Item 4C

Report to the UK Advisory Panel for healthcare workers infected with blood borne viruses on the investigation of UKAP case 08/26 and the related patient notification exercise

Report prepared by the Lanarkshire hepatitis C infected healthcare worker Incident Management Team

September 2016

This report contains confidential information and has been prepared to be submitted to UKAP via the UKAP Medical Secretary. Sections of the report that may be of value to health protection teams that are preparing for or managing blood borne virus healthcare worker incidents will have confidential information removed prior to being shared.

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Abbreviations

Ab	Antibody
BBV	Blood borne virus (Hepatitis B, hepatitis C or HIV)
CMT	NHS Lanarkshire corporate management team
DBST	Dried blood spot test
EPP	Exposure prone procedure
HCV	Hepatitis C virus
HCW	Healthcare worker
HPS	Health Protection Scotland
HR	Human resources
HSE	Health & Safety Executive
ID	Infectious disease
IMT	Incident management team
PCR	Polymerase chain reaction
PHE	In this report PHE usually refers to Public Health England, however, in some documentation used which is included in the appendices, PHE may refer to Public Health Exercise as this term was considered to be more meaningful to NHS Lanarkshire members of staff than PNE (Patient Notification Exercise).
PNE	Patient notification exercise
RLE	Record linkage exercise
RMS	Referral management service – the service which books and manages clinic appointments.
RNA	Ribonucleic acid
SVC	Specialist virology centre
UKAP	United Kingdom Advisory Panel for healthcare workers infected with blood borne viruses
WoS	West of Scotland

Executive Summary

Background

An NHS Lanarkshire employed healthcare worker was identified in January 2008 to have hepatitis C infection as a result of routine testing by Salus, the NHS Lanarkshire occupational health service, in preparation for starting a locum post. The HCW was non-infectious for hepatitis B infection and HIV negative.

A detailed investigation was carried by NHS Lanarkshire and Health Protection Scotland to establish if there was any evidence of healthcare worker to patient transmission of infection. A record linkage exercise using data from the Scottish hepatitis C database and Scottish Morbidity Records data for all patients admitted under the care of the healthcare worker. This investigation did not identify any evidence that healthcare worker to patient transmission of hepatitis C infection had taken place.

A report was submitted to the UK Advisory Panel on Healthcare Workers Infected with Blood Borne Viruses (UKAP). UKAP advised that as there was no evidence of healthcare worker to patient transmission a patient notification exercise was not indicated.

During 2015 two patients were identified for whom, based on epidemiological and virological findings, it was concluded that healthcare worker to patient transmission of hepatitis C infection during surgery had probably occurred. UKAP endorsed a proposal by NHS Lanarkshire to carry out a patient notification exercise.

Patient notification exercise

A patient notification exercise went live on Tuesday 23 February 2016 with a press release being issued and a press conference held. Letters were sent to 8,432 patients in Lanarkshire, other parts of Scotland and other UK countries. This covered the period of time when the healthcare worker was an NHS Lanarkshire employee and when they did a three months long locum post in Kent. Media coverage of the exercise has been assessed by the NHS Lanarkshire communications team as being positive and, overall, the exercise has been well delivered across Lanarkshire, other parts of Scotland and other parts of the UK.

125 clinics were held in ten locations across Lanarkshire from 25 February to 17 March 2016 involving 150 members of staff. An incident room operated from 23 February to 25 March.

During April to July 2016 there was ongoing work to test some patients who were unable to be tested in February or March, to follow up actions relating to specific patients, and to obtain and reconcile data from different sources.

To date four complaints have been received. Each complaint was in relation to patients not being informed of the risk of hepatitis C infection when the healthcare worker was diagnosed. Responses have been made to each complainant, or their representative, explaining the sequence of events and the rationale for the way in which the situation has been managed.

Uptake of testing

The uptake for hepatitis C testing for Lanarkshire residents was 81%, 5,899 of 7,311 Lanarkshire residents who were sent a letter were tested, with the uptake being 78% for all patients – 6,553 of 8,432 patients. These are very high uptake percentages for a patient notification exercise and they were achieved in Lanarkshire by integrated working across acute care, primary care and corporate divisions and with partners including Health Protection Scotland and NHS24, and across Scotland and the other UK countries by good joint working and local leadership. The results of tests have been provided to all patients tested.

Patients who tested hepatitis C antibody reactive, antibody positive or virus positive

To date no further cases of probable HCW to patient transmission have been identified in residents in Lanarkshire or elsewhere. Three patients tested hepatitis C virus negative and antibody positive; two patients tested hepatitis C virus negative and antibody equivocal. However, as none of these five patients have hepatitis C virus it is not possible to carry out further virological testing.

Patients diagnosed with chronic hepatitis C infection

As a consequence of the patient notification exercise seven patients with chronic hepatitis C infection have been identified and they have all engaged with specialist hepatitis C care - none of these patients are cases of healthcare worker to patient transmission.

Whole system, integrated working

One of the key aspects of the way in which NHS Lanarkshire responded to the incident, and in particular to the patient notification exercise, was that a whole system approach was taken. The incident needed a whole NHS system response with integrated working from public health, information services, eHealth, clinical specialties, laboratories, service managers, and communications team members. This required members of the health protection team and the wider Department of Public Health to work in a different way from usual and to interact with people in other departments and divisions to achieve significant specific objectives over short periods of time. Each individual involved already had a full workload and work relating to the incident needed to be prioritised whilst at the same time maintaining normal services. The involvement and support of the Board Chair, Chief Executive and Director of Public Health were essential with regards to the exercise being treated as a priority by those involved. It was also important for NHS Lanarkshire to work closely with Health Protection Scotland which provided BBV and healthcare worker incident expertise and was also able to provide a national perspective. This happened during each of the periods of investigation and in relation to the patient notification exercise and was facilitated by well established good working relationships.

Recommendations

A series of recommendations have been made and they have been collated and put into a table at the end of Section F. (Link)

The most important recommendations that the Incident Management Team is making to UKAP are:

- UKAP should link with the Expert Advisory Group on AIDS, the Advisory Group on Hepatitis, and the four UK Departments of Health to review the current policy of non-disclosure to patients of information about levels of risk which have been assessed as being very low or very, very low.
- UKAP should consider how best to engage with patients and members of the public in order to inform policy development and in order to make UKAP policy and the process of policy review and development open, honest and transparent.
- UKAP should consider whether recurrent record linkage exercises should be advocated when a hepatitis C infected healthcare worker is identified and a PNE is not advised.
- UKAP should work with the Expert Advisory Group on AIDS, the Advisory Group on Hepatitis, and the four UK Departments of Health to review the current policy regarding the testing of healthcare workers who perform exposure prone procedures for blood borne viruses.

Report to be submitted to NHS Lanarkshire Board

NHS Lanarkshire Board has requested a report of the investigation and management of the incident which includes details of learning points that were identified and the response made by UKAP to this report and in particular to the recommendations made to UKAP.

Report aims and objectives

Aims:

1. To document the work that was undertaken to a) investigate a hepatitis C infected healthcare worker situation and b) conduct a patient notification exercise

2. To report on the findings of the patient notification exercise.

Objectives:

1. To note good practice points[1] which incorporate learning arising from the investigation and patient notification exercise.

2. To identify recommendations for NHS Lanarkshire and other organisations which will contribute to:
- the prevention of healthcare associated BBV transmission
- a reduction in the BBV related morbidity and mortality of patients to whom HCW to patient transmission of a BBV occurs
- a reduction in the BBV related morbidity and mortality of healthcare workers who carry out exposure prone procedures
- the investigation and management of BBV infected healthcare worker situations and
- generic improvements in healthcare services

3. To develop a resource which, in addition to the UKAP toolkit, will be of value to other public health services to use in preparation for possible BBV infected healthcare worker investigations and patient notification exercises or, in the absence of such preparation, to use in the event of such situations.

[1] Good practice points can be found by using the Ctrl+F function and searching for “good practice”.

Exposure prone procedures

The following information about exposure prone procedures is taken from a document published recently in 2016 by UKAP entitled *General dentistry exposure prone procedure (EPP) categorisation*[2]. The explanation and definitions apply to all medical and surgical procedures as well as to dental procedures.

Exposure prone procedures (EPPs)

Provided appropriate infection prevention and control precautions are adhered to scrupulously at all times, the majority of clinical procedures (including many which are invasive) in the healthcare setting pose no risk of transmission of bloodborne viruses (BBVs) from an infected healthcare worker (HCW) to a patient, and can safely be performed.

Those procedures where an opportunity for HCW-to-patient transmission of BBV does exist are described as exposure prone, where injury to the HCW could result in the worker's blood contaminating the patient's open tissues. This is described as 'bleed-back'. The majority of HCWs do not perform EPPs.

EPPs include procedures where the worker's gloved hands may be in contact with sharp instruments, needle tips or sharp tissues inside a patient's open body cavity, wound or confined anatomical space where the hands or fingertips may not be completely visible at all times. Other situations, such as pre-hospital trauma care, should be avoided by HCWs restricted from performing EPPs, as they could also result in the exposure of the patient's open tissues to the blood of the worker.

The definition of EPPs given above embraces a wide range of procedures, in which there may be very different levels of risk of bleed-back. A risk-based categorisation of clinical procedures has been developed, including procedures where there is negligible risk of bleed-back (non-EPP) and three categories of EPPs with increasing risk of bleed-back.

The definitions of categories 1, 2 and 3 are:

Category 1

Procedures where the hands and fingertips of the worker are usually visible and outside the body most of the time and the possibility of injury to the worker's gloved hands from sharp instruments and/or tissues is slight. This means that the risk of the HCW bleeding into a patient's open tissues should be remote.

Category 2

Procedures where the fingertips may not be visible at all times but injury to the worker's gloved hands from sharp instruments and/or tissues is unlikely. If injury occurs it is likely to be noticed and acted upon quickly to avoid the HCW's blood contaminating a patient's open tissues.

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2 www.gov.uk/government/uploads/system/uploads/attachment_data/file/511570/UKAP_General_Dentistry_EPP_Categorisation_FINAL_to_be_uploaded.pdf

Category 3

Procedures where the fingertips are out of sight for a significant part of the procedure, or during certain critical stages, and in which there is a distinct risk of injury to the worker's gloved hands from sharp instruments and/or tissues. In such circumstances it is possible that exposure of the patient's open tissues to the HCW's blood may go unnoticed or would not be noticed immediately.

Non-exposure prone procedures

Non-EPPs are those where the hands and fingertips of the worker are visible and outside the patient's body at all times, and internal examinations or procedures that do not involve possible injury to the worker's gloved hands from sharp instruments and/or tissues, are considered not to be exposure prone provided routine infection prevention and control procedures are adhered to at all times.

UKAP's role, terms of reference and accountability

UKAP's role and terms of reference are detailed on the UKAP website[3].

Role

UKAP gives advice on guidance on healthcare workers infected with HIV, hepatitis B and hepatitis C. The panel also provides support for local incident management teams and maintains a register of infected healthcare workers.

The panel's terms of reference are:

- to establish, and update as necessary, criteria on which local advice on modifying working practices may be based
- to provide supplementary specialist occupational advice to physicians of healthcare workers infected with bloodborne viruses, occupational physicians and professional bodies
- to advise individual healthcare workers or their advocates how to obtain guidance on working practices
- to advise directors of public health on patient notification exercises, where these are indicated, of patients treated by healthcare workers infected with bloodborne viruses
- to keep under review the literature on occupational transmission of bloodborne viruses and revise guidelines as necessary

Membership

The CEO of Public Health England appoints members with specialist medical and scientific expertise, as well as lay members.

The UKAP Code of Practice[4] details UKAP's accountability:

"UKAP is an independent advisory committee accountable to the Chief Medical Officer via the Health Protection Agency (HPA). In the past, UKAP was accountable to the Chief Medical Officer through the Department of Health. Since 1st April 2003, the UKAP secretariat has been provided by what is now the HPA Centre for Infections. Policy responsibility remains with the Department of Health and the health departments of Scotland, Wales and Northern Ireland, taking account of expert advice from EAGA and the Advisory Group on Hepatitis (AGH)."

[3] https://www.gov.uk/government/groups/uk-advisory-panel-for-healthcare-workers-infected-with-bloodborne-viruses

[4] http://webarchive.nationalarchives.gov.uk/20140629102627/http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1296680606637

Section A. Incident investigation – 2008

A copy of the following documents is appended to this report (See Appendix A.01)

1. Letter of 15 August 2011 from Dr Logan on behalf of the NHS Lanarkshire Director of Public Health to Dr Ncube, UKAP Medical Secretary regarding UKAP case 08/26.
2. Completed UKAP enquiry *pro forma*.
3. A table listing the nine appendices referenced in the *pro forma* and in Dr Logan's 15 August 2011 letter.
4. Letter of 17 October 2011 from Dr Ncube to Dr Logan.

The documents provided details of the outcome of the local risk assessment that had been carried out regarding case 08/26.

1. Notification of hepatitis C positive HCW to the Department of Public Health

The Department of Public Health was notified on 21 January 2008 that the healthcare worker had been identified as being hepatitis C positive by the NHS Lanarkshire Occupational Health Department.

2. Occupational health routine hepatitis C screening test

The healthcare worker was tested for hepatitis C as part of routine screening by the NHS Lanarkshire Occupational Health Department as the healthcare worker was starting a new locum contract. [redacted] The NHS Lanarkshire protocol in existence at that time required them to have an occupational health assessment to be assessed for fitness to practice. The HCW did not have symptoms of hepatitis C.

Blood had been taken from the patient on 11 January 2008 and the result had been received by the Occupational Health Department on 21 January 2008. A further sample taken on 21 January 2008 confirmed that the patient was hepatitis C PCR positive. The sample taken on 11 January 2008 was reported as being HCV genotype 3.

The HCW had evidence of [redacted] of being non-infectious for hepatitis B [redacted] and was HIV negative when tested on 22 January 2008.

3. Cessation of exposure prone procedures

The healthcare worker was advised on 21 January 2008 that they had tested positive for hepatitis C and to stop performing exposure prone procedures by the Occupational Health Department. The healthcare worker ceased exposure prone procedures immediately and did not return to clinical practice involving carrying out exposure prone procedures.

4. History of sharps and needlestick injuries

The healthcare worker gave a history to occupational health of sustaining “minor needlestick injuries”. This was presented as being similar to the needlestick injuries that many [redacted] sustain. The history given by the patient was that there was no particular significant needlestick injuries or other sharps incidents during their [redacted] career. [redacted]

5. Occupational history

[redacted]

The HCW was employed [redacted] by NHS Lanarkshire in 1982. Prior to working in Lanarkshire the HCW had trained and worked in England.

The HCW [redacted] did locum posts in Lanarkshire and also a 3 month locum post in Kent in 2006.

6. Record linkage exercise

Due to the long period of employment with NHS Lanarkshire and the high quality of the Scottish hepatitis C database and the NHS Scotland Scottish Morbidity Record systems it was possible to carry out a high quality record linkage exercise. At the time of the record linkage exercise in 2008 UKAP policy was that the details of patients who had undergone category 3 exposure prone procedures should be checked again hepatitis C diagnoses data.

Six patients were identified who had undergone a category 3 exposure prone and who were diagnosed hepatitis C positive after date of discharge from hospital.

Two patients were excluded from further investigation as it was established that they had been found to have hepatitis C genotype 1 infection – whereas, the HCW had genotype 3 infection. The notes of three of the remaining patients were relatively easy to obtain, review and report on. Information about the sixth patient was initially obtained from forensic medical records. The patient had died due to morphine use and was known from the Scottish hepatitis C database to have the hepatitis C risk factor of being a person who injected drugs. It took some time to complete a search for the hospital medical records of this patient and establish conclusively that their

medical records had been destroyed in 2001 in line with the NHS Lanarkshire Medical Records Retention and Destruction Policy.

7. Risk assessment

On the basis of a detailed review of available hard copy and electronic medical records, hepatitis C test results, history of operative procedures including exposure prone procedures, history of risk factors for hepatitis C, and clinical assessments prior to and after exposure prone procedures were carried out by the HCW, the Lanarkshire Incident Management Team concluded that it was unlikely that any of the patients identified from the record linkage exercise had become infected as a result of transmission of infection from the HCW. The documents referred to above were submitted to UKAP.

8. Advice provided by UKAP

The concluding paragraphs of the 17 October 2011 letter from Dr Ncube, on behalf of UKAP, to Dr Logan were:

“Following a review of the outcomes of five hepatitis C look backs recommended by UKAP in 2003, the panel has decided that, in the absence of documented cases of secondary iatrogenic transmission to a patient, no further patient notification exercises should be recommended in relation to healthcare workers infected with hepatitis C. This advice is given on the basis that it will be revised should new evidence come to light which indicates that a risk to patients who have undergone high risk exposure prone procedures does exist.”

“Since no evidence has been found of transmission from this [redacted] to patients, the Panel advises that no patient notification exercise need be undertaken.”

Section B. Further incident investigation - 2015

Further investigation was carried out in 2015 when a patient was identified for whom it was considered possible that they had acquired infection from the HCW. The further investigation is described in detail in the 8 October 2015 letter and report sent by Dr Logan to Dr Ncube which are appended to this report (See Appendix B.01) as is the letter of advice received by NHS Lanarkshire from Dr Ncube dated 25 November 2015. (See Appendix B.02).

1. Identification of patient 1 as a possible case of HCW to patient transmission

   A patient, patient 1, was diagnosed with hepatitis C infection in 2010. They were referred for assessment for hepatitis C treatment in August 2014. At a clinical multidisciplinary meeting held in February 2015 a possible link to a

HCW (UKAP case 08/26) who had been found to have hepatitis C infection in 2008 was identified. The NHS Lanarkshire Health Protection Team was informed of this situation on 25 February 2015. Patient 1 had been [redacted] by the HCW on two occasions - firstly, an exposure prone procedure (EPP) category 3 procedure in [redacted] 2001 and two weeks [redacted] an EPP category 2 procedure. Patient 1 [redacted] did not have any other significant risk factors for hepatitis C infection. Patient 1 had HCV genotype 3 infection as did the HCW.

2. The healthcare worker

[redacted] The HCW's virus was not sequenced in 2008 and a sample was not stored. Extensive attempts were made during 2015 to try to obtain a stored blood sample and to obtain possible pathology samples, however, it was not possible to obtain such samples. The Scottish National Blood Transfusion Service did not have a record of the HCW ever having been a blood donor.

3. Identification of patient 2

Subsequent to patient 1 being identified as a possible case of HCW to patient transmission of HCV a record linkage exercise was carried out by Health Protection Scotland and the Information Services Division of NHS National Services Scotland. A second patient, patient 2, was subsequently identified for whom there was concern that they may have acquired infection associated with an EPP performed by the HCW. This patient [redacted], had HCV genotype 3 infection and did not have significant risk factors for HCV infection. Patient 2 had normal liver function tests documented in October 1996, an EPP procedure performed by the HCW in October 1997 that was categorised as EPP category 2, abnormal liver function tests around February 1998 and was first diagnosed with HCV infection in July 1998. [redacted]. The source of the patient's HCV infection was never clearly established. [redacted]

4. Interim advice from UKAP

UKAP directed the NHS Lanarkshire incident management team to seek to obtain as much virological information as possible in relation to patients who had had an EPP performed by the HCW and who were on the Scottish HCV database, with a particular focus on patients 1 and 2 for each of whom samples of blood positive for HCV RNA were available.

5. Virological testing

The overall conclusion of the virological testing was that the viruses from patients 1 and 2 could be related. Analysis of information obtained from genomic sequencing did not conclude that the viruses were definitely related, nor that the viruses were definitely not related.

The key paragraph from the virology report available at the time of submitting a report to UKAP on 8 October 2015 was:

"The data provided for the additional HCV regions (NS3, NS5A and NS5B) all suggest the two patients *could* have a common source as for all regions examined the two patients are found to cluster together – albeit with low bootstrap value or homology. This data should be treated with caution and interpreted alongside existing epidemiological data."

6. Assessment by the Incident Management Team

A section of the report submitted to UKAP provided answers to the following questions using available information:

- Did the HCW and patient 1 or patient 2 have the same virus ?
- What risk factors, aside from [redacted] by the HCW, did patient 1 have for HCV infection ?
- What factors suggest that patient 1 may have acquired hepatitis C infection from the HCW?
- What risk factors, aside from [redacted] by the HCW, did patient 2 have for HCV infection?
- What factors suggest that patient 2 may have acquired hepatitis C infection from the HCW?
- What factors are relevant to patient 1 and patient 2?

With reference to the precautionary principle, patient 1 was considered to be an index case of HCW to patient transmission of hepatitis C, and patient 2 was considered to be either a second case of HCW to patient transmission of hepatitis C from the HCW, or, if transmission from the HCW to patient 1 has not occurred, to be a separate index case.

The Lanarkshire IMT proposed the following actions:

1. A patient notification exercise is undertaken with letters being sent to all patients who:

   Are identified as having undergone one or more exposure prone procedures (Category 1, 2 or 3) performed by the HCW between their appointment [redacted] in 1982 and the end of their [redacted] career in January 2008.

   OR

Are identified as having undergone one or more exposure prone procedures (Category 1, 2 or 3) which may have been performed by the HCW between their appointment [redacted] in 1982 and the end of their [redacted] career in January 2008. For example, a patient who was admitted under the care of the HCW who had an EPP performed but for whom it is not possible to identify the [redacted].

AND

Are not known to have died.

The objectives of this exercise would be to inform patients of the situation, to offer testing for HCV infection, to arrange clinical assessment and treatment where indicated, and to inform further risk assessment of the situation.

2. Joint working with Public Health England Kent regarding the conduct of the patient notification exercise.

3. Testing of any patient who is found to be HCV antibody positive for HCV RNA and genomic sequencing of the virus and comparing virus sequences for any patient found to be HCV genotype 3 RNA positive.

4. Provision of a report to UKAP on the conduct of the patient notification exercise with a request for further advice as to whether any further action is required.

The Incident Management Team and the Director of Public Health sought the endorsement of UKAP to the actions proposed and requested any advice that UKAP may have regarding further investigation of the situation and management of the PNE.

An assessment of extent of a possible PNE required that would cover the HCW's career from 1982 onwards estimated that it would involve writing to approximately 7,000 patients.

7. Advice provided by UKAP

The advice provided by UKAP as detailed in a letter of 25 November 2016 from Dr Ncube to Dr Logan was as follows:

[Start of letter extract]

Panel Advice

The Panel concluded that this was a probable transmission of hepatitis C from the HCW to the two patients because of, the findings of the phylogenetic analysis, the epidemiological link to the infected HCW through category 2/3 EPPs performed in both patients, the absence of any other risk factors for hepatitis C in both patients and the observation that the two patients had no other link between them.

The Panel therefore advises that, since these are documented HCW to patient probable HCV transmissions, a patient notification exercise and offer of HCV testing is required for all patients where the HCW performed EPPs, defined as;

"Exposure prone procedures are those invasive procedures where there is a risk that injury to the worker may result in the exposure of the patient's open tissues to the blood of the worker ['bleed-back']. These include procedures where the worker's gloved hands may be in contact with sharp instruments, needle tips or sharp tissues (e.g. spicules of bone or teeth) inside a patient's open body cavity, wound or confined anatomical space where the hands or fingertips may not be completely visible at all times."
(Annex A, Para 1, *Hepatitis C Infected Health Care Workers*. Department of Health, August 2002)

Further, the Panel advises that, since there is no information regarding a point in time when the HCW is known to have been HCV antibody and RNA negative, the patient notification exercise and the offer of testing spans the whole career of the HCW where EPPs were performed. The rationale for this advice is that, the HCW could have transmitted HCV at any point in their EPP career since it is not possible to identify times when s/he could have been more or less likely to transmit HCV to his/her patients.

[End of letter extract.]

The proposals that NHS Lanarkshire had asked UKAP to provide advice on were not specifically addressed, however, the response to each proposal could be inferred from the overall advice given. It was particularly helpful that the UKAP Medical Secretary was available to discuss the advice provided in greater detail and that he was willing and able to take part in meetings with the Lanarkshire IMT and colleagues representing the health protection organisations of other UK countries.

8. Discussion regarding the timing of the patient notification exercise

NHS Lanarkshire had identified a window of opportunity for a PNE to be conducted after advice was received from UKAP and before the Christmas 2015 holidays commenced for school children which would have affected the availability of staff to participate in a PNE which required staff to work additional hours over and above their normal working hours.

NHS Lanarkshire was keen to carry out the PNE during 2015 if logistically possible. It was recognised that the exercise would need to run for three to four weeks due to the large number of people being written to and allowing for an uptake rate of up to 60% (about 4,400 Lanarkshire patients), and that there were limited opportunities to deliver a PNE in the first half of 2016 allowing for pressure on NHS Lanarkshire resources due to winter factors (bed pressure, number of admissions, flu cases, staff absences, risks associated with snow and ice) and an early date for Easter school holidays.

8.1. The need to carry out a whole of career PNE at the same time

The Lanarkshire IMT put forward the view that there was a clear rationale for carrying out a two phased approach to the PNE due to the long period of time that the HCW had worked for NHS Lanarkshire and due to the large number of patients

who had been admitted under their care in Lanarkshire. In essence what was being proposed was that a first phase PNE should be conducted involving patients of the HCW from 1982 onwards and the findings of the PNE would inform decision making about whether a second phase PNE, involving contacting patients of the HCW prior to 1982, who could be identified, should be carried out or if such further work was not indicated.

If a significant number of patients came forward for testing and patients were identified who were probable cases of transmission back to a certain year but not before it, it could have been inferred that the HCW may have become infected at or close to this time and that whilst the HCW being infected with hepatitis C prior to 1982 may have remained a possibility there would have been some evidence that this was unlikely.

For example, if 5,000 patients who had undergone an EPP across the years 1982 to 2008 had come forward for testing – just under 200 for each year if they had been evenly distributed – and if positive cases had been found in patients who had an EPP performed in 1996, 1998, 2001, 2003, 2004, and 2007 and about 2,000 people who had undergone an EPP prior to 1996 had been tested with none of them being identified as probable cases of HCW to patient transmission, this would have been good evidence that the HCW probably did not have infection prior to 1982 and that a pre-1982 search for cases by carrying out a PNE for this period was not required.

When UKAP is asked to advise on whether a PNE should be undertaken if a HCW has been identified as being BBV positive and after a thorough investigation and risk assessment including a record linkage exercise, no evidence is found of transmission to a patient, UKAP will usually advise that a PNE does not need to be conducted. In such scenarios the approach UKAP is taking is a risk management one and not a risk elimination one. If UKAP was providing advice about the management of incidents on the basis of eliminating all risk that a patient may have become infected UKAP would advise that a PNE is carried out on every occasion when a HCW who carries out EPPs is diagnosed with a BBV infection.

Australian guidelines (Australian National Guidelines for the Management of Health Care Workers known to be infected with Bloodborne Viruses[5]) state that the duration of a lookback exercise should be decided on a case by case basis.

"Lookback investigation will depend on the results of a full risk investigation following disclosure of a diagnosis of a BBV in a HCW who has undertaken EPPs. The duration of the lookback should be decided on a case-by-case basis."

Teleconference meetings involving NHS Lanarkshire, Health Protection Scotland, UKAP, Public Health England, Public Health Wales, and Public Health Northern

5 www.health.gov.au/internet/main/publishing.nsf/Content/36D4D796D31081EBCA257BF0001DE6B7/$File/Guidelines-BBV-feb12.pdf

Ireland were held to discuss the issues. It was agreed that the PNE would not be conducted in November and December 2015 and that Public Health England undertake work to assess the feasibility of identifying and contacting patients who may have had an EPP performed by the healthcare worker prior to 1982 in England. It was agreed that the PNE would take place in 2016. Subsequently, NHS Lanarkshire identified a period of time in late February and March when staff would be able to set up and run testing clinics. This was after the Christmas and New Year period, likely to be after the worst of the winter weather and before Easter school holidays. Public Health England understood the need for NHS Lanarkshire to proceed with the notification exercise in February and the exercise went ahead covering the 1982 to 2008 period of the healthcare worker's career and Public Health England proceed to further assess the options which were available to it regarding the pre-1982 period.

9. Proposal to seek an injunction

During a meeting of the NHS Lanarkshire, Health Protection Scotland, UKAP, Public Health England and other countries group a question was raised as to whether an injunction should be sought to prevent the media disclosing identifying details of the healthcare worker.

This was discussed further out with the meeting and a decision made that seeking an injunction would not be pursued. The following points influenced this decision:

- An injunction is a legal term used in England. In Scotland, which has its own legislation, the equivalent term is "interdict". An injunction that had been successfully obtained in England would have had no force in Scotland and an interdict would have had to have been sought in Scotland to prevent the Scottish media from providing details of the healthcare worker.
- There was uncertainty about the extent to which injunctions and interdicts would apply to electronic sources of information as opposed to printed media.
- There was uncertainty about how effective an injunction and an interdict would be given the access that people have to electronic media out with the UK. People in the UK may have access to computer servers which are located under the jurisdiction of non-UK countries.
- A considerable public health resource had been deployed to prepare for the PNE which was large and complex. There was no public health resource with detailed knowledge of the law and the procedures of the English and Scottish legal systems that was immediately available to explore the range of issues in detail.
- A decision had been made by the IMT to take a public health approach to the PNE and follow the example of the approach taken by Aneurin Bevan University Health Board and Public Health Wales in the management of a large scale hepatitis C PNE in 2013. An injunction had not been sought for the 2013 incident and there was concern that if an injunction and an interdict were

sought and either obtained or not obtained that this may make the media focus of the incident the healthcare worker rather than the public health situation, and that it may create an impression that NHS Lanarkshire and Public Health England were trying hide something which they were not.

An assessment was made that seeking an injunction and an interdict may lead to more disclosure in the media about the healthcare worker than if this course of action was not taken. The IMT had decided that details of the HCW would not be disclosed to the media, unless findings of the PNE suggested that this was required for public health reasons, for example, to assist with identifying patients who may have been at risk who had not already been identified.

A small number of media organisations published details of a healthcare worker in electronic and print media and asserted that the HCW named was the HCW involved in the PNE. At no stage has NHS Lanarkshire disclosed details of the HCW to the media and it did not engage in dialogue with the media when they were seeking confirmation that a name that they were putting forward was the name of the HCW involved.

Section C. Preparation for the patient notification exercise

1. Underlying principles and values

The following principles and values underpinned the approach taken by the IMT and the various subgroups to prepare for and deliver the patient notification exercise:

- Integrated, whole system work by members of staff in various divisions and departments in NHS Lanarkshire
- close working by IMT with Corporate Management Team
- briefing of Board members
- Working in collaboration with other NHS Boards, other parts of NHS Scotland, other UK countries and with UKAP
- patient centred approach with a focus on provision of easy to understand information, support for people with questions, facilitation of making appointment bookings and empathy for those who felt anxious or displeased about the exercise
- team work recognising that many people would be working as part newly formed, short life teams
- distributed leadership
- continuous learning and sharing of learning
- thorough preparation with consideration of possible ways in which things might be misperceived or might go wrong with an expectation of challenges and a no blame problem solving approach to dealing with them
- information management

- communications plan based on principles of being open, honest and transparent
- maintenance of routine services.

2. Achieving high reliability

   In an article entitled Achieving high reliability in healthcare[6] summaries are provided of five characteristics described by Weick and Sutcliffe in their book *Managing the unexpected*[7] of organisations that achieve high reliability. These are:

   1. Sensitivity to operations

   A constant awareness by leaders and staff to risks and prevention, a mindfulness of the complexities of systems in which they work and on which they rely.

   2. Reluctance to simplify

   Avoidance of overly simplistic explanations for risks or failures and a commitment to delve deeply to understand sources of risk and vulnerabilities within systems.

   3. Preoccupation with failure

   A focus on predicting and eliminating catastrophes rather than reacting to them; a "collective mindfulness"[8] that things will go wrong and that near misses are opportunities to learn.

   4. Deference to expertise

   Leaders and supervisors listening to and seeking advice from frontline staff that know how processes really work and where risks arise.

   5. Resilience

   Leaders and staff trained and prepared to respond when systems fail and that work effectively as teams to overcome urgent challenges.

   Members of the incident project team were familiar with the work of Weick and Sutcliffe and the above characteristics were very much part of the approach that was taken by the incident management team, the incident project team and each of the subgroups.

3. Establishment of subgroups

   In order to manage the work required to prepare for and deliver the PNE the IMT established four subgroups. Membership of the IMT and the subgroups is detailed in Appendix C.01.

[6] www.datix.co.uk/ddme_cms/userfiles/files/blogs/High-Reliability%20in%20Healthcare%20-%20UK%20-%20screen.pdf

[7] Weick KE, Sutcliffe KM. Managing the unexpected: resilient performance in an age of uncertainty. 2nd ed. San Francisco (CA): Jossey-Bass; 2007.

[8] Chassin MR, Loeb JM. The Ongoing Quality Improvement Journey: Next Stop, High Reliability *Health Affairs*, 30, no.4 (2011):559-568.

3.1. Lanarkshire PNE Subgroup

As most of the patient who were to be written to lived in Lanarkshire a subgroup was established to prepare for and manage the delivery of the PNE to Lanarkshire residents. This was chaired by the Lanarkshire BBV Prevention and Care Network Manager

3.2. Other Scottish Boards Subgroup

Teleconference meetings with held with representatives of all the other NHS Boards with a detailed agenda used to ensure relevant information was shared, and necessary points were covered. Follow up with Boards took place by way of emails to all Boards and one to one emails between Board representatives and a member of the NHS Lanarkshire project team regarding specific situations and patients.

3.3. Other UK countries and UKAP

Meetings comprising representatives of Public Health England, Public Health Wales, Public Health Northern Ireland and UKAP were held to discuss and agree the advice that had been provided by UKAP, the timing of the PNE, the need for a PNE to include patients who may had an EPP performed by the HCW pre-1982 and arrangements in place for joint working and linking with communications teams.

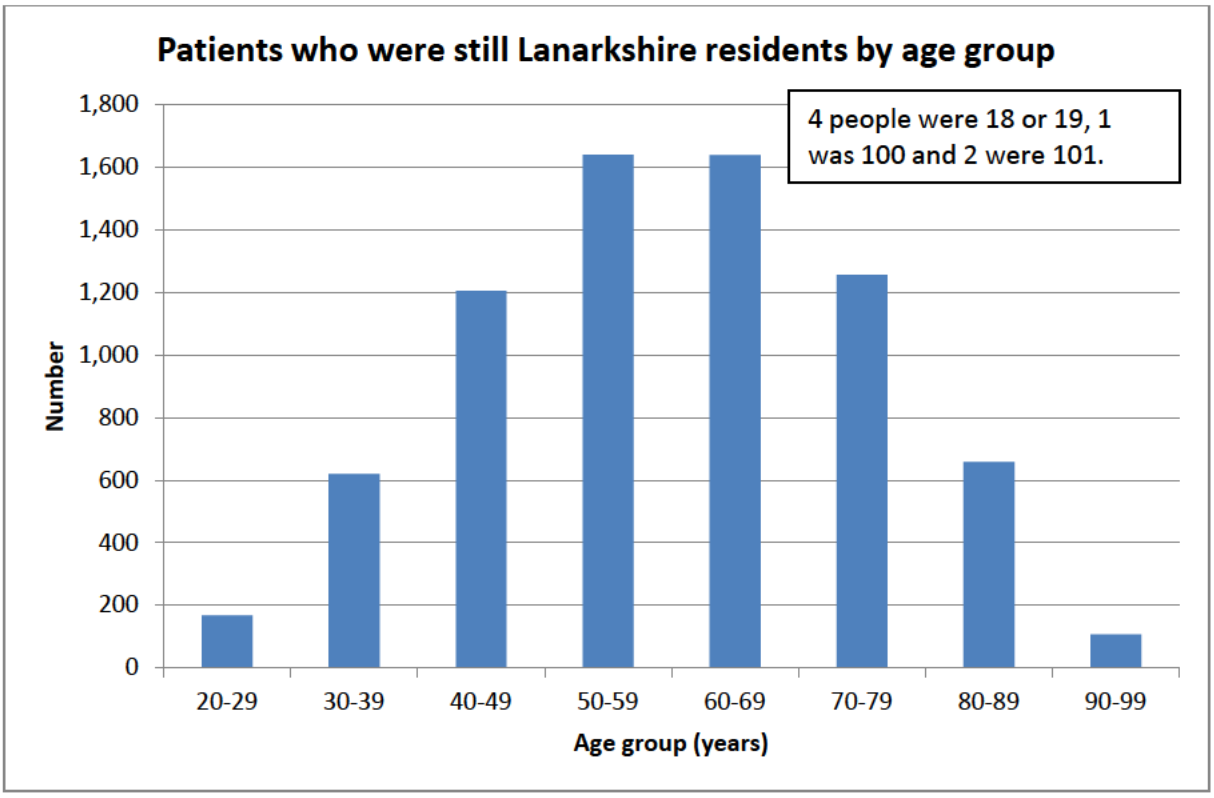
3.4. Communications sub-group

The Communications subgroup was chaired by a NHS Lanarkshire communications manager. All meetings were held as teleconferences and involved the communications officers of national health protection organisations and also, at times, representatives of government health departments.

4. Analysis of Lanarkshire residents' data

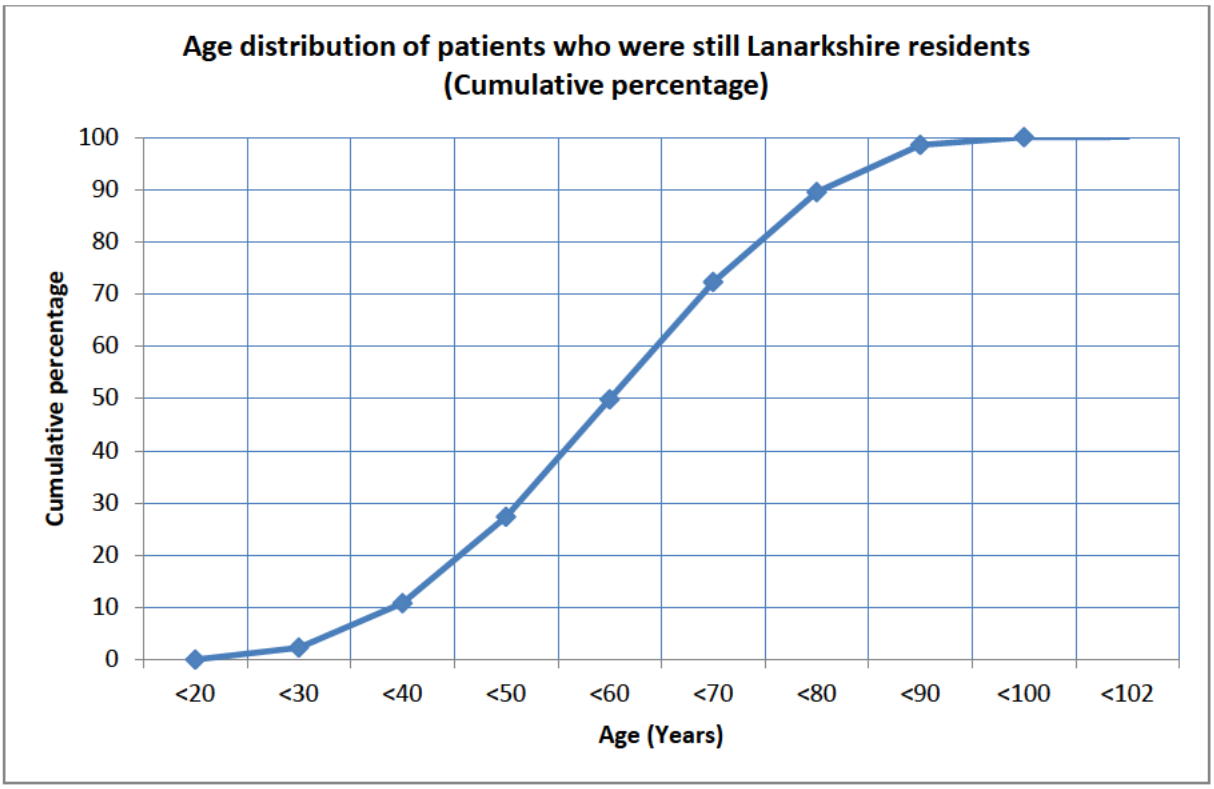
In order to understand the needs of patients who were Lanarkshire residents a senior information analyst worked closely with members of the public health project team to analyse data by age and health board operating unit of residence using look up tables and the postcode of patients. This enabled good quality information to be used to plan for testing clinics and to link with district nurses regarding their patients. The following table and graph show the number of patients by age group.

Age group	18-19	20-29	30-39	40-49	50-59	60-69	70-79	80-89	90-99	100-101
Number	4	168	620	1,205	1,640	1,638	1,256	658	108	3
Percentage	0	2	8	17	22	22	17	9	1	0



The following table and graph show the cumulative percentage of people by age:

Age	<20	<30	<40	<50	<60	<70	<80	<90	<100	<102
Number	4	172	792	1,997	3,637	5,275	6,531	7,189	7,297	7,300
Cumulative percentage	0	2	11	27	50	72	90	99	100	100



50% of patients who were Lanarkshire residents were aged 60 years or more.

5. Identification of NHS Lanarkshire resources

It was recognised as the investigation progressed during 2015 that it was likely that a patient notification exercise would be required and that this would have significant resource implications for NHS Lanarkshire.

5.1. Support from NHS Lanarkshire Corporate Management Team

Regular reports, often provided as SBARs (Situation, Background, Assessment, Recommendations reports), were provided to the NHS Lanarkshire CMT and during October and November 2015 a CMT subgroup met with the chair of the IMT to receive progress reports regarding the incident investigation and the preparation for a PNE. The chair of the IMT also reported regularly to the Director of Public Health. (See Appendix C.02 for an example of an SBAR.)

5.2. Resources required to meet the needs of patients in care homes

It was felt that it was inappropriate to invite patients living within care homes to the clinics, as it was likely that the stresses and risks associated with attending a clinic would outweigh the benefits for this particular patient group. Clinics were being arranged for February and March, with some clinics being held in the evening, and various risks associated with travel, mobility and falls were identified. Instead patients living in care homes were offered testing within their homes. To decide on the how this could best be delivered, and to take into account the specific needs of this group, for example around

capacity, a group was brought together to create a strategy. This group included representatives from the Department of Public Health, the Care Home Liaison Nurse Team Leader, and the team leader of the Harm Reduction Team which provided the testing.

5.3. Securing financial resources

At the start of the exercise there was discussion and agreement between the Incident Management Team and NHS Lanarkshire Corporate Management Team about the funding that would be required to support the exercise. The support and commitment provided by NHSL CMT was significant in allowing the IMT to move forward in a less restrained manner to develop options to support the development of a testing plan.

One of the key issues discussed at these initial meetings with NHS Lanarkshire CMT was the issue of paying staff overtime. This issue had been raised by front line managers and was discussed and agreed with the HR Director of NHS Lanarkshire at an early stage which enabled planning and subsequently recruitment to be progressed on schedule.

6. Information and documentation

6.1. Range of information sharing methods

The exercise had many stakeholders both within and out with NHS Lanarkshire. Information was shared through several methods: email, face to face small group discussions, and through managed access to shared electronic folders on NHS Lanarkshire computer network drives. Meetings of the IMT provided a good opportunity to share information and problem solve during meetings. Having representatives from all the key areas of the PNE present at, or dialled in to, meetings ensured a chance to highlight any cross working issues and clarify actions and information to be communicated to others. and that the messages were then disseminated throughout the system. Out with the IMTs, subgroups met to continue progress of the work. A four member incident project team and named individuals responsible for each area, meant that it was clear who to go to regarding a specific enquiry.

6.2. Incident response room

Information sharing was also crucial once the PNE had ‘gone live’. A situation room hosted in the public health department from 23 February to 25 March 2016. It was set up with computers and phone lines including teleconferencing equipment, and had wall and whiteboard space for updates and reactive notes. The incident project team members were based there, which facilitated daily meetings and was a useful hub for other members of the IMT and CMT to drop in when they had a query.

6.3. Shared spreadsheets

A central spreadsheet of all patients and their testing status enabled quick access to understand what was going on with specific patients. Furthermore colleagues across eHealth, laboratories and the Child Health Department (which coordinated

mail out of negative result letters) had a joint spreadsheet to reconcile numbers of samples and results and the number of patients for whom details were forwarded to ATOS to mail merge and post a negative result letter.

6.4. Documentation

Documents were created for each component in the exercise. (See Appendix C.03 for table listing the various documents produced.) Collaboration between departments was required to ensure the documents both fulfilled their practical needs and delivered consistent messages.

One of the most important sets of documents was the letter, appointment booking form and Questions and Answers sheets which were sent to the majority of patients. These documents were worked on extensively to ensure content was as clear as it could be, to consider ways in which people receiving these documents might take a different meaning or impression from what was intended, to format them so that numbers that might be dialled were in a large font size and to make the appointment booking form easy to understand and easy to fill in correctly. (Appendix C.04)

The exercise grew in complexity from initial clinics at three sites only to ten sites in additional to alternative testing for housebound and those living in care homes. This meant that the number of pathways and associated documents also grew. Documentation attempted to provide information and support at all steps - within the testing clinics themselves the different categories of staff received tailored information to their roles; there were spare appointment forms for patients who had not brought their own; slips for patients giving them a phone number to call if they did not receive their results by a certain time; and feedback forms for the clinics.

The aim was to provide consistent messages across Lanarkshire, and across the other Scottish NHS Boards and other UK countries, but with flexibility for the documents to be adapted as required to their own situations. Copies of documents from each location were requested so that the NHSL incident project team could check them for consistency of message.

6.5. Situation reports

Once the project had gone live situation reports were created as needed to provide updates on exercise progress and issues that had arisen.

Good practice points

Information

The inter-departmental and cross-organisation membership of the IMT and IMT subgroups enabled relationships to be established and developed which were crucial to the success of the exercise. Time spent discussing issues and agreeing actions during these meetings was valuable.

The situation room provided a useful hub for people to contact regarding the exercise. It was particularly useful that it was available for several weeks, so that work in progress could be kept accessible in the locked room, and that it helped focus work on the exercise and not be distracted by other work.

Documentation

- Reading other exercises reports, as well as speaking to those involved, provided insight and example documentation to build upon.
- Version control was crucial. It is advisable to have everyone in the team use the same format when naming documents. For example:
  Date (in YYYY_MM_DD format) - Document name - Version number.
  For example: 2016_02_16 - Letter to care home residents - V 1.3
  with the document being "Saved up" each time it was amended, for example, to V 1.4.
- Have a central electronic folder on a shared computer drive for document versions and clearly labelled 'final versions' to prevent the wrong version being reissued.
- When there are various iterations of a document (for example, standard patient letter, care home patient letter, patient who is a prisoner letter), try to create these iterations when the final document wording is agreed. Otherwise it can result in having to go to multiple documents and change the same bits multiple times, giving more opportunity for mistakes and inconsistencies.
- Give people as much time as possible to comment on documents.
- Wherever possible only send the final version out to other organisations. Due to changes decided late on in the process, an updated version of some letters needed to be sent to some external organisations.
- Be conscious that different organisations may want to use different letter heading and formatting, and provide sufficient time for these edits.

7. Establishing acute and community clinics

Representation from across NHS Lanarkshire divisions and departments on the Lanarkshire PNE subgroup, particularly from senior management in the acute and primary care divisions, was crucial to the delivery of a testing plan that would meet the needs of patients and support testing of patients across Lanarkshire.

7.1. The testing model

The testing model needed to take into account where patients would be tested; the age of the cohort; their likely mobility; length of appointment time; location of patients (where they lived); clinic availability; and the need to accommodate a mixture of daytime, evening and weekend clinics.

7.2. The testing clinics

Establishment of clinics, staff required and the skills they would need to have to undertake the specific roles, training, appropriate clinic environment, flow and available amenities.

7.3. Role of Primary Care

Establishment of processes and communications to ensure GPs were not involved at any part of the exercise and were kept informed generally regarding the incident and specifically in relation to patients who were registered with their practice who were being sent a letter.

7.4. Results process

Time frame for results, reporting and recording of results and informing patients of the outcome.

There were four options:

- Testing clinics in acute and primary care.
- Home visits for patients invited to attend testing clinics but unable to attend.
- Testing in care homes across Lanarkshire.
- Home visits to patient on district nurse lists.

7.5. Testing clinics in Acute and Primary Care

Intelligence from previous patient notification exercises was used to support the development of a 'Testing Clinic Plan', with previous exercises indicating a 30% to 60% uptake percentage. Consequently a plan was established which allowed for an uptake percentage of 57% with monitoring of appointment bookings and attendances to determine during week 2 if further appointments and clinics were required.

Overall testing clinics across acute and primary care venues were established. The PNE went live on Tuesday 23 February, with clinics starting Thursday 25 February and ending on Thursday 17 March. The delayed start date was agreed as advice from RMS colleagues indicated that it would have been unlikely that clinics set up any earlier would have been filled and this would have been a waste of resource. This proved to be a useful strategy. In total 4,700 clinic appointments were established across the four week period. (See Appendix C.05 for the testing clinic timetable.)

7.6. Testing clinics in acute and primary care: Contingency plan A

During week one of the patient notification exercise it became apparent that initial engagement and patient uptake was high, so additional clinics were established for week 2 and 3.

7.7. Impact of reminder letter: Contingency plan B

It became clear from week 1 and 2 uptake rates that appointment slots in certain clinics were filling up very quickly. Furthermore the sub-group felt that the reminder letter sent to non-engagers at the end of week 2 would also induce a further surge in patients engaging with the exercise. This proved to be the case.

7.8. Addition of clinic appointments

In response to the high engagement figures and the anticipated demand as a result of the reminder letter an additional 1,000 appointments were added to week 3 and 4 clinics. This included increasing the number of testing appointments at established clinics, adding new days and times for certain locations where there was high demand and standing down planned clinics where numbers had become significantly low (Monklands Hospital). Standing down clinics allowed staff time and resources to be optimised and reallocated to busier clinics.

NHSL Referral Management System (RMS) staff were invaluable in their support in building additional clinics at short notice and supporting the additional appointments for week 3 and 4.

The final testing clinic plan developed supported an 81% uptake rate.

7.9. Location of clinics

Early analysis of patients being invited to test and still living in Lanarkshire showed a clustering with high number living in certain localities. The age of the cohort was also significant in ensuring that clinics were spread across Lanarkshire to enable easier access and transport to clinic appointments. There was a particularly high number of patients living in the Bellshill, Motherwell and Wishaw localities with significant numbers also in Hamilton, East Kilbride and Clydesdale.

Another key factor in determining the location of clinics was available clinic space. In total there were 10 clinic locations. These were:

- Bellshill Health Centre, Bellshill
- Carluke Health Centre, Carluke
- Douglas Street Health Centre, Hamilton
- Hairmyres Hospital, East Kilbride
- Monklands General Hospital, Airdrie
- Motherwell Health Centre, Motherwell
- Stonehouse Community Hospital, Stonehouse
- Viewpark Health Centre, Viewpark
- Wishaw General Hospital, Wishaw
- Wishaw Health Centre, Wishaw

7.10. Acute and community hospitals

The availability of clinic space in the acute and community hospitals proved invaluable and enabled clinics to run across the weekends (Saturdays and Sundays) from 9 am to 5 pm and 5 pm to 9 pm in the evenings. Up to six clinic rooms were available concurrently to use which accommodated large numbers of patients in these clinics. The acute hospitals also had the additional bonus of being open during the weekends and evenings and having janitorial and security staff available as a matter of routine. This was not the case within Primary Care clinics where additional members of staff were recruited to support the opening and closing of buildings.

7.11. Primary Care

A further 5 clinics were established in local Health Centres to enable daytime appointments, as well as evening and weekend appointments to be offered to patients. This supported easier access and helped to overcome any potential transport problems that may have arisen.

As more members of staff became involved in supporting the exercise a further suggestion came from front line staff in Primary Care that a clinic should be

established in the Viewpark area. This proved to be a useful development and a busy clinic was held there across the four weeks of the exercise.

7.12. Access and transport: Assessing need

Whilst it was appreciated that a spread of locations would support easier access, there was an appreciation that there may be mobility issues for some patients. An additional set of questions were developed and built into at the initial appointment booking stage. This enabled Referral Management System (RMS) staff to determine if a patient had any mobility problems that might prevent attendance at a local clinic. Where mobility was deemed to be a significant issue a home visit was arranged. RMS staff passed on the patient's details to the public health incident room team which liaised with the NHS Lanarkshire Harm Reduction Team. The Harm Reduction Team facilitated the home visit and was able to provide a Dried Blood Spot Test (finger prick test) for people in their own homes and for those identified as in Care Homes.

7.13. Length of appointments at clinics

The length of the appointment time for clinics was an issue that was discussed and changed on several occasions moving from 5 minutes to 10 minutes and finally to 15 minutes.

Initially it was felt that due to the efficiency of phlebotomy staff only a 5 minute appointment was required. However based on examples of other patient notification exercises it was established that time was needed to enable a pre-test discussion to take place to enable key information to be clarified and for patients to ask questions.(detailed in the Health advisor Information pack).

A 15 minute appointment time was therefore agreed for each patient and this proved adequate, especially given that many patients had read the Q&A sent to them with their invitation letter.

7.14. Managing throughput and clinic atmosphere.

Clinics were generously staffed and a key outcome of this was that patients rarely waited for their appointment, with the vast majority arriving at clinic, being booked in and then being taken immediately. As a result there were few times when patients were sitting with other patients and staff reported that this caused a relaxed and potentially less charged atmosphere. The staffing levels was felt to be a key element to the successful operation of the clinics and maintaining strong clinical control and ensuring flow of patient.

7.15. Staffing at clinics

Each clinic was staffed with a trained receptionist, phlebotomist, health advisor who provided the BBV specialist support role and a clinic supervisor who provided leadership. All staff who supported the clinics took part in training

sessions relevant to their role. Training sessions included information about the situation, the importance of confidentiality for all staff and a briefing on their role. Section 22 provides more detail on the extent and content of training conducted.

In a bid to maintain confidentiality of the exercise materials that were developed to support staff were not provided at the time of training. Staff were provided with these on Monday 22 February 2016 - the day before the exercise went live and three days before the first testing clinics took place.

7.16. Admin. and reception staff

Preparation of reception staff for the PNE:

1) Compile a reception procedure manual detailing protocols; potential scenarios; and IT system crib sheets.
2) Secure confirmation regarding the PNE clinic timetable including dates; times; locations; number of patient appointment slots.
3) Secure reception staff availability to provide reception cover for the clinics.
4) Foster good team working to ensure provision of cross site cover and back up support cover, in the event of unexpected reception staff shortfalls or changes to clinic schedules.
5) Secure training of reception staff, for example, reception procedures and protocols; PNE specific “soft admin” training; and IT systems training for PMS and SCI MPI.
6) Encourage and seek daily reception staff feedback particularly in initial stages, for example, feedback regarding planned protocols & procedures or any unforeseen issues; and manage any reception staff concerns.
7) Actively check scheduled clinics in advance and re-confirm clinic times and locations with reception staff regarding planned cover.
8) Ensure staff are paid accordingly by their respective site line manager via the payroll system.

<u>Admin and reception staff</u>

Admin and reception staff played a key role in the testing clinics, booking patients into the clinics, checking demographic details and patient contact details. Admin and reception staff were recruited from across Primary Care and Acute Hospitals. This caused some issues with regards knowledge of different IT systems with training developed for all staff on both SCI Store and TrakCare systems.

7.17. Clinic audit

An audit had previously taken place within all of the clinics by the IT Department to ensure the correct hardware, labels (2 D labels), passwords for staff to access systems were in place.

7.18. Information packs (Crib sheets)

A detailed information pack, which was referred to as a crib sheet, was also developed and disseminated to all clinic staff. This included supporting difficult situations with patients (for example, a patient, who had not booked an appointment, attending a clinic and requesting a test) and answers to technical difficulties, including the provision of emergency IT numbers during clinic times.

7.19. Reception procedure manual

The health records manager compiled a reception procedure manual detailing protocols, potential scenarios and IT system crib sheets to be used by reception staff. (Appendix C.06) Reception staff availability was confirmed in line with the confirmed PNE clinic timetable dates, times, locations and number of appointments. Good team working was vital to ensure provision of cross-site cover and back-up support in the event of a staff shortfall or short notice changes to clinic schedule.

Secure training of reception staff was required, for example, reception procedure protocols; PNE specific ‘soft’ training in relation to patient interaction; IT systems training for patient management system (PMS), Scottish Care Information (SCI) and master patient index (MPI).

Daily feedback from reception staff was encouraged, particularly in the initial stages of the exercise – for example, regarding planned protocols & procedures or any unforeseen issues; and manage any reception staff concerns.

Prompt processing by their respective line managers to ensure staff were paid accordingly.

7.20. Phlebotomy

Phlebotomy was undertaken by phlebotomists or nurses with the appropriate skills, who were present at all clinics. It is worthy of note that Senior Managers for staff undertaking phlebotomy were keen to ensure that staff were not expected to answer any questions related to the exercise or to hepatitis C.

7.21. Training

Training for all staff took place to ensure there was a common understanding of their role and the role of others in the clinic, particularly the role of the health advisor. Indeed, staff were reassured that all questions should be answered by the Health Advisors, and that there were other mechanisms for patients to

receive support with questions that could not be answered at clinic (such as the clinic feedback form) with their key role solely to take blood and to explain the results process. Where bloods were unable to be taken staff were asked to write patient details on the clinic feedback form and follow up was arranged by Public Health.

7.22. Blood forms

All blood forms were marked with 'PHE 2016' standing for "Public health exercise 2016" to ensure the laboratory were able to link the samples to the notification exercise process when reporting results.

7.23. Two weeks result form

A form was also developed for phlebotomy staff called the 'Two Weeks Result Form'. This provided the patients with the date of their test and the last date they should expect their result. Should their result not arrive a telephone number was provided for patients to call. Negative results were notified by a letter and positive results by a telephone call.

7.24. Health advisor role

There was much discussion about the length of appointments and the importance of giving patients the opportunity to raise questions and to express any anxieties or concerns they had about the test or indeed about the situation. It was agreed that 15 minutes per patient would provide a good time allocation to allow this to happen and within this a pre-test discussion was also provided, with only a short amount of time needed for the experienced phlebotomy staff to take bloods.

<u>Pre-test discussion</u>

The pre-test discussion was based on good practice guidelines and provided the patients with information on what the test, invited and also confirmed how results would be provided. The latter was again reiterated by phlebotomy staff along with the provision of the 'Two Week Result Form'.

<u>Skills and experience needed for the health advisor role</u>

There was a realisation that the specialist health advisor role would require two elements in terms of knowledge and skills. The former was a basic knowledge of hepatitis C and the latter was the skill and experience to be able to deal with anxious and angry patients.

After much debate it was decided that the latter was more significant and that the knowledge aspect could be provided via training and the provision of detailed question and answer sheets. With hindsight this was the right decision and allowed the incident project team to recruit staff from a range of services beyond BBV Services. It was clear also that the numbers of staff required to support clinics would be much greater than those in specialist BBV services.

Staff who undertook the health advisor role were recruited from a range of services across NHS Lanarkshire including:

- BBV Specialist Services
- Community Mental Health Teams
- Ending Violence Against Women Service
- Harm Reduction Services
- Health Improvement Staff
- Primary Care Nursing Staff
- Psychology Services
- Sexual Health Services
- Third Sector BBV Services

7.25. Staff rotas

Allocating shifts for the health advisor role across the four weeks of the exercise required significant resources. Staff were provided with a blank template of all clinics and asked to confirm which clinics they were able to support. Shifts were then confirmed vie email and telephone call to ensure that there were sufficient Health Advisors in each clinic. There was also the additional problem of ensuring that there was a specialist BBV member of staff at every clinic to support other Health Advisors on hepatitis C related questions should they arise. Ensuring there was a skill mix for every clinic was significant to the success of the clinics.

7.26. BBV specialist support role

Staff from any of the statutory or voluntary sector BBV services who had good knowledge of hepatitis C were spread across clinics to ensure there was always a specialist on hand to answer any questions.

7.27. Clinic supervisor

Every clinic also had allocated an experienced clinical team leader to provide leadership and ensure all members of staff were clear about their role and how to deal with any challenges.

7.28. Troubleshooting: On-call support

A further layer of support was added for each clinic via a help-line on call telephone number during all clinic times.

8. Role of Harm Reduction Team

The primary role of the Harm Reduction Team (HRT) during the PNE was to provide a dedicated service to those patients who were living in care homes. The testing method agreed for carrying out tests on such patients, most of whom were elderly, was dried blood spot testing (DBST) which is a reliable alternative laboratory testing method to venous blood testing.

A secondary role was to provide home dried blood spot testing and follow-up for the following situations: (a) where a venous blood sample could not be obtained by district nurses (b) where a venous blood sample was not obtained at a testing clinic (c) where patients could not attend a PNE testing clinic.

The HRT team members are proficient in blood borne virus testing using the DBST method. They are also trained in venepuncture and were able to offer patients in (c) the option of both methods.

Initially there was a list of 71 patients in care homes and approximately 26 for home visits. However, by the end of June 2016 176 dried blood spot tests had been performed. As a result of the extended home visit list, additional support was provided by members of staff in the Keep Well community health promotion team for two weeks.

Preparatory work

In preparation for the PNE, all team members with additional care home and home visit roles had attended health advisor briefing sessions. They were provided with a detailed health advisor's information pack and carried out this role at designated clinics. In their exisitng NHS role, they were experienced community staff and familiar with policies and procedures regarding working alone.

A workload allocation meeting was arranged with Harm Reduction Team and Keepwell staff prior to commencing home visits. All the necessary paperwork and equipment was provided, including patient labels. At the end of each working day a telephone progress report took place with each staff member and the HRT team manager.

A shared, password protected, centrally located spreadsheet was used when recording progress of testing and results. The team manager was given permissions to access SCI Store Lab results and was responsible for checking all testing done via the dedicated team on a weekly basis and updating the spreadsheet. Results were obtained within two weeks for venous bloods and within three week for DBST as this test is performed at the West of Scotland Specialist Virology Centre.

Home visits commenced towards the end of March and continued to the end of May 2016.

On the whole the staff reported they felt the exercise was well organised and they had been briefed and supported adequately. The service was not delivered in the same way most community 9-5 pm services are offered. Staff had to be very

flexible approach in their approach to accommodate patients working hours. Some appointments were provided as early as 8 am and as late as 9 pm and at

weekends. All blood samples were delivered to Wishaw General Hospital by the end of each working day or first thing in the morning on the next working day to ensure there was no unnecessary delay in getting tests processed and making results available.

The vast majority of patients who were visited at home were thankful to staff and felt they were provided with a good service and adequate information about the notification exercise in the letters they were provided.

Whilst a high number were able bodied and could get to clinics, they were offered appointments at clinics quite far from where they lived. For those who could not drive, there was limited public transport after 6pm was the main reason they gave for not getting to a clinic.

Good practice points
Give consideration to rural areas for clinic access.
DBST method would still be a good choice. It is a quick and easy method (providing staff are proficient in this testing method); no special requirements for transportation of samples; some homes were not suitable for taking venous blood samples; less risk of needle stick injury to staff working out with a clinical environment.

Consideration should be given to which members of staff involved in the PNE, who do not normally have access, would benefit from having access to patient label printers. This was considered for the public health department but was thought to not be needed, however, given the number of people who did contact the public health department in the subsequent weeks and months easy access to printing patient labels would have been helpful.

The Harm Reduction Team carried out 60 tests (all DBST) at care homes. A number of patients at care homes were not tested for the following reasons:

- For 7 patients consent was declined by a relative.
- 4 patients died during the PNE.
- 2 patients were too agitated at the time of visits to permit testing.
- For 6 patients calls were not returned by care homes to arrange visits and to arrange for consents to be obtained.
- 2 patients were too ill at the time of test for a sample to be taken.

For two patients a report was received to say there had been insufficient sample submitted. In both cases the family of the patient do not wish a further sample to be collected. None of the DBST carried out on care home patients were positive or equivocal for HCV Ab and none were positive for HCV PCR.

170 patients had a test done during a home visit. Most of these were DBST with 8 being recorded as venous blood samples. 13 patients did not respond to messages left to arrange for a test; three patients were out of the country during the PNE and

were given contact details for the Harm Reduction Team so that they could contact it upon their return to Lanarkshire. There were no reports of insufficient samples received.

One patient had a DBST reported as HCV Ab equivocal and was referred to the BBV clinical service where a further test on a venous blood sample was also reported as equivocal. One patient was found to be HCV PCR positive and was referred to BBV clinical services for further testing. Other than these two patients no other patients had HCV Ab positive or equivocal results, or HCV PCR positive results.

The patient who was HCV PCR positive was found to have genotype 3 virus but when it was gene sequenced it was found to not be related to the virus of patient 1 or the virus of patient 2.

9. Care Homes

9.1. Distributing information

Those patients who were identified as living in a care home, had their letter (Appendix C.07), Questions and Answers sheets (Appendix C.08) and a guardian consent form (Appendix C.09) sent via the Care Home Manager. The Care Home Manager was provided with a cover letter (Appendix C.10) and information sheet (Appendix C.11) to inform them of the situation, their role, and answer common questions. The Care Home Manager was asked to distribute the letter to the patient or their guardian, as appropriate. If the patient had capacity to consent they would go to the patient directly. If they required guardian consent, then the manager should provide the guardian with a copy of the 'Guardian consent form' to complete. If the patient had no capacity and no legal guardian in place, then the manager should ensure there is a certificate of incapacity under section 47 (Part V) of the Adults with Incapacity (Scotland) Act 2000 with wording or a treatment plan which will cover the test.

The affected care homes were contacted by the Harm Reduction Team to organise testing, for those who patients for whom consent had been given. Some care homes required more than one posting to get the materials to them, and it could also take quite a while to get consent forms back.

9.2. Dried blood spot test offered

Residents within care homes were offered a dried blood spot test, rather than a venous blood sample. The dried blood spot test was used as it is considered less invasive, it is a reliable testing tool for HCV antibody and PCR, and there is no risk of needlestick injury to the nurse during the process when working with elderly confused patients. Unfortunately for some patients who lacked capacity and were unable to understand why they were having the test done, administration of the dried blood spot test was difficult. When patients were distressed, it was decided that it was better to come back and try testing another time. Within the team it was agreed that it was appropriate to try testing on two occasions and if unsuccessful the need to re-contact the guardian on

whether it was valuable progressing this further, weighing up the benefits of testing with the distress of being tested.

9.3. Recording results

A shared, password protected, centrally located spreadsheet was used when recording progress of testing and results, this was helpful in monitoring progress with testing, and planning workload for the team. However initially some patients were not identified as living in a care home, so the workload increased.

9.4. Results

By end of June 2016 of the 81 care home residents within the exercise 60 had been tested, of these 2 samples were insufficient and the family did not want the patient retested. Of the remaining 21 care home residents, they were not tested for the following reasons: consent refused by relative (7); patients died during the notification exercise (4); patients too agitated at the visit (2); calls not returned by care homes to arrange a visit and consent (6); and patients too ill at the time of test (2).

Good practice points

Having a team with relevant members (those who work with care homes, those who would provide the service) at the start ensured the planning highlighted the majority of potential problems and provided perspectives on attributes of the patient group, and the care home setting, to make the process as smooth as possible.

Some care homes did not receive their letters on the first mail out. It was very helpful having administrative and Care Home Liaison Nurse Team support to clarify where there were gaps in receipt of letters. However it does raise the question of where these letters that were posted but did not reach the care home managers went.

The Care Home Liaison Nurse Team Leader planned that her team would have availability to support care homes during the exercise. This proved helpful, as they were able to provide support that included:

- Informing the Care Home Managers about the exercise and requesting a named person to plan relevant consents and support for the Harm Reduction Team who visited to carry out the dried blood spot test.
- Highlighting the importance of confidentiality for the affected residents.
- The team also reinforced the relevant sections in the NHS Lanarkshire Infection Control manual.
- The Care Home Nurses helped to locate a few patients who had moved into a Care Home after the contact lists had been prepared.

- The Care Home Liaison team were a dedicated point of contact for Care Home staff to provide support and signpost to the relevant specialist if required.

Using dried blood spot tests in this group was the best choice, albeit it was difficult to get a sample from some of the frail elderly patients. Most of the samples were taken within the privacy of the patient's own room, however on one or two occasions the sample was discreetly taken within the sitting area of the care home due to the patient's unwillingness to be moved to their room.

Accessing dried blood spot tests uses a different laboratory results system (as they are not tested locally) therefore consider who needs access to this service and give advanced notice to the relevant department to set this up.

Requesting the care homes to organise consent resulted in delays. If doing this another time it would be better to have the Care Home Liaison team link with the care homes to find out the consent categories and then send the consent forms directly to the families.

Despite a dedicated team conducting the testing, the process of testing care home residents took a long time. Progress was delayed by post being lost, delays in receiving guardian consent, care homes being closed and because sometimes patients were distressed or unwell and unable to be tested. When planning to reach this patient group it is important to have a dedicated team and to have a realistic and flexible timeframe.

10. District nurses

There were significant numbers of patients who were elderly, frail and would have significant difficulty in getting to clinics. It was also identified during the initial stages of the exercise that many of these patients (339) would be on the local district nurse lists. Having representation from primary care on the Incident Management Team was significant to ensuring that the identification of these patients took place and that engagement via district nurses was facilitated.

Dual role of district nurses

District nurses played a dual role of both health advisor and phlebotomist. Specific letters were developed for patients on the district nurse lists explaining that their district nurse would be in touch to arrange a time to visit their home to provide a test. All district nurse staff who were testing patients were provided with training and a detailed 'Information Pack' adapted for the district nurse situation.

11. Specific Settings

11.1. The State Hospital, Carstairs

Three patients were identified as being inpatients at The State Hospital. Each patient has been tested for hepatitis C as part of their care. The tests had been carried out subsequent to six months after their last admission under the care of the healthcare worker during which they had an EPP performed and no further testing was required.

11.2. HMP Shotts

Three patients were identified as being inmates at Shotts Prison. Arrangements were made with the Shotts Prison health centre manager for letters to be uplifted from NHS Lanarkshire headquarters and delivered to each patient. Subsequently these patients were tested, found to be hepatitis C antibody negative and were sent a negative result letter.

12. Primary Care and GPs

Due to the size of the exercise it was decided that testing would not be offered through General Practices. The Associate Medical Director for Primary Care was one of the members of the steering group and able to advice on best course of action. Project team members also met with the Local Medical Committee (LMC) to discuss options.

General Practitioners were sent an email (Appendix C.12) informed of the exercise, which of their patients were being invited for testing, and given a flow diagram for their receptionists to follow in the event that a patient contacted them rather than the testing clinics to gain access to testing (Appendix C.13).

Good practice points

Engaging with GP leads up front was useful in getting agreement over actions.

Having a clear pathway of patient testing was useful, as was advising GPs and other primary care colleagues in advance, in case they were contacted.

13. eHealth and ICT

The eHealth team processed the majority of letters. eHealth expertise was used to format the letter to printing standards, insert the mail merge components and work with the external printers to test the letter printing, mailing and posting process.

A shared folder was accessible by different departments. An outline of the time frames of different stages of the printing process was helpful in organising the materials and clarifying understanding of what was needed at each stage.

Strict version control was essential to ensure all involved knew which version of each document was the most up to date.

The process of finalising documents that are to be sent to over 7,000 people, and then testing mail merge against the final version of the patient dataset, and the testing the subsequent steps of the letters being sent to external printers is an important and pressurised step in preparation for the PNE. Sufficient time needs to be allowed for each step in the process in order to ensure that the deadline for this work to be completed is met..

13.1. Mail merge and processing

As discussed above eHealth ensured that letter content was formatted appropriately and liaised with the external printers to ensure the printing and posting process worked. The Child Health Department was responsible for mail merging appropriate letters to patients. Checks of letters were carried out at regular intervals to ensure accuracy of this method. As initial letters were staggered over three days, this slightly complicated the mail out process.

Several different letters were sent out to patients – the initial notification letter, negative result letters and reminder letters. It was difficult to estimate the daily workload. Close working between departments was needed to ensure all letters were sent at the appropriate time.

Public Health was responsible for posting a minority of more specific letters, for example the letter packs to care home managers.

As batch of negative result letters had not been printed, enveloped, franked and posted and this had not been identified until several days later when some patients contacted the helpline an assurance system was set up requiring a member of the Child Health Department to receive an email from the external printer confirming when each batch of letters had been processed and posted.

Good practice point

When more than one department or organisation is responsible for the printing process it is valuable to set up an assurance system to provide assurance that the process performs as intended and if not to highlight any problems.

13.2. Strategy to identify patients at risk of hepatitis C transmission

It was recognised that a strategy was required to identify patients who may have been at risk of hepatitis C transmission and that such a strategy needed to be developed in detail and recorded as a written document. The scenario was considered in which a patient may contact NHS Lanarkshire in the years to come, having been diagnosed with hepatitis C infection with a history that they were, or may have been, operated on by the healthcare worker and a question as to why

NHS Lanarkshire had not identified the patient as being at risk and sent a letter to them. It was also recognised with this work that there may have been, or there may be, cases of litigation and that particular documents developed and used as part of the investigation and the patient notification exercise may be requested in association with litigation, or may be requested under the Freedom of Information Act. The strategy that was developed is included as an appendix to this report. (Appendix C.14).

For those patients who were identified as having been admitted under the care of the HCW and had one or more EPPs performed attempts were made to ensure that the most up to date information regarding a patient's address was obtained and a process was in place to follow up regarding any letters or envelopes which were returned to the Health Board as being undelivered to the individual from a particular address. A process was in place to make contact with a patient's GP to see if a more up to date address which had not yet been entered onto TrakCare could be obtained and if the patient could be contacted in this way.

13.3. Establishment of contract with ATOS-Canon

Due to the volume of patients that would need to be mailed NHSL contracted with ATOS to utilise their mail merge, printing, enveloping and patient mailing service. This allowed NHSL to concentrate on the key task of patient booking and follow up. Using the ATOS MyMail service required mail merged word letters and supporting documentation to be provided to ATOS for both the initial and reminder mailing. A number of test mailings was undertaken to check the process, delivery times and the content of the pack. In doing so it was identified that there was no postmark date on the envelope but the letter stated 'date as per postmark'. This required the letter to be dated. ATOS was used to mail negative result letters to patients on a daily basis matching laboratory results to patient cohort demographics and providing a mail merged Word letter. Despite having some control checks in place there were some technical and process issues which resulted in some letters being delayed.

Good practice points

A shared folder which was accessible by different departments, and an outline of the timeframes of different stages of the printing process was helpful in organising the materials and clarify understanding on what was needed at each stage.

Strict version control was essential to maintain confidence that the most up to date versions of letters were being used. It should be noted that any late changes to letters can invalidate previous rounds of testing.

The process of mail merge and processing of letters, and them being sent to external printers in sufficient time for testing, can be quite a timely procedure, allow sufficient time for this.

13.4. Process of preparing template letters

The eHealth team processed the majority of letters. eHealth expertise was used to set up a new server and the mailing application (including external firewall access to the printers) as well as formatting the letter to printing standards, inserting the mail merge components, and working with the external printers to test the letter mailing and posting process.

13.5. Process for obtaining and processing data from ATOS

13.5.1. Preparation of data for other organisations

With respect to the other 12 Scottish Boards and three other countries and [redacted] as well as supplying information from the main index report related data was supplied from the SMR01 dataset for each of the patients.

13.5.2. Steps undertaken to minimise risk of sending a letter to a deceased patient

The “Known Deaths” dataset was established using datamarts from ACaDMe GRO, iSoft PMS and TrakCare PMS. The three datasets where combined and duplicate CHI’s removed. The data-linkage exercise with the National CHI database (via ATOS) resulted in a further 291 deaths being identified.

Before the “go live” date of 23 February 2016 TrakCare was interrogated daily via a BOXI report to check for any recent deaths.

13.6. Audit of IT infrastructures and staff capacity to use IT systems

NHSL took an early decision to utilise existing IT estate and software to reduce risk of implementing new equipment and software. eHealth undertook an audit of the IT requirements in conjunction with locality service managers. The main requirement was for additional patient identification label printers (plus contingency supply). eHealth also undertook an assessment of staff training requirements based upon their use of TrakCare. It was specifically requested that the service tried where possible to identify additional reception and booking staff who were already trained in TrakCare to prevent the need for additional training.

13.7. Use of 2D labels

Utilising the SCI laboratory label functionality meant that patient identification labels with 2D bar codes could be provided as per the laboratory’s specification.

13.8. Arrangements for test result information and issuing of result letters

A file was issued each day onto a shared drive by laboratory staff. This file was then picked up by a senior information analyst to reconcile against the Master Index. A member of staff from Lanarkshire's referral management service team then picked up any negative results and completed a mail merge which was used to generate letters daily to the patients - see use of ATOS mail merge above.

Positive or non-negative test results were communicated to a member of the public health team by phone or secure email and these were then communicated to the BBV clinical team whose members then made contact with patients.

13.9. eHealth - Information service

13.9.1. Identification of patients at risk

An initial data linkage exercise was carried out by ISD (Information Services Division of National Service Scotland) and HPS (Health Protection Scotland). The first part of the record linkage exercise was completed based on CHI number. Assigned during routine CHI record linkage rules applied by ISD.

On the basis of the first linkage:

- The HCW, during the HCW's 26 year career in Scotland, was assigned to patients for whom 41,742 episodes were recorded by ISD, relating to 26,021 patients.
- Of the 26,021 patients, 145 were, according to HPS's National HCV Diagnosis Database, known, as at December 2014, to be HCV positive (antibody positive or PCR positive or antibody and PCR positive, indicating past or current infection).
- Of the 26,021 patients, associated with HCV positive patients, 114 related to patients who were diagnosed HCV positive after their first date of admission to hospital under the care of the HCW.
- Of the 114 patients associated with HCV positive patients diagnosed after the date of discharge, 55 were associated with the management of patients, by the healthcare worker, who did not undergo an operative procedure.
- The remaining 59 discharge diagnoses were associated with patients who underwent an operative procedure.
- The linked records were further filtered to identify those with specific genotypes. This exercise identified 28 patients, 15 of whom had a specific non-healthcare risk factor for HCV infection recorded – with 13 patients with no non-healthcare risk factor recorded.

The findings of the above stage were then submitted to the UK Advisory Panel for healthcare workers infected with blood borne viruses.

Further investigation commenced based on the 26,021 patients identified by Health Protection Scotland. This involved closer working between Information Services and NHSL public health. Further investigation led to the creation of a BOXI report using ACaDMe SMR01 datamart filtered by [redacted] number or HCW name with a date range of 1982 – 2008. Work was undertaken by a consultant general surgeon to assign an EPP category to the procedures that were not covered by the EPP categorisation table of general surgery procedures that had been provided by UKAP.

In order to ascertain the patients that may be consulted as part of a patient notification exercise the output from above was then used to complete another data linkage exercise to identify patients who were known to have died. The “Known Deaths” dataset was established using datamarts from ACaDMe GRO, iSoft PMS and TrakCare PMS. The 3 datasets were combined and duplicate CHI numbers removed. The output from this exercise resulted in identification of 7,021 patients.

Note that there were limitations as ACaDMe was unable to provide information between 1982-1986. Therefore ,the process and output from the above process identified patients from 1987-2008 that had been recorded as under the care of the healthcare worker and had one or more EPPs categorised as EPP 1, 2 or 3 and who were not known to have died.

It was agreed that the output from above would be sent to ATOS as this is the process for obtaining the most up to date, best available contact details for patients. Therefore, authorisation was given by NSS Practitioner and Counter Fraud Services Manager on 30 September 2015 to go ahead and forward the records for patients identified as having had an exposure-prone procedure performed when admitted under the care of the healthcare worker to the national CHI to obtain the most up to date contact details of patients irrespective of which Scottish NHS Board they were currently registered with. In addition, information would be requested from national CHI regarding patients who did not appear to be registered with NHS Scotland and any other information that was available about such patients which could be used to link with other parts of the UK.

Through further investigation with ISD a file was obtained on the 15 October that would allow exploration of whether it was possible to identify patients that had been under the care of the healthcare worker in 1982 to 1986. ISD also confirmed that the information should have been available via ACaDME (which was the source for 1986-2008 data) and that this would be raised as a national issue. In the interim it was agreed with ISD that NHS Lanarkshire would use an SMRO1 file dating from 1979 in an attempt to source the relevant data from 1982 -1986. This proved to be particularly challenging as the dataset was not formatted under particular headings. In addition, it became evident that the healthcare worker’s [redacted] number did not appear to be showing within the dataset. A further discussion was held with ISD on

Tuesday 20 October and it was confirmed that during that time period superannuation numbers were used as an identifier of the [redacted] whom patients were admitted under the care of.

Information services liaised with public health to obtain the superannuation number of the healthcare worker. Public health was able to obtain this number via Human Resources. The HCW's superannuation number was then used to identify patients who had been admitted under the care of the HCW during 1982-1986.

One complication that was identified whilst using the superannuation number was that superannuation for 1982-85 period has "0" as a lead in number and those for 1986 did not. Confirmation of this was sought from ISD on Wednesday 28 October 2015 and it subsequently confirmed this fact. Ultimately, this caused a slight delay in the investigation but on Friday 30 October 2015 a final number of patients from 1982-1986 were identified and sent to ATOS to carry out their CHI linkage exercise.

As at 23 February 2016 , the following patients had been identified:

- 8,532 - Overall number of patients that have been in contact with the HCW having and an EPP 1,2 or 3 and not known to have died.
- 7,311 - The number of patients that have a Health Board of residence as NHS Lanarkshire and are to be notified.
- 713 – The number of patients with a Health Board of residence within Scotland, that is not Lanarkshire, who are to be notified.
- 326 - The number of patients within NHS Lanarkshire that are known to the district nursing service. These patients will not be invited for an appointment at a testing clinic. A district nurse will arrange a visit with each of these patients.
- 70 - The number of patients known to be in a care home within Lanarkshire.
- 3 - The number of patient that are to be contacted who are patients at The State Hospital, Carstairs.
- 3 - The number of patients that are to be contacted within Shotts Prison.
- 508 - Patients out with NHS Scotland.
- 370 - Number of patients with a health board or health authority of residence within England, Wales and Northern Ireland
- 138 - Number of patients classed as untraceable as there is no known address for these patients (370+138 = 508)

13.9.2. Development of spreadsheets to support the exercise

A file containing 8,851 CHI numbers was transferred via NHS-SFT to ATOS.

ATOS data-linked these CHI numbers to the latest national CHI database producing output data in a predetermined format. This output was data-Input to Excel producing a spreadsheet with a total of 26 columns and 8,851 rows.

In order to maintain an audit trail and maintain integrity of the original dataset none of the fields were changed in the dataset. A series of VLookup tables (24 in total) was developed to analyse and adjust the dataset.

These VLookup tables resulted in an additional 41 columns being added to the original dataset.

Excel pivot tables (20 in total) were in turn used to analysis this revised dataset into the required subsets and cohorts, for example, patients in care homes, on a district nurse list, negative results, clinic outcomes, and patients in other Scottish NHS Boards, other UK countries and [redacted]

This report was referred to as the *Master Index*.

13.9.3. Management of access to incident spreadsheets

The password protected Master Index report was uploaded to FirstPort, the NHS Lanarkshire intranet, to allow members of the HCW incident investigation and project team to access the file as required.

Only NHSL staff with proper login credentials are able to access FirstPort.

13.9.4. Specific data requests

Specific data requests were managed via a single senior information analyst. The analyst was part of the HCW investigation and project team and liaised directly with the team to turnaround specific requests as effectively and efficiently as possible whilst maintaining confidentiality.

For example, separate password protected reports for Care Home patients and patients on the district nurse list were completed and posted to FirstPort. The SMR01 dataset was interrogated (via ACaDMe) to obtain relevant information for specific patients.

13.9.5. Use of date of birth in letters sent to patients

A patient was sent a letter to their correct address, however, their father who had the same name, lived at the same address and who was not part of the cohort opened the letter and subsequently contacted the helpline to ask why he had been sent a letter. The patient's CHI number was included in the patient's letter in order to be able to assist with

identifying the patient if the patient phoned the helpline or NHS Lanarkshire services. The CHI number contains the patient's date of birth[9], however, this is usually not apparent to people who are not familiar with CHI numbers. It would have been easy to have included the date of birth field at the time of drafting the template letter to patients and this may help patients to clarify who correspondence is intended for.

Good practice point
Include the patient's date of birth in the letter addressed to them.

13.9.6. Review of PNE cohort data

Records should be examined electronically to identify if there are any duplicate entries such as CHI number and names and where duplicates are found further examination of records should be carried out to review dates of birth and addresses, and to look for different name spellings, reversal of forename and surname, or possible data entry mistakes.
Data quality issues include:

Incorrect date of birth - for example, 5-3-89 v 5-3-80 with a "9" being read as a"0", or vice versa, and being keyed in as intended; or the digit being read correctly but keyed in by pressing "9" rather than "0", or vice versa.

Good practice point
Review PNE cohort data for duplicates.

14. Referral Management Service

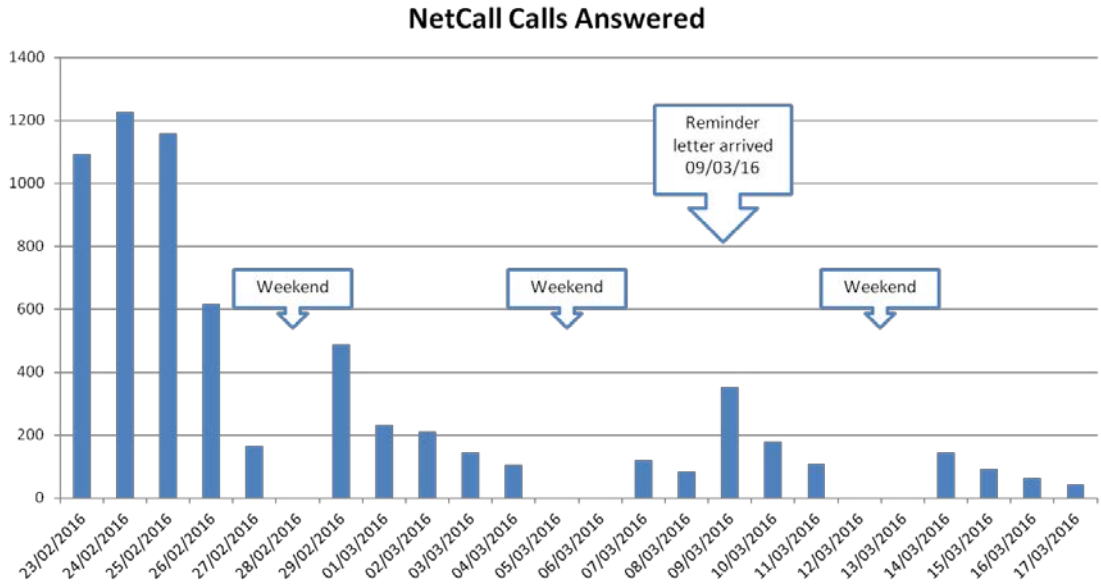
Planned Review List entries for all patients in the cohort were added to TrakCare in advance of the public health exercise to ensure booking process would be handled correctly and providing reporting on progress from TrakCare. This was carried out by RMS staff in additional hours due to the volume of patients in the cohort.
The "trainers" room was identified as being an excellent area to set up an additional contact centre for the exercise due to the proximity to the main RMS and the layout of the area. The relocation of the trainers for a 5 week period was agreed in order to facilitate this.

Following review of current RMS operations and limitation of BT lines on the Kirklands site it was agreed that a separate Netcall System would be put in place utilising 11 lines based on the Monklands Hospital site. This would allow 11 lines to be utilised at any one time but did not allow for Netcall to provide further queue management beyond these 11 lines. The telecoms supplier provided a "Cloud" queue facility that would allow the RMS managers and team leaders to manage and monitor a queue after all

[9] The format of the 10 digit CHI number is DDMMYYXXXX where DDMMYY are the patients date of birth in Day/Month/Year format, for example, 03/05/92.

11 lines were busy and provided the ability to flex this queue further depending on the number of calls in the system therefore minimising waiting times for patients. Netcall set-up, with scripted messages, was agreed in conjunction with public health input along with the call-handling scripts to ensure consistency of call-handling for all staff participating in the exercise. Additional equipment – phones, headsets, PCs were installed in advance and testing of full contact centre process and queue management was undertaken.

To ensure resourcing of an additional contact centre and still maintain an RMS service, staff within the RMS volunteered to carry out additional hours and staff from other service areas were also deployed into the public health contact centre for call-handling. All staff deployed into the public health contact centre had training around the Netcall software/TrakCare and scripts were devised to aid patient booking. RMS restrictions were agreed in advance to ensure that the public health contact centre could be staffed appropriately at all times.



15. NHS24

15.1. Meeting of NHSL CMT with NHS24 CMT members

Conveniently at a time when some issues had arisen regarding the service which NHS24 would be able to provide for NHS Lanarkshire a meeting had been scheduled at NHS Lanarkshire Headquarters involving the NHS Lanarkshire Corporate Management Team and members of the NHS24 Corporate Management Team. The chair of the IMT and several other IMT members were able to attend the start of the meeting between NHSL and NHS24 and briefly describe the situation that was being dealt with and outline the needs which NHS Lanarkshire had. In attendance at the meeting was the Chief

Operating Officer of NHS24 and there was the opportunity to have discussion about what the issues were to clarify what the needs were, and to agree on specific actions that could be taken by both NHS24 and NHS Lanarkshire, to ensure that needs were met. This proved to be an extremely helpful way to progress this work and enabled the good relationships that had already been established with NHS24 to be maintained and developed further.

15.2. Development and agreement of service level agreement

Liaison between NHS24 and the exercise was primarily through an NHS24 representative on the IMT and via regular discussions between that staff member and a member of the public health team. Updates were provided to the NHS Lanarkshire CMT. The scope of what NHS24 could provide and the needs of the exercise were discussed, at one point, this included a meeting of NHS Lanarkshire CMT and the NHS24 CMT members. A service level agreement was developed and agreed, with further modifications being made as the exercise preparations progressed. It is recommended that when a service is being provided by a different organisation that the details of what will and will not be provided are detailed in a written document, and this is shared between both organisations and worked up further and signed off when it is complete and agreed. The final version of the service level agreement is appended. (Appendix C.15)

Prior to staffing the helplines, NHS24 produced projections of call volumes to enable appropriate levels of staffing. These projections, as well as NHS24 advice and the desire that patients had the optimum experience, formed the basis of the decision to stagger the mail out, rather than send all patients their letters at the one time. This decision was brought to IMT meetings for discussion and had knock-on implications for other areas of the PNE, for example the appointment booking line and clinic timetabling.

15.3. Service provided

NHS24 provided and staffed two helplines for the exercise: one helpline for members of the general public; one helpline for patients who had been sent a letter. In addition the service kept several daily logs of issues that would need to be resolved by the Lanarkshire exercise team: request for a reminder letter; advising of a deceased patient; advising of a patient based overseas; and if a patient had not received test result within the expected timeframe. NHS24 was provided with an extensive questions and answers document which provided answers to most of the queries experienced. (Appendix C.16) For a small number of queries that NHS24 was not able to answer

NHS24 contacted the NHSL public health team to hand over the query or to obtain advice on how to answer it.

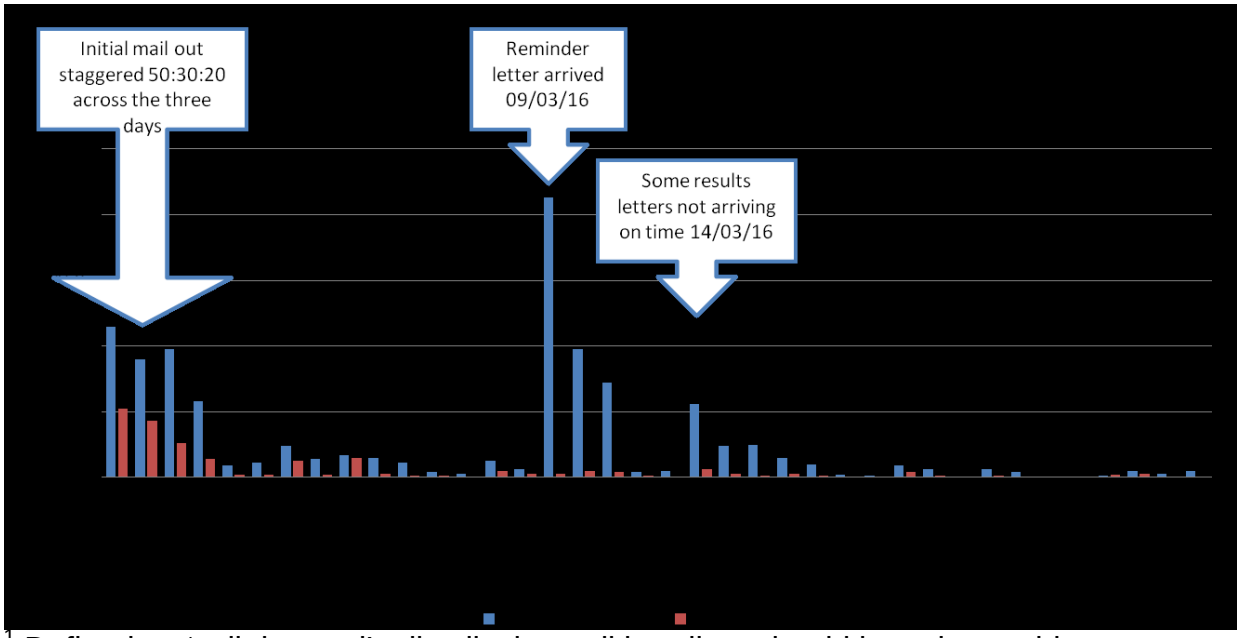
15.4. Use of service by people who did not live in Lanarkshire

The patient helpline phone number had been provided to other Scottish NHS Boards and the health protection organisations of other countries. Call handlers were prepared to handle calls from anyone linked with the exercise, not just Lanarkshire residents. In the event the majority of calls were from Lanarkshire residents.

15.5. Results

The operation of the helplines ran smoothly. Between 23 February and 31 March 2016 the patient phoneline received 1087 calls[10], of which 1053 (97%) were answered. The general public phone line received 229 calls and 220 were answered (96%) Figure 1. shows the distribution of calls. The decision to spread the initial mail out over three days may have spread the timing of calls across the first three days. The peak on 9 March 2016 was mainly due to the reminder letter only having the NHS24 patient helpline number on it, not the appointment booking line number; therefore NHS24 received quite a few calls requesting this number.

Figure 1: Calls answered by NHS24 Information helplines



[1] Defined as 'call demand', all calls that call handlers should have been able to get to – this does not include people who had not been answered yet but hung up before

60 seconds calling.

Phone line managers were able to brief the Lanarkshire PNE team of issues early on - for example, when the RMS booking phone line went down - highlighting patients who had not received their negative letter. This interaction was very helpful and influenced resolving these problems.

Good practice point
The speed with which the helpline could be set up was impressive. The PNE had a long lead in time, but in an emergency situation, this would be a very helpful resource. It would have been helpful to have extended the length of time the helpline ran for to respond to patients who rang up as they had not received their results.

16. Patient Affairs

There was recognition that an accessible feedback and complaints process would be needed. Members of staff in Patient Affairs handle this work on a daily basis and they managed the workload related to the exercise.
The Patient Affairs phone number had been distributed to other boards and countries, so they were set to handle calls from anyone linked with the exercise, not limited to Lanarkshire residents. In reality the majority of calls were from Lanarkshire residents. Result

Patient Affairs handled 39 calls in relation to the public health exercise. Four formal complaints were logged through patient affairs in relation to the exercise. The majority of the calls were from Lanarkshire residents, 27 Lanarkshire, 7 other, and 5 from unknown locations. Calls covered topics such as:

- Frustration over not being told about this situation in 2008
- Patient thinks they should have received a letter.
- Patient not sure if they should have received a letter, not thinking they had a surgery
- Wanting to know what surgery their letter relates to.
- Specific clinic locations being booked up
- Patient was away during clinic time period.
- This concern was about not having received a result letter within 10 working days time frame.

Good practice points
Normally the patient affairs department has a separate phone number for each site. It was considered that this may be confusing for patients who wished to contact the patient affairs department in relation to the exercise. Instead a single phone number was established for the duration of the exercise. This number linked to each of the

three hospital patient affairs numbers, therefore distributing calls between the patient affairs call handlers, and preventing any one team becoming overloaded.

Consideration was given to providing further information about lodging complaints in the patient questions and answers document, and highlighting a range of methods of accessing a wider range of complaints services. However, it was decided that provision of a single phone line number with an explanation that comments, feedback or complaints could be left on the answerphone if no one was able to take the call was sufficient, particularly in the context of an already information letter and questions and answers document.

17. [redacted]

From an early stage of the investigation, and as it became clear that a patient notification exercise was likely, the importance of providing information [redacted] Confidentiality had been emphasised to all NHS Lanarkshire members of staff at all stages of the investigation and as the preparation for the PNE progressed. The importance of confidentiality regarding the healthcare worker was also emphasised to the media and in information sent out to patients. [redacted]

18. Liaison with patient 1 and patient 2

Patient 1 and patient 2 were contacted separately prior to the press release being issued and informed that NHS Lanarkshire had concluded that it was likely that they had each been infected as a result of surgery performed by the healthcare worker. They were also informed that a large patient notification exercise would be taking place, that letters had been sent to them from the Medical Director and the Director of Public Health which included an apology and provided more details about the investigation and the conclusions which had been drawn, and that NHS Lanarkshire would not be providing any identifying information about them to the media. Any questions that patient 1 or patient 2 had were answered. Each patient was provided with contact details for the chair of the IMT in case they had any further questions they wished to ask and separate meetings were arranged with patients 1 and 2.

The chair of the IMT visited patient 2 in their home. This followed making telephone contact with patent 2 prior to the visit. The chair of the IMT explained

the content of the letter and gave details of the investigation which had been carried out both in 2008 and also in 2015 and then responded to various questions which the patient and the patient's relatives had. The chair of the IMT apologised on behalf of NHS Lanarkshire that the transmission of infection had occurred and regarding any distress or any anxiety that the notification exercise may cause to the patient. However, the chair of the IMT felt that he was not in a sufficiently senior position to apologise on behalf of the organisation and following discussion with the Chief Executive of the organisation a further meeting was arranged and took place in the home of patient 2, during which the Chief Executive apologised on behalf of NHS Lanarkshire regarding the probable transmission of infection. The Chief Executive also answered the questions which the patient and their family had on that occasion and also said that he was happy to answer any further questions or respond to any other issues that the patient or their family may have in the future.

[redacted]

Patient 1 and [redacted] were given an explanation of how the investigation had been conducted and the preparations that had been made for the notification exercise and the importance of maintaining confidentiality about the situation.

It had been recognised as the patient notification exercise launch drew closer and more staff across NHS Lanarkshire were informed of the notification exercise being prepared for that there may be individuals who would identify who the healthcare worker may have been and that this may affect individuals in a particular way with regards to either themselves or relatives or friends who they thought may have had a procedure carried by the healthcare worker.

19. Microbiology Laboratories

19.1. Lanarkshire

19.1.1. Initial Laboratory testing proposal

Segregation of samples

- Recommend - Sample request forms to be labelled with PNE 2016 label
- Propose-Microbiology to print labels and distribute via identified person. Microbiology can also email template to identified person(s)
- Recommend- Individually bagged samples to be gathered and sent in labelled blue plastic carrier bags to allow complete segregation of samples from routine bloods
- Propose-Microbiology will provide labelled blue bags for distribution via identified person

19.1.2. Transport of samples to lab

- Recommend- Batched at on-site clinics and handed in to the on-site laboratory, in blue labelled bag, at the end of clinic. Samples taken in primary care settings should, where possible, also be collected into blue labelled bags
- Propose-Delivered to specimen reception by identified individual each evening/weekend. Specimen reception at each site is always staffed. Primary care samples come by hospital transport as normal, but identifiable by blue, labelled carrier bag.

19.1.3. Equipment for processing

- Recommend-All PNE samples are run at the Monklands Hospital site, between 5pm and 10pm.
- Propose-Monklands Hospital analyser is less busy in the evenings, PNE samples could be loaded by biochemistry backshift staff and left to run.

19.1.4. Reagents and consumables

- Recommend - Reserving 5000 hepatitis C antibody tests with Roche
- Propose - Contact Roche to investigate reserving 5000 tests of the same batch number to minimise kit calibrations/QC problems. Also requirement for extra pipette tips.

19.1.5. Staffing requirements

There are 3 microbiology laboratories in NHS Lanarkshire. All GP and community services are centralised at Wishaw Hospital, with an acute service offered at Monklands Hospital and Hairmyres Hospital sites.

Staffing and reagent requirements were altered from the original proposals to accommodate the increased number of patients and structure of clinics.

19.1.6. Turnaround time

- Recommend: Negative results should be available in 48 hours. Positive results 7-10 days.
- Propose: State minimum of 1 week to allow for transport of samples from Hairmyres, any major peak/technical issues/staffing problems. Positive result reporting could be speeded up by requesting results via nhs.net account.

19.1.7. Reporting of results

- Recommend: Daily report to Public Health using reporting module on TrakCare. Arrangements for weekend to be discussed.
- Propose: Investigate possible use of special interest groups on TrakCare, an extract of which can be converted into a PDF each day and either emailed securely or saved to a secure shared folder.

Considerations

- How will patient information labels be printed? Will they have 2D barcode to incorporate patients' GP details? If not, sample registration will take considerably longer with higher risk of wrong location and sample registration errors ? Need input from IT/SCI store staff.
- Sample transport around sites - will extra pick-ups be needed or is routine van service adequate?
- Analyser contingency? Batch test at WGH at weekend if analyser issues at MK - will delay results.
- Staffing agreement in principle - may need to be increased depending on ease of registration, distribution of sample delivery (peaks & troughs). Initial work is based on testing up to 300 samples per evening and bar coded patient labels.

Reporting to Public Health - Prefer Excel format report. Investigate possible use of BI (Business Intelligence) (however, after initial investigation looks unlikely). Needs IT input.

19.2. Role of the West of Scotland Specialist Virology Centre (WoS SVC) .After liaison with both the incident team and the main testing laboratories in Lanarkshire it was agreed that the WoS SVC would offer the following testing algorithm.

19.2.1. Samples from NHS GG&C
Samples collected from patients living within Greater Glasgow & Clyde would be tested for HCV antibody. If positive for HCV antibody (Abbott) these patients would then be tested by HCV PCR (Abbott) to determine whether these patients had current HCV infection.

19.2.2. Samples received from NHS Lanarkshire
Samples received from Lanarkshire would have already been tested for HCV antibody in the referring laboratory. As a result referred samples would initially be tested for HCV PCR to determine whether the patients had past or current infection.

19.2.3. HCV RNA positive results

All HCV RNA positive patients would be genotyped as results would inform clinical management.

19.2.4. Reporting of test results
HCV antibody, RNA and genotype (if carried out) results would be reported back both to the requesting laboratories or physicians and to the incident management team.

19.2.5. Sequencing of HCV genotype 3 virus samples
The virus from all HCV genotype 3 patients would be sequenced in order to determine whether they were related to the original 2 patients. To do this the NS5B region would be sequenced. The results of this would be shared with the incident management team only.

It was agreed all samples arriving in the laboratory would be marked with the study code PHE2016 (standing for Public Health Exercise 2016). Laboratory staff were informed of the study code/notification exercise and the testing algorithm prior to beginning testing. This code would be entered into the laboratory system also to allow regular oversight/audit of the samples arriving in the laboratory. This would ensure the WoS SVC staff were aware of the numbers of samples tested and would ensure that the correct tests had been carried out for each patient.

20. Transport of samples

The timely uplift from primary care and two acute sites of samples and delivery of them to the main testing site (Monklands Hospital) was vital to the success of the exercise. Liaison with hospital transport services was made in September 2015 and again December 2015 when the "go live" date was confirmed. A number of transport issues which arose during the first weekend of testing clinics highlighted the need for a much closer liaison with the hospital drivers. This resulted in a very detailed, timed uplift schedule together with a text message being sent when each uplift and final delivery to lab reception was made.

Good practice point

Consider arranging face to face meetings with all staff involved in the exercise, particularly those such as hospital drivers who will hold a vital strategic role in the process, rather than simply relying on information being passed to staff by line managers or supervisors.

21. Domestic services

Early contact with Hospitality services who manage domestic services for acute and primary care sites initiated from September 2015 when the first draft of the testing clinic schedule was considered, it was confirmed that site/service managers would liaise directly with their local domestic services to

provide notice in due time of additional requirements supported by funding for additional hours as required.

22. Training sessions for receptionists, phlebotomists and health advisors

22.1. Training schedule

Forty-three training sessions (32 reception/phlebotomy sessions and 11 health advisor sessions) were organised and a few additional ad hoc training sessions were also conducted. Over the course of the training, a total of 234 people were trained: 70 receptionists,63 phlebotomists, 58 health advisors, 24 dual role (health advisor and phlebotomist), and 19 'other' staff were trained. Other defined as:-

BBV Support – 1, Staff in Charge – 7, Unknown 3, health advisor shadow – 1, health advisor support 7. The training schedule is appended. (Appendix C.17)

22.2. Testing clinics – Staff training

Four groups of staff were trained in relation to the exercise:

1. Reception staff to cover the arrival of the patient, booking in and demographic checks.
2. Health advisors to discuss the exercise with patients, ascertain whether they would like to be tested, and answer any questions.
3. Phlebotomy staff to take blood in the clinics.
4. District nurses and harm reduction staff who covered the dual health advisor and phlebotomist role, as they would be attending patients in their homes/care homes.

22.3. Training materials

Training materials were created for the different staff groups who would play a key role in testing. The content of the training included, its learning objectives, an emphasis on the confidential nature of the situation, a summary of the exercise and its scope, the roles and responsibilities of the different staff, how the testing clinics would function and provided responses to a range of possible scenarios. This gave a clear vision of what was wanted in the exercise, and helped staff engage and feel part of and invested in the exercise.

No handouts were given at the training sessions in the aim of maintaining confidentiality about the exercise prior to the 'go live' date. Materials were provided to all staff prior to their clinics starting, with sufficient time for them to re-familiarise themselves with the set up. Members of staff were provided with public health staff contact details at the end of the training, to enable further discussion if needed.

Extra training was an option for health advisors - they could either complete training available via the NHS Lanarkshire HIV and hepatitis website[11], or the RCPG online hepatitis B and hepatitis C module. If staff needed to complete training out with their normal working hours they were reimbursed for additional hours spent.

Within each location there was a 'receptionist champion' and a key testing clinic contact, to whom members of staff could go to for more information.

Good practice points

Taking the time to train staff was crucial in this role, it resulted in a much more empowered workforce that shared the vision. In addition, giving time for them to ask questions or make suggestions resulted in several beneficial changes to the programme set up.

With such a complex training programme it was helpful having administrative support to coordinate it.

Good staff understanding and attitudes meant that despite so many people knowing about the exercise before it went "live" information about the situation and the patient notification exercise media did not hear about the exercise prior to the 'go live' date, the confidential message was taken seriously. This was a focus of the training, including emphasising that it related to a colleague and what kind of behaviour would be desired if they were in their colleagues' position.

23. Further record linkage exercise with data to February 2016

The record linkage exercise that had been conducted by Health Protection Scotland in March 2015 had used the most up to date data on the Scottish hepatitis C database at that time. Given the time taken to carry out the further investigation during 2015 and the decision to conduct the patient notification exercise in 2016 a further search for patients who had linked records was requested. This was carried out on 6 February 2016 and identified 2 further patients. Each of these patients had had one or more exposure prone procedures performed while admitted under the care of the HCW and had been diagnosed with hepatitis C infection and had their details added to the Scottish hepatitis C database subsequent to 31 December 2014. On further investigation one of these patients was found to have hepatitis C 1a genotype. The other patient had genotype 3a, the same genotype as the HCW, but gene sequencing was reported as showing that this patient's virus was significantly different from viruses of patient 1 and patient 2.

[11] www.lanarkshirehivandhepatitis.org

24. Blood Borne Viruses Clinical Services

24.1. Patient pathway

All positive HCV test results, including HCV antibody positive but PCR negative results, were forwarded to the Lanarkshire BBV specialist nursing staff. The BBV nurses contacted the individuals who had tested positive by telephone to inform them of their test result and to answer any initial questions, pending a more detailed discussion at a dedicated outpatient clinic visit. The BBV nursing staff also coordinated the appointments for these individuals to attend the dedicated hospital clinic appointments, where they were assessed by an Infectious Disease (ID) consultant.

24.2. Scheduling of clinics

It was anticipated that given the large number of patients who were undergoing HCV testing up to 20-25 new cases of HCV infection might be identified - with the majority of these expected to be unrelated to any form of HCW-related transmission. To allow flexibility of appointment times, 6 additional dedicated new-patient ID consultant clinics were established. However, in the event only 3 of these clinics were utilised and the others were cancelled.

25. Functions covered by the Department of Public Health

25.1. Specific letters

The majority of patient letters were sent via ATOS-Canon, as detailed previously, however, it was agreed that some groups of patients required a tailored letter and attachments specific to their situation. Members of staff in the Department of Public Health sent letters to the following letters:

- Patients who were residents of care homes
- Patients who were inmates at HMP Shotts
- Patients at The State Hospital, Carstairs
- Patients who lived in NHS Greater Glasgow & Clyde's catchment area

Information was provided about the patient notification exercise to the managers of care homes which had patients who were being written to.

25.2. Clinic packs

Clinic packs were collated for each clinic by date and location throughout the period of exercise and circulated to sites by public health via transport services and courier. The packs included a feedback sheet for clinic staff to comment on patient issues, throughput of patients and to identify additional resources required. Also included were additional appointment booking forms, in the event patients had brought their own to clinic, reminder slips

customised by date and the 10 day timescale by which patients could expect their result and sufficient blue bags per 30 samples for each clinic.

25.3. Maintenance of the DBST database

Maintenance of the Dried Blood Spot Test database and liaison with the Harm Reduction Team aided the management of result letters for patients who had been tested in this way. The number of patients requiring DBST was greater than had initially been estimated. Apart from those patients initially identified as requiring DBST the following patient categories required a DBST, in some cases more than 12 weeks after the close of blood testing clinics:

- People who were inpatients during the clinic testing period or who were discharged from hospital during that period
- Patients on holiday
- Patients living abroad
- Patients who had mislaid the letter
- Patients who gave a history of receiving the letter more than four 6 weeks after it was posted
- Patients who had received the letter but made contact until after clinics had closed. For some such patients there had been other things going on in their lives – such as medical investigations, caring for ill relatives or bereavement – and they had set aside the PNE letter until their circumstances had changed.

25.4. Maintenance of the incident room database

Maintenance of the incident room database on which were recorded details of all specific patients who contacted any of the services supporting the PNE and original documents such as the daily checklists and tables of patient contact via the NHS24 and public health helplines.

25.5. Maintenance of a helpline from 18 March 2016

The RMS helpline closed on Thursday 17 March and the telephone number given on the NHS24 helpline recorded message was subsequently changed to the public health helpline number which was managed by public health support staff. This helpline operated from Monday to Friday during normal office hours and a recorded message advised callers who phoned out with these hours to call back. On Friday 18 March 23 calls were received by the public health helpline; the following week a total of 70 calls were received, and call subsequently reduced by one or two each day tailing off completely by 9 June – nearly three months after the dedicated help lines had been closed and nearly four months after letters were sent to patients. The total number of call received by this helpline was 247.

The majority of the calls were in the following categories:

- Patient on vacation or out of the country during the exercise. The patient's details were passed to the Harm Reduction Team and a blood test was arranged by that service.
- Negative result letter not received. There were approximately 8 patients during the period from 18 March who did not receive their results within the timescale expected. Public health support staff checked the result for each patient and sent a copy letter. Patient details were confirmed to ensure the patient's name and address details were correct on NHS Lanarkshire systems. In none of the cases had details changed and the reason for the patient not having received their letter was not identified.

Good practice point
Ensure arrangements are in place to extend the helpline facility for as long as it may be required. This can be relatively straightforward if this facility can be supported in-house, but would be more difficult if extension of a helpline requires external support.

25.6. Administrative support to IMT and various sub-groups

Two senior members of the public health support team provided administrative support to the Incident Management Team, its four subgroups and the incident project team. This involved arranging meetings and preparing for them, taking notes of meetings and circulating them, and following up on actions arising from meetings and others aspects of the work of these groups.:

Meetings of the IMT started on 16 June 2015 and continued approximately 6 weekly until commencement of the PNE on 23 February 2016. The Lanarkshire PNE sub-group met monthly from September 2016 and bi-weekly from 8 January 2016.

Good practice point
Ensure that consideration is given to the extensive administrative support required to support the number of meetings required to manage such an incident and that it can be sustained to include periods of planned and unplanned leave. Continuity of members of staff involved in this work was important.

26. Functions covered by Child Health Department

The Child Health Department is part of the health records service and its resources were used to support clinic reception, handle returned mail, to carry out mail merging and management of result letters and the collection of the clinic attendance forms for subsequent scanning and long term archiving.

27. Equality and Diversity Impact Assessment

Whilst organising the exercise an equality and diversity impact assessment was carried out. Consideration around meeting the needs of the patient population being contacted in the exercise was an ongoing process, heavily influenced by

the experience of other exercises and the views of front line staff with experience of caring for vulnerable patients and running clinics. The exercise plan changed from moving from hospital based clinics only to hospital and community based clinics with additional support from district nurses providing home visits and the Harm Reduction Team attending patients living in care homes. The information provided to patients was in English. Some information was provided on the NHS Lanarkshire public website[12], to which patients had been referred in documents for further information, in a number of other languages. A copy of the assessment is appended. (Appendix C.18)

28. Management of finances

The majority of funding was required for the staffing costs of members of staff who helped to deliver the patient notification exercise by providing helplines and testing clinics.

A specific cost code for the PNE was provided to all team leaders and senior managers (in NHS Lanarkshire and in NHS24) with responsibility for recruiting staff, ordering equipment including lab equipment, printing and posting of letters, and enhancing telecommunications facilities such as creating additional phone lines.

The items recorded against the PNE cost code are detailed in the following tables with the total cost being £256,550.

PHE2016 costs

Staffing costs	£
Health advisors	62,186
Health advisor support	7,333
Staff in charge	11,753
Phlebotomy	28,848
Reception	32,464
BBV support staff	1,860
RMS staff	6,186
Child health	1,325
EHealth desk top support	2,600
Medical records staff	4,337
Public health management	7,425
Labs staffing	2,699
Domestic & transport staff	1,325
Other	3,299
Subtotal	173,640

[12] http://www2.nhslanarkshire.org.uk/news/news/Pages/patients-contacted-re-health-worker.aspx

Supplies etc.

Lab testing costs	33,180
ATOS mailing costs	20,546
Oricom contact centre phone lines	8,190
Oricom staff equipment	2,700
Oricom label printers and supplies	4,000
NHS National Services Scotland costs	8,399
Clinic consumables	3,182
Pathology bags	1,666
Other including patient and staff travel	1,047
Subtotal	82,910
Total reported costs at March 2016	£256,550

The costs listed do not include staffing costs which were not additional costs to the organisation – for example, the opportunity costs of members of staff who were involved in the incident instead of performing their usual work. Such members of staff may have been involved in the incident during their normal working hours or during other hours but the opportunity cost arose if the member of staff took time off in lieu of the hours they worked as part of the PNE.

One of the significant issues identified at the start of the exercise was the rate of pay for overtime. Advice was obtained from the Human Resources Directorate that overtime would be paid in accordance with Agenda for Change regulations.

An estimate of the costs incurred by other Scottish NHS Boards and other UK countries and [redacted] has not been made. These would include the costs in taking part in IMT subgroup meetings, the cost of preparing for and delivering the PNE in their areas and the cost of two Public Health England members of staff travelling to Lanarkshire to meet with IMT members and participate in the media conference.

Section D. Delivery of the patient notification exercise

1. Lanarkshire
    1.1. Process of assuring the quality of testing clinics

    There were a number of ways that performance quality in the testing clinics was promoted and assured.

    1.1.1. Clinic feedback forms

    Clinic feedback forms were provided for every clinic to record the date and time of the clinic, the number of patients who attended, patient information

requiring follow-up, patient comments, clinic staff comment and additional paperwork required.

These were returned daily to the incident management room by email to the generic account or by fax to public health and proved an invaluable resource and cross-check in some cases with information coming back to public health via appointment booking forms. The forms were reviewed daily by one or more members of the incident project team. Clinic staff were diligent in returning these either immediately after the clinic or the following day and this diligence continued to the final clinic on the evening of 17 March 2016.

Feedback information was collated and circulated to the clinic managers enabling small positive changes to be made to the way clinics were run which assisted in assuring the quality of testing clinics. This direct daily contact with clinic sites proved invaluable in allowing public health and the wider project team to develop close working relationships with the various sites. The feedback from managers and members of staff at the clinics regarding how well the clinics had been organised and supported was very positive.

1.1.2. Details noted on appointment booking forms

Clinic staff recorded information about blood samples that had been taken or not taken on each patient's appointment booking form. In some cases more detail information provided by a patient was also recorded. The process for transferring this additional information to daily feedback sheets was put in place prior to launch and in the majority of cases the information was copied to the daily feedback sheet or sent by secure email to generic email account. However, in a very small number of cases this was not done, possibly due to pressures at clinics. The ability to cross-check between appointment booking forms and clinic feedback sheets was helpful at times when following up patient queries or requests for additional information. To the knowledge of the incident project team only one patient who required follow up was not picked up in this way and the action requiring follow up was identified informally.

1.1.3. Use of internal mail

Appointment booking forms were batched after each clinic and returned to the Child Health Department via internal mail to be scanned and retained for the records. During the scanning process forms were checked for additional information which was fed back to public health via generic email address, in the majority of cases this information was coming in via clinic daily feedback sheets but this was a useful cross-check and provided confidence the process was working. There was not option of transferring these bulk envelopes between sites other than via hospital transport services which in some cases took 3 days to arrive at Child Health Department.

1.1.4. Non-delivery of envelopes containing ABFs from clinics

Two bulk envelopes containing completed appointment booking forms with patient identifiable data were picked up from primary care sites and were mislaid by transport services on 2 March and 13 March 2016. Datix reports were completed for each incident and were investigated by hospitality services which line manages transport services, however, the envelopes were not found. This should be noted for the wider NHSL internal mail services and has been raised with the service as a risk via the Datix risk management system. The envelopes did not contain highly sensitive or clinically important information, however, such information is sent through the internal mail service.

Good practice point

An uplift form should be completed at clinics and a delivery form at labs by porters and /or drivers who uplift and deliver clinical samples and parcels with relevant information (date, time, name, mobile number) which could be matched against clinic schedules and enable gaps (delayed delivery or non-delivery of samples or parcels) and other issues to be followed up quickly.

1.1.5. Patient and clinic staff queries

Patient and clinics staff queries were followed up daily. If patient contact was required within 24 hours this was almost always achieved. For some patients where making contact was difficult contact made before 9 am or after 5 pm often proved successful.

1.1.6. Resources

Requests for additional resources such as paperwork were addressed in preparation for clinics. Additional paperwork was needed for clinics as the exercise progressed as appointments were increased to two appointments every ten minutes.

1.1.7. Email contact

Regular email contact was maintained within sites via the generic email address and others to ensure staff in clinics were supported quickly regarding additional paperwork or other resources as required.

1.2. Transport of blood samples from clinics to labs

1.2.1. Wishaw General Laboratories (First Stop)

With the exception of one site (Monklands Hospital) all samples from across the other nine sites needed firstly to be transported to Wishaw General Hospital laboratories. At WGH they were registered and spun prior to being transported to Monklands Hospital for testing.

1.2.2. Additional uplifts from out of hours clinics

Given that many of these clinics were operating during the evening and at weekends this required additional up-lifts from clinics to Wishaw General Labs.

1.2.3. Established Primary Care uplift

For clinics that were taking part during the day in Primary Care settings bloods were uplifted utilising the already established Primary Care uplift.

1.2.4. Daily transport Wishaw General Hospital to Monklands Hospital

A daily uplift from Wishaw General Hospital took place every day at 4 pm to Monklands Hospital whereupon lab staff at Monklands Hospital would work from 5 pm to 11 pm on testing the samples.

1.2.5. Transporting Samples: Blue cool bags

Given the number of additional samples being transported daily for the four week period special blue transport cool bags were purchased to transport the bags safely and to distinguish them from normal sample uplifts/deliveries. Samples were delivered to lab specimen reception by named van driver each evening/weekend.

1.2.6. Confirmation by text of sample bag uplifts and deliveries

A text confirmation process was put in place from week 2 of the exercise to give reassurance to the project team, particularly at weekends when the uplift of samples was specially organised, that samples had been uplifted and delivered. Primary care samples were delivered by hospital transport as part of the routine Monday – Friday uplift and by specially arranged uplift at weekends. All samples were batched and transported in blue, labelled carrier bags.

1.3. Communications

1.3.1. Communications plan

The approach to communications involved detailed planning and preparation ahead of the launch of the exercise including media training and practice for press conference panel members, and in particular the lead public health medicine consultant. This included filming and videoing a mock press conference and mock interviews and using an online media training package. The communications team worked jointly with the public health colleagues to identify likely difficult questions that both patients and the media would ask – and prepared question and answers documents to address these.

Learning from the experiences of colleagues who had previous experience of dealing with similar public health exercises and lessons learned from these was sought. The healthcare worker incident communications plan is appended. (Appendix D.01)

1.3.2. Provision of information to NHSL members of staff

Information was provided to NHS Lanarkshire members of staff by use of email with information sent to all staff in NHS Lanarkshire and a request that the information provided was brought to the attention of those staff who did not have access to email and also by providing comprehensive information on the NHS Lanarkshire FirstPort intranet and by providing links to the extensive information that was uploaded to the NHS Lanarkshire public website[13]. During the eight weeks, starting from when the notification exercise was launched one of the four rotating banners on the FirstPort intranet homepage was regarding the hepatitis C notification exercise. (Appendix D.02) If a member of staff clicked on this banner, this brought them to information about the situation on the NHS Lanarkshire public website.

1.3.3. Information provided to primary care

Information was sent to all GPs in Lanarkshire about the PNE and GPs were provided with details of patients who were registered with their practice who were being sent a letter.

1.3.4. Issue of press release

A press release was issued on 23 February 2016. (Appendix D.03) to all in the NHS Lanarkshire media distribution list. (Appendix D.04)

1.3.5. Press conference, and radio and TV interviews

A press conference invitation was sent out to media contacts (Appendix D.05) and a media handling schedule drawn up. (Appendix D.06) The press conference was well attended by the media including The Herald, Daily Record, STV, BBC and Sky News. Members of the panel for the press conference were the NHS Lanarkshire communications manager, the NHSL Medical Director, the NHSL consultant in public health medicine who was the chair of the IMT, a Health Protection Scotland consultant clinical epidemiologist who was also the chair of UKAP, and a public health representative of Public Health England. (Appendix D.07)

1.3.6. Coverage of the incident in the media

Despite the potential controversial nature of the incident the vast majority of the widespread media coverage was positive with the intended key messages featuring prominently. A media coverage report was produced. (Appendix D.08)

1.3.7. Provision of information via the NHS Lanarkshire public website

[13] http://www2.nhslanarkshire.org.uk/news/news/Pages/patients-contacted-re-health-worker.aspx

A link to more information about the hepatitis C public health situation was prominently displayed on the NHS Lanarkshire public website. (Appendix D.09) Clicking on the link brought people to a webpage that had detailed information about the incident and how it was being managed (Appendix D.10) and linked to updates (Appendix D.11), videos (Appendix D.12) and photographs of key members of the IMT.

1.3.8. Subsequent media enquiries

There has to date been very little subsequent enquiry by the media regarding the incident.

Good practice points

The benefit of preparation cannot be underestimated. Detailed planning ensured:

- No unanticipated questions at the media conference or subsequent interviews.
- Consistent messages from all spokespeople.
- A clear sense of professionalism in the handling of the media announcement which helped to promote confidence in the overall handling of the public health exercise.
- Close and collaborative working between communication and public health colleagues.
- Joined up approach across the UK promoted through early and regular contact across all agencies involved.
- Detailed preparation for the media launch.
- Preparation of extensive Questions & Answers documents.

An area where further work would have been beneficial would have been, in addition to contact made by telephone, to have had a face-to-face meeting between a member of NHS Lanarkshire's communications team and [redacted]

1.4. Incident room

Preparation for setting up incident room

The NHS Lanarkshire Public Health Department has a designated room at the Kirklands Headquarters equipped with additional telephone lines, teleconferencing, a projector that be linked to laptops, wi-fi, video conferencing and other equipment required to support a major incident. When the room is not required as an incident room it is available as a meeting room. Four weeks notice to existing room bookings was provided before the "go live" date to provide sufficient time for other departments to source alternative meeting accommodation. The room was prepared and viewed by public health staff a number of times well in advance of the "go live" date to

ensure preparedness. Public health retain a major incident 'kit' stocked with sufficient stationery and coloured recording forms which is kept stocked and readily available in the event of an incident. Public health retained locked access to the incident room for three weeks. The was longer than the initial scheduled one week mainly due to the issue of non-receipt of negative result letters referred to later in the report which generated a significant number of unplanned patient telephone contacts.

Good practice points

Maintain flexibility to operate the incident room beyond the initial planned for period, and possibly to maintain it for the full duration of the period when clinics are being held.

Regular testing of telephones and other equipment that is in use in the incident room should be carried out.

1.5. Exercise email account

A generic email account was set up and details circulated to key members of the Lanarkshire PNE subgroup. Consideration was given to the naming of the account with criteria being that it should be easy to remember, appear logical to those who would be using it and be unlikely to be mistaken for another similar email address. It did not need to be short as most people who would be using it would either be responding to an email from the exercise email account or would be able to select the address from an auto prompt when they typed in the first couple of letters of it. The address that was chosen was feb2016phexercise@lanarkshire.scot.nhs.uk. Members of the incident project team and public health admin support staff were given access to the email account Inbox and folders that were created. 1809 emails were received by the account and 1020 were sent from it.

Appointment booking forms, NHS24 reports, patient affairs reports came through this account daily. One member of the incident project team had lead responsibility for managing the account to ensure other members of the project team had access to incoming information, to enable actions as required in response to emails and to archive files. This information is retained as part of the PHE16 archive files. Advice regarding the management of shared incident email accounts provided by Public Health England was helpful in informing the process for managing the account. (Appendix D.13)

1.6. Template agenda for daily meetings

A template agenda was developed and used to direct discussion and manage time during meetings of the project team held in the incident room sometimes with project team members dialling in.

1.7. Responses to enquiries from patients and members of the public

Systems were set up to try to ensure that people who contacted NHS Lanarkshire with an enquiry related to the incident were able to speak to a member of the project team with a minimal amount of delay. Calls were responded to as quickly as possible and when a specific member of staff was not available to answer a question or respond to a patient or member of the public a call was made to let the enquirer know that their message had been received and that a further call would follow shortly. A patient centred approach was taken to these calls and most people were please to have their questions answered as fully as they could be – allowing for the answers to some questions that were asked not being known to the project team and allowing for confidentiality of the HCW.

1.8. Further investigation of patients identified during the record linkage exercise

Where possible detailed investigation of notes available for patients who were identified as matches between the list of people admitted under the care of the HCW who had one or more EPPs and whose details were on the Scottish hepatitis C database. Patients were contacted when this was possible to inform them of the situation and to answer any questions that patients had. None of these patients – other than patient 1 and patient 2 – had hepatitis C virus still present in their blood or available through a stored sample.

1.9. Situation reports

Situation reports were produced on a weekday daily basis initially when the incident room was established and they provided a summary of information regarding the number of people who had made appointments, the number who had been tested, the number of people phoning the NHS24 helplines, significant developments and date when the next situation report would be produced. These reports were circulated to staff within the public health department and to members of the NHSL corporate management team. They were also used to keep the Scottish Government informed of how the PNE was proceeding. An example of a situation report is appended (Appendix D.14) as is some guidance that was developed regarding the process of producing a situation report (Appendix D.15).

1.10. Phone calls to patients who had not received the result of their test

Two members of staff, independently of each other, contacted the public health team directly as they had not received the result of their test a week after attending a clinic on 25 February. This alerted the team to a fault, as it was thought the letters had gone out soon after the clinic, and it was identified that when the system put in place to communicate results from the lab to eHealth had been tested using results from the first day of testing a sample of details for five

patients had been used and the remaining 142 results for that day had not been added to the shared drive. Results for samples tested on subsequent days had been uploaded appropriately and eHealth was able to use the data uploaded to generate negative result letters. This led to further calls from patients who were among the 142 patients in the subsequent days stating that they had not received a letter and asking for their result. For each patient an apology was given, the situation was explained, their test result was checked and – as all results were hepatitis C antibody negative – the patient was given their result, and advised that a negative result letter would be posted first class to them on Friday 11 March and would arrive on the next day, Saturday 12 March, or on the following Monday. If the patient's test result had been positive (that is, reactive) a member of the BBV clinical team would have been asked to speak to the patient.

However, having identified an error and analysed its cause unfortunately there was a further error in implementing the solution. eHealth sent the data for the 142 patients who had not received a negative result letter to ATOS/Canon for processing but there was a failure to print the mail merged document which contained 142 letters and this was not notified to the public health team. The letters that should have been printed on Friday 11 March were not printed.

This resulted in the NHS24 helpline receiving more calls – from some patients who were phoning for the first time to say they had not received a result letter and from patients who have previously phoned and had been told they would receive a letter on Saturday or Monday. A decision was made to ring all patients in the cohort of 142 patients who had not already been given their negative result by phone to notify them of their negative result. This work was shared by the Public Health and Child Health departments due to the numbers of patients involved and to ensure quick contact with patients to allay worries. eHealth obtained confirmation that letters to these patients were fully processed and put in place further assurance mechanisms.

Good practice point

When aspects of a process are devolved, or contracted to another service or organisation, an assurance system should be put in place which provides feedback to confirm that actions which were due to take place have been completed within correct timescales. Any exception to this should be notified by means of an exception report. As part of this process it may be helpful to include the use of dummy data, for example, to include the coded name of a member of the project team and the address of the health board with each batch of data that is transferred for mail merging, printing, enveloping, franking and posting. For example, if batch 3 of data contains details for JohnBatch3 Logan and an envelope is subsequently received at the health board addressed in this way this would provide assurance that the other letters in batch 3 had been processed appropriately.

1.11. Referral Management Service

The public health incident Referral Management Service (RMS) contact centre was staffed for a 4 week period from the 23rd February – 17th March 2016. The opening hours for call-handling were 11 am - 8 pm Monday – Thursday and 8 am – 4 pm on Friday. This allowed the main RMS to deal with the normal busy call-handling duties in the morning before the public health incident contact centre opened. One Saturday morning was also provided on the 27th February.

There were 2 short episodes of telephone downtime on the first and the last day of operation and both episodes were technical and out with the RMS staff control. These were identified quickly and contact made with technical support in order to resolve the situation as soon as possible.

Clinic capacity was an issue throughout the exercise and additional clinics in certain hospital/health centres were added as required to allow booking to continue and this did involve an element of phoning patients back once capacity was available.

Call-handling throughout the exercise was closely monitored by RMS Managers/Team Leaders and with flexing of the “Cloud” queue and moving staff in as required the booking process was successful with only a very small number of patient complaints within the overall volume of calls handled.

1.12. Strategy for responding to requests for health records

The health records service identified all health records of patients who may have been positively linked to the health worker. This included patients identified from the record linkage exercise and also the records of people who tested hepatitis C antibody reactive and who may have been found to have been further probable cases of transmission but who were subsequently shown to not have been. If the health record was available, that is if it was still within records retention time periods and had not been destroyed, these records were ‘protected’ from any future destruction without permission of the Public Health Department. A health records search strategy was developed. (See Appendix D.16.)

1.13. Transport of blood samples from clinics to labs

In the early planning stages labs recommended samples be batched at on-site clinics and handed in to the on-site laboratory in blue labelled bag, at the end of each clinic. Samples taken in primary care settings should also be collected and placed in blue labelled bags. Samples were picked up from primary care and one acute site and delivered to lab specimen reception by named van driver each evening/weekend. In the case of weekday evening clinics samples were refrigerated overnight and picked up the following day. A text alert was put in place from week 2 of the exercise to give reassurance to project team, particularly at weekends when the uplift was specially organised rather than part

of the routine Monday – Friday uplift of samples. Primary care samples delivered by hospital transport as part of the routine Monday - Friday uplift and by specially arranged uplift at weekends. All samples batched and transported in blue, labelled carrier bags.

1.14. Laboratories – Lanarkshire

1.14.1. Wishaw lab

Samples received at Wishaw- Samples will be numbered, using the dedicated number stream (1605xxxx) and PID'd as per LI-LMIC-PHEPID2016. Samples are centrifuged and loaded into the plastic trays provided, lids are secured using 3 elastic bands and placed inside a clear bag inside the large, blue transport bags. The clear bag is then secured using a cable tie and the bag is zipped closed. The bags must be ready for the van driver to pick up at 4 pm.

1.14.2. Hairmyres lab

Samples received at Hairmyres – Samples taken at on-site clinics will be brought up to reception at the end of the clinic. They will be in blue, labelled plastic bags. Samples will be stored in the fridge overnight and put into blue transport bags for transport to Wishaw in the van the following day. A van will pick up Saturday samples after the clinics on Saturdays.

1.14.3. Monklands Hospital lab

All PNE samples will be run at the Monklands Hospital site, between 5 pm and 10 pm. The reasoning was that the Monklands Hospital analyser is less busy in the evenings, PNE samples would be loaded by biochemistry backshift staff and left to run.

1.14.4. SOP for processing and testing samples

- Sample request forms to be labelled with PNE 2015 label
- Samples taken at on-site clinics will be brought up to reception at the end of the clinic.
- Individually bagged samples to be gathered and sent in labelled blue plastic carrier bags to allow complete segregation of samples from routine bloods in blue, labelled plastic bags Samples will be numbered, using the dedicated number stream (1605xxxx) and PID'd as per LI-LMIC-PHEPID2016.
- Samples are centrifuged and taken to biochemistry to feed on to the c6000.
- Pre-spun samples received from Wishaw will be delivered to Biochemistry and loaded on to the analyser there.

- Post processing-Negative samples can be stored by date tested and do not need to be electronically archived.

1.14.5. Reagents and consumables required

Reserve 5000 hepatitis C antibody tests with Roche of the same batch number to minimise kit calibrations/QC problems. 200 test kit, however, this is not 200 patient tests as kits are QC'd and calibrated. Also requirement for extra pipette tips.

1.14.6. Lab data management

- Transfer of results to R.drive
  - BI search daily
  - NEG & PTC sorted on Excel Sheet→shared folder and Email PROMPT
  - Positive and Negative Folders
- Post processing - Negative samples can be stored by date, tested and do not need to be electronically archived.

1.14.7. Forwarding of samples to WoS SVC

Positive samples are reported as "PTC" (Primary Testing Complete) as usual and sent to WoS SVC for confirmation of antibody status and PCR testing. Please ensure requests are marked "PHE 2016" and "A2016" to ensure the virus lab does further testing for hepatitis C antibody. Reports returned from the WoS SVC for this exercise must not be sent to the patients' GPs. Once scanned, please send the paper copy of the WoS SVC report to: *Dr John Logan, Department of Public Health*.

1.15. Laboratories - West of Scotland Specialist Virology Centre

1.15.1. Protocol for testing sample referred

Samples collection from notified patients arriving from within GGC were tested for HCV antibody using the Abbot Architect System. Patient samples that were antibody positive were then tested using PCR to determine whether these patients had current HCV infection. Samples arriving out with GGC were likely to have already been tested for HCV antibody. These samples were tested for HCV RNA to determine whether the patients had current HCV infection. In some cases HCV antibody testing was also carried out in order to try and confirm the HCV antibody results of the referring laboratory.

1.15.2. Dried blood spot testing

As the investigation proceeded a small number of dried blood spot samples were also received and tested for both HCV antibody and, if positive, HCV RNA.

1.15.3. Genotyping of HCV RNA positive patients

All HCV RNA positive patients were genotyped. If the patients were found to have genotyped 3 virus the NS5B region was then sequenced in order to compare the HCV sequence to that of the original 2 patients. Diagnostic and specialist results were then passed back both to the requesting laboratories/physicians and to the incident team.

1.15.4. Provision of testing history for specific patients

In a small number of cases retrospective results for specific patients were provided to the incident team in order to gain an insight into the testing history of the patient.

1.16. Public Health Department

1.16.1. Paperwork for clinics

Checklists, ABFs, printing and posting

It was agreed with NHSL sub-group that clinic packs would be provided to them directly from public health - the reasoning was to ensure no additional workload burden was passed to the acute and primary care testing clinic sites. Packs for all 150 clinics noting date/time/number of patients.

- Appointment booking form noting date/time/number of patients on which staff were asked to record patient specific information/patient comments/clinic staff comments, for example, need for additional paperwork required/patient queuing issues/any other comments.
- Patient aide memoire of the date by which result letter should be received and to contact NHS24 helpline in the event if non-receipt
- Blood request forms labelled PHE2016
- Blue poly bags labelled PHE2016 to allow batching of 30 blood samples

Information sheets for patients regarding receipt of result

Patient aide memoire of the date by which result letter should be received and to contact NHS24 helpline in the event if non-receipt – this was a key tool in highlighting very quickly three separate situations during the exercise whereby results letters had not been sent within the target timescales.

Additional blank appointment booking forms for use at clinic.

Patients were asked at the point of booking to record the time, date and location of their appointment on the booking form and to bring their appointment booking form to clinic. The form was used by clinic staff to record whether blood was taken or not. In some cases additional information and comments were recorded on the form and in the

majority of cases this information was transferred to the daily checklist return. Blank appointment forms were provided to each clinic in order to be able to deal with the scenario of a patient attending who did not have an appointment booking form.

1.16.2. Blood request forms labelled with PHE2016

Blood request forms were pre-labelled with PHE2016 (standing for Public Health Exercise 2016) and included in each clinic pack x 1 per patient + a few spares.

1.16.3. Preparation, labelling and delivery of blue bags

Labs had identified at an early stage highly visible blue polythene bags should be used to batch blood samples, these bags were labelled PHE2016 and included in clinic packs, sufficient per clinic to batch 30 samples per bag.

1.16.4. Protocol for informing the BBV clinical team of patients with positive results

All positive HCV test results were forwarded to the Lanarkshire BBV specialist nursing staff, as described under 25a. The BBV Nursing staff linked with the ID consultants regarding any immediate concerns or questions that needed to be addressed prior to the formal outpatient visit.

1.16.5. Initial contact with patients

The BBV nurses contacted the individuals who had tested positive by telephone to inform them of their test result and to answer any initial questions, pending a more detailed discussion at a dedicated outpatient clinic visit. One patient who was contacted by telephone said they would have preferred to have received a letter. It was thought that this patient may have been at their work place at the time of receiving their call and not been able to take the call in privacy. There are advantages and disadvantages to the first contact with a patient about a positive result being made by letter or by phone. GPs were not involved in the conduct of the exercise and it was considered preferable for the a member of the BBV clinical service to make contact. A letter which does not provide information about the test result but which asked the patient to contact the BBV service at a time that is suitable to them could be sent but such a letter may be opened in the evening or at a weekend when members of the BBV service are less available and may cause undue worry.

1.16.6. Clinical management of patients at hepatitis C clinic

Additional clinics were established for individuals who had tested positive for HCV Ab and/or HCV PCR positive to allow time for further detailed discussion of the implications of the test result, undertake a full clinical assessment and provide reassurance.

For these dedicated clinics an offer was made to see individuals who were HCV antibody positive but PCR negative – who would not normally be referred for assessment – to address any questions or concerns they might have regarding past infection.

For HCV PCR positive patients the assessment process itself followed the standard HCV clinical protocol, including confirmatory HCV testing, HCV genotyping (if not already available and all other relevant investigations (for example, fibrosis assessment). PCR negative patients were offered a further confirmatory HCV antibody and PCR test 6 months after the initial test.

2. Other Scottish NHS Boards

2.1. Key issues discussed and agreed at subgroup meetings

All but one of the fourteen territorial NHS Boards had one or more patients. Good representation was made by the other Scottish NHS Boards to the subgroup audio-teleconference meetings that were held. Key issues discussed were which organisation would write to patients resident in other Boards; how patient data would be prepared, processed and sent to other Boards; the further data validation and review that other Boards would carry out including checking locally for hepatitis C test results, recent deaths and validating CHI data field; the models that Boards were considering for testing; linking between Board communications teams; who to contact regarding various issues; and arrangements for reporting on the delivery of the PNE.

2.2. Arrangements for management of the PNE

All but one Board undertook to receive data from NHS Lanarkshire, to process it as above and generate letters, to organise local testing clinics or distributed testing through GPs or community nurses, and to report on progress made and the final outcome of the PNE. This approach by these Boards was appreciated by the Lanarkshire incident project team and enabled local Boards to review the data for their patients in greater detail and to customise the local response in order to best meet the needs of their residents.

One Board asked NHS Lanarkshire to write to patients in their Board area. This board made arrangements with GPs in their Board area so that patients receiving a letter about the incident were able to visit their GP to have a hepatitis C test. This was additional work for the Lanarkshire incident project team at a time when it was fully stretched preparing for the notification of 7,311 patients who were Lanarkshire residents and managing the PNE across Scotland, the other UK countries and [redacted].

2.3. Delivery of the PNE across the other NHS Boards

Other NHS Boards reported that the PNE had generally been well delivered with no challenges encountered that could not be managed relatively easily.

In one Board area letters were posted to patients without being franked by the company that had responsibility for doing this. A patient contacted the NHS Board to inform it that they had been required to pay the Post Office a fee (approximately £1.80) for release of a letter addressed to them. The Board quickly identified what had happened and reissued letters to patients with an apology and offer to reimburse any patient who had paid a fee to the Post Office. A detailed investigation was carried out by the Board to identify learning points and to put in place procedures that would make the recurrence of such a situation less likely.

The crude hepatitis C testing uptake percentage for all the participating Boards excluding NHS Lanarkshire was 63.8%, that is the percentage uptake using the number of patients tested (445) as the numerator and all patients for whom boards were sent data as the denominator (698).
Local Boards removed patients from their mailing list if the patient had died, or their GP had advised that they should not be contacted, or, in some NHS Boards, if the patient was found to have had hepatitis C tests which excluded them from being a case of HCW to patient hepatitis C transmission. The total number of patients written to was 679. Using this figure as the denominator the uptake percentage for patients written to in Boards excluding Lanarkshire was 65.5%.

3. Other UK countries and [redacted]

3.1. Key issues discussed and agreed at subgroup meetings

The key issues discussed at audio-teleconference subgroup meetings were the timing of the launch of the PNE; the cohort of patients who would be written to – in particular, whether this needed to be all patients that the HCW may have performed an EPP on across all of their career, or, initially as part of a first phase, just those patients who had had one or more EPPs and had been admitted under the care of the HCW during their years of working in Lanarkshire – from 1982 to January 2008.

It was very helpful to have the contributions of Dr Ncube, who was the Medical Secretary of UKAP at that time, as he was able to contribute his expertise and experience of dealing with BBV infected HCW incidents to the meetings and he was also able to represent the position of UKAP. The rationale for a phased approach to PNEs in general, and to this incident in particular, is covered above in Section B. 8.1 and is also discussed below in Section F.

At one meeting there was some discussion of the arguments for and against an injunction (and an interdict) being applied for. This is covered in more detail above in a subsection at the end of Section B.

3.2. Arrangements for management of PNE

In an approach that was similar to the management of the PNE across the other Scottish NHS Boards a distributed leadership approach was taken for the management of the PNE in each of the other countries. Following discussion with National Records Scotland, and submission of written documents requesting that data be shared as part of the public health exercise, and approval by National Record Scotland, data was shared with a public health lead in each of the other countries.

3.3. Delivery of PNE across the other UK countries and [redacted]

3.3.1. England

3.3.1.1. Patients who had been patients in Lanarkshire

Data for patients who showed in the Scottish CHI (Community Health Index) system as having left Scottish CHI to go to England was shared with Public Health England which then checked the data centrally and locally to validate it and local health protection teams wrote to patients in their areas.

3.3.1.2. Patients who had been patients at the William Harvey Hospital, Kent

One of the Kent Health Protection Team Consultants in Communicable Disease Control undertook the work required to identify patients who had had one or more exposure prone procedure carried out by the HCW when they did the three months locum post in Kent, to identify any deaths that had occurred among such patients and to arrange to write to patients who were not known to have died and recommend that they arrange to have a hepatitis C test.

The CCDC was a member of the *Other countries and UKAP* subgroup which proved to be a helpful arrangement and he worked closely with the Public Health England lead CCDC for the incident.

3.3.2. Wales

Public Health Wales had available technology that enabled, after security arrangements were put in place, a member of the Lanarkshire incident

project team to upload data to a secure server which Public Health Wales colleagues could then access.

3.3.3. Northern Ireland

Information about patients was faxed to the Northern Irish Public Health Agency as colleagues in Northern Ireland did not have nhs.net email addresses and secure email transfer could not be assured.

3.3.4. [redacted]

There were 3 patients in [redacted] and communications were carried out by phone and by email with members of [redacted] health protection team.

4. Communications

4.1. Key issues discussed during subgroup meetings

Subgroup meetings were held by audio-teleconference The key issues discussed were details of the 2008 and 2015 investigations; the communications approach that had been taken during the Welsh hepatitis C infected HCW PNE in 2013; the need for UK country government health departments to be kept informed as well the country health protection agencies; the range of issues that the media may focus on and various ways in which the media may respond; the development of a set of questions and answers covering possible questions the media may ask; the development of a communications plan; and the need for confidentiality.

4.2. Approach taken to managing communications throughout UK and [redacted]

A regular communications sub-group teleconference was established to plan a co-ordinated and consistent approach to communications across other Scottish Boards, other UK countries and [redacted]. This was achieved by developing a communications plan, preparing a detailed press release and by preparing well for a media conference.

Good practice point

The benefit of preparation cannot be underestimated. Detailed planning ensured:

- No unanticipated questions at the media conference or subsequent press conference or subsequent interviews
- Consistent messages from all spokespeople
- A clear sense of professionalism in the agencies' handling of the media announcement which helped promote confidence in the overall handling of the public health exercise
- Close and collaborative working between communication and public health colleagues
- Joined up approach across the UK promoted through early and regular contact across all agencies involved

- Detailed preparation of media launch
- Preparation of extensive Q&As

5. Issues arising for specific patients and members of the public

5.1. Records management

5.1.1. Lever arch files and incident patient ID number

Documents relating to specific patients were filed in a series of lever arch files. The first file contained detailed of the 28 patients who were identified as having been admitted under the care of the healthcare worker, having had one or more EPPs, and having a record on the Scottish hepatitis C database with the date of diagnosis of hepatitis C (Ab or RNA positive) being after the date of the first EPP. An electronic folder was also created which held electronic details of specific patients. Each patient for whom there was a specific investigation, interaction or non-negative test result was allocated an unique two digit incident ID number and this was used to file hard copy notes and/or to create an electronic subfolder. An index table was generated for the hard copy file with columns for incident ID number, forename, surname and CHI number. Each space for the CHI number was divided into 10 cells in order to promote accurate recording of the 10 digit CHI number.

5.1.2. Database of people who communicated with the PNE response team

Patient information, comments, specific needs including language issues and difficulty taking blood, perhaps requiring dried blood spot test, were noted on appointment booking forms and actioned daily, direct patient contact via NHS24 helpline, Patient Affairs line, and in some cases simply comments on the process requiring no specific follow-up action or feedback was required however all contacts/comments were noted for the master database – currently 842 entries are recorded.

5.2. Patients written to

Out with the standard letters to the various categories of patient as detailed previously, public health sent the following additional patient letters:

- Patients testing primary test completed (PTC).
- Members of the general public who contacted the helpline, felt they may have had a procedure during the significant period and requested a search be done in the event their case had been missed.
- Patients requiring DBST who were not contactable by phone to advise they would be contacted to arrange a convenient appointment or to ring HRT to arrange one.
- Negative test result letters to:

    - care home patients
    - patients receiving DBST
    - patients whose negative test result had been sent via ATOS but was reported by the patient or their carer as not having been received.
- Patients for whom letters were returned *addressee gone away* and through investigation a possible alternative address was identified
- Patients for whom letters were returned *addressee gone away* and through investigation no forwarding address was identified

5.3. Members of the public who did not receive a letter and thought they should have

Two members of the public contacted the NHS Lanarkshire Department of Public Health and expressed a view that they thought they should have been sent a letter.

One patient had been scheduled to have a procedure performed by a HCW who was on leave. The HCW (08/26) was doing a locum post which covered the work of the HCW who was on leave. Review of the Scottish Morbidity Record SMR01 which covers admissions to hospital showed that the patient was recorded as having been admitted under the HCW who was on leave on the day of their admission and that the procedure, an EPP1 procedure, was coded as having been done during this admission, and also that the patient's care was transferred on the same day to HCW (08/26), however, an EPP was not coded as having been done under this HCW. It was considered that this was likely to be an unusual occurrence. Attempts were made to obtain information about the locum work that the HCW had performed to see if it was possible to identify any other cases where a patient may have been coded as having received care under the [redacted] who was on leave rather than HCW (08/26), however, it was not possible to obtain any further useful information. For most of the locum work performed by the HCW the [redacted] position was vacant rather than the HCW covering for someone who was on leave.

Another patient was found to have had a procedure carried out which did not have the "[redacted] admitted under" field coded. Due to the high quality of SMR01 records, and quality control processes incorporated in the coding of records, this is a very unusual occurrence. The patient was able to provide definitive information about their procedure and who had performed it. The patient was given an appointment at a testing clinic and was confirmed to be negative for the hepatitis C antibody screening test.

5.4. Other members of the public

A small number of patients attending clinics nominated carers or relatives as their first point of contact for results for reasons including frailty, learning

disability and hearing problems. The appointment booking forms which were emailed or faxed to public health daily were invaluable in highlighting these situations. This enabled an enhanced patient experience to be provided by addressing the needs of individuals by contacting the named individual to inform them of the test result.

Residents receiving mail for previous residents in three cases made contact with the public health department to advise of an alternative address. In two of the three cases enquiries were made and patients successfully traced – one residing in another Scottish NHS Board area and one in England. In both cases the relevant health board or health authority was notified and requested to follow-up their patient.

6. Support and interactions with voluntary sector organisations

Lanarkshire has three voluntary sector services which specialise in HIV and/or viral hepatitis and which are commissioned by NHS Lanarkshire to deliver specific services – THT Scotland, Waverley Care and Positive Support (Addaction). Staff from these services were key to delivering specialist hepatitis C support to NHS Lanarkshire members of staff and patients at clinics. Lanarkshire has a long history and good track record of working with these services and it was good that staff from the voluntary sector saw themselves as part of the team responding to the situation.

Section E. Follow up to the patient notification exercise

1. Collation of results from the patient notification exercise

1.1. Data reconciliation

A significant amount of work was required to reconcile data from various sources due to the complexity of the exercise. For most patients the pathway was simple and consisted of the following steps:

Letter received; Clinic appointment booked; Attended clinic for scheduled appointment; Venous blood sample taken; Sample and form appropriately labelled and transported to Wishaw lab for registration; Sample transported to Monklands Hospital lab for testing; Test reported as negative; Details entered on lab database; Data uploaded to negative results file on shared computer drive; Data picked up by eHealth from shared computer drive; Data transmitted to ATOS and subsequently to Canon for negative result letter printing, enveloping and mailing; Letter received by patient and opened.

For a relatively small number of patients the pathway was not so straightforward and the following are examples of challenges encountered:

- Patients attending a testing clinic without an appointment
- Patients forgetting to attend an appointment and needing to book another one
- Unable to obtain any or sufficient sample
- A Dried Blood Spot Test being performed at a clinic if venous access was not possible
- Sample tubes not labelled adequately
- Sample tubes received but without a request form
- Patients who had been living in the community who had moved into a care home.

Fourteen patients were identified on the non-engagement list who were also showing as having had a blood sample taken. Details for each patient were sought by checking with the Referral Management Service and by reviewing appointment booking forms that were available for these patients. An appointment booking form had been collected in from each patient who attended a clinic. For patients who attended a clinic without an appointment booking form a blank form was completed at the clinic. These forms were then scanned so that they could be searched at a later date if required. The findings of further investigation regarding these fourteen patients were as follows:

Number of patients	Findings
2	Did not attend a clinic. Incorrect information on TrakCare. Confirmed that no appointment booking form had been completed. “Blood taken” errors on TrakCare have been corrected. Both patients remain categorised as non-engaged and are counted in the non-engagement total.
4	Four patients added to DBST list. Two tests taken at clinic had not been notified to Public Health. One patient was inpatient during the exercise and was tested later. One patient was notified to Public Health via the helpline but had not been added to list.
6	Six patients had had blood taken at a clinic and had tested negative and been informed of their result. Total of negative blood tests increased by six.
1	One patient had a venous blood sample tested and was then tested again but their details did not appear on the lab negative result list. Negative blood tested total increase by one.
1	One patient who had attended a clinic was recorded as having had blood taken but no result was available. Patient was contacted and they confirmed that they did have blood taken and that they had not received a negative result letter. The patient said they had assumed the result was negative. They were advised that despite 80% of people being tested no further cases of probable transmission of infection had been identified. A further test was offered to the patient, however, the patient did not wish to have a further test.

Total = 14	

Summary uptake figures are shown on the next page.

1.2. Summary uptake figures

Patients admitted under the care of the HCW who had one or more EPPs, who were not known to have died and who had been identified from national CHI as being resident in Lanarkshire.	7,311	A

Patients who were identified during the 2015 record linkage exercise to be part of A above and who had previously been found to have tests results of being hepatitis C antibody positive and /or hepatitis C virus positive recorded on the Scottish hepatitis C database.	13	B
Patients that national CHI identified as "new area assigned Lanarkshire" but who had not yet registered with a GP and no contact details were available.	3	C
	16	B + C = D

Patients from A whose hepatitis C status was not known to the IMT and for whom national CHI had been able to provide an address.	7,295	A – D = E

Breakdown of patients who were sent a letter or contacted in another way

Standard letter	6,893	F
Letter referring to District Nurse involvement	326	G
Care home residents	70	H
Patients who were in The State Hospital, Carstairs	[redacted]	I
Patients who were in Shotts Prison	[redacted]	J
	7,295	F + G + H + I + J = E

Patients who did not undergo a test as they had been tested negative for for hepatitis C as part of ongoing haematology care or had recently donated blood and had a hepatitis C screening test.	6	K
Patients for whom their letter was returned as unknown at the address to which the letter had been sent and for whom no further address could be identified.	37	L
	43	K + L = M

	Reactive	Negative	Total
Clinic – venous blood sample	16	5,623	5,632
Community - Dried Blood Spot Test	1	179	176
Care homes – Dried Blood Spot Test	0	80	80
Total	17	5,882	5,899

5,899 Lanarkshire residents had one or more hepatitis C tests during the PNE.

The uptake percentage using the following denominators are shown:

Patients admitted under the care of the HCW who had one or more EPPs, who were not known to have died and who had been identified from national CHI as being resident in Lanarkshire. (7,311)	5,899 / 7,311	80.7%
Lanarkshire residents who were sent a letter recommending that the patient arrange to be tested for hepatitis C. (7,295)	5,899 / 7,295	80.9%
Patients who were not known to not be resident at the address to which a letter had been sent and who were not known to have tested negative for hepatitis C through unrelated clinical care or associated with blood donation. (7,252) (E-M)	5,899 / 7,252	81.3%

Uptake percentages by various cohorts

Cohort	No. of patients	No. of patients tested	Uptake %
Lanarkshire	7,311	5,899	81
Other Scottish NHS Boards	698	445	64
Scotland	8,009	6,344	79
Other countries – England (including Kent patients), Wales, Northern Ireland and [redacted]	423	209	49
All patients	8,432	6,553	78

1.3. Test results for patients who did not test negative

Tests results for patients tested directly or indirectly as part of the HCV infected HCW PNE who did not test negative for HCV antibody by Monklands lab

Clinic sample Monklands test reactive	WoS PCR result	WoS Ab result	Additional testing	Genotype	Sequence result	Number with this testing profile	Testing follow up no.
Yes	Neg	Pos				3	1, 3, 10
Yes	Neg	Neg				4	4, 9, 11, 12
Yes	Neg	Neg	HCV Ab not confirmed by SNBTS.			1	20. History of acquiring HCV associated with bone marrow transplant.
Equivocal	Neg	Neg				1	5
Yes	Neg	Equivocal				1	13
Yes	Neg	Equivocal	Ab Equivocal (WoS)			1	14
Yes	Pos			Not 3		5	2,15, 16, 18, 19,
Yes	Pos			3	Not same	1	6
No – did not have clinic sample taken.	Pos			3	Not same	2	7, 21
No – did not have clinic sample taken.	Pos			Not 3		2	8, 22
No – did not have clinic sample taken and declined home visit test.						1	17 – Did not consent to being tested. Had an EPP while under the care of the HCW but not performed by the HCW.
						22 (Total)	

No further cases of probable transmission were identified among Lanarkshire residents and no such cases were reported to NHS Lanarkshire by other Scottish NHS Boards or by health protection representatives in England, Wales, Northern Ireland and [redacted]. That is, no further patients were identified who were HCV RNA positive and had genotype 3 virus and had a virus gene sequence that was similar to the gene sequence of the virus of patient 1 or the virus of patient 2 – the Lanarkshire cases who were assessed as probably having acquired infection from the HCW.

Three patients tested antibody positive and hepatitis C virus negative.
(Patients 1, 3 and 10 in the table above.)

Two patients tested antibody equivocal and hepatitis C virus negative.
(Patients 13 and 14 in the table above.)

No historical samples were available for these five patients which may have contained hepatitis C virus which could have been genotyped and sequenced.

Details of the exposure prone procedures and risk factors identified for HCV infection for these 5 patients are as follows:

	No. of EPPs by category				Nature of EPP 1, 2 or 3 procedure.	Risk factors for hepatitis C
Testing follow up number	0	1	2	3		
1 Ab pos.	2	1	0	1	EPP1: Other operations on unspecified organ. EPP3: Sigmoid colectomy and end to end anastomosis of ileum to rectum.	None identified.
3 Ab pos.	0	0	1	0	EPP2: Appendicectomy.	Injecting drug use.
10 Ab pos.	0	0	1	0	EPP2: Excision of lesion (lipoma) of skin.	None identified.
13 Ab equiv.	0	0	1	0	EPP2: Primary repair of inguinal hernia.	None identified.
14 Ab equiv.	5	1	1	0	EPP1: Gastric intubation with related procedures. EPP2: Repair of perforated duodenal ulcer.	None identified.

The cases who were assessed as having acquired infection from the HCW had both had EPP 3 surgery performed by the HCW. Patient 1 was coded as having had an EPP3 procedure and also an EPP2 procedure. Patient 2 was coded as having had a procedure categorised as EPP2, however, on review of clinical notes by a consultant surgeon it was thought that due to the challenges and complications of the surgery required it was probably more appropriate to categorise the procedure as EPP3.

1.4. Patients found to have hepatitis C virus

Seven people were identified directly or indirectly due to the PNE being conducted to be positive for hepatitis C virus and therefore to have the potential to benefit from clinical assessment, advice and treatment. All seven people engaged with the BBV clinical service and their care is ongoing. None of these patients were cases of HCW to patient transmission.

Six people who had been admitted under the care of the HCW and had one or more EPPs performed were found to be hepatitis C RNA positive with hepatitis C viruses that were different from those of the two patients assessed as being probable cases of transmission of infection. These patients had the following testing follow up numbers in the table above: 2, 6, 15, 16, 18, and 19. Also, the partner of one of these six patients was found to be hepatitis C RNA positive with a non-genotype 3 virus.

Three patients who were sent a PNE letter were identified as already being on the NHS Lanarkshire hepatitis C care pathway. Two patients (8, 21) had already been diagnosed with hepatitis infection and had attended the hepatitis C clinical service and been given drug treatment. The third patient (7) had tested positive for hepatitis C virus several months before the PNE started.

2. Further assessment of matches from the 2015 record linkage exercise

During the preparation for the PNE further work was carried out to examine the records of two patients for whom risk factors for hepatitis C, other than healthcare, had not been identified. Both patients were hepatitis C RNA negative and there were no virus positive samples available for either of them.

One patient had had several EPP3 procedures performed by the HCW, however, associated with procedures performed in 1983 and 1985 the patient had been transfused with a total of five units of blood. It was not possible to identify details of the units that had been transfused from the hard copy and electronic health records available and not possible to obtain information from the Scottish National Blood Transfusion Service (SNBTS) as to whether specific units transfused had been identified subsequently by SNBTS as having been positive for hepatitis C infection. The genotype of the virus that this patient had had was not known.

In addition to further review of secondary care notes for the other patient who was known to have had genotype 3 virus, primary care notes were obtained and discussed with the patient's GP. At the time of the patient being diagnosed with hepatitis C infection in 2001 a detailed review had been carried out to identify possible sources of infection but none had been identified. This patient had had an EPP2 performed by the HCW – an inguinal hernia repair - and the surgical notes recorded that the procedure was uneventful.

3. Further assessment of the needs of patients in the 1982 to 2008 cohort

   The objectives of the PNE were to inform patients of the situation, to offer testing for hepatitis C infection, to arrange clinical assessment and treatment where indicated, and to inform further risk assessment of the situation.

   1,358 Lanarkshire residents who were sent letters did not engage in the PNE. Should any of these patients be diagnosed with hepatitis C in the future they would be assessed for further clinical assessment and management.

   The IMT discussed whether there was an indication to carry out further record linkage exercises to cross-match the data for patients in this group of 1,358 patients against the Scottish hepatitis C database – for example, on an annual

basis – in order to identify other patients for whom healthcare worker to patient transmission may have occurred. It was agreed that this was not required as all patients had been written to and provided with information about the incident already and the key objective of the PNE had been to identify patients with hepatitis C infection who may be able to benefit from clinical assessment and treatment.

Also, as no further cases of probable transmission had been identified among the 5,899 who had been tested the probability that any particular patient among the 1,358 who had not been tested would be positive for hepatitis C RNA was very low and there was no indication to persist with seeking to identify cases of chronic infection who may be able to benefit from treatment.

A further question to be answer was whether, having conducted the PNE, there was a need to take further action to identify people who may have been at risk of acquiring BBV infection but who had not been identified. The approach that had been taken of contacting patients admitted under the care of the HCW who had had one or more EPPs was assessed, on the basis of coding quality assurance processes and practice, as being highly sensitive but not especially specific. Only one person had contacted the incident project team to say that they had been operated on by the person they thought was the HCW but they had not received a letter. Review of this patient's electronic notes showed that the admission had not been coded for "[redacted] admitted under the care of" – an unusual occurrence, even when a locum HCW is providing the service. Given this information, the large number of people tested and the high testing percentage there was no justification for disclosing the name of the HCW to the public. It had been agreed by the IMT that if data available did not appear to be of sufficient quality to identify at risk patients that the name of the HCW may need to be disclosed to the public so that members of the public could consider if they had had one or more EPPs carried out by the HCW. Data available turned out to be of a high standard and a decision was made to continue to not disclose the name of the HCW.

4. RLE performed by Health Protection Scotland after the PNE

It was identified after the PNE had been launched that the record linkage exercises which Health Protection Scotland had carried out had not included data for the period 1982 to1986. A further RLE linking a) data for patients who had one or more EPPs and who were admitted under the care of the HCW during 1982 to 1986 with b) patient data held on the Scottish hepatitis C database was performed by Health Protection Scotland and with the following findings:

18 patients were treated under [NI number] identified in record linkage.

5 of these patients had had one or more EPPs during 1987 to 2008 and so had already been identified under [number].

Therefore, 13 patients were not previously known of.

Of the 13 new patients 6 had no procedures carried out.

Of the 7 remaining patients:

- all were diagnosed post procedure
- 5 were genotype 1 and for 2 the genotype was not known (NK)
- Of the 2 for whom the genotype was not known one patient had died and the remaining patient had drug injecting risk.

2 further new patients treated under number] identified. Both were diagnosed in 2015 and their data had been added to the database after the record linkage exercise which had been run in February 2016 which included HCV database data to the end of March 2015. Both patients were diagnosed post procedure. One had genotype 1 virus and the other patient had died and their virus genotype was not known.

These findings lead to the answers below to the following questions:

Q: Is there any additional information arising from the further RLE that helps to inform to incident investigation – for example, a patient with no history of non-healthcare risk factors for hepatitis C, who had one or more EPP3 procedures and who had hepatitis C genotype 3 and for whom there might be clinical information suggesting hepatitis C infection may have taken place during an EPP, such a liver function test results prior to and subsequent to an EPP ?

A: No. There were no additional patients identified from the RLE who were known to have, or have had, hepatitis C genotype 3 virus. Given the findings of the PNE further work will not be undertaken to examine the health records of those patients whose virus genotype is not known.

Q: Had the RLE included data for the 1982 to 1986 patients when it was performed in 2008 might this have affected the decision made following the first investigation to not conduct a PNE ?

A: No. Both patients of the 13 identified who had had one or more EPPs and were not known to have a non-genotype 3 virus were both diagnosed after 2008.

Q: When the RLE had been performed in 2008 and in also in February 2016 were 1982 to 1986 patients included ?

A: No. Both of these RLEs were undertaken using the HCW's number and not also their national insurance number.

Q: Might a patient in the 1982 to 1986 cohort who had been diagnosed with hepatitis C in 2005 and who had died in 2013 have been identified as a match in 2008 if details of the 1982 to 1986 patients had been included, but not have been identified in the post-PNE RLE in 2016 as they had died ?

A: No. Health Protection Scotland did not exclude patients in the 1982 to 1986 cohort who had died when they performed the first stage of the record linkage exercise. The record of any such matches would have been examined to see if there was evidence of the patient having a genotype other than 3 and if that was not the case they would have been highlighted as a match.

5. Further assessment of the risk of transmission prior to 1982
   Public Health England conducted an exercise with NHS Trusts to establish if the records of any patients who may have had an exposure prone procedure performed by the HCW could be identified. No such records were identified.

   The findings of the PNE and the information detailed above regarding risk information about the five patients who had a hepatitis C antibody positive or equivocal result were shared with Public Health England.

   As of the end of September 2016 information is awaited from Public Health England regarding the assessment of the risk of transmission of hepatitis C from the HCW to patients prior to 1982. An addendum to this report will be sent to UKAP when information is received from Public Health England.

6. Further meetings of the IMT and subgroups
   Further meetings of the IMT and its subgroups were held after the end of March when the active phase of the PNE had concluded. The focus of these meetings was to share information, to review the follow up of actions, to consider further work which needed to be undertaken and to plan for the writing up of the investigation and management of the incident.

   6.1. Analysis of factors influencing the uptake of testing
   Given the quality of data that is available regarding patients who chose to have a hepatitis C test and those who did not there is an opportunity to carry out analyses in order to identify factors which may have influenced testing behaviour which may help to inform the management of PNEs. Representatives of NHS Lanarkshire and Health Protection Scotland have discussed this opportunity and will link together to carry out this work. Variables that will be looked at include age, sex, dates of admissions under the care of the HCW, number of admissions, number of EPPs, category of EPPs, time since EPPs, co-morbidity, type of residence, distance from residence to testing clinic.

Recommendation 1
NHS Lanarkshire and Health Protection Scotland should collaborate to analyse factors influencing the uptake of testing.

7. Benefits arising from networking during the PNE

7.1. Awareness raising, education and training

There have been a number of benefits arising from the networking that took place during the PNE. As a result of the PNE there are approximately over 280 staff briefed about hepatitis C. All of these individuals are now on the BBV Network database and are receiving regular communications from the network as well as invitations to take part in further BBV related training opportunities.

7.2. Increased networking

A key benefit has also been the connection between services that otherwise would not normally work with each other. Members of staff found working with people from other parts of NHS Lanarkshire and from voluntary sector organisations to be a positive experience and they also enjoyed the camaraderie of working together to meet the challenge of preparing for and delivering the PNE.

There is a greater awareness of hepatitis C and blood borne viruses across NHS Lanarkshire and an appreciation of the importance of BBV work. This has been recognised in relation to education and training sessions regarding sharps and needlestick injuries prevention with greater engagement by primary and secondary care as a result of staff connecting with each other during clinics.

7.3. Passing on unused resources to other teams

Unused supplies of blood test request forms, blue bags and treatment room supplies were passed to microbiology and primary care centres.

Good practice point

It should be recognised at the start of the investigation and management of a BBV infected HCW situation there will be opportunities to develop and progress aspects of BBV work. It may be possible to take action regarding such opportunities during the investigation and management of the situation, however, some opportunities may need to be identified and noted and action taken after to situation has been dealt with. Such opportunities include raising awareness of BBV issues across NHS organisations, including with senior managers and Board members; awareness raising of BBV issues at population level and through proactive and reactive work with the media; establishing and building relationships with individuals, teams and organisations; developing work force capacity by delivering education and training sessions to develop knowledge, attitudes and skills.

8. Letter to members of staff from the Board Chair and Chief Executive

A letter was sent to all members of staff who were involved in preparing for and delivering the PNE by the Board Chair and Chief Executive recognising the exceptional work that had been done, the patient centred approach that had been taken and thanking people for the contribution that had been made. (Appendix E.01)

Section F. Discussion and recommendations

Discussion points and recommendations arising from the initial (2008) and subsequent (2015) investigations and from the preparation for and delivery of the patient notification exercise are detailed in the following pages. Recommendations made to UKAP are made in relation to the role and terms of reference of UKAP[14].

1. Identification of chronic hepatitis C infection in the HCW

The healthcare worker was identified as having hepatitis C due to routine testing. Had this testing not taken place the HCW would have continued to carry out EPPs and may not have been diagnosed with hepatitis C infection [redacted] The earlier of the two probable transmissions took place in 1997. [redacted]

[redacted]

Most [redacted] do not acquire a BBV infection occupationally during their [redacted] career. If a HCW does acquire a BBV infection, this raises a question about the quality of the HCW's [redacted]. There may be many other factors which may have contributed to a HCW acquiring infection such as the prevalence of BBV infection in the population of people being operated on; staffing levels; the number and categories of EPPs carried; and the clinical areas that EPPs have been carried out in – for example, busy A&E or trauma units.

Acquiring a BBV infection occupationally may be a risk factor for some aspect of surgical practice which increases the likelihood of bleed back incidents happening when a HCW is carrying out an EPP.

[redacted]

[14] https://www.gov.uk/government/groups/uk-advisory-panel-for-healthcare-workers-infected-with-bloodborne-viruses

[redacted]

Recommendation 2

[redacted]

3. UKAP guidance on EPP categories to use during record linkage exercises

UKAP guidance in 2008 when the first record linkage exercise was carried out advised records of patients who had been identified as having hepatitis C should be cross matched against patients who had had an EPP3 category procedure carried out by a HCW (or admitted under their guidance) and did not include cross-matching against EPP1 and EPP2 procedures.

The record linkage exercise carried out in 2015 identified patient 2 initially as a possible case of transmission and subsequently as a probable case.

The procedure – repair of an abdominal hernia - that patient 2 had undergone had been coded as being a category 2 procedure and so was not identified as a match when the record linkage exercise was carried out in 2008. Review of clinical notes by a consultant surgeon concluded that the procedure may have been more appropriately categorised as a category 3 EPP due to the challenges and complications encountered during surgery as recorded in the clinical notes.

The fact that a record linkage exercise using EPP category 3 procedures (and not also category 1 and category 2) did not identify a patient who at the time of the record linkage exercise was a diagnosed case of hepatitis C with their details on the Scottish hepatitis C database, and the fact that the patient had a procedure that was categorised as being an EPP2 procedure, but upon scrutiny of clinical notes was thought to more appropriately considered to have been an EPP3 procedure,

provides evidence to support the change in guidance to perform record linkage using all EPP2 as well as EPP3 categories.

EPP1 category procedures should also be included as the example above shows that a procedure coded as EPP2 may be viewed on more in depth assessment to be an EPP3 procedure - in the same way a procedure categorised as EPP1 may be assessed on scrutiny of clinical records to be more appropriately categorised as an EPP2 or possibly even as EPP3.

4. EPP categorisation of procedures

The document *General dentistry Exposure Prone Procedure Categorisation*[15] published by UKAP in March 2016 details the EPP categories of general dental practice and it is a very helpful resource.

It would be helpful for UKAP to develop a final version of a similar guidance document which categorises [redacted] procedures – and in due course, similar documents for procedures carried out in other specialties. UKAP provided a fourteen page document entitled *Categorisation of exposure prone procedures in* [redacted] in 2008. The document had a footer of "Draft 04.04.06". When an updated version of this document was requested in 2015 the same version of the document was provided. About 120 procedures that the HCW had performed were not included in the [redacted] document and these procedures were categorised by a consultant general surgeon in Lanarkshire. Given that all patients who had had one or more EPP1 and/or EPP2 and/or EPP3 procedures were being written to the key issue was to decide whether a procedure was or was not exposure prone – that is was it a) EPP0 or b) EPP 1, 2 or 3.

5. Development of the UKAP toolkit

UKAP has developed a toolkit to support the investigation of incidents and related PNEs. The toolkit provides some useful reference documents, however, many of the files are out of date and some resources which would be helpful are not included. The UKAP toolkit should be developed in the following ways:

- Details of quality assurance aspects of management of the development of the toolkit: date of approval of the toolkit; approving group/committee; dates when next review is due to commence and to be completed; and for the most up to date version to be available for download from the UKAP website.
- The toolkit should be user friendly with detailed contents listing.
- Introduction and features that enable easy navigation around the resource such as use of hypertext links between sections and to specific resources.
- A Frequently Asked Questions section.

15 www.gov.uk/government/uploads/system/uploads/attachment_data/file/511570/UKAP_General_Dentistry_EPP_Categorisation_FINAL_to_be_uploaded.pdf

- Provision of information about resources that are available and also information about what resources are not currently available and what plans there may be to develop them.
- Details of who to contact regarding particular sections of the toolkit.
- Given that there are differences between UK countries regarding the patient data systems (hospital admission records, morbidity and mortality recording systems, and unique NHS patient number) consideration should be given to either a) making the toolkit applicable to all UK countries with need for customisation highlighted as required or b) listing the various parts of the toolkit where customisation of a generic document is required by each country. The preferred option would probably be a), however, if b) were chosen it would be pragmatic approach for the toolkit to be developed to meet the needs of Public Health England and NHS England with organisations in the other UK countries making changes for their countries as required.

It would be helpful for the toolkit to include the following resources:

- Hypertext linked references to key guidance documents.
- A comprehensive electronic listing of the EPP categorisation of procedures - especially those that are carried out most frequently by HCWs who work in the specialties that are most frequently associated with BBV infected EPP HCWs – which can be used by Incident Management Teams to code the procedures which patients in their cohort have had.
- Discussion of the suggestion that an injunction should be sought is covered above at the end of Section B. It would be helpful for the toolkit to include information about injunctions and interdicts – what they are, when to consider seeking one or both, how to apply, how to seek expert opinion from, costs involved, how long they last and how they are lifted.
- Resources that facilitate learning about the investigation and management of incidents such as questionnaires.
- Resources that support the evaluation of various aspects of an incident including questionnaires for staff involved in strategic and operational work, costing templates and patient satisfaction questionnaires.
- A document describing UKAP policy with regards to categories of EPPs that should be included in record linkage exercises. (It is understood that current UKAP policy for incidents when an EPP HCW is found to have hepatitis C and no patients are known to have been infected by the HCW is that a RLE should include all patients who have had EPP1s and/or EPP2s and/or EPP3s. It is not clear if a similar approach to RLEs is taken if an incident involves an EPP HCW who has been found to be HIV positive.)
- Guidance on when a whole of career PNE may not be required and a phased approach can be taken for a hepatitis C infected HCW incident in which there is some evidence that HCW to patient transmission has occurred with some examples of scenarios that help to illustrate the guidance principles.

Recommendation 3
NHS Lanarkshire should offer to work with UKAP to contribute to the development of the UKAP toolkit using the knowledge, understanding and resources developed by NHS Lanarkshire during the preparation for and delivery of the PNE.

6. Coding of SMR01 records

When NHS Lanarkshire was preparing for the PNE a check was made of the distribution of the dates upon which EPPs had been performed. This identified that no EPP dates were recorded for the years 1982 to 1986. NHS Lanarkshire linked with the Information & Statistics Division of National Services Scotland to find the solution to this unexpected finding. It was discovered that prior to 1987 the [redacted] that a patient was admitted under was coded using the [redacted] national insurance number (or a coded version of this) and not, as from 1987 onwards, the [redacted] number.

Recommendation 4
National Services Scotland should consider how best to note and make relevant members of staff aware that prior to 1987 the [redacted] that a patient was admitted under was coded using the [redacted] national insurance number (or a coded version of this) and not, as currently, [redacted] number.

7. Review of the quality of the 2008 investigation

A review of the investigation carried out in 2008 has been undertaken to see if there may have been information available, or which could have been obtained, that would have suggested that transmission of infection from the healthcare worker had taken place. In 2008 patient 1 had not been diagnosed and therefore their details had not been recorded on the Scottish hepatitis C database. Patient 2 had been diagnosed in 1998 and their details were recorded on the hepatitis C database, however, as detailed above they had had a procedure performed by the HCW which had been categorised as EPP2 and the UKAP guidance at that time was that record linkage exercises should be run using only category 3 EPPs. No evidence was found that any relevant information that was available at that time had been missed.

8. Retrospective application of updated policy

It is the understanding of the IMT that when national policy changes it is not then applied retrospectively. For example, when policy changed to being that records of patients who had undergone procedures of all EPP categories (1, 2 and 3) should be cross-matched against hepatitis C databases UKAP did not advise that further record linkage exercises should be carried out for incidents that had carried out a RLE using only category 3 EPPs.

This incident, 08/26, raises the question of whether changes to policy should be applied retrospectively. If a further RLE had been undertaken when the UKAP guidance was updated patient 2 may have been identified then as a case of HCW to patient transmission and this may have prompted a PNE.

If patient 1 had not been identified as a case of probable HCW to patient transmission a PNE would not have been carried out in relation to this HCW – unless another index case had been identified. Given that no further cases of probable transmission were identified by the PNE carried out in 2016 the health gain related to cases of transmission of infection from the HCW that would have arisen from carrying out a RLE using the revised guidance before 2015 would have been minimal – and would have related to a patient or patients who would have come forward for testing then and had died before the PNE was conducted in 2016 or to a patient or patients who may have come forward for testing during a PNE held earlier but who did not come forward for testing in 2016. As the identification of cases of transmission of infection tends to be minimal [16,17,18,19,20] and given that policy in relation to hepatitis C infected HCWs can be considered to be mature, having been developed and amended over the last twenty years, it is likely that, should the policy be further amended, if it was applied retrospectively to incidents that had already been investigated, that no significant health gain would be realised.

The argument in favour of applying updated guidance retrospectively would have been strengthened if the PNE conducted in 2016 had identified previously undiagnosed cases of HCW to patient transmission of infection who would have been identified in a PNE conducted after the guidance was revised. This would have been important for two reasons: Firstly, the cases identified would have been identified several years earlier; secondly, the trigger for the PNE being carried out in 2016 was the identification by a clinical team of patient 1 being a possible case of transmission which then led to further investigation. Had this case not been identified and there had been other patients who had acquired infection from the HCW they may not have been diagnosed until they developed chronic infection morbidity or may not ever have been diagnosed.

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[16] www.cdc.gov/hepatitis/outbreaks/healthcarehepoutbreaktable.htm

[17] Donohue S, Thornton L, Kelleher K. Blood-borne virus transmission in healthcare settings in Ireland: review of patient notification exercises 1997–2011. Journal of Hospital Infection. 2012, 80 (3):265-268.

[18] Ross RS , Steinbrückner B , Böhm S , Viazov S , Jilg W, Roggendorf M. Outcome of an exercise to notify patients treated by a general surgeon infected with the hepatitis C virus. J Clin. Viroly. 2008, 41(4):314-317.

[19] Dawar M, Stuart TL, Sweet LE, Neatby AM, Abbott LP, Andonov AP et al. Canadian hepatitis C look-back investigation to detect transmission from an infected general surgeon. Can J Infect Dis Med Microbiol. 2010 Spring; 21(1): e6–e11.

[20] Beltrami EM, Williams IT, Shapiro CN, Chamberland ME. Risk and management of blood-borne infections in health care workers. Clin Microbiol Rev. 2000 Jul;13(3):385-407.

The question in relation to whether further RLEs should be undertaken for other incidents in which a record linkage exercise using EPP3 data had not identified any cases of transmission is: “Would adding EPP2 and EPP1 data to the RLE have resulted in any cases of transmission being identified ?” This was not the case with the Lanarkshire RLE carried out in 2015. Had cases of transmission been identified by the PNE in patients who had had EPP1 and/or EPP2 procedures but who had not had one or more EPP3 procedures this would have supported a case for applying the updated policy retrospectively.

Patient 2 had a procedure that was coded as being an EPP2 procedure, however, upon review of clinical notes by a consultant surgeon it was considered that the challenges and complexity of the surgery required would have meant this was more appropriately categorised as a category 3 EPP. This illustrates the limitation of categorising procedures as being EPP 1, 2 or 3 on the basis of the operation code alone. However, when carrying out risk assessments it is usually not feasible to review the clinical notes of each procedure in order to make a more specific assessment of the EPP category.

There is also a question to consider of “Would patient 2 have been identified as a case of HCW to patient transmission if the RLE had included EPP1s and EPP2s as well as EPP3s?”. This may or may not have happened. Patient 2 was identified as a case of possible HCW to patient transmission after very detailed investigation of patient 1 leading to a high enough level of suspicion of transmission to justify a PNE being conducted. Patient 2’s hard copy health records and electronic health records were scrutinised for evidence of possible transmission. Clinical records contained details suggesting that patient 2 had acquired hepatitis C from infected blood during blood transfusion. Detailed examination of records refuted this possibility. Therefore, even though a RLE may have identified patient 2 as a match, further investigation at that time, prior to patient 1 being identified as a probable case of transmission, may not have resulted in patient w being considered to have been a case of transmission.

9. The case for a PNE on the basis of investigating patient 1

The IMT was of the view that the evidence regarding patient 1 that had been collated prior to patient 2 being identified as a possible case was sufficient to justify a PNE being carried out – even though virus was only available for patient 1 and not, in 2015, for the HCW. As patient 2 was identified prior to submission of the full report of the investigation carried out in relation to patient 1, it was possible to identify additional epidemiological and virological evidence that supported the view that patient 1 and patient 2 had both probably been infected by the HCW. UKAP was not required to advise on whether it would have recommended a PNE on the basis of the evidence that had been collated about the probable transmission of infection from the HCW to patient 1.

10. The case a PNE in the absence of evidence of transmission

On the basis of information submitted from the 2008 investigation UKAP advised that in the absence of evidence of transmission of infection after a thorough risk assessment, including a record linkage exercise, that a PNE was not necessary. As subsequent events have led to the conclusion that transmission of infection had probably occurred to two patients the question must be considered of whether a PNE should have been carried out even in the absence of evidence of transmission.

The evidence from previous incidents leads UKAP to the policy position that if there is no evidence of transmission of hepatitis C infection having occurred after a thorough investigation the risk that transmission has occurred to the cohort of patients that the HCW has performed EPPs on is minimal. To a large extent the findings of the 2016 PNE provide evidence to support the current policy. If UKAP had advised in 2011 on the basis of the findings of the first investigation that a PNE be conducted no additional cases of hepatitis C among people who had acquired infection from the HCW would have been identified. Both patient 1 and patient 2 had already been diagnosed and were receiving clinical care and no additional cases of probable transmission were identified from the PNE. There are two caveats: firstly, that one or more of the following five patients who came forward for testing during the 2016 PNE may have been virus positive in 2011 and subsequently cleared the virus - 2 patients tested hepatitis C antibody positive and virus negative; 3 patients tested hepatitis C antibody equivocal and virus negative; secondly, some patients who may have come forward for testing in 2011 and did not come forward for testing in 2016 may have been have been virus positive in 2011 – this would include patients who may have died between 2011 and 2016.

The conclusion of these findings could be that the current policy is sound and that if there is no evidence of transmission of hepatitis C infection having occurred after a thorough investigation the risk that transmission has occurred to the cohort of patients that the HCW has performed EPPs on is minimal and the use of limited NHS resources to try to identify cases of HCW to patient transmission by conducting a PNE is not indicated.

However, whilst the fact that no further cases of probable transmission of infection from the HCW to a patient were identified despite a large number and high percentage of people notified being tested may be considered to support UKAP policy, and to some extent the UKAP advice following the first investigation, a question remains as to whether people should be informed of the risk to which they have been exposed even if it is very low.

The position is that a healthcare authority is in possession of information which could be used to identify specific patients in order to inform them of an infectious disease health risk that they have.

This is different to a decision about whether to inform a patient of a near miss situation that may have occurred during an operation and for which the risk of health

loss has passed. In a situation in which a patient has been exposed to a risk of infection from an infected HCW the risk is ongoing for the patient, as is the risk that if they have become infected they may pass on infection to others.

On 11 September 2016 the topic for the BBC Radio 4 programme *The Reunion* was hepatitis C and HIV infected blood[21]. During the programme several points of relevance to UKAP policy were raised by patients and a carer including information about risk being known to medical practitioners but not disclosed to patients and carers; limited access to medical records which contained information about infection and risk of transmission of infection; and non-provision of information to patients and carers about infection and the risk of infection being transmitted to other people.

A further argument in favour of disclosure is that people who have been exposed to infection and who have been infected may, if they have not been tested for BBVs, unknowingly, pass the infection on to another person or persons. This can have a devastating impact on an individual and their relationships if a BBV is subsequently diagnosed and if the likely route of transmission is identified. This is especially the case if information about BBV exposure risk has been known to health authorities but not been disclosed, and if effective treatment has been available that would have stopped disease progression and transmission of infection.

A particular situation, which occurred during the Lanarkshire PNE and was reported in the media[22], arises when a patient has had an EPP performed under the care of a BBV infected healthcare worker, they have not been informed when the health authority has first become aware of the HCW's infection, the patient subsequently becomes pregnant one or more times and a PNE is subsequently carried out. The risk of vertical transmission of hepatitis C is estimated to be 3 to 5%. The notification to such a patient causes anxiety that she may be infected and additional anxiety that infection may have been transmitted from her to her child or children during pregnancy or delivery. Even if the patient tests negative for hepatitis C antibody a question remains regarding the decision that the health authority took to not inform patients about a risk to their health, albeit a very low or very, very low one, especially when that risk could have resulted in a child being born with a BBV infection.

Also, notification of patients, as part of a PNE, provides patients with information that they have been exposed to a risk of one or more blood borne virus infections. Whilst a patient may choose not to come forward for testing at the time of a PNE, were they to develop symptoms in subsequent years the fact that they had been provided with

[21] www.bbc.co.uk/programmes/b07tqtbs

[22] Why has it taken so long to tell me that I might have passed on Hep C to my little girl *(Daily Record, Wednesday 24 February 2016, p4&5, lead)* – Thousands face tests as health board send out warning letters. http://www.dailyrecord.co.uk/news/health/mum-quizzes-health-board-over-7428244

information during the PNE about their exposure risk may lead to diagnosis, and perhaps an earlier diagnosis, of a BBV infection.

Four policy options can be considered for a scenario in which a HCW is identified as being hepatitis C RNA positive and there is no evidence from a risk assessment, including a record linkage exercise, of HCW to patient transmission of infection:

a) Continue with the policy of not notifying patients assessed as being at very low or very, very low risk of infection.
b) Continue with a) but seek public endorsement of this policy.
c) Carry out a PIE – Patient Information Exercise. Move to a policy of writing to all patients who have been exposed to a transmission risk from a HCW who was not known to the healthcare service to be BBV positive at the time of the EPP and may have been infectious when they performed the patient's EPP and:
    a. Inform them of the situation and provide a Qs and As document.
    b. Inform them that there is currently no evidence of transmission of infection to a patient.
    c. State UKAP's position that testing is not clinically indicated when the probability of infection is less than 1 in xx,000.
    d. Advise that further annual checks for possible transmission will take place and if evidence of transmission of infection were to be identified patients would be contacted and advised to have a test and provided with details of how to arrange this.
    e. Inform them that a helpline is available if they have any questions that are not answered by the Qs and As document.

d) PIRTE – Patient Inform and Recommend Testing Exercise
    This exercise would be the same as a PNE in which a recommendation is made to patients that they arrange to have a test but would be referred to as a PIRTE to distinguish it from a PIE.

Trials of the PIE approach could be conducted and evaluated from various perspectives in order to inform whether such a policy should be adopted and if so how it might need to be amended.

For a scenario in which a HCW is identified as being HIV positive and there is no evidence from a risk assessment, including a record linkage exercise of HCW to patient transmission of infection, a PIRTE would be carried out for all patients who had had one or more EPP3s. If no cases of transmission of infection were identified among patients who had had EPP3s a PIE would then be carried out for patients who had had one or more EPP1s and/or EPP2s but no EPP3s. If one or more cases of transmission were found among patients who had had EPP3s a PIRTE would be carried out with all patients who had had one or more EPP1s and/or EPP2s.

There is therefore a rationale for UKAP to link with EAGA and AGH and the Departments of Health to reconsider the arguments for and against different policy options. If non-disclosure of very small risks of transmission of infection to patients continues to be considered to be acceptable there is a need from a governance perspective, for consultation and involvement of stakeholders, including patient representatives and members of the public, regarding such a policy position and for the outcome of such consultation to inform further decisions about policy.

Recommendation 5
UKAP should link with the Expert Advisory Group on AIDS, the Advisory Group on Hepatitis, and the four UK Departments of Health to review the current policy of non-disclosure to patients of information about levels of risk which have been assessed as being very low or very, very low.

Recommendation 6
UKAP should consider how best to engage with patients and members of the public in order to inform policy development and in order to make UKAP policy and the process of policy review and development open, honest and transparent.

11. Recurrent record linkage exercises when a PNE is not advised
Whilst the current policy referred to in the section above may be considered to be sound it may be possible to strengthen it. UKAP should consider whether the following steps should be incorporated into policy:

If a HCW is found to have a BBV infection, and a thorough investigation including a record linkage exercise finds no evidence of transmission of infection, and a PNE is not advised, a record linkage exercise should be undertaken every X years to identify if any patients who may be cases of transmission have been diagnosed and their details added to the hepatitis C database. If any such cases are identified they should be investigated to assess if they are probable or confirmed cases of transmission, and if they are further consideration should be given to conducting a PNE. The frequency of carrying out a record linkage exercise and the period of time they should continue for should be decided on a case by case basis. For example, UKAP may advise that a record linkage exercise be carried every 2 years for ten years. The dataset of patients who had had an EPP performed by the HCW would not change from the first record linkage exercise and it would be a quick administrative task to carry out the further check every two years.

Recommendation 7
UKAP should consider whether recurrent record linkage exercises should be advocated when a hepatitis C infected healthcare worker is identified and a PNE is not advised.

12. Advice to do a PNE in the absence of sequenced virus from the HCW

The incident reported on is unusual in that the HCW's virus had not been gene sequenced, and a sample of blood from the HCW had not been stored and it was not possible in 2015 to run tests to determine the HCW's virus gene sequence. This incident is thought to have been the first incident for which UKAP has advised that a PNE should take place in the absence of having virus from the HCW that could be compared with virus from one or more patients.

13. Check list for advice provided by UKAP

The members of UKAP consider many requests for advice each year about BBV infected HCW situations whereas most health protection teams deal with such situations infrequently – perhaps seeking advice from UKAP every 2 to 10 years. The members of UKAP, who often serve for several years, therefore build up considerable expertise regarding the management BBV infected HCW incidents whereas many Directors of Public Health have relatively little experience of such incidents and related expertise. Advice should be provided by UKAP to Directors of Public Health with regards to the following points, especially in situations in which UKAP advises that "no patient notification exercise need be undertaken":

- Whether to genotype and/or partial or whole gene sequence the virus that the HCW has been found to have.
- Whether different labs should be asked to sequence the virus so that information about different parts of the sequence is available. (This requirement would be redundant if whole genome sequencing is carried out.)
- Whether to save a sample of blood from the HCW and if so how long to save it for.
- Whether to repeat a record linkage exercise at a later time in order to identify possible cases of transmission in people whose details have been added to the hepatitis C database since the previous linkage exercise.

14. Representation on UKAP

The UKAP terms of reference[23] detail that UKAP should advise Directors of Public Health on patient notification exercises. It may be helpful to the work of UKAP for representation to be sought from the Association of Directors of Public Health and/or from a health protection team CCDCs/CPHMs in order to have input from those who have responsibility for making the final decisions about PNEs and for conducting them.

[23] www.gov.uk/government/groups/uk-advisory-panel-for-healthcare-workers-infected-with-bloodborne-viruses#terms-of-reference

Recommendation 8
UKAP should consider whether to seek representation from the Association of Directors of Public Health and/or from a health protection team consultant in communicable disease control or a consultant in public health medicine.

15. Risk management and possible phased approach to PNEs
Details of the discussion that took place between the IMT and UKAP about PNE covering 1982 to 2008 as phase 1 versus the need to carry out a whole of career PNE at the same time are provided in Section B. 8.1 above.
The policy that was being referred to[24] during discussions was issued in 2003 and was due to be reviewed in 2007.

"Patient notification exercises

6. Whenever a transmission of hepatitis C from an infected health care worker to a patient is detected, notification of other patients of that health care worker who have undergone exposure prone procedures, with the offer of serological testing, should normally follow."

This policy was referred to during discussions as to whether the PNE should go ahead in November 2015 with only patients of the HCW from 1982 and subsequent years being contacted or whether a whole of career approach needed to be taken with work undertaken to try to identify patients who had undergone an EPP performed by the HCW prior to 1982. At one stage during discussions the possibility of trying to identify patients who may have had an EPP performed by the HCW when they were a medical student in the early 1960s was being considered as a possible onwards

It would be helpful for details of scenarios when a whole of career PNE is not required and a phased approach can be taken to be included in the UKAP toolkit. Taking such an approach would be in keeping with other aspects of the risk management approach, rather than risk elimination approach, that UKAP takes.

For example, in the event of a HCW who carries out EPPs being identified as HIV positive the guidance document *HIV infected healthcare workers: Guidance on management and patient notification*[25] an initial phase PNE involving EPP3 patients and going back over 10 years is recommended. Even though the guidance is different for HIV situations compared to hepatitis C ones the principles of risk assessment and risk management are used in the HIV guidance to inform how far

[24] http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4012217.pdf

[25] http://www.gov.scot/Resource/Doc/57346/0016315.pdf

back the initial PNE should go and which patients it should involve with the findings of the initial phase of the PNE informing whether the PNE should be extended to include other patients (who have had EPP1s and EPP2s) and to include more years.

16. Data sharing and data linking

Extensive discussion took place with National Record Scotland about the need for data to be shared with other UK countries as part of the public health exercise that was taking place. There was a need to explain the nature of the incident to several different people in National Services Scotland and National Records Scotland and also for documents to be drafted detailing the request that was being made for data to be shared with other UK countries. This aspect of the PNE was very important but also very time consuming for the IMT chair at a time when many other demands were being made. It would have been helpful to have an agreed process, and template documents, in place in advance of public health incidents arising which require data sharing and data linkage.

Recommendation 9

Health Protection Scotland should work with NHS Boards, including NHS Lanarkshire, and with National Records Scotland to review issues that may arise during public health incidents in relation to data sharing and data linking, within Scotland and with other UK countries and [redacted], which are not already covered by existing guidance and protocols.

17. The need for regular testing of healthcare workers who carry out EPPs

It is recognised that some articles which report on HCWs who sustain sharps and needlestick injuries cover HCWs who do not perform EPPs a well as HCWs who do. The reason for the focus on HCWs who carry out EPPs in this report is due to the nature of the incident being reported on – the HCW was an EPP performing HCW - and the fact that whilst a HCW who does not perform EPPs may become infected from a sharps or needlestick injury (or mucocutaneous exposure) and not seek PEP and BBV testing, their cumulative risk of becoming infected is much less than that of a HCW who performs EPPs, and if they do become infected there is a very low risk that they would transmit infection to a patient.

17.1. Context of the discussion of regular testing of EPP HCWs

The discussion about regular testing of HCWs who perform EPPs takes place in the context of:

- No reported cases of HCW to patient transmission of HIV in the UK and very few cases reported worldwide.
- A small number of historical cases of HCW to patient transmission of hepatitis B in the UK. The risk of such transmissions has now been virtually eliminated through previous hepatitis B vaccination policy and is lessened even further

through the updated healthcare worker clearance guidance[26] which requires not only vaccination and testing for response to vaccination (anti-HBs) but also requires pre-vaccination testing for hepatitis B infection (HBsAg).

- Five PNEs which have identified HCW to patient transmission of hepatitis C in the UK.
- The introduction of Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 and year on year progress being made to promote and audit implementation of these regulations which includes increased use of sharp safety devices.
- Changes to surgical practice which have reduced the risk of HCWs who perform EPPs sustaining a BBV exposure. For example, the replacement of EPP3 procedures with EPP1 procedures such as the frequent replacement of cholecystectomy via laparotomy by laparoscopic cholecystectomy.
- Changes to the cohort of staff performing EPPs which may have resulted in fewer injuries being sustained and a higher percentage of injuries sustained being reported, for example, a greater recognition by HCWs who perform EPPs of the importance of infection control practice and procedures to prevent the transmission of infection from patient to HCW and from HCW to patient including the use of personal protective equipment.
- Changes to the cohort of staff who perform EPPs with regards to non-occupational risk factors for BBV infection, in particular, changes to country of birth and residence prior to working in the NHS.

17.2. Learning from [redacted] a HCW who performed EPPs

The incident can be summarised as follows:

- An HCW who had worked for NHS Lanarkshire for 26 years was identified as having a BBV infection – hepatitis C.
- A detailed investigation carried out in 2008, which included a risk assessment informed by a record linkage exercise using only category 3 EPPs, did not identify any evidence of probable or confirmed transmission of infection.
- UKAP's advice based on national policy at that time was that a PNE was not needed.

[redacted]

- Two patients were identified in 2015 who were assessed as probably having acquired infection from the HCW. Infection with hepatitis C has had a major impact on the physical, mental and social health and well-being of both patients.
- A large UK-wide PNE was carried out in 2016 – 8,320 people were sent a letter and 6,473 (78%) were tested for hepatitis C.

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26 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/382152/health_clearance_tuberculosis_hepatitis_hiv.pdf

- No further cases of probable transmission were identified, however, other cases of transmission of infection which have not been identified may have occurred.

An NHS Lanarkshire employee who probably acquired hepatitis C infection occupationally [redacted]

NHS Lanarkshire had duties and responsibilities to the HCW [redacted] they were an NHS Lanarkshire employee [redacted]

[redacted]

Many patients who attended a clinic for testing spoke very positively about the HCW with two particular sentiments being expressed:

- How much they appreciated the HCW, the treatment the HCW had given them, the way in which the HCW had cared for them and interacted with them, with some people saying that the HCW had saved their life.

[redacted]

It is important that all learning that can be taken from this incident is identified [redacted] It is likely that there are currently HCWs in the UK who perform EPPs who have chronic hepatitis C infection (or HIV infection) who are not being tested for hepatitis C (or HIV infection) - regular testing for hepatitis B would not be required if evidence of hepatitis B immunity has been established for a HCW.

Had regular compulsory testing of HCWs who perform EPPs for BBVs been in place in the 1990s and 2000s the HCW would have been diagnosed earlier and may have been able to benefit [redacted] from treatment and from clinical advice.

17.3. Risks that HCWs who perform EPPs are exposed to

It is known that some HCWs who carry out EPPs and sustain a needlestick or other sharps injury do not report that they have sustained the injury and do not attend their

occupational health service for testing. [redacted]

Makary et al [27] carried out a study of needlestick injuries among surgeons in training. They found that factors that were significantly associated with not reporting the most recent needlestick injury were:

- Male sex.
- The lack of involvement of a patient known to be a high risk.
- Occurrence in the operating room.
- The lack of knowledge of the injury by another person.
- The total number of needlestick injuries during training.

51% of surgical residents who had sustained a needlestick injury did not report the injury to their occupational health service.

Articles in the scientific literature which document the non-reporting of sharps and needlestick injuries have been published over the last twenty years, and evidence that this behaviour found is pervasive being found in different countries, and is persistent, being reported in articles published in recent years [28,29,30] .

The key points to take from the scientific literature with regards to the health and safety of HCWs who carry out EPPs, and consequently with regard to patient safety, are:

- A significant number and percentage of sharps and needlestick injuries are not reported to occupational health and the HCW who has sustained the injury is not tested for BBVs.
- There are actual and perceived barriers to reporting injuries and being tested.
- It is highly likely that despite progressive introduction of safety devices and safer ways of providing treatment, and despite education and training programmes, and provision of user friendly reporting and testing arrangements that a significant proportion of HCWs who perform EPPs will continue to sustain sharps and needlestick injuries and will continue to underreport these injuries and not be tested for BBVs.

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[27] Makary M et al. Needlestick Injuries among Surgeons in Training. N Engl J Med 2007 356: 2693-9. http://www.nejm.org/doi/pdf/10.1056/NEJMoa070378

[28] Trim JC, Elliot TSJ. A review of sharps injuries and preventative strategies. Journal of Hospital Infection. (2003) 53: 237-242

[29] Sharps Safety. Royal College of Nursing. 2013. https://www2.rcn.org.uk/__data/assets/pdf_file/0008/418490/004135.pdf

[30] Voide C, Darling KE, Kenfak-Foguena A, Erard V, Cavassini M, Lazor-Blanchet C. Underreporting of needlestick and sharps injuries among healthcare workers in a Swiss University Hospital. Swiss Med Wkly. 2012 Feb 10;142:w13523. doi: 10.4414/smw.2012.13523.

- HCWs who perform EPPs are not always aware that they have sustained a needlestick or other sharps injury.

The last of these points – that HCWs who perform EPPs are not always aware that they have sustained a needlestick or other sharps injury – is supported by the second sentence of the UKAP definition of a category 3 exposure prone procedure[31]:

EPP3
"Procedures where the fingertips are out of sight for a significant part of the procedure, or during certain critical stages, and in which there is a distinct risk of injury to the worker's gloved hands from sharp instruments and/or tissues. In such circumstances it is possible that exposure of the patient's open tissues to the HCW's blood may go unnoticed or would not be noticed immediately."

HCWs who have sustained high risk injuries and do not report them are unable to benefit from post exposure prophylaxis and from treatment if they have a BBV infection but do not have it diagnosed.

Voide et al[32] carried out an extensive survey among HCWs in a Swiss university hospital. Questionnaires were sent to 6,367 HCWs and 2,778 (44%) were returned. It was found that 69% of the HCWs who had reported none of their sharps and needlestick injuries were doctors who performed EPPs.

The principal reasons for not reporting were:

1) Self-estimation that the injury was low risk with respect to BBV transmission.
2) Perceived lack of time.

None of the respondents listed lack of knowledge that reporting was required nor lack of knowledge about reporting procedures as reasons for not responding.

Whilst the risk to a HCW who carries out EPPs of acquiring a BBV infection during a specific procedure may be very small the cumulative risk builds up over days, weeks, months and years.

Westermann et al carried out a systematic review and meta-analysis of the prevalence of hepatitis C among healthcare workers[33] and conclude:

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31 www.gov.uk/government/uploads/system/uploads/attachment_data/file/511570/UKAP_General_Dentistry_EPP_Categorisation_FINAL_to_be_uploaded.pdf

32 Voide C et al. See footnote above or on previous page.

33 Westermann C, Peters C, Lisiak B, et al. The prevalence of hepatitis C among healthcare workers: a systematic review and meta-analysis. Occup Environ Med 2015;0:1–9.

http://oem.bmj.com/content/early/2015/10/05/oemed-2015-102879.full.pdf+html

"This meta-analysis shows a statistically significant increase in the prevalence of HCV infection in HCWs compared to controls. Medical and laboratory personnel, and staff members who perform EPPs, are particularly affected."

17.4. Expectations and confidence of patients and members of the public

The expectation of many patients is that healthcare workers are tested regularly for blood borne viruses and that those who are found to have a blood borne virus are not permitted to perform EPPs. Were members of the public to be made aware that HCWs who carry out EPPs are not regularly checked for BBV infection it is likely that there would be an increased demand from members of the public for regular testing. During the conduct of the patient notification exercise several patients expressed their view at the testing clinics that they should have been informed of the situation in 2008 when the HCW was diagnosed with hepatitis C infection. Four complaints were received by NHS Lanarkshire regarding the decision to not conduct a patient notification exercise in 2008. These complaints were received directly from one patient to the patient affairs manager, from a Citizens' Advice Bureau and on behalf of a patient from a Member of the Scottish Parliament.

Probably every PNE that takes place gets reported to some extent in the UK national media and to some extent such reporting undermines the confidence that people can have in the quality of healthcare that they have received in the past or may receive in the future. People are left thinking they might get a PNE letter in the future to do with an operation that they or a relative have had or in relation to an operation that they or a relative may be due to have.

An opinion piece in The Herald newspaper expressed the view that it was patients should have been informed when the HCW was identified as being infected with hepatitis C. (See Appendix F.01)

17.5. The views of Hepatitis Scotland and the Hepatitis C Trust

Hepatitis Scotland supports and leads the work of voluntary sector groups in partnership with statutory agencies and patients in Scotland to promote high quality viral hepatitis prevention, diagnosis, treatment, support and care, and reduce stigma associated with viral hepatitis. Hepatitis Scotland was planning to facilitate discussion of the issue of the need for regular testing of healthcare workers who carry out EPPs using social media (Hepatitis Scotland website blog, Twitter and Facebook). However, after a meeting at which the process of reporting to UKAP on the incident investigation, the PNE findings and the recommendations of the IMT was explained, and following a request for Hepatitis Scotland to produce a paper which could be included as an appendix to this report, Hepatitis Scotland decided to suspend plans for social media discussion and await the receipt by NHS Lanarkshire of the response from UKAP to the report submitted. Hepatitis Scotland has stated the following on its website[34]:

[34] www.hepatitisscotland.org.uk/publications-policy/press-releases/nhs-lanarkshire-patient-testing-programme-after-potential-exposure-worker-hepatitis-c/

"There appears to be a case for regular in-work BBV testing of workers who perform the most exposure prone procedures as even with the best infection control unknowing exposure can occur when using fine and very sharp instruments. With the highly effective treatments now available this should not be detrimental to a healthcare worker's continuing employment after successful treatment."

Hepatitis Scotland produced a paper "on behalf of those affected or potentially affected by iatrogenic infections" (See Appendix F.02) which makes the following two recommendations:

[Start of extract.]

1. All healthcare workers who perform high level exposure prone procedures should be tested on a regular basis for hepatitis B and C.

2. All NHS boards across the UK should assess whether any previous reviews of potential exposure to hepatitis B or C during level 3 Exposure Prone Procedures (EPP)[35] should now be expanded to a patient recall exercise, whether or not there has been any identified cases. The review must prioritise current patient need and longer term cost-effectiveness.

[End of extract.]

The Hepatitis C Trust called for all healthcare workers to be tested for hepatitis C and also advocated general population screening[36].

17.6. PNEs – a managed proactive approach or a continued reactive one

There are likely to be other EPP HCWs who currently have HIV or hepatitis C infection who have not been diagnosed. In addition, there are likely to be EPP HCWs who are not infected with HIV or hepatitis C infection now, but who will become infected with HIV or hepatitis C – either occupationally or through personal activities. If regular testing of EPP HCWs is not introduced there are likely to continue to be, in the coming decades, significant incidents with HCWs who have performed EPPs being identified as HIV or hepatitis C positive leading to complex and resource intensive investigations to assess the possibility of transmission of infection from the HCW to one or more patients, and, if transmission of infection is not thought to have been unlikely, large scale PNEs needing to be carried out because there is no known date when the HCW was last known to be HIV or hepatitis C negative, or, for HCWs who did have a health clearance test for HIV and hepatitis C in 2007 or in subsequent years, because a considerable time has passed since a negative test

[35] http://cid.oxfordjournals.org/content/40/11/1665/T3.expansion.html

[36] http://www.eveningtimes.co.uk/news/14297815.Hep_C_charity_calls_for_mandatory_testing_for_surgeons_after_patients_treated_by_Lanarkshire_medic_are_infected/

result. The health clearance guidance was first published in March 2007[37]. A PNE required for an incident involving an EPP HCW who tested negative in 2007, and who did not have any further HIV or hepatitis C negative test results, but who is found in 2016 to have HIV or hepatitis C infection would need to cover the nine year period from 2007 to 2016. Both the HCW in the Welsh 2013 hepatitis C infected HCW incident[38] and the Lanarkshire HCW were diagnosed at the end of their careers [redacted]. Both were thought to have acquired infection occupationally. Given current policy it is possible that an incident similar to the Welsh or Lanarkshire incidents could occur at any time in the future with a PNE being recommended that covers the whole of the HCW's EPP career which may be forty years or longer. The lack of availability of health records for patients in the Lanarkshire incident who had an EPP performed prior to 1982, when the HCW commenced their NHS Lanarkshire post, curtailed the extent of the PNE to the years 1982 to 2008. With the development and retention of electronic records it may be possible for PNEs to cover longer periods and they may be required to – although record retention policies may result in records not being retained. For example, if an EPP HCW who was tested as part of health clearance testing at entry to the NHS in 2007 at the age of 23, works for forty years and retires in 2047, and is diagnosed with hepatitis C infection in retirement three years later in 2050, based on current policy a PNE covering patients who had EPPs performed by the HCW from 2007 to 2047 would be advised if there was evidence of HCW to patient transmission of infection.

Another scenario is that a HCW who is aware that they have a BBV infection may decide not to disclose their BBV status to their employer and may continue to perform EPPs knowingly putting patients at risk of acquiring BBV infection. Such a scenario is seen from time to time, often coming to light because of severe illness in the HCW, and an extensive, complex, expensive PNE is often required.

Each of scenarios described above would be prevented, or would be significantly curtailed and much easier to manage with less resource required, by the introduction of regular testing of EPP HCWs for BBVs.

17.7. Current practice in other countries

It is difficult to identify the policy that other countries have regarding testing healthcare workers who perform EPPs for BBVs, however, policies have been found for Australia and for part of Canada – Ontario.

[37] Health clearance guidance for tuberculosis, hepatitis B, hepatitis C and HIV: New healthcare workers. Department of Health. March 2007. www.gov.uk/government/uploads/system/uploads/attachment_data/file/382152/health_clearance_tuberculosis_hepatitis_hiv.pdf

[38] http://www.cardiffandvaleuhb.wales.nhs.uk/news/28800

17.7.1. Australia

Australian National Guidelines for the Management of Health Care Workers known to be Infected with Blood-Borne Viruses[39] detail that HCWs who perform EPPs should undergo regular testing for BBVs:

"HCWs who perform EPPs should know their BBV status and be encouraged and supported to undergo regular testing. Annual testing is considered to be appropriate in most cases, with immediate retesting and follow-up care after a potential occupational or non-occupational exposure."

17.7.2. Canada (Ontario)

It has not been possible to identify if the policy extant in Ontario is also in force across other parts of Canada, however, Ontario is Canada's most populous province and accounts for 40% of the Canadian population.
Current policy in Ontario[40] is for HCWs who perform EPPs to be tested for BBV at least every three years and after any risk exposure incident.

17.8. The importance of policies in Australia and Ontario

Australia and Ontario direct that HCWs who carry out EPPs should undergo regular testing for BBVs.

The Scottish Public Inquiry into hepatitis C and HIV acquired infection from NHS treatment in Scotland with blood and blood products, known as the Penrose Inquiry[41], sought information about what was known in the UK and internationally about HIV, AIDS, viral hepatitis and best practice with regards to blood safety management for various time periods.

The following paragraphs taken from the start of Chapter 14 of the Penrose Inquiry report[42] are relevant to consideration of UK policy on the testing of healthcare workers who carry out exposure prone procedures in the context of other countries having introduced regular, recurrent testing for such healthcare workers:

> 14.2 In this Report, it is appropriate to discuss more fully the response of the UK Government and other agencies to the emerging knowledge of viral hepatitis during the period when it presented a threat to NHS patients receiving blood, blood components or blood products in the course of medical treatment.

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39 www.health.gov.au/internet/main/publishing.nsf/Content/36D4D796D31081EBCA257BF0001DE6B7/$File/Guidelines-BBV-feb12.pdf

40 www.cpso.on.ca/policies-publications/policy/blood-borne-pathogens

41 www.penroseinquiry.org.uk/finalreport/

42 http://www.penroseinquiry.org.uk/finalreport/text/354876_chapter_14.html

Understanding the risk: background

14.3 The aim of this part of the Report is to describe what was known at critical stages to scientists, practitioners and relevant authorities, not what 'ought' to have been known or accepted. In this early period, scientific developments were reported that, in time, became generally accepted medical knowledge. Developments can often be best identified and described chronologically, by date of publication, as was done in the Preliminary Report. However, inherent in this approach is a risk of representing as contemporaneous knowledge material that would not, and in some cases could not have, at that time, been known or understood by practitioners generally. Further, published data and discussion will reflect work carried out over a period prior to publication. In general, first publication of a finding or theory is more likely to mark the beginning of critical examination of ideas rather than the date of their general acceptance. Scientists exploring the boundaries of current knowledge inevitably develop theories that may be backed up by limited empirical data. Such theories are perhaps unlikely to meet with immediate acceptance by a critical peer group and even less likely to survive challenge by related, or unrelated, specialists. Scientific orthodoxy may resist novel ideas and inhibit their acceptance. Those with control of the funds necessary for the validation of a theory and the implementation of changes required to give practical expression to emerging ideas are even less likely to be easily satisfied.

Given the information that is available in the scientific literature it may be difficult to defend current UK policy regarding not regularly testing HCWs who carry out EPPs especially in light of the approaches that have been taken in Australia and Ontario.

17.9. Financial and reputational risk management

NHS and other healthcare organisations need to consider short and long term financial and reputational risks and how these should best be managed.

The scenario of a healthcare worker being identified after many years of carrying out EPPs as having a BBV infection may lead to:

- A resource intensive investigation and PNE. Resources required include the opportunity costs for all the members of staff involved at local, regional and national level; printing and posting; setting up and staffing one or more helplines;
- Payments for additional hours worked; costs and opportunity costs associated with running clinics, obtaining blood samples, transporting them, carrying out primary and secondary testing, reporting of results and communicating results to patients.
- Follow up work after the PNE concludes including responding to complaints, inquiries from elected representatives and the media, preparation of documents for requests under the Freedom of Information Act, work

associated with responding to litigation. The amount of work required after a PNE may be as much as that required to conduct an investigation and to prepare for and deliver the PNE.
- Reputational damage due to the way the incident may be reported in the media.
- Risk of litigation (See subsection below.)

In the Lanarkshire incident neither patient 1 or patient 2 has chosen, to date, to engage with the media. If one or both patients had wished to engage with the media there may have been a significant negative impact on NHS Lanarkshire's reputation – and associated with this a reduction in the confidence of Lanarkshire residents in the quality of services provided. Various negative scenarios could have arisen if patients had been identified who were assessed as being probable cases of transmission.

NHS organisations may prefer to do small PNEs to minimise and manage the risk associated with:

- HCW health and safety – compliance with HSWA and COSHH.
- Patients who may be possible, probable or confirmed cases.
- Conducting large PNEs which cover many years, and in some cases decades, and which require extensive resources.
- Reputational damage.

Employers may move to introduce regular testing in order to protect and promote the health of their employees. Rather than regular testing being seen as a negative practice which HCWs don't wish to have done it can be presented and seen as a positive approach which an employer is taking as it wishes to protect and promote the health of its current workforce, and to support workforce recruitment and retention.

17.10. Risk of litigation

Employers have a duty to comply with legislation including the Health and Safety at Work Act; Control of Substances Hazardous to Health Regulations; and Health and Safety (Sharp Instruments in Healthcare) Regulations 2013.

Based on legislation, HSE guidance and code of practice, evidence available in the scientific literature and established practice in other countries it is likely that in future health service organisations such as NHS Trusts and NHS Boards will be sued because of failure to require HCWs who carry out EPPs to undergo regular testing (for example, on an annual or 2, 3, 4 or 5 year basis).

Litigation may be brought by:

- BBV infected patients (or relatives of deceased patients) who assert that they have become infected by transmission from an infected healthcare worker and that the health service organisation failed in its duty of care to them,

whilst a patient, to provide safe care and minimise risks to the patient in the work place.

- Patients who wish to take legal action due to anxiety experienced when informed about an infected HCW incident, while waiting to be tested and while waiting to receive a result. Such patients may not be found to have a BBV infection, and they may not succeed in their legal action, however, there is a risk that such action may be taken and health authorities may wish to take action to minimise the risk that such an approach would be possible.

- BBV infected healthcare workers who assert that their employer failed in its duty of care to the employee under the Health and Safety at Work Act, and with regard to COSHH Regulations, by not providing appropriate health surveillance for an employee who is required to wear personal protective equipment in order to protect themselves from ACDP classified group 3 human pathogen hazards (HIV, hepatitis B, hepatitis C), when it was known (from scientific literature) that HCWs who carry out EPPs frequently sustain BBV exposure risk injuries – some of which they are unaware of - and do not report them and do not get tested for BBVs, in the context of regular testing for BBVs in EPP performing HCWs taking place in other countries, and in the context of intelligence within the medical community that some such HCWs acquire BBV infections occupationally and become seriously ill and die prematurely.

- Patients, relatives or HCWs against government ministers and/or against members of policy making bodies and/or people who implement policy which is subsequently deemed to have caused harm to patients or HCWs, or not protected them from harm. (Such actions have been seen in the UK and in France in relation to HIV and hepatitis C infected blood.)

17.11. Reasons why EPP HCWs may not present for BBV testing

Current policy relies on HCWs to present for testing if they think they have had a BBV exposure or if they think they may have a BBV infection. Whilst EPP HCWs have professional and ethical duties to be tested there are many reasons why HCWs may not present for testing in addition to the time required to report an exposure and arrange testing being a barrier[43]. For example, they may be in psychological denial that they may have an infection which they may think would have catastrophic consequences for their career and personal life; (conscious) concern about the impact that diagnosis may have on their career; lack of confidence in the confidentiality of local and national record systems; concern regarding the perceptions of others who may be informed (for example, occupational health physicians, department clinical directors, educational supervisors) regarding their surgical practice and/or regarding their personal lifestyle; concern about the impact of a diagnosis on personal relationships.

[43] Voide C, Darling KE, Kenfak-Foguena A, Erard V, Cavassini M, Lazor-Blanchet C. Underreporting of needlestick and sharps injuries among healthcare workers in a Swiss University Hospital. Swiss Med Wkly. 2012 Feb 10;142:w13523. doi: 10.4414/smw.2012.13523.

Some EPP HCWs may be working in an environment, service or specialty that they consider to be “macho”, sexist, racist, homophobic or oppressive in other ways and they may be concerned that were they to be tested and found to have a BBV infection that they were face stigma and discrimination. Such concerns may exist if a HCW thinks they may have been exposed to an occupational risk, however, they are likely to be greater for HCWs who carry out EPPs who may have been exposed to a BBV risk through a non-occupational route – for example, by sexual transmission, by injecting drug use or through being tattooed.

The College of Physicians and Surgeons of Ontario found that physicians were not being tested despite an ethical obligation to be tested[44] and this is one of the reasons given for introducing regular testing of EPP HCWs in Ontario.

Introducing regular testing for all UK HCWs who carry out EPPs would overcome the issue of a HCW who knows they have been exposed to a risk of acquiring a BBV infection not coming forward for testing and also the issue of a HCW who performs EPPs not disclosing to their occupational health service if they have been diagnosed with a BBV by another service.

17.12. Changes for HCWs who carry out EPPs

Changes have taken place in recent years that profoundly change the position for HCWs who carry out EPPs and are diagnosed with a BBV infection.

17.12.1. Highly effective treatment

Highly effective treatment is now available for the treatment of HIV and hepatitis C infections and effective treatment is available for people who have chronic hepatitis B infection. HCWs who sustain a high risk exposure are able to benefit from HIV post-exposure prophylaxis if this is assessed as being indicated.

17.12.2. Continuing surgical career

The evidence base has been developed based on reports of investigations of incidents in which a HCW has been found to have a BBV infection and based on reports of patient notification exercises. Guidance has been issued which enables HCWs who have HIV or hepatitis B infection to carry out EPPs as long as certain criteria are met on an ongoing basis. HCWs who have hepatitis C infection can be given highly effective treatment and are very likely to achieve a sustained viral response and be able to return to performing EPPs as long as certain criteria are met on an ongoing basis. For a HCW whose work involves

[44] www.cpso.on.ca/CPSO/media/documents/Policies/Policy-Items/BBV-FAQ.pdf

carrying out EPPs their career is no longer at risk to the same extent by being found to have a BBV infection.

17.13. The duty of employers to protect their employees

The duty of employers to protect the health and well-being of their employees is described clearly in legislation. Given that the opportunity to benefit from being diagnosed with a BBV has increased – due to the development and availability of highly effective treatment – it is more important than previously for employers to promote BBV exposure prevention and management policies, including promoting the importance of testing.

The prospect for the NHS in the UK in the coming decade is for the service to be under increased pressure due to increased work load and funding challenges. These circumstances are known to be associated with increased risk of BBV exposure incidents.

It is important that national guidance promotes the health and well-being of patients and healthcare workers and also supports employers to fulfil their statutory duties under various health and safety laws such as the Health & Safety at Work Act and the Control Of Substances Hazardous to Health Regulations.

Should a view be taken in relation to litigation brought against an employer by an employee that an employer had not fulfilled their statutory duties to protect and promote the health and safety of an employee who became infected with a blood borne virus, and who was thought to have acquired the infection occupationally, the employer would be at financial and reputational risk. Should employers be of the view that following national guidance regarding testing of HCWs who carry out EPPs leaves them exposed financially to litigation, (for example, by a HCW who becomes infected occupationally and is not diagnosed and offered treatment, or by the HCW's family), on the basis that they may be found to have failed to comply with health and safety legislation, (for example, to ensure that appropriate health surveillance was carried out), employers may choose to implement policies similar to those in force in Australia and Ontario which include regular testing for BBVs of all healthcare workers who carry out EPPs.

17.14. Frequency of regular testing

The frequency of testing would be influenced by various factors, and could be customised according to the type and number of EPPs performed, the discipline the HCW is practicing in, including:

- The urgency with which patients and HCWs who have been infected need to be identified and referred for clinical assessment and management.
- The duration that any PNE may need to cover if an infected HCW is identified and either a) policy changes so that a PNE is carried out routinely upon diagnosis of an infected HCW who performs EPPs, or, b) the current risk

assessment and management policy continues with PNEs only being carried out if there is evidence suggesting that transmission of infection from a HCW to a patient has taken place.

If regular testing of HCWs who perform EPPs were to be introduced the value of carrying out record linkage exercises at the time of diagnosing a HCW would be reduced as patients who may have become infected may not have developed symptoms and may not have been diagnosed in which case their details would not be recorded on a database that would be used to carry out the record linkage exercise. In such a scenario a decision may be made that a PNE is not indicated but that further record linkage exercises should be run in subsequent years to identify possible cases of transmission. Developments in whole genome sequencing practice, with the sequence of a virus found in a HCW, may enable cases of HCW to patient transmission to be identified and possibly also to identify a patient from whom a HCW may have acquired infection.

It is recognised that regular testing is unable to guarantee that a healthcare worker who carries out an EPP does not have a BBV infection. For example:

- A HCW may have become infected shortly before the test and be in a testing window period and not test positive.
- A healthcare worker may become infected with a blood borne virus immediately after being tested for a BBV.
- A false negative result may be obtained. Given the sensitivity of current BBV tests this is very unlikely.

The probability that a HCW who carries out EPPs might be infected with a BBV would increase as the time between testing increases due to the increase in cumulative risk with time.

The College of Physicians and Surgeons of Ontario policy statement #3-12 on Blood Borne Pathogens[45] published in 2012 stated:

"Routine testing
Physicians performing or assisting in performing exposure prone procedures must be tested for blood borne pathogens (HBV, HCV and HIV) annually."

The policy was reviewed and updated in December 2015 and published as the College of Physicians and Surgeons of Ontario policy statement #7-15 on Blood Borne Pathogens[46] and stated:

"Periodic Testing

[45] www.cpso.on.ca/CPSO/media/uploadedfiles/policies/policies/policyitems/Blood-Borne-Pathogens_Policy.pdf?ext=.pdf

[46] www.cpso.on.ca/CPSO/media/documents/Policies/Policy-Items/Blood-Borne-Viruses.pdf?ext=.pdf

Physicians who perform or assist in performing exposure prone procedures must be tested for HCV and HIV every three years.

Physicians who perform or assist in performing exposure prone procedures must be tested annually for HBV unless the physician has been confirmed immune to HBV."

The 2015 version of the policy is due to be reviewed by December 2020.

17.15. The family and friends test

The family and friends tests is sometimes referred to as a way of people who provide and/or make decisions about healthcare services being reminded of how they would feel if they or a close family member or friend were the recipient of an aspect of healthcare. With regards to the current issue one question is:

Would you wish your self / parent / grandparent / sibling / child / partner / friend to be operated on by someone who:

a) has never been tested for BBVs

b) was tested once several years ago

c) was tested within the last 1 / 2 / 3 years ?

Ii is likely that the clear preference of most people would be c).

A further question is:
If your son / daughter / nephew / niece / friend / son or daughter of a friend were embarking on a 35 to 45 year career of carrying out exposure prone procedures which of the BBV testing regimes would you wish to see in place:

a) An initial test at time of entry to the NHS and the start of performing EPPs with subsequent tests if the person knows they have, or thinks they have, sustained an injury and arranges to be tested.

b) Regular testing at 1 / 2 / 3 year intervals which would enable the person to be reassured if they tested negative or, if they were positive, to be diagnosed, referred for clinical assessment and treatment and supported to return to carrying out EPPs when various criteria were met.

Further questions can be asked from the perspective of a close household contact or a sexual partner of a HCW who performs EPPs and does not undergo regular testing for BBVs.

17.16. Lack of knowledge of possible transmission of BBV infection

Current policy results in HCWs being at risk of having a chronic undiagnosed BBV infection which is causing significant damage to the HCW's organs but which is not causing symptoms, or is causing symptoms which are not leading the HCW to seek clinical investigation, or which are being investigated but without hepatitis C and HIV testing being carried out.

A key issue for patients who undergo an EPP is that if transmission of infection to the patient does occur there is currently no mechanism in place for this to be identified and if a patient to whom transmission of infection has occurred is not diagnosed due to investigation of acute symptoms, or due to a screening test (such as during pregnancy or associated with donating blood) the patient may not be diagnosed until they develop manifestations of chronic infection by which time they may have irreversible morbidity and may be terminally ill.

The introduction of regular testing of HCWs who perform EPPs would provide the assurance retrospectively that when a particular EPP was performed the HCW did not have a BBV infection – in cases where a HCW was found to have a BBV infection further investigation and possibly a PNE would take place. Regular testing would also provide reassurance to HCWs that they have not acquired a BBV infection since the last time they were tested, and that they have not been a possible source of BBV infection to the patients upon whom they have performed EPPs.

Patients could be informed of the low risk of BBV transmission associated with EPPs prior to an EPP being carried out – and at the same time be informed that regular testing of HCWs takes place and what the policy is regarding a situation in which a HCW is found to have a BBV infection – whether this be a) a risk assessment approach involving a record linkage exercise to determine if a PNE should or should not be conducted or b) if a patient notification exercise would be carried out routinely. Such an approach would be in keeping with the principles of openness, honesty and transparency.

17.17. The health economics of introducing regular testing

There would be various direct costs and opportunity costs of introducing a policy of regular testing of HCWs who do EPPs, however, if fully identified it is likely that the cost savings of such a policy would be significant and one of the key outcomes would be the provision of safer care.

When incidents occur there is often considerable pressure and expectation that a significant resource will be invested to contact patients to try to identify cases of transmission of infection. Often the number of cases identified is small or none and for some cases identified the opportunity for health gain may be limited. The low yield, in terms of number of patients identified with chronic hepatitis C infection, whether thought to have been acquired from a HCW or be incidental, is known about by Directors of Public Health and health protection organisations. However, it seems to be that the ethics and politics of these situations require considerable resources to be spent with, usually, little health gain expected or achieved. If part of the health service is aware that a specific cohort of people has been exposed to a low risk of being infected as a result of healthcare it seems to be very difficult to not take action which from a health economics perspective may be the preferred option.

From a public health perspective it would be better to invest resources in regular testing of HCWs who perform EPPs as this provides outcomes that are of value:

- Regular negative test results provide reassurance and useful information for the HCW and their family.
- Patients, carers, the public and the healthcare service provider obtain reassurance from the knowledge that a regular testing programme is in place.
- Early identification of infection in patients and HCWs enabling prevention of morbidity and mortality.
- It helps to inform the risk assessment of a situation in which there is bleeding from a HCW into the tissues of a patient – if this happens and is identified.

17.18. Transitional period

In the same way that revalidation of doctors was introduced using a five year introductory period with doctors being identified to undergo revalidation assessment during a specific year based on the last digit of the GMC number, a transitional period could be used to move to regular testing.

During the transition period it is likely that some HCWs would be identified who test positive for a BBV requiring risk assessments to be carried out, advice to be provided by UKAP, and in some incidents a PNE to be conducted. Resources that may be needed at national and regional level during a transitional period could be commissioned in preparation the transition.

Alternatively there would be arguments in favour of changing to regular testing over a one year period.

Contact could be made with authorities in Australia and Ontario in order to identify challenges that were encountered and learning points identified when they introduced regular testing.

17.19. Work load for occupational health departments

If a policy of regular testing of EPP HCWs were to be adopted it is likely that the regular testing required could be managed efficiently by occupational health services. Initial testing of EPP HCWs in a hospital, trust or health board could be phased in over a period of time equal to the regular testing interval so that there would be an even spread of work. For example, if regular testing were to be carried out every three years the first phase of testing could be carried out over three years and the dates when the subsequent tests would be due, unless a HCW had been tested following an exposure incident, would be evenly distributed over the following three years. Also, information about testing could be provided ahead of venepuncture resulting in the only task being for an Identified, Validated Sample to be obtained. To facilitate testing it would be possible to consider amending the current standards for IVS samples[47] so that samples could be taken in clinical areas and did not need to be taken in occupational health departments.

[47] Health Clearance for Tuberculosis, Hepatitis B, Hepatitis C and HIV for New Healthcare Workers with Direct Clinical Contact with Patients. Scottish Government. April 2008. ***http://www.gov.scot/Resource/Doc/221201/0059484.pdf***

17.20. Primum non nocere (First do no harm)

This is one of the key principles of medicine and healthcare. Whilst this principle is being implemented to a large extent through current policy a policy of regular testing would enable it to be implemented to a greater extent.

17.21. Patients with hepatitis C and no identified source of infection

There has been disquiet about the source of hepatitis C infection among people who do not have risk factors for hepatitis C. Some such patients have had one or more episodes of healthcare, however, systems are not set up and are not used to identify if patients may have been infected through healthcare.

Work is being undertaken by Health Protection Scotland to see if criteria can be developed which could be used to identify cases of possible healthcare associated infection which should be investigated further.

Introducing regular testing of HCWs who carry out EPPs would enable specific HCWs to be excluded as a potential source of infection on the basis of negative BBV test results for samples taken after a patient had had an EPP performed.

17.22. Reasons given by CPSO for requiring periodic testing for BBVs

The College of Physicians and Surgeons of Ontario published a document entitled Blood Borne Viruses: Frequently Asked Questions – Mandatory

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Identification and validation of samples submitted for testing

It is important that those commissioning laboratory tests for HIV, hepatitis B and hepatitis C ensure that samples tested are from the healthcare worker in question. Healthcare workers must not provide their own specimens.

The following standards of good practice for occupational health data recording have been agreed by the Association of NHS Occupational Physicians (ANHOPS) and the Association of Senior Occupational Health Nurse Managers NHS Scotland Group as the two relevant professional bodies:

- Laboratory test results required for clearance for performing EPPs must be derived from *an identified, validated sample (IVS)*. Results should not be recorded in occupational health records if not derived from an IVS.
- An IVS is defined according to the following criteria:
  - The healthcare worker should show a proof of identity with a photograph - NHS Board identity badge, new driver's licence, some credit cards, national identity card or passport - when the sample is taken.
  - The sample of blood should be taken in the occupational health department.
  - Samples should be delivered to the laboratory in the usual manner, not transported by the healthcare worker.
  - When results are received from the laboratory, the occupational health record should be checked for a record that the sample was sent by the occupational health department at the relevant time.

Questions for Registration Renewal[48] which answers questions that physicians may have about the College's BBV policy. It includes the following question and answer:

"Why do you require periodic testing for BBVs?

In the absence of a firm testing requirement, we found that physicians were not routinely testing despite their ethical obligation to know their serologic status. Testing allows physicians to monitor and safeguard their own health. As well, periodic testing will reassure the public that the profession is doing everything possible to ensure public and physician safety."

17.23. Possible perspective of vested interest

There is a risk that the medical profession could be seen as, and could be presented by others as, having a vested interest in the policies that UKAP has developed and that patient safety and the rights of patients to know about risks that they may have been exposed to have not been prioritised.

17.24. Enhanced testing recommendation made by ABUHB

Aneurin Bevan University Health Board recommended what they described as an enhanced testing policy after the hepatitis C PNE that it conducted in 2013[49].
"Health Boards should ensure that all HCWs performing Exposure Prone Procedures (EPPs) receive enhanced checks for Blood Bourne Viruses. This is particularly important if initial NHS employment in the Health Board occurred before enhanced screening guidance was introduced."

The policy that was being advocated in light of the incident that Aneurin Bevan University Health Board had managed was different from the national policy suggesting that it did not consider the national policy to be adequate.

17.25. Points made during presentation by the former UKAP Medical Secretary

In a presentation given to HEOPS (Higher Educational occupational Physicians and Practitioners) in April 2016 by Dr Ncube[50], who was at the time the UKAP Medical Secretary, Dr Ncube presented a slide in relation to the change to HIV infected EPP HCW policy introduced in January 2014[51] and how the new policy would lead to EPP

[48] www.cpso.on.ca/CPSO/media/documents/Policies/Policy-Items/BBV-FAQ.pdf

[49] www.cardiffandvaleuhb.wales.nhs.uk/sitesplus/documents/1143/1.20%20Hepatitis%20C%20Review%20QSE%20Jan%2015%20DRAFT%20v2.pdf

[50] http://www.heops.org.uk/BBV_Presentation_Fortune_Ncube_April_2016.pdf

[51]

HCWs coming forward for testing earlier if they thought they had HIV infection or had been exposed to a risk of acquiring it.

"Benefits to the wider NHS

Earlier testing amongst HCWs that carry out EPPs has additional public health and cost benefits:

- Avoids onward transmission
- Reduces the number (and extent) of PNE
- Retains qualified and skilled HCWs in the career they have trained for
- Avoids legal challenges
- Reduces the fear amongst HCWs of HIV and the potential for transmission from HCW to their patient"

Dr Ncube also made the following point:

"Many employers going beyond policy, testing existing EPP HCWs."

17.26. Inconsistent national policy in practice

It would appear that practice with regards to testing EPPs HCWs for BBVs has become inconsistent. This may be because the positions, perspectives and needs of health authorities may not be fully understood and appreciated by those who have responsibility for developing and reviewing policy. A national policy may exist in that there may be a document that details what the national advisory bodies consider the policy should be, however, if trusts and health boards do not have confidence that the national policy is adequate and adopt an enhanced approach there is effectively no coherent national policy in practice.

NHS Lanarkshire will wait to see if UKAP accepts the recommendation to review current policy on the testing of HCWs who carry out EPPs for BBVs. If UKAP does not accept the recommendation NHS Lanarkshire will consider further whether any enhancement of local policy is required. If UKAP does accept the recommendation NHS Lanarkshire will wait to see the findings of the policy review before deciding on any changes that may be required to local policy.

The various points made above lead to the following recommendation:

Recommendation 10
UKAP should work with the Expert Advisory Group on AIDS, the Advisory Group on Hepatitis, and the four UK Departments of Health to review the

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The Management of HIV infected Healthcare Workers who perform exposure prone procedures: updated guidance, January 2014. UK Departments of Health. Public Health England. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/333018/Management_of_HIV_infected_Healthcare_Workers_guidance_January_2014.pdf

current policy regarding the testing of healthcare workers who perform exposure prone procedures for blood borne viruses.

The following perspectives should be considered:

- The health and safety of patients.
- The expectations of members of the public.
- The health and safety of HCWs who perform EPPs.
- The well-being of partners and relatives of HCWs who perform EPPs.
- The duties of employers under the Health & Safety at Work Act.
- The financial risk that employers may be exposed to if their health and safety policies and practice fail to provide adequate protection to their employees.
- Current policy and practice in other countries which have highly developed healthcare systems which promote best practice and value patient and employee safety and well-being regarding testing of HCWs who perform EPPs.
- The duties of doctors[52], nurses and midwives[53], and other HCWs in relation to their respective professional standards.
- Patient safety programmes[54].
- Current enhanced practice by "many employers" across the UK.

The review should be conducted in an open, transparent and inclusive way and when completed the findings of the review and the basis for continuing or revising policy should be published.

The review group should include representation from the following groups and organisations:

- Patients / service user representatives
- Members of UKAP, EAGA, and AGH
- General Medical Council
- Nursing and Midwifery Council
- Academy of Royal Medical Colleges and Faculties
- Royal Colleges of Surgeons
- Faculty of Occupational Medicine
- BMA
- Royal College of Nursing
- Confederation of NHS Employers
- Health & Safety Executive

The rationale for including representation from the General Medical Council arises from its role which is described as follows on its website[55] :

[52] http://www.gmc-uk.org/guidance/good_medical_practice/duties_of_a_doctor.asp
[53] https://www.nmc.org.uk/standards/code/
[54] http://www.scottishpatientsafetyprogramme.scot.nhs.uk/

"We are an independent organisation that helps to protect patients and improve medical education and practice across the UK.

- We decide which doctors are qualified to work here and we oversee UK medical education and training.
- We set the standards that doctors need to follow, and make sure that they continue to meet these standards throughout their careers.
- We take action to prevent a doctor from putting the safety of patients, or the public's confidence in doctors, at risk.

Every patient should receive a high standard of care. Our role is to help achieve that by working closely with doctors, their employers and patients, to make sure that the trust patients have in their doctors is fully justified."

The review should include representation from the Health & Safety Executive so that expert opinion can be provided about the strengths and weaknesses of current guidance and where it may need to be developed. In particular, an opinion should be provided by the HSE as to whether, given evidence available in the scientific literature of the failure or non-implementation of control measures by some HCWs, regular testing for BBVs of HCWs who carry out EPPs is required in order to comply with the health surveillance duties of employers under Control of Substances Hazardous to Health Regulations 2002 (as amended)[56].

Factors which may affect the prevalence of BBV infection among the current and future work force of HCWs who carry out EPPs should be considered. For example, changes in sexual health and practice, injecting drug use, tattooing, country of origin, sex of HCW and expected duration of EPP career.

Consideration should also be given to protected characteristics[57] that HCWs who perform EPPs may have as these may influence decisions made regarding compliance with policy.

18. Health surveillance

The Health and Safety Executive published the most recent edition of *The Approved List of biological agents*[58] in 2013 for the purposes of the Control of Substances

[55] www.gmc-uk.org/about/role.asp
[56] http://www.hse.gov.uk/pubns/priced/l5.pdf

[57] www.equalityhumanrights.com/en/equality-act/protected-characteristics
[58] www.hse.gov.uk/pubns/misc208.pdf

Hazardous to Health Regulations 2002 (SI 2002/2677). The Approved List provides the approved classification of biological agents as referred to in COSHH. A biological agent is assigned to a group according to its level of risk of infection to humans.

Hepatitis C, hepatitis B and HIV are all classified as being in human pathogen hazard group 3. The definition for this hazard group is "Can cause severe human disease and may be a serious hazard to employees; it may spread to the community, but there is usually effective prophylaxis or treatment available."

Health surveillance is covered by Chapter 11 of the COSHH Approved Code of Practice and guidance (2013)[59].

The regulation states that:

(2) *Health surveillance shall be treated as being appropriate where –*

(a) *the employee is exposed to one of the substances specified in Column 1 of Schedule 6 and is engaged in a process specified in Column 2 of that Schedule, and there is a reasonable likelihood that an identifiable disease or adverse health effect will result from that exposure; or*

(b) *the exposure of the employee to a substance hazardous to health is such that –*
(i) *an identifiable disease or adverse health effect may be related to the exposure;*
(ii) *there is a reasonable likelihood that the disease or effect may occur under the particular conditions of his work; and*
(iii) *there are valid techniques for detecting indications of the disease or effect,*

and the technique of investigation is of low risk to the employee.

The Guidance states that the objectives of health surveillance are to:

- check the health of individual employees by detecting, as early as possible, adverse changes which may be caused by exposure to substances hazardous to health;

- collect, keep up-to-date and use data and information for determining and evaluating hazards to health so that action can be taken to prevent more serious disease from developing;

- check control measures are working effectively by providing feedback on the accuracy of the risk assessment and the effectiveness of control measures to identify where further steps to manage risk are needed.

The Approved Code of practice gives examples of where health surveillance is appropriate under the criteria in regulation 11(2)(b):

- where there have been previous cases of work-related ill health in the workforce/place;

[59] www.hse.gov.uk/pubns/priced/l5.pdf

- where there is reliance on PPE, for example, gloves or respirators, as an exposure control measure; for example, printers wearing gloves to protect against solvents used during press cleaning, or paint sprayers using two-pack paints wearing respirators to prevent asthma. Even with the closest supervision there is no guarantee that PPE will be effective at all times;

The need for health surveillance of HCWs who carry out EPPs and who may be exposed to hepatitis C, hepatitis B and HIV is stronger than the case may be for health surveillance of other biological agents as infection with a BBV may not lead to a healthcare worker developing symptoms which would lead to the diagnosis of one of these infections and the HCW may have chronic infection leading to severe morbidity and death.

19. Promoting the health and safety of NHS Lanarkshire EPP HCWs

Review of the scientific literature, of legislation and of the Health & Safety Executive Approved Code of Practice and Guidance regarding COSHH has highlighted that it may be possible for NHS Lanarkshire to carry out targeted work to support HCWs who carry out EPPs, over and above work that is already ongoing.

Recommendation 11

The NHS Lanarkshire occupational health and safety service, Salus, should review the costs and benefits of establishing and maintaining a list of NHS Lanarkshire healthcare workers who carry out exposure prone procedures.

Such a list could be used to:

- Provide assurance that all appropriate actions have been taken for such HCWs including, where appropriate:
    - Testing for blood borne viruses.
    - Hepatitis B vaccination.
    - Post-hepatitis B vaccination titre level testing.
    - Regular testing for hepatitis B markers for HCWs who do not show development of immunity following vaccination.
    - Registration on the UKAP Occupational Health Register.
- Provide such HCWs with BBV exposure prevention and management education and training resources:
    - To increase knowledge and understanding of measures that can be taken to prevent BBV exposure incidents occurring.
    - To develop a positive culture of prevention and also of reporting exposures which do occur.
    - To highlight the importance of incident reporting with regards to system learning from incidents and the protection of work colleagues through the prevention of incidents.

- Promote testing for BBVs among such HCWs who have sustained a BBV exposure
    - By providing education and training about reporting exposure incidents and the importance of being tested for the HCW, their family, patients and work colleagues.
    - By providing information about the availability of highly effective treatment for HIV and hepatitis C infections and the effective treatment that is available for chronic hepatitis B infection.
    - By informing such HCWs of the regulations that permit HCWs to continue to perform EPPs even if they have HIV or hepatitis B infection as long as certain criteria are met on an ongoing basis.
    - By providing information about the practice of under-reporting and the factors which promote under-reporting.
- Provide evidence of compliance with aspects of COSHH with regard to such HCWs
- Enable discussion and other interactions between such HCWs and members of staff with responsibility for implementation of BBV exposure prevention and management policy.
    - To identify education and training needs.
    - To review opportunities for processes to be redesigned, and practice to be altered, in order to prevent exposures happening or lessen the likelihood of them happening.

20. Opportunity for UKAP leadership, research and evaluation

This report advocates that UKAP should review the evidence and rationale for developing policy so that:

- Patients who have been exposed to a risk of BBV infection during an EPP from a HCW who has subsequently been found to have a BBV infection, but who was not known to the healthcare service at the time of the EPP to have a BBV infection, are informed of the risk and advised that a) testing is not recommended or b) testing is recommended.
- HCWs who perform EPPs are tested regularly for hepatitis C and HIV infection; and also for hepatitis B if they do not have evidence of hepatitis B immunity and hepatitis B non-infectiousness.

This report provides the impetus for UKAP to demonstrate leadership and make these strategic decisions proactively rather than pass on this opportunity and be required, at some stage in the future, to make them reactively. There is an opportunity for UKAP to direct a five to ten year programme of work which would lead to an end to patient notification exercises which need to cover longer than the period of time decided for regular testing of EPP HCWs. With a proactive approach

the process of change could be managed effectively and efficiently. In addition a research and evaluation programme could be developed in order to maximise learning opportunities both during a phase of implementing new policy and when a new policy steady state position is reached.

21. Table of recommendations

The recommendations that the Incident Management Team has made in the previous sections of the report have been collated in the table below. The recommendation number is hypertext linked to the part of the report that the recommendation has been taken from.

No.	Recommendation	To
1	NHS Lanarkshire and Health Protection Scotland should collaborate to analyse factors influencing the uptake of testing.	NHSL, HPS
2	[redacted]	UKAP
3	NHS Lanarkshire should offer to work with UKAP to contribute to the development of the UKAP toolkit using the knowledge, understanding and resources developed by NHS Lanarkshire during the preparation for and delivery of the PNE.	NHS Lanarkshire
4	National Services Scotland should consider how best to note and make relevant members of staff aware that prior to 1987 the [redacted] that a patient was admitted under was coded using the [redacted] national insurance number (or a coded version of this) and not, as currently, the [redacted] number.	National Services Scotland
5	UKAP should link with the Expert Advisory Group on AIDS, the Advisory Group on Hepatitis, and the four UK Departments of Health to review the current policy of non-disclosure to patients of information about levels of risk which have been assessed as being very low or very, very low.	UKAP
6	UKAP should consider how best to engage with patients and members of the public in order to inform policy development and in order to make UKAP policy and the process of policy review and development open, honest and transparent.	UKAP
7	UKAP should consider whether recurrent record linkage exercises should be advocated when a hepatitis C infected healthcare worker is identified and a PNE is not advised.	UKAP
8	UKAP should consider whether to seek representation from the Association of Directors of Public Health and/or from a health protection team consultant in communicable disease control or a consultant in public health medicine.	UKAP

No.	Recommendation	To
9	Health Protection Scotland should work with NHS Boards, including NHS Lanarkshire, and with National Records Scotland to review issues that may arise during public health incidents in relation to data sharing and data linking, within Scotland and with other UK countries and [redacted], which are not already covered by existing guidance and protocols.	Health Protection Scotland
10	UKAP should work with the Expert Advisory Group on AIDS, the Advisory Group on Hepatitis, and the four UK Departments of Health to review the current policy regarding the testing of healthcare workers who perform exposure prone procedures for blood borne viruses.	UKAP
11	The NHS Lanarkshire occupational health and safety service, Salus, should review the costs and benefits of establishing and maintaining a list of NHS Lanarkshire healthcare workers who carry out exposure prone procedures.	Salus (NHS Lanarkshire)

Listing of appendices by section

Section A: Incident investigation - 2008	
A.01	1. Letter of 15 August 2011 from Dr Logan on behalf of the NHS Lanarkshire Director of Public Health to Dr Ncube, UKAP Medical Secretary regarding UKAP case 08/26. 2. Completed UKAP enquiry *pro forma*. 3. A table listing the appendices referenced in the *pro forma* and in Dr Logan's 15 August 2011 letter. 4. Letter of 17 October 2011 from Dr Ncube to Dr Logan.
Section B: Further incident investigation - 2015	
B.01	8 October 2015 letter and report sent by Dr Logan to Dr Ncube
B.02	Letter of UKAP advice received by NHS Lanarkshire from Dr Ncube dated 25 November 2015
Section C: Preparation for the patient notification exercise	
C.01	IMT and sub-group membership
C.02	Examples of SBAR
C.03	Table detailing various documents produced
C.04	Letter to Lanarkshire residents, Appointment Booking Form and Questions and Answers document for patients
C.05	Testing clinics timetable
C.06	Reception procedure manual
C.07	Care home patient letter
C.08	Care home patients Questions and Answers
C.09	Care home patient – guardian consent form
C.10	Care home manager cover letter
C.11	Care home manager information sheet
C.12	Email to GPs
C.13	Flow diagram for primary care receptionists
C.14	Strategy to identify patients at risk of hepatitis C
C.15	NHS Lanarkshire and NHS24 Service Level Agreement
C.16	Questions and Answers document prepared for NHS24
C.17	Training schedule
C.18	Equality and diversity impact assessment
Section D: Delivery of the patient notification exercise	
D.01	HCW Incident Communications Plan
D.02	FirstPort intranet home page banner
D.03	Press Release
D.04	Media Distribution list
D.05	Press conference invitation
D.06	Media handling schedule
D.07	Photograph of members of the press conference panel
D.08	Media coverage report
D.09	NHS Lanarkshire public website home page link to hepatitis C information
D.10	NHS Lanarkshire public website – incident home page
D.11	NHS Lanarkshire public website – link to updates
D.12	NHS Lanarkshire public website – link to videos
D.13	Advice on management of incident email account
D.14	Example of situation report

D.15	Guidance on the process of producing a situation report
D.16	Health records search strategy
Section E: Follow up to the patient notification exercise	
E.01	Letter to members of staff from the Board Chair and Chief Executive
Section F: Discussion and recommendations	
F.01	Opinion piece in The Herald newspaper
F.02	Paper produced by Hepatitis Scotland

END