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A Laing HCV CASE – PENROSE

At 8 September 2010 SNBTS Penrose Inquiry Team meeting, the subject of this case was discussed and I pointed out that we should not sign this off until we ascertained the HCV genotype of the patient as it was well known that in particular HCV genotypes 2 and 3 were unlikely to be detected with first generation HCV tests.

Unfortunately the medical records failed to show any evidence of the HCV genotype for patient Laing, but through the HCV National Lookback process, we were able to extract information on the implicated donation (transfused on 7.8.90) involved with patient Laing (letter from Dr Urbaniak to Mr Keenan ARI dated 7 April 1985).

Information from Dr Yates (SNBTS Aberdeen) showed that the implicated donor was found to be HCV positive on second generation HCV tests on 8 January 1992 and on 13 September, I was able to identify this Aberdeen HCV positive donor through our SNBTS NMRU HCV database as being T2103, a donor who had been genotyped as genotype 3 with strong (4+) antibodies to c22 and c33 (core and NS3 regions of HCV) that were only able to be detected with second generation HCV tests. (*First generation HCV tests only had 5-1-1 and c100 components from the NS4 region of HCV*). This pattern of RIBA-2 reactivity was consistent for many HCV genotype 3 samples. Furthermore on 12 March 1992, as part of a small research project in NMRU, we tested T2103 along with 49 other HCV positive donation samples and found this sample to be **negative** with Abbott HCV first generation beads. This overall work was published in Transfusion in 1993 (Transfusion 33, 7-13, 1993) – see Table 1 – showing that only 13 (33%) of 40 HCV genotype 3 donations detected by second generation HCV tests were reactive with first generation HCV tests. The details of the above were e-mailed to the SNBTS PIT on 13 September 2010.

Furthermore anti –HBc testing had also been performed on a number of HCV positive donations, including sample T2103. Overall 19% of the first 100 HCV positive donors were anti-HBc reactive showing evidence of previous infection with Hepatitis B virus (a different blood-borne virus from HCV). Sample T2103 was anti-HBc **negative** (*data incorporated into the Transfusion 1993 paper*).

Unfortunately ALT (or SGPT) testing had not been performed on the donor of sample T2103 (*but had been for 90 of the 100*).

During March 2011, Dr Jack Gillon (SNBTS) managed to get access to follow-up case records of the donor implicated with patient Laing. These records showed that the donor had normal ALT levels on 4 occasions over the period February 1992 to October 1994.

Date	ALT value (upper limit of normal 31u/L)
February 1992	11
August 1992	9
December 1993	17
October 1994	22

The donor admitted to no high risk activity for hepatitis C, but had received a blood transfusion approximately 20 years earlier. The donor was well at clinical review in 1994, with no evidence of chronic liver disease. In the light of this and the consistency of the ALT results, it is likely that ALT would have been normal in 1990 had blood donor testing for ALT been in place at that time.

Conclusions:

a) First generation HCV testing of donor T2103 previous donation in July 1990 would have resulted in a negative result and the donation would still have been cleared for use.
b) Had surrogate anti-HBc testing been performed on donor T2103 previous donation in July 1990, it would also have resulted in a negative result and the donation would still have been cleared for use.
c) Had first generation HCV tests been in use in July 1990, 61% of donations found reactive with second generation HCV tests would have been detected – 39% would have not been detected as in this example.

d) It is likely that had ALT surrogate testing been in place during 1990, that the implicated donation would have given a normal ALT value. The Transfusion paper suggested that only17% of HCV genotype 3 donations would have normal ALT values and this donor would appear to be in this minority.

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