

PENROSE INQUIRY

RESPONSE TO LETTER DATED 27 SEPTEMBER 2012

ON BEHALF OF
THE PATIENT INTEREST CORE PARTICIPANTS

INTRODUCTION

On 27 July 2012 the Inquiry wrote to the legal representatives of the core participants, inviting written submissions on the topic of statistics. The letter referred to eight items including a detailed paper dated 1 March 2012 by Professor Goldberg and Dr Schnier on “the Number of Individuals Infected and Alive in 2011 as a Consequence of Blood Transfusion in Scotland 1970-1991”¹ and a second edition of the UKHCDO report on “Bleeding Disorder Statistics for the Penrose Inquiry”.² None of the referenced additional material had been made available to the patient interest core participants before 27 July 2012. None of it has been the subject of any analysis at the oral hearings held between March 2011 and January 2012. The end of August 2012 was set as the deadline for written submissions.

A submission on behalf of the patient interest core participants was forwarded to the Inquiry on 31 August 2012. It contained a respectful invitation to the Inquiry to consider recalling Professor Goldberg, Dr Charles Hay, Dr. McClelland and Dr. Gillon to give further oral evidence and to consider asking Dr Kate Soldan to give evidence orally for the first time.³ By letter dated 27 September 2012 the Inquiry has asked for certain information in order to consider the invitation to recall/call these witnesses. The purpose of this response is to provide that

¹ PEN.019.0899

² PEN.019.0927

³ PEN.019.1171 @ 1172

information. The current state of the evidence following receipt of the detailed additional material is summarised in the Appendix.

THE IMPORTANCE OF THE TOPIC OF STATISTICS

The terms of reference for the Inquiry include the following:-

TERM OF REFERENCE 4

To investigate the systems for recording and monitoring the numbers of NHS patients in Scotland treated with blood or blood products, with particular reference to the numbers exposed to risk of infection with the Hepatitis C virus and HIV and the numbers contracting either or both such infections as a consequence of such treatment

When introducing the topic at the public hearings on 15 March 2011 Counsel to the Inquiry stated that

“We are going to try to ascertain, as accurately as possible, the numbers for four different groups of people in Scotland. First would be those who acquired HIV from blood products, the second would be those who acquired HIV from blood transfusion, the third would be those who acquired Hepatitis C from blood products and the fourth would be those acquiring Hepatitis C from transfusion”⁴

The importance of this exercise in the context of the Inquiry as a whole should not be underestimated. It is self-evident that it is necessary to calculate as accurately as possible the numbers of individual patients infected (or co-infected). This matters very much to the patients. Tracing, supporting and treating those infected is an urgent public health challenge now and in the future. An accurate understanding of the numbers infected also informs the Inquiry's

⁴ See Transcript Day 5 15 March 2011 40 (17) to (24)

detailed scrutiny of the significant decisions made during its reference period. Further and in any event, if there are major difficulties in calculating the numbers then the reasons for those have to be identified and explained. Any defects in the systems for recording and monitoring should be acknowledged and recommendations made as to how such systems could be improved in the future so that similar problems can be avoided. In relation to this last aspect term of reference 11 which is **“to identify any lessons and implications for the future, and make recommendations”** is particularly relevant.

WHY IS ORAL TESTIMONY REQUIRED

It is submitted that it is necessary to examine the witnesses orally in relation to this topic for the following reasons:-

1. The importance of the topic (see above);
2. The significant controversial issues which the Inquiry has to resolve on this topic (see below);
3. The Inquiry has sought generally to take evidence orally from witnesses. Rightly it has been made clear that evidence that has not been open to be tested may be inherently less satisfactory than evidence that has been led orally⁵. The methodology and assumptions which form the basis of the submitted figures should not be accepted at face value. They need to be tested. It is only fair to do so orally;
4. The examination of Professor Goldberg is incomplete. It was necessary for him to give oral evidence in March 2011. He did not complete his evidence because at that stage he had not carried out the work necessary to produce his estimates for the Inquiry⁶. His incomplete oral evidence has been superseded but the justification for hearing from him orally has not; and
5. The examination of Dr Charles Hay is incomplete. His oral evidence has also been superseded but the justification for hearing from him orally has not.

⁵ Transcript for Day 54 13/10/2012; 3 (14) to 4 (10)

⁶ Transcript for Day 6 16 /03/2011; 135 (6 to 12)

THE WITNESSES TO BE RECALLED/CALLED

These were specified in the written submission. For the avoidance of doubt they are

1. Professor David Goldberg (recall);
2. Dr. Brian McClelland and Dr. Jack Gillon (recall);
3. Dr. Kate Soldan (call);
4. Dr Charles Hay (recall).

THE ADDITIONAL INFORMATION OR EVIDENCE EACH WITNESS CAN REASONABLY PROVIDE**1. PROFESSOR DAVID GOLDBERG****THE NUMBER OF PATIENTS INFECTED WITH HEPATITIS C AS A RESULT OF BLOOD TRANSFUSIONS.**

For all practical purposes Professor Goldberg has not yet given oral evidence about this aspect of the topic.

He requires to:-

- Explain the epidemiological analysis undertaken by him;
- Explain the assumptions he has made which underpin his analysis in reaching an estimated number of infections;
- Explain why look back data was not used;
- Explain why he uses a factor to account for the introduction of blood donor deferral in 1984. This was not used by Dr Soldan⁷;
- Explain how robust and reliable the data is relative to prevalence rates of hepatitis C infection in the Scottish blood donor community;
- Explain why he has deemed the number of units generated from one blood donation to be 1.25 as opposed to 1.6;
- Identify the limited local data and expert opinion;
- Explain the basis for saying that HCV transmission in Scotland only really began “to take off” in the late 1970’s/1980’s;
- Outline the relative merits of his method of analysis when compared with the analysis of others including Dr Soldan and Professor James; and
- Explain his assumption that the survival rate of recipients of HCV contaminated units did not and does not differ from the survival rate of recipients of non-contaminated units.

⁷ See PEN.019.0896 at PEN.019.0897 Response to Question 4 second paragraph

2. DR BRIAN MCCLELLAND AND DR JACK GILLON

THE NUMBER OF PATIENTS INFECTED WITH HEPATITIS C AS A RESULT OF BLOOD TRANSFUSIONS.

Professor Goldberg has identified Dr McClelland and Dr Gillon as having been involved in supporting some of the assumptions in his report⁸. The involvement of SNBTS in this exercise was referred to in passing in the evidence of Dr Gillon who stated (a) that he (and others) had been involved in the analysis being undertaken by Professor Goldberg and (b) that Dr Soldan's estimate of the numbers infected in this cohort was too high.⁹

Dr McClelland and Dr Gillon should be asked about:-

- Assumption iii - reduction in the number of HCV-positive donors in the donor population as a result of deferral policy. This has a critical impact on reducing the estimated number of hepatitis C positive donations. The validity of this information not only has important implications for the accuracy of Professor Goldberg's work but also for other topics within the Inquiry's remit (and in particular the B1¹⁰ topic);
- Assumption iv - the use of evidence relating to the number of HCV positive injecting drug users in estimating the number of HCV positive blood donors in Scotland;
- Assumption v – the number of units generated from one blood donation;
- Assumption vi - the proportion of units transfused;
- Assumption vii – the age at transfusion of a contaminated unit; and
- Any other involvement they may have had in the production of the Goldberg analysis.

⁸ See PEN.019.0900 Assumptions iii, v, vi and vii and PEN.019.0922

⁹ Transcript for 18 January 2012 (day 86); 94 (21) to 95 (19)

¹⁰ "The efforts made to discourage 'higher risk' donors from giving blood (by the dissemination of information, including leaflets); whether these efforts went far enough and began early enough."

The input of Dr. McClelland and Dr. Gillon is not independent of SNBTS. SNBTS has made a submission to the Inquiry on the topic of statistics¹¹. SNBTS appear to contend for lower figures for the numbers of patients infected. We are unclear whether the Inquiry will take account of its submission and perhaps more importantly the documents referred to¹² and enclosed¹³. If it is the intention of the Inquiry to take this material into account we would wish Dr McClelland and Dr Gillon to be questioned in relation to these matters and in particular the apparent scepticism relative to the use of information from the Skipton Fund and the content of the article by Franklin *et al* insofar as it purports to address the likely true incidence of transfusion transmitted HCV before the introduction of anti-HCV donor testing.

3. DR KATE SOLDAN

THE NUMBER OF PATIENTS INFECTED WITH HEPATITIS C AS A RESULT OF BLOOD TRANSFUSIONS.

Dr Soldan should be asked to speak to the methodology applied in her epidemiological analysis of the numbers infected with Hepatitis C from blood transfusions in the UK and in Scotland. She was identified by Professor Goldberg as the foremost authority in the UK in this area.¹⁴ It seems likely that she would be able to assist the Inquiry team in its investigation of this important area in light of the current contradictions in the evidence. In particular:

- Dr Soldan's methodology is different to that of Professor Goldberg. The difference requires to be explained. Which method is likely to produce the more accurate estimate of the numbers infected and the numbers who have died?
- The analysis carried out by Dr Soldan is restricted to the period from 1 January 1980 to 1 September 1991 (when routine anti-HCV was introduced). During her examination of Professor Goldberg, Counsel to the Inquiry made reference to the figure of 10,000 UK

¹¹ PEN.019.1232 and PEN.019.1233

¹² PEN.019.1233

¹³ PEN.019.1236

¹⁴ Transcript for 16/03/2011 (day 6); 132 (24) to 133 (1)

infections allocated to the 1970s in a recent Department of Health paper.¹⁵ Professor Goldberg was unable to assist but indicated that Dr Soldan might be able to do so. This aspect requires explanation from her.

- Professor James has introduced alternative methods of analysing the numbers infected. Dr Soldan should give a view on the likely accuracy of these methods, at least as cross-checks on the figures arrived at by the epidemiologists.

4. DR CHARLES HAY

THE NUMBER OF PATIENTS WHO ACQUIRED HIV THROUGH BLOOD PRODUCTS

THE NUMBER OF PATIENTS WHO ACQUIRED HEPATITIS C THROUGH BLOOD PRODUCTS

The evidence relating to the number of HIV infections amongst the bleeding disorder community in Scotland (spoken to in the oral hearings by Dr Charles Hay, Professor Christopher Ludlam and Dr Campbell Tait) has been superseded by the additional material provided to the Inquiry by the UKHCDO.¹⁶ Dr Hay should be questioned in an oral hearing about the newly produced UKHCDO statistical material, in accordance with the practice adopted by the Inquiry to this point. It was clear from Dr Hay's evidence at the oral hearings that the UKHCDO was in a position to provide the Inquiry with further data. However, the new report submitted by the UKHCDO goes beyond the provision of data but provides an analysis of that data.

In particular he should be asked about:

- Where the new data which has been provided came from, its reliability and comprehensiveness.
- The reasons for the different figures that he has arrived at from those of the Scottish directors for the number of patients with bleeding disorders likely to have been infected with HIV in Scotland. The Inquiry requires to determine which methodology (if either) is the more likely to provide an accurate conclusion.

¹⁵ Transcript for 16/03/11 (day 6); 139 (2) to 140 (1) (Inquiry Counsel) and PEN.013.1580 @ 1584

¹⁶ PEN.019.0927

- Whether detailed treatment information is available for all of the individuals identified by him as having been infected with HIV in the haemophilia community in Scotland corresponding to that provided in the tables submitted by the Scottish directors.
- Reconciliation of the figures contained in the second UKHCDO paper for the number of infections with hepatitis C in the bleeding disorder community in Scotland (447¹⁷) with the figure from the same paper for the number of patients registered with a Scottish centre (690/778¹⁸).

¹⁷ PEN.019.0927 @ 0984

¹⁸ PEN.019.0927 @ 0956/0957

APPENDIX**STATISTICAL INFORMATION AVAILABLE TO THE INQUIRY REGARDING NUMBERS INFECTED****OCTOBER 2012****Numbers infected in Scotland with HIV in the bleeding disorder community**

Source	Evidence
1) The UKHCDO initial analysis in the preliminary report	<ul style="list-style-type: none"> • 72 infections¹⁹
2) Health Protection Scotland	<ul style="list-style-type: none"> • 87 infections²⁰ (the cumulative total number of HIV infected persons who have been resident in Scotland who are believed to have been infected by treatment with coagulation factors) • 76 patients with haemophilia assumed to have been infected by their receipt of contaminated blood products in Scotland²¹
3) Answer to parliamentary question on 21 December 1989	<ul style="list-style-type: none"> • 76 infections in Scotland²²
4) Statements and oral evidence of the Scottish haemophilia directors	<ul style="list-style-type: none"> • 58/59 infections²³
5) Analysis conducted by Dr Charles Hay on behalf of the UKHCDO	<ul style="list-style-type: none"> • 68 - 70 infections²⁴ • Extrapolated from a starting point of the number of individuals reported to UKHCDO as having been

¹⁹ PR, paras 3.60 to 3.61 and footnote

²⁰ PR, paras 3.60 to 3.61 and footnote

²¹ PEN.012.0151

²² SGF.001.1246

²³ Transcript for 30/03/11 (day 14); 57 (16) to 58 (3) (Professor Ludlam)

²⁴ PEN.019.0927 @ 0961

	infected with HIV by a Scottish centre ²⁵
<u>Numbers infected in Scotland with hepatitis C in the bleeding disorder community</u>	

Source	Evidence
a) Health Protection Scotland	<ul style="list-style-type: none"> HPS was aware of 351 infected individuals with no information that they had received blood products outside Scotland²⁶
b) UKHCDO	<ul style="list-style-type: none"> Number of patients treated or registered in Scotland between 1970 and 1989 was 715²⁷
c) Statement and oral evidence of Dr Charles Hay, Dr Campbell Tait as well as UKHCDO spreadsheets	<ul style="list-style-type: none"> 410 - number of patients whom UKHCDO knew were first exposed to a factor concentrate in Scotland (considered to be a conservative figure by Dr Hay)²⁸ 459 - 715 figure above subject to deductions²⁹ The spreadsheets³⁰ and the evidence of Dr Tait³¹
d) Analysis conducted by Dr Charles Hay on behalf of the UKHCDO	<ul style="list-style-type: none"> 447 (adjusted for double counting)³²
e) Analysis by Dr Kate Soldan	<ul style="list-style-type: none"> Analysis used as the basis for the recommendations of the Ross Committee - 500 infections in Scotland³³
f) UKHCDO on total number of patients registered with a Scottish centre	<ul style="list-style-type: none"> 690 in 1985³⁴ 778 in 1990³⁵ Taken with epidemiological evidence regarding likely infection after exposure to a factor concentrate (unheated) and/or large amounts of cryoprecipitate

²⁵ PEN.019.0927 @ 0961

²⁶ PEN.019.0206

²⁷ PEN.013.0016

²⁸ Transcript for 18/03/2011 (day 8); 60 (6 to 8) (Dr Hay)

²⁹ PEN.013.0016

³⁰ Spreadsheet was originally provided under reference PEN.001.0062 and then an update was provided entitled " Scot HCV Full Final Spreadsheet"

³¹ Transcript for 30/03/2011 (day 14); From 75 (Dr Tait)

³² PEN.019.0927 @ 0984

³³ Report of the Expert Group on Financial and other Support (March 2003) @ paragraph 4.8 - <http://www.scotland.gov.uk/Resource/Doc/47034/0024918.pdf> (including the material to be found in SGH.005.7203)

³⁴ PEN.019.0927 @ 0957

³⁵ PEN.019.0927 @ 0958

Numbers infected in Scotland with HIV from blood transfusions

Source	Evidence
Statement and oral evidence of Dr Jack Gillon	<ul style="list-style-type: none"><li data-bbox="667 618 1225 654">• 18 infections (including information from HPS)³⁶

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³⁶ PEN.001.0038

Numbers infected in Scotland with Hepatitis C from blood transfusions

Source	Evidence
1. Statement and oral evidence of Dr Jack Gillon	<ul style="list-style-type: none"> Confirmed positives via this route to include (a) 59 positive blood donors with blood transfusion as only risk factor³⁷ (b) 28 identified through clinician reporting³⁸ (c) 133 identified through the lookback exercise³⁹ and (d) 18 from the west of Scottish renal unit⁴⁰ and so a total of 238 (accepted as minimum number⁴¹)
2. Statement and oral evidence of Professor David Goldberg	<ul style="list-style-type: none"> 304⁴²
3. Analysis by Dr Kate Soldan	<ul style="list-style-type: none"> Analysis of numbers in this cohort in the UK infected between 1980 and 1991 - circa 13,500⁴³ Analysis used as the basis for the recommendations of the Ross Committee - 3,498 infections in Scotland (1980s)⁴⁴ Need to factor in infections in the 1970s - figure of 10,000 for the UK mentioned in the Soldan article⁴⁵
4. Analysis by Professor David Goldberg	<ul style="list-style-type: none"> A report in this regard was provided in October 2011.⁴⁶ This paper estimated the likely number of infections by way of lower, mid and upper estimates, which are 1183, 1532 and 1978 respectively.⁴⁷

³⁷ PEN.001.0043

³⁸ PEN.001.0043 @ 0044

³⁹ PEN.001.0043 @ 0044

⁴⁰ PEN.001.0043

⁴¹ Transcript for 16/03/11 (day 6); 77 (15 to 20) (Dr Gillon)

⁴² PEN.013.0014

⁴³ PEN.013.1580 @ 1583

⁴⁴ Report of the Expert Group on Financial and other Support (March 2003) @ paragraph 4.8 -

<http://www.scotland.gov.uk/Resource/Doc/47034/0024918.pdf> (including the material to be found in SGH.005.7203)

⁴⁵ PEN.013.1580 @ 1584

⁴⁶ PEN.018.1561

⁴⁷ PEN.018.1561 @ 1563

An analysis by the Assessor to the Inquiry Professor Oliver James has produced figures in a range between 1800 and 7,150 (+).⁴⁸In response, Professor Goldberg has produced an alternative range of 1110 to 6784 but maintains that there is not a compelling enough case to make any alteration to “our existing approach”⁴⁹.

⁴⁸ PEN.019.0916

⁴⁹ PEN.019.0922