PENROSE INQUIRY

Statistics – follow up queries

C – Dr Gillon's statements

HIV

1. The patient referred to is patient 9 in the table of dates of transfusion. This patient was reported to HPS (then SCIEH) by the Consultant Virologist at the Western Infirmary, Glasgow, in 1986 after a sample tested in the laboratory in February of that year was found to be positive for antibodies to HIV. The only additional information in the HPS database is that the patient had sickle cell anaemia and had received multiple transfusions, and that HIV had been acquired in 1984. It is not known whether these transfusions were given in Scotland or elsewhere.

   When tests for HIV became available in 1985 HPS(SCIEH) agreed a reporting mechanism with all virology laboratories in Scotland. The information supplied by the laboratory was limited to that contained on the test request form, but subsequent reporting to HPS(SCIEH) by clinicians or others (e.g. SNBTS) would usually permit additional information to be included.

   The lack of further information on this case (beyond the information supplied by the reporting laboratory) suggests that the clinician involved did not report the case to HPS(SCIEH), nor to the SNBTS. West of Scotland BTS have no record of this patient, so to the best of SNBTS knowledge the question of transfusion transmission has never been invested in detail. In seeking to reconcile SNBTS and HPS data on transfusion transmission of HIV, however, (this exercise having been carried out during the summer of 2010), it was felt that it was reasonable to include this case, as the circumstances are compatible with a relatively high risk of exposure through transmission.

   There has never been an agreed policy, nor a DoH/SHHD requirement, for clinicians to report possible transfusion transmitted infection to the SNBTS for investigation. Through routine clinical contacts with colleagues in relevant disciplines, the SNBTS has sought to encourage the reporting of all such cases for investigation by SNBTS.

2. There are 4 patients in the list of 18 where the dates of transfusion could be considered vague. In reference to the 3 patients in para 2, I was referring to patients 2, 9 and 12 as I considered them to have transfusion dates which were more vague than all the other 15 patients including patient 13. Patient 13 was not referred to in paragraph 2 as I considered that "early 1984" gave a reasonably clear indication of the likely transfusion date. Patients 2, 9, 12 and 13 all had conditions necessitating multiple transfusions prior to the establishment of sample archives. The transfusion transmission in these 4 cases is therefore presumptive, based on the limited information available, but the circumstances are such that these are accepted as cases of probable transfusion transmission.

HCV

3. While it is acknowledged that the patient groups in paragraphs 1.1, 1.2 and 1.3 could theoretically overlap, I think it is unlikely that double counting could have occurred. I am not aware that any of the HCV positive donors in 1.1 were identified as patients in 1.2 subsequent to their donation at which they were found to be HCV positive. Patients in 1.2 were exclusively identified through the targeted lookback, which used formal documentation procedures different from those in use for either donors or patients reported by clinicians. The latter group, described in 1.3, is small in number and each case was investigated individually, with details held in individual case records. There is, however, a finite risk that a patient initially reported to the SNBTS through this route might subsequently have been identified by the targeted lookback without a connection having been made between the two incidents. In view of the anonymisation of the data recorded by HPA, and also of the numbers of patients identified through lookback for reporting to the DoH, it is not possible to rule out such an occurrence, though in numerical terms the impact would clearly be small.

I would emphasise that the numbers given in 1.1 and 1.3 cannot be regarded as definitive as in those patients with a presumptive diagnosis of TT HCV transfusion may not have been the cause and there may have been other risk factors. For those patients in 1.2, transfusion transmission has been established beyond reasonable doubt.

Equally, as previously acknowledged, there are cases which have not been accepted for inclusion because it has not been possible to amass sufficient evidence of transfusion transmission, though in a proportion of these it is possible that transfusion transmission did occur. In evaluating these cases we have tried to err on the side of inclusion, but in my view the number given in 1.3 is likely to be an underestimate, by a considerable margin, of the residual number of undetected transfusion transmitted cases of HCV.

4. The high prevalence of parenterally transmitted virus infections in dialysis unit patients has been a longstanding concern which is still incompletely misunderstood. Patients with renal failure are usually anaemic and require transfusions, and this has been a contributory factor to the high rates of HBV and HCV infection seen in the past. Organ transplantation carried a similar risk for these patients. However, there is a considerable body of literature attesting to the high risk of nosocomial transmission in this environment. The risk attributable to reuse of dialysis machines is the subject of debate, but has probably been a factor, as have insufficiently rigorous hygiene practices in the past.

   Further details can be found in the following references:

   Wreghitt TG. Blood-borne virus infections in dialysis units – a review. Rev Med Virol 1999; 2: 101-9.

   Natov SN, Pereira BJ. Hepatitis C virus in chronic dialysis patients. Minerva Urol Nephrol 2005; 57(3): 175-197.

5. The National HCV register was established as a research tool at HPA, Colindale, in 1998. Once SNBTS participation had been agreed, Dr Helen Harris, the Register Coordinator, visited each transfusion centre on a single occasion. There was no requirement for SNBTS to report cases on an ongoing basis. She included all patients identified through the targeted lookback who had a known date of transfusion (in principle all of those identified by lookback). I have discussed the discrepancy in numbers with Dr Harris, and she has assured me that she included all patients whose details were made available to her at the time of her visits. The reasons why some patient records were not available at the times of her visits are not clear. These visits took place around the time when the SNBTS lookback was terminated (in May 1998, only in terms of data collection), so it is likely that work was ongoing in certain cases, for instance with ongoing correspondence with hospital clinicians and/or GPs of the patients. Nevertheless, the 103 patients can be taken as unselected, and therefore representative of the 133 in the whole cohort.

6. This point is being addressed by colleagues in HPS.

Dr Jack Gillon

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