.



**Table 4: Summary of annual budget impact over five years.**

Resource	Costs included	Annual cost
<b>Additional initial HCV screening tests</b>	Number of tests and costs included	
Household contacts	100 anti-HCV tests (staff, consumable and lab costs)	€5,512
PWID	200 anti-HCV tests (staff, consumable and lab costs)	€11,024
Repeat screening of PWID	825 anti-HCV tests (staff, consumable and lab costs)	€45,474
Non injecting drug users	2000 anti-HCV tests (staff, consumable and lab costs)	€110,240
Prisoners	3,120 anti-HCV tests (staff, consumable and lab costs)	€171,974
Homeless	292 anti-HCV tests (staff, consumable and lab costs)	€16,060
Migrants	4,856 anti-HCV tests (staff, consumable and lab costs)	€267,663
People with tattoos	2,533 anti-HCV tests (staff, consumable and lab costs)	€139,619
Post kidney transplant	85 anti-HCV+Ag tests (lab costs)	€3,485
Historical kidney transplant recipients	184 anti-HCV tests (lab costs)	€2,576
Deceased solid organ donors	77 HCV-RNA tests (lab costs)	4,235
Living solid organ donors	34 HCV-RNA tests (lab costs)	1,870
Healthcare workers		
New entrants	625 anti-HCV test (lab costs)	€8,750
Existing HCWs performing EPPs	240 anti-HCV (staff, consumable and lab costs)	€13,229
Healthcare students	2500 anti-HCV tests (lab costs)	€35,000
<b>Additional HCV-RNA tests</b>		
On those who are anti-HCV positive	<i>Unknown and will differ by risk group. If 10% of those tested are anti-HCV positive then there would be 2,190 additional HCV-RNA tests on the initial sample (lab cost only)</i>	€96,580
	<i>If 60% return in six months for repeat HCV-RNA testing (consumables, staff time and lab test)</i>	€101,272
<b>Subtotal – testing costs</b>		€1,034,563
<b>Other costs</b>		
0.5 WTE communicable disease nurse for contact tracing	CNM 2 at point 1 of salary scale	€33,897
Information and promotion campaign		€15,864
<b>Total</b>		<b>€1,084,324</b>

## Other potential additional resources which are not costed

### Additional healthcare for detected cases

It is expected that implementation of the guideline will result in increased numbers of people diagnosed with HCV. Therefore, there will be an increase in the numbers of patients being referred for specialist assessment and treatment.

Their eligibility for antiviral treatment will be subject to prioritisation on the basis of clinical need as defined in the clinical guidelines developed by the HSE NHCTP. The HSE NHCTP has a fixed annual budget, therefore, there should be no additional impact on this budget.

There will be an increase in the number of newly diagnosed patients who will be referred for an initial assessment, advice and possibly ongoing monitoring until eligible for treatment. The number of new cases that will be diagnosed and so require additional care is not known. However, it is likely that existing services will have the capacity within their current resources to meet this need. An increasing number of patients currently attending services are now being treated with newer treatments which have a shorter duration, require less monitoring and have fewer adverse events and so place less of a burden on services (22). Also, given the high cure rates, treated patients will no longer need care and may be discharged from the services.

### New services for testing

A challenge to the success of this guideline is ensuring that those at risk are offered screening and that uptake is high. A number of those for whom screening is recommended will not be currently attending specific health services. They also may be poorly reached by existing healthcare services such as primary care services.

There are a number of initiatives underway, funded or partly funded by the HSE, to improve access to testing and to treatment for certain at risk groups. One such example is the HepCare Europe project. Such initiatives should continue to be supported and expanded if shown to be effective in reaching their target risk groups. Further initiatives such as walk-in services or outreach testing may be required to reach certain risk groups, such as migrants or homeless people.

While the National Clinical Guideline recommends that these be considered, their implementation is not within the scope of the guideline and not costed here.

### A national HCV programme

One of the recommendations of this guideline is that a national HCV programme be established with a remit across the entire HCV continuum of care. While the scope of this guideline is limited to screening, it is recognised that in order to achieve the goal of HCV elimination by 2030, action is required across the entire continuum of HCV care including reducing vulnerability to HCV infection, primary prevention of infection, diagnosis, linkage to care, treatment, and ongoing care.

Although a commitment of €30 million a year has been made by the Department of Health to the HSE to fund the antiviral drug treatment for HCV, resources have not been allocated to support other activities along the continuum of care. The HSE NHCTP aims to treat all those infected with HCV in order to reach elimination. However, this requires that cases are first identified and linked

into care. Therefore, additional resources to support access to screening and linkage to care are needed to reach the goal of HCV elimination by 2030.

### **Potential cost saving**

It is anticipated that the implementation of the National Clinical Guideline on Hepatitis C Screening will result in the identification of previously undiagnosed cases of HCV infection, many of whom will be asymptomatic. They are likely to be diagnosed at an earlier stage of infection, rather than presenting when they become symptomatic in the later stages of advanced liver disease. Diagnosis of HCV infection with referral for specialist assessment has the following advantages: the patient can be advised about lifestyle factors such as alcohol use which can have an additive harmful effect on the liver; the patient can be advised about how to prevent onward transmission of infection to others; the patient can be offered antiviral treatment. Antiviral treatment is now highly effective. Treatment at an earlier stage of infection is more effective and may involve a shorter course of treatment, but is still effective in many cases of advanced liver disease. Treatment and cure of infection in these population groups will result in improved survival, improved quality of life, reduced requirement for inpatient and outpatient hospital care, some of which would otherwise be very high cost such as intensive care for decompensated liver disease and liver transplantation. However, these savings may not be realised on any significant scale within the next five years. There are also advantages to the wider population in terms of reduced opportunities for transmission of infection to others.

### **Summary**

The estimated annual cost of implementation of this guideline is €1.1 million. This should be considered in the context of a budget of €30 million which has been allocated for antiviral drug treatment of HCV infection. However, in order to avail of drug treatment, cases need to be first diagnosed, linked into care and retained in care. Given that those most at risk of HCV are often from marginalised groups, resources will be required in these aspects of care.

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## Appendices

### Appendix 1: Supplementary Detail on the resource implications for each recommendation

#### Women who are pregnant

##### **Recommendations:**

- *Standardised targeted risk based HCV screening of antenatal women is recommended.*
- *Universal HCV screening of antenatal women is not recommended.*
- *Universal antenatal HCV screening may be reconsidered in the future if HCV treatment during pregnancy becomes possible. Also, if national policy progresses to a policy of birth cohort or total population screening, antenatal screening offers an opportunistic method to reach this particular population cohort.*

#### **Current situation and anticipated change in practice**

The current practice in most maternity units in Ireland is to offer a HCV test at the first antenatal visit to women who are considered to be at risk of HCV, e.g. having a history of injecting drug use, being born in a high prevalence country, having a tattoo. This test is taken at the same time as the blood samples for other booking blood tests. The recommendation for selective screening of antenatal women based on identification of a risk factor should provide clarification and streamlining of a practice that is already in place in most maternity units. It may result in some increase or decrease in testing. However, any increase in testing may be offset by the fact that at least one large Dublin maternity hospital (>8,000 births per year) currently offers HCV testing to all women at their first antenatal visit and the new recommendation would not support this practice. Therefore, no substantial change in numbers of tests is anticipated in the antenatal population. The Rainbow Clinic guide on the prevention of perinatal transmission of infectious diseases recommends that women with risk factors for HCV infection should be offered HCV antibody testing; those who are anti-HCV positive should be tested for HCV-RNA, and newly diagnosed women should be referred to hepatology services (6). The Rainbow Clinic guide is accepted to be standard national best practice in maternity units.

#### **The additional resource requirements will be:**

- Information leaflets for mothers

#### Children born to HCV positive women

##### **Recommendations:**

- *Infants of HCV-RNA positive women should have HCV-RNA checked at six weeks and six months of age and, if both are negative, HCV anti-HCV at  $\geq 18$  months of age.*
- *Infants who are HCV-RNA positive at any time, or who are anti-HCV positive at or after 18 months of age should be referred to the Rainbow Clinic.*
- *Infants of anti-HCV positive but HCV-RNA negative women, where eradication of infection, either spontaneously or by treatment is not assured (i.e. by serial negative HCV-RNA tests) should be tested for anti-HCV at  $\geq 18$  months of age.*

- *Infants of anti-HCV positive but HCV-RNA negative women where eradication of infection, spontaneously or by treatment is assured (i.e. persistent negative HCV-RNA tests and no ongoing risk for reinfection), should be managed as infants of uninfected women and do not require HCV follow-up.*
- *If a woman is found to have current or resolved HCV infection, any previous children she has given birth to should be tested for HCV, unless the woman was known to be HCV-RNA negative at the time of their delivery.*

### **Current situation and anticipated change in practice**

The first four points are consistent with the Rainbow Clinic guideline, which is accepted to be standard national best practice in paediatric hospitals (6). The fifth point may be difficult to implement on a systematic basis, particularly as information on previous testing may be difficult to establish on population groups such as migrants; testing may be carried out opportunistically and is unlikely to result in substantial numbers of additional tests.

### **The additional resource requirements will be:**

- Information leaflets for mothers

### **Household contacts of a person who is HCV positive**

#### ***Recommendations:***

- *In general, HCV screening of household contacts (with no sexual or vertical exposure to the HCV positive household member) is not necessary due to the low risk of horizontal household transmission. However, there may be circumstances where household transmission is more likely to have occurred. Screening may be considered based on clinical judgement or a risk assessment for factors such as:*
  - *HIV co-infection or high HCV viral load in the HCV positive household member*
  - *A history of current injecting drug use in the HCV positive household member*
  - *If there has been a potential exposure to blood of the HCV positive household member e.g. sharing razors*
  - *If the HCV positive household member is on dialysis in the home*
  - *If there are environmental risks within the household such as discarded needles.*
- *Where a household contact requests testing for reassurance, this should not be denied.*

### **Current situation and anticipated change in practice**

A risk assessment to advise on the need for testing household contacts will need to be carried out preferably by Departments of Public Health. Although follow-up of notified cases of HCV is carried out on many cases in other regions, in HSE East (the greater Dublin area) the majority of cases are not followed up by the Department of Public Health due to the high volume of cases (400-500/year). Additional resources would be required to allow for this to take place.

*Implementation of this recommendation may also result in some additional testing. If 10% of PWID cases per year were assessed to be at higher risk of transmitting infection, and testing for two*

*household contacts occurred for each of these cases, then an estimated 100 additional tests would be carried out (660 notifications x 75% PWID = 495, x 10% = 50, x 2 = 100).*

**The additional resource requirements will be:**

- 0.5 WTE communicable disease control nurse in the Department of Public Health in HSE East
- *Additional HCV screening tests – approximately 100 per year*
- Information leaflets for cases

**People who use illicit drugs**

***Recommendations:***

- *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.*
- *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.*
- *Testing should be available during this interval if a risk exposure is known to have occurred.*
- *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.*
- *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).*

**Current situation and anticipated change in practice**

The current standard of care for patients presenting for treatment at addiction treatment centres in Ireland is outlined in the contract of service for doctors working in these centres (7). The majority of those attending addiction treatment centres are currently offered a HCV test on starting treatment, and the majority accept this offer (8). This includes those who snort or inhale drugs, as well as those who inject.

The publication of the guidelines, may result in some additional testing among people who use illicit drugs but do not attend addiction treatment centres and those who may have used illicit drugs in the past. In addition, the guidelines now recommend that those who continue risk taking behaviour and who test HCV negative should have a repeat HCV test every six to 12 months. It is not known to what extent this is current practice in the addiction services so it is possible that this recommendation may result in some increase in the level of testing.

*Approximately 10,000 attend addiction treatment services (Personal communication; Dr Eamon Keenan, HSE Addiction Services). An estimated one third of these are anti-HCV negative (3,300) (9) and should be re-tested annually if still risk-taking (estimated 50% = 1,650). If re-testing is currently*



*being carried out in only 50% of these, then implementation of the guidelines would result in an additional 825 tests per year.*

*An estimated 2,000 PWID never attended drug treatment(9). If 50% of these came forward for testing over a 5 year period then an additional 1,000 tests would be carried out over 5 years, 200 per year.*

For non-injecting drug users, screening is current practice for those attending addiction services. There may be some additional testing among people who do not attend addiction treatment centres and those who may have used illicit drugs in the past. The number of such people who will be eligible for screening or who will present for screening is not known.

*The NACDA 2016 drug prevalence study reports on the lifetime prevalence of use of different drugs in the adult population (10). While it doesn't report on route of administration, the non IDU drug with the highest prevalence, which also has a biologically plausible transmission potential for HCV, was cocaine with a lifetime prevalence of 6.6%. Applying age specific prevalence of use to 2016 Census data, it can be estimated that 226,935 persons have used cocaine in their lifetime. Between 2004 and 2014 there were approximately 7,000 new entrants to drug treatment services where cocaine was the main problem drug. Of note polydrug use is common in Ireland. If it is assumed that the majority of PWID are also included in this prevalence estimate, then excluding PWID and those who have entered treatment for cocaine results in approximately 200,000 being eligible for screening. This is likely an overestimate as a number may have attended addiction services with other drug problems and have been tested. If 5% of the 200,000 present for screening then 10,000 additional tests would be performed over five years, or approximately 2,000 per year.*

**The additional resource requirements will be:**

- *Additional HCV screening tests for those at ongoing risk of infection– approximately 825 per year*
- *Additional one-off screening tests of PWID not in addiction services– approximately 200 per year*
- *Additional screening on non-IDU not in addiction services – approximately 2,000 per year*
- Information and promotional material

**Prisoners or former prisoners**

***Recommendations:***

- *Screening for HCV 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, while also ensuring the early identification of infections in order to minimise the risk of transmission to others.*
- *Those found to have HCV infection should be linked into specialist care and treatment should be facilitated while in prison.*
- *Prisoners who initially test HCV negative should be offered repeat testing on an annual basis, or six monthly if deemed clinically appropriate, 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 should be considered, although implementation may be difficult.*

### **Current situation and anticipated change in practice**

On committal to prison, each prisoner is interviewed by a nurse and is offered a “viral screen” by blood testing, which includes HCV. However, these interviews are often conducted under time pressure and at a stressful time for the prisoner and, anecdotally, there is a poor uptake of the offer of testing with the result that only a minority (5%-10%; personal communication Ursula Norton, Irish Prison Service) actually get tested on committal. This would suggest that, of approximately 13,000 people committed to prison each year, only 650-1,300 are tested for HCV.

*If 80% of prisoners with a history of IDU were tested on committal, and 20% of those without a history of IDU were tested, this would result in approximately 2,470-3,120 additional tests per year. These figures are based on the following:*

*15% have a history of IDU:  $1,950 \times 80\% = 1,560$*

*85% without a history of IDU:  $11,050 \times 20\% = 2,210$*

*(26% in 2011 prison study had a history of IDU (11), however the proportion of committals having a history of IDU is likely to be lower given that, in 2015, 9,883 committals were for the non-payment of court ordered fines (12).*

*Regarding the recommendation to test ex-prisoners, the size of this population is unknown, but the expected number of additional tests is expected to be low. It is likely that many will already have been tested through the prison service or through other services such as addiction services. The rate of reoffending, or recidivism, for prisoners released in 2010 was 45.1% (defined as an individual committing a criminal offence within a three year period following their release from prison and being subsequently convicted for that offence) (13), thus some will be offered testing in the future on committal to prison.*

### **The additional resource requirements will be:**

- *Additional HCV screening tests – approximately 2,470-3,120 per year*
- *Information leaflets for prisoners*

### **People who are homeless**

#### **Recommendations:**

- *Homeless people who have a history of engaging in risk behaviours associated with HCV transmission, or who have had a potential HCV risk exposure, should be offered screening.*
- *Those who initially test HCV negative should be offered repeat testing on an annual basis, or six monthly if deemed clinically appropriate, if there is an ongoing risk of transmission.*

### Current situation and anticipated change in practice

There is currently no national policy on HCV testing of homeless people. Homeless people may be at higher risk of HCV infection because of risk behaviours such as injecting drug use and in this context they may be offered HCV screening if they attend a service for PWID, such as drug treatment clinics. Homeless people in general are difficult to reach and are poor attenders at other services. However, it is estimated that the majority of at risk people in homeless hostels and emergency accommodation in Dublin are screened for HCV currently. It is likely that the same situation applies outside Dublin as HCV testing is part of the usual health needs assessment in these services (Personal communication Joe Doyle, HSE Social Inclusion). In order to improve the availability and accessibility of screening for homeless people at risk of HCV infection, current services to homeless people (e.g. HSE services, SafetyNet and HepCare Europe) should continue to be supported and may need to be expanded. There will also be a need to raise awareness amongst homeless people who may have engaged in HCV-related risk behaviour, to encourage them to accept the offer of testing.

*In February 2017, the number of homeless adults in temporary emergency accommodation and supported temporary accommodation was 2,604 (14). If it is estimated that 50% are at risk of HCV infection (1,300) and current uptake of HCV testing is 60%, and raising awareness increases this to 80%, then an additional 260 tests would be carried out over 5 years on the existing cohort of homeless people, 52 per year.*

*There are approximately 4,500 new presentations per year to homeless accommodation services (15) Assuming that 53% are to temporary emergency accommodation and supported temporary accommodation (2,400), and 50% are at risk of HCV infection (1,200) and current uptake of HCV testing is 60%, and raising awareness increases this to 80%, then an additional 240 tests would be carried out per year on the new cohort of homeless people.*

#### The additional resource requirements will be:

- *Additional HCV screening tests – approximately 292 per year*
- Information leaflets and posters for homeless people

### Migrants from high prevalence countries

#### **Recommendation:**

- *Migrants from a country with an intermediate to high prevalence of HCV (anti-HCV  $\geq 2\%$ ) should be offered one-off HCV screening.*

### Current situation and anticipated change in practice

Until 2015, the only national guideline on screening of migrants for infectious diseases (2004) referred specifically to asylum seekers alone. It did not make any recommendation on screening for HCV. However, it is known that some asylum seeker centres chose to include HCV when testing for other BBVs. National screening guidelines for all migrants published in July 2015 recommended that HCV testing (anti-HCV, followed by HCV-RNA for anti-HCV positive) be offered to all migrants from countries with a prevalence of  $\geq 3\%$  and to those with a history of HCV risk behaviour (PWID and MSM). However, the extent to which these guidelines are implemented is unknown as there is no dedicated service in Ireland for screening of migrants.

Migrants entering as asylum seekers or refugees are currently offered screening. However, asylum seekers and refugees represent only a minority of all migrants in Ireland.

*According to the 2011 census there were 164,820 residents in Ireland from countries with a prevalence greater than 2%. If 10% of these present for testing over five years, this would result in approximately 3296 tests per year.*

*There will be new migrants each year to Ireland from high prevalence countries. Based on PRSI allocations, there were approximately 26,000 new entrants from countries with a prevalence of 2% or greater in 2016. This number will include children who are less likely to be at risk as in a number of countries the increased risk is due to historically poor infection prevention and control practices. If it is assumed that 60% are eligible for screening, and 10% of these present for screening then there could be an additional 1,560 tests per year.*

The additional testing is costed here by test, assuming this group will access testing through existing services. However, consideration may need to be given to alternative methods of reaching this group. A specific screening service, or outreach testing services may be needed. These are not costed here.

**The additional resource requirements will be:**

- *Additional testing – approximately 4,856 per year*
- Information and promotional material which is culturally sensitive and available in different languages.

**People who received medical or dental treatment abroad**

***Recommendation:***

- *Screening for HCV should be considered in people who have received medical or dental treatment in countries where HCV is common (anti-HCV prevalence  $\geq 2\%$ ) and where infection control may be poor.*

**Current situation and anticipated change in practice**

The number of Irish residents who have had medical or dental treatment in such circumstances is not known. The numbers presenting for screening are likely to be low.

**The additional resource requirements will be:**

- Additional testing – likely to be low
- Information and promotional material

**People with tattoos or body piercings**

***Recommendations:***

- *Screening for HCV should be considered for all those with a tattoo. Those most at risk of having acquired HCV through tattooing are those who received tattoos a number of decades*

*ago, in non-professional settings, in prison, in high prevalence countries or in other circumstances where infection control was poor.*

- *There is insufficient evidence to support screening of recipients of body piercings (including ear piercings).*

### **Current situation and anticipated change in practice**

The prevalence of tattoos in the Irish population is unknown. A study in a Dublin maternity hospital found that 47% of women had a tattoo (23). A study in Irish prisons in 2011 found that 68% of prisoners had a tattoo (11).

It is not anticipated that an active screening programme be implemented for this group but that screening is offered on an opportunistic basis or as part of other screening programmes. It is likely that many people with a tattoo will be offered HCV screening as part of screening in antenatal clinics, addiction services, STI clinics or prisons. But some additional testing would be likely to result from awareness raising among health professionals and the public. The extent of this increased testing is difficult to estimate.

*Table 5 outlines an estimate of the number of additional tests that may be undertaken. If 20% of the population aged 20-50 years have a tattoo, then 422,199 people in Ireland have a tattoo. If it is assumed that two thirds of women in this age group have already been screened in the antenatal setting, and a further 10% of males and females have been screened in other settings such as addiction services, STI clinics, prisons, other clinical services, there would remain 253,265 persons to be screened. If 5% come forward for testing as a result of raised awareness over a five year period then there could be an additional 2,533 tests per year.*

**Table 5: Estimate of the number of people with tattoos who will present for screening**

	Males	Females	Total
Residents in Ireland aged 20-50 years	1,044,374	1,066,623	2,110,997
Number with a tattoo – if 20%	208,875	213,325	422,199
Number which may have been already screened			
Antenatal screening		140,794	140,794
Other services (addiction services, prison, STI services)	20,887	7,253	28,141
Remainder still to be screened	187,987	65,277	253,265
Number presenting for screening over five years – if 5% uptake	9,399	3,264	12,663
Numbers screened per year			2,533

### **The additional resource requirements will be:**

- *Additional HCV screening tests – approximately 2,533 per year*

### **Heterosexual partners of those who are HCV positive**

**Recommendations:**

- *In general, HCV screening of sexual partners of known HCV cases is not recommended in heterosexual couples who are both HIV negative.*
- *Sexual partners of known HCV cases should be considered for screening in the following situations:*
  - *If the HCV infected case is a PWID*
  - *If the case or contact is also HIV positive*
- *Sexual contacts of a PWID, but where HCV status is unknown or where there is evidence of resolved infection, should be considered for screening.*
- *If testing of a sexual partner of a HCV infected cases is requested for reassurance, then this should not be denied.*

**Current situation and anticipated change in practice**

This is current practice and therefore any change in the number to be tested is likely to be small. Where required, contact tracing could be undertaken by Departments of Public Health.

**The additional resource requirements will be:**

- Information material on the risk of sexual transmission for cases.
- Contact tracing where required. Included in the resource for a communicable disease control nurse under the recommendation on household contacts.

**Men who have sex with men****Recommendations:**

- *HIV positive MSM should be screened at least annually for HCV. More frequent testing may be required if clinically indicated eg. an unexplained rise in ALT, a diagnosis of a new STI, or if a risk exposure has occurred such a contact with a known case of HCV, or other risk behaviours including chemsex.*
- *HIV negative MSM should be offered testing annually for HCV as part of an overall STI screen. More frequent testing may be required if clinically indicated eg. an unexplained rise in ALT, a diagnosis of a new STI, or if a risk exposure has occurred such a contact with a known case of HCV, or other risk behaviours including chemsex.*

**Current situation and anticipated change in practice**

Annual HCV screening of HIV positive MSM is current practice as part of their HIV care. For HIV negative MSM attending sexual health services for STI screening the practice around HCV screening can vary. In some high volume centres it is undertaken routinely at each visit, which may be multiple times a year. In other centres it is done on a case-by-case basis. The recommendation may therefore lead to some change in the number of tests performed. However, if the aforementioned high volume centre changes to annual testing, it is anticipated that there will not be a net increase in testing.

**The additional resource requirements will be:**

- Nil anticipated for HIV positive MSM
- For HIV negative MSM there may be a change in number of tests but it is unlikely to be significant
- Information and promotional material

### **People having sexual health screening**

#### ***Recommendation:***

- *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 are present.*

#### **Current situation and anticipated change in practice**

There is no national policy on HCV testing of all STI clinic attendees. It is standard practice in some STI clinics to offer HCV testing to attendees who have other risk behaviours such as a PWID, partners of PWID, people who have had bites or needlestick injury, and MSM. It is also standard practice in all STI clinics to test HIV positive patients for other BBVs including HCV.

#### **The additional resource requirements will be:**

- Nil additional anticipated

### **People on renal dialysis or who have had a kidney transplant**

#### ***Recommendations:***

- *Patients commencing, or on maintenance, haemodialysis or peritoneal dialysis should be screened according to the current recommendations of the Standing National Advisory Committee on the Prevention of Transmission of Blood-Borne Diseases in the Health-Care Setting and any ensuing updates from this committee.*
- *All patients having a kidney transplant should be tested for HCV by a combined antigen-antibody test, or anti-HCV test AND HCV-RNA at three months post-transplant.*
- *Patients transplanted before the introduction of the above, unless already known to be HCV positive, should be tested on a one-off basis by a combined antigen-antibody test, or anti-HCV test AND HCV-RNA to out rule the possible acquisition of HCV infection through past treatment for renal failure.*

#### **Current situation and anticipated change in practice**

Screening of new and current patients on dialysis is current practice since 2005 and the recommendation was updated in 2014 (16). The recommendation will not result in change in practice or have additional resource implications.

Post-transplant testing has also been recommended nationally since 2008 (16). The extent of current adherence with this recommendation is unknown. This guideline may reinforce practice resulting in some additional testing.

*Between 2011 and 2015 the average annual number of kidney transplants was 169. If at present only 50% are tested post-transplant, and implementation of this guideline increases this to 100%, this would result in an additional 85 tests per year.* The laboratory costs are the only additional resources as these patients are already attending services and having regular blood samples taken.

The recommendation on historical recipients of kidney transplants may result in some additional testing. The number eligible for testing and that will come forward is not known. At the end of 2014 there were 2,300 recipients of kidney transplants alive. *If it is estimated that 80% of the 1,149 people who had a transplant between 2008 and 2014 were still alive, then approximately 1,380 of the 2,300 alive in 2014 were transplanted before 2008 and the issuing of the recommendation on post-transplant screening. Also, if only 50% of those transplanted since 2008 had post-transplant screening then 460 of this group would require screening. In total there may be 1,840 eligible for screening under this recommendation. If 50% presented for screening, then 920 additional tests would be performed over five years, or approximately 184 per year.*

**The additional resource requirements will be:**

- *Additional testing – approximately 269 per year (laboratory costs only)*

**Recipients of substances of human origin**

***Recommendations:***

- *Recipients of blood or blood components in Ireland prior to October 1991 who have not yet been tested should be offered screening.*
- *All recipients of anti-D in Ireland between 1st May 1977 and the end of July 1979, and 1st March 1991 to 18th February 1994 who have not yet been tested should be offered screening.*
- *Recipients of plasma derived clotting factor concentrates in Ireland prior to 1992 who have not yet been tested should be offered screening.*
- *Recipients of blood components and blood products overseas in any country where a quality assured blood donor screening programme may not have been in place should be offered screening.*
- *Screening should be considered in recipients of solid organ transplants in Ireland who have not yet been tested.*

**Current situation and anticipated change in practice**

Extensive screening of historic recipients of potentially contaminated blood and blood products in Ireland has already taken place. The number of any additional people coming forward for testing is likely to be very low.

The number of recipients of blood or blood products overseas who are now resident in Ireland and who will present for screening is not known, but the numbers are likely to be low.

*It is estimated that approximately 2,000 solid organ transplants other than kidney transplants have taken place in Ireland since 1964. Approximately 1,300 of these have been since 2010 when screening practices will have been adequate. Given the survival rates post-transplant in previous years, the*



*number of historic transplant recipients from a time before screening was adequate who are still alive is likely to be low.*

**The additional resource requirements will be:**

- Some additional testing but numbers likely to be very low.

**Donors of substances of human origin**

***Recommendations:***

- *Screening of donors of blood, organ, tissue and cells, including reproductive cells, should at a minimum comply with legislative requirements.*
- *NAT for HCV-RNA of donors of blood should be performed and the results available prior to the use of the donation. The test must be designed and approved for screening of blood donations.*
- *NAT for HCV-RNA of donors of tissues and cells, including reproductive cells, and living solid organ donors, should be performed in addition to current legislative requirements.*
- *For deceased donors of solid organs:*
  - *Anti-HCV and HCV-antigen testing should be done and the results available prior to donation.*
  - *NAT should be considered where feasible. NAT results may not be available prior to transplantation but NAT should still be performed to ensure the rapid identification of the recipients of potentially infectious organ*
- *Any external laboratories used for microbiological screening of donors should be accredited and comply with the standards of the appropriate regulatory authority. Laboratories in Ireland should be accredited by the Irish National Accreditation Board (INAB) to undertake testing in compliance with the International Standard ISO 15189.*
- *A national advisory committee on the safety of blood, organs and tissues should be established to advise on best practice in relation to donor selection, and testing of potential donors.*

**Current situation and anticipated change in practice**

NAT is current practice for blood donors in the Irish Blood Transfusion Service (IBTS) so no additional resources will be required for blood donors.

Regarding living organ donors, antigen-antibody testing is current practice. NAT will be additional. Between 2012 and 2015 the average annual number of living solid organ donors was 34. As this group is already having microbiological testing undertaken, the laboratory cost is the only additional resource.

It is not known if NAT is current practice in other services that process tissues and cells. Also the number of donors is not known. Donations within the fertility sector are likely to be the largest group.

For deceased solid organ donors, combined antigen-antibody testing is current practice. NAT will be additional. No additional staff time or consumables will be required as microbiological testing is

already being undertaken for this cohort. Between 2013 and 2015 the average annual number of deceased organ donors was 77.

**The additional resource requirements will be:**

- NAT for living solid organ donors – approximately 34 per year
- NAT of deceased solid organ donors - approximately 77 per year
- NAT for donors of other tissues and cells- unknown

**Healthcare workers**

***Recommendations:***

- *All new healthcare workers should be offered HCV screening on voluntary basis.*
- *Mandatory HCV screening of all new HCWs who will perform EPPs is recommended.*
- *Existing healthcare workers who perform EPPs and have not yet been screened should be offered HCV screening.*
- *Mandatory screening of all new healthcare students is recommended.*
- *Interval testing of HCWs who perform EPPs is not recommended. However, HCWs should be informed of their professional responsibility to seek appropriate assessment if any possible risk exposure has occurred.*

**Current situation and anticipated change in practice**

Testing of new HCWs who will perform EPPs has been recommended since 2008 and therefore there will be no change in practice.

Offering testing to all new HCWs is not current practice. There are approximately 16,000 new appointments to the HSE each year. However, a significant number of these will not be new employees. *If it is estimated that half of new appointments are new employees, and half of these are healthcare workers, there would be approximately 4,000 new staff eligible for screening. It is known that there are approximately 1,000 new entrant NCHDs each year who are all screened at present (personal communication; Lynda Sission, HSE). A number of other new employees will be involved in EPPs and are screened under existing practice. If this number is assumed to be 500, then there would remain 2,500 newly eligible for screening. As this group will likely be having blood tests as part of their occupational health screening anyway, uptake is likely to be reasonable. If 25% of these accept screening this would result in an additional 625 tests per year. As bloods are already been taken for offer testing, the laboratory cost is the only additional cost.*

*It is estimated that there are approximately 4,000 HCWs (2,000 doctors and 2,000 nurses) who perform EPPs and were appointed prior to the commencement of screening. If 10% of doctors accept an offer of screening, and 50% of nurses, this would result in 1,200 additional tests on a once off basis. If these occur over a five year period, this would result in 240 additional tests per year. Staff time and consumable are included in the cost for this group as they would not be having blood samples anyway.*

There are approximately 2,500 new healthcare students commencing courses each year (18).

**Additional Resources**

- *Additional testing of new healthcare workers – approximately 625 per year (laboratory costs only)*
- *Additional testing of existing healthcare workers who perform EPPs – approximately 240 per year*
- Additional testing of new healthcare students – approximately 2,500 per year.

**Specimen type*****Recommendation:***

- *Serum or plasma are the preferred specimen types for screening and diagnostic testing for HCV infection using quality assured assays.*
- *Screening and diagnostic testing for HCV infection should not be performed on oral fluid samples due to the low sensitivity and positive predictive value.*
- *Where concerns exist about hard-to-reach populations or linkage-to-care then consideration could be given to using approved (eg CE marked) rapid diagnostic tests on blood specimens.*
- *If RDT/PoCTs are introduced into standard clinical practice then a quality assurance programme should be established that addresses internal quality control and external quality assurance.*

**Current situation and anticipated change in practice**

Serum or plasma are the current specimen types used in clinical practice. As the guideline is not specifically recommending the use of RDT/ PoCTs, any potential change in resources from their use will not be costed here.

Of note, there may be cost savings with RDT/PoCTs as results are available in a short time, meaning a second patient visit is not required. However, confirmation with a blood sample is required which may neutralise any potential savings.

**The additional resource requirements will be:**

- Nil anticipated at present

**Test type and sequence of testing*****Recommendation:***

- *Individuals being investigated for evidence of HCV infection should be screened with an anti-HCV antibody or combined HCV antigen/antibody EIA screening assay.*
- *If the initial HCV EIA is reactive (positive), then the sample should be tested for the presence of HCV antigen, or HCV-RNA, to test for current infection.*
- *Current infection should be confirmed on a second sample and HCV-RNA should be performed (if not already performed) and HCV genotyping should be carried out.*
- *Those individuals with evidence of a resolved HCV infection (i.e. anti-HCV positive and antigen/RNA negative) should have a further sample drawn after six to 12 months for HCV-RNA testing to confirm their resolved infection status.*

**Current situation and anticipated change in practice**

This is the current practice of testing sequence.

**The additional resource requirements will be:**

- Nil anticipated as current practice
- Information campaign for healthcare professionals

**Frequency of testing*****Recommendation:***

- *Individuals who initially test HCV negative but who remain at risk of HCV infection should be offered repeat testing on an annual basis, or six monthly if deemed clinically appropriate.*

**Current situation and anticipated change in practice**

The main group this will apply to is illicit drug users. This is currently recommended for those attending drug treatment centres, although adherence is not known.

**The additional resource requirements will be:**

- See recommendation on illicit drug users.

**Birth cohort screening*****Recommendation conditional on the result of a HTA:***

A recommendation could not be made for birth cohort screening without first carrying out a health technology assessment.

- *Birth cohort screening cannot be recommended at present due to the likely huge cost implications and uncertain benefit. Such a programme would require a full health technology assessment (HTA) and approval of funding prior to being considered.*
- *Birth cohort screening should be considered if a HTA shows it to be cost effective and affordable in the Irish context.*

**The additional resource requirements will be:**

- Pending a HTA