STATEMENT OF PROFESSOR DAVID GOLDBERG

1.

Penrose Enquiry – Statistics – Number of Haemophilia patients infected with Hepatitis C: Response

Question 1. The number of haemophilia patients treated at each of the Scottish Haemophilia Centres who contracted NANBH or Hepatitis C.

We are unable to categorise the patients by Treatment Centre but we are able to provide information on the NHS Board of Residence or, where this is not known, the NHS Board of source of the original specimen taken for diagnostic purposes. As you will see below, HPS is aware of 351 individuals who have received blood factor and have been diagnosed as Hepatitis C antibody positive (ever having been infected); for all 351 there was no information to indicate that blood factor was received outside Scotland.

Question 2. The type of blood disorder of each such patient.

The table below is self-explanatory.

Question 3. For each such patient i) the date the patient was diagnosed as having contracted NANBH and, ii) the date of the first Hepatitis C positive sample taken from the patient.

As you can see in the table below, the year of the earliest positive sample for Hepatitis C antibody is provided. Note that in most instances this will co-incide with the year of diagnosis. However, in some instances earlier stored samples will have been tested and this explains why dates pre-1991 (when the diagnostic test became available) are applicable. Note also that we do not have any information in relationship to NANBH.

Question 4. The blood products prescribed to each such patient..... whichever date is the earlier.

HPS does not hold any such information.

Question 5. The number of patients infected with NANBH or Hepatitis C have died of NANBH or Hepatitis C or whose death has been materially contributed to by NANBH or Hepatitis C.

As at December 2009, 273 of the 351 cases were not known to have died. Of the 78 known to have died, 15 had a primary liver-related cause of death recorded on their death certificate and 15 had a secondary liver-related cause of death recorded; it is not possible to conclude from this information alone, if Hepatitis C materially contributed to death in these instances.

Question 1

NHS board[1]	Individuals positive for hepatitis C antibody and reported as having received blood factor
Ayrshire & Arran	28
Borders	6
Dumfries & Galloway	5
Fife	11
Forth Valley	13
Grampian	25
Greater Glasgow & Clyde	102
Highland	19
Lanarkshire	33
Lothian	71
Orkney	2
Shetland	2
Tayside	32
Western Isles	2
Total	**351**

[1] "NHS board" refers to the persons NHS board of residence, or where this is not known, the NHS board of source of diagnostic blood specimen

Question 2

Reported Blood Disorder[2]	Individuals positive for hepatitis C antibody and reported as having received blood factor
Haemophilia A	66
Haemophilia B	29
Haemophilia (Not Specified)	25
Von Willebrands Disease	16
Disorder Not Specified	215
Total	**351**

[2] Recorded in a free-text additional information field

Question 3 (ii)

Year of earliest specimen positive for hepatitis C antibody[3]	Individuals positive for hepatitis C antibody and reported as having received blood factor
1985	4
1986	8
1987	3
1989	1
1990	4
1991	125
1992	74
1993	27

1994	22
1995	27
1996	15
1997	8
1998	6
1999	7
2000	11
2001	4
2002	2
2004	1
2005	1
2006	0
2007	0
2008	0
2009	1
2010	0
Total	**351**

[3] Earliest positive specimens with specimen dates prior to 1991 were identified through retrospective testing of stored sera

Question 5

Known Dead (all causes)[4]	Individuals positive for hepatitis C antibody and reported as having received blood factor
No	273
Yes	78
Total	**351**

[4] Information on death sourced through data linkage to GROS register of deaths (December 2009)

Causes of death[5]	Individuals positive for hepatitis C antibody and reported as having received blood factor
Primary Cause Liver Related[6]	15
Secondary Cause Liver Related[6]	15
Other causes of death	48
Not known to be dead	*273*
Total	**351**

[5] Based on ICD9 and ICD10 codes

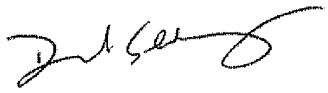
[6] Includes viral hepatitis, liver cancer, alcoholic and non-alcoholic liver disease

THE PENROSE INQUIRY

Witness statement of Professor David Goldberg

Statement of Truth

I believe that the facts stated in this witness statement are true.



Signed .....

Dated .....1st February 2011.....

Methodology involved in collecting, and the composition of data on HIV and Hepatitis C held at HPS and relevant to the Penrose Inquiry

The following explains the processes involved in collecting, and the composition of data on HIV and Hepatitis C held at HPS and relevant to the Penrose Enquiry.

HIV

- Following the development of an HIV antibody test in 1985, HPS (formerly Communicable Diseases (Scotland) Unit) established an HIV Diagnosis Database for Scotland. The Database holds data on all individuals diagnosed HIV antibody positive in Scotland and individuals, previously diagnosed outside Scotland, who come to reside in Scotland; for this latter group, a repeat HIV antibody test result is required for an individual to be eligible for entry onto the Database.

- Information on diagnoses is obtained from HIV testing laboratories throughout Scotland. Since 1989, to assist the collection of data, a National HIV Test Request Form has been used by laboratories; this form is made available to clinicians in clinical settings, allowing relevant information to be recorded by the clinician at the time of blood sampling.

- The following information on HIV diagnoses is obtained by HPS from the HIV testing laboratories:

    * Gender
    * Date of Birth
    * Initials
    * Soundex of Surname
    * CHI/Clinic Number(s)
    * Postcode District of Residence
    * Ethnicity
    * Risk Group
    * Geographical Location of Exposure
    * Laboratory Number and Date of Specimen
    * Clinical Source of Referral
    * Reason Tested
    * NHS Board of Referral
    * Name/Address of referring clinician
    * Minimum Dataset required for record to be entered on to Database

- Thus, HPS does not hold the names and addresses of persons diagnosed HIV antibody positive and, consequently, this means that the Database cannot be considered a Register. The decision to restrict the amount of information HPS holds on HIV diagnoses was agreed by HPS, the Scottish Government, virologists and clinicians on the grounds that HIV infection was not (and still is not) a "notifiable disease" and that the use of the data would be for epidemiological purposes and not patient identification ones. Also, in the context of the sensitivity associated with HIV, it was considered essential that any security breach could not lead to information, identifying individuals, getting into the hands of anyone. It is well understood that organisations within the NHS, such as HPS, should only hold data items for which there is an agreed purpose.

- Apropos risk factor information on individuals diagnosed with HIV, HPS collects this from request forms via the testing laboratories. If a risk factor(s) is attributed to an individual, it does not necessarily mean that the infected person acquired their infection through the stated risk activity(ies). Nevertheless, different risk factors convey different degrees of likelihood of the risk having resulted in infection. If an HIV infected person is an injecting drug user, or a man who has had sex with another man, or a haemophiliac, or a child born to an HIV infected mother, it is very likely (though not certain) that infection was acquired through the sharing of injecting equipment or unprotected anal sexual intercourse or the receipt of blood factor or through exposure to maternal blood in the womb at the time of birth or through breastfeeding, respectively. If the risk factor stated is heterosexual intercourse, the likelihood of this experience having resulted in infection is considerably less; such individuals may have had other risk factors but didn't declare them.

Blood Transfusion

- For the relatively small number of HIV infected individuals for whom the risk of "blood transfusion" was/is mentioned on the HIV test request form, two approaches are taken, depending on where the transfusion was received. If information on the request form indicated that the transfusion occurred outside of Scotland, no further information would be pursued. Such cases would be categorised by HPS as having a "blood transfusion" risk; however, the likelihood of this being the route of HIV acquisition is uncertain. If information on the request form indicated that the transfusion was received in Scotland or no information on place/country of receipt was available, HPS would liaise with the Scottish National Blood Transfusion Service to ascertain if, indeed, there was further information available to indicate that infection had been acquired in Scotland through this route; cases confirmed as having acquired HIV through blood transfusion would be allocated to the "blood transfusion" risk category. If HPS could not confirm the acquisition of HIV through blood transfusion in such an instance, the individual would be allocated to the "not known" category for risk.

Blood Factor (Haemophilia)

- HPS does not check with clinicians if an individual recorded as being a haemophiliac/blood factor recipient has indeed received blood factor; nor does HPS pursue information on such blood factor (i.e. quantity, type, source and place of receipt). Nevertheless, if information, for example country in which the blood factor was received, was recorded on the HIV test request form, it would be entered onto the patient's database record. All individuals, for whom information indicated haemophiliac/blood factor recipient on the HIV test request form, would be categorised as such by HPS in terms of risk.

Hepatitis C

All of the above applies to Hepatitis C except for the following:

- The Hepatitis C antibody test was introduced in 1991 and the Hepatitis C Laboratory Diagnosis Database for Scotland was established in 1996.
- Hepatitis C data are collected from Hepatitis C Testing Laboratories in Scotland; unlike for HIV, a National Hepatitis C Request Form does not exist.

Accordingly, Hepatitis C information available to HPS, via ubiquitous test request forms, is not as comprehensive or accurate.

- With regard to risk factor information, HPS would regard the risk factors of injecting drug use, being a haemophiliac/blood factor recipient and being born to an HCV infected mother, as ones for which the experience is very likely to be associated with the acquisition of infection.
- Data collected by HPS for entry onto the HCV Diagnosis Database are identical to those for HIV except for the test result (HCV positivity as opposed to HIV positivity).

Blood Transfusion

- In contrast to HIV, in instances where information indicating "blood transfusion" had been recorded on request forms accompanying a sample for HCV testing, HPS has not sought information to confirm acquisition of infection through this route because of the relatively large numbers involved (though these represent only about 3% of all Hepatitis C diagnoses in Scotland) in the context of a surveillance initiative which is slightly less robust than that for HIV and one which is not about patient identification but about epidemiology for public health action. The lack of confirmation associated with "blood transfusion" is a weakness in the system; however, it should be noted that Scotland's Hepatitis C Diagnosis Database is more comprehensive and accurate than that existing for any other country including those elsewhere in the UK and the European Union.
  Individuals, for whom the risk of "blood transfusion" applies, are categorised as such (unless they have other "more likely" risks – namely haemophilia, injecting drug use); accordingly, such individuals, unlike those who have received blood factor or who have injected drugs, are considered by HPS to have possibly (as opposed to likely) acquired their infection through this route (i.e. blood transfusion).

Blood Factor (Haemophilia)

- As applicable for HIV, as above.

THE PENROSE INQUIRY

Witness statement of Professor David Goldberg

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed ....

Dated .....1st February 2011.....