



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Look back Exercise

Hepatitis C in a Healthcare Worker

HSE West 2009-2010

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Abbreviations and Acronyms

GUH: Galway University Hospital

HCW: Health Care Worker

HIPE: Hospital Inpatient Enquiry database

HPSC: Health Protection Surveillance Centre

HSE W: Health Service Executive MGH: Mayo General Hospital

INR: International normalized ratio

LEG: Local Expert Group

LIG: Local Incident Group

NSAC: National Standing Advisory Committee of Blood-borne Diseases in the Health-Care Setting

SIMT: Serious Incident Management Team

UKAP: UK Advisory Panel for Health Care Workers infected with Blood-borne Viruses

Acknowledgements

This project was enabled by team work involving the Department of Public Health HSE W, Galway University Hospital, Mayo General Hospital and Letterkenny General Hospital. The team would like to sincerely thank the Hospital Managers and their teams for their co-operation. In addition, thanks are due to the local advisory group for their expert advice.

Summary

In June 2009 the Director of Public Health, HSE West (Galway, Mayo and Roscommon) was notified of a case of Hepatitis C (HCV) in a health care worker (HCW). This HCW was employed by HSE West from July 2004 to June 2008. In 2005, a blood sample identified as from this HCW had tested negative for HCV infection. Since 2005 the HCW had worked in Galway University Hospital (GUH), Mayo General Hospital (MGH), and in a short locum post in Letterkenny General Hospital (LGH). Following the notification, a multidisciplinary local advisory group was convened immediately that concluded that a lookback exercise for the period the HCW worked in the region was indicated. The purpose of this look-back was to ascertain if any patient had been infected by Hepatitis C as a result of contact with the HCW. A validated review of charts was carried out. All procedures that represented a potential risk for HCV transmission (exposure prone procedures (EPP's)) at which the HCW was present were identified and a database was created. All surviving patients were invited for precautionary testing for evidence of infection with HCV. A total of 454 patients were invited for blood tests. Within 6 weeks of the start of testing 90% of these people were tested. The results show no evidence that the people tested are now or have ever been infected with Hepatitis C Virus.

Key Areas that enabled this lookback exercise

- The understanding and support of the patients concerned their families, friends and carers.
- Collaboration and cooperation at all levels among stakeholders.
- A willingness among GPs, their staff, hospital personnel including clinic staff and laboratory staff to provide as much assistance as they could so that individuals were contacted, tested and received their test result in a short time and in a manner that minimized inconvenience to them.
- Clear briefing of the media resulted in an accurate message being provided to the public which minimised anxiety and promoted a high level of response from the public.
- A clear and concise process map provided clarity to all the personnel involved regarding the overall process and their own role. This was very effective given the number of locations involved.

Background

The HCW concerned commenced employment with HSE West in July 2004. This person worked in GUH until the end of May 2005 and in MGH between January 2006 and May 2008. It was established that there was no ongoing risk to current patients.

In June 2009 the Department of Public Health, HSE West, Galway was informed that this HCW had attended a specialist clinic for treatment of Hepatitis C genotype 3A. The hepatitis C viral load on the patient was 381705 IU/ml. Tests for infection with Hepatitis B and HIV were negative. The Occupational Health Department at GUH was informed. In accordance with the 2005 Dept of Health and Children policy on *The Prevention of Blood-Borne Diseases in the Health-Care Setting*¹, a local expert group (LEG) was convened to consider the implications. This group included representatives from public health, occupational health, microbiology, hospital management and legal advisers. The LEG considered all the available information and considered that although the likelihood of HCV transmission was very low it was not possible to entirely exclude that possibility and therefore a lookback exercise was recommended to determine if there was any evidence of HCV transmission.

The Chair of the National Standing Advisory Committee of Blood-borne Diseases in the Health-Care Setting (NSAC) and the HSE Serious Incident Management Team (SIMT) were notified.

Terms of Reference for the Lookback Exercise

- A lookback study of all exposure prone procedures as defined by the UK Advisory Panel for Health Care Workers infected with Blood-borne Viruses (UKAP)² will be carried out for the period of employment in HSE West i.e. July 1st 2004 to June 30th 2008.
- All surviving patients identified as having EPP's carried out in the presence of this HCW will be invited for precautionary screening for hepatitis C infection.

The NSAC agreed with these terms of reference.

Employment History

HSE West

The employment history of the HCW in HSE West was confirmed by Human Resources Department.

Private Hospitals

There was anecdotal evidence that the HCW had carried out procedures in a private hospital in the region and there was concern that the HCW may have carried out locum work in other private hospitals. All private hospitals in the region were formally notified. Private Hospital 1(PH1) replied and identified nine patients from theatre log books who had EPPs at which the HCW had attended. Private Hospital 2(PH2) reported that this HCW did not carry out any procedures in that hospital. Private Hospital 3(PH3) carried out a chart review which identified twenty one patients.

Lookback - Local Expert Group (LEG)

A multidisciplinary local expert group was set up and chaired by the Director of Public Health in HSE West, Galway.

Members included:

- Consultants in Public Health Medicine x 4 (including one from the Health Protection Surveillance Centre, HPSC)
- Consultant Microbiologist (an external microbiologist was involved in the initial meetings)
- Consultant in Infectious Diseases
- Consultant in Occupational Medicine
- Hospital Managers from each HSE hospital
- HSE Communications
- Representative from the HSE Serious Incident Management Team
- Assistant National Director for Health Protection
- Solicitor

A negative test for HCV for the HCW was documented in 2005, however there was an element of uncertainty regarding the time at which the HCW became infected with HCV. This issue was referred to the NSCBBV who advised that in the first instance a thorough lookback relating to the HCW's period of employment in HSE-West would be carried out and the results of this would inform the need for a further investigation. A lookback exercise of patients who had EPPs carried out by the HCW during his term of employment in HSE West was carried out. The lookback was coordinated by HSE West and a lead Consultant in Public Health Medicine was identified to manage the process.

Lookback Exercise

A local incident group (LIG) was convened which included staff from Public Health, the GUH hospital manager, the MGH hospital manager, hepatitis C liaison nurses, nurse managers, Microbiology, Phlebotomy and Communications. This group was chaired by the Consultant in Public

Health. Working groups were also convened in the individual hospitals to carry out the tasks agreed at the LIG meetings.

Identification of Patients:

An independent surgeon agreed to conduct the process of validating EPP's in the patients identified.

Exposure Prone Procedures (EPPs)

Exposure Prone Procedures were classified in accordance with recommendations from the UK Advisory Panel for Health Care Workers infected with Blood-borne Viruses (UKAP)²

Meetings were held with the hospital managers and one person in each centre was identified to review the theatre register. All procedures carried out by the HCW were identified. A database was set up.

Fields included:

Board number

Date of surgery

Details of Surgery

Title

Forename

Surname

Date of Birth

Date of Death (if applicable)

Address 1

Address 2

Address 3

GP Name and address

GP Telephone number

Next of kin Name and Address (where applicable)

On completion of the databases, theatre registers were transferred to the Department of Public Health to cross-check and validate accurate data transfer. Any errors were identified and corrected.

A form was designed to aid the review by the independent expert (Appendix A). The independent expert categorized each procedure using one of the three categories; EPP, Non-EPP or 'more info' where more information was required to confirm whether the procedure was an EPP.

Charts were obtained on all patients who had procedures classified as EPP or 'more info'. Surgical notes from all charts pulled were photocopied and personal details were cross-checked and updated with the most recent details on the PAS system. All surgical notes were reviewed by the independent expert and classified as EPP or non-EPP. One theatre register could not be found and the Hospital Inpatient Enquiry database (HIPE) was used to identify these patients.

Communications

A communications plan was developed with the communications officer in HSE West. It described the key objectives of the plan for communicating with patients and other stakeholders for the lookback exercise and identified actions and responsibilities

Helplines

Part of the communications plan was to ensure that the patients involved would have easy access to the process once it was underway. A communications process map was devised demonstrating the planned communication flow with the planned patient helplines (Appendix B). The provision of a

national helpline was agreed, primarily to deal with enquiries from the public: the telephone number of this helpline was provided in the press release for use by the media. In addition each hospital centre provided helplines for their patients. These numbers were included in the patient letters only.

Letters

Letters to the patients affected and to GPs involved were drafted in consultation with Public Health, Hospital Management and Communications staff (Appendix C). All letters were adapted for the specific hospital centre. The content of the letter included details of the incident and offered precautionary testing for HCV. It also provided the helpline numbers that patients could contact at their discretion for further information.

Press Release

HSE policy and procedure in reviews of this kind is that, insofar as is possible, patients are informed of their inclusion in a review before the review is publicised. A press release was drafted highlighting the nature of the incident and the measures that were being taken in accordance with national and international best practice and guidance. The plan was to issue this after letters were sent to patients, with a contingency to respond to media queries that might arise in advance of this (Appendix D).

Frequently asked questions for health care workers

Responses to frequently asked questions were prepared by public health in consultation with the consultant with responsibility for the regional hepatitis C service, and the hepatitis C liaison nurses in the region and the LIG (Appendix E). Issues covered included transmission, transmission risk, diagnosis, test result interpretation, further diagnostic tests, symptoms signs and treatment of infection and implications of testing on insurance premiums.

Information for patients

A leaflet with information for patients who were offered precautionary testing was prepared by public health in consultation with the LIG (Appendix F).

Script for telephone call to GP's

A script was devised for telephone calls to GPs to standardize information collection and distribution (Appendix G). These ensured standard details were collected from each GP.

Script for follow-up telephone call to patients who did not attend their GP

A script was prepared for telephone calls to patients to standardize information collection and distribution (Appendix H).

Patient Advocacy Groups

Contact details of all relevant advocacy groups were collected. This included Transfusion positive, Irish Haemophiliac Society, Positive Action and the Irish Kidney Association. These groups were informed of the lookback process before the press release was issued.

General Practitioners

GP Fee

A fee of €50/patient for GP's providing the screening service to be paid by the respective hospitals was agreed. (Appendix I)

GP Packages

A standard pack was assembled for GPs of all patients identified in the study. These packs included the following contents:

- Letter to GP
- Frequently asked questions for health care workers
- Guidelines on taking and returning blood sample (Appendix J)
- Information for patients
- Claim form (per patient)
- Serum bottle/ form / labels (per patient)
- Transport container for serum bottle (per patient)
- Stamped addressed padded envelope for return of blood sample to the virology laboratory

Database

The total number of relevant EPPs in each HSE hospital was:

GUH 206

MGH 319

LKH 6

The final dataset was mined for the following:

- Identifying Deceased Patients

The national Registrar General was consulted about identifying deceased patients and the issue of searching the patient list for registered deaths was discussed. The most efficient and effective method of searching was using the Department of Finance Death Event publishing system. This is a database which contains all registered deaths. This database is updated weekly with the most recent events from the registrar general. A 'certificate of access' was obtained by the HSE Department of Public Health from the Department of Finance. In total 71 deaths were identified.

- Previously infected hepatitis c patients

The final dataset was crosschecked against the Computerised Infectious Disease Register (CIDR) and the Regional Hepatitis C clinic database.

Two patients were identified.

- Children

All datasets were searched for date of birth after May 1992. This identified all patients who would be less than eighteen years of age at the time of notification: 11 children were identified.

- Patients outside Republic of Ireland

All patients with addresses outside the Republic of Ireland were identified (6 patients in total, 5 from the UK and 1 from Germany). These patients were referred to the HPSC who contacted the relevant health authorities in each of the countries to identify each patient's GP and subsequently contact each patient. Table 1 describes the number of patients and procedures involved in each hospital centre.

Table 1 Number of patients and procedures involved in each hospital centre

	GUH	MGH	LGH
Total EPPs	206	319	6
Alive EPPs	175	279	6
GP screening	147	240	5
Hospital screening	18	29	1
Children	4	5	2

Hepatitis C +	1	1	0
Next of Kin*	4	4	0
HPSC	1	5	0

**Number of patients where it was appropriate to contact the next of kin*

Process Map

A process map was developed outlining timing and systems which would be in place in order to carry out the lookback exercise (Appendix K). This included helplines, clinics and laboratory testing.

Laboratory

Testing

The screening test for antibodies to Hepatitis C virus which was used is the ARCHITECT Anti-HCV assay – a chemiluminescent microparticle immunoassay (CMIA). Any samples which tested positive or equivocal on this screening test were referred to the National Virus Reference Laboratory (NVRL) in Dublin for further testing. The tests which they performed included Hepatitis C Ag-Ab Monolisa, Hepatitis C antigen Architect, Inno-Lia for Hepatitis C Ab and HCV RNA as appropriate for each sample.

Process

Guidelines regarding the taking, labelling and returning of blood samples to the laboratory were developed by public health in consultation with microbiology (Appendix J). Labels were colour-coded by hospital centre (GUH pink and MGH green) to enable ready identification of samples when received by laboratory staff. In addition an outbreak code was placed on all labels which was hospital specific, LKG2010 for GUH and LKM2010 for MGH. Once again this enabled ready identification of result reports belonging to the lookback exercise and the hospital centre in which they originated.

Education and Training

An education session was held in GUH with a video link to MGH. All staff dealing with the public attended. This included presentations by the Consultant Gastroenterologist with the responsibility for the Hepatitis C service in the region and the hepatitis C liaison nurse. This was followed by a question and answer session. This session was very informative and enhanced the development of the Frequently Asked Questions document. A subsequent educational session was given in Mayo General Hospital by the hepatitis C liaison nurse.

Process

Monday May 10th

The HCW was contacted and informed that the lookback would commence soon and that patients would be contacted shortly. By Monday May 10th all case notes had been reviewed and the list of patients to be called for precautionary screening was finalized. Letters to GPs were finalized and GP packs were assembled by public health staff. These were delivered to the hospital centres. Letters to GP's were reviewed and signed by hospital managers.

Friday May 14th

On Friday May 14th GP packs were sent by registered mail from the hospital centres to GP Practices. These were received on Monday May 17th.

Monday May 17th

Contacting of GP's

On Monday May 17th a team of public health medical staff and hospital staff involved in the lookback phoned all the GPs using a standard script to deliver and obtain standard information. (Appendix G).

Wednesday May 19th

Datasets were organized and finalized for each hospital centre. Each hospital received a dataset with a number of work sheets. These included:

1. **Total** - this represented all patients alive or dead who had EPPs carried out in that hospital in which the HCW was documented as being involved in the procedure.
2. **Alive** - all living patients
3. **GP's** – all living patients whose GP agreed to carry out the screening.
4. **Clinics** – all living patients whose GP details were not available or whose GP opted not to conduct the screening process
5. **Next of Kin (NOK)** – living patients where the GP recommended contacting the next of kin rather than that patient (on the grounds of dementia, limited understanding etc.)
6. **Children** – living patients who were now less than eighteen years of age. This worksheet included parent contact details
7. **HPSC** - patients who had addresses outside of Republic of Ireland.

Thursday May 20th

Risk Communication

On Thursday May 20th a press release was distributed, following a query from the media. There was extensive national and regional media coverage and the general national helpline number was given to allow queries from patients.

Friday May 21st

Letters to Patients

On Friday May 21st letters were sent to patients from the hospital managers' offices. Those who had a nominated GP and whose GP had agreed to carry out the screening received a letter recommending them to contact their GP for screening. Those who did not have a nominated GP or whose GP opted

not to carry out precautionary screening were offered a clinic appointment in the hospital where they had their procedure carried out.

Advocacy groups

All advocacy groups were contacted and informed of the lookback process.

Tuesday May 25th

Regional Health Forum

On Tuesday May 25th a briefing and presentation was given by a Consultant in Public Health Medicine to the Regional Health Forum, HSE West, on the lookback exercise.

Wed May 26th and Fri May 28th

Clinics

In total 18 patients in GUH and 29 patients in MGH were offered clinic appointments. Clinics were held on Wed 26th and Fri 28th of May. Two different booking systems were used in the hospital centres. In Galway patients were given a number to ring in order to arrange an appointment at a time that would suit them. In Mayo patients were given a pre-arranged appointment in their letter and a number which they could contact if the pre-arranged appointment did not suit them. In total 13 patients attended the clinic in GUH and 20 attended the clinics in MGH. Clinics were staffed by nursing staff including a Hepatitis C liaison nurse, administrative staff and a phlebotomist. Medical back up was available if necessary.

Monday May 31st

By Monday May 31st approximately 70% of samples were received and were reported negative. Updates were prepared and given on request to the media.

Monday June 14th

All patients who had not presented to their GP were identified. These patients were contacted by telephone to ensure they received the initial letter on May 24th and ascertain if these patients wished to avail of the screening offered. A script was devised for these telephone calls (Appendix H). Calls were made by nominated persons in each of the hospital centres.

Helpline Activity

Table 2 Helpline activity

Centre	Number of Calls
National helpline	65
Galway University Hospital helpline	53
Mayo General Hospital helpline	60
Letterkenny General Hospital helpline	3

Results

There was no evidence of Hepatitis C virus infection in any patient tested. Four specimens which gave equivocal results on initial screening were sent to the NVRL for definitive additional testing. This process took 2-3 working days. All four samples showed no evidence of infection. In light of a history that one of the patients had hepatitis C in the past, one sample was sent for detection of HCV nucleic acid. Viral RNA was reported as not detected.

Hospital clinic patients - Patients who attended the hospital clinics were phoned by the nursing staff within 48 hours with the result of their tests. A paper copy was sent to the relevant GP and to the Department of Public Health.

GP patients – Patients who attended their GP for screening were given their result by their GP. Healthlink, the electronic system which provides an interface between GP's and the laboratory aided the timely communication of results. Seventy five per cent (157/210) of GP's involved in the screening process were on Healthlink. The remaining 25% (53/210) of GP's received the paper results not later than 7 days after the test, and in the majority within 72 hours. Results were also available immediately by telephone to GP's in the event that the GP considered it necessary to telephone for the result.

Table 3, 4, and 5 represent the results in the respective centres. The 'Total tested' column represents those who had the blood test. Tests outstanding represent those who have been contacted and have either deferred the test or have chosen not to have the test done. Every effort has been made to contact all patients including contacting GP's, getting forwarding addresses where available, and getting addresses and contact details of next of kin where applicable. All avenues have been pursued in those described as non-contactable and no further leads are available.

Table 3 Results Galway University Hospital*

	GUH	Total tested	Tests outstanding	Number not contactable	Results to date
Alive EPP's	175**(174)	147	24	3	negative
GP screening	155	135	17	3	negative
Hospital screening GUH	14**(13)	10	3	0	negative
Hospital screening Other	5	2	3	0	negative
HPSC	1	0	0	1	

*All results documented represent figures on 01/07/2010

** inclusive of 1 new deceased person

Table 4 Results Mayo General Hospital*

	MGH	Total tested	Tests outstanding	Number not contactable	Results
Alive EPPs	279**(275)	242	19	15	negative
GP screening	244** (241)	221	8***	12	negative
Hospital screening	30	20	7	3	negative
HPSC	5**(4)	2	2	0	negative

*All results documented represent figures on 01/07/2010

** inclusive of new deceased persons (3 GP screening; 1 HPSC)

*** inclusive of 2 who opted not to have screening

Table 5 Results Letterkenny General Hospital*

	LGH	Total tested	Number not contactable	Tests outstanding	Results
Alive EPP's	6	5	0	1	
GP screening	5	4	0	1	negative
Hospital screening	1	1	0	0	negative
HPSC	0	0	0	0	

*(All results documented represent figures on 01/07/2010)

Conclusions

454 patients were called for precautionary screening for hepatitis C infection following possible exposure from an infected HCW. All tests to the end of August 2010 were negative. Testing remains available at any time to the 44 (9.6%) patients who have not yet availed of testing. Nineteen patients (4.1%) were not contactable. The LIG and the LEG agreed that based on the results of this lookback there was no evidence of transmission of infection from the provider to a patient and there was no benefit in contacting relatives of deceased patients.

A number of issues arose during the lookback process which could be avoided in future lookback exercises.

This lookback exercise raises the question of the efficiency of occupational screening of health care workers for blood borne viruses. In July 2008 a new HSE occupational health policy was introduced that requires all new entrants to a post which involves carrying out EPPs should be screened for Hepatitis C infection¹. This policy only recommends once off testing at time of entry to the service. Interval testing should be considered in the future.

In some instances errors occurred in transfer of data from theatre registers to the lookback database. These errors could have been avoided if double entry was used as the process for transfer of data.

In the letter to the patient it was not clear that the screening test would carry no cost to the patient. Initially this prevented a small number of patients from availing of the screening test. It is important that this should be stated clearly in the letter to the patient in future lookback exercises.

This lookback exercise took 11 months from the time of notification to the Department of Public Health to the notification of patients. This had no ultimate impact on patient outcomes. This was as a result of the extensive and thorough process that was carried out to identify appropriate patients which was in accordance with international best practice guidelines. It was also during a time when public health resources were stretched due to the Pandemic Influenza A(H1N1)v and also industrial action by public service unions. This process could have been completed more rapidly if there was more surge capacity.

An electronic theatre register system is necessary for standard recording of theatre events. This will require significant investment. In the interim a logging system to document the location of theatre registers at all times is necessary to avoid misplacement.

A lookback exercise is very labour intensive and time consuming. It may be worthwhile considering evaluation of the compliance with the occupational health screening programme for HCW's carrying out EPPs and avoid the need to carry out these exercises in the future.

In addition it is also appropriate to consider that given the body of evidence including this exercise that transmission from provider to patient is very rare. This should inform future decisions on carrying out lookback exercises.

Recommendations

- The HSE should examine the feasibility of performing an evaluation of the compliance with the requirement for occupational screening for BBV among HCW carrying out EPP's
- General Practitioners in the region should adopt the use of the healthlink electronic laboratory result system as soon as possible.
- All theatre facilities should adopt the use of electronic theatre register systems to standardise recording of information regarding theatre events. In the interim a logging system to document the location of theatre registers at all times should be implemented immediately
- Governance of theatre registers needs to be addressed.
- Given the disturbance and inconvenience to patients, the health care costs and the very low probability of finding any evidence of transmission in scenarios such as this it is appropriate to consider a review of criteria for assessing the need to perform a lookback when a health care worker is identified as positive for hepatitis C virus infection where there is no evidence of poor practice or virus transmission.

References

1. Department of Health and Children. The prevention of transmission of blood-borne diseases in the health-care setting. Dublin: Department of Health and Children, 2005.
2. Department of Health, UK. HIV and an infected health care worker - guidelines on management and patient notification. *Annex A*. London: Department of Health, England.

Appendix A - Review of patient procedures

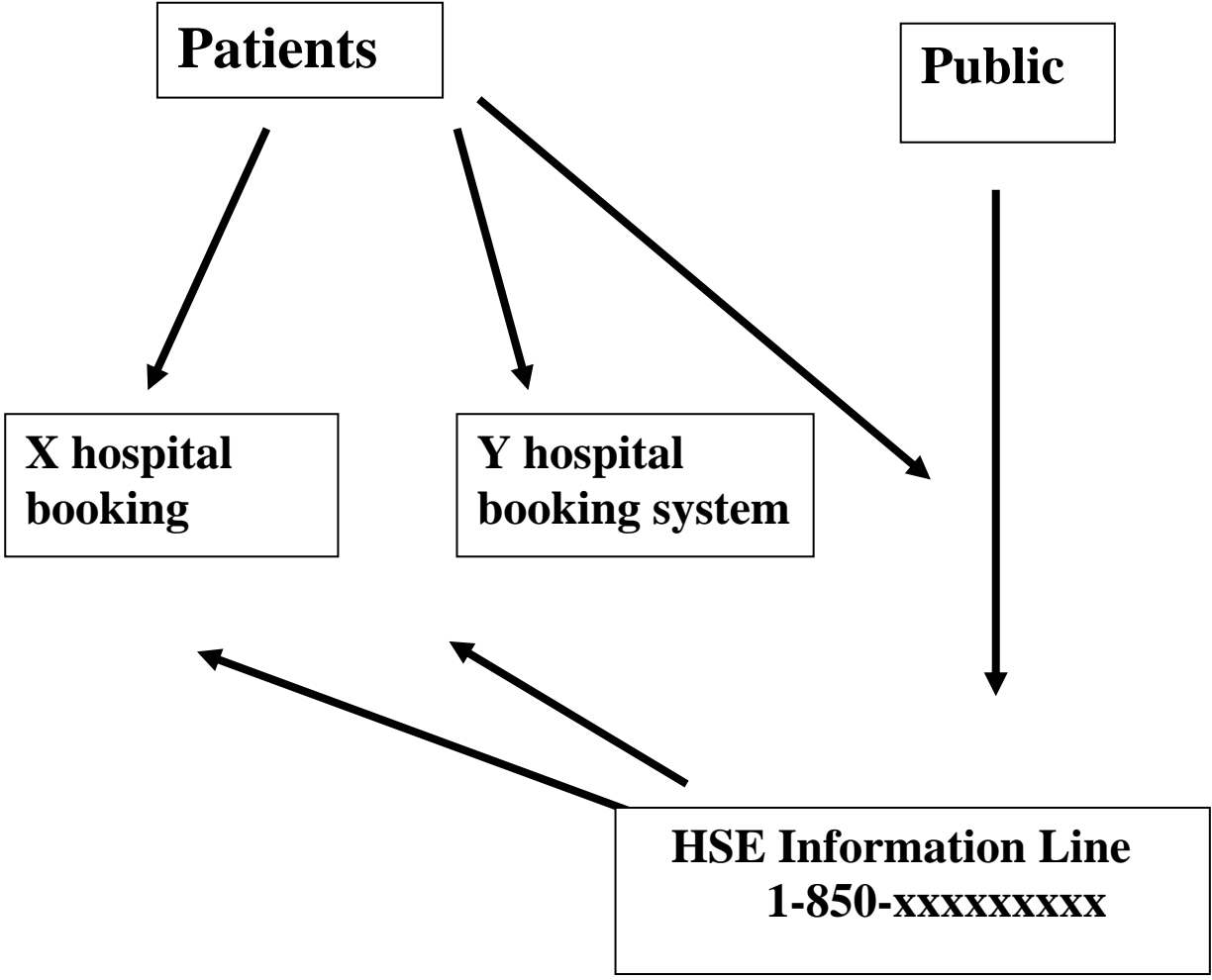
Please tick where appropriate

BN	Details of procedure	Date	EPP	Non-EPP	More Info
XXXXX		XXXXX			
XXXXX		XXXXX			
XXXXX		XXXXX			
XXXXX		XXXXX			
XXXXX		XXXXX			
XXXXX		XXXXX			
XXXXX		XXXXX			
XXXXX		XXXXX			
XXXXX		XXXXX			
XXXXX		XXXXX			
XXXXX		XXXXX			

Appendix B – Communications process map

Communications

Helplines



Appendix C - Letters

Appendix C1- Letter to GP

PRIVATE AND CONFIDENTIAL
FOR DR X ATTENTION

Please treat this matter as highly confidential

DATE

Dear Doctor

A health care worker who worked in xxxx Hospital has been found to have Hepatitis C virus infection. This health care worker was involved in a number of operations classified as exposure prone procedures (EPP) between 2004 and 2005. While we are confident that the risk to patients involved in these procedures is very low, in accordance with national guidelines a look-back exercise is necessary. We and the Department of Public Health, HSE xxx are working closely together to plan this look-back process. A parallel exercise is underway at xxxx and xxxxx General Hospital.

According to our records XX patients in your practice had an exposure prone procedure (EPP) between the relevant dates, and will need to be followed up with a blood test to screen for Hepatitis C. We will shortly be writing directly to all patients who need to be screened, and these letters will be delivered to patients from next Monday 24th May.

The letters to patient(s) outline the reason for the review process and give details of how their screening test will be carried out. It also includes the phone number of a dedicated patient information line at the hospital.

I am asking for your help in taking these/this blood test(s). You will be paid a €50 fee / patient for this work by the HSE. Enclosed is an invoice and pathology kit(s) with instructions to help you with the test.

Where GPs carry out tests, test results will be available as soon as possible and not later than 7 days of receipt of blood test to the lab. Again, the risk for these patients is very low but in the event of a patient testing positive for hepatitis C, you will be telephoned with this result and a rapid referral to specialist care will be facilitated.

If it is not possible for you to take the samples, your patient will be offered an appointment at a special clinic in xxx hospital. **The Department of Public Health will be phoning you in the coming days to ask which of these options you consider to be most appropriate for your patient.** This will allow our letters to patients next week to direct them either to make an appointment at the hospital or to contact your surgery for testing.

We would like to stress again that patients have not yet been informed of this issue. Our purpose in writing to you in advance is to ensure that the service in place for the people involved is as supportive and streamlined as is possible. I would request that confidentially be assured on this matter to avoid unnecessary worry for patients in advance of the notification letters being sent.

As you are aware, the risk of any patient who was looked after by this health care worker contracting hepatitis C is very low. Our priority now is to give as much reassurance as we can to the patients involved and to complete the blood sampling as quickly as possible. Your support in this work is greatly appreciated and we thank you for your help.

Yours sincerely,

General Manager
xxxxxx Hospital

<p>Enclosures: Blood taking kit Information for the patient Information for GPs Fee claim form</p>

Appendix C2 – Letter to adult patient attending GP

Private and Confidential

Xxx first name and second name

Address 1

Address 2

Address 3

Address 4

May 21st 2010

Dear XX surname

I am writing to advise you that a healthcare worker who worked in xxxxx Hospitals has been diagnosed with Hepatitis C infection. Our records indicate that you were a patient of xxxx Hospital at this time and that the healthcare worker had an involvement in your surgery. I understand that this information is upsetting but please be assured that the risk of you getting Hepatitis C is very low.

We are erring on the side of caution and request that you should now contact your GP so that a test can be done. Results will be available as soon as possible but no later than 7 days of receipt of your blood test to the laboratory. Results will be sent to your GP who will contact you at that stage.

Again I would like to stress that the risk of any patient contracting Hepatitis C is remote but nevertheless I want to provide you with as much information as you might need. An information line is open from 8am to 10pm Mon – Wed of this week and 9am to 5pm thereafter. You should not hesitate to call with any queries you may have.

The number is 1-800-xxxxxxx.

As Manager of the hospital I am sorry to have to contact you in this way. I hope that our information line can provide you with whatever information you might need and that the arrangements which I have put in place for prompt blood testing will provide you with the reassurance you need as quickly as possible.

Yours sincerely,

Xxxxxxxx General Manager,
Xxxxxxxx Hospital

PLEASE NOTE: We have checked our patient records carefully in order to send this letter, but if you have received it in error, we sincerely apologise for any inaccuracy or any inconvenience it may have caused.

Appendix C3 – Letter to adult patient attending hospital clinic

Private and Confidential

Xxx first name and second name

Address 1

Address 2

Address 3

Address 4

May 21st 2010

Dear XX surname

I am writing to advise you that a healthcare worker who worked in xxxxxx Hospital has been diagnosed with Hepatitis C infection. Our records indicate that you were a patient of xxxxx Hospital at this time and that the healthcare worker had an involvement in your surgery. I understand that this information is upsetting but please be assured that the risk of you getting Hepatitis C is very low.

We are erring on the side of caution and would like to offer you an appointment at which you may speak to specialist nurses and have a blood test carried out. Your results will be phoned to you as soon as possible but no later than 7 days after having your test. You should now contact the following number 1-800-xxxxxxx to make this appointment.

Again I would like to stress that the risk of any patient contracting Hepatitis C is remote but nevertheless I want to provide you with as much information as you might need. An information line is open from 8 am to 10pm Mon – Wed of this week and 9am to 5pm thereafter. You should not hesitate to call with any queries you may have. **The number is 1-800-xxxxxxx.**

As Manager of the hospital I am sorry to have to contact you in this way. I hope that our information line can provide you with whatever information you might need and that the arrangements which I have put in place for prompt blood testing will provide you with the reassurance you need as quickly as possible.

Yours sincerely,

General Manager,
xxxxxx Hospital

PLEASE NOTE: We have checked our patient records carefully in order to send this letter, but if you have received it in error, we sincerely apologise for any inaccuracy or any inconvenience it may have caused.

Appendix C4 – Letter to Parent of child

Private and Confidential

Xxx first name and second name

Address 1

Address 2

Address 3

Address 4

May 21st 2010

Dear XX surname

I am writing to advise you that a healthcare worker who worked with us here in xxxx Hospital has been diagnosed with Hepatitis C infection. Our records indicate that your child was a patient of ours during this period and that the healthcare worker had an involvement in your child's surgery. I understand that this information is upsetting but please be assured that the risk of your child getting Hepatitis C is very low.

We are erring on the side of caution and want to offer your child a blood test. You should now contact your GP so that the test can be done. Results will be available as soon as possible but no later than 7 days of receipt of the blood test to the laboratory. Results will be sent to your GP who will contact you at that stage.

Again I would like to stress that the risk of any patient contracting Hepatitis C is remote but nevertheless I want to provide you and your child with as much information you might need. An information line is open from 8 am to 10 pm Mon – Wed of this week and 9am to 5pm thereafter. You should not hesitate to call with any queries you may have. The number is 1-800-xxxxxxx.

As Manager of the hospital I am sorry to have to contact you in this way. I hope that our information line can provide whatever information you might need and that the arrangements which I have put in place for prompt blood testing will provide you with the reassurance you need as quickly as possible.

Yours sincerely,

xxxxxxxxx General Manager,
xxxx Hospital.

PLEASE NOTE: We have checked our patient records carefully in order to send this letter, but if you have received it in error, we sincerely apologise for any inaccuracy or any inconvenience it may have caused.

Appendix D- Planned press release

To be issued if media query arises once patients are informed/ proactively once letters arrive
HSE West to provide Hepatitis C Screening to Patients

May 2010

HSE West today confirmed that 454 patients have been asked to attend for precautionary Hepatitis C screening. This is being done as a result of a diagnosis of Hepatitis C in a healthcare worker who worked at three hospitals in HSE West.

The healthcare worker concerned was involved in a number of surgical procedures at xxxx Hospital, xxxx General Hospital and xxxxx General Hospital between 2004 and 2008. While the risk to patients is considered to be very low, screening is good practice and will allow patients to be reassured of their own safety. The Public Health Department of the HSE xxxx has implemented a process to follow up on patients who were operated on during that time and have been identified as requiring screening.

Dr. xxxxxxxxxx, Public Health Specialist said today, 'International research indicates that the risk of transmission from a healthcare worker to a patient is remote. Nonetheless as a precaution, national guidelines recommend follow-up of such patients. The management of the three hospitals have been working closely on this review with the Department of Public Health in HSE xxxx and with the Health Protection Surveillance Centre. We intend to complete the review in a very short timeframe and are very confident that any risk to patients is very low indeed'

In accordance with best practice, the hospitals have carried out a detailed review of all patient records to identify the patients who require follow up. Contact has been made with patients' GPs, and patients affected have been written to and offered a blood test for Hepatitis C screening. A single blood test will be offered, to rule out infection, which may be carried out by the patient's GP or at a dedicated HSE xxxx clinic. Results will be returned to patients and GPs as soon as possible but not later than seven days of the test. This is a very fast timeframe and additional resources have been put in place to enable this.

The letters also contain details of a special patient information line set up for making of appointments or for any queries that patient may have about the test or the review.

During the period covered by the review the three hospitals treated over 800,000 inpatients and daycase surgery patients – however the review only relates to 454 patients. Any former patient who does not receive a written communication is **not** affected and **no further action** is required.

This look back does not affect staff working in the hospitals as they have not undergone procedures.

Relevant Hospital Manager; HSE xxxx sincerely regrets the worry that reviews like this can cause, but they are carried out with patients' best interest in mind. We will make sure the review is carried out swiftly and efficiently, and that we provide clear and accurate information to everyone affected.

Ends

For further information please contact...

Appendix E – Frequently asked questions for health care workers

For Healthcare Workers

FAQs Hepatitis C

What is hepatitis C?

Hepatitis C infection (also known as Hep C or HCV) is a virus that can cause long-lasting infection and can lead to liver disease

How can I get hepatitis C?

Hepatitis C is spread when blood or body fluids from an infected person enter the body of a susceptible person. This occurs in a variety of ways, including the sharing of needles and other drug injecting equipment, receipt of contaminated blood and blood products, and injury from a needle or sharp instrument contaminated with blood from an infected person. Less common routes of transmission include transmission through sexual contact with an infected person, household contact. Mother to child transmission occurs rarely.

Hepatitis C CANNOT be spread by:

- Being in the same room as a person with Hepatitis C
- Coughing or sneezing
- Food
- Cutlery or crockery
- Social contact (e.g. holding hands, hugging)

What is the risk of getting Hepatitis C from an infected Healthcare Worker (HCW) during an operation?

We know the risk is very low from other lookback exercises. These investigations examined situations like this where a health care worker who has hepatitis C was involved in surgical procedures.

How do you identify a patient with Hepatitis C infection?

Hepatitis C is diagnosed by testing the patient's blood. If a person has ever been exposed to Hepatitis C, the blood carries a permanent memory of that infection. It does this in the form of antibodies to the virus.

The tests that are performed include:

- Screening to detect the presence of antibodies to Hepatitis C.
- 'Anti-HCV' test (antibody to Hepatitis C virus) – shows whether production of antibodies has occurred. This initial blood test is called the ELISA test (enzyme linked immunosorbent assay test)
- Another test which can be used is called the RIBA (recombinant immunoblot assay)
- Antibodies do not always appear in the blood immediately – usually 2-3 months after exposure, and up to six months later

What does a negative result mean?

- A negative antibody result means there are no antibodies to the Hepatitis C virus and no further testing is required.

What if my result is positive?

- If the antibody test (Anti-HCV) is positive, then further testing will be required (This is a Polymerase Chain Reaction test which detects if the virus is in the blood).
- A positive PCR test indicates the presence of the Hepatitis C virus in the blood
- A negative PCR test may indicate past exposure but the virus is now cleared

We want to stress that the chances of your test result being positive are very low. If your result is positive we will arrange for immediate referral to a specialist (hepatologist) and counselling for you and your family. Again we would like to reiterate that we do not expect your test result to be positive.

How accurate is the Anti-HCV test?

Anti-HCV can be detected in >97% of persons by 6 months after exposure.

How soon after exposure to HCV can HCV RNA be detected by PCR?

HCV RNA detected by the PCR test appears in blood and can be found as early as 2–3 weeks after infection.

Under what circumstances is the anti-HCV test positive even if I do not have the disease?

False-positive anti-HCV tests appear more often when persons at low risk for HCV infection (e.g., blood donors) are tested. Therefore, it is important to confirm a positive anti-HCV test with a supplemental test, such as RIBA (recombinant immunoblot assay), as most false positive anti-HCV tests are reported as negative on supplemental testing.

Under what circumstances might the anti-HCV test be negative even if I have the infection?

Persons with early HCV infection might not yet have developed antibody levels high enough that the test can measure. In addition, some persons might lack the (immune) response necessary for the test to work well. In these persons, further testing (such as PCR for HCV RNA) may be considered.

What is the long term outlook for the patient diagnosed with Hepatitis C?

- The evidence suggests that 20% of those infected will clear the virus
- Of the remaining 80%, 25% develop acute hepatitis
- 75% develop chronic infection
 - of these, the majority will remain well, with no liver damage
 - some will develop mild to moderate liver damage
 - 25% will develop cirrhosis and ultimately some will progress to liver cancer.

Will getting tested for Hepatitis C affect my Insurance premiums?

The majority of insurance companies no longer ask about whether you have ever been tested for Hepatitis C however certain companies may still put this question on the form and grade your risk according to the risk calculations of that company.

If it is confirmed that you do have Hepatitis C then this will be taken into consideration by the insurance company as would any other form of chronic illness.

Can I pass on hepatitis C infection to my sexual partner?

Unlike many other blood borne viruses, sexual transmission is thought to be relatively rare. Nevertheless, it may occur and people with new or casual sexual partners are advised to use condoms to protect them against all sexually transmitted infections.

What is the risk of passing on infection to my close contacts/ family members?

Infection is not acquired through normal social contact, but it can occur in situations where blood can be transferred from one person to another, for example by sharing razors or toothbrushes. It is also possible to acquire hepatitis C infection during body piercing (like tattooing or acupuncture) if sterile needles are not used.

What are the symptoms of hepatitis C?

The majority of people (around 85%) show no signs or symptoms of the initial infection.

The most common symptoms are loss of appetite, abdominal discomfort, nausea and vomiting and jaundice.

About 60%-85% of cases develop chronic (long-term) hepatitis C infection.

10%-20% of those with chronic infection eventually develop cirrhosis and a smaller number develop cancer of the liver.

What percentage of persons infected with HCV develop symptoms of acute illness?

Approximately 20%–30% of those newly infected with HCV experience fatigue, abdominal pain, poor appetite, or jaundice.

How soon after exposure to HCV do symptoms appear?

In those persons who do develop symptoms, the average time period from exposure to symptom onset is 4–12 weeks (range: 2–24 weeks)

How likely is HCV infection to become chronic?

HCV infection becomes chronic in approximately 75%–85% of cases.

What are the signs and symptoms of chronic HCV infection?

Most persons with chronic HCV infection have no symptoms. However, many have chronic liver disease, which can range from mild to severe, including cirrhosis and liver cancer. Chronic liver disease in HCV-infected persons is usually deceptive, progressing slowly without any signs or symptoms for several decades. In fact, HCV infection is often not recognized until infected persons are identified as HCV-positive when screened for blood donation or when elevated alanine aminotransferase (ALT, a liver enzyme) levels are detected during routine examinations.

Can a patient have a normal liver enzyme (e.g., ALT) level and still have chronic Hepatitis C?

Yes. It is common for patients with chronic Hepatitis C to have liver enzyme levels that go up and down, with periodic returns to normal or near normal levels. Liver enzyme levels can remain normal for over a year despite chronic liver disease.

Is it possible for someone to become infected with HCV and then spontaneously clear the infection?

Yes. Approximately 15%–25% of persons clear the virus from their bodies without treatment and do not develop chronic infection; the reasons for this are not well known.

Why do most persons remain chronically infected with HCV?

A person infected with HCV mounts an immune response to the virus, but replication of the virus during infection can result in changes that are not captured by the immune response. This may explain how the virus establishes and maintains chronic infection.

Can Hepatitis C be treated?

The treatment of choice for individuals with chronic hepatitis C infection is a combination of two drugs: interferon and ribavirin. This combination therapy is successful in clearing virus from the blood of around 40% of those treated. However, not everybody is suitable for treatment or can tolerate it. Factors such as age, sex, duration of infection, the strain of the virus, and the degree of existing liver damage determine the effectiveness of treatment. New more effective treatments are likely to become available in the near future.

Is there a vaccine available for hepatitis C?

Currently there is no vaccine available for hepatitis C.

Appendix F – Information for patients

Patient Information Sheet.

What is hepatitis C?

Hepatitis C causes inflammation of the liver. The most common causes of hepatitis are viral infections. Hepatitis C infection (also known as Hep C or HCV) is a virus that can cause long-lasting infection and can lead to liver disease.

What is the risk of getting Hepatitis C from an infected healthcare worker during an operation?

We know the risk is very low from other lookback exercises. These investigations examined situations like this where a health care worker who has hepatitis C was involved in surgical procedures.

How will I know if I have the virus? What tests can be done?

There are two tests that can be done on your blood which will tell you if you have the infection.

The first test finds out if you ever had direct contact with the hepatitis C virus. Your blood carries a permanent memory of that infection. It does that in the form of antibodies to the virus.

If the result of the first test is **negative** (that is, no antibodies to hepatitis C are found in your blood) this indicates that you do not have hepatitis C infection.

If antibodies for hepatitis C are found, then you may have been exposed to hepatitis C in your lifetime so further testing is done on your blood to determine if you have an ongoing infection with the hepatitis C virus.

How long after I get the blood taken will I know the result?

The results will be available as soon as possible and not later than 7 days after receipt of the blood sample by the laboratory. Your GP or a nurse specialist from the designated clinic will inform you of the result as soon as it becomes available.

What does a negative result mean?

A negative antibody result means there are no antibodies to the Hepatitis C virus and no further testing is required.

What if the result is positive?

We want to stress that the chances of your test result being positive are very low.

If your result is positive we will arrange for immediate referral to a specialist (hepatologist) and counselling for you. Again we would like to reiterate that we do not expect your test result to be positive.

Appendix G – Form for telephone call to GP

Date:
Caller:

Patient Label:

Good morning. My name is _____. I am calling from the public health department at the HSE xxxx to talk to you about a patient(s) of yours. A health care worker who worked in **xxxxx hospital** has been found to have Hepatitis C virus infection. This health care worker was involved in a small number of exposure prone procedures and these patients should now be followed up in accordance with the Irish National Guidelines

1. Have you received a registered letter from us with a blood sampling pack?

Yes No

(if yes continue with the rest of the questions, if no, document this and arrange a follow-up call the next day)

2. We have identified X number of patients that are under your care. I'd like to ask you some details about each patient individually. Is _____ (name of above patient) still under your care?

Yes No

(if yes continue with the following questions, if no then ask if they know who is their current GP.)

Name of GP:

Address:

Telephone:

3. Is the patient alive or dead?

Yes No

4. Would you be willing to participate in caring for the patient identified by taking their blood?

Yes No

(if yes continue with the following questions, if no document this and continue with the following questions.)

5. Has the patient ever been diagnosed with hepatitis C in the past?

Yes No

If yes – what is the date of diagnosis of infection?

- what genotype is/was the infection?

- does this patient have an identified risk factor?

6. Is this patient severely immunocompromised?

(Conditions that would contribute to severe immunocompromise include:

Advanced HIV infection,

A transplant patient.)

Yes No

7. If this patient is a child:

Who is the next of kin of this patient and what are the contact details?

NOK

Name:

Address:

Telephone:

Appendix H – Form for follow-up telephone call to patients who did not attend their GP

Date:

Patient Label:

Time:

Caller:

Good morning. My name is from GUH/MGH and I am looking for name? address.....? DOB:.....?

If wrong numberThank you, Goodbye. If details correct continue.

I am calling from xxxxx on behalf of our General Manager. A letter was sent to you from the General Manager which you should have received on May 24th.

Q1. Did you receive this letter? Yes No

If yes, SKIP TO Q2.

If no, reconfirm name, address and date of birth. If correct this patient should have received a letter.

The reason why you did not receive the letter on May 24th is unknown to me however it will be investigated promptly. You will receive a copy of this letter immediately from our General Manager. This is in regard to a health care worker who worked in xxxxxxxl that was found to have Hepatitis C virus infection. This health care worker was involved in a small number of operations. The hospital is offering precautionary screening for hepatitis C for patients who had operations which involved this health care worker. Your GP has agreed to do this blood test for you.

I would like to check a few details. **SKIP TO Q. 4**

Q2. Do you understand the letter? Yes No

Q3. Do you plan to have this blood test? Yes No

Details:.....

.....

....

Q4. Can I just recheck the name and address of your GP?

Name of GP:

Address:

Telephone:

4. Do you have any further questions? A helpline is available if you have any further queries

Thank you for your time. Goodbye.

Appendix I – Claim form for GP



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Private and Confidential Fee Claim Form

Date:

Patient Label

Hepatitis C antibody test taken from named patient.

YES

Doctor's Signature _____

Date _____

Appendix J – Guidelines for taking, labelling and returning serum samples

The Testing Kit contains:

1. A laboratory request form pre-stamped and pre-labelled with the relevant client's details.
2. A yellow top serum bottle for the sample. This is unlabelled.
3. A separate label with the patient details to be placed on the serum bottle as soon as the blood is drawn.
4. An outer container for the serum bottle.
5. A stamped addressed jiffy envelope

Instructions for testing:

1. Ensure that the correct person is getting the blood drawn.
2. Once the blood has been taken, label the sample immediately. **N.B. The person who draws the blood sample is the only person who is authorised to label the sample.**
3. **Ensure that the details on the request form match that of the blood sample label.**
4. The clinical details section of the form may remain blank.
5. Place the sample in the plastic container.
6. Place the container in the plastic pocket attached to the request form and seal it.
7. Put the container and request form in the jiffy envelope and seal.
8. Arrange delivery to the relevant laboratory in the usual manner.
9. Test results will be sent to you, the GP, by the screening laboratory in the usual manner.

The utmost care should be taken when labelling samples, as incorrectly labelled samples will not be processed.

Bottles should not be pre-labelled under any circumstances.

Appendix K– Process Map

May 4th Final database lists - letters, envelopes, labels prepared by hospitals
 - GP packs prepared

May 10th

Week 1	Monday	Prep
	Tuesday	Prep
	Wednesday	Prep
	Thursday	Packs delivered to Hospital Centres
	Friday	Registered packs to GP's

May 17th

Week 2	Monday	Ring GP's
	Tuesday	Ring GP's
	Wednesday	Prepare database- forward to clinics
	Thursday	Prepare database- forward to clinics
	Friday	letter sent to pt's

May 23th

Week 3	Monday	Pt's receive letter- helpline starts	Helpline- patients	Helpline-public
	Tuesday	GP's testing	Helpline -pts	Helpline-public
	Wednesday	Clinic and GP's - Testing	Helpline -pts	Helpline-public
	Thursday	GP testing	Helpline -pts	Helpline-public
	Friday	Clinic and GP's - Testing	Helpline -pts	Helpline-public

May 31st

Week 4	Monday	GP's - Testing	Helpline -pts	Helpline-public
	Tuesday	GP's -Testing	Helpline -pts	Helpline-public
	Wednesday	Clinic and GP's - Testing	Helpline -pts	Helpline-public
	Thursday	Results to pts and GP's	Helpline -pts	Helpline-public
	Friday	Clinic and GP's - Testing	Helpline -pts	Helpline-public

June 2nd

Week 5	Monday	GP's - Testing	Helpline -pts	Helpline-public
	Tuesday	GP's - Testing	Helpline -pts	Helpline-public
	Wednesday	Clinic and GP's - Testing	Helpline -pts	Helpline-public
	Thursday	Results to pts and GP's	Helpline -pts	Helpline-public
	Friday	Clinic and GP's - Testing	Helpline -pts	Helpline-public