PENROSE INQUIRY

LORD PENROSE’S WRITTEN DECISION - APPLICATION TO HEAR FURTHER ORAL EVIDENCE

HEARD AT A PROCEDURAL HEARING
Apex International Hotel, Edinburgh
29 October 2012
1. A public procedural hearing of an application by patient interest core participants to hear further oral evidence took place on 29 October 2012. The witnesses proposed were:

   - Professor David Goldberg (to speak to the epidemiological analysis undertaken by him since he last gave evidence)
   - Dr Kate Soldan (to speak to the methodology applied in her epidemiological analysis of the numbers infected with Hepatitis C from blood transfusions in Scotland)
   - Dr Gillon and/or Dr McClelland (to speak to the evidence they have provided to Professor Goldberg and its influence on the assumptions which underpin his epidemiological analysis) and Dr Charles Hay (to speak to newly produced UKHCDO\textsuperscript{1} statistical material).

2. In substance, the application raised two issues, first whether the terms of reference of the Inquiry required further investigation of the matters identified in the application, and discussed more extensively in the patient interest core participants' submissions lodged after the close of oral proceedings,\textsuperscript{2} and, in particular, justified calling or re-calling witnesses to give additional oral evidence, and second whether those matters could, if investigated, contribute to the discharge of the terms of reference.

3. Term of Reference (TOR) 4 is relevant, and the specific issue is whether it requires the Inquiry to reach final and definitive numbers of NHS patients infected with Hepatitis C, generally, but with particular reference to blood transfusion transmitted infection. The TOR is in these terms:

   To investigate the systems for recording and monitoring the numbers of NHS patients in Scotland treated with blood and 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.

\textsuperscript{1} United Kingdom Haemophilia Centre Doctors' Organisation
\textsuperscript{2} PEN.019.1171
4. As is the case with other terms of reference, TOR 4 is concerned with systems. In its broadest sense, the term of reference requires the Inquiry to investigate recording and monitoring systems relating to the numbers of patients in Scotland treated with blood and blood products, encompassing transfusion of blood and its components and infusion of blood products. The requirements are the same for the general class of NHS patients as they are for the specific sub-classes of persons infected with Hepatitis C Virus (HCV) or HIV or both.

5. At one end of the spectrum of possible answers was, and is, that there were, in place and enforced, fully adequate systems that followed whole blood, components, and manufactured products from donor to recipient and provided an audit trail that would ensure identification of all recipients of each unit of blood, enabled identification of donors so far as alive or, if dead, to trace stored samples of blood or serum for testing to determine their infectivity, and thereafter enabled recall of recipients to trace those who may have been infected, for testing, counselling and treatment.

6. It could not be assumed that that would prove to be the case, and alternatives had to be explored. The most obvious alternative was to attempt to use such data as could be traced and analysed to provide a platform for statistical or epidemiological investigation that would either make good any deficiencies in primary records or would enable a reliable estimate of numbers to be made that would not be undermined by the lack of, or deficiencies in, those records. One way of investigating that possibility was to engage appropriate experts and seek advice on the numbers that might be developed from the data available. The present application is focused on that aspect of the investigation and, essentially, reflects an opinion that it should be extended further with a view to providing a precise and accurate assessment of those numbers.
7. This is not the occasion to comment on the exercises that have been carried out to date: the final report will deal with each, and, as seems likely at present, it will comment on the reliability of the results achieved. But it is not necessary for the purposes of TOR 4 to attempt to reach such a precise number or numbers as proposed by the applicants. If it were, it would amount to a need to investigate this issue until any problems associated with the primary records had been resolved, professional opinion had converged, and one had values for the several groups of patients and infected patients that were generally accepted to be both accurate and reliable. There would be no predictable end to that exercise.

8. In my opinion, however, having regard to the evidence already led, further oral evidence on the issues proposed is not required for the proper discharge of TOR 4.

9. Further, additional oral evidence would not add significantly to the evidence already available to instruct a proper analysis in the final report of the estimates that have been provided to date. Those exercises, like all exercises based on hypotheses, could undoubtedly be amended, refined and extended. But they would never be more than they currently are: estimates made on the data and assumptions available to the experts.

Dr Soldan

10. In 2002 Dr Soldan, then an epidemiologist based at the Communicable Disease Surveillance Centre, Public Health Laboratory Service, and a large team of collaborators estimated the number of individuals who might have been infected with HCV by blood components administered in England.

11. The data used were derived from the English Hepatitis C look-back study and was based on an analysis of the fate of a number of blood components, and extrapolating from these the probable fates of specified groups of other
components. The work carried out by the Soldan group in England was duly published. The exercise can be analysed and understood by reference to that publication. It is not necessary to call Dr Soldan to learn what she did in respect of England.

12. In 2002 Lord Ross’s Expert Group asked Dr Soldan to provide an estimate of the number of patients in Scotland likely to have contracted Hepatitis C as a result of transfusion. Dr Soldan used the same statistical model as in England and applied some of the same assumptions, for example in relation to the probability of a blood component being transfused. She also factored in the information available from the Scottish Hepatitis C look-back exercise and the higher prevalence of HCV among blood donors in Scotland in the first four months of HCV screening when compared with the prevalence among blood donors in England. Again, the exercise is readily understood in terms of the documents prepared at the time.

13. In each case, the modelling exercise was heavily dependent on assumptions, clearly specified and, typically of statistical models, the results would vary if the assumptions changed. The Inquiry attempted to engage Dr Soldan’s assistance. Her superior, Dr Helen Harris of the Health Protection Agency, indicated that some limited assistance could be provided in terms of up-dated information but that it was unlikely that Dr Soldan would repeat or update the modelling work she had published in 2002. It is understood that Dr Soldan has moved away from this area of work.

14. The Inquiry could require Dr Soldan’s attendance, but it could not require her to perform further work. Comment on the exercise she did carry out as a useful source of material in discussing TOR 4 is unlikely to be affected by lack of oral evidence from her.

15. It would now be an unacceptable imposition to require her to attend to support her Scottish exercise, completed in 2002, simply to narrate the work
she has already put into print, in published form in England and in unpublished writing in Scotland.

Professor Goldberg

16. Professor Goldberg and his colleague at Health Protection Scotland, Dr Schnier, undertook a separate modelling exercise to estimate the number of people infected with HCV as a consequence of blood transfusion in Scotland during the period 1970 to 1991 and the number who were alive at June 2011.

17. In consultation with Dr McClelland and Dr Gillon, Schnier and Goldberg made certain assumptions, in particular an assumption that the size of the HCV infected injecting drug users (IDU) population in Scotland was directly proportional to the HCV infected donor population. In addition they used a factor to account for the introduction of blood donor deferral policies in 1984. Two other factors also used by Soldan were modified for Scottish purposes. There were other assumptions relevant to the estimation of the numbers of deceased patients.

18. Using their statistical model, Professor Goldberg and Dr Schnier provided an initial estimate of the number of individuals in Scotland infected with Hepatitis C as a result of transfusion in their reference period. That was followed up by a fuller document in the form of an academic paper. In their paper Goldberg and Schnier set out the various assumptions upon which their model was based, and made clear that the probability of a transfused blood component being infected with HCV was influenced by factors including: the size of Scotland’s hepatitis C infected population in any particular year; and the effectiveness of SNBTS’s deferral policy during the period 1984 – 1991. Direct evidence of the size of the HCV infected blood donor population was not available.

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3 Scottish National Blood Transfusion Service
19. Again, the acceptability of the assumptions made is fundamental to the exercise, and comment on these matters is properly for the final report. But, as with Dr Soldan’s work, there is no difficulty in understanding what was done, or in understanding the significance of the assumptions.

20. Professor Goldberg would willingly continue his investigations, an understandable position for an epidemiologist to adopt in the face of alleged uncertainty. But, given the heavy dependence of any modelling exercise of the kind carried out on stochastic projection of variables, it is impossible to predict the outcome of the adoption of alternative hypotheses for individual components, and there is no basis for a view that a further exercise by Professor Goldberg and Dr Schnier would advance matters generally or provide more accurate estimates of the numbers.

21. It should be noted that Professor Goldberg was asked to vary some of his assumptions and re-run his model. He did so and the widely different values brought out are instructive of the impact of assumptions on the operation of the model, and may be of considerable value in supporting views on the outcome of the exercise overall.

Dr McClelland and Dr Gillon

22. Some of the assumptions factored into Professor Goldberg’s model depended on local knowledge and expert opinion: assumptions iii, v, vi and viii, supported by advice from Dr Gillon and Dr McClelland. Assumptions v and vi relate to the practical operation of the SNBTS. The yield of blood component units from donations passed for transfusion or manufacturing purposes is a function of local processing methods and efficiencies, and it appears that again the model was supported by advice from Dr Gillon and Dr McClelland.
23. Two of the assumptions made in the HPS model are common with Dr Soldan, namely that every recipient of a contaminated unit subsequently developed HCV infection, and that the risk of an individual receiving two or more infected units was negligible. Those relating to mortality are less material for purposes of this application.

24. In what appears to be common form in epidemiological papers, the Schnier/Goldberg paper refers generally to the use of data and materials based on expert and on local knowledge without further explanation. For present purposes, that is not satisfactory. Interested parties are entitled to know what information was provided and by whom, what data were relied on, what degree of accuracy was attributed to data and the advice based on it, and what significance the information had in instructing the conclusions reached by Professor Goldberg and Dr Schnier. There is no need for oral evidence on these matters, however. Dr McClelland and Dr Gillon will be asked to provide written responses to questions arising from the Goldberg/Schnier evidence.

Dr Hay

25. As the evidence stands, there is an apparent conflict between UKHCDO and the Scottish Haemophilia Directors relating to the precise numbers of patients with coagulation deficiencies who became infected with HCV and HIV. Since much work has clearly been done on this matter since Dr Hay, Professor Ludlam and Dr Tait gave evidence, it is important to ascertain whether issues relating to patient numbers have been resolved, or, if not, what outstanding issues remain. It again appears likely that a written explanation of the current position will either resolve the apparent differences or explain them sufficiently to avoid oral hearings. Dr Hay and Dr Tait will be asked to advise in writing.
Programme and cost implications.

26. As with other areas of the Inquiry’s remit, extending as it does over two different infections suffered by two different categories of patients over a reference period of at least seventeen years, it would be possible to carry on investigation and the leading of evidence indefinitely. It has been, and remains, necessary to strike a balance and bear in mind the need for proportionality in relation to costs. Total numbers of people ever infected with one or other or both diseases include those who died, before and after the diseases were identified, often of underlying conditions not relating to infection or without anyone being aware of their infection during life or at death; people who acquired infection but cleared it naturally, and people still alive who are infected, or who have antibodies indicative of previous infection, but who remain wholly unaware of their condition (and who may often be unwilling to undergo examination to ascertain whether or not they might be infected – a factor that can have economic implications for patients of the NHS). A sense of proportion is clearly required.

27. It was, in the end, not in dispute that the applicants did not know what the outcome of the proposed exercise in examining and re-examining these witnesses would be. A number of specific questions have been posed which might result in witnesses supporting assumptions used in the statistical models produced to date, or might result in variations or modifications of the assumptions or the values attributed to them for purposes of calculation. The outcome of the examination proposed cannot be predicted. But it might involve another application for further study by existing witnesses or others and yet more evidence. There is no natural limit to the scope for exploration of hypotheses. The questions posed would not yield answers on numbers. And the process would take time and involve considerable expense. Oral hearings are not particularly suitable for the examination of numerical data in any event.
28. What is proposed is indeed a step into the dark. It would involve a commitment of unknown duration and involve unknown cost. And it would not of itself add information likely to support the answer to TOR 4.

29. The Inquiry has sufficient information to enable the expression of views on approximate numbers of individuals in each of the relevant groups. The material gathered will be available for further study by interested parties.

30. After the oral hearings concluded on 30 March 2012, the Inquiry Team undertook further work on the topic of Statistics, and further evidence was made available to the solicitors acting on behalf of core participants, who were given the opportunity to comment upon it.

30. This Inquiry has a clear duty under section 17 (3) of the Act in these terms:

   'In making any decision as to the procedure or conduct of an inquiry, the chairman must act with fairness and with regard also to the need to avoid any unnecessary cost (whether to public funds or to witnesses or others).''

31. The final report will deal with the evidence of all of the witnesses so far as necessary to ensure that the position is fairly presented. The lines of enquiry proposed are unnecessary for that purpose. The cost, in time and resources, cannot be justified. The exercise would inevitably delay the completion of the report.

32. The sole application was to re-open the oral hearings stage of the Inquiry and to call or re-call the specified witnesses. That application is refused. There is no justification for further oral evidence.

33. As indicated above there are issues on which it is appropriate to have further information, concerning the basis on which Dr Schnier and Professor
Goldberg proceeded and concerning the up to date data supplied by UKHCDP. These are simple matters of fact, and written answers to questions will be sought as seems appropriate. This was not proposed by the applicants, although raised at the hearing, and will be done at the initiative of the Inquiry.

9 November 2012