Hepatitis C Screening Guideline Development Group Background to recommendation 21: Healthcare workers

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

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

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

Please note, that this document is being made available for information purposes only. It should not be reproduced or cited. Please refer to the National Clinical Guideline for the final evidence analysis, value judgements and recommendations.

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History of development of the recommendation

Date	Process	Outcome
02/06/2015	Recommendations from quality appraised	Agreed that guidelines on
	national and international guidelines reviewed	healthcare worker occupational
		health should be reviewed also
19/01/2016	GDG subgroup meeting to undertake considered	Formulation of recommendation
	judgement process	
23/02/2017	Review of subgroup recommendation by GDG	Recommendation accepted
25/04/2017	Consultation feedback reviewed by GDG	No changes to recommendation
June – July	Editing	Recommendation reworded in
2017		final editing process

Considered judgement process

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

Date: 20/01/2017 Attendees: JG (on phone), ER, NOF, JC, CDG

Table 1: Considered judgement form

1. What is the question being addressed?

Screening of healthcare workers

The guideline will make recommendations relating to screening of healthcare workers (HCWs) for hepatitis C virus (HCV) pre-employment or during employment, for the purpose of minimising healthcare provider to patient transmission of HCV in the healthcare setting.

For recommendations on the management of healthcare workers following an exposure to potentially infected material, readers will be referred to Guidelines on the Emergency Management of Injuries (1).

Recommendations on the assessment of HCWs found to be infected with hepatitis C, or management of their employment while undergoing treatment or post treatment will not be addressed as this is not within the scope of the guideline.

Also, this guideline will not address wider issues relating to prevention of hepatitis C transmission in the healthcare setting (e.g. patient to patient transmission due to poor infection control practices).

The following questions should be addressed:

- Which, if any, HCWs should be screened for HCV?
- When should screening occur?
- Is interval screening needed?

2. What evidence is being considered to address this question and why? (This section will explain the approach taken to address this question and what GDG members are being asked to consider)

To make a recommendation on this key question it was deemed appropriate to refer to occupational health policy and guidance. Known healthcare policy and guidance from Ireland, the UK and the US is referred to. A search for further guidance was not undertaken.

The evidence presented includes:

- Recommendations from international hepatitis C guidelines (section 3).
- Recommendations from occupational health guidelines (section 3).
- National policy and guidance (section 3).
- Literature on the risk of transmission from an infected HCW to patient (section 5).

3. What is the body of evidence?

Source of evidence: (tick all that apply)

Guidelines V

Primary literature \mathbf{V}

Other V; specify: na onal policy

Recommendations from other hepatitis C guidelines

SIGN *Management of hepatitis C: A national clinical guideline* recommends that HCWs who intend to pursue a career in a speciality that requires them to perform exposure prone procedures (EPPs) should be screened for hepatitis C (Grade D).(2) *HIQA Quality Score of 127.7*

The US Centers for Disease Control and Prevention **Recommendations for prevention and control of hepatitis C virus (HCV) infection and HCV-related chronic disease** (1998) state that routine testing for HCV is not recommended for healthcare or emergency medical staff. (3) *HIQA Quality Score of 98*

Recommendations from occupational health or infection prevention and control guidance

To make a recommendation on this key question it was deemed more appropriate to refer to occupational health policy and guidance. Known healthcare policy and guidance from Ireland, the UK and the US is referred to. A search for further guidance was not undertaken.

Irish policy and guidance

The **Prevention of Transmission of Blood-borne Diseases in the Health care-setting** was published by the **Department of Health** in 2005 (4). This policy is currently being updated in relation to screening of HCWs. The policy was developed by the Standing Advisory Committee on the Prevention of Transmission of Blood-Borne Diseases in the Health-Care Setting and outlines the code of practice to be adhered to. The policy applies to all HCWs in Ireland, in both public and private health care settings.

It recommends that screening of all HCWs who perform EPPs should be initiated in Ireland. The recommendation applies to all HCWs who perform EPPS, including temporary workers, students, trainees, locums and supernumeraries.

The recommended screening process was an anti-HCV test, followed by PCR for hepatitis C RNA if positive.

It was proposed that implementation of the recommendation be introduced on an incremental basis, with new trainees, new entrants and re-entrants to the Irish health system, as the initial cohort for testing. This phase was to be evaluated and the outcome to inform the subsequent implementation of the process. An evaluation has not taken place.

The policy advocates voluntary disclosure of risk of infection. It recommends that all employees are informed of the risk factors and their ethical duties to disclose to an appropriate physician any BBV infection or risk of infection on commencement of employment. The policy states that any HCW who suspects that he/she may have been exposed to HCV must seek professional advice and diagnostic HCV testing.

Regarding HCWs found to be PCR positive, the policy states they must not carry out EPPs until a risk assessment has been undertaken. If a HCW is antibody positive but PCR negative for HCV they can continue to perform EPPs, but should have a PCR test annually while they continue to undertake EPPs.

The operational plan for the implementation of this policy within the HSE was outlined in *HSE HR Circular* 19/2008: Implementation of Recommendations of Report on The Prevention of Transmission of Blood Borne Diseases in the Health Care Setting issued by the National Director of Human Resources in July 2008 (5). An amendment was issues in April 2009 (6)

This stated that from 7July 2008, all new staff commencing in a post which involves EPPs should be tested for hepatitis C.

New staff are defined as those staff entering the Irish public health system for the first time or those staff currently in the system but now transferring to or taking up employment in an area that involves EPPs e.g. a nurse undertaking midwifery or a medical intern taking up a post of Surgical Senior House Officer.

Regarding repeat testing and testing of HCWs already in post, the circular states:

"Professional codes of practice from regulatory bodies require healthcare workers who may have been exposed to infection with a serious communicable disease, in whatever circumstances, promptly to seek and follow confidential professional advice about whether to undergo testing. Failure do so may breach the duty of care to patients. This means healthcare workers are under an ongoing obligation to seek professional advice about the need to be tested if they have been exposed to a serious communicable disease, obviating the need for repeat testing. This obligation applies equally to healthcare workers already in post."

International guidance

The Society for Healthcare Epidemiology of America (SHEA) in SHEA Guideline for Management of Healthcare Workers Who Are Infected with Hepatitis B Virus, Hepatitis C Virus, and/or Human Immunodeficiency Virus (2010) (HIQA Quality Score of 98) do not recommend mandatory HCV screening of HCWs (recommendation is graded A III: good evidence to support a recommendation; evidence comes from opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees) (7).

They recommend that:

- A provider who conducts Category III (see appendix 2) procedures is ethically obligated to know his or her infection status (A-III).
- Institutions should provide voluntary confidential testing for their employees (A-III).
- A provider who knows that he or she is the source of a patient exposure (ie, as defined by the CDC—a
 percutaneous, mucous membrane or nonintact-skin exposure) to his or her blood or hazardous blood or
 body fluid should report the exposure and should undergo testing for infection with blood borne
 pathogens (A-III).

The **UK**, **Department of Health** policy *Hepatitis C Infected Health Care Workers* (2002) reported that the Advisory Group on Hepatitis assessed the risk of transmission of HCV from a HCW of unknown HCV status during EPPs to be low (8). It therefore did not advise that all HCWs doing EPPs be routinely tested for HCV. It did recommend testing of:

- HCWs already known to be infected with hepatitis C and who perform EPPs for HCV RNA. This recommendation does not apply if already known to be RNA positive.
- Testing for antibodies to hepatitis C virus, and if positive for hepatitis C virus RNA, for HCWs intending to undertake professional training for a career that relies upon the performance of EPPs. They state that this should include:
 - Doctors entering surgical specialties
 - Dental students before entry into dental school
 - Midwifery students before commencing training
 - Nurses before moving to specialised areas of work
 - Ambulance staff
 - Podiatrists before commencing training

The report also stated that HCWs who perform EPPs who believe that they may have been exposed to hepatitis C infection should promptly seek and follow confidential professional advice on whether they should be tested for hepatitis C.

A more recent **UK Department of Health** policy *Health clearance for tuberculosis, hepatitis B, hepatitis C and HIV: New healthcare workers* (2007) outlines the health clearance requirements of new HCWs (9). It applies to new HCWs, defined as an individual who has direct clinical contact with patients whether as an employee of a trust or with the trust's agreement (e.g. students, visiting fellows) for the first time; existing HCWs who are moving to a post or training that involves EPPs; returning HCWs depending on what activities they engaged in while away.

It recommends that standard health clearance which includes testing for HCV **be offered** to all categories of new HCWs.

Additional health clearance, which involves Anti-HCV Ab test, and RNA if positive, **is required** for all new HCWs who will perform EPPs. This extends the previous 2002 guidance to all new staff and not just new trainees.

It recommends one off testing rather than repeat testing stating that professional codes of practice from professional bodies require HCWs who may have been exposed to seek advice about testing.

Regarding students, the recommendation applies to medical students who will be involved in EPPs but is not a requirement for all medical students. Additional health clearance is recommended for dental, midwifery, paramedic, ambulance technician and podiatric surgery students.

Healthcare students

The Irish DoH 2005 policy does state that it applies to students (4). The HSE circular does not make reference to undergraduate students training within the HSE (5).

The *Infectious disease policy for medical students in Ireland* (2011) agreed by the six medical schools in Ireland states in relation to HCV that:

"Any student who suspects he or she may have been exposed to HCV must notify the relevant office immediately for advice and support". No further guidance on hepatitis C screening is provided".

University College Cork (UCC) *Infectious Disease Screening And Immunisation Policy (Including Blood Borne Virus Policy) For Students of College of Medicine and Health Version 4.0 August 2015* requires applicants for places in dentistry, dental nursing and dental hygiene to provide laboratory evidence of their hepatitis C infectivity before registration. Any applicant or student identified as HCV antibody positive is required to undergo PCR testing for RNA.

In the UK a guidance document for medical and dental students, *Medical and dental students: Health clearance for Hepatitis B, Hepatitis C, HIV and Tuberculosis*, was developed by medical and dental school councils, Public Health England, Health Protection Scotland, the Association of UK University Hospitals, and Higher Education Occupational Practitioners.

For medical students it recommends voluntary testing early in training before exposure to EPPs. If testing is refused, or the student is found in be positive, the student will only be allowed to continue the course and proceed to registration with the medical council, provided that they formally accept the requirement they will not be allowed to perform EPPs or enter postgraduate clinical training in certain specialties until they have satisfied the requirements of the DH Health Clearance Guidance.

Potential dentistry students must undergo additional health clearance before acceptance onto the course. This includes those entering courses in dental hygiene and therapy. This applies to international students transferring to the UK.

4. What is the quality of the evidence? To be considered if primary literature was reviewed.

4.1. How reliable are the studies in the body of evidence?

If there is insufficient evidence to answer the key question go to section 11. Comment here on any issues concerning the quantity of evidence available on this topic and its methodological quality.

The supporting evidence of the UK guidance is not presented. The SHEA guideline is of good quality.

4.2. Are the studies consistent in their conclusions – comment on the degree of consistency within the available evidence. Highlight specific outcomes if appropriate. If there are conflicting results highlight how the group formed a judgement as to the overall direction of the evidence

Guidelines are consistent in requiring testing or emphasising the ethical obligation of those performing EPPs to know their status. They are consistent in recommendations around interval testing not being needed based on professional codes of conduct.

Some also suggest that all HCWs be offered testing.

4.3. Generalisability – are the patients in the studies similar to our target population for this guideline? is it reasonable to generalise

Yes, the risk of transmission from an infected HCW to a patient would be the same in Ireland as elsewhere

4.4. Applicability - Is the evidence applicable to Ireland? Is the intervention/ action implementable in Ireland?

Yes. Screening of those undertaking EPPs is current policy in Ireland.

4.5. Are there concerns about publication bias? Comment here on concerns about all studies coming from the same research group, funded by industry etc

Not relevant.

5. Additional information for consideration

5.1. Additional literature if applicable e.g. Irish literature

Literature on the risk of healthcare provider to patient transmission of hepatitis C

HCW to patient transmission of hepatitis C has been documented. A number of reports describe the detection of index patient cases, and subsequent lookbacks of potentially exposed patients. One case of acute HCV occurred during cardiovascular surgery in the UK where an operative assistance was found to be infected (10). The subsequent lookback tested 270 patients who had high risk EPPs where this HCW was involved. No other linked cases were identified. In Spain, six (two index and four identified in a lookback exercise) of 222 patients operated on by a chronically infected surgeon were infected, with five having strains closely related to the surgeons' (11). A lookback involving a gynaecologist in the UK was found seven infections with similar strains among 3628 people who had EPPs involving this HCW over 20 years of practice. In Germany a lookback of 207 patients of an orthopaedic surgeon found one linked infection in a patient who had undergone a total hip arthroplasty (12). Again in Germany, a patient who had a Caesarean section presented with strain almost identical to the obstetrician who performed surgery. A lookback of 2286 patients found no further cases (13).

A cluster of five cases was associated with an anaesthetic assistant was reported from Germany (14). The HCW reported acquiring infection through an occupational exposure. In the subsequent three weeks he infected five patients. During this time he worked with a weeping wound on his finger without wearing gloves. It is thought that viral burden was likely to have been very high during this period, contributing to the transmission.

A case of transmission from a mother with chronic infection who administered clotting factor infusions to her child with haemophilia was also reported (15). The mother did not wear gloves and reported instances of needle

stick injuries.

A number of reports, from the US, Spain and Israel, have described transmission from an anaesthetist or anaesthetic assistant who were, or were suspected of, diverting drugs, self-injecting and re-using needles on patients (16).

When the risk of provider to patient transmission is summarised based on published studies of lookbacks, studies from the UK yield a transmission rate of 0.19% (15/7656 patients tested) and 0.26% if index cases are included (7). Studies from Germany found no transmission in lookback exercises, but a transmission rate of 0.13% if index cases are considered (7).

Provider to patient transmission of hepatitis C, or investigations in Ireland

No known cases of provider to patient transmission of hepatitis C have been reported in Ireland.

In 2009 a lookback exercise was conducted in HSE West after the Department of Public Health was notified of a HCW who was infected with HCV (17). The HCW had worked in a number of hospitals in the region between 2004 and 2008. The HCW had a documented negative HCV test in 2005. The lookback invited 454 patients who had EPPs involving the HCW for testing. No cases of transmission were identified. The lookback team recommended that the HSE examine the feasibility of performing an evaluation of the compliance with the requirement for occupational screening for BBV among HCW carrying out EPPs.

They also recommended that interval testing be considered given that this HCW had tested negative early in the period of their employment.

A review of patient notification exercises (PNEs) in Ireland between 1997 and 2011, involved a survey of those with regional and national responsibility for the management of incidents of possible BBV transmission in healthcare settings to identify incidents (18). No other PNE due to an HCW infected with HCV were identified other than the one described above. In PNEs due to HCWs with others BBVs, no cases of provider to patient transmission were identified amongst almost 500 patients tested. The survey respondents did recommend more rigorous occupational health screening for BBVs and an audit of compliance with occupational health screening.

5.2. Relevant national policy

See DoH and HSE policy on testing in section 3 above

Guidance from professional regulators on testing for infectious diseases

A number of policies and guidance doucments refer to HCWs professional duty to seek testing if they believe themselves to be at risk. Both UK and SHEA guidance state that this professional duty obviates the needs to recommend interval testing of HCWs.

In Ireland the Guide to professional conduct and ethics for registered medical practitioners (2009) states that:

"If you think you might be infected with a serious communicable disease, you must seek appropriate medical advice without delay and ensure that your condition does not pose any risk to patients or others. The colleague(s) you consult in this regard has a dual role to both help and counsel you and to make sure that you do not pose a risk to patients and others. If such a risk exists, the Medical Council must be informed as soon as possible. " (19)

The Nursing and Midwifery Board of Ireland Code of Professional Conduct and Ethics (2014) states:

"You are responsible and accountable for your own health and well-being. If you become aware that your own health is affecting your ability to practise safely, you must get help to manage your condition." (20)

The Dental Council Code of Practice Relating to: Infection Prevention and Control states that:

"It is the ethical responsibility of DHCWs who believe that they may have been infected with a blood borne virus to obtain medical advice, including any necessary testing, and, if found to be infected, to place themselves under

specialist medical care. Their medical supervision will include counselling about changes in the healthcare worker's practice which might be considered appropriate in the best interest of protecting patients." (21)

(For information: At the time of publication of the UK DH 2007 guidance the General Medical Council did have a guidance document *Serious Communicable Disease* which stated the responsibilities of doctors who have been exposed to a serious communicable disease as follows:

- "If you have any reason to believe that you have been exposed to a serious communicable disease you must seek and follow professional advice without delay on whether you should undergo testing and, if so, which tests are appropriate."
- "You must not rely on your own assessment of the risks you pose to patients." (22)

This document was withdrawn in 2007. The current Good Medical Practice Guidelines (2013) state that:

"If you know or suspect that you have a serious condition that you could pass on to patients, or if your judgement or performance could be affected by a condition or its treatment, you must consult a suitably qualified colleague. You must follow their advice about any changes to your practice they consider necessary. You must not rely on your own assessment of the risk to patients." (23)

5.3. Epidemiology in Ireland if available and applicable

nil

6. Potential impact of recommendation

6.1. Benefit versus harm

What factors influence the balance between benefit versus harm? Take into account the likelihood of doing harm or good. Do the desirable effects outweigh the undesirable effects?

Benefits:

Of screening new HCW who will do EPPs:

- Avoid the risk of transmission to a patient. Avoids the cost, resources and human impact of lookback exercises.
- Identified HCWs can be treated and may be able to return to EPPs.

Of offering to all HCWs:

• Identified HCWs can be linked into care.

Of interval screening of HCWs who do EPPs:

• Identifies cases and limits lookback periods

Of screening existing HCWs doing EPPs, who have not been screened:

- Identified HCWs can be linked into care.
- Avoid the risk of transmission to a patient. Avoids the cost, resources and human impact of lookback exercises.

Of screening healthcare students:

- Identified students can be linked into care.
- Treatment can occur early and if successful will mean that career choices are not affected

- Avoid the risk of transmission to a patient.
- Allows decisions regarding career choices be made early if necessary

Harms:

- Inconvenience to HCW while follow up testing or assessment is being undertaken. Absence of a national occupational health system may confound this for HCWs that move post regularly eg NCHDs.
- Stigmatisation of detected cases
- Possible discrimination of HCWs regarding employment despite not being infectious.
- Detection of cases in existing HCWs doing EPPs may result in the need for lookbacks which are resource intensive, can distress patients, and can have a very low yield (i.e. no transmission events identified).
- May result in undue influence on a student's career choices
- **6.2. What are the likely resource implications and how large are the resource requirements?** Consider cost effectiveness, financial, human and other resource implications

Screening of HCWs who perform EPPs at initiation of employment is current practice and should not require additional resources. However, there is a need for a standardised system for monitoring update and results of testing.

Any recommendation for interval screening would require additional resources, mainly in the monitoring of the programme.

Recommending screening of existing workers who have not been screened would require resources.

Offer of screening to all HCWs would require an additional laboratory test. Blood sample usually already taken to prove immunity to HBV.

Screening of students will have resource implications. However, as above, students are currently tested for HBV immunity.

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

The risk of provider to patient transmission of HCV, even during EPPs, is extremely low. However, in the context of healthcare provision any potential risk is likely to be considered unacceptable. It is likely to be considered acceptable to the general population and the health service that those performing EPPs be screened.

The acceptability of interval testing to existing HCWs performing EPPs is not known. Similarly the acceptability of screening existing HCWs who have not been screened is not known. These may also have IR issues.

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

Screening of HCWs undertaking EPPs is current practice. The level of compliance with this recommendation is not known.

Any recommendation on interval testing or testing of existing HCWs may be more difficult to implement than screening at the start of employment.

Screening of locums, or ensuring they have been screened by their employing agency, may be difficult.

Screening of medical students who perform EPPs would be difficult to implement and enforce. The opportunity to perform an EPP may arise during a placement rather than being a planned intention. Screening of all students would be more feasible than determining if a student was negative prior to being allowed to do an EPP.

An offer of a HCV screen to all new HCWs would be feasible as new HCWs undergo an occupational health assessment.

6.5. What would be the impact on health equity?

If identified cases are linked into care and have access to treatment, no impact is foreseen.

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

In the context of healthcare provision any risk of provider to patient transmission of HCV needs to be minimised.

8. Final Recommendations

√ Strong recommenda on

 $\hfill\square$ Condi onal/ weak recommendation

Text:

- All new healthcare workers should be offered voluntary hepatitis C screening
- Mandatory screening of all new healthcare workers who will perform EPPs is recommended
- Existing healthcare workers who perform EPPs and have not yet been screened should be offered hepatitis C 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.

9. Justification

While there is no risk of provider to patient transmission of hepatitis C in HCWs who do not perform EPPs, the offer of hepatitis C screening to all new HCWs confers a personal benefit to HCWs by identifying undiagnosed cases and allowing linkage to care and treatment.

Screening of HCWs who perform EPPs is justified to reduce the risk of provider to patient transmission of hepatitis C.

Screening of existing HCWs who have not been previously screened is considered best practice.

Screening of healthcare students early in the course of their training is recommended to identify undiagnosed cases and link them to care and treatment. Successful treatment will avoid implications for their future career choices.

10. Implementation considerations

Audit of compliance should be undertaken by institutions. Compliance could also be audited though DIME (IT database of NCHD occupational health records).

Clear service level agreements are required with agencies who provide locums to ensure all staff have been screened.

11. Recommendations for research

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

Review by GDG

Date: 23/02/2017

It was raised if mandatory screening of students would be acceptable. JG advised that this is current practice in UCC. That it would allow treatment take place early and therefore not impact on career decisions.

The recommendation was accepted.

Consultation feedback and review by GDG

Please see <u>Report of the consultation process</u> for feedback received.

No material change to recommendation.

Final recommendation

Recommendation 21

- 21.1. All new healthcare workers should be offered HCV screening on a voluntary basis.
- 21.2. Mandatory HCV screening of all new HCWs who will perform EPPs is recommended.
- 21.3. Existing HCWs who perform EPPs and have not yet been screened should be offered HCV screening.
- 21.4. Mandatory screening of all new healthcare students* is recommended.
- 21.5. Interval HCV 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.

*This includes students who may be undertaking EPPs as students or in their future careers, such as dental, medical, nursing, midwifery, or paramedical students.

Quality/level of evidence: moderate Strength of recommendation: strong

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- 2007.
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Appendices

Evidence search and results

International and national guidelines

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

Other guidelines reviewed

Key international guidelines on healthcare worker screening were identified by expert GDG members.

Grey literature

Irish policy on HCW screening was identified by expert GDG members.

Primary literature

A systematic literature review was not undertaken. Literature identified by expert members of the GDG was included for review where relevant.