ANNEX B

Information Requested

-----Original Message-----
From: [*text redacted – personal data*]
Sent: 18 March 2015 16:12
To: Brown GJ (Gareth) <Gareth.Brown@scotland.gsi.gov.uk>
Cc: [*text redacted – personal data*]; [*text redacted – personal data*]
Subject: FW: Written PQ Answers

BACKGROUND NOTE FOR PQ S4W-23405
(To be completed as necessary with any additional information)

Penrose Inquiry –

The inquiry is currently in the process of issuing warning letters arising from the final report, the process of which taking longer than anticipated. A final figure for the total cost of the Penrose Inquiry will be published when the inquiry has completed its work. The most recent information relating to the report can be found on the inquiry's website at: http://www.penroseinquiry.org.uk/

[*text redacted – out of scope*]

Contact Name: [*text redacted – personal data*]
Ext: [*text redacted – personal data*]

_____

From: Brown GJ (Gareth) <Gareth.Brown@scotland.gsi.gov.uk>
Sent: 26 March 2015 11:43
To: Cabinet Secretary for Health, Wellbeing and Sport <cabsechealth@scotland.gsi.gov.uk>
Cc: First Minister <FirstMinister@scotland.gsi.gov.uk>; Permanent Secretary <PermanentSecretary@scotland.gsi.gov.uk>; DG Health & Social Care <DGHSC@scotland.gsi.gov.uk>; Director of Population Health Improvement <Directorofpopulationhealthimprovement@scotland.gsi.gov.uk>; McQueen F (Fiona) <Fiona.Mcqueen@scotland.gsi.gov.uk>; Matheson J (John) <John.Matheson@scotland.gsi.gov.uk>; Paterson J (John) <John.Paterson2@scotland.gsi.gov.uk>; Keel A (Aileen) <Aileen.Keel@scotland.gsi.gov.uk>; Henderson D (Donald) <Donald.Henderson@scotland.gsi.gov.uk>; [*text redacted – personal* data]; Minister for Public Health <MinisterforPublicHealth@scotland.gsi.gov.uk>; Lloyd E (Elizabeth) <Elizabeth.Lloyd@scotland.gsi.gov.uk>; Hutchison D (David) <David.Hutchison@scotland.gsi.gov.uk>
Subject: RE: OFFICIAL SENSITIVE – INFORMATION EMBARGOED UNTIL 12.15 PM ON 25th MARCH 2015 - PENROSE INQUIRY DRAFT STATEMENT

[*text redacted – personal* data]

I attach the final clean version. The only change I made was to add the paragraph below in the section about the Penrose recommendation – [*text redacted*].

[*text redacted*]

Inserted paragraph:

However, anyone who wants to know more will be able to find information on the NHS Inform website or from organisations such as Hepatitis Scotland, Haemophilia Scotland and the Scottish Infected Blood Forum

[*link to final statement provided in covering letter*]

Gareth Brown
Head of Health Protection | Public Health Division | Population Health Improvement Directorate
Scottish Government |Tel: [*text redacted – personal data*]

From: Brown GJ (Gareth) <Gareth.Brown@scotland.gsi.gov.uk>
Sent: 16 March 2015 11:50
To: Cabinet Secretary for Health, Wellbeing and Sport <cabsechealth@scotland.gsi.gov.uk>; Cabinet Secretariat inbox <CabinetSecretariat3@scotland.gsi.gov.uk>
Cc: [*text redacted – personal* data]; Henderson D (Donald) <Donald.Henderson@scotland.gsi.gov.uk>; Director of Population Health Improvement <Directorofpopulationhealthimprovement@scotland.gsi.gov.uk>; Communications Healthier <CommunicationsHealthier@scotland.gsi.gov.uk>; Minister for Public Health <MinisterforPublicHealth@scotland.gsi.gov.uk>; Minister for Sport, Health Improvement and Mental Health <MinisterforSportHealthImprovementandMentalHealth@scotland.gsi.gov.uk>
Subject: RE: Penrose Inquiry: Scance Note

[*text redacted – personal* data]

I attach an updated version with a few speaking points included for the Minister for Public Health. As discussed late last week with [*text redacted – personal* data] and Cabinet Secretariat this speaking note does not provide any information on the detail of the Penrose report given other Cabinet members and cabinet attendees have not signed the pre-release undertaking – it provides only some very broad comments about the process we are not following.

Happy to discuss further

[*redacted*]

Attachment

[Text redacted – out of scope]

The Penrose Inquiry into NHS infected blood (hepatitis C and HIV) in Scotland will be published on 25 March. The Scottish Government received a pre-release copy of the Inquiry report yesterday – Monday 16 March – and a reading team has been established to analyse the report and provide briefings before publication. Other core participants to the Inquiry will receive pre-release copies of the report tomorrow, Wednesday 18 March.

The Cabinet Secretary will meet affected individuals and families on the day of publication and a statement will be given to Parliament on the day after publication setting out the Government's response; detailing the various steps and actions which have been taken and which will now commence; and referencing the review of financial support schemes which will be undertaken on a UK-wide basis.

The Inquiry was announced in 2008 and the costs associated with the Inquiry's work are significant. The Inquiry provided an update on costs in June 2014 (£11.3 million). [*redacted*].

Speaking Note

[Text redacted – out of scope]

- Copies of the Penrose Inquiry report were received by Government yesterday, on 16 March.
- The reading team has been in place since yesterday morning and is working through the report.
- A first briefing on the content of the report was received yesterday evening by those who have been given approval by the Inquiry to have advance sight of the report.
- Further advice will be provided over the coming week which will support our response to the Inquiry in Parliament next week.

From: [*text redacted – personal* data]
Sent: 24 March 2015 17:37
To: Brown GJ (Gareth)
Subject: NHS 24 line: Penrose Inquiry

The Penrose Inquiry was established by Nicola Sturgeon when she was Cabinet Secretary for Health and Wellbeing. Lord Penrose was formally appointed with effect from 12 January 2009. The Inquiry was established to investigate the circumstances contributing to Hepatitis C/HIV acquired infection from NHS treatment in Scotland with blood and blood products. Under its terms of reference the Inquiry was also tasked with investigating the tragic circumstances which gave rise to certain specific deaths associated with those infections.

Due largely to the historic nature of the Inquiry there was only one specific 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 tested for HCV***.**

Look-back exercises have been carried out in the past to trace recipients of infected NHS blood and blood products, but anyone who is concerned that they may have been exposed via blood transfusion before September 1991, or by treatment for a bleeding disorder with blood products prior to May 1987, should approach their GP to arrange a test.

The following organisations provide support to people affected by the issue of infected blood in Scotland:

Haemophilia Scotland, 0131 524 7286, hello@haemophiliascotland.org
Scottish Infected Blood Forum, 0141 649 0050, mail@sibf.org.uk
Hepatitis Scotland, 0141 225 0419, enquiries@hepatitisscotland.org.uk

[*text redacted – personal* data] | **Policy Manager- Population Health Improvement Directorate (Health Protection: Blood policy)**
t: [*text redacted – personal* data]| e: [*text redacted – personal* data]@scotland.gsi.gov.uk
HEALTH AND SOCIAL CARE DEPARTMENT: SCOTTISH GOVERNMENT

_____
From: Brown GJ (Gareth) <Gareth.Brown@scotland.gsi.gov.uk>
Sent: 18 March 2015 16:17
To: Cabinet Secretary for Health, Wellbeing and Sport <cabsechealth@scotland.gsi.gov.uk>; Minister for Public Health <MinisterforPublicHealth@scotland.gsi.gov.uk>
Cc: First Minister <FirstMinister@scotland.gsi.gov.uk>; Permanent Secretary <PermanentSecretary@scotland.gsi.gov.uk>; DG Health & Social Care <DGHSC@scotland.gsi.gov.uk>; Scott A (Andrew) Dr (Personal Mailbox) <Andrew.Scott2@scotland.gsi.gov.uk>; McQueen F (Fiona) <Fiona.Mcqueen@scotland.gsi.gov.uk>; Matheson J (John) <John.Matheson@scotland.gsi.gov.uk>; Paterson J (John) <John.Paterson2@scotland.gsi.gov.uk>; Keel A (Aileen) <Aileen.Keel@scotland.gsi.gov.uk>; Henderson D (Donald) <Donald.Henderson@scotland.gsi.gov.uk>; [*text redacted – personal* data]
Subject: OFFICIAL SENSITIVE – INFORMATION EMBARGOED UNTIL 12.15 PM ON 25th MARCH 2015 - PENROSE INQUIRY DRAFT STATEMENT
Importance: High

Cabinet Secretary
Minister

Please see the attached further briefing in response to the Penrose Inquiry. This includes (separate attachment) a first draft of the statement to Parliament to be given next Thursday. [*text redacted*].

There is a date in the diary to discuss this further on 24 March. Happy to discuss before then if useful to do so.

From: **Gareth Brown**

Head of Health Protection

18 March 2015

Cabinet Secretary for Health and Wellbeing
Minister for Public Health

cc: Director Level Inquiry Advisory Team

PENROSE INQUIRY: PARLIAMENTARY HANDLING AND NEXT STEPS

Purpose

1. Following my note of 16 March, to provide a first draft of the Parliamentary statement in relation to the Penrose Inquiry publication, and other relevant briefing.

Priority

2. **Immediate**

Overview

3. You are aware of the high-level findings and outcomes of the Penrose Inquiry. The report is due to be published on 26 March. This note provides the first draft of the proposed Parliamentary Statement (Annex A) and additional briefing on [*redacted*]. I also attach a high level timeline summarising the key events as described by Penrose, as a means of capturing some of the rationale for Penrose's conclusions that little could have been done differently (Annex C).

4. Finally, at Annex E I attach a very brief summary of the narrative Lord Penrose provides around the experiences of patients. In discussions with patient groups and the media it will be useful to be aware of the key experiences Penrose relates. We can provide a more detailed summary of these if that would be helpful.

5. So, in summary, the following is attached:

Annex A: Draft Parliamentary Statement (attached separately)
Annex B: [*redacted*]
Annex C: Timeline of key events as described by Penrose
Annex D: Next steps overview
Annex E: Summary of written accounts/oral testimonies

6. [*text redacted*]. The attached briefing and statement assumes that you are generally content with the proposed approach but we can fine tune the detail if necessary.

Next Steps

7. As well as the Parliamentary statement there are various other activities that we will undertake around or after the publication of the Inquiry, and these are summarised at Annex D.

8. [*text redacted*]

Conclusion

9. We are meeting on the 24th discuss further, and I would be happy to discuss any of this then, or earlier if preferred.

Gareth Brown
Head of Health Protection
Ext [*text redacted – personal data*]

Copy List:	For Action	For Comments	For Information		
			Portfolio Interest	Constit Interest	General Awareness
First Minister					x
Permanent Secretary DG Health and Social Care Dr Andrew Scott Fiona McQueen John Matheson John Paterson Dr Aileen Keel Donald Henderson [*text redacted – personal* data]					

Annex B

[*text redacted*]

Annex C

PENROSE INQUIRY: TIMELINE OF KEY EVENTS

Date	Event
1940	Scottish National Blood Transfusion established
1940s	Recognition that blood transfusion could transmit hepatitis, associated with clinical jaundice and then generally known as 'jaundice'.
1950s	Blood products manufactured in Scotland.
1950s	Early forms of factor concentrates produced
1963	Liver disease associated with early concentrates first reported
1966	Cryoprecipitate became widely used in haemophiliacs in the UK
1969	Liver disease associated with cryoprecipitate was first reported
1970s	Increase in the transfusion of individual components rather than whole blood, these being red cells, platelets and plasma
1970s	Commercially produced factor concentrates, made from large pools of donations, began to be available from the USA and similar products were manufactured in the UK by NHS facilities – in Scotland, by Protein Fractionation Centre (SNBTS) in Edinburgh
1972	An NHS Factor IX concentrate (DEFIX), was developed in Edinburgh
1973	Large-pool concentrates made by commercial companies in the USA became available in the UK
1973	PFC was producing concentrates from batches of 100 litres of plasma
1974	Suggestions being made that many cases of hepatitis in recipients of blood or blood products were not caused by either hepatitis A or hepatitis B (i.e. hepatitis C circulating by this time and probably earlier)
1975	From 1975, manufacture of blood products was undertaken by the SNBTS.
1978	AIDS first affects individuals in the US.
1979	AIDS first affects individuals in the UK
4 July 1981	British Medical Journal editorial states that Hepatitis Non-A Non-B is the major cause of chronic liver disease in patients with haemophilia. It points to the dangers of large donor pool sizes
1981	First reports of AIDS in the US published.
1982 (Jul)	PCP (AIDS) was reported in three patients with haemophilia, from geographically distant parts of the USA.
1982 (Dec)	Report of what appeared to be a case of AIDS in a 20 month old child in San Francisco who had received a blood transfusion
1982/83	Studies published indicating that Non-A Non-B Hepatitis is more serious than previously thought
18 May 1983	The Haemophilia Society appeals to the UK Government not to ban imported blood products and urges patients not to stop treatment in response to concerns over potential risks
1983	HIV (initially known as LAV) was first identified in Paris.
Early 1984	The Haemophilia Society maintains its position that there was no reliable evidence that AIDS was transmitted by blood products.
1984 (Feb)	First report of a case of AIDS in a Scottish patient. He had an episode of illness in 1982, although the nature of his condition was not diagnosed at that time.

1984 (Mar)	The collection of blood from prisons and borstal institutions in the UK continues until March 1984
1984 (summer)	Tests for HIV virus developed and in the UK, testing for blood samples from patients to ascertain if they had the HIV virus began

19 November 1984	Blood Products Laboratory (BPL) announces that by April 1985 it will begin heat-treating factor concentrates to 60^{o}C for thirty minutes
27 November 1984	DHSS Working Party on AIDS unanimously recommends donor screening and heat-treatment as soon as possible
1984	International acceptance that the HIV virus caused AIDS
1985 (Mar)	Testing for HIV with the new ELISA test begins late March 1985
15 October 1985	The Blood Transfusion Service Board commences the testing of donors for HIV
1985	Growing perception that the seriousness of Non-A Non-B Hepatitis had been underestimated
1985	Heat treated concentrates for Haemophilia B
1986	HIV virus named
1987 (Apr)	The SNBTS is able to make their Factor VIII product available for clinical use. The product is heat treated at 80^{o}C for 72 hours.
1987 (Dec)	Testing of HIV becomes mandatory in US plasma centres
1987	Heat treated concentrates for Haemophilia A
10 March 1988	The government agrees funding for the MacFarlane Trust charity to assist haemophiliacs who contracted HIV from contaminated blood products
1989 (Apr)	HCV (Hepatitis C Virus) is finally isolated and fully identified. Details of the discovery of HCV were published
1989 (Jun)	Co-ordinated litigation of haemophiliacs against DH commenced in June 1989 with a hearing before the nominated judge, Mr Justice Ognall
1989 (Jun)	Initial UK evaluation (including Glasgow RTC) of 1st generation anti-HCV ELISA test
2 August 1989	SNBTS had evaluated the Ortho-Chiron ELISA Hepatitis C test kits
29 January 1990	The Macfarlane (Special Payments) Trust is established (partly out of funds provided by the Secretary of State). The Government, in acknowledgement of its responsibilities for haemophiliacs who contracted HIV from contaminated blood products, makes and *ex gratia* payment to each one (or to the bereaved families) of £20,000 each
2 July 1990	UK (including Glasgow) comparative study of the Ortho and Abbott tests for Hepatitis C.
30 April 1991	Newcastle Regional Centre unilaterally (against UK policy) introduce screening using Abbott 2nd generation tests
3 May 1991	The Macfarlane (Special Payments (No 2) Trust is established (partly out of funds provided by the Secretary of State). Further capital payments are made in settlement of potential litigation; these payments, which vary in amount according to the recipient's age and family status, total (by May 1993) about £44million (including £316,000 paid to 158 people who had begun litigation proceedings).
15 May 1991	Glasgow centre produced a preliminary report on their evaluation of the Abbott 2nd generation anti-HCV ELISA test
1991 (Sep)	Second-generation HCV screening assays become widely used in the screening of donor blood in the UK
29 March 1993	The Eileen Trust is established out of funds provided by the Secretary of State to support people who have become HIV positive because of NHS treatment, transfusions or needle-stick injury

1998 (Feb)	Government announces Recombinant Factor (lab-made) is to be made available in the UK for all children under 16 or all previously untreated patients (PUPs)

26 March 2001	A landmark case, *A vs National Blood Authority*, is brought by 114 people infected with HCV via infected blood. Mr Justice Burton rules compensation be paid by the National Blood Authority and Velindre NHS Trust. The decision by the High Court has no implications for anyone infected with hepatitis C before the Consumer Protection Act came into force in March 1988
14 April 2003	GMC guidelines state health professionals "must obtain consent before testing for a serious communicable disease"
14 September 2003	Scottish Health Minister, Malcolm Chisholm gave evidence to the Health Committee with reference to the Hepatitis C ex gratia payment scheme for NHS patients who became infected via blood products. In defence of his decision to make *ex gratia* payments short of the recommendations made by Lord Ross in the Expert Group Report, the Minister stated several times that the amount he suggested was based on the limitations of the health budget he has to spend.
25 March 2004	The Skipton Fund (a UK wide ex gratia payment scheme) was established to make payments to certain people who were infected with hepatitis C through treatment with NHS blood or blood products prior to September 1991 and other persons eligible for payment in accordance with the scheme's provisions.
26 June 2006	The PFC (SNBTS) at Liberton is deemed no longer viable following a strategic review of the plasma products manufacturing division of the SNBTS. Due to the move away from plasma-derived blood clotting factors and the risks of vCJD, plasma is to be obtained from sources outside of the UK
13 January 2009	The Scottish Penrose Inquiry is formally set up (announced April 2008)
23 February 2009	Release of the report of the Archer Independent (not statutory) Inquiry on NHS Supplied Contaminated Blood and Blood Products
2011 (Mar)	DH-led Contaminated Blood Review report published
2011 (Dec)	New increased payments from Skipton Fund implemented. Caxton Foundation created to make discretionary payments to those infected with HCV by NHS blood products.
March 2015	Penrose Inquiry reports

Annex D

PENROSE INQUIRY: NEXT STEPS

Date	Event
18 March	Core participants receive pre-release copies of the Inquiry report
25 March	11:00 am - Press conference to formally publish the report at National Museum of Scotland, Edinburgh. Media and families will be given copies of the report. We do not expect a media Q&A at the launch. Campaign groups may talk to press after the launch. *redacted – out of scope* Letters from Cabinet Secretary will be issued to Health and Sport Committee, UK Ministers, NHS Boards and other interested stakeholders. Letters will draw attention to publication and highlight next steps.
26 March	*redacted – out of scope*
Following recess	Attendance at Health and Sport Committee to discuss the report (if needed)
April	*redacted – out of scope*
Following UK General election	*redacted – out of scope*

Annex E

SUMMARY OF WRITTEN ACCOUNTS AND ORAL TESTIMONIES

Introduction

1. Term of Reference 10 of the Penrose Inquiry was:

> *"To examine any particular adverse consequences for patients treated by the NHS in Scotland and their families of infection through blood and blood products with Hepatitis C and HIV, including the treatment offered."*

2. More than 200 pages of the Penrose Inquiry report is given over to providing a summary of the experience of patients, and to investigating the four specific cases the Inquiry looked at in detail. This Annex provides a very brief summary of the key issues emerging from this narrative.

General

3. The key points are:

- Separate to the investigation of the 4 specific cases, a total of 159 patients and relatives provided statements to the Inquiry, 135 in writing and 24 orally. Some of these informed the content of the 2010 Preliminary Report as well as nearly 300 pages of Chapters 4,5 and 6 of Volume 1 of the Final Report.

- There are 90 patient witness statements utilised within the Report. **To be aware that several of these patients have since died.** There are also 45 relatives' witness statements within the Report, relating to 22 of the patients.

- In his Executive Summary Lord Penrose notes that:

> *"…the majority of people had suffered dreadfully and for most of them, life was irremediably altered by viral infection."*

He also states that, in providing oral testimony:

> *"…Every witness showed great courage in attending to speak of such painful experiences. Many suffered considerable distress in doing so. The Inquiry wishes to pay tribute to them all."*

Chapter 4 Summary – Witness Statements

4. The chapter summarises and provides quotes from many of the statements received. These are often distressing where they relate to the symptoms and treatment side-effects patients have dealt with. Some other impacts of HIV and Hep C are equally distressing, especially in relation to the adverse effects on family and spousal relationships and changes to patients' personalities and lifestyles, often as a result of societal stigma.

5. Impact on education, work and financial security is also covered, with many patients and families reporting loss of income due to reduced hours and redundancy, with knock-on adverse impacts on pensions and delays in obtaining state benefits.

6. Payments made to patients by The MacFarlane Trust, the Eileen Trust, the Skipton Fund and the Caxton Foundation are set out as well. Whilst the Report notes that 'many patients and their relatives' did not feel the Skipton Fund payments were sufficient, the Report makes no additional comment on this.

Chapter 5 – Effects of HIV on Patients and Families

7. This chapter deals specifically with the evidence given by six witnesses at the Oral Hearings on their own or their relative's infection with HIV. Only first or false names are provided, and some employment and other details have been omitted to preserve anonymity. The stories are detailed, graphic and frequently distressing to read. The following summarises these cases:

- Christine – whose son John had haemophilia and was infected with HIV and Hep C when he was nine or ten years old. He died in March 1995.

- Amy – whose son 'Luke' (not his real name) was infected with HIV as a result of a blood transfusion at the time of his birth in the mid-80s.

- Frances – whose father 'James' (not his real name) acquired HIV and Hep C from his treatment for Haemophilia A. Born in the 1940s, he died in 1990.

- David – acquired Hep C and HIV from treatment with blood products for his Haemophilia B. He is married with a daughter born as a result of donor insemination.

- Elaine - whose husband 'Brian' (not his real name) had Haemophilia A and acquired HIV through treatment of blood products. He died of AIDS in 1992 at age 47.

- Mark - has Haemophilia A and contracted both HIV and Hepatitis C from blood products

Chapter 6 – Effects of Hep C on Patients and Families

8. This chapter deals specifically with the effects of infection with Hepatitis C, on those who were infected by blood and blood products, and on the families of infected persons.

- Stephen – married with a daughter. Has haemophilia A and acquired Hep C and HIV from blood products. He recalls the HIV diagnosis from when he was 18 years old, but does not recall knowing he also had Hepatitis C until years after this.

- Bridie - mother acquired Hepatitis C from a blood transfusion in 1974 and died as a consequence of this on 10 April 2009.

- Colin – is the third of four brothers. He had Haemophilia B, as did two of his three brothers. All three brothers with Haemophilia B contracted Hepatitis C from their treatment with blood products.

- Gordon – when Gordon gave evidence he was 65 years of age and he lived with his wife in England. Before he retired he was a senior academic. Sadly, Gordon died in the summer of 2013. He acquired Hepatitis C from one of a number of blood transfusions he received at the RIE in December 1975 and/or early 1976.

- Laura – is married with two children. She acquired Hep C from her husband, who has mild haemophilia.

- Anne - contracted Hepatitis C from a blood transfusion she received in a local hospital in January 1986 when she was 31 years old.

- Alex – is in his twenties and has severe Haemophilia A. He was infected with Hepatitis C, Genotype 1a, from his treatment with blood products. His parents believe they were given the Hep C diagnosis when Alex was about seven years old.

- Christine – has a family history of haemophilia. Her son acquired HIV as a result of contaminated blood products and she acquired Hep C in the same way.

_____
From: Brown GJ (Gareth) <Gareth.Brown@scotland.gsi.gov.uk>
Sent: 16 March 2015 16:53
To: Cabinet Secretary for Health, Wellbeing and Sport <cabsechealth@scotland.gsi.gov.uk>; Minister for Public Health <MinisterforPublicHealth@scotland.gsi.gov.uk>
Cc: DG Health & Social Care <DGHSC@scotland.gsi.gov.uk>; McQueen F (Fiona) <Fiona.Mcqueen@scotland.gsi.gov.uk>; Matheson J (John) <John.Matheson@scotland.gsi.gov.uk>; Paterson J (John) <John.Paterson2@scotland.gsi.gov.uk>; Keel A (Aileen) <Aileen.Keel@scotland.gsi.gov.uk>; Henderson D (Donald) <Donald.Henderson@scotland.gsi.gov.uk>; [*text redacted – personal data*]; Scott A (Andrew) Dr (Personal Mailbox) <Andrew.Scott2@scotland.gsi.gov.uk>; [*text redacted – personal data*]
Subject: OFFICIAL SENSITIVE – INFORMATION EMBARGOED UNTIL 12.15 PM ON 25th MARCH 2015: PENROSE INQUIRY INITIAL ASSESSMENT
Importance: High

Please see the attached minute providing an initial summary of the Penrose Inquiry report.

Please note that this information should not be shared with anyone not on this copy list, or with anyone who has not signed the pre-release undertaking.

From: **Gareth Brown**

Head of Health Protection

16 March 2015

Cabinet Secretary for Health and Wellbeing
Minister for Public Health

cc: Director Level Inquiry Advisory Team

PENROSE INQUIRY

Purpose

1. To provide you with an overview of the Penrose Inquiry following the receipt of the pre-release copy of the report earlier today.

Priority

2. **Immediate**

Content

3. Attached to this note are the following annexes, which provide more detail on the Inquiry report:

Annex A: Initial Overview Summary
Annex B: Table of high-level criticisms and positive statements contained within the Executive Summary
Annex C: Summary of report sections, including key points identified
Annex D: Summary of investigations into specific named individuals
Annex E: Initial assessment of the Inquiry recommendation
Annex F: Updated press lines/handling

Summary

4. The Inquiry report is 1,800 pages long and comprises five volumes, with each volume dealing with a different topic. The Report is presented largely as a narrative history of events, or a factual description of key topics such as bleeding disorders, viruses and statistics. On balance there is very little criticism and no criticism we would consider to be significant. There is also recognition of the challenges clinicians, blood services and policy makers faced at the time, and some commentary where Lord Penrose found Scotland's response to be 'world-leading' or 'remarkable'.

5. In his introduction to the Inquiry Report, Lord Penrose says:

> *Much of the comment made over the years on the topics discussed in the Final Report has reflected strongly-held beliefs. Some commentators believe that more could have been done to prevent infection in particular groups of patients. Careful consideration of the evidence has, however, revealed few respects in which matters could or should have been handled differently*.

6. The only point where the Inquiry concludes that more could have been done was in the delay in the introduction of screening for hepatitis C. This relates to a delay of 10 months between when the decision to introduce screening across the UK had been taken (21 November 1990) until screening actually commenced (starting across the UK on 1 September 1991). This delay was found to be because a policy set across UK – that the introduction of screening across the UK should take place at the same time – was maintained despite some areas, including Scotland, being ready to begin considerably earlier than others.

7. The Inquiry finds that some of this delay was due to a reluctance by officials to bring the issue to the attention of the Secretary of State for Scotland. The report says:

> *"…Secretary of State for Scotland and his Ministers should have been alerted that delays to the start date were being caused by problems in other parts of the UK to allow them to make a decision on the most appropriate course of action for Scotland."*

8. However the report also observes that for earlier screening in Scotland to have occurred it would have required the Minister in Scotland to depart from the policy of a uniform start date to screening across the UK, and it is not certain that that would have happened.

9. The Inquiry makes only a single recommendation – that the Scottish Government should ensure anyone who received a blood transfusion before 1991 who has not previously had a test for hepatitis C should get one. We can accept this recommendation without reservation. **Annex E** provides some further discussion.

Next Steps

9. The reading team will continue to analyse the Inquiry report over the course of this week, and more detailed advice on handling of the publication of the Inquiry Report will be provided at the end of the week. This will include a first draft of the statement for the Cabinet Secretary to give to Parliament on 26 March.

10. [*redacted*].

Conclusion

11. You are invited to note the above and the attached annexes. I am available to discuss further if that would be useful.

Gareth Brown
Head of Health Protection
Ext [*text redacted – personal data*]

Copy List:	For Action	For Comments	For Information		
			Portfolio Interest	Constit Interest	General Awareness
					x

DG Health and Social Care
Dr Andrew Scott
Fiona McQueen
John Matheson
John Paterson
Dr Aileen Keel
Donald Henderson
[*text redacted – personal data*]

Annex A

PENROSE INQUIRY: INITIAL OVERVIEW SUMMARY

Overview of Structure of Report

- 1,779 pages in total. 5 volumes and a further, separate Executive Summary.
- The Executive Summary is 43 pages in total.
- Each of the five volumes deals with different issues:
  - Volume 1: Patients' Experiences, including witness statements
  - Volume 2: Knowledge of HIV/AIDS and hepatitis C
  - Volume 3: Blood and Blood Products
  - Volume 4: Donor Selection and Screening of Donated Blood
  - Volume 5: Information to Patients, including an investigation of the look-back exercise
- There are five short appendices on procedural matters and listing witnesses and core participants.
- The report contains a single recommendation for Scottish Government.

Overall Context

- The Inquiry is presented largely as a narrative history of events, or a factual description of key topics such as bleeding disorders, viruses and statistics.
- On balance the report contains no significant criticism. In his foreword Lord Penrose says:

> *"Much of the comment made over the years on the topics discussed in the Final Report has reflected strongly-held beliefs. Some commentators believe that more could have been done to prevent infection in particular groups of patients. Careful consideration of the evidence has, however, revealed few respects in which matters could or should have been handled differently*."

- The only significant criticism relates to the 10-month delay in the introduction of screening for hepatitis C between November 1990 and September 1991
- The report explicitly recognise the devastating impact on individuals and families affected, but also comments on the suffering of clinical staff who were operating with the best of intentions.
- The report also provides estimates for the number of people affected:

	Number infected	**Number known to have died**
Bleeding disorder infected with hepatitis C	478	193
Hepatitis C transmitted by transfusion	2,500 (estimate)	Unknown
Bleeding disorder infected with HIV	60	39
HIV transmitted by transfusion	18	15

Impact on Scottish Government

- The Inquiry's single recommendation is for the Scottish Government to implement (discussed below) but otherwise there is no particular impact on Scottish Government within the Inquiry report.

[*text redacted*]

Financial implications

- The Inquiry report provides a great deal of detail on the difficulties faced by affected individuals. The Report also acknowledges that many affected people believe that the payments they are receiving are insufficient – but our reading thus far does not find any point where the Inquiry comments in anyway on this opinion
- The detail on the impact on individuals will be relevant to the work of the UK administrations to review payment schemes. This may have financial implications if Ministers wish to provide additional funding.

[*text redacted*]

Summary of Recommendations/who for

- There is a single recommendation for Scottish Government: that further efforts should be made to assist anyone who received a blood transfusion before September 1991 who has not had a test for hepatitis C.

Annex B

PENROSE INQUIRY: SUMMARY OF POSITIVE STATEMENTS AND CRITICISMS FROM EXECUTIVE SUMMARY
(all page numbers refer to the Executive Summary)

Topic	Positive Statements	Criticisms
Specific Deaths	Victor Tamburrini – the Inquiry concluded that the evidence did not demonstrate that he acquired HCV from NHS treatment with blood or blood products. (p10)	
Specific Deaths	David Black – the Inquiry concluded that he probably acquired HCV from treatment with blood or blood products in the 1960s, and there were no reasonable precautions whereby his death could have been prevented. With the exception of the failure of communication with regards to the cancer diagnosis in his own liver, his medical management was at all times of a high standard. (p10-11)	David Black – The Inquiry found that Mr Black's own liver was discovered to be cancerous after it was removed. That information was not communicated to Mr Black, apparently due to an oversight. (p11)
Specific Deaths	Eileen O'Hara - The Inquiry concluded that there were no reasonable precautions which might have been taken to avoid her death. (p11-12)	Eileen O'Hara – The Inquiry concluded that there was a significant lapse in patient management as the gastroenterologist who reviewed her Hepatitis C at Stobhill hospital did not see her in person. (p12)
Specific Deaths	Alexander Black Laing – The Inquiry was not able to identify any precautions whereby Mr Laing's death could be avoided, and noted that once HCV was identified, Mr Laing's management as a patient was an example of exemplary care. (p12-13)	
Blood Products		Risk of blood products – The Inquiry found that the risk of infection from blood products was not always fully understood by those involved, including the patients. (p14)

Haemophilia therapy 1981-1984		As far as government was concerned, the official line… in relation to… blood products and AIDS since the summer of 1983 was that there was 'no conclusive evidence' that AIDS was transmitted by blood or blood products. This line was dropped, apparently between January and March 1984. The Inquiry considers the line to have involved a highly nuanced use of language, carrying a risk of misinterpretation. (p17)
Haemophilia therapy 1981-1984	The Inquiry found that other than by a general cessation of therapy with concentrates, the infection of haemophilia patients with HIV over the period 1980-1984 could not have been prevented. The earliest infections in Scotland occurred before 1 January 1981, meaning that any such general cessation would have needed to occur before AIDS itself had been reported. The Inquiry concluded that it was reasonable to treat patients with concentrates. (p18)	
Haemophilia therapy 1985-1987		The Inquiry concluded that it was unfortunate that no information about potential use of 8Y [a heat-treated concentrate] in treatment was disseminated from Edinburgh. However there was no basis for a finding that a general supply of the product could have been made available treatment patients in Scotland. It was noted that it was being sourced from England and Wales, where there was a shortage of supply. (p20)
		The Inquiry found that there was a lack of provision of guidance to hospitals in Scotland that did not have haemophilia centres, but where in an emergency a haemophilia patient would be treated. There should have been written protocols in place for junior staff less familiar with the challenges and drawbacks of the forms of therapy available. (p20)

Viral Inactivation of blood products up to December 1984	The Inquiry investigated whether the viral inactivation programme in 1983 and 1984 was informed by a sufficiently serious view of the risk of AIDS. It concluded that risk was viewed appropriately. There was no evidence the heat-treatment programme could have been accelerated to any significant extent. The Inquiry concluded that there was no basis in the evidence for a finding that the UK licensing of commercial heat-treated product should have taken place earlier than it did. (p22)	
Viral Inactivation of blood products up to December 1984	The Inquiry had no criticism to make of those involved in viral inactivation in Scotland. (p22)	
Viral Inactivation of blood products after 1984		The Inquiry considered that the time it took to resolve concerns about compensation for any harm suffered by patients involved in trails for Z8 was unsatisfactory, and delays were caused to the clinical trials. However, there was no delay to the issue of Z8 to existing patients, but there was delay in issuing the product to previously untreated patients, and adverse impact on specific individuals cannot be excluded. (pp23-24)
Viral Inactivation of blood products after 1984	The Inquiry noted that the Protein Fractionation Centre's success in being able from 1987 onwards to provide all Haemophilia A patients with a product that did not transmit HCV was a considerable achievement. (p24)	
Donor Selection (Hepatitis)		None of the Scottish or UK guidance documents on the selection of donors contained any reference to the collection of blood from prisons. (p25)
Donor Selection (Hepatitis)		The Inquiry found no evidence that any additional steps were taken at prison donor sessions in Scotland to screen out higher risk donors, such as those who had ever injected drugs. (p25)
Donor Selection (Hepatitis)		The Inquiry found that blood collection from prisons was inadvisable and should have been stopped earlier. (p26)

Donor Selection: AIDS	The Inquiry concluded that the steps taken in Edinburgh in 1983 were taken as soon as could have been expected, indeed those involved were prescient in identifying that action was needed. The Inquiry found that, in relation to the question of the prevention of donation by those who were at risk of transmitting the virus, the Inquiry did not identify other measures which should have been adopted but were not. (p28)	
Introduction of screening for HIV	It would have been irresponsible to have introduced US-manufactured test kits in the UK without evaluation. (p29)	
Introduction of screening for HIV		Whether or not to introduce testing in Scotland was a Scottish matter. The SHHD elected to follow the lead of the DHSS in relation to kit evaluation. The Inquiry found that it was unfortunate that the West of Scotland service was not able to participate in the early field test of the kits proposed in June 1984. (p29)
Introduction of screening for HIV	The proposal in early 1985 that Scotland proceed independently with evaluation would not in reality have been practicable, and independent screening in Scotland was not feasible. The Inquiry concluded that there is no legitimate criticism of the processes employed for the introduction of HI screening on the grounds of delay. Screening was introduced as soon as reasonably practicable. (p30)	

Surrogate testing for non-A, non-B Hepatitis		A study by the West of Scotland concluded that Post Transfusion hepatitis (PTH) 29-40% could be prevented by alanine aminotransferase (ALT) testing and 3% of blood donations would be lost. The study was not detailed enough to form firm conclusions, as the recipients of the donations were not followed up. It was concluded on the basis of reported cases that post transfusion non-A non-B hepatitis was not a major problem in the region. The Inquiry considers it unfortunate that these conclusions were used for several years to support the view in Scotland that PTH was not a significant problem. (p31)
Surrogate testing for non-A, non-B Hepatitis		It is likely that ALT screening of donors would have reduced the transmission of hepatitis C to some extent, but it is impossible to quantify that reduction with any degree of accuracy. (p31)
Surrogate testing for non-A, non-B Hepatitis	The Inquiry does not attribute blame for the fact that surrogate testing was not introduced, as there was never enough concrete evidence to justify such a recommendation. (p32)	
Introduction of screening for HCV	The inquiry concluded that while setting up an expert committee was a well-founded decision – Advisory Committee on the Virological Safety of Blood (ACVSB) (p33)	
Introduction of screening for HCV		The ACVSB missed two opportunities to recommend the introduction of screening at an earlier point. It is the view of the inquiry that decision to recommend the introduction of screening should have been taken by middle of May 1990 (p34)
Introduction of screening for HCV		Secretary of State for Scotland and his Ministers should have been alerted that delays to the start date were being caused by problems in other parts of the UK to allow them to make a decision on the most appropriate course of action for Scotland (p34)

Information to patients		Many patients were given little or no information from their treating clinicians about the risks of infection from their treatment with blood or blood products and therefore felt that they were denied the opportunity to make information decision about their treatment. Many patients complained they were tested for HIV or HCV without their consent. Many were unhappy with the manner in which their diagnosis was conveyed. This often reflected a paternalistic attitude to patients which persisted into the 1980s. (pp34-36)
Information to patients	It appears that there has been a move from the essentially paternalistic culture in medicine to a relationship where the patient is fully involved in decision-making. The experience of AIDS appears to have accelerated the move, and the inquiry considers that the effect of AIDS and responses to it have had a more profound effect on doctor/patient relationships that any other single event. (p36)	
Warning of risks of HIV	The inquiry found there is no basis for criticism of individual clinicians about the provision of information about the risk of HIV infection (p36)	
Immunological studies and the Edinburgh 'cohort'	In Edinburgh – in contrast to Glasgow – no specific consent was obtained from patients for investigations for immune abnormalities. The revelation of this work has caused disquiet among patients and their relatives. Its labelling as 'AIDS study' has increased concern. There have been suggestions that it involved experimentation on patients. During the hearings it was acknowledged on behalf of the patients, relatives and the Haemophilia Society that there was no factual basis for this suspicion, and the Inquiry reached the that any such suspicion was without foundation. (p37)	

Immunological studies and the Edinburgh 'cohort'	The inquiry concludes that studies to see if there were immune abnormalities in Glasgow and Edinburgh patients similar to those related to haemophilia patients in the USA was in the best interests of patients, even though there was no structured or systematic approach to providing relevant information to patients. (pp36-37)	
Testing of blood samples for HIV		Samples were tested for HIV without patients' consent, although the inquiry found that was not unusual in December 1984. (p37)
Communication of results		The inquiry noted that there were challenges in informing patients of positive HIV results – the approach taken in Glasgow was considered to be preferable to that in Edinburgh, where many patients were apparently unaware that they were required to ask for test results (pp38-39)
Warning of risks for NANB hepatitis	The inquiry did not find any breach of any ethical provision in relation to warnings given or not given to patients at a time when information about the risk was sparse and important information about NANB hepatitis were not known (p40)	
Testing of samples for hepatitis C – communication of results		The inquiry found that delay in telling patients of their HCV positive status in Edinburgh and Dundee was unacceptable (p41)
Look-back	The inquiry found that an earlier decision on the UK-wide look-back exercise could not have been reached. The look-back was one of the earliest comprehensive look-backs instituted in the world. (p43)	

Annex C

PENROSE INQUIRY REPORT: CHAPTER SUMMARIES

This Annex summarises all chapters of the report. Particularly important comments made by the Inquiry are underlined.

Volume 1: Patients' Experiences

Chapter 1: Introduction

Chapter 2 : Patients at risk In this chapter, the focus is on the groups of people who were potentially at risk from infection and the procedures that gave rise to risk. It noted that successive developments in clinical practice reduced risks to patients, although, on the whole, they did not change patients' needs for treatment.

Chapter 3: Statistics This chapter attempts to estimate the numbers of patients infected with one or other or both viruses. The search for reliable data has proved for the most part to be extremely difficult. Further epidemiological investigation would not produce a more reliable estimate, at least without disproportionate expense. Excluding the extremes, a wide range of values remain as indications of the possible incidence of infection. Only a rough and speculative estimate is possible. If the Scottish Government is persuaded that, for health policy and strategy, or budgeting or other reasons, it is necessary to develop a more accurate figure, it may be that further research and further expert opinion might eventually converge. That cannot be recommended by this Inquiry.

Chapter 4: Experiences of the patients and their families – witness statements
This chapter and the following two chapters explores the evidence available to the Inquiry from patients and their families about their experiences of the infections and of the impact of these on their lives. In total the Inquiry has taken statements from 159 patients and relatives. The Inquiry selected six witnesses to give oral evidence in respect of the effects of infection with HIV, including the effects of treatment, on patients and their families, and seven witnesses to give oral evidence in respect of the effects of infection with Hepatitis C, including the effects of treatment, on patients and their families. It paints a distressing picture of seriously debilitating and sometimes fatal illness that makes its own impact. Many witnesses described having to deal with the stigma associated with the viruses as being the worst aspect of the infection. A number of patients stated that they had lost substantial earnings as a result of having had to reduce their working hours or stop working altogether due to their symptoms or to the side-effects of treatment. A number of patients highlighted the difficulties they had faced obtaining life assurance, travel insurance, critical illness cover and private health insurance. Many patients and their relatives are of the view that the payments they receive from the Skipton Fund are insufficient. A number of patients had accrued debt as a result of their infection. A number of patients were declared bankrupt. Others had their homes and other possessions repossessed.

Chapter 5: An examination of the effects of infection with HIV on patients and their families, including treatment: This chapter deals specifically with the evidence given by six witnesses at the Oral Hearings on their own or their relative's infection with HIV.

Chapter 6: An examination of the effects of infection with Hepatitis C on the patients and their families, including treatment: It is a matter of sorrow to the Inquiry team that some of the witnesses who provided statements and Gordon, who gave oral evidence to the Inquiry, died before this report was published.

Chapter 7: An investigation into the deaths of the Reverend David Black, Mrs Eileen O'Hara, Mr Alexander Black Laing and Mr Victor Tamburrini. Term of Reference 6 required the investigation of the deaths of certain named individuals.

Volume 2: Knowledge of HIV/AIDS and Hepatitis C

Chapter 8: Knowledge Of HIV/AIDS Now This chapter provides an account of what is known now, in 2014, about HIV infection and the AIDS complex of diseases, in particular in relation to the two affected groups. Almost none of this would or could have been known before 1991.

Chapter 9 And 10: Knowledge of the geographical spread and prevalence of HIV/AIDS: In these chapters, the evolving picture is examined from a narrow perspective, tracing developing knowledge of the incidence of diseases associated with HIV infection from the end of 1980, when cases of AIDS were first observed in the USA, to 1984, when testing for antibodies for HIV began to become available in the USA.

Chapter 11: HIV/AIDS aetiology. This chapter discusses the cause or causes of the AIDS that exposed individuals to disproportionate risk of opportunistic infection, cancers and other diseases of the AIDS complex, as disclosed in public debate, professional literature and the written and oral evidence provided to the Inquiry.

Chapter 12: HIV/AIDS: Response And Clinical Practice. Discusses aspects of the response to HIV/AIDS by haemophilia clinicians over the early and middle years of the 1980s. In particular, the question to be addressed is whether clinicians in Scotland should have adapted their treatment regimes sooner than they did, in response to the threat of AIDS.

Chapter 13: Knowledge of viral hepatitis now. This chapter provides an account of what is known now, in 2014, about Hepatitis C virus (HCV) infection, in particular in relation to the two affected groups with whom. the Inquiry is concerned: blood disorder patients receiving therapy and people infected by blood transfusion in the course of medical or surgical procedures. Includes material in relation to the pain and discomfort associated with investigative procedures and the side-effects of drug therapy.

Chapter 14: Knowledge of viral hepatitis 1. Discusses more fully the response of the UK Government and other agencies to the emerging knowledge of viral hepatitis during the period when it presented a threat to NHS patients receiving blood, blood components or blood products in the course of medical treatment.

Chapter 15: Knowledge of viral hepatitis 2 – 1975 to 1985. This chapter traces developments in the understanding of viral hepatitis from 1975 to around 1985.

Chapter 16: Knowledge of viral hepatitis 3 – 1986 onwards. This chapter continues the account of the development of knowledge of non-A, non-B Hepatitis (NANB Hepatitis) from 1986 through to the discovery of the Hepatitis C virus (HCV) and beyond. There was no generally accepted view prior to 1985 that NANB Hepatitis had other than a generally benign prognosis. From 1985 it became increasingly understood that NANB Hepatitis infection could be associated with serious disease.

Volume 3: Blood and Blood Products

Chapter 17: Blood And Blood Products Management. This part of the report deals generally with questions related to the collection of blood and its adaptation for clinical use.

Chapter 18: Collection Of Blood – General. This chapter discusses blood donation collection practice generally. Ignoring later scientific developments, so far as general members of the public offering blood donation were concerned, there was no method of identifying with interview those potential donors who were infected with NANB Hepatitis, but who remained asymptomatic at the donor session. No such interview could have been conceived at the time.

Chapter 19: Production Of Blood Products – Facilities. This chapter deals with the provision of facilities for the production of blood components and blood products, and in particular with the assumptions made as to process capacity in the development of plans for capital projects in the 1970s. In the circumstances, it is somewhat surprising that Scottish needs were as well catered for as, in the event, they proved to be.

Chapter 20: Haemophilia Therapy – The Period Up To The Early 1980s. This chapter deals with developments in technology up to 1982–83. Up to that point the risk of infection, so far as it was understood, was of transmission of hepatitis, first Hepatitis B and then non-A, non-B Hepatitis (NANB Hepatitis). On the eve of the outbreak of AIDS there was a step change in perception of the possibilities of heat treatment to inactivate hepatitis viruses, but continuing scepticism among scientists. Meantime, research in England, led by Dr John Craske, was reaching the conclusion that all Factor VIII concentrates in production in the early 1980s, imported or NHS, were potentially infective for NANB Hepatitis.

Chapter 21: Haemophilia Therapy – Use Of Blood Products Deals with treatment policy and self-sufficiency. There was no evidence before the Inquiry that would support a finding that Scottish practitioners were influenced in their choice of therapeutic products by benefits provided by pharmaceutical companies. Nothing could have been done to prevent the provision of blood and blood products infected with NANB Hepatitis in the 1970s and early 1980s or, when it emerged, HTLVIII/HIV. There was no possibility of detection of either virus until each had been identified (HIV in 1983–84 and HCV in 1988–89). The NHS in Scotland could not have restricted the import and use of commercial products once they were licensed. That was a function of the UK Government. There is no criticism that can legitimately be made of practice in relation to the use of factor concentrates over this period.

Chapter 22: Haemophilia Therapy – Use Of Blood Products 1985–1987 This chapter deals primarily with the treatment of patients with Haemophilia A following the introduction in Scotland in December 1984 of heat treatment of blood products. It cannot be concluded on the evidence available that a barter or other arrangement could have been negotiated that might have procured a supply of 8Y (heat treated concentrate) for use in Scotland in exchange for reciprocal supplies of PFC products. For these reasons, it is highly unlikely that regular supplies of 8Y would have been made available for use in Scotland. There was a failure to provide information that could have informed clinicians of the possibility of obtaining access to the product in appropriate circumstances. In addition, no steps were taken to draw to the attention of physicians outwith Edinburgh the fact that there was already a small stock of 8Y held there.

Chapter 23: Viral Inactivation Of Blood Products for Haemophilia therapy up to 1985 This chapter examines the efforts of the Protein Fractionation Centre (PFC) in Edinburgh, in the period up to 1985, to inactivate viruses (initially hepatitis viruses and later HIV) which were present in its Factor VIII and Factor IX concentrates in this period. The approach taken to viral inactivation at the Protein Fractionation Centre in the period 1980–84 was reasonable. The degree of priority accorded to viral inactivation by the Protein Fractionation Centre during this period was also reasonable. In order to have advanced the provision of effectively heat-treated products so as to have ensured their supply in Scotland before the end of December 1984 as a matter of general prescription, the SNBTS would have required to be satisfied that the products were safe and effective to a degree that indicated that domestic research should be suspended or discontinued. The evidence has not disclosed any rational basis on which that could have been decided. Nor could one form or express any view on the likely reaction of the regulatory agencies if a licence application had been made.

The work of the PFC was done effectively, and it was done with remarkable expedition. There is no basis in evidence for a view that a UK policy decision directing collaboration between the two services would have resulted in more effective research progress than was achieved in Scotland.

Chapter 24: Viral Inactivation of Blood Products For Haemophilia Therapy 1985–1987 This chapter considers the steps undertaken at the Protein Fractionation Centre, Edinburgh (PFC) between 1985 and 1991 to inactivate virus in blood products so as to prevent transmission of non-A, non-B Hepatitis (NANB Hepatitis)/the Hepatitis C virus (HCV). Until it was established that the processing of PFL/BPL's 8Y Factor VIII concentrate was effective to inactivate HIV and NANB Hepatitis/HCV in source plasma, there was no scientific basis for a decision to prefer dry heat treatment over pasteurisation in the manufacture of factor concentrates. The PFC's research into pasteurisation was fully justified. There is no factual basis for any suggestion that the PFC should have decided to develop a Factor VIII product that could be severely heat-treated earlier than it did. The PFC applied appropriate resources in the research and development work necessary to achieve an acceptable Factor VIII product dry heat-treated to inactivate HIV and NANB Hepatitis/HCV. Professor Van Aken's assessment of the success of the PFC as 'quite an achievement' is accepted.

The demand by Haemophilia Directors (and Professor Ludlam in particular) for appropriate provision for compensation for individuals who agreed to undergo trials of and treatment with Z8 before licensing of the product was in the interests of patients and was reasonable**.** The commitment of resources for compensation ought to have been dealt with by the Scottish Home and Health Department from the outset in consultation with the Treasury. Failure to address the specific issue with reasonable expedition resulted in the delay of clinical studies and the resultant availability of Z8 for therapy for PUPs by three months. Because of policy decisions related to batch dedication the delay of clinical studies did not affect established patients.

'Outstanding results': Scotland appears to have been the first country in the world that was able to supply all of its haemophilia patients with a Factor VIII product that did not transmit Hepatitis C.

Volume 4: Donor Selection and Screening of Donated Blood

Chapter 25: Screening Of donated blood for Hepatitis B: In this chapter screening tests are discussed in an attempt to understand their development and the reliance placed on them at the time.

Chapter 26: Donor Selection – Higher Risk Donors: This chapter sets out donor selection policies and practice in the 1970s and early 1980s relating to the acceptance of blood from particular groups of donors who, either at the time or with the benefit of hindsight, might be considered to present a higher risk of transmitting hepatitis viruses than the general population. The main groups under discussion in the chapter are intravenous drug users and prisoners. All that can be concluded, with the benefit of hindsight, is that blood collected from prisoners during that period is likely to have had an increased risk of transmitting HCV, albeit the chance of receiving blood collected from prisoners was, overall, relatively low given that only approximately 1% of all donations collected in Scotland between 1975 and 1984 was collected from penal institutions.

Chapter 27: Surrogate testing of donated blood for Non-A, Non-B Hepatitis This chapter deals with the topic of surrogate testing of blood donors for non-A, non-B Hepatitis (NANB Hepatitis) in the late 1980s. Where UK government funding was required for major projects, the SHHD had limited scope for major independent initiatives. SHHD officials were not persuaded of the merits of surrogate testing and did not put the issue to ministers for a decision. As a result, ministers did not take part in the decision-making process, for which they were responsible**.**

With the establishment of the Advisory Committee on Virological Safety of Blood (ACVSB) in early 1989, it was reasonable for government to act on the expert advice received from that committee**.** The ACVSB did not, in the event, recommend the introduction of surrogate testing.

In the final outcome, there was no definitive decision by Scottish officials whether or not to recommend the introduction of surrogate testing. The Inquiry does not attribute blame for the fact that surrogate testing was not introduced, given the diversity of respected medical and scientific views over the period 1986–91.

Chapter 28: Donor Selection – AIDS. 'Donor selection' was among the several approaches taken to minimise the emerging risk of AIDS transmission. So far as central government action is concerned, it is impossible to avoid the conclusion that, to some extent at least, leaflet preparation and distribution were hampered by the number of interests involved. None of the many groups and individuals involved has suggested what else could have been done but was not done.

Chapter 29: The discovery Of HIV and the development Of screening tests. This chapter describes the discovery of the Human Immunodeficiency Virus and the scientific research that led to the development in the UK of screening tests for infection.

Chapter 30: Screening of donated blood for HIV This chapter deals with the general introduction of screening of donated blood in the UK for the AIDS virus, HIV. The production of screening tests for antibodies to HIV in 1984 and 1985 involved research and development work, in the USA, in France and in England, that was carried out with remarkable expedition and commendable success. Suggestions that UK BTS researchers, and in particular SNBTS researchers, could have made more rapid progress with evaluation of an acceptable assay than was achieved by private sector researchers are without foundation. There is no legitimate ground for criticism of the processes adopted for the introduction of anti-HIV screening that can be founded on delay. It was achieved as soon as was reasonably practicable.

Chapter 31: The introduction Of screening of donated blood for Hepatitis C. This chapter concerns the introduction of screening for antibodies to the Hepatitis C virus (HCV) in the blood donor population in Scotland. It follows the progress towards and up to the introduction of UK-wide screening on 1 September 1991 The decision to establish the ACVSB was well founded. There was a delay of almost ten months because a policy set at the outset – that the introduction of screening across the UK should take place at the same time – was maintained despite some areas being ready to begin considerably earlier than others. It is much less straightforward to explain why there was no deviation from this policy. The period 21 November 1990 to 12 June 1991 included a number of missed opportunities for more prompt introduction of screening in Scotland.

Any suggestion that taking one or more of these steps would have led to earlier introduction of screening involves a determination that the position of the responsible Minister in Scotland would have permitted different dates for the introduction of screening in Scotland and in England/Wales. It is not possible to make such a determination. Serious problems in relation to the introduction of a measure which would improve that safety should have been communicated to Ministers, in order that they could decide what should be done.

Volume 5: Information to Patients

Chapter 32: An investigation into the systems in place for informing patients about the risks – ethical context. This chapter looks at the development of the relationship between clinician and patient during the reference period. Best practice now in relation to informed consent and even in the sharing of information differs from the practices which prevailed during the reference period, or at least up until 1988 when the influence of HIV/AIDS helped to bring about significant changes. The requirements for informed consent and information to patients were less onerous in relation to Hepatitis C.

Chapter 33: An investigation into the systems in place for informing the patients about the risks – HIV/AIDS. The treatment of events in this chapter is largely chronological. Specific

topics discussed include: tests of patients' immune functions; testing of patients' sera stored from earlier investigations; obtaining informed consent for anti- HTLV-III testing and pre- and post-test counselling. Today failure to discuss treatment with patients and to obtain their consent to treatment would be unacceptable. It is clear that standards were different in 1984.

Professor Ludlam's approach of not telling patients their test results unless they asked for them was consistent with the UKHCDO advice and it is clear that many doctors at that time considered that testing for HIV was simply an extension of the monitoring of patients which was already being done. Professor Ludlam did not make it *sufficiently* clear to all of his patients that they had to ask him if they wanted to know their results. It should be noted that with the emergence of AIDS, an entirely new disease, almost all haemophilia clinicians found themselves in an extraordinarily difficult situation.

If a new, potentially fatal disease like AIDS were to emerge today it is likely that patients would be made aware of the medical profession's ignorance of it and share all the uncertainties and anxieties consequent upon that. Unfortunately, patients would, in all likelihood, still suffer and die.

Chapter 34: An investigation into the systems in place for informing the patients about the risks – Hepatitis C This chapter deals with the evidence on the information and advice given to patients, and where appropriate to their parents, in Scotland in the course of the reference period with regard to NANB Hepatitis/Hepatitis C. Patients infected with a potentially fatal virus such as HIV, or infected with HCV and at risk of developing the serious complications of cirrhosis, possibly hepatocellular cancer, and other fatal complications, are entitled to this information and should not have to wait while the medical profession deliberates on general ethical issues.

Chapter 35: An investigation into the steps taken to identify the individuals who were infected (look-back). This chapter deals with the methods available to identify patients put at risk of HCV transmission by treatment with blood or blood products, and with the steps taken in that regard. The look-back study lacked the highly efficient patient tracking systems available today. Early donor card records were not searchable and different transfusion centres and hospitals had different record keeping systems. Difficulties were encountered in cross referencing donation numbers and recipients and vice a versa. Medical records had been lost or destroyed. Some recipients had changed their names through marriage or other causes. Some recipients had changed addresses.

Due to the inevitable limitations of the look-back exercise as described above, there will still be recipients of HCV positive blood who remained, or remain, unaware of that fact.

Annex D

PENROSE INQUIRY: SUMMARY OF SPECIFIC INDIVIDUAL CASE STUDIES

Background

1. Terms of Reference 6 for the Penrose Inquiry was:

> "To investigate the deaths of Reverend David Black, Mrs Eileen O'Hara, Alexander Black Laing and Victor Tamburrini, with particular reference to the circumstances in which they became infected with the Hepatitis C virus, HIV or both."

2. This Annex summarises the Inquiry's finding in relation to these four specific cases, and also provides a summary of the general comments made in relation to the impact on affected individuals and their families.

High Level Summary

- Criticism is confined to one specific doctor in one specific case (Mrs O'Hare), although this is about lack of advice and counselling and did not contribute either to her acquiring hepatitis C infection or to her death.
- One case (Mr Laing) is described in the Report as an example of exemplary care.
- One case (Mr Tamburrini) did not acquire Hep C as a result of any NHS treatment.
- The report also notes that, as it turned out, none of the four individuals had acquired infection with HIV.
- No recommendations are made by the Inquiry in respect of these four cases.

Reverend David Black

3. Mr Black was born on 1 May 1937. He died on 31 October 2003 at Strathcarron Hospice, Stirlingshire. The cause of death was registered as hepatocellular cancer in a transplanted liver, Hepatitis C, transfusion of blood products and haemophilia.

4. The Report notes that there was a history of haemophilia in Mr Black's family and Mr Black's early medical history was typical of a child with relatively mild haemophilia. Mr Black received treatment for his haemophilia in the UK and in the USA during the 1960s and 1970s. He first developed symptoms associated with Hep C infection in 1979, with the diagnosis confirmed in 1985. In the 1990s, he received a liver transplant in Edinburgh but the recurring presence of Hep C meant that the new liver developed cirrhosis, which led to the liver cancer from which he died.

5. The Report concludes that:

> *"…on the balance of probabilities Mr Black acquired Hepatitis C infection before the end of the 1960s in the course of haemophilia therapy in Scotland."*
>
> *"…the cancer which developed in Mr Black's liver graft was likely to have been a new tumour."*
>
> *"…failure to inform Mr Black of the cancer in the explanted liver deprived him of the chance, however remote, of a longer life that might have followed successful earlier antiviral treatment and eradication of Hepatitis C."*

"…with that one exception Mr Black's management as a patient was at all times appropriate and of a high standard and reasonably related to his needs."

6. The Executive Summary states: *"there were no reasonable precautions whereby his death could have been prevented and, with the exception of the failure of communication referred to, his medical management was at all times of a high standard."*

Mrs Eileen O'Hara

7. Mrs O'Hara died on 7 May 2003, at the age of 72. The immediate cause of her death was acute pancreatitis complicated by sepsis and multi-organ failure. She was also suffering from Hepatitis C, chronic heart failure and type 2 diabetes.

8. Mrs O'Hara had a complicated medical history, starting in about 1963, involving cardiac, obstetric and gynaecological problems and involving various blood transfusions at different periods. Following the diagnosis of liver problems she tested negative for Hep C in 1990, which is now known to have been a false negative.

9. The Report concludes that:

"…it is highly likely Mrs O'Hara was infected with Hep C by an infected blood transfusion, probably during the course of a hysterectomy in 1979."

"…her infection with the virus at that time could not have been prevented."

"…the failure to record Hep C as a cause of death was an error, but given the complexity of Mrs O'Hara's medical conditions, it was not found to be a systemic defect in procedure."

"…there was a significant lapse in Mrs O'Hara's management as a patient after she was referred to Dr Forrest (Stobhill Hospital) on 11 September 1995."

"…this 'lapse' amounted to unacceptable delay on the part of Dr Forrest in responding to the referral and a failure in management attributable to his repeated 'desk-top' disposal of issues relating to Mrs O'Hara. Nor did she receive available advice and counselling about her Hep C status."

"…these deficiencies in Mrs O'Hara's management as a patient were attributable to Dr Forrest, stemming from his failure to see Mrs O'Hara in person, and did not evidence a universal or general failure on the part of the hospitals involved, nor on the part of the NHS as a whole."

10. From the Executive Summary: *"In mid-1995, she was diagnosed as having cirrhosis. Review of her Hepatitis C was sought from a gastroenterologist at Stobhill Hospital. This doctor never actually saw Mrs O'Hara, and issued his opinion on her treatment based on a review of her notes. This deprived her of an opportunity to gain information, and to receive counselling and advice in connection with the illness. The Inquiry concludes that this was a significant lapse in patient management. Mrs O'Hara experienced serious and increasing symptoms of her liver disease from the middle of 1995 onwards. Her cardiac condition also caused concern, particularly between 1999 and 2002. She became very unwell in March 2003, and underwent surgery, which was not straightforward, for the removal of gallstones. She developed a septic illness and died on 7 May. There were no reasonable precautions which might have been taken to avoid her death."*

Mr Alexander Black Laing

11. Mr Laing died on 4 September 2003 at the age of 79. The immediate cause of his death was liver disease caused by Hepatitis C. In 1990, at the age of 66, Mr Laing received blood transfusions as a result of cancer surgery at Aberdeen Royal Infirmary. At the end of a course of out-patient care following surgery, lasting some five years, Mr Laing was told that the cancer was clear but that he had contracted Hepatitis C infection from the blood transfusion. Mr Laing had been identified as being at risk by the UK-wide look-back exercise into transfusion-related Hepatitis C virus (HCV) infection which was in progress in 1995.

12. The Report concludes:

> *"Mr Laing was infected with Hepatitis C as a result of transmission of blood at the time of his surgery for Duke's C carcinoma on 7 August 1990."*
>
> *"…the surgery saved his life. It was never suggested that surgery could have been carried out without transfusion."*
>
> *"…if the first-generation ELISA tests that were available at the time in 1990 had been used, the donor's Hepatitis C would not have been discovered."*
>
> *"Mr Laing's management as a patient was an illustration of exemplary care*."

13. The Executive Summary states: *"The Inquiry was not, therefore, able to identify any precautions whereby Mr Laing's death could have been avoided. The view of the independent expert was accepted, to the effect that, once HCV was identified, Mr Laing's management as a patient was an example of exemplary care."*

Mr Victor Tamburrini

14. Mt Tamburrini died at the Royal Infirmary of Edinburgh on 17 November 2004, at the age of 47, the immediate cause of his death being liver transplant failure and recurrent Hepatitis C. His widow is noted in the Report as having called for a Fatal Accident Inquiry into her husband's death. Mr Tamburrini was diagnosed with Hep C in 2001, at which time he was already showing signs of serious liver damage. He underwent liver transplant surgery twice in 2002 and again in 2004.

15. The Report concludes:

> *"…on the evidence available, with the exception of the possibility of hospital acquired infection, it was established to varying standards of probability that the known NHS procedures in Mr Tamburrini's case did not transmit Hepatitis C infection.*
>
> *"…on epidemiological grounds, it is likely that Mr Tamburrini acquired HCV infection in his late teens or early 20s."*
>
> *"…the cause of that infection is unknown."* (Although there is reference in the main body of the report to non-evidenced speculation from others as to possible drug use in Mr Tamburrini's teenage years.)
>
> *"…consumption of alcohol did not contribute to the failure of either the first or second liver transplant grafts received by Mr Tamburrini, or cause, or contribute to the cause*

of, his death. It is accepted that the cause of death was unrelated to alcohol consumption."

"Mr Tamburrini's care and management as a patient were appropriate."

16. The Executive Summary says: *"In these circumstances, the Inquiry concluded that the evidence did not demonstrate that Mr Tamburrini acquired HCV from NHS treatment with blood or blood products and did demonstrate that none of the occasions on which he was known to have received such treatment was the cause of his infection. It is likely that he was infected during the period between his late teens and his early twenties, the cause of that infection being unknown."*

Annex E

PENROSE INQUIRY: INITIAL ASSESSMENT OF RECOMMENDATION

Introduction

1. The Inquiry Report makes only a single recommendation: that *the Scottish Government takes all reasonable steps to offer a hepatitis C test to everyone in Scotland who had a blood transfusion before September 1991 and who have not been tested for HCV.*

2. This recommendation reflects the fact that there will be some people in who transfusion-transmitted hepatitis C infection is still undiagnosed. The report recognises that there will be people who received a 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. This links to the main criticism that there was a delay to the introduction of screening for hepatitis C.

3. The Scottish Government can unequivocally accept this recommendation.

Need for Testing

4. Lord Penrose is not specific about how he wishes the Government to undertake this recommendation and this likely reflects the uncertainty which exists about the number of people who are infected who remain undiagnosed, as well as previous efforts at a look back exercise to identify infected individuals. There may be very few individuals who have been infected, who are not diagnosed and who are still alive. The period referred to is more than twenty years ago and it is likely that most people affected by hepatitis C who did not clear the virus naturally would have become unwell by now. Patients were not always informed that they had received a transfusion during surgery and transfusion was not always recorded.

5. It should also be noted that there is no current barrier to hepatitis C testing in Scotland. All GPs can take a blood sample for hepatitis C testing, and in many places in Scotland it is also now possible to have a finger-prick blood-spot test for hepatitis C. The testing and diagnosis infrastructure for hepatitis C has been scaled up significantly as a result of the Government's investment in hepatitis C. In 2005 around 20,000 tests for hepatitis C were undertaken in Scotland – that rose to more than 30,000 by 2012 (with significant increases in testing by GPs)

6. In the recent past (2008-09) the Scottish Government has also delivered targeted awareness-raising campaigns focussing on potential risks of hepatitis C transmission. This awareness-raising was targeted at all individuals potentially infected with hepatitis C (including individuals who were not infected through blood products – so a much bigger cohort) but this evaluated poorly in terms of impact and success in increasing diagnosis. The campaign was not cost effective. We have not therefore repeated this awareness raising approach.

7. However the ready availability of testing, and the public messages we have previously issued, do not necessarily mean that everybody who is at risk has been tested. Hepatitis C can present with vague, non-specific symptoms, and there may be people who were infected by blood transfusion pre-1991 who are not aware they received a transfusion. GPs and other health professionals may not always consider hepatitis C as a potential cause of ill-health.

Implementation

8. In light of the above we will need to give consideration to how we respond to this recommendation. Recognising the likely tiny number of people who may potentially be infected but undiagnosed we have to be proportionate – and this may be why Lord Penrose specifically asked that we take all '*reasonable'* steps. But clearly we have to make a concerted effort to reach the few infected people who have not been diagnosed.

9. We will consider options further and seek clinical opinion, but potential options for responding to this recommendation include:

- Using the Penrose Inquiry publication and the Ministerial statement as a perfect opportunity to raise awareness and issue a call-to-action to anybody who believes they may have received a blood transfusion before 1991.
- Issuing advice to the NHS and to all General Practitioners asking that any patients whose records indicate a blood transfusion was received before 1991, and who have not previously been tested, should now be tested. It is unlikely that this will identify any or many patients as a look back exercise was conducted previously, to little success (as reported by the Inquiry Report).
- Undertake some form of public awareness raising, either targeted or general, to raise awareness and the need for testing.
- Fund third sector organisations to undertake targeted awareness raising.

10. There may be other options, and we will provide further advice on these once we have discussed with clinical colleagues.

11. Any work we undertake should also ensure an evaluation of the steps taken is included so we can measure the impact of how we respond to this recommendation.

Annex F

PENROSE INQUIRY: UPDATED HANDLING LINES

Key messages

- What happened was a tragedy, particularly for the individuals and families involved, and we hope that the publication of this report will go some way to giving them closure.

- As the inquiry report makes clear, this was an issue that affected the NHS throughout the UK. However, we felt that it was crucial to find out exactly what happened in Scotland, so that all possible lessons are learned to help prevent it from happening again. This is the first statutory Public Inquiry into these matters in the UK.

- [*redacted*]

- We will carefully consider all of Lord Penrose's findings.

- In line with the inquiry's recommendations, anyone who had a blood transfusion in Scotland before September 1991 who has not already been tested for hepatitis will be offered a test. We believe that very few people will be in this position, but anyone who believes they are should speak to their GP. [*redacted*.]

- As the inquiry acknowledges, there have been very considerable advances in medical and scientific knowledge with regard to blood safety and the prevention/treatment of HIV and hepatitis C infection since the early 1980s.

- Scotland is now leading the way on patient safety and was the first country in the world to implement a national patient safety programme across the whole healthcare system.

- Since devolution, the Scottish Government has already contributed more than £30 million in direct ex-gratia payments to those affected by NHS infected blood.

- We intend to work with the other UK Health Departments to review the current UK-wide ex-gratia financial support system for those infected and their families.

- The procedure and conduct, including the timing of publication, of a public inquiry is determined by the Inquiry's Chairman – in this case Lord Penrose. This is entirely independent of Government, in accordance with the Inquiries Act 2005.

_____

From: [*text redacted – personal data*]@scotland.gsi.gov.uk>
Sent: 26 March 2015 12:34
To: Brown GJ (Gareth) <Gareth.Brown@scotland.gsi.gov.uk>; Cabinet Secretary for Health, Wellbeing and Sport <cabsechealth@scotland.gsi.gov.uk>
Cc: First Minister <FirstMinister@scotland.gsi.gov.uk>; Permanent Secretary <PermanentSecretary@scotland.gsi.gov.uk>; DG Health & Social Care <DGHSC@scotland.gsi.gov.uk>; Director of Population Health Improvement <Directorofpopulationhealthimprovement@scotland.gsi.gov.uk>; McQueen F (Fiona) <Fiona.Mcqueen@scotland.gsi.gov.uk>; Matheson J (John) <John.Matheson@scotland.gsi.gov.uk>; Paterson J (John) <John.Paterson2@scotland.gsi.gov.uk>; Keel A (Aileen) <Aileen.Keel@scotland.gsi.gov.uk>; Henderson D (Donald) <Donald.Henderson@scotland.gsi.gov.uk>; [*text redacted – personal data*]; Minister for Public Health <MinisterforPublicHealth@scotland.gsi.gov.uk>; Lloyd E (Elizabeth) <Elizabeth.Lloyd@scotland.gsi.gov.uk>; Hutchison D (David) <David.Hutchison@scotland.gsi.gov.uk>
Subject: RE: OFFICIAL SENSITIVE – INFORMATION EMBARGOED UNTIL 12.15 PM ON 25th MARCH 2015 - PENROSE INQUIRY DRAFT STATEMENT

For info ahead of the statement:

NEW INQUIRY 'NOT IN BEST INTERESTS'

COMMONS Blood
Mar 26, 2015 11:51:36 AM
By Lindsay Watling and Richard Wheeler, Press Association Political Staff

Page 1

Another inquiry into the contaminated blood scandal would not be in the best interests of victims and their families, health minister Jane Ellison has said.

She told MPs the Government's "initial reaction" was that it was "time for action" instead.

Yesterday the Prime Minister apologised on behalf of the British Government to those affected by the scandal.

David Cameron also confirmed GBP25 million of funding to improve financial support for the NHS patients who were infected with hepatitis C and HIV during the 1970s and 1980s.

It came after a comprehensive inquiry, set up by the Scottish Government to investigate what went wrong, called for people who had a blood transfusion before 1991 to now be tested for hepatitis C.

But victims have reacted angrily to the findings of the long-awaited inquiry, describing the report as a "whitewash".

Shadow health secretary Andy Burnham today asked whether there now needed to be a further process of inquiry in the next Parliament to bring full accountability.

He said: "The apology will only have real meaning if it is followed by

efforts to bring truth, accountability and redress."

Ms Ellison, who was responding to an urgent question on the report, replied: "The Government's initial reaction is that another inquiry would not be in the best interests of sufferers and their families as it would further delay action to address their concerns.

"The strong message I have had is that it is time for action."

She said the probe, chaired by Lord Penrose, had been "thorough" and that for the first time it provided an "authoritative narrative of events".

_____

From: Brown GJ (Gareth) <Gareth.Brown@scotland.gsi.gov.uk>
Sent: 25 March 2015 10:49
To: Cabinet Secretary for Health, Wellbeing and Sport <cabsechealth@scotland.gsi.gov.uk>
Cc: First Minister <FirstMinister@scotland.gsi.gov.uk>; Permanent Secretary <PermanentSecretary@scotland.gsi.gov.uk>; DG Health & Social Care <DGHSC@scotland.gsi.gov.uk>; Director of Population Health Improvement <Directorofpopulationhealthimprovement@scotland.gsi.gov.uk>; McQueen F (Fiona) <Fiona.Mcqueen@scotland.gsi.gov.uk>; Matheson J (John) <John.Matheson@scotland.gsi.gov.uk>; Paterson J (John) <John.Paterson2@scotland.gsi.gov.uk>; Keel A (Aileen) <Aileen.Keel@scotland.gsi.gov.uk>; Henderson D (Donald) <Donald.Henderson@scotland.gsi.gov.uk>; [*text redacted – personal data*]; Minister for Public Health <MinisterforPublicHealth@scotland.gsi.gov.uk>; Lloyd E (Elizabeth) <Elizabeth.Lloyd@scotland.gsi.gov.uk>; Hutchison D (David) <David.Hutchison@scotland.gsi.gov.uk>
Subject: RE: OFFICIAL SENSITIVE – INFORMATION EMBARGOED UNTIL 12.15 PM ON 25th MARCH 2015 - PENROSE INQUIRY DRAFT STATEMENT

[*text redacted – personal data*]

I attach some further briefing on the issues discussed yesterday, one page each on the financial support schemes; the Irish comparison; public inquiries generally; and hepatitis C treatment.

On the treatment of patients who were infected via blood products with the new, expensive therapies, we are checking with hepatitis clinical leads. [*text redacted*] I am pursuing information from the other main treatment centers and will update when I have it – but certainly we are not aware that anyone has been refused treatment and no complaints have come to us.

I'll be at my desk for the rest of this morning and can deal with any further queries or questions that arise.

Gareth Brown
Head of Health Protection | Public Health Division | Population Health Improvement Directorate
Scottish Government |Tel: [*text redacted – personal data*]

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Text redacted – out of scope

Penrose Timetable

- 23 April 2008: Nicola Sturgeon, announced the public inquiry and that Lady Cosgrove would chair the Inquiry.
- Lady Cosgrove subsequently withdrew for family reasons.
- 13 January 2009: The Inquiry was set up with Lord Penrose appointed as Chair.
- 8 September 2010: Preliminary report published.
- March 2011 March 2012 – public hearings (89 days over this period)
- 29 October 2012: additional procedural hearing on the topic of statistics
- 25 March 2015: Inquiry report published

Public Inquiries – Supported by other parties

Redacted – out of scope

HEPATITIS C TREATMENT

[*redacted*]

Background

- Scotland has invested significant in hepatitis C diagnosis, treatment and care, since the Hepatitis C Action Plan in 2008. This has led to a significant increase in treatment in Scotland, rising from ~400 treatment initiations a year to more than ~1000 a year.
- Our response to hepatitis C has been recognised by the World Hepatitis Alliance – an alliance of patient groups – as a model of best practice, and has informed the World Health Organization's global hepatitis programme.

New Therapies

- New treatments for hepatitis C which are >95% effective and which have no side effects are now available on the NHS. These are Sofosbuvir ([*redacted*] per 12 week treatment course – but needs to be used with other drugs so total cost is higher) and Harvoni ([*redacted*] for a 12 week treatment). This compares to [*redacted*] for standard therapies
- [*redacted*].
- Total of ~38,000 people estimated to have ever been infected with hepatitis C in Scotland
- Even limiting the new therapies to those who are most unwell who have ever been in specialist care (3,400 people) would cost [*redacted*] at current prices.
- Many people want to be treated with the new therapies, particularly those who have failed treatment with current therapies.
- Minister for Public Health set up Treatment and Therapies Subgroup in early 2014 to provide advice on these issues. That group will report in early April and once we receive that report Government will take a view on treatment/funding policy for future years.

Infected patients accessing treatment

- [*redacted*].
- We are not aware that anyone who has been infected by blood products has been refused treatment – and no complaints have been made to us.