The Penrose Inquiry
Witness Statement of Professor Philip Cachia
On Topic C5

1. Current position

1.1 I was appointed to my current post of Postgraduate Dean for the East of Scotland Deanery, NHS Education for Scotland in 2004 when I left my post as consultant Haematologist and Director of Haemophilia services in Tayside. I have not had any ongoing clinical practice or professional involvement in Haemophilia care over the last 7 years and did not keep any personal records or departmental documents in relation to my actions as Haemophilia Director. Given the timescale requested by the Inquiry, this statement is based on my memories of my clinical practice in the 1990s without access to any personal records, supporting documentation or patient records.

2. Consultant Haematologist and Director of Haemophilia in Tayside

2.1 In 1992, I was appointed as a consultant Haematologist in Tayside with general Haematology duties and an interest in lymphoproliferative disorders. This was my first consultant post having completed Haematology training in 1991 in Cardiff. The post in Tayside was a replacement for a non-clinical laboratory consultant so I had no clinical practice to take over when I started. Cardiff was one of the leading academic Comprehensive Care Haemophilia Centres in the UK so Professor Martin Pippard, the head of department, asked me (while my patient referrals in general and malignant Haematology were accumulating) to undertake a needs assessment for the Haemophilia service in Tayside which was recognised as failing to meet UKHCDO standards.

2.2 An integrated clinical and laboratory Haematology service had only been developed in the late 1980s with the establishment of a chair and the appointment of Professor Martin Pippard. Prior to this, laboratory Haematology services had been provided through the department of Pathology and clinical Haematology service by general physicians with an interest in Haematological disease. It is my understanding that Haemophilia care prior to the mid 1980s was provided by a nominated consultant physician without specialist training in Haematology or Haemophilia care.

2.3 With the development of the local Haematology team over the next two years, my job plan was modified to include the role of Director of Haemophilia for Tayside.

3. Assessment of Tayside Haemophilia service in 1992

3.1 My initial assessment of the Tayside Haemophilia service in 1992, was primarily derived from conversations with Dr Heppleston as the named consultant responsible for the inpatient care of patients with Haemophilia, Dr Eva Brookes, the Director of the SNBTS regional centre, Dr George Urquhart, consultant Virologist and Haematology laboratory staff. From memory, I did not produce a formal written report but presented my findings and recommendations at a Haematology consultant meeting and from there agreed to develop plans to bring the Haemophilia service up to national standards of care.

3.2 In 1992, the only documentation available to me in relation to Haemophilia care (other than individual patient case notes) was a box of file cards held by Dr Heppleston with approximately 200 names, diagnoses, basic coagulation factor analyses and addresses. There were also records of factor concentrate issue for hospital and home use held by the Scottish National Blood Transfusion service (which had onsite laboratories providing the regional transfusion service and

hospital blood banking services for Ninewells Hospital) and records of coagulation investigations in the Haematology coagulation laboratory.

3.3 There was no Haemophilia Centre or dedicated location (patients with an acute bleeding problem requiring hospital assessment were seen on the general Haematology ward or day unit) and no dedicated Haemophilia staff (eg specialist nurse, data manager etc).

3.4 The Haematology service predominately consisted of a 'crisis intervention service' in the form of emergency and inpatient care in the event of acute bleeding or other medical problems. Medical staff may have provided pro-active advice and routine assessment of Haemophilia and its complications on an opportunistic basis but there was no managed or organised system of routine or prospective review of patients with clotting disorders in terms of their general health, joint disease or any of the complications of Haemophilia or its treatment. A nominated consultant Paediatrician did provide continuous care for boys with Haemophilia but there was little planned networking or linkage between the Paediatric service and Haematology Department.

3.5 Adult patients on home factor concentrate therapy received their supplies by contacting a technician in the SNBTS laboratory and were issued with the required product without regular medical supervision or formal review of their treatment usage as should happen as part of routine care.

3.6 There were no formal liaisons between the Haematology department and key specialist services required by Haemophilia patients including dentists, HIV specialists, Hepatologists, Orthopaedic surgeons, physiotherapists, social workers, trained counsellors.

3.7 The Haematology coagulation laboratory provided a comprehensive coagulation service including factor and inhibitor assays required to monitor Haemophilia care although not every on call biomedical

scientist was able to perform these assays as an emergency, out of hours procedure.

3.8 From discussion with Dr Heppleston, there were two major areas of clinical need that required urgent addressing:

3.9 Firstly, there was a backlog of severe Haemophiliac arthropathy that had not been managed because there was no organised system or specialist Haematological support for elective joint replacement surgery. Once I started meeting patients, it became clear that there were in the order of 15 – 20 knee and hip joint replacements that were clinical priorities on the basis of severe arthritic pain.

3.10 Secondly, when the HCV antigen test was introduced in 1991, the virology lab had retrospectively analysed around 30 stored sera from Haemophilia patients and identified around 25 who were HCV positive. It was unclear to me what patient consent had been obtained on collection of these samples. The patients who had tested positive had not been told of the result.

4. Development of Tayside Haemophilia service from 1992 – 2004

4.1 After discussion within the department and the appointment of an additional consultant (probably 1993 or 94), it was agreed that a new consultant with an academic interest in malignant haematology would be recruited and my job plan should be modified to transfer the immediate care of patients with Haemophilia and other clotting disorders from Dr Heppleston and that the department should aspire to deliver high quality, comprehensive Haemophilia care to UKHCDO standards. This was a substantial and fairly daunting challenge for a newly qualified and appointed consultant although the department in general and Professor Pippard in particular provided enormous

personal and practical support (particularly in relation to the business planning and change management processes).

4.2 I joined the Haemophilia Directors of Scotland and Northern Ireland organisation (and became secretary) in order that I could maintain up to date knowledge of changes in Haemophilia care, be involved in SNBTS clinical trials of new factor concentrates and had a formal relationship and access to advice from the senior Haemophilia Directors from the comprehensive Centres in Edinburgh and Glasgow.

4.3 With immediate effect, I would assess any patients with Haemophilia presenting with clinical problems to establish contact, start the process of regular, routine care, assessment of complications and to institute medical scrutiny of their factor concentrate prescription and usage. However, I realised that I had no realistic prospect of addressing all clinical problems or delivering comprehensive care as a lone worker.

4.4 I therefore prepared a business case submitted to Dundee University NHS Trust making the case (from memory) for a dedicated unit/space in the department as a Haemophilia Centre, a full-time specialist Haemophilia nurse, data manager and administrative support. I have not kept personal records and all my work related files were left in the department at the time I left Haematology in 2004. I cannot remember the precise timing but the business case was approved, a dedicated Haemophilia Centre (including a treatment area and office) established in the department and our part-time specialist Haemophilia nurse (June Ward) recruited, appointed and started work (initially 21 hours a week) in January 1995.

4.5 At a later date (from memory 1997) when I became Postgraduate Tutor for two sessions a week, I used the backfill funding from this post to employ a clinical assistant for 1-2 days a week to further develop the Haemophilia team and to undertake routine clinical assessments.

4.6 From 1995, June and I set about establishing the Haemophilia Centre and the delivery of comprehensive care in Tayside. There were a number of priority areas for action:

1) Establishing the Centre management, documentation and local protocols
2) Training and education for other haematology staff (medical and nursing) to ensure that the standards of care and treatment protocols would be delivered in our absence
3) Developing formal links with the local Haemophilia Society to engage with the patient, parent and carer community. This would include our attendance at local meetings and presentations to explain our ambitions for improving care
4) Establishing a working relationship with SNBTS so that all requests for factor concentrates came through June Ward or myself so that we could ensure there was patient engagement and a regular review of bleeding history and factor concentrate usage.
5) The introduction of regular reviews for all patients to include general health review, assessment of Haemophiliac joint disease, factor concentrate usage, viral status, education, social aspects of Haemophilia
6) Establishing formal links between paediatric and adult Haemophilia care to ensure consistency of clinical protocols and management of seamless continuity of care as the boys with Haemophilia transferred to the adult service. There was initial suspicion and an element of hostility from Paediatrics given the historical lack of support from the Haematology Department. An excellent working relationship was, however, soon established by our demonstration of specialist support and partnership working. June's remit was extended to support paediatric care in hospital and the community (home, schools etc) and I would attend Paediatric clinics to get to know the boys and their parents.
7) Introducing prophylactic home factor concentrate therapy for boys with Haemophilia in Tayside as best clinical practice to prevent joint bleeds

and the long term complication of arthritis. This involved education, support and encouragement of staff in paediatrics, parents and the boys

8) Close working with the Haematology laboratory staff in the coagulation laboratory to ensure the 24/7 availability of all factor and inhibitor assays required for emergency haemophilia care.
9) Establishing formal agreements, clinical policies and access to shared care for patients with Haemophilia with:
    - Orthopaedic surgery
    - Anaesthetics
    - Physiotherapy
    - Dentistry
    - Hepatology
    - Infectious Diseases
    - Obstetrics
    - Clinical Genetics
    - Social Work
10) Participation in Scottish National Blood Transfusion clinical trials of highly purified clotting factor concentrates as part of the Scottish and Northern Ireland Haemophilia Directors group.
11) Elective orthopaedic surgery. The backlog of severe Haemophiliac arthropathy was a priority service development. At that time, all orthopaedic surgery was performed in Dundee Royal Infirmary while the Haematology clinical and laboratory services were in Ninewells Hospital. Given the need for close clinical and laboratory monitoring, I arranged with the Professor of Orthopaedics for a series of operating dates in Ninewells on a Friday morning linked with my on call weekends so that I was available for the immediate post-operative management. I wrote protocols for the peri-operative and anaesthetic care of a patient with Haemophilia. Over the next few years this service provided elective joint replacement surgery for around 10 patients with severe joint disease often affecting several joints.

5. Practice in relation to testing, consent and communication of Hepatitis C status

5.1 In response to the Inquiry's request for information about local practice and policy in relation to Hepatitis C testing, the practice in Tayside should be considered in three separate phases:

a) Pre-1992: When there was no comprehensive Haemophilia care and I have no personal knowledge of the practice of the staff caring for patients with Haemophilia
b) 1992 – 1995: When I was in post and developing the case for comprehensive Haemophilia care but largely acting as a lone consultant and seeing patients largely on an opportunistic basis
c) Post-1995: When June Ward was appointed as a Specialist Haemophilia Nurse and local protocols for Haemophilia care were developed and implemented

5.2 Testing and Consent

5.2.1 When did they start testing their patients for HCV?

Pre-1992 a cohort of around 30 patients were tested retrospectively from stored sera by the Virology department without, to my knowledge, specific informed consent. From 1992 onwards all Haemophilia patients contacted and offered comprehensive care were tested at first meeting and at their 6 monthly reviews.

In what circumstances were blood tests carried out during the periods 1990–1995 and from 1995 onwards? Were patients tested individually or as a group? Were fresh blood samples taken for the purpose of testing or were stored samples used? Who carried out the HCV tests?

A single group of around 30 patients were tested for HCV from stored serum samples but all patients were tested or re-tested from fresh samples before the diagnosis was confirmed. The laboratory tests were performed by the Ninewells Hospital virology laboratory.

Did they tell their patients that HCV tests were being carried out? What did they tell their patients about HCV testing? Did they obtain consent from their patients before carrying out HCV tests?

All patients tested after 1992 were counselled (almost exclusively by myself and/or June Ward) and verbal informed consent obtained.

Were there any written guidelines or policies on HCV testing produced by their unit at this time?

Departmental guidelines were developed and introduced from 1995.

5.3 Communication of results and implications of diagnosis

5.3.1 What was their practice in relation to telling their patients the results of an anti-HCV positive test? Did they inform their patients immediately upon receiving their results? If not, why not?

Our intention and practice was to provide patients with a full explanation of contemporary information on HCV infection, implications for future health and treatment options as these evolved. Patients would be given a follow up appointment at the time of initial assessment and be informed of the results at the planned follow up meeting or the next available meeting.

5.3.2 What arrangements were made for patients to be told of positive test results?

Between 1992 and 1995, patients would have been told of positive results by myself. From 1995 onwards, they would have been informed at routine Haemophilia review appointments (by myself and/or June Ward) or at planned appointments with Dr John Dillon, consultant Hepatologist.

5.3.3 What did they tell their patients about the implications of HCV?

Knowledge of the complications and therapeutic options for HCV were continuously changing over the period from 1992. The approach taken by June Ward and myself (based on my training in the Cardiff Comprehensive Care Centre) was to have an open and frank discussion using non-technical terms to explain the nature of the infection and its origin, risks of spread including sexual intercourse (but not through normal social contact), the importance of monitoring clinical signs and blood tests, the potential benefits and risks of liver biopsy and treatment options as they evolved including Interferon, dual Interferon and Ribaviron and pegylated interferon. Our aim was to enable patients to make informed decisions in relation to requesting approval for anti-viral therapy.

5.3.4 Were there any written guidelines or policies on communicating positive results to patients produced by their unit at this time?

Written policies were developed with the introduction of comprehensive care from 1995.

Professor Philip Cachia
Dated: