Witness Name: William Wright
Statement No.: WITN2287019
Exhibits: WITN2287020 –
WITN2287086
Dated: 15th April 2021

INFECTED BLOOD INQUIRY

EXHIBIT WITN2287054

The Penrose Inquiry Recommendation

Report of a Scottish Government Commissioned Short-Life Working Group

Final Copy for submission to the Scottish Government on 08/07/2016

August 2016

Scottish Government
Riaghaltas na h-Alba
gov.scot

Contents

Short-Life Working Group Report on the Penrose Inquiry Recommendation

1 Introduction

On 18th April 2006, the Health Committee of the Scottish Parliament called for a Public Inquiry into the infection of people with Hepatitis C (HCV) from NHS treatment. The then Scottish Executive decided not to hold an Inquiry but the Scottish National Party made a commitment in its 2007 Manifesto to hold such an Inquiry if elected to form the Government in Scotland.

On 23 April 2008, the Cabinet Secretary for Health and Wellbeing made a statement to the Scottish Parliament, announcing the establishment of the promised Inquiry which would examine the circumstances in which the infections occurred, up to the introduction for a test for Hepatitis C in donated blood in 1991. A Judicial Review, challenging the original decision by the Scottish Executive, was critical in securing the Penrose Inquiry.

The Cabinet Secretary confirmed that the Inquiry would also examine infection with HIV in the course of NHS Treatment in Scotland. The Inquiry was to be chaired by Lady Cosgrove but, in September 2008, she withdrew for family reasons and Lord Penrose was appointed to succeed her.

The Penrose Inquiry, published on March 25, 2015, concluded that there will be people in Scotland who received transfusion of blood or blood components from a donor who was HCV-positive in the period before the introduction of screening for the virus and who acquired HCV but have not yet been diagnosed. The Inquiry therefore recommended "**that the Scottish Government takes all reasonable steps to offer an HCV test to everyone in Scotland who had a blood transfusion before September 1991 and who has not been tested for HCV**".

In light of the Penrose Inquiry recommendation, the Scottish Government recommended that a Short-Life Working Group, involving key stakeholders including those from the Scottish Government and the Scottish National Blood Transfusion Service, be established by Health Protection Scotland.

2 Terms of Reference of the Short-Life Working Group

- To assess the extent of the problem – i.e. estimated numbers of living HCV-infected individuals who acquired their infection through blood transfusion in the

UK pre-1991 and who remain undiagnosed and the estimated number of living HCV-infected individuals who acquired their infection through the receipt of plasma products pre-1987 and who remain undiagnosed.

- To monitor the impact of the media coverage, following the publication of the Penrose Report and its recommendation, on HCV testing uptake and HCV positive yield in the relevant population.
- To review past and current interventions to promote the diagnosis of HCV-infected individuals as above.
- To consider if any further national/centralised action should be taken to identify such individuals in the context of action already taken and the likelihood of appreciable benefits.
- To oversee the implementation of any additional national/centralised intervention if such an intervention is recommended by the Working Group and approved by Scottish Government.

3 Executive Summary

- The Penrose Inquiry, published on March 25, 2015, recommended "that the Scottish Government takes all reasonable steps to offer an HCV test to everyone in Scotland who had a blood transfusion before September 1991 and who has not been tested for HCV".
- A Short-Life Working Group (SLWG), established by the Scottish Government, was asked to consider what specific actions should be taken in the context of the Inquiry recommendation. The SLWG's response to each of its terms of reference is as follows:
- **To assess the extent of the problem - i.e. estimated numbers of living HCV infected individuals who acquired their infection through blood transfusion in the UK pre-1991 and who remain undiagnosed and the estimated number of living HCV infected individuals who acquired their infection through the receipt of plasma products pre-1987 and who remain undiagnosed.**

    - The Penrose Inquiry Report provided an estimate of the number of people who had acquired HCV infection through blood transfusion pre-September 1991 - "around 2500" - but it did not provide an estimate of the number of HCV infected people who were still alive and undiagnosed. The SLWG undertook further work to generate such estimates; to avoid the potential for underestimating the scale of the problem, a precautionary approach was taken when factoring in assumptions used in the analytical work.

    - It is estimated that:

(i) approximately 100,000 people who received a blood transfusion pre-1991 in Scotland are still alive;
(ii) approximately 100 of these 100,000 (0.1%) are HCV infected[1];
(iii) around 30 of the 100 remain undiagnosed.

- It is unknown what proportion of the 100,000 people, who received a transfusion pre-1991 and are still alive, have been offered an HCV test and what proportion of these have been tested.

- Between 0 and 71 people with a mild blood factor disorder who received occasional plasma product treatment, may still be alive and not have been offered an HCV test.

- **To monitor the impact of the media coverage, following the publication of the Penrose Report and its recommendation, on HCV testing uptake and HCV positive yield in the relevant population.**

  - Both the initiation and the publication of the Penrose Inquiry generated considerable high profile media attention, not least because statements on the Inquiry and its recommendation were made by the Prime Minister and Scotland's First Minister in the Westminster and Holyrood parliaments respectively. Additionally, a number of infected individuals and family members gave interviews about their predicament; in the context of what is a stigmatised condition, their courage is acknowledged and greatly appreciated.

  - During the three months following the Inquiry publication, it is estimated that at least 1,000 Hepatitis C tests were performed on people seeking a test because of concerns about a previous blood transfusion.

- **To review past and current interventions to promote the diagnosis of HCV-infected individuals who acquired their infection through blood transfusion pre-1991**

  - Numerous national and local initiatives - specifically designed to raise awareness among both professionals and the public about the risks associated with Hepatitis C acquisition and the benefits of getting tested - have been undertaken over the last 25 years. All or nearly all

[1] See last paragraph 6.1.3

have made reference to blood transfusion risk pre-September 1991 but none have solely targeted this population.

- Further, Scotland's Hepatitis C Action Plan - one of the world's most comprehensive government sponsored programmes to develop services for those infected with, and at risk of acquiring, Hepatitis C made the infection and associated disease a special public health issue in Scotland; accordingly, many awareness raising spin-offs have stemmed from the enormous amount of investment and activity connected with the Plan since 2008.

- **To consider if any further national/ centralised action should be taken to identify such individuals in the context of action already taken and the likelihood of appreciable benefits.**

  - The SLWG fully acknowledges the importance of ensuring that anyone still alive and infected with Hepatitis C as a consequence of blood transfusion pre-September 1991 should be given the best possible chance of taking advantage of the stunning new advances in treatments which are safe, easy to administer and highly effective. Taking account of the Inquiry's recommendation that any steps to offer an HCV test to such individuals should be "reasonable", the SLWG also recognised the need to ensure that any new intervention(s) are optimally cost-effective and proportionate in the context of the scale of the problem.

The SLWG unanimously agreed on the following:

- **Delivering a targeted awareness campaign focussed <u>solely</u> on individuals who received a blood transfusion pre-September 1991**

  This awareness campaign should aim to reach all targeted individuals through the use of traditional (e.g. leaflets and posters) and more modern (e.g. social media) approaches. Such approaches recognise that an appreciable minority of people do not access information from more traditional sources. The details surrounding the design and implementation of the campaign would be worked on following any such Scottish Government approval. The SLWG agreed that any such campaign should be evaluated to determine its impact.

- **The identification and written offer of an HCV test to a group of (up to 71) plasma product factor recipients who are as yet not known to have been HCV tested.**

- **A Chief Medical Officer letter should be sent to all clinicians in Scotland to remind them of certain risk factors (including pre-September 1991 blood transfusion and injecting drug use) and clinical (including otherwise unexplained Alanine Aminotransferase liver enzyme level) indicators for HCV infection and making them aware of the recent advances in therapy and thus the benefits of HCV testing.**

4 Membership of the Short-Life Working Group

See Appendix 1.

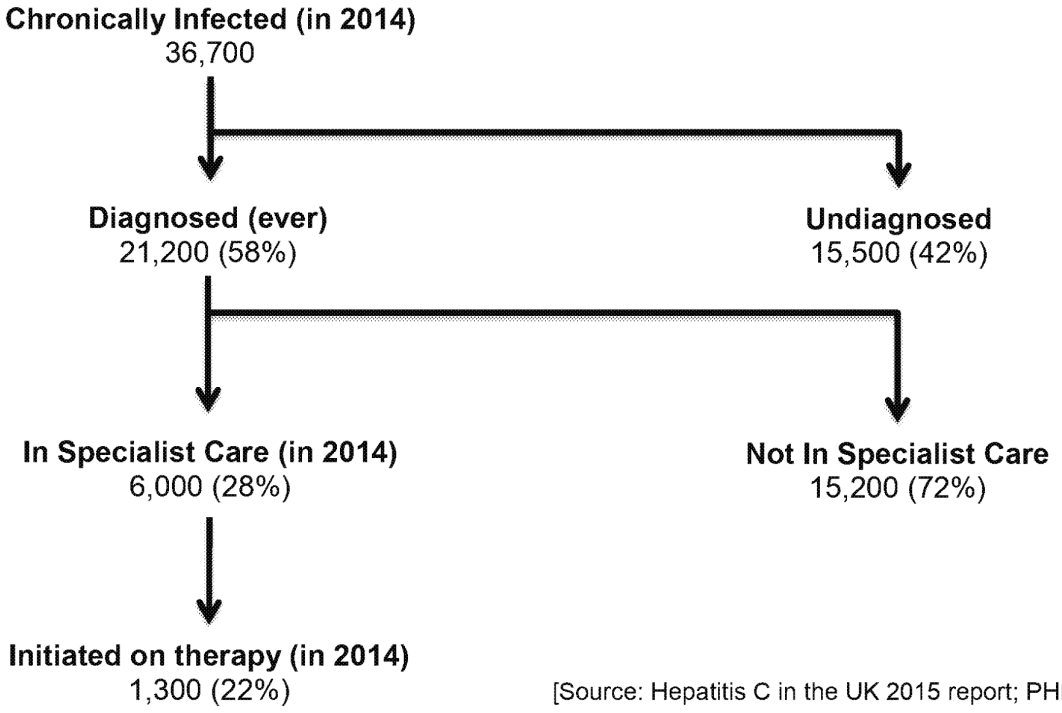
5 Background

5.1 Hepatitis C: Key facts

5.1.1 General

- Between 100 and 200 million people worldwide are infected with Hepatitis C. In the EU the figure is around 6 million; in the UK 214,000 and in Scotland 37,000.
- In resource-rich countries, injecting drug use is the principal route of Hepatitis C transmission while in resource-poor ones, sub-optimal infection control associated with healthcare procedures is the main cause.
- 8-16% of people infected with Hepatitis C for 20 years have cirrhosis of the liver. Disease progression is accelerated by, in particular, excessive alcohol consumption and HIV co-infection. People who acquired their HCV through blood transfusion, generally, have a disease progression rate at the lower end of the spectrum, probably because they tend to have less liver disease co-morbidities such as excessive alcohol consumption.
- Hepatitis C's role in causing serious illness and death from cancer or liver failure is well recognised but infection is also associated with non-liver related disease and psycho-social morbidity.
- Prevention of Hepatitis C is dependent on interrupting routes of transmission. A vaccine is unavailable and is unlikely to become available in the near future.
- Diagnosis of Hepatitis C is imperative to allow people to be assessed for treatment but also provides an opportunity to drive home behavioural change messages in terms of preventing onward transmission of infection (especially among people who inject drugs) and reducing the risk of disease progression (e.g. warnings about the dangers of excessive alcohol consumption).
- The efficacy of antiviral treatments which eradicate HCV infection has increased dramatically over the last 20 years; oral safe, short duration therapies with cure rates of over 90% will be available for all major genotypes in 2016.

5.1.2 Scotland: Estimates for Scotland's HCV Chronic Population



[Source: Hepatitis C in the UK 2015 report; PHE 2015]

5.2 Scottish Government Response to Hepatitis C

2006: Launch of Scotland's Hepatitis C Action Plan Phase I: Development of a case for investment in Hepatitis C service provision.

2008: Launch of Scotland's Hepatitis C Action Plan Phase II: Investment of £43 million for Hepatitis C prevention, diagnosis and care services during 2008-11.

2011: Launch of Scotland's Sexual Health & Bloodborne Virus Framework (Phase I) incorporating continued investment in Hepatitis C services and adopting an outcome indicator approach to monitoring the impact of the investment.

2014: The establishment of Scotland's HCV Treatment & Therapies Group to generate guiding principles for service providers and users in the era of new highly effective antiviral therapies.

2015 Launch of Scotland's Sexual Health & Bloodborne Virus Framework (Phase II) incorporating continued Hepatitis C service investment, the employment of which is to be steered by the principles generated by the Hepatitis C Treatment & Therapies Group.

5.3 Impact of Scotland's Response to Hepatitis C and the Challenges Ahead

During 2006/07-2014/15:

- An estimated 50% reduction in the annual number of new HCV infections from 1,500 to 750.
- An increase in the proportion of the total estimated infected population who are diagnosed, from 38% to nearly 60%.
- A four-fold increase in the number of new initiates onto antiviral therapy annually from 450 to approximately 1600.
- An overall reduction in the estimated number of people infected from 38,000 to near 36,000; the figure probably would have been around 42,000 if there had been no response since 2006.

However, very considerable challenges exist:

- The annual number of new presentations of HCV-related liver failure/hepatocellular carcinoma (HCC) increased from 100 to 190; approximately 40% occurred in people who had been HCV diagnosed within five years of presentation.
- 15,500 infected people, a high proportion of whom are older, former people who inject drugs (PWID) with moderate or severe liver disease, remain undiagnosed.
- Most (near 75%) diagnosed HCV infected people are not in specialist care.
- Near 10,000 infected people likely have either cirrhosis of the liver (stage F4) or are in the pre-cirrhotic stage (F3) and, thus, are in urgent need of therapy; most are undiagnosed or are not in specialist care.
- Optimal therapies, while highly cost-effective for those with F3/F4 liver disease, are costly, particularly in the context of large numbers of such individuals being eligible for therapy now.

6 Response to each of the Terms of Reference of the Short-Life Working Group

6.1 To assess the extent of the problem – i.e. estimated numbers of living HCV-infected individuals who acquired their infection through blood transfusion in the UK pre-1991 and who remain undiagnosed.

6.1.1 Number of people who received a blood transfusion pre-September 1991 and are still alive

The Scottish National Blood Transfusion Service (SNBTS) estimates that 93,600 people who received a blood transfusion before-September 1991 were still alive in 2015. This figure is a best estimate, based on incomplete data; it is possible that an error of 10 - 20% in either direction exists (See Appendix 2 for detail). The estimate is based on (i) an estimate of the proportion of Scotland's population transfused, based on SNBTS data, and (ii) an estimate of the life expectancy of people transfused at the time of transfusion, based on General Registry Office life expectancy data for the general population. To ensure that any potential for underestimating the scale of the problem was minimised the figure of 93,600 was rounded up to 100,000.

6.1.2 Number of people who received a blood transfusion pre-September 1991, are still alive but have not been tested for HCV.

It is not possible to estimate, with any degree of accuracy, the proportion of the 100,000 people who received a blood transfusion in Scotland prior to September 1991 and who are still alive and have been tested for HCV. It is likely that a small proportion of these people will no longer be living in Scotland, but this is likely to be offset by people from, in particular, the rest of the UK now living in Scotland. The 2007 SIGN (Scottish Intercollegiate Guideline Network) Guidelines on the management of Hepatitis C recommend that people who had a blood transfusion pre-1991 should be offered an HCV test. However, data from surveys of HCV testing practice among general practitioners in Scotland in 2007 and 2013 indicate that few i) determine if a patient received a blood transfusion pre-September 1991 and, thus, ii) offer an HCV to such individuals. It is uncertain why such practice does not happen to any appreciable extent but it may be partly because the (correct) perception among general practitioners is that the prevalence of infection among the transfused population is extremely low. General Practitioners have not been resourced to perform a significant case finding exercise for these people.

In the absence of evidence indicating what proportion of the 100,000 have been HCV tested the SLWG considers it reasonable to assume - again, for the purposes of avoiding any underestimation of the size of the task - that almost all have not been tested. Accordingly, this assumption would correspond to an average of 17 from the average patient list (1,142) of a general practitioner.

6.1.3 Number of people who received a blood transfusion pre-September 1991, were infected with HCV and are still alive. (Figure 1)

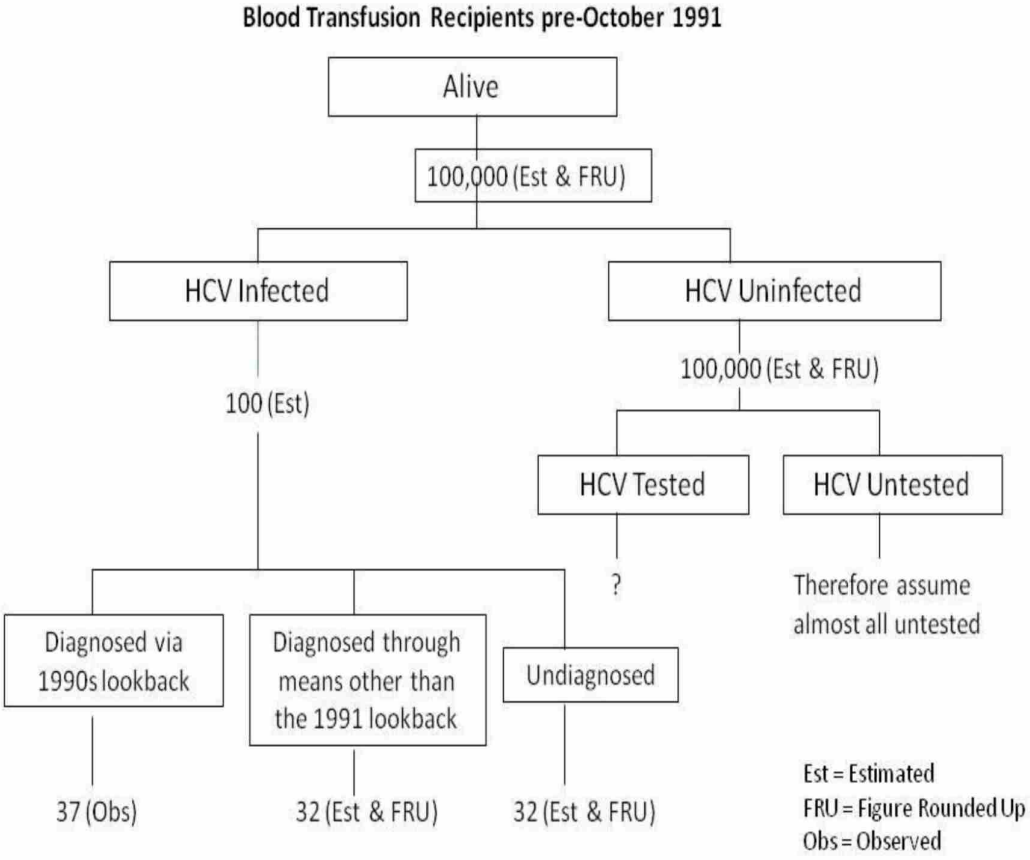
How many of the estimated 100,000 people who received a blood transfusion in Scotland prior to September 1991 and are still alive were infected with HCV as a consequence of blood transfusion? While Scotland does have a database of all HCV antibody positive people diagnosed in Scotland and a database of nearly all HCV-infected people in specialist care, available information on how people became infected is often suboptimal. Where a history of injecting drug use is recorded, one can be fairly confident that this behaviour was the means through which HCV was acquired. Where blood transfusion is recorded as the risk, in most instances no validation has been undertaken to ascertain if a transfusion was received, where and when it was received, and whether or not the transfused blood was sourced from an HCV RNA positive donor; this is why, for a few hundred living HCV-infected individuals in Scotland, "blood transfusion" is recorded as a possible risk factor.

Accordingly the number of infected individuals is very difficult to estimate; however, we know that the proportion of people receiving a blood transfusion during January – September 1991 who acquired HCV was approximately 1 in 1500; this proportion is based on the observation that 159 of 180,000 (0.088%) donors tested for HCV antibodies by SNBTS during September 91 – February 92 were antibody positive and that an estimated 119 of 180,000 were viraemic on the assumption that 25% of antibody positive individuals would have spontaneously cleared their HCV. It is unlikely that, for any year prior to 1991, the proportion was higher than 1 in 1000 – taking into account both the HCV preventing impact (among donors) of implementing, in 1984, the exclusion of high risk individuals for blood donation and the HCV promoting impact (among donors) of the rapidly increasing prevalence of HCV in the population of Scotland throughout the 1980s. If a 1 in 1000 proportion (i.e. worst case scenario) is assumed, then approximately 100 of the 100,000 individuals transfused prior to September 1991 and still alive are infected.

It is acknowledged that considerable uncertainty surrounding this estimate exists. As at November 2015, 344 living people from Scotland, still alive, had received a payment from the Skipton Fund because it was considered that on the balance of probabilities they had acquired HCV infection through a blood transfusion pre-September 1991.

Figure 1

Estimated Number of People who i) received and ii) became infected as a consequence of, a Blood Transfusion Pre October 1991 and are still alive



6.1.4 Number of people who received a blood transfusion pre-September 1991, were infected with HCV and are still alive and have not been tested.

The proportion of the estimated 100 who had been HCV tested and diagnosed will bear no relation to the proportion of the uninfected people having been tested because of the much greater likelihood of an infected, compared to an uninfected, person being tested. This is because of a) the, albeit not fully comprehensive, lookback exercise of the mid 1990s which identified 85 individuals alive at that time who definitely were infected as a consequence of blood transfusion in Scotland pre-September 1991, b) the practice of HCV testing of people in hospital or in the community who have abnormal liver function tests – in particular a raised Alanine Amino transferase (ALT) enzyme (note that the 2006/7 SIGN Guidelines on the management of Hepatitis C recommended that anyone with an otherwise unexplained raised

ALT should be HCV tested), c) the HCV testing of people who present clinically with symptoms and signs suggestive of liver disease and, d) the HCV testing of the more at risk transfusion recipients with conditions requiring multiple transfusions; such individuals, because of their underlying conditions may be more likely to be no longer alive but some, especially younger people, will still be living.

So, even if only a small proportion of the 100,000 people estimated to have had a blood transfusion pre-September 1991 and still alive, have been tested for HCV, a much larger proportion of those infected as a consequence of transfusion pre-1991 will have been diagnosed already.

If we assume 100 infected people, having acquired their HCV infection in Scotland as a result of blood transfusion pre-1991, are still alive in Scotland, it is likely that well over 50% of these will have been diagnosed; this is because the number of infected people diagnosed through the lookback exercise, and still alive in 2014, is 37 and an unknown number of others will have been diagnosed as a consequence of reasons b, c and d as above.

Accordingly, the number of undiagnosed HCV-infected people, having acquired their HCV in Scotland as a result of blood transfusion pre-1991, is within the range of 0 and 63 (where 0 assumes everyone is diagnosed and 63 assumes no cases over and above the 37 lookback ones have been diagnosed). As explained above, a proportion of the non-lookback cases will have been diagnosed. If we assume half of the 63 have been diagnosed, the figure is 32 (figure rounded up); this means that in the context of an estimated 100,000 untested individuals having had a blood transfusion pre-1991, the ratio of HCV infected to HCV uninfected individuals, not yet tested for HCV, is about 1 in 3000 (i.e. 32/100,000). This figure of 32 means that only 1 in 50 individual GPs will have one of these infected, undiagnosed people on their list.

6.1.5 Number of people who received a blood transfusion pre-September 1991, were infected with HCV and are still alive, have not been tested and have, or are likely to progress to severe liver disease.

Of the 32, the proportions of those with no, mild, moderate and severe disease are unknown; however it is possible that the majority of this undiagnosed cohort, currently, are more likely to belong to the milder end of the spectrum because of the greater chance of being diagnosed if one is symptomatic; that said, people with severe disease can remain undiagnosed because of lack of symptoms or failure to be tested despite symptoms.

6.2 Number of people who received plasma products pre-May 1987, were infected with HCV and are still alive but have not been tested.

Virtually all such individuals have been tested. A total of 478 persons with a bleeding disorder were identified as HCV infected; of these, 193 were alive as at March 2015. Group Members representing blood factor recipients indicated that a small number of people, with mild blood factor conditions, who only received occasional treatment, need to be traced and contacted; this work is being undertaken by Dr Campbell Tait in association with Health Protection Scotland and the Information and Statistics divisions of Public Health and Intelligence, National Services Scotland. The work involves securing approval to link identities from a list of individuals on a blood factor deficiency database held by clinicians, with a register of people currently assigned to a general practitioner in Scotland, and then making contact with "linked" people about Hepatitis C testing. For those individuals not known to be dead and not identified as being assigned to a general practitioner in Scotland, additional efforts to trace them will be undertaken.

6.3 What impact did the media response to the publication of the Penrose Inquiry have on HCV testing uptake and HCV positive yield in the relevant population? (Appendix 3)

The Penrose Inquiry Report was published on the 25th March 2015. That day, apologies to all those affected were made in UK and Scotland Parliaments by the Prime Minister, David Cameron and the Cabinet Secretary for Health and Wellbeing, Shona Robison, respectively. Additionally, a number of infected individuals and family members gave interviews about their predicament; in the context of what is a stigmatised condition, their courage should be acknowledged and greatly appreciated. The Report's conclusions and its only recommendation, regarding HCV testing, were the lead stories in most newspaper and TV news programmes. It is acknowledged that an appreciable minority of people do not access information through such media.

A letter from Scotland's Chief Medical Officer was sent, on 27th March, to all GPs in Scotland; it stated that "every effort should continue to be made to offer testing to anyone who may have been exposed to Hepatitis C via infected blood".

An analysis of HCV test data from three of Scotland's Health Boards: Lothian, Tayside and Grampian, was undertaken to examine the impact of the media response. During the 12 weeks before March 25, seven HCV tests, for which there was an indication (in accompanying blood sample report forms) of blood transfusion risk, were performed. During the 12 weeks after March 25, 400

HCV tests, for which there was a mention of blood transfusion and/or the Penrose Inquiry, were performed; females over the age of 50 were particularly represented. This figure is an underestimate as in many instances clinical details on request forms were either unavailable or may not have indicated the reason for the test being done. Less than five of the 400 HCV tests performed generated an HCV antibody positive result. No validation was undertaken to ascertain if the individual(s) had a blood transfusion in Scotland pre-1991 and, if so, whether or not the infection was acquired through blood transfusion. Extrapolating the 400 for Lothian, Tayside and Grampian to all Scotland would generate a figure of approximately 1,000. Note that figures here have been rounded up.

6.4 To review past and current interventions to promote the diagnosis of HCV-infected individuals who acquired their infection through blood transfusion in Scotland pre-1991.

- In 1995, a look back exercise was undertaken to identify transfusion recipients of blood from HCV antibody positive donors diagnosed following the introduction of the HCV antibody test in 1991; this initiative led to the identification of some but not all individuals infected with HCV as a consequence of transfusion.
- In 1999/2000, a Scottish Needs Assessment Report on Hepatitis C listed a range of population groups who should be offered an HCV test; the list included people who had received a blood transfusion pre-1991. In 2002, the Scottish Government distributed an educational Hepatitis C pack to general practitioners throughout the country; the list of people who should be offered a test, as above, was incorporated into the pack's literature.
- In 2006/07, SIGN Guidelines on the management of Hepatitis C were published; these included a list of people who should be offered an HCV test and within this list was "people who had received a blood transfusion pre-September 1991".
- In 2007, the Scottish National Party published, in its Manifesto, a commitment to hold an inquiry into "the infection of people with Hepatitis C from NHS Treatment"; in April 2008, the Cabinet Secretary for Health and Wellbeing made a statement to the Scottish Parliament announcing the establishment of the promised Inquiry. Once established, the Inquiry issued a public call for evidence inviting all interested parties to contact the Inquiry to provide statements. These announcements, accompanied by news stories and adverts, drew public attention to the issue.
- In 2009, within the context of the Scottish Government's Hepatitis C Action Plan, the Chief Medical Officer for Scotland sent a letter to GPs, outlining the at-risk groups (including the blood transfusion one) who should be offered an HCV test; the SIGN Guidelines, as above, were referred to.

- In 2010, the Scottish Government sponsored a national poster campaign involving, in particular, the placement of such materials on the sides of bus shelters.
- In recent years, the UK Hepatitis C Trust and Hepatitis Scotland have staged major awareness campaigns around, in particular, World Hepatitis Day (July 28th).
- In 2015, the publication of the Penrose Inquiry Report was a leading news story – one which generated, arguably, the greatest intensity ever experienced in Scotland of awareness-raising around the issue of Hepatitis C risk and blood transfusion pre-September 1991.
- Note that numerous local awareness-raising initiatives have been performed by NHS Boards over the years; most, however, have focussed attention on people who have injected drugs and/or people who have originated from high HCV prevalence countries.
- See 6.1.2 for an assessment of the impact of such transfusion specific guidance on HCV testing offer.

6.5 To consider if any further national/centralised action should be taken to identify such individuals in the context of action already taken and the likelihood of appreciable benefit.

The following appraisal of potential actions to identify infected, undiagnosed persons, was undertaken; each was assessed in terms of its practicality, effectiveness and cost.

6.5.1 Potential action: The retrospective testing of blood donor specimens Detail: see Appendix 4

- HCV testing of stored specimens from people who donated blood between 1984 and 1991.
- Following the identification and confirmation of HCV infected components, the tracing of recipients through hospital blood bank and patient records.
- For those who may have received such a donation, a further investigation to determine if they are still alive and, if so, are not already known to be HCV infected.
- Finally, the tracing of such individuals, making contact with them and then offering them an HCV test.

Practicality/effectiveness

- An enormous task involving an estimated 2 to 2.5 million specimens and associated paperwork which will need to be searched, tested and reconciled by hand. For comparison SNBTS currently tests around 250,000 samples per annum using automated testing and IT linkage.

- There are many issues with the reliability of the archive related to the integrity of the samples and records:
    - Linking tested samples to specific donors, components and the hospitals they were provided to is likely to be difficult and may not be possible in many cases due to the variety of paper-based and early IT systems used at the time.
    - The samples were collected in a variety of different formats in different centres and have been stored under a variety of conditions over a long period of time. In addition, assay methodologies have not been optimised for this nature. Therefore the quality of the samples and the integrity of the results cannot be guaranteed.
    - Hospital record retention does not extend back to the 1984-1991 period and it would be unlikely that patients who received specific components could be identified (or traced).
    - An effort would also need to be made to trace test positive donors to inform them and carry out confirmatory testing. Most of these people will no longer be blood donors and may have moved or themselves be deceased.
- This would be a major exercise, incurring significant costs and requiring 6 - 7 or more years to complete.
- A break in the chain of traceability in any of the above areas would negate the benefit of testing. In reality there are significant weaknesses in all areas. The likelihood of being able to trace significant numbers of infected patients through this route is small.

Cost

- £8 - 10 million not including the costs of patient tracing.

6.5.2 Potential Action: The interrogation of clinical records to determine blood transfusion history

Detail

- The interrogation of all GP or hospital records of individuals born before 1991 to determine who had received a blood transfusion pre 1991 and were still alive.

Practicality/Effectiveness

- The mostly manual investigation of case notes of all people in Scotland before 1991
- It is likely that many records for the period pre 1991 no longer exist

- Information indicating whether or not someone had been transfused may not have been communicated to the GP
- In the context of an estimated 93,600 living people having received a blood transfusion pre-September 1991 and around 29 of them having undiagnosed HCV infection - effectiveness likely to be extremely low.

Cost

- Probably millions of pounds for administrative/ clerical activity.

6.5.3 Potential Action: Notifying all GP patients about the pre-1991 transfusion risk

Detail

- A letter from GPs to all patients asking them if they had received a blood transfusion pre 1991 or if they had a condition which conveyed a high risk of transfusion.
- Offering those saying "yes" to either of the above, a hepatitis C test

Practicality/Effectiveness

- Essentially writing to all adults in Scotland over the age of 25.
- Very considerable uncertainty about the number of people who might respond to the ask; many might not know or remember having had a transfusion.
- Potential to create unnecessary anxiety amongst the population leading to requests for reassurance from the worried well.
- Probably only a minority of the total number of individuals transfused and not tested before, plus an unknown number of people who thought they might have had a transfusion but did not, would be tested
- Effectiveness probably low.

Cost

- Probably millions taking into account general practice admin costs plus testing ones.

6.5.4 Potential Action: Delivering a targeted awareness campaign focussed on the pre-September 1991 blood transfusion risk and the recent advances in Hepatitis C treatment and care.

Detail

- An initiative run by the Scottish Government in association with Health Scotland, National Services Scotland (SNBTS and HPS), Hepatitis Scotland and the UK Hepatitis C Trust.
- An initiative involving the health sector and other agencies, using traditional (e.g. leaflets and posters) and non-traditional (e.g. social media) methods.
- Building on the publicity generated through the launch of the Penrose Inquiry report.

Practicality/Effectiveness

- Effectiveness in raising awareness among most of the population of Scotland likely to be high. Effectiveness of identifying the remaining smaller number of HCV infected, undiagnosed individuals uncertain.

Cost

- Hundreds of thousands of pounds for the campaign and the cost of testing those coming forward for a test.

OTHER NON-SPECIFIC ACTIONS WHICH MIGHT HAVE AN EFFECT

6.5.5 Potential Action: General population HCV screening

Detail

- Offering, via a letter, an HCV test to all individuals in Scotland over the age of 24.

Practicality/Effectiveness

- Only an unknown proportion would take up the offer.
- The action would identify some of the 15,000 undiagnosed HCV infected individuals in Scotland; nearly all would be people who had ever injected drugs.
- In the context of around 30 undiagnosed infected people who acquired their HCV through transfusion pre 1991 - the action is likely to be very ineffective. However, in the context of the rest of the undiagnosed HCV infected population it is likely to be more effective. To achieve much greater effectiveness in relation to identifying people who had injected drugs in the past, such general population screening would be best confined to certain geographical areas where injecting drug use is and has been highly prevalent.

Cost

- Tens of millions of pounds

6.5.6 Potential Action: Reminder to all clinicians to test for hepatitis C if someone has an otherwise unexplained raised ALT

Detail

- A letter from the CMO to all hospital clinicians and general practitioners to remind them of the 2006/7 SIGN guidelines on testing people who have an otherwise unexplained raised Alanine Amino transferase (ALT).
- The letter would also ask the clinicians to test for HCV even if the raised ALT might be explained by excessive alcohol consumption (EAC); this is because of the strong relationship between EAC and injecting drug use (and thus hepatitis C infection).
- It is uncertain what proportion of individuals with a raised ALT, as above, are tested for hepatitis C but preliminary information indicates that clinical adherence to the guidance around the ALT criterion is suboptimal.
- Research is being undertaken in 2016 to assess clinical adherence to such testing and, thus, whether or not a CMO letter as above would be warranted.

Practicality/Effectiveness

- Not everyone has their liver function tested and not everyone with advancing HCV disease has a raised ALT at the time the test is performed
- In the context of the 15,000 undiagnosed infected individuals in Scotland, increasing awareness around ALT-based hepatitis C testing might be effective; however, it is uncertain what impact a CMO letter might have on clinical practice
- Nevertheless, current guidelines state that HCV testing of individuals with an otherwise unexplained raised ALT should be undertaken as part of routine clinical investigation.

Cost

- Any increase in HCV testing to identify the cause of liver damage, as indicated by a raised ALT, should not be judged in terms of cost (and cost effectiveness) in the same way that a "screening" intervention should be. The difference between clinical investigation and screening is a critical one.

6.6 SLWG: Recommendations

The SLWG fully acknowledges the importance of ensuring that anyone still alive and infected with Hepatitis C as a consequence of blood transfusion pre-September 1991 should be given the best possible chance of taking advantage of the new advances in treatments which are safe, easy to administer and highly effective. Appropriate opportunities to access counselling and psychological therapies should also be available for the newly diagnosed, as is already good practice. Taking account of the Inquiry's recommendation that any steps to offer an HCV test to such individuals should be "reasonable", the SLWG also recognised the need to ensure that any new intervention(s) are optimally cost-effective and proportionate in the context of the scale of the problem. Accordingly, the proposed Actions 6.5.1, 6.5.2, 6.5.3 and 6.5.5, as above, were regarded by the SLWG as inappropriate because of their high cost (millions of GBP) and very likely low effectiveness.

Accordingly, the SLWG unanimously agreed on the following:

- **Delivering a targeted awareness campaign focussed solely on individuals who received a blood transfusion pre-September 1991**

  This awareness campaign should aim to reach all targeted individuals through the use of (e.g. leaflets and posters) and more modern (e.g. social media) approaches. Such approaches recognise that an appreciable minority of people do not access information from more traditional sources. The details surrounding the design and implementation of the campaign would be worked on following any such Scottish Government approval. The SLWG agreed that any such campaign should be evaluated to determine its impact.

- **The identification and written offer of an HCV test to a group (up to 71) of plasma product factor recipients who are as yet not known to have been HCV tested.**

- **A Chief Medical Officer letter should be sent to all clinicians in Scotland to remind them of certain risk factors (including pre-September 1991 blood transfusion and injecting drug use) and clinical (including otherwise unexplained Alanine Aminotransferase (ALT) liver enzyme level) indicators for HCV infection and making them aware of the recent advances in therapy and thus the benefits of HCV testing.**

7 Conclusion

The SLWG recognises that Scotland has probably done more than any other country in addressing the challenges of Hepatitis C infection affecting both blood transfusion recipients and people predisposed to infection through other routes.

The SLWG, however, was determined that very considerable efforts should be made in ensuring that people at risk of infection through the transfusion route be offered an HCV test so that anyone infected can take full advantage of new, highly effective therapies.

The SLWG strongly and unanimously urges the Scottish Government to approve its three recommendations.

Appendix 1: Membership of the Penrose Short Life Working Group

Member	Organisation	Title
Professor David Goldberg (Chair)	Health Protection Scotland	Consultant Epidemiologist
Mr Gareth Brown	Scottish Government	Head of Health Protection Division, Directorate for Population Health
Dr Nicola Steedman	Scottish Government	Senior Medical Officer
Mr Robert Girvan	Scottish Government	Policy Manager, Health Protection Division, Directorate for Population Health
Professor Sharon Hutchinson	Glasgow Caledonian University	Professor of Epidemiology and Population Health
Mr Hamish Innes	Glasgow Caledonian University	Epidemiologist
Dr Kirsty Roy	Health Protection Scotland	Senior Epidemiologist
Dr Amanda Weir	Health Protection Scotland	Principal Information Analyst
Mr Allan McLeod	Health Protection Scotland	Epidemiologist
Professor Marc Turner	Scottish National Blood Transfusion Service	Medical Director
Dr Lucy Munro	NHS National Services Scotland	Associate Medical Director (Primary Care)
Dr Ewen Stewart	NHS Lothian	General Practitioner
Dr Helen Harris	Public Health England	Clinical Scientist/Research Associate
Dr Sema Mandal	Public Health England	Consultant Epidemiologist
Mr Charles Gore	Hepatitis C Trust	Chief Executive, Hepatitis C Trust
Mr Leon Wylie	Hepatitis Scotland	Lead Officer, Hepatitis Scotland
Mr Philip Dolan	Scottish Infected Blood Forum	Convener, Scottish Infected Blood Forum

Professor Campbell Tait	Scottish Haemophilia Centres	Consultant Haematologist
Mr Dan Farthing-Sykes (Deputy to Mr Farthing Sykes: Mr Bill Wright)	Haemophilia Scotland (Haemophilia Scotland)	CEO (Chairman)

Appendix 2: Transfusion Survivors Estimate for Penrose HCV Response

Transfusion survivors estimate for Penrose HCV response

Years of exposure 1971-1991

Estimate	93,624 persons

Age adjustment only; gender differences averaged

Life expectancy from NRS Scotland decennial life tables 1970-72 to 1990-92, assigned from mid decade prior to mid decade post

Same transfusion rate used throughout so likely to produce an underestimate of exposed survivors

Same life expectancy for transfused likely to produce an overestimate of exposed survivors

YEAR Age Group	per 1000 1st Transf Rate	1971 POP	1st Tx Pop	per 1000 Death Rate	1st Tx deaths	1st Tx surv 71	Exp life years	Year of Death	Pop Alive at 2015
<1 yr	7.7	88,681	682.84524	18.7	12.76920599	670.076034	70.5	2041.5	
1-4 yrs	0.8	354,725	283.77984	0.8	0.227023872	283.5528161	69.45	2040.45	
5-9 yrs	0.4	468,587	187.4348	0.4	0.07497392	187.3598261	65.15	2036.15	
10-14 yrs	0.5	443,534	221.767	0.3	0.0665301	221.7004699	60.2	2031.2	
15-24 yrs	1.2	780,809	936.9708	0.7	0.65587956	936.3149204	52.95	2023.95	2299.004067
25-34 yrs	2.1	617,344	1296.4224	1.0	1.2964224	1295.125978	43.3	2014.3	
35-44 yrs	2.4	611,770	1468.248	2.4	3.5237952	1464.724205	33.9	2004.9	
45-54 yrs	3	619,850	1859.55	7.1	13.202805	1846.347195	25.05	1996.05	
55-64 yrs	6.3	600,014	3780.0882	17.8	67.28556996	3712.80263	17.25	1988.25	
65-74 yrs	12.6	429,860	5416.236	41.5	224.773794	5191.462206	10.85	1981.85	
75-84 yrs	24.4	182,620	4455.928	93.9	418.4116392	4037.516361	6.3	1977.3	
85+ yrs	38.5	37,806	1455.531	211.5	307.8448065	1147.686194	2.9	1973.9	
		5,146,919	22044.80128						

YEAR		1972							
Age Group	1st Transf Rate	POP	1st Tx Pop	Death Rate	1st Tx deaths	1st Tx surv 72	Exp life years	Year of Death	Pop Alive at 2015
<1 yr	7.7	85,803	660.68464	18.7	12.35480277	648.3298372	70.5	2042.5	
1-4 yrs	0.8	343,213	274.57024	0.8	0.219656192	274.3505838	69.45	2041.45	
5-9 yrs	0.4	466,208	186.4832	0.4	0.07459328	186.4086067	65.15	2037.15	
10-14 yrs	0.5	449,539	224.7695	0.3	0.06743085	224.7020692	60.2	2032.2	
15-24 yrs	1.2	770,009	924.0108	0.7	0.64680756	923.3639924	52.95	2024.95	2257.155089
25-34 yrs	2.1	638,199	1340.2179	1.0	1.3402179	1338.877682	43.3	2015.3	
35-44 yrs	2.4	605,284	1452.6816	2.4	3.48643584	1449.195164	33.9	2005.9	
45-54 yrs	3	622,116	1866.348	7.1	13.2510708	1853.096929	25.05	1997.05	
55-64 yrs	6.3	589,653	3714.8139	17.8	66.12368742	3648.690213	17.25	1989.25	
65-74 yrs	12.6	436,370	5498.262	41.5	228.177873	5270.084127	10.85	1982.85	
75-84 yrs	24.4	185,730	4531.812	93.9	425.5371468	4106.274853	6.3	1978.3	
85+ yrs	38.5	38,476	1481.326	211.5	313.300449	1168.025551	2.9	1974.9	
		5,230,600	22155.97978						

YEAR		1973							
Age Group	1st Transf Rate	POP	1st Tx Pop	Death Rate	1st Tx deaths	1st Tx surv 73	Exp life years	Year of Death	Pop Alive at 2015
<1 yr	7.7	82,759	637.24584	18.7	11.91649721	625.3293428	70.5	2043.5	
1-4 yrs	0.8	331,037	264.82944	0.8	0.211863552	264.6175764	69.45	2042.45	
5-9 yrs	0.4	461,734	184.6936	0.4	0.07387744	184.6197226	65.15	2038.15	
10-14 yrs	0.5	455,066	227.533	0.3	0.0682599	227.4647401	60.2	2033.2	
15-24 yrs	1.2	775,225	930.27	0.7	0.651189	929.618811	52.95	2025.95	
25-34 yrs	2.1	651,411	1367.9631	1.0	1.3679631	1366.595137	43.3	2016.3	3598.24533
35-44 yrs	2.4	601,776	1444.2624	2.4	3.46622976	1440.79617	33.9	2006.9	

45-54 yrs	3	629,210	1887.63	7.1	13.402173	1874.227827	25.05	1998.05	
55-64 yrs	6.3	573,221	3611.2923	17.8	64.28100294	3547.011297	17.25	1990.25	
65-74 yrs	12.6	444,886	5605.5636	41.5	232.6308894	5372.932711	10.85	1983.85	
75-84 yrs	24.4	188,383	4596.5452	93.9	431.6155943	4164.929606	6.3	1979.3	
85+ yrs	38.5	39,192	1508.892	211.5	319.130658	1189.761342	2.9	1975.9	

YEAR		1974							
Age Group	**1st Transf Rate**	**POP**	**1st Tx Pop**	**Death Rate**	**1st Tx deaths**	**1st Tx surv 74**	**Exp life years**	**Year of Death**	**Pop Alive at 2015**
<1 yr	7.7	78,959	607.98738	18.7	11.36936401	596.618016	70.5	2044.5	
1-4 yrs	0.8	315,838	252.67008	0.8	0.202136064	252.4679439	69.45	2043.45	
5-9 yrs	0.4	454,892	181.9568	0.4	0.07278272	181.8840173	65.15	2039.15	
10-14 yrs	0.5	461,284	230.642	0.3	0.0691926	230.5728074	60.2	2034.2	
15-24 yrs	1.2	785,574	942.6888	0.7	0.65988216	942.0289178	52.95	2026.95	
25-34 yrs	2.1	666,729	1400.1309	1.0	1.4001309	1398.730769	43.3	2017.3	3602.302472
35-44 yrs	2.4	599,222	1438.1328	2.4	3.45151872	1434.681281	33.9	2007.9	
45-54 yrs	3	636,028	1908.084	7.1	13.5473964	1894.536604	25.05	1999.05	
55-64 yrs	6.3	557,664	3513.2832	17.8	62.53644096	3450.746759	17.25	1991.25	
65-74 yrs	12.6	452,670	5703.642	41.5	236.701143	5466.940857	10.85	1984.85	
75-84 yrs	24.4	191,726	4678.1144	93.9	439.2749422	4238.839458	6.3	1980.3	
85+ yrs	38.5	40,214	1548.239	211.5	327.4525485	1220.786452	2.9	1976.9	

YEAR		1975							
Age Group	**1st Transf Rate**	**POP**	**1st Tx Pop**	**Death Rate**	**1st Tx deaths**	**1st Tx surv 75**	**Exp life years**	**Year of Death**	**Pop Alive at 2015**
<1 yr	7.7	75,147	578.62882	18.7	10.82035893	567.8084611	72.2	2047.2	
1-4 yrs	0.8	300,586	240.46912	0.8	0.192375296	240.2767447	70.65	2045.65	
5-9 yrs	0.4	444,300	177.72	0.4	0.071088	177.648912	66.25	2041.25	
10-14 yrs	0.5	466,537	233.2685	0.3	0.06998055	233.1985195	61.3	2036.3	
15-24 yrs	1.2	791,772	950.1264	0.7	0.66508848	949.4613115	54	2029	

25-34 yrs	2.1	677,635	1423.0335	1.0	1.4230335	1421.610467	44.4	2019.4	3590.004415
35-44 yrs	2.4	595,135	1428.324	2.4	3.4279776	1424.896022	34.85	2009.85	
45-54 yrs	3	623,017	1869.051	7.1	13.2702621	1855.780738	25.9	2000.9	
55-64 yrs	6.3	563,289	3548.7207	17.8	63.16722846	3485.553472	18	1993	
65-74 yrs	12.6	457,021	5758.4646	41.5	238.9762809	5519.488319	11.5	1986.5	
75-84 yrs	24.4	197,126	4809.8744	93.9	451.6472062	4358.227194	6.6	1981.6	
85+ yrs	38.5	40,835	1572.1475	211.5	332.5091963	1239.638304	2.65	1977.65	

YEAR		**1976**							
Age Group	**1st Transf Rate**	**POP**	**1st Tx Pop**	**Death Rate**	**1st Tx deaths**	**1st Tx surv 76**	**Exp life years**	**Year of Death**	**Pop Alive at 2015**
<1 yr	7.7	71,490	550.47608	18.7	10.2939027	540.1821773	72.2	2048.2	
1-4 yrs	0.8	285,962	228.76928	0.8	0.183015424	228.5862646	70.65	2046.65	
5-9 yrs	0.4	437,750	175.1	0.4	0.07004	175.02996	66.25	2042.25	
10-14 yrs	0.5	466,142	233.071	0.3	0.0699213	233.0010787	61.3	2037.3	
15-24 yrs	1.2	806,205	967.446	0.7	0.6772122	966.7687878	54	2030	
25-34 yrs	2.1	692,081	1453.3701	1.0	1.4533701	1451.91673	44.4	2020.4	3595.484998
35-44 yrs	2.4	591,027	1418.4648	2.4	3.40431552	1415.060484	34.85	2010.85	
45-54 yrs	3	614,582	1843.746	7.1	13.0905966	1830.655403	25.9	2001.9	
55-64 yrs	6.3	564,192	3554.4096	17.8	63.26849088	3491.141109	18	1994	
65-74 yrs	12.6	460,011	5796.1386	41.5	240.5397519	5555.598848	11.5	1987.5	
75-84 yrs	24.4	202,345	4937.218	93.9	463.6047702	4473.61323	6.6	1982.6	
85+ yrs	38.5	41,613	1602.1005	211.5	338.8442558	1263.256244	2.65	1978.65	

YEAR		**1977**							
Age Group	**1st Transf Rate**	**POP**	**1st Tx Pop**	**Death Rate**	**1st Tx deaths**	**1st Tx surv 77**	**Exp life years**	**Year of Death**	**Pop Alive at 2015**
<1 yr	7.7	67,528	519.96868	18.7	9.723414316	510.2452657	72.2	2049.2	
1-4 yrs	0.8	270,114	216.09088	0.8	0.172872704	215.9180073	70.65	2047.65	
5-9 yrs	0.4	425,076	170.0304	0.4	0.06801216	169.9623878	66.25	2043.25	

10-14 yrs	0.5	464,920	232.46	0.3	0.069738	232.390262	61.3	2038.3	
15-24 yrs	1.2	823,609	988.3308	0.7	0.69183156	987.6389684	54	2031	
25-34 yrs	2.1	701,175	1472.4675	1.0	1.4724675	1470.995033	44.4	2021.4	3587.149924
35-44 yrs	2.4	589,620	1415.088	2.4	3.3962112	1411.691789	34.85	2011.85	
45-54 yrs	3	607,162	1821.486	7.1	12.9325506	1808.553449	25.9	2002.9	
55-64 yrs	6.3	564,399	3555.7137	17.8	63.29170386	3492.421996	18	1995	
65-74 yrs	12.6	462,037	5821.6662	41.5	241.5991473	5580.067053	11.5	1988.5	
75-84 yrs	24.4	208,090	5077.396	93.9	476.7674844	4600.628516	6.6	1983.6	
85+ yrs	38.5	42,470	1635.095	211.5	345.8225925	1289.272408	2.65	1979.65	

YEAR		**1978**							
Age Group	**1st Transf Rate**	**POP**	**1st Tx Pop**	**Death Rate**	**1st Tx deaths**	**1st Tx surv 78**	**Exp life years**	**Year of Death**	**Pop Alive at 2015**
<1 yr	7.7	64,835	499.2295	18.7	9.33559165	489.8939084	72.2	2050.2	
1-4 yrs	0.8	259,340	207.472	0.8	0.1659776	207.3060224	70.65	2048.65	
5-9 yrs	0.4	408,212	163.2848	0.4	0.06531392	163.2194861	66.25	2044.25	
10-14 yrs	0.5	460,161	230.0805	0.3	0.06902415	230.0114759	61.3	2039.3	
15-24 yrs	1.2	837,864	1005.4368	0.7	0.70380576	1004.732994	54	2032	
25-34 yrs	2.1	706,420	1483.482	1.0	1.483482	1481.998518	44.4	2022.4	3577.162405
35-44 yrs	2.4	593,167	1423.6008	2.4	3.41664192	1420.184158	34.85	2012.85	
45-54 yrs	3	601,118	1803.354	7.1	12.8038134	1790.550187	25.9	2003.9	
55-64 yrs	6.3	560,094	3528.5922	17.8	62.80894116	3465.783259	18	1996	
65-74 yrs	12.6	463,429	5839.2054	41.5	242.3270241	5596.878376	11.5	1989.5	
75-84 yrs	24.4	213,939	5220.1116	93.9	490.1684792	4729.943121	6.6	1984.6	
85+ yrs	38.5	43,721	1683.2585	211.5	356.0091728	1327.249327	2.65	1980.65	

YEAR		**1979**							
Age Group	**1st Transf Rate**	**POP**	**1st Tx Pop**	**Death Rate**	**1st Tx deaths**	**1st Tx surv 79**	**Exp life years**	**Year of Death**	**Pop Alive at 2015**
<1 yr	7.7	63,805	491.30158	18.7	9.187339546	482.1142405	72.2	2051.2	

1-4 yrs	0.8	255,222	204.17728	0.8	0.163341824	204.0139382	70.65	2049.65	
5-9 yrs	0.4	387,800	155.12	0.4	0.062048	155.057952	66.25	2045.25	
10-14 yrs	0.5	453,076	226.538	0.3	0.0679614	226.4700386	61.3	2040.3	
15-24 yrs	1.2	852,602	1023.1224	0.7	0.71618568	1022.406214	54	2033	
25-34 yrs	2.1	711,632	1494.4272	1.0	1.4944272	1492.932773	44.4	2023.4	3582.995156
35-44 yrs	2.4	598,572	1436.5728	2.4	3.44777472	1433.125025	34.85	2013.85	
45-54 yrs	3	594,933	1784.799	7.1	12.6720729	1772.126927	25.9	2004.9	
55-64 yrs	6.3	556,733	3507.4179	17.8	62.43203862	3444.985861	18	1997	
65-74 yrs	12.6	464,598	5853.9348	41.5	242.9382942	5610.996506	11.5	1990.5	
75-84 yrs	24.4	219,638	5359.1672	93.9	503.2258001	4855.9414	6.6	1985.6	
85+ yrs	38.5	44,989	1732.0765	211.5	366.3341798	1365.74232	2.65	1981.65	

YEAR		**1980**							
Age Group	**1st Transf Rate**	**POP**	**1st Tx Pop**	**Death Rate**	**1st Tx deaths**	**1st Tx surv 80**	**Exp life years**	**Year of Death**	**Pop Alive at 2015**
<1 yr	7.7	63,504	488.98234	18.7	9.143969758	479.8383702	72.2	2052.2	
1-4 yrs	0.8	254,017	203.21344	0.8	0.162570752	203.0508692	70.65	2050.65	
5-9 yrs	0.4	368,198	147.2792	0.4	0.05891168	147.2202883	66.25	2046.25	
10-14 yrs	0.5	441,027	220.5135	0.3	0.06615405	220.447346	61.3	2041.3	
15-24 yrs	1.2	867,872	1041.4464	0.7	0.72901248	1040.717388	54	2034	
25-34 yrs	2.1	718,051	1507.9071	1.0	1.5079071	1506.399193	44.4	2024.4	3597.673454
35-44 yrs	2.4	600,105	1440.252	2.4	3.4566048	1436.795395	34.85	2014.85	
45-54 yrs	3	590,489	1771.467	7.1	12.5774157	1758.889584	25.9	2005.9	
55-64 yrs	6.3	553,285	3485.6955	17.8	62.0453799	3423.65012	18	1998	
65-74 yrs	12.6	464,992	5858.8992	41.5	243.1443168	5615.754883	11.5	1991.5	
75-84 yrs	24.4	225,681	5506.6164	93.9	517.07128	4989.54512	6.6	1986.6	
85+ yrs	38.5	46,679	1797.1415	211.5	380.0954273	1417.046073	2.65	1982.65	

YEAR		**1981**							
Age	**1st Transf**	**POP**	**1st Tx Pop**	**Death**	**1st Tx**	**1st Tx surv**	**Exp life**	**Year of**	**Pop Alive at**

Group	Rate			Rate	deaths	81	years	Death	2015
<1 yr	7.7	63,582	489.57832	18.7	9.155114584	480.4232054	72.2	2053.2	
1-4 yrs	0.8	254,326	203.46112	0.8	0.162768896	203.2983511	70.65	2051.65	
5-9 yrs	0.4	347,713	139.0852	0.4	0.05563408	139.0295659	66.25	2047.25	
10-14 yrs	0.5	432,712	216.356	0.3	0.0649068	216.2910932	61.3	2042.3	
15-24 yrs	1.2	874,746	1049.6952	0.7	0.73478664	1048.960413	54	2035	
25-34 yrs	2.1	723,718	1519.8078	1.0	1.5198078	1518.287992	44.4	2025.4	3606.290621
35-44 yrs	2.4	602,910	1446.984	2.4	3.4727616	1443.511238	34.85	2015.85	
45-54 yrs	3	585,233	1755.699	7.1	12.4654629	1743.233537	25.9	2006.9	
55-64 yrs	6.3	555,401	3499.0263	17.8	62.28266814	3436.743632	18	1999	
65-74 yrs	12.6	459,546	5790.2796	41.5	240.2966034	5549.982997	11.5	1992.5	
75-84 yrs	24.4	231,643	5652.0892	93.9	530.7311759	5121.358024	6.6	1987.6	
85+ yrs	38.5	48,670	1873.795	211.5	396.3076425	1477.487358	2.65	1983.65	

YEAR		1982							
Age Group	1st Transf Rate	POP	1st Tx Pop	Death Rate	1st Tx deaths	1st Tx surv 82	Exp life years	Year of Death	Pop Alive at 2015
<1 yr	7.7	64,860	499.41892	18.7	9.339133804	490.0797862	72.2	2054.2	
1-4 yrs	0.8	259,438	207.55072	0.8	0.166040576	207.3846794	70.65	2052.65	
5-9 yrs	0.4	327,745	131.098	0.4	0.0524392	131.0455608	66.25	2048.25	
10-14 yrs	0.5	418,592	209.296	0.3	0.0627888	209.2332112	61.3	2043.3	
15-24 yrs	1.2	880,836	1057.0032	0.7	0.73990224	1056.263298	54	2036	
25-34 yrs	2.1	713,833	1499.0493	1.0	1.4990493	1497.550251	44.4	2026.4	
35-44 yrs	2.4	623,340	1496.016	2.4	3.5904384	1492.425562	34.85	2016.85	5083.982348
45-54 yrs	3	581,370	1744.11	7.1	12.383181	1731.726819	25.9	2007.9	
55-64 yrs	6.3	558,933	3521.2779	17.8	62.67874662	3458.599153	18	2000	
65-74 yrs	12.6	450,750	5679.45	41.5	235.697175	5443.752825	11.5	1993.5	
75-84 yrs	24.4	235,458	5745.1752	93.9	539.4719513	5205.703249	6.6	1988.6	
85+ yrs	38.5	49,385	1901.3225	211.5	402.1297088	1499.192791	2.65	1984.65	

YEAR		1983							
Age Group	1st Transf Rate	POP	1st Tx Pop	Death Rate	1st Tx deaths	1st Tx surv 83	Exp life years	Year of Death	Pop Alive at 2015
<1 yr	7.7	65,701	505.90078	18.7	9.460344586	496.4404354	72.2	2055.2	
1-4 yrs	0.8	262,806	210.24448	0.8	0.168195584	210.0762844	70.65	2053.65	
5-9 yrs	0.4	314,315	125.726	0.4	0.0502904	125.6757096	66.25	2049.25	
10-14 yrs	0.5	400,934	200.467	0.3	0.0601401	200.4068599	61.3	2044.3	
15-24 yrs	1.2	882,497	1058.9964	0.7	0.74129748	1058.255103	54	2037	
25-34 yrs	2.1	712,274	1495.7754	1.0	1.4957754	1494.279625	44.4	2027.4	
35-44 yrs	2.4	636,303	1527.1272	2.4	3.66510528	1523.462095	34.85	2017.85	5108.596111
45-54 yrs	3	578,971	1736.913	7.1	12.3320823	1724.580918	25.9	2008.9	
55-64 yrs	6.3	565,015	3559.5945	17.8	63.3607821	3496.233718	18	2001	
65-74 yrs	12.6	437,742	5515.5492	41.5	228.8952918	5286.653908	11.5	1994.5	
75-84 yrs	24.4	240,754	5874.3976	93.9	551.6059346	5322.791665	6.6	1989.6	
85+ yrs	38.5	50,808	1956.108	211.5	413.716842	1542.391158	2.65	1985.65	

YEAR		1984							
Age Group	1st Transf Rate	POP	1st Tx Pop	Death Rate	1st Tx deaths	1st Tx surv 84	Exp life years	Year of Death	Pop Alive at 2015
<1 yr	7.7	65,508	504.41468	18.7	9.432554516	494.9821255	72.2	2056.2	
1-4 yrs	0.8	262,034	209.62688	0.8	0.167701504	209.4591785	70.65	2054.65	
5-9 yrs	0.4	310,661	124.2644	0.4	0.04970576	124.2146942	66.25	2050.25	
10-14 yrs	0.5	380,642	190.321	0.3	0.0570963	190.2639037	61.3	2045.3	
15-24 yrs	1.2	881,784	1058.1408	0.7	0.74069856	1057.400101	54	2038	
25-34 yrs	2.1	718,368	1508.5728	1.0	1.5085728	1507.064227	44.4	2028.4	
35-44 yrs	2.4	646,860	1552.464	2.4	3.7259136	1548.738086	34.85	2018.85	5132.122317
45-54 yrs	3	576,644	1729.932	7.1	12.2825172	1717.649483	25.9	2009.9	
55-64 yrs	6.3	571,220	3598.686	17.8	64.0566108	3534.629389	18	2002	
65-74 yrs	12.6	426,688	5376.2688	41.5	223.1151552	5153.153645	11.5	1995.5	
75-84 yrs	24.4	246,199	6007.2556	93.9	564.0813008	5443.174299	6.6	1990.6	

85+ yrs	38.5	52,272	2012.472	211.5	425.637828	1586.834172	2.65	1986.65	

YEAR		1985							
Age Group	1st Transf Rate	POP	1st Tx Pop	Death Rate	1st Tx deaths	1st Tx surv 85	Exp life years	Year of Death	Pop Alive at 2015
<1 yr	7.7	65,051	500.8927	18.7	9.36669349	491.5260065	74.25	2059.25	
1-4 yrs	0.8	260,204	208.1632	0.8	0.16653056	207.9966694	72.55	2057.55	
5-9 yrs	0.4	310,556	124.2224	0.4	0.04968896	124.172711	61.2	2046.2	
10-14 yrs	0.5	362,257	181.1285	0.3	0.05433855	181.0741615	56.75	2041.75	
15-24 yrs	1.2	873,314	1047.9768	0.7	0.73358376	1047.243216	55.7	2040.7	
25-34 yrs	2.1	728,195	1529.2095	1.0	1.5292095	1527.680291	46.05	2031.05	
35-44 yrs	2.4	655,723	1573.7352	2.4	3.77696448	1569.958236	36.5	2021.5	5149.651291
45-54 yrs	3	573,951	1721.853	7.1	12.2251563	1709.627844	27.35	2012.35	
55-64 yrs	6.3	560,881	3533.5503	17.8	62.89719534	3470.653105	19.1	2004.1	
65-74 yrs	12.6	432,528	5449.8528	41.5	226.1688912	5223.683909	12.3	1997.3	
75-84 yrs	24.4	250,207	6105.0508	93.9	573.2642701	5531.78653	7.25	1992.25	
85+ yrs	38.5	55,023	2118.3855	211.5	448.0385333	1670.346967	2.5	1987.5	

YEAR		1986							
Age Group	1st Transf Rate	POP	1st Tx Pop	Death Rate	1st Tx deaths	1st Tx surv 86	Exp life years	Year of Death	Pop Alive at 2015
<1 yr	7.7	64,665	497.92358	18.7	9.311170946	488.6124091	74.25	2060.25	
1-4 yrs	0.8	258,662	206.92928	0.8	0.165543424	206.7637366	72.55	2058.55	
5-9 yrs	0.4	313,040	125.216	0.4	0.0500864	125.1659136	61.2	2047.2	
10-14 yrs	0.5	343,154	171.577	0.3	0.0514731	171.5255269	56.75	2042.75	
15-24 yrs	1.2	862,892	1035.4704	0.7	0.72482928	1034.745571	55.7	2041.7	
25-34 yrs	2.1	738,734	1551.3414	1.0	1.5513414	1549.790059	46.05	2032.05	
35-44 yrs	2.4	664,985	1595.964	2.4	3.8303136	1592.133686	36.5	2022.5	5168.736902
45-54 yrs	3	568,105	1704.315	7.1	12.1006365	1692.214364	27.35	2013.35	
55-64 yrs	6.3	553,951	3489.8913	17.8	62.12006514	3427.771235	19.1	2005.1	

65-74 yrs	12.6	434,861	5479.2486	41.5	227.3888169	5251.859783	12.3	1998.3	
75-84 yrs	24.4	251,916	6146.7504	93.9	577.1798626	5569.570537	7.25	1993.25	
85+ yrs	38.5	56,795	2186.6075	211.5	462.4674863	1724.140014	2.5	1988.5	

YEAR		1987							
Age Group	**1st Transf Rate**	**POP**	**1st Tx Pop**	**Death Rate**	**1st Tx deaths**	**1st Tx surv 87**	**Exp life years**	**Year of Death**	**Pop Alive at 2015**
<1 yr	7.7	64,430	496.11408	18.7	9.277333296	486.8367467	74.25	2061.25	
1-4 yrs	0.8	257,722	206.17728	0.8	0.164941824	206.0123382	72.55	2059.55	
5-9 yrs	0.4	318,745	127.498	0.4	0.0509992	127.4470008	61.2	2048.2	
10-14 yrs	0.5	323,828	161.914	0.3	0.0485742	161.8654258	56.75	2043.75	
15-24 yrs	1.2	846,961	1016.3532	0.7	0.71144724	1015.641753	55.7	2042.7	
25-34 yrs	2.1	751,315	1577.7615	1.0	1.5777615	1576.183739	46.05	2033.05	
35-44 yrs	2.4	669,373	1606.4952	2.4	3.85558848	1602.639612	36.5	2023.5	5176.626614
45-54 yrs	3	565,828	1697.484	7.1	12.0521364	1685.431864	27.35	2014.35	
55-64 yrs	6.3	548,552	3455.8776	17.8	61.51462128	3394.362979	19.1	2006.1	
65-74 yrs	12.6	437,669	5514.6294	41.5	228.8571201	5285.77228	12.3	1999.3	
75-84 yrs	24.4	254,879	6219.0476	93.9	583.9685696	5635.07903	7.25	1994.25	
85+ yrs	38.5	59,718	2299.143	211.5	486.2687445	1812.874256	2.5	1989.5	

YEAR		1988							
Age Group	**1st Transf Rate**	**POP**	**1st Tx Pop**	**Death Rate**	**1st Tx deaths**	**1st Tx surv 88**	**Exp life years**	**Year of Death**	**Pop Alive at 2015**
<1 yr	7.7	64,492	496.5884	18.7	9.28620308	487.3021969	74.25	2062.25	
1-4 yrs	0.8	257,968	206.3744	0.8	0.16509952	206.2093005	72.55	2060.55	
5-9 yrs	0.4	322,042	128.8168	0.4	0.05152672	128.7652733	61.2	2049.2	
10-14 yrs	0.5	310,507	155.2535	0.3	0.04657605	155.206924	56.75	2044.75	
15-24 yrs	1.2	821,426	985.7112	0.7	0.68999784	985.0212022	55.7	2043.7	
25-34 yrs	2.1	758,829	1593.5409	1.0	1.5935409	1591.947359	46.05	2034.05	
35-44 yrs	2.4	671,747	1612.1928	2.4	3.86926272	1608.323537	36.5	2024.5	5162.775793

45-54 yrs	3	568,851	1706.553	7.1	12.1165263	1694.436474	27.35	2015.35	
55-64 yrs	6.3	545,007	3433.5441	17.8	61.11708498	3372.427015	19.1	2007.1	
65-74 yrs	12.6	436,513	5500.0638	41.5	228.2526477	5271.811152	12.3	2000.3	
75-84 yrs	24.4	257,477	6282.4388	93.9	589.9210033	5692.517797	7.25	1995.25	
85+ yrs	38.5	62,581	2409.3685	211.5	509.5814378	1899.787062	2.5	1990.5	

YEAR		**1989**							
Age Group	**1st Transf Rate**	**POP**	**1st Tx Pop**	**Death Rate**	**1st Tx deaths**	**1st Tx surv 89**	**Exp life years**	**Year of Death**	**Pop Alive at 2015**
<1 yr	7.7	65,012	500.59394	18.7	9.361106678	491.2328333	74.25	2063.25	
1-4 yrs	0.8	260,049	208.03904	0.8	0.166431232	207.8726088	72.55	2061.55	
5-9 yrs	0.4	321,653	128.6612	0.4	0.05146448	128.6097355	61.2	2050.2	
10-14 yrs	0.5	308,112	154.056	0.3	0.0462168	154.0097832	56.75	2045.75	
15-24 yrs	1.2	793,390	952.068	0.7	0.6664476	951.4015524	55.7	2044.7	
25-34 yrs	2.1	771,844	1620.8724	1.0	1.6208724	1619.251528	46.05	2035.05	
35-44 yrs	2.4	677,840	1626.816	2.4	3.9043584	1622.911642	36.5	2025.5	
45-54 yrs	3	574,458	1723.374	7.1	12.2359554	1711.138045	27.35	2016.35	6886.427727
55-64 yrs	6.3	542,486	3417.6618	17.8	60.83438004	3356.82742	19.1	2008.1	
65-74 yrs	12.6	437,374	5510.9124	41.5	228.7028646	5282.209535	12.3	2001.3	
75-84 yrs	24.4	260,125	6347.05	93.9	595.987995	5751.062005	7.25	1996.25	
85+ yrs	38.5	65,847	2535.1095	211.5	536.1756593	1998.933841	2.5	1991.5	

YEAR		**1990**							
Age Group	**1st Transf Rate**	**POP**	**1st Tx Pop**	**Death Rate**	**1st Tx deaths**	**1st Tx surv 90**	**Exp life years**	**Year of Death**	**Pop Alive at 2015**
<1 yr	7.7	64,963	500.21664	18.7	9.354051168	490.8625888	74.25	2064.25	
1-4 yrs	0.8	259,853	207.88224	0.8	0.166305792	207.7159342	72.55	2062.55	
5-9 yrs	0.4	321,510	128.604	0.4	0.0514416	128.5525584	61.2	2051.2	
10-14 yrs	0.5	309,582	154.791	0.3	0.0464373	154.7445627	56.75	2046.75	
15-24 yrs	1.2	768,454	922.1448	0.7	0.64550136	921.4992986	55.7	2045.7	

25-34 yrs	2.1	788,015	1654.8315	1.0	1.6548315	1653.176669	46.05	2036.05	
35-44 yrs	2.4	687,187	1649.2488	2.4	3.95819712	1645.290603	36.5	2026.5	
45-54 yrs	3	576,746	1730.238	7.1	12.2846898	1717.95331	27.35	2017.35	6919.795524
55-64 yrs	6.3	540,044	3402.2772	17.8	60.56053416	3341.716666	19.1	2009.1	
65-74 yrs	12.6	437,189	5508.5814	41.5	228.6061281	5279.975272	12.3	2002.3	
75-84 yrs	24.4	260,368	6352.9792	93.9	596.5447469	5756.434453	7.25	1997.25	
85+ yrs	38.5	67,359	2593.3215	211.5	548.4874973	2044.834003	2.5	1992.5	

YEAR		**1991**							
Age Group	**1st Transf Rate**	**POP**	**1st Tx Pop**	**Death Rate**	**1st Tx deaths**	**1st Tx surv 91**	**Exp life years**	**Year of Death**	**Pop Alive at 2015**
<1 yr	7.7	64,821	499.11862	18.7	9.333518194	489.7851018	74.25	2065.25	
1-4 yrs	0.8	259,282	207.42592	0.8	0.165940736	207.2599793	72.55	2063.55	
5-9 yrs	0.4	320,400	128.16	0.4	0.051264	128.108736	61.2	2052.2	
10-14 yrs	0.5	313,221	156.6105	0.3	0.04698315	156.5635169	56.75	2047.75	
15-24 yrs	1.2	746,151	895.3812	0.7	0.62676684	894.7544332	55.7	2046.7	
25-34 yrs	2.1	795,480	1670.508	1.0	1.670508	1668.837492	46.05	2037.05	
35-44 yrs	2.4	696,120	1670.688	2.4	4.0096512	1666.678349	36.5	2027.5	
45-54 yrs	3	580,520	1741.56	7.1	12.365076	1729.194924	27.35	2018.35	6941.182532
55-64 yrs	6.3	536,887	3382.3881	17.8	60.20650818	3322.181592	19.1	2010.1	
65-74 yrs	12.6	441,094	5557.7844	41.5	230.6480526	5327.136347	12.3	2003.3	
75-84 yrs	24.4	259,086	6321.6984	93.9	593.6074798	5728.09092	7.25	1998.25	
85+ yrs	38.5	70,268	2705.318	211.5	572.174757	2133.143243	2.5	1993.5	

93623.36509

Life expectancy

1970-72				1980-82				1990-92				2000-02			
Age Group	Male	Female	Person	Age Group	Male	Female	Person	Age Group	Male	Female	Person	Age Group	Male	Female	Person
<1 yr	67.3	73.7	70.5	<1 yr	69.1	75.3	72.2	<1 yr	71.4	77.1	74.25	<1 yr	73.3	78.8	76.05
1-4 yrs	66.4	72.5	69.45	1-4 yrs	67.6	73.7	70.65	1-4 yrs	70	75.1	72.55	1-4 yrs	71.3	76.7	74
5-9 yrs	62.1	68.2	65.15	5-9 yrs	63.3	69.2	66.25	5-9 yrs	51.7	70.7	61.2	5-9 yrs	66.9	72.3	69.6
10-14 yrs	57.2	63.2	60.2	10-14 yrs	58.3	64.3	61.3	10-14 yrs	47.8	65.7	56.75	10-14 yrs	61.9	67.3	64.6
15-24 yrs	50	55.9	52.95	15-24 yrs	51.1	56.9	54	15-24 yrs	53	58.4	55.7	15-24 yrs	54.7	59.9	57.3
25-34 yrs	40.5	46.1	43.3	25-34 yrs	41.6	47.2	44.4	25-34 yrs	43.5	48.6	46.05	25-34 yrs	45.3	50.1	47.7
35-44 yrs	31.2	36.6	33.9	35-44 yrs	32.2	37.5	34.85	35-44 yrs	34.1	38.9	36.5	35-44 yrs	36	40.5	38.25
45-54 yrs	22.5	27.6	25.05	45-54 yrs	23.4	28.4	25.9	45-54 yrs	25.1	29.6	27.35	45-54 yrs	27	31.2	29.1
55-64 yrs	15	19.5	17.25	55-64 yrs	15.8	20.2	18	55-64 yrs	17.1	21.1	19.1	55-64 yrs	18.9	22.5	20.7
65-74 yrs	9.4	12.3	10.85	65-74 yrs	9.9	13.1	11.5	65-74 yrs	10.7	13.9	12.3	65-74 yrs	12.1	14.7	13.4
75-84 yrs	5.6	7	6.3	75-84 yrs	5.7	7.5	6.6	75-84 yrs	6.3	8.2	7.25	75-84 yrs	7.1	8.6	7.85
85+ yrs	2.8	3	2.9	85+ yrs	2.4	2.9	2.65	85+ yrs	2.4	2.6	2.5	85+ yrs	2.7	2.8	2.75

Appendix 3: Examples of Media

Scottish Government Press Release
Penrose Inquiry 25/03/2015

Health Secretary responds to findings on infected blood

Health Secretary Shona Robison has apologised on behalf of the NHS and Government in Scotland to all patients and families affected by infected NHS blood and blood products in Scotland during the 1970s and 1980s.

The Penrose Inquiry, which was announced by the Scottish Government in 2008, published its final report today.

Lord Penrose chaired the inquiry, which looked in detail at how patients were infected hepatitis C and HIV/AIDS through blood transfusions and other procedures carried out at NHS hospitals from 1974 onwards.

Ms Robison accepted the report's recommendation – that steps should be taken to offer blood tests to anyone in Scotland who had a blood transfusion before 1991 and who has not already been tested for hepatitis C.

She also confirmed that the Scottish Government will carry out the following measures:

- An immediate commitment to review and improve the financial support schemes on offer to the people affected, and their families, to be concluded before World Haemophilia Day in April 2016. The Scottish Government will work with the rest of the UK nations in undertaking this review
- A reference group of patients and families set up to contribute to that review
- Funding for a pilot scheme for additional psychological support for those affected, rolled out wider if needed
- Continued Scottish Government funding for Haemophilia Scotland and Scottish Infected Blood Forum for at least the next three years

Shona Robison, Cabinet Secretary for Health, Wellbeing and Sport, said:

"On behalf of the NHS and Government in Scotland I would like to say sorry to everyone who has been affected by this terrible tragedy. We recognise just how catastrophic this was for everyone affected.

"While this was a UK – indeed international issue – I hope that today's report means that those affected in Scotland now have at least some of the answers they have long called for.

"I will meet families and those affected today to personally express that apology, and to talk about our response to the inquiry report. The First Minister will confirm that

apology on behalf of the NHS and Government in Scotland in Parliament tomorrow, and I will make a full statement in the chamber tomorrow afternoon.

"The people affected are first and foremost in our minds, and I hope that the publication of this detailed and thorough report will, at the very least, give them the comfort of knowing that the circumstances have now been thoroughly investigated in Scotland.

"As Lord Penrose acknowledges, there have been considerable advances in medical and scientific knowledge about blood safety since the early 1980s. Due to stringent testing of blood donations and blood donor selection criteria I am confident that today the blood supply is as safe as it possibly can be. But there is clearly more we can do in this area to support those affected in Scotland, and I am determined we will act quickly to do so.

"We accept the recommendation that blood tests should be offered to anyone who had a transfusion before 1991 and who has not yet been tested. Hepatitis C testing is already freely available on the health service, and awareness campaigns and look back exercises have already been carried out to find people in this situation.

"Our belief is that very few people have not been tested, but we will look at any steps that can be taken to locate anyone who has not yet come forward, including anyone who was treated with blood products for bleeding disorders and not just those who had transfusions.

"The Scottish Government has already contributed around £30 million over the last ten years to the financial support schemes for those people in Scotland people affected by this tragedy. We acknowledge that – as Lord Penrose indicates - some people believe the levels of payments to be insufficient. That is why we will review the financial support schemes on offer, working with the other UK nations. I will establish a reference group of patients and families in Scotland to help us guide this work and I am committed to concluding this review before World Haemophilia Day 2016.

"We are also funding a pilot for additional psychological support for anyone affected, and if that proves effective and identifies a need, we will go on to roll out further counselling services. We will also continue to fund Haemophilia Scotland and Scottish Infected Blood Forum for at least the next three years, to ensure they can continue to perform a vital role in supporting those affected."

Background:

Health Secretary Shona Robison will make a full statement to parliament at 2pm tomorrow (Thursday).

Anyone who believes they were exposed to NHS blood products in Scotland before 1991, and has not already been tested for Hepatitis C, should contact their GP practice to arrange for a blood test to be carried out.

Press Examples

The Times (23rd March 2015) **Claims to soar after blood scandal report.** Available at: http://www.thetimes.co.uk/tto/news/uk/scotland/article4390376.ece [Paywall] (Accessed 01/08/2016)

STV News (25th March 2015) **Blood inquiry calls for hepatitis C tests for Scots treated before 1991**. Available at: http://stv.tv/news/scotland/315034-scots-infected-by-contaminated-blood-get-results-of-penrose-inquiry/ (Accessed 01/08/2016)

Daily Record (25th March 2015**) Penrose Inquiry urges Scots to get tested if they received blood products before 1991 and says nothing could have been done to prevent the infections of 3000 people**. Available at: http://www.dailyrecord.co.uk/news/scottish-news/penrose-inquiry-urges-scots-tested-5397016#AT1KDQQyJUsRbDWq.97 (Accessed 01/08/2016)

Telegraph (25th March 2015) **What is the Penrose Inquiry?** Available at: http://www.telegraph.co.uk/news/health/news/11493063/What-is-the-Penrose-Inquiry.html (Accessed 01/08/2016)

BBC News (25th March 2015) **Penrose inquiry: David Cameron apologises over infected blood**. Available at: http://www.bbc.co.uk/news/uk-scotland-32041715 (Accessed 01/08/2016)

International Business Times (25th March 2015) **Penrose inquiry: David Cameron apologises over infected blood scandal**. Available at: http://www.ibtimes.co.uk/penrose-inquiry-david-cameron-apologises-over-infected-blood-scandal-1493590 (Accessed 01/08/2016)

The Sun (25th March 2015) **Cameron says sorry to thousands infected by HIV in NHS blood scandal**. Available at: https://www.thesun.co.uk/archives/news/212427/cameron-says-sorry-to-thousands-infected-by-hiv-in-nhs-blood-scandal/ (Accessed 01/08/2016)

Independent (25th March 2015) **Penrose report: Blood scandal inquiry branded a 'whitewash'**. Available at: http://www.independent.co.uk/news/uk/home-news/penrose-report-blood-scandal-inquiry-branded-a-whitewash-10134095.html (Accessed 01/08/2016)

The Herald (25th March 2015) **£12m contaminated blood probe branded a whitewash** Available at: http://www.heraldscotland.com/news/13207377.Penrose_Inquiry___12m_contaminated_blood_probe_branded_a_whitewash/ (Accessed 01/08/2016)

ITV News (25th March 2015) **Borders victim: Penrose report is 'a total whitewash'**. Available at: http://www.itv.com/news/border/update/2015-03-25/borders-victim-penrose-report-is-a-total-whitewash/ (Accessed 01/08/2016)

Daily Mail (25th March 2015) **Blood scandal 'whitewash': After four decades and 2,000 deaths, victims blast £6million report into contaminated NHS supplies.** Available at: http://www.dailymail.co.uk/news/article-3011317/Families-thousands-NHS-patients-given-infected-blood-react-fury-whitewash-report-clearing-NHS.html (Accessed 01/08/2016)

The Times (25th March 2015) **Victims of poisoned blood transfusions demand answers**. Available at: http://www.thetimes.co.uk/tto/news/uk/scotland/article4392290.ece [Paywall] (Accessed 01/08/2016)

Scotsman (25th March 2015) **Blood scandal victims condemn Penrose inquiry**. Available at: http://www.scotsman.com/news/blood-scandal-victims-condemn-penrose-inquiry-1-3728511 (Accessed 01/08/2016)

Guardian (26th March 2015) **Scottish government tells contaminated blood victims: "We will do all we can to deliver justice and support".** Available at: https://www.theguardian.com/uk-news/scotland-blog/2015/mar/26/scottish-government-tells-contaminated-blood-victims-we-will-do-all-we-can-to-deliver-justice-and-support (Accessed 01/08/2016)

Daily Record (26th March 2015) **Furious HIV and Hep C blood mix-up campaigners burn report that blames no one for their agony**. Available at: http://www.dailyrecord.co.uk/news/health/furious-hiv-hep-c-blood-5401444#yQteG4wKQ2JVoOGj.97 (Accessed 01/08/2016)

Daily Express (26th March 2015) **'Whitewash' fury of blood scandal victims: £12m six-year inquiry only makes ONE suggestion**. Available at: http://www.express.co.uk/news/uk/566411/inquiry-blood-scandal-victims (Accessed 01/08/2016)

The National (26th March 2015) **Victims' fury over result of blood inquiry**. Available at: http://www.thenational.scot/news/victims-fury-over-result-of-blood-inquiry.1456 (Accessed 01/08/2016)

Pink News (26th March 2015) **David Cameron apologises over HIV and hep C infected blood scandal**. Available at: http://www.pinknews.co.uk/2015/03/26/david-cameron-apologises-over-hiv-and-hep-c-infected-blood-scandal/ (Accessed 01/08/2016)

Independent (27th March 2015) **The NHS tainted blood scandal will not go away**. Available at: http://www.independent.co.uk/voices/comment/for-all-his-faults-russell-brand-is-utterly-sincere-something-politicians-should-emulate-10140020.html (Accessed 01/08/2016)

Appendix 4: Testing of Scottish National Blood Transfusion Service donor archive samples collected and stored prior to the implementation of routine anti-HCV testing

1 Introduction

The Penrose Inquiry Final Report (March 2015) made a single recommendation: 'That the Scottish Government takes all reasonable steps to offer an HCV test to everyone in Scotland who had a blood transfusion before September 1991 and who has not been screened for HCV'.

In evaluating options to address this recommendation, SNBTS has been asked to assess the feasibility of testing archived donor samples from 1984 to 1991 for the presence of HCV. Although the reference period for the Inquiry was 1st January 1974 to 1st September 1991 there are no archived samples from prior to 1984. Routine testing of all donations for anti-HCV antibodies commenced as a mandatory requirement from September 1991.

Since 1984 SNBTS has, where possible, retained a small sample from every blood donation which are stored frozen, off site, in a warehouse. The main purpose of the archived samples is to support the investigation into infections or adverse reactions in patients where the transfusion of blood components may be implicated. The testing of archive samples from implicated donors can help confirm whether the transfused blood components were the source of the infection or adverse reaction. It is unusual for a Blood Service to retain a sample archive of this duration, there is no legal requirement to do so and other Blood Services only retain donor samples for up to 3 years. Around 10 years ago SNBTS considered discarding the older samples in the archive due to concerns over their identification, provenance and key data linkages, however this was put on hold because of the genesis of the Inquiry.

In conducting this review it was necessary to consider the sample archive over two different periods, the first being all the samples collected and stored between 1984 and 1992 and the second being the National Sample Archive which was established from 1998. The differences between these two archives are significant and are explained in the following sections so that the difficulties and limitations in screening the former can be understood. Archive samples from 1992 to 1998 fall somewhere between the two. The review also explores the availability of SNBTS records from this period, the challenges and costs of performing the actual tests, the availability of hospital blood bank and clinical records and the issues relating to dealing with the outcomes of testing for donors and patients. Finally we make an estimate of the likely feasibility, work and cost involved in retrieving, testing and reconciling the estimated 2 – 2.5 million samples stored from this period.

2 Blood Donation, Processing and Testing, Distribution and Transfusion (Appendix 4.1)

We thought it would be helpful to first provide an explanation of the main processes involved from blood donation through to transfusion to a patient and the way in which these are supported across NHS Scotland today through partially-automated testing, positive sample identification (bar codes) and integrated IT systems. These are depicted in the appended high level process maps (Appendices 4.1a – 4.1e). It should be remembered that over the years these systems have replaced manual systems where paper records were the norm, transcriptions errors frequent and timely access poor.

In the current system, there are three essential elements in the tracking of blood components between donors and recipients:

The first is the donor record and the unique identification number created for every donor. This number is used at every attendance and provides assurance that it is the correct donor and record, that has been identified at the collection session (Appendix 4.1a).

The second is the use of a unique bar-coded donation number which is applied to each donation session record, each donation, the 3 analytical samples taken during blood collection, and to all components manufactured from the donation. This donation number is permanently linked to the donor record. Every time the donor donates a different unique donation identification number is applied to the donation, samples etc and this is again linked to the donor record on the computer system (Appendices 4.1b and 4.1c).

During component manufacture the bar-coded donation identification number is scanned at each processing step and is automatically recorded in the computer system. During testing the bar-coded donation identification number is automatically scanned by the analysers and the results associated with this number electronically transferred into the computer system. The components from the donation cannot be released to hospital blood banks until all the test results are available (and negative). The donation number is also used to track the release of components to hospital blood banks (Appendix 4.1d).

The third is the hospital blood bank itself. The components held are anonymised (*i.e.* they don't have the personal details of the donor) but are identified by the unique donation number and component code. Patient blood samples are received from the clinical environment by the hospital blood bank for blood grouping, red cell antibody testing and cross match against potential donations. The patient records are maintained by the hospital blood bank identified by name, gender, date of birth and CHI number. These are reconciled against the donations selected and issued to that patient. The clinical team administering the donation should also record the transfusion in the clinical notes of the patient.

Modern transfusion is therefore highly reliant on robust integrated systems to ensure appropriate records can be maintained for all transactions and that they are readily available and accessible. The use of internationally agreed barcode numbers and the scanning of these numbers at all stages of the process provide a high degree of accuracy and ensure traceability of all elements of the blood supply. SNBTS introduced its first fully integrated computer system to manage donor administration, blood collection, component manufacture, testing, component labelling and issue to hospitals in 1998. Prior to that records were maintained on first generation fragmented computing systems and / or local manual systems (Appendix 4.1e).

3 Archive Samples 1984 – 1991 (Appendix 4.2 and Figure 4.1)

During the period in question SNBTS carried out processing and testing of donations at 5 semi-autonomous Regional Transfusion Centres (RTCs) in Aberdeen, Dundee, Edinburgh, Glasgow and Inverness. Each RTC retained and stored their own sample archive and a variety of methods and storage containers were employed. Quality, IT and record systems were quite rudimentary when compared to contemporary standards. The methods employed to test donor samples and to prepare each sample archive would not be considered suitable in today's environment.

Archive records for this time period were mainly paper-based, and may now be weak or patchy as evidenced by the poor success rate in tracing pre-1991 samples in previous 'look-back' investigations.

In addition, sample labelling and therefore identification is poor and sample volume low such that automated screening, as is routine now, would not be possible on these samples. Although manual testing is acceptable for small scale testing in investigations it is a very significant undertaking for the large scale screening required for this exercise.

Finally there are concerns around the integrity of the samples after such prolonged storage and confidence in the results obtained would be reduced.

In essence the further one goes back in time within the archive, the more difficult it is to be confident of the identity, provenance and linkage of the samples.

4 The National Sample Archive (Appendix 4.3 and Figure 4.2)

The National Sample Archive in Scotland was established in 1998 and was the first standardised approach to archiving donor samples within SNBTS with all samples collected throughout Scotland being archived under one system. It is managed under Good Manufacturing Practice (GMP) conditions and is prepared and stored in a controlled manner with good electronic record retention, availability and access. Although it cannot be considered equivalent to the testing of 'fresh' donor samples it does provide a high degree of confidence in sample integrity and provenance, and therefore also in the accuracy of the results obtained, when performing retrospective testing investigations.

5 Testing Methodology (Appendix 4.4)

In 1991 a serological test for anti-HCV was introduced for all blood donations. Currently all samples are still tested for anti-HCV but are also tested for HCV Nucleic Acid (NAT).

Due to the volume of archive sample available it is not possible to perform both tests in this exercise. From a practical standpoint it is believed that the serological anti-HCV test is the more practical to complete. However it should be borne in mind that samples can and do degrade with time even under optimal storage and that continuous temperature monitoring records are unlikely to be available over a period of more than 30 years. Current generation virology assays are optimised for fresh samples and contemporary automated testing platforms whereas this testing will almost certainly have to be carried out using manual methods.

It is routine practice that any initial screen reactive (potential positive) test result is repeated in duplicate generating 3 results in total. This is because some donor samples can give rise to a false positive result in virological testing due to technical reasons. If 2 or 3 of the 3 tests are reactive then the sample is considered repeat reactive and the blood components are not issued.

With the highly sensitive screening assays used in SNBTS, >90% of repeat reactives will not be confirmed as 'true' positive infections. All repeat reactive donations are therefore referred for further testing and complex confirmatory algorithms are followed to ensure that only donors will real infections are informed of their infective status.

Due to the lack of sample volume it will not be possible to follow the above procedure for all samples and SNBTS would require to identify, trace and re-test all the donors of repeat reactive samples in order to confirm the veracity of the result (other than those who continued as donors after September 1991 who would have been tested for HCV and those already involved in lookback carried out for any HCV positive patients).

It needs to be borne in mind that whilst donors are, by definition, healthy individuals, there is still a high level of attrition over a 25-32 year period. Many of these people will have moved and some will be deceased and there will be no way of knowing this before we attempt to trace them. The emotional impact of contact on some donors and their families (particularly if the donor is deceased) needs to be taken into account.

6. SNBTS Donor and Donation Records (Appendix 4.5)

As noted above SNBTS introduced its first National IT system (Progesa) to manage donor, donation, testing and manufacturing and issue records electronically in 1998. Other IT systems had become available from the late 1980s/early 1990s but different systems were in use in different regions (*e.g.* Dobbin/Lablan) and they were not as

comprehensive as Progesa. Records prior to this were mainly paper based which in many cases were subsequently micro-fiched to reduce the bulk of paper storage.

For much of the 1984-1991 sample archive, there were no electronic records linking of testing to donors, donations collected, components manufactured and subsequently issued to hospitals.

It is unknown if access to paper or micro-fiche records remains possible for 1984-1991 but even if they are extant reconciling them is likely to be challenging and incomplete.

From the available information related to records it is likely that in a significant number of cases it would not be possible to unequivocally link a tested archive sample to a donor, to the components manufactured, or to the hospital to which they were issued.

7. Hospital Records (Appendix 4.6)

In the past hospitals were not required to maintain hospital blood bank records for the same length of time as SNBTS (this changed when the Blood Safety and Quality Regulations came into effect in 2005). Therefore if a confirmed anti-HCV positive result was obtained on testing of a 1984-1991 archive sample, even if traceable to the hospital blood bank, it is unlikely that in the majority of cases it could be traced to a specific patient. Even if or where the hospital blood bank records were extant, one would then require the clinical hospital records to confirm transfusion, identify the attending Consultant or General Practitioner and contact details for the patient. Most clinical records are not retained for this length of time (25-32 years), most of the attending clinicians will have retired and many of the patients will have moved or be deceased (50 % of blood components are administered to patients who die within 5 years of their underlying condition or age). It may well not be possible to identify whether a patient is alive or deceased prior to trying to contact them. It is very difficult to estimate the workload involved in trying to trace these records and individuals but it is likely to be a very labour intensive.

8. Logistics and Costs of Testing the 1984 – 1991 Sample Archive (Appendix 4.7)

For the purposes of this review, one scenario was explored to allow the logistics and indicative costs of testing to be estimated. Other scenarios are possible where additional resource could be employed to reduce the overall timescales.

From the foregoing it can be seen that testing the 1984-1991 would require considerable effort and resource in terms of identifying, retrieving and manually testing the samples, and reconciling the test results with the original donations and donors on the one hand and the components manufactured and issued to hospital blood banks on the other. As a reference point, SNBTS currently tests around 250,000 samples *per annum* using automated systems This work would require the

testing of 2 to 2.5 million samples (10x the current annual SNBTS throughput) using manual methods for retrieval, sampling, testing and record reconciliation.

A separate team would need to be employed and trained to undertake this and currently we do not have additional laboratory facilities in which it could be undertaken. It is possible that with the opening of the new National Centre in mid-2017, one of the existing laboratories could be retained rather than decommissioned to provide space, but this would need to be formally explored. It would also be necessary to purchase additional equipment, validate the assays and protocols and recruit and train a dedicated team of suitably qualified staff before testing could be commenced.

The estimate in this scenario is that testing would take approximately a year to establish and 5-6 years to complete at a cost of between £8.2 million and £9.7 million. It should be borne in mind that this is only a high-level estimate of likely SNBTS costs only, the costs to other parts of NHS Scotland of searching hospital blood bank and patient records and tracing individuals is difficult to estimate.

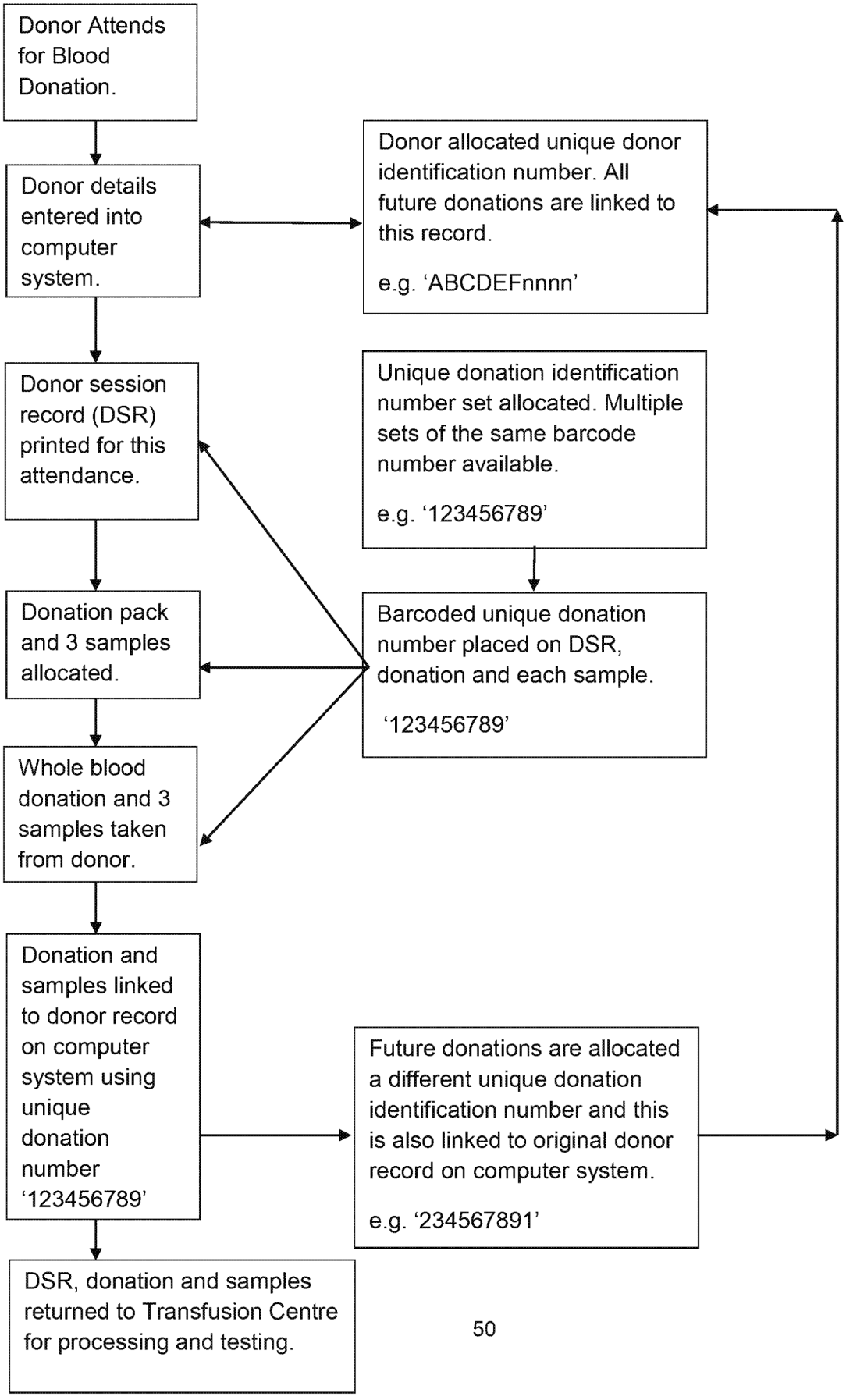
9. Summary

The 1984-1991 sample archive was collected and stored between 25 and 32 years ago when assays, technology, record keeping, quality and IT systems were rudimentary and dispersed across 5 centres.

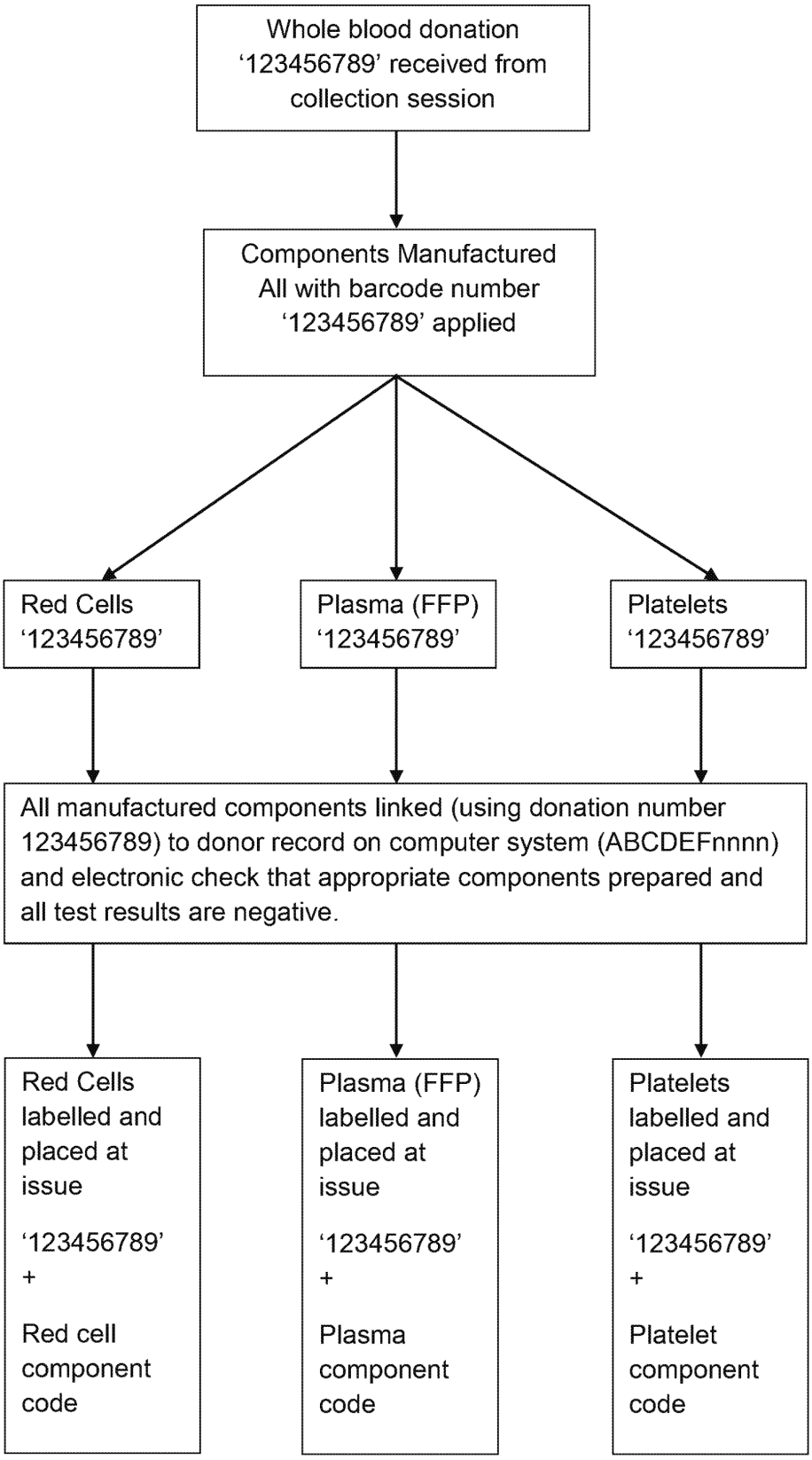
This review has identified that there are a number of challenges and limitations in testing the 1984-1991 archive:

1. There are many concerns with the reliability of the archive in relation to sample identification, provenance and security of linkage to other key data.
2. For many samples there will be insufficient sample volume to carry out testing to resolution.
3. Linking tested samples to specific donors, components and the hospitals they were provided to will be difficult due to the variety of paper-based and early IT systems used at the time.
4. An effort would need to be made to trace repeat reactive donors to inform them and carry out confirmatory testing. Most of these people will no longer be blood donors and may have moved or themselves be deceased.
5. Hospital record retention does not extend back to the 1984-1991 period and it is likely to prove difficult to identify and trace which patients received specific components.
6. A break in the chain of traceability in any of the above areas would negate the benefit of testing. In reality there are significant weaknesses in all areas. The likelihood of being able to trace significant numbers of infected patients through this route is small.
7. This would be a major exercise, incurring costs of between £8m-£10m and requiring 5-6 years to complete.

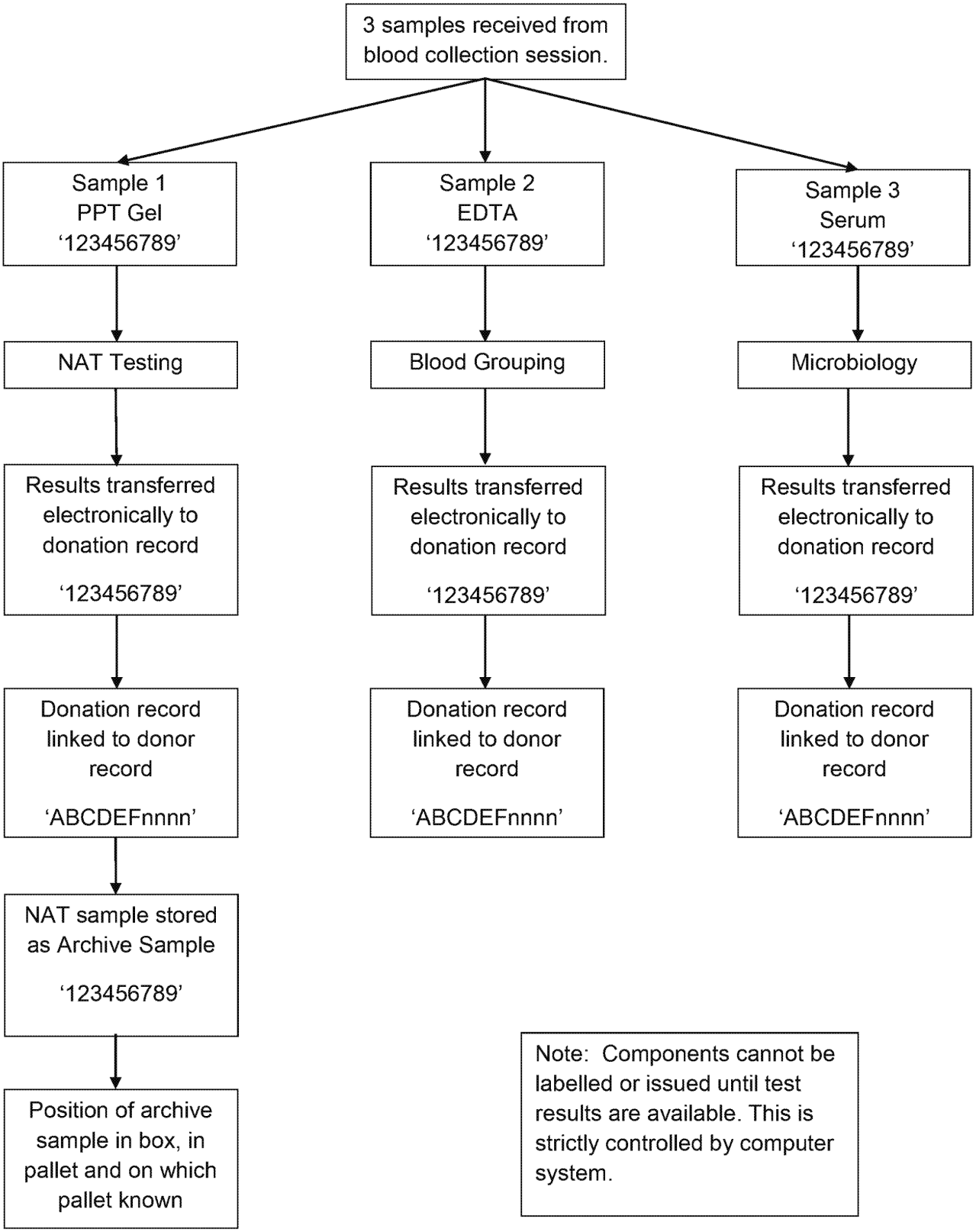
Appendix 4.1a: Simplified Process Map of Blood Collection



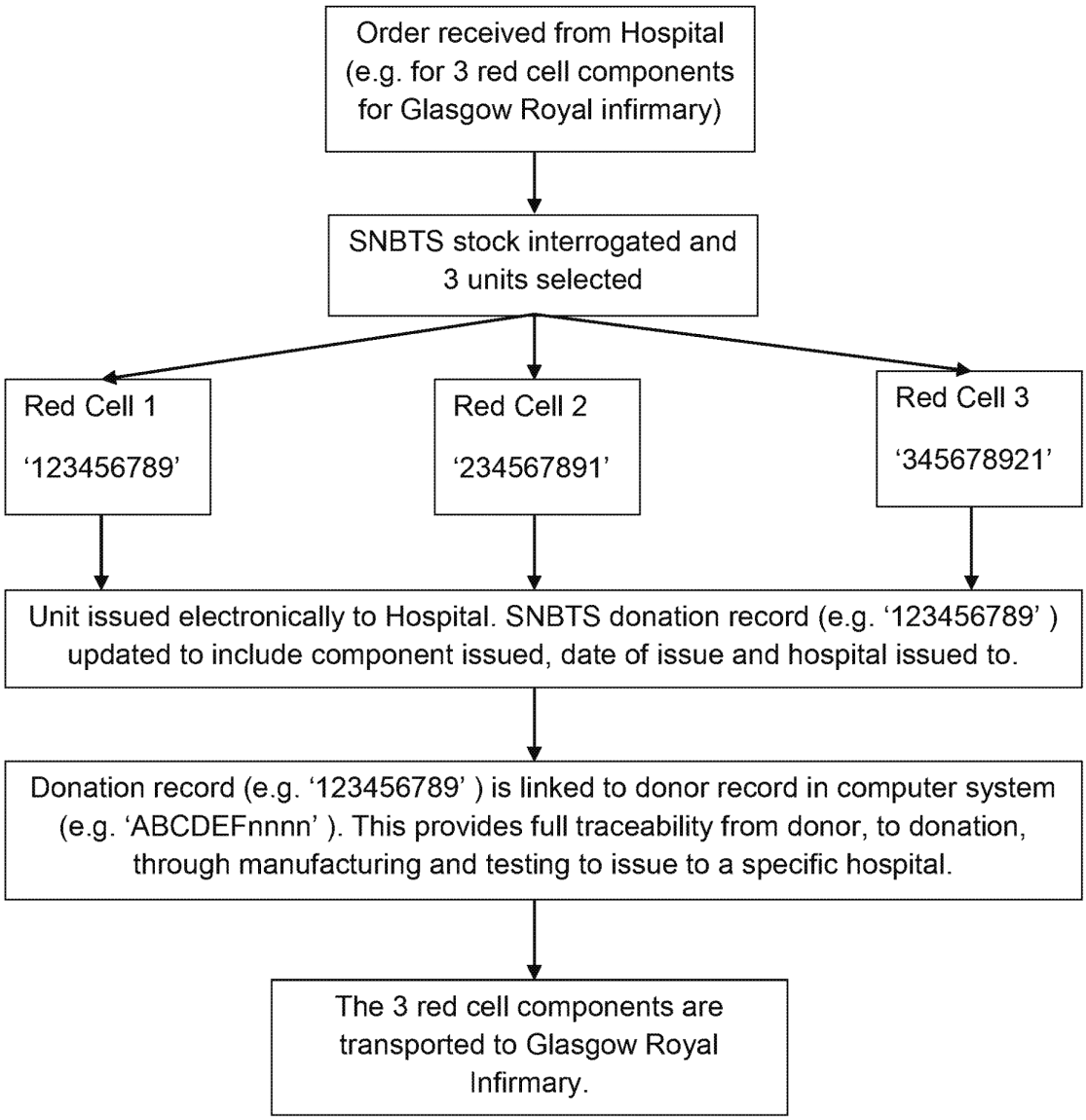
Appendix 4.1b: Simplified Process Map of Donation Processing



Appendix 4.1c: Simplified Process Map of Donation Testing



Appendix 4.1d: Simplified Process Map of Order, Issue and Distribution

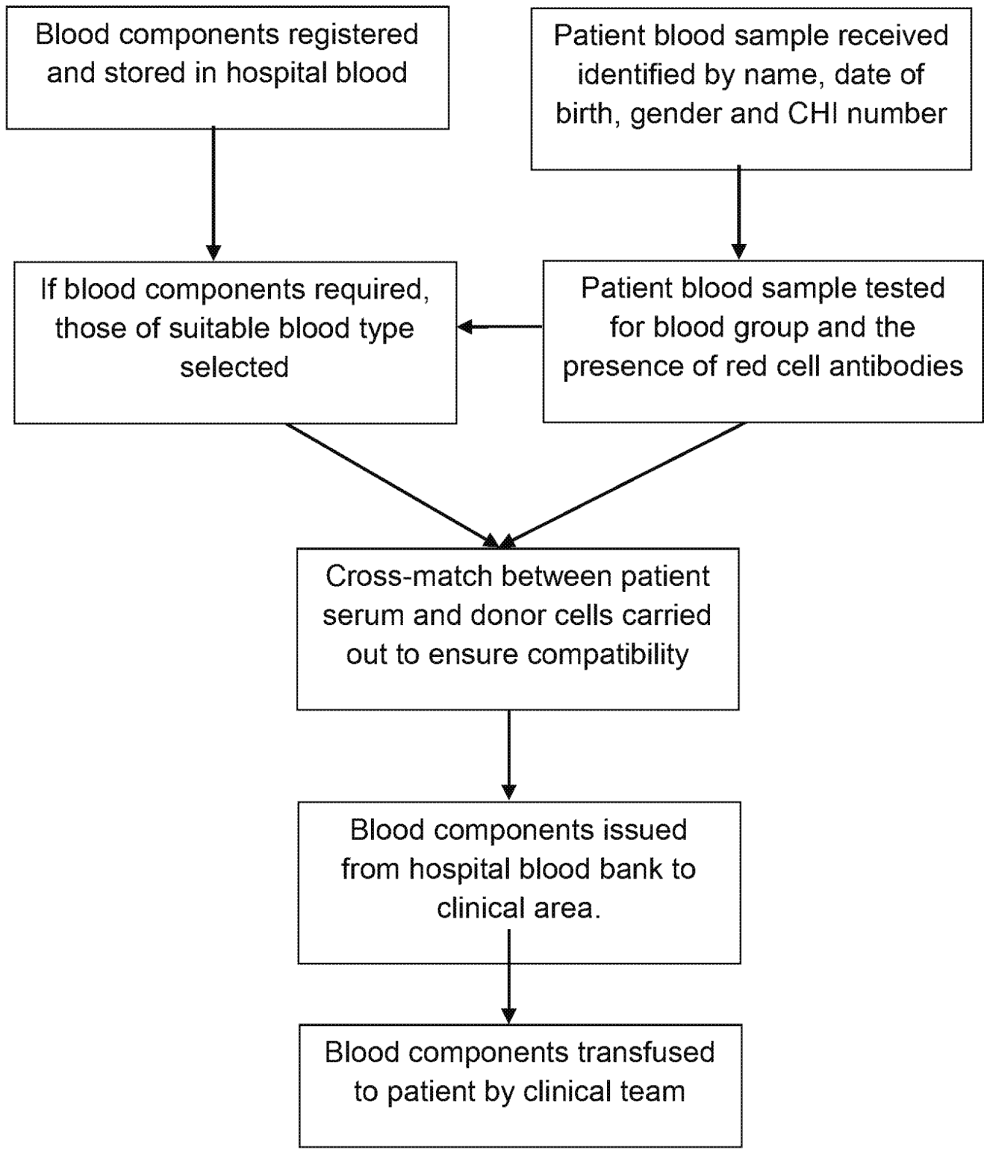


Note:

Hospitals maintain and retain records of components transfused and the patients they are transfused to.

If donation number provided to SNBTS computer system can be searched and full donor/donation history traced.

Appendix 4.1e: Simplified Process Map of Hospital Blood Bank Testing and Issue



Appendix 4.2: Testing Sample Archive for HCV – 1984 – 1991 (see Figure 4.1).

All samples were collected, prepared and stored in the then five regional centres in Aberdeen, Dundee, Edinburgh, Glasgow and Inverness.

Archive samples were prepared by different means i.e. non-standardised in each region.

Archive samples were stored in a variety of containers – poly-tubes, 'small plugs', 96 well micro-plates, 96 deep-well micro-tubes, plugs, etc.

Record keeping and IT systems were not as developed as the systems in use today. Paper and/or electronic records are therefore poor and patchy. As with the storage containers a variety of record formats were used (for those that are available).

Archive sample volume varies, from a few micro-litres to about 1ml.

Most archive samples do not have bar-code identification labels or check digits with some having hand written donation numbers. The year of donation is not on the label and the numbers used were repeated each year, for example number range started at 000001 in 1984 would be repeated as 000001 at some time in the future. Those on micro-titre plates will not be individually numbered – would depend on whether plate maps or copies of test results are available (we know many are missing) for individual sample identification.

Many of the archive samples were prepared manually and this is known to be subject to human error (in sampling and transcription).

Archive sample condition (suitability) for testing is unknown, i.e. we don't know how well they have been stored (thawed and/or re-frozen) or how many temperature excursions there have been.

Current assay package inserts require frozen thawed samples to be well mixed and centrifuged before testing – some package inserts require ultra centrifugation. This is clearly not possible with micro-titre plates or for large scale screening which this exercise would require. However such testing is acceptable for small numbers such as the occasional investigation.

Success (based on experience) in trying to locate samples from this era is relatively poor.

We cannot test the archive samples on automated platforms, they will have to be tested manually.

Many of the poly-tube archive samples were removed from storage trays and placed in plastic bags. They would take considerable time and effort to sort.

The entire Glasgow, Aberdeen, Inverness and Dundee sample archives were sent to Edinburgh around about 1998 – many records are missing.

The staff who dealt with this at the time have long since left the organisation. No 'organisational memory' available to assist with process.

Not possible to create/retrieve lists of all donations collected by Date of Withdrawal (DOW) – no way to reconcile what we have in archive against what was actually collected and tested at the time.

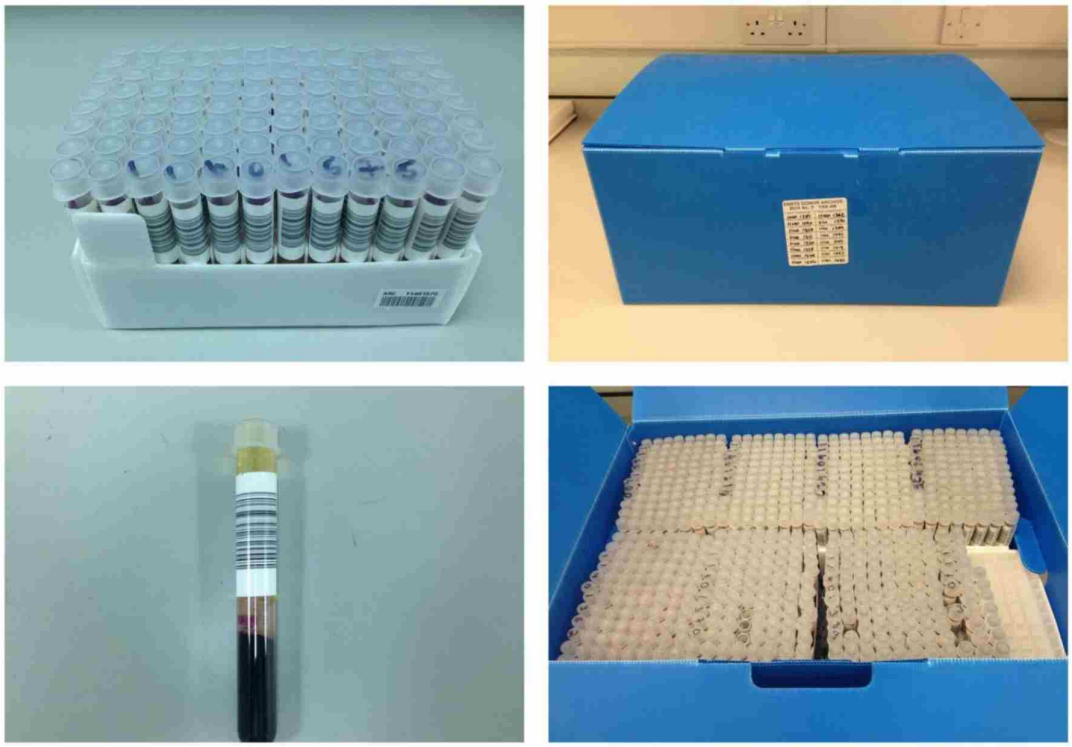
Of 19 requests for 'look-back' samples covering this time period only 11 could be found.

Some archive samples, directly relevant to this exercise, may have already been removed from the archive for previous look-back investigations.

We may know what archive samples have been stored – but we don't know what samples are missing. It may not be possible to identify them so the exercise cannot ever be entirely complete.

Figure 4.1: Photograph of the 1984 – 1991 Sample Archive.

Figure 4.2: Photograph of the post-1998 National Sample Archive.



Appendix 4.3: Testing Sample Archive for HCV – post-1998

First established 1998.

PPT gel tube stores plasma and red cells separated by a gel interface after centrifugation – so no cellular contamination.

Good volume for further testing – initial sample 6-7ml on collection and prior to routine NAT testing.

Bar coded sample (and eye-readable) with appropriate check digits incorporated – provides confidence when sampled and tested on automated instruments.

Low risk of contamination from other samples as disposable tips used.

It is used as routine NAT testing sample prior to be used for archive purposes.

All archive samples prepared in Edinburgh P&T laboratory – standardised approach with no variation from different sites.

Good electronic records – can confidently link archive sample to test results through to full donor records.

For each sample we know position in archive rack, in which box rack stored, on which pallet box stored, and location in commercial store. Fairly easy to locate if required although we need permission to access commercial store as they have to retrieve pallet using forklift truck.

Prepared and stored to contemporary GMP standards.

Can be tested on automated assay analysers if required (not sure this is actually true given need to remove debris).

Current process provides confidence that the sample is from identified donor.

Samples have been stored well throughout their archive life (controlled).

We have a good success rate in finding and retrieving these samples when required to do so.

Stored in commercial cold store under contract to an agreed specification.

Very happy to use these samples and have high confidence in them (for testing small numbers)

Requirement of current package inserts to have frozen/thawed samples ultra centrifuged to remove any debris prohibits large scale screening on a routine basis. This is a complication that needs to be explored further as large scale screening of current archive may not be as easy as initially thought.

Appendix 4.4: Testing methodology

There are two broad methods of testing samples for HCV, serology (antibody response) and nucleic acid testing (NAT).

NAT is more sensitive and would pick detect donors with active infection who are more likely to have transmitted infection, however with the age and unknown storage conditions of samples the titre may have dropped off from the original titre leading to at least some loss of sensitivity (increased false negatives). Practical issues associated with NAT however include the need to make artificial pools which would have to be done manually given the variety of sample storage containers, with manual transcription of sample numbers introducing another level of possible error. Also there would be a sample volume issues for NAT (we routinely test 0.5ml) and any positive pools would require further resolution/further samples which are unlikely to be available.

Serological assays require less sample volume. The sensitivity and specificity of current HCV antibody screening assays are assay dependent but are in the region of 99.7 - 99.9% . That of course is based on testing samples as defined in the kit insert (usually 7-14 days old and stored at 4 degrees C). We're not sure we can say what impact the storage of samples over 25-30 years would have on the sensitivity and specificity of the test though in broad general terms these are likely to drop somewhat with old samples.

So in light of the age and variable storage of the samples, either testing approach will lead to a higher level of false negatives (reduced sensitivity) and/or false positives (reduced specificity) compared to fresh samples.

An initial screen reactive result is not a confirmed result and a donor couldn't be classified as HCV positive based on this.

Repeat tests are normally performed in duplicate, considered repeat reactive if 2 of the 3 tests are reactive. All assays have samples that will be non-specific false positives – so being reactive is not confirmed as due to HCV.

Where there is sufficient volume (unlikely) repeat reactives would be referred for confirmatory testing. Negative, indeterminate or confirmed possible outcomes.

Unable to test actual donation to ensure correct donor has been identified.

Assume we will begin to trace donor based on these results. Need to explore Dobbin/Lablan records to identify donor.

Uncertain whether donor will be at same address and some will themselves be deceased.

Significant workload for medical staff in following up donors (this has not been quantified and will depend on test results).

Appendix 4.5: Records – SNBTS

During the period 1984 to 1991 IT systems were rudimentary or non-existent, both within Donor Services, Testing, Components and Distribution. Paper records were primarily maintained and due to their bulk and the space required to store them many were micro-fiched and are therefore difficult to access now (if they can be located at all and not electronically).

Electronic Donor database system did not become available until the late 1980s and these were more rudimentary than the systems currently in use today. Dobbin was the system in use throughout SNBTS with the exception of Glasgow where a system called LabLan was utilised.

When Progesa was introduced in 1998, donor records were migrated from both LabLan and Dobbin. However due to the number of records to be migrated it was agreed that the details of only the most recent donation for every donor would be transferred into Progesa. Therefore many, if not most, of the donation details for the period 1984 – 1991 will not be available electronically now in eProgesa.

Currently, when investigating possible transfusion transmitted infections or adverse reactions, the IT department write an extraction programme to interrogate Dobbin records for each and every request (with limited success).

Many of the paper records are stored off-site in commercial stores and access to them and locating what is needed would be logistically challenging.

Paper records of components manufactured were maintained, we don't know if these are still available or traceable.

Issues of components to hospitals were simply recorded manually in ledgers, again we don't know if these are still available.

In summary, records for this period are poor, patchy and in some cases no longer extant.

Appendix 4.6: Records - Hospitals

The timescales Hospitals are required to retain patient records are detailed below.

Adults

6 years from date of last entry.

3 years from date of death.

Children

From birth until 25th birthday.

If date of entry is at aged 17 years until 26th birthday.

3 years from death.

Any archive sample from 1984-1991 SNBTS tested now and found to be positive is therefore, on balance, unlikely to be able to be traced to a specific patient because it is likely that hospital blood banks records and patient notes from the time have been destroyed.

Many of the patients may have died for other reasons or the illness they were admitted for.

Many patients may have moved address.

The current universal NHS Scotland CHI identification system was not in place during this time period.

Many changes to hospitals have occurred since this time and it is likely that this would also impact on record availability and traceability (closure, consolidation and rationalisation of services for example).

Appendix 4.7: Logistics and Costs of Testing

This is based on manually testing up to 1500 samples per day in a manual system.

Bring 3 pallets/cages of frozen samples from commercial store into SNBTS hands per day.

Need freezers to store within SNBTS.

Estimate 6 staff required to remove sufficient samples from pallet prior to each day testing.

Samples will require to be thawed and centrifuged – not possible for micro-titre plates unless decanted into other tube – this would be extremely onerous and alone could take 6 staff per day.

Need to prepare lists of samples available for testing – this would require to be done manually i.e. hand written – this would be a lengthy process and prone to transcription error.

Set up tests manually – need to identify and procure a suitable assay – this would need to be validated for the method and samples used. It is difficult to say whether any manufacturer would support their test being used for this purpose. Assume need 6 staff to set up and test around 1500 samples per day by hand.

Need equipment to perform manual test – no positive sample ID available – wash, add reagents and read results. Printout of results would not have donation numbers. Unable to link results to donation number electronically. We don't have this type of equipment for large scale screening – would need to procure and validate.

Don't have space to locate and operate this equipment – a specific laboratory would need to be created for this purpose. Need cold room space for thawed samples and reagents. Could be considered for 'development' space within new National Centre (not available until middle of 2017).

Manual reconciliation of results would be onerous, labour intensive and time consuming.

Recruitment and training of staff must also be considered and set up time is likely to take a year.

Test is likely to cost around £2 and test around 400,000 samples per year – so around £800,000 per year.

Around 20 new staff would need to be recruited and trained. Say 16 at Band 6, 3 at band 7 and 1 at band 8 from 6 years (inclusive of set up year) = £700,000 per year.

Approximately 2-2.5 million samples – so a year set up and 5-6 years to complete testing = £8.2 million – £9.7 million.

Please note there are likely to be other costs not covered in the above analysis – for example the full costs of laboratory set up and equipment purchase and the costs to the broader NHS Scotland of trying to trace patients through hospital blood bank and patient records.

By increasing staffing numbers, equipment and laboratory space it would be possible to reduce the overall timescales with some increase in costs.

Scottish Government
Riaghaltas na h-Alba
gov.scot

© Crown copyright 2016

OGL

This publication is licensed under the terms of the Open Government Licence v3.0 except where otherwise stated. To view this licence, visit **nationalarchives.gov.uk/doc/open-government-licence/version/3** or write to the Information Policy Team, The National Archives, Kew, London TW9 4DU, or email: **psi@nationalarchives.gsi.gov.uk**.

Where we have identified any third party copyright information you will need to obtain permission from the copyright holders concerned.

This publication is available at **www.gov.scot**

Any enquiries regarding this publication should be sent to us at
The Scottish Government
St Andrew's House
Edinburgh
EH1 3DG

ISBN: 978-1-78652-390-7 (web only)

Published by The Scottish Government, August 2016

Produced for The Scottish Government by APS Group Scotland, 21 Tennant Street, Edinburgh EH6 5NA
PPDAS77648 (08/16)

w w w . g o v . s c o t