SNBTS DOCUMENT REQUEST No:

2011/00134

The Penrose Inquiry

Dr John Gillon – Witness Statement: Topic C5(b)

I, Dr John Gillon, do say as follows in response to the questions put to me in respect of this topic (Hepatitis C Lookback):

1 What was Dr Gillon's involvement in the lookback exercise?

I was appointed as a Consultant in Edinburgh and S. E. Scotland Blood Transfusion Service in April 1985. My areas of responsibility included the Selection and Medical Care of Donors and the Cell Separator Unit, and I also had the right to retain clinical activities as an Honorary Senior Lecturer in the University of Edinburgh and Honorary Consultant Physician in Lothian Health Board. Shortly after appointment I became a member of the Hepatitis Advisory Group of the LHB, and took over as Convener of this group when Dr Niall Finlayson demitted office in 1986.

Having responsibilities which spanned the donor service, clinical transfusion medicine and outpatient clinical work, it fell naturally to me to take responsibility for liaising with clinicians about post-transfusion complications where an infective component was suspected. When routine HIV testing began in 1985 SNBTS adopted the agreed UK policy of lookback, and this was my responsibility.

In June 1990, when SNBTS was planning the introduction of testing for anti-HCV, I was asked by Dr Cash and the SNBTS Directors to chair a working party to provide recommendations for the counselling and management of blood donors found positive once testing was under way (SNB.005.5023). One of the key recommendations of this group

was that lookback should be part of this process. The report produced by the working party (SNB.001.8803) was shared with the other UK transfusion services, who accepted the recommendations on donor counselling, but rejected the proposal that lookback should be initiated from the commencement of testing. This decision was communicated to me by Dr Cash in a letter dated 12 March 1991 (Appendix 1).

I strongly disagreed with this stance, and, with the agreement of the Director of SEBTS, Dr Brian McClelland, I undertook lookback on all anti-HCV positive donors with previous donations in SE Scotland as a routine from the onset of testing in September 1991. The National Medical and Scientific Director, Dr Cash, was aware of this, and it was later agreed that this should be seen as a "pilot study". In 1994 SNBTS senior management was made aware that I and my colleagues had submitted a paper on our experience of lookback for publication (Ayob et al, Transfusion Medicine 1994;4:269-272). Our conclusion, stated in the paper, was that lookback was feasible with little in the way of extra resource, and justified in terms of outcome. As described in the Preliminary Report (Chapter 9.929, p 322) this paper was instrumental in the decision reached by the Committee for the Microbiological Safety of Blood and Tissues (MSBT) at its meeting on 15 December 1994 to recommend to Ministers that lookback should be undertaken UK wide. This recommendation was accepted and announced on 11 January 1995 (SGH.004.7020). On 3 April 1995 the Chief Medical Officer, Dr Kenneth Calman, wrote to all doctors in the UK announcing the lookback and enclosing the guidelines for implementation (SGH.002.8373, Preliminary Report page 323). An identical letter was issued by the CMO in Scotland to all doctors working in Scotland.

A working party answerable to MSBT was set up under the chairmanship of the Deputy CMO to develop a set of formal procedures and documentation for the lookback exercise, based largely on the procedures established in Edinburgh. I was a member of the working party.

Following implementation in 1995 the course of the retrospective lookback was monitored by MSBT, and I was asked to collate and report data from all five SNBTS regions at intervals as requested, usually quarterly. I had no responsibility for the management or documentation of the lookback in the other four regions of SNBTS.

Formal monitoring of the lookback ceased in 1998, when the SHHD accepted that SNBTS had done everything possible trace patients retrospectively (SGF.001.2172, Preliminary Report page 326). It remains the case, however, that a donor found to be positive for HCV, and with a history of previous donations, will trigger a lookback using the same procedures, according to the current SNBTS National Standard Operating Procedure.

Full details of the lookback, including the formal standard letters and forms for documenting each part of the process, are to be found in Appendix 2, a paper which was prepared by me as part of the SNBTS preparations for this Inquiry.

2. Why was the lookback not commenced earlier given that a screening test for anti-HCV was available from 1991?

As described above, lookback was introduced in SEBTS as soon as screening for anti-HCV began. All other Regional Transfusion Centres in the UK adhered to the policy of the UK Regional Transfusion Directors not to implement lookback. No reasons were given for this

policy decision in the letter from Dr Cash in July 1990 communicating it to the SNBTS Directors (Appendix 3), nor, after further discussion at ACVSB (Appendices 4 and 5), in Dr Cash's letter to me of 12 March 1991 (Appendix 1).

3. How useful does Dr Gillon think the look-back exercise was?

The usefulness, or utility, of any medical intervention is assessed firstly in terms of efficacy, i.e. whether it results in more benefit than harm for the patient, and secondly, assuming there is net benefit in terms of efficacy, whether it is cost-effective.

The best measure of benefit is mortality. The earliest studies of PTNANBH showed no difference in all-cause mortality between patients with PTNANBH and untransfused controls after 20 years' follow-up. The same was found in a recent study from Denmark documenting the outcome of their HCV lookback which was begun in 1996 (Just S A et al, Transfusion (in press): doi: 10.1111/j.1537-2995.2011.03309.x, copy attached as Appendix 6). They did, however, show an increase in liver-related mortality in the PTHCV patients, only 11.8% of whom were still alive 20 years after exposure. Thus, in spite of the availability of effective treatment for HCV, no clear net benefit in survival was demonstrated from having identified these patients.

In the absence of any demonstrable effect on mortality, whether positive or negative, was there any benefit in terms of morbidity? The Danish researchers showed that PTHCV patients suffered considerable morbidity, with 26% of those examined histologically having cirrhosis. Only 28% of the PTHCV patients received antiviral treatment, but 46% of those were "cured", indicating that for some

patients major benefit was obtained, though as described above this was not reflected in the overall mortality data.

The patients identified in the UK lookback were recruited to a long-term follow up study, referred to as the National HCV Register and managed by Dr Helen Harris at the Health Protection Agency, the initial findings from which were supplied to the Inquiry earlier (PEN0010043). Further useful information is expected from this study, and it is likely that better quality information will emerge, as this study is prospective, and thus likely to be able to avoid some of the flaws acknowledged in the Danish work, which was retrospective.

From my own personal experience of counselling and following up these patients, I have no doubt that they were unanimous in feeling that it was correct for them to have been given this information. I have never been told by a patient that they would have preferred not to have been told about their possible exposure to HCV.

However, since clearly measurable benefit has not (yet) been demonstrated, a cost-effectiveness analysis cannot be undertaken. Such an analysis would be extremely difficult because of the complexity of these circumstances. Previous studies have attempted to determine the cost of identifying each case of PTNANBH, as described Appendix 2, but there is a wide variation in outcome. It is reasonable to point out that the UK lookback was pursued with very little additional central funding, though of course many man-hours were expended in the process.

4. What does he think was achieved?

The UK lookback was conceived in a storm of media criticism, and this followed 10 years of persistent adverse publicity in the wake of the association of HIV and HCV with transfusion. I have no doubt that in instituting lookback ahead of most Western countries the UK transfusion services regained a measure of trust that is of vital importance to the maintenance of donor support, and of confidence among patients that their best interests are being served.

Most importantly, some patients at least are likely to have had successful treatment and a prolonged period of healthy life, instead of living with the misery of end-stage liver disease.

5. What, if anything, would he have done differently in hindsight?

I do not regret the stance I took in respect of lookback, nor do I think that anything I could have done would have hastened the change in policy at UK or Scottish national levels.

I have also been asked to comment on my paper entitled "Lookback on Hepatitis C Lookback", which was published in "Transfusion Today", the quarterly newsletter of the International Society of Blood Transfusion (Transfusion Today; 39: p14. June 1999). The article was written as an opinion piece at the request of the Editor, who expressly asked me whether, in my opinion, the HCV lookback was "worthwhile". Having responded, briefly, in the affirmative, I went on to address the question of the delay in the UK transfusion services implementing HCV lookback when HIV lookback had been undertaken as soon as routine testing was in place. I could give no definitive answer to this question, as the reasons for the policy of non-implementation had never been made explicit. After describing

some of the reasons that might have underlain the policy, I went on to speculate that there may have been a collective psychological aversion to addressing the issue, though clearly this is impossible to prove. There is no doubt that HCV was seen by many as less serious than HIV, and that the outcome of lookback in terms of clinical benefit was likely to be modest and disproportionate to the expenditure of time and resources it would require, and it may be that my speculation about less tangible reasons for the collective view that lookback was not indicated were wide of the mark.

In the event, the UK was still one of the first of the developed countries to implement a systematic lookback on a national level. It was only in 1998, 3 years after the UK, that the USA accepted, with great reluctance in many quarters, the need to follow suit.

I have also been asked to address 2 specific practical matters, which I shall do as follows.

1. How was the lookback "taken forward" for "all areas of Scotland"?

On 6 January 1995 Dr Cash wrote to Mr David McIntosh, General Manager, SNBTS, suggesting that SNBTS should proceed to implement lookback as soon as possible, and describing the work that was nearing completion on guidelines and procedures. It was suggested that these be used by RTCs to develop local SOPs (Appendix 7). Mr McIntosh responded in positive terms by letter on 9 January 1995 (Appendix 8).

In common with standard practice in SNBTS at that time, the policy decision to implement lookback was transmitted to the relevant medical staff in each centre by the Regional Director. It would fall to the consultant or associate specialist with responsibility for routine administration of lookback procedures to ensure that all outstanding cases stemming from HCV screening were fully investigated and documented, using the agreed procedures and forms.

2. How were the procedures attached to the CMO letter of 3 April 1995 implemented in practice?

The documentation designed by the Working Party and disseminated to all doctors by the Departments of Health for implementation, as described above, ensured that the process was essentially the same for every lookback. In essence, it was the responsibility of the SNBTS to identify blood components from donors now known to be positive for HCV, and to inform the recipient blood banks, whose task it was to identify the patient who received any given component. In the case of SNBTS Blood Banks, e.g. the Royal Infirmary of Edinburgh, SNBTS had direct access both to any existing blood bank records, and usually also to existing patient hospital records.

Attempts were then made to establish whether the patient was still alive. If so, or if this was unknown, SNBTS then wrote using the standard letters to the clinician responsible for the patient at the time of transfusion, suggesting that the patient should be informed, counselled, and offered testing. If the clinician declined, a letter was sent to the patient's GP along similar lines. In the event that the GP also felt unable to approach the patient for these purposes, the SNBTS consultant with responsibility for lookback in the region would write directly to the patient offering an appointment. Each individual lookback ended with a consistent record for each patient identified.

These records have been retained in the Regional Transfusion Centres to this day. The process was monitored by SNBTS Directors and the SHHD in the person of the Deputy CMO for Scotland, Dr Aileen Keel, who was a member of MSBT and reported to the committee on the progress of the lookback.

As far as I am aware no extra resource was required in any region with the exception of the West of Scotland, where, because of the scale of the problem and the diversity of hospitals involved, a nurse/administrator was employed by SCIEH (now HPA), and medical manpower provided from existing establishment to facilitate the search for blood bank and hospital records in outlying hospitals.

Dr J Gillon

8 November 2011