Question 5 (c) To what extent are cases of post-transfusion hepatitis C likely to have been prevented [by surrogate testing] … ?

Summary

This supplementary statement has been prepared as a result of a conversation with Inquiry Counsel, following my evidence on Wednesday November 16, 2011, during which I realised that I had not provided a sufficiently definite response to question 5c (above). I therefore agreed to provide this statement.

The conclusion of my statement is that the data from the only published prospective study on the impact of surrogate testing is inadequate to form the basis of an estimate of the impact of surrogate testing.

Effect of surrogate testing on rate of hepatitis C in blood recipients

My initial submission presented an estimate that was based on data from the published paper of Blajchman et al (1995). This study compared the rate of hepatitis in two groups of recipients - (a) those who received blood from which surrogate test positive units had been removed and (b) those who received blood from which surrogate positive units had not been removed. The study was initiated shortly before the commencement of hepatitis C testing of donors in Canada and enrolled a rather small number of patients in the time before hepatitis C testing began. To my knowledge this is the only prospective study of the impact of surrogate testing. The authors stated that surrogate testing appeared to reduce the transmission of hepatitis C by about 70%.

I noted in my evidence given earlier that the number of recipients in the relevant categories was small and that as a result there was a wide margin of uncertainty about any estimates based on this study. I also said that an expert statistical opinion was required.

I have now received a statistical opinion on this paper from Dr Christian Schnier, senior statistician at Health Protection Scotland. His conclusion is that while the recipients in the surrogate test group described by Blajchmann et al had a 70% lower risk, this figure cannot be relied upon because the 95% confidence intervals range from 0 to 92%. Further, for the small subgroup of patients studied in the period before the beginning of HCV testing, recipients in the surrogate test group had 83% lower risk, with an even wider confidence interval of minus 36% to 98%.

As a result of the limitations of the data in this paper it should not be used as the basis for any conclusions about the impact of surrogate testing and I therefore conclude that it is not possible to provide an estimate of the impact of surrogate testing.

DBL McClelland

February 6th 2012

Reference

Blajchman et al (1995) LIT.001.3223