

SKIPTON FUND DATA AND LOOKBACK STUDIES

Information from the Skipton Fund is as follows:

405 individuals alive in Scotland after 2003 received Stage 1 payments, these were recipients of blood or platelet transfusions. (A further 231 received payments who had Haemophilia.)

On the whole, while one or two exceptions are known, we should assume that this figure of 405 has been reasonably verified as “post transfusion” by the consultants who have filled in the information and by the Skipton Fund Expert Assessor Panel.

Danish Look-Back Study

While it is very difficult to estimate current/recent survivors from blood transfusions in the 1980s, still less the 1970s, there has been one very recent paper to help us (Just SA et al. Long-term follow-up among Danish transfusion recipients identified in the national hepatitis C lookback. Transfusion: published online 29 August 2011.) This uses evidence from the Danish blood transfusion lookback of 1996. It is particularly useful because lookback in Denmark was at a very similar time post-introduction of screening to the UK lookback. Furthermore, the characteristics of the Danish population might be perceived as similar to those of Scotland. As you are doubtless very well aware, the Danish Health Information Systems were apparently much more well organised than in the UK so their data retrieval was very much more complete. This study suggests that by 2009 only 121/1,018 (11.8%) of recipients of HCV infected blood prior to 1991 remained alive.

Extrapolating the Skipton data (405 alive post-2003) would suggest that, if one said that this represented, say, 15% of those infected then there would have been about 2,670 infected by HCV infected blood. Nb The Danish lookback follow up went to 2009 whereas Skipton is “alive post 2003”, but not necessarily alive by 2009. Hence I have made an adjustment from 11.8% to 15% estimated survival in Scotland versus the 11.8% reported from Denmark.

We have no idea of the proportion of individuals who remain infected but who have not applied to the Skipton Fund: undiagnosed, and/or have forgotten-about transfusions of blood or blood products (or never knew of it), or chose not to apply. While your research (Dr Hutchinson’s Gut 2004, and Hepatology 2005 papers) suggests “60%-80% of the total HCV infected population likely remain undiagnosed”, one would accept that, in this particular population (ie post-transfusion HCV infected), this is likely to be an overestimate. Nonetheless, assuming 33% of the infected individuals have never applied to the Skipton Fund then, by extrapolation, the total PT HCV infected population post 2003 would be about 607 ($405 = 2/3$ total alive) and, correspondingly, the total infected would be c. 4,000, if the above assumptions were made. ($2670 = 2/3$ total)

UK Look-Back Study

As far as the UK lookback is concerned, Dr Gillon told the Inquiry (Day 6 – Pages 26-30) that among 880 recipients of HCV infected blood who were identified 536 were already dead before the exercise began (this was from a total of 2,026 HCV infected components which had been prepared). By 2004 a further 27% of these

individuals had died (Harris et al 2006). So, by 2004 681/880 (77%) were known to have died after mean FU 16 years, so maximum 23% survivors to 2004. Among the 344 identified recipients who were not known to be dead, some were not traceable and some were very elderly, very ill or had low life expectancy. Hence, the likelihood is that the survival overall of the cohort is significantly less than 23% by 2004.

If 405 Skipton recipients were to represent 23% of those originally chronically infected, then this would suggest c1800 originally chronically infected by PT HCV. Again, assuming c33% of the total Scottish PT HCV chronically infected individuals in 2004 had not come forward to Skipton, then this 607 would represent 23% of those originally chronically infected – c2700.

Scotland-Specific Update

In a reply to the Scottish Parliament Health Committee: 31 January 2006 (PEN.002.0803), the then Scottish Minister for Health, Andy Kerr MSP, gave the following figures for the results of the lookback for Scotland. HCV positive donors who had given before 1991 360, donations by these donors 1,658. Components prepared from these donations 2,026 (the figure also quoted by Dr Gillon). Of which 1,356 traced, 670 not traced. For the UK lookback as a whole, Soldan et al (2002) estimated that 9,222 components entered the lookback and 19,525 HCV positive components did not enter the Programme.

Extrapolating this proportion (9,222/19,525) to the Scottish figure, this would suggest that c. 4,290 infected components did not enter the Scottish Look back Programme, and a total of 6,316 infected components entered the Scottish Programme from 1980-1991. Andy Kerr stated that the majority of the 670 not traced components were not transfused, a proportion would merely have been those not traced through hospital records. Assuming that the proportion of 1,356/2,026 is agreed as transfused then extrapolating to the total 6,316 which may have entered the Scottish Programme from 1980-1991 then this would suggest that about 4,227 HCV positive components may have been transfused in this period. Assuming 25% clearance of the virus, this would leave c. 3,170 chronically infected recipients. Again, assuming 75%-87% mortality to 2009, this would leave between 412 and 792 survivors in Scotland in c. 2010. Not far from the Skipton Fund figure of 405, or the figure of 607, assuming 33% of PT HCV infected individuals were unaware of their diagnosis/had not applied to Skipton.

SUMMARY of “LOOK BACK/SKIPTON ESTIMATES”

1 Denmark Look Back (Best look back, but not Scotland)

Alive post 2003 405 (Skipton)	Estimated chronically infected 2670
Alive post 2003 607 (Skipton +)	Estimated chronically infected 4000

2.UK Lookback

Alive post 2003 405	Estimated chronically infected 1800
Alive post 2003 607	Estimated chronically infected 2700

2. Scotland Specific Update (Kerr), uses one Soldan assumption, not based on Skipton.

Alive post 2003 412 – 792	Estimated chronically infected 3170
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QUESTION 5

In respect of our Question 5 and your response, and the estimates which arise from it, together with your original March 2011 paper to the Inquiry, you state “The number possibly infected through transfusion alone is 344.” (These are presumably those estimated to be alive in September 2011).

In our Question 5 we used the figure of “30,934 diagnoses” in Scotland and the accompanying 1,662 “other” risk factors as the basis for the Question. This comes from the HPScotland Bulletin for September 2011.

However, in your Hepatology paper (2005) it is stated that “During 2003 a total of 17,400 and 42,900 HCV-infected IDUs were estimated in Glasgow and Scotland respectively, this compares with approximately 5,000 and 13,900 diagnosed respectively.”

Based upon the 2003 figures, assuming, as you do, that 90% of HCV infected individuals were IVDUs around that time, then the estimated total HCV population for Scotland would be 47,666 (90% of this figure is the 42.9k estimated Scottish HCV infected IVDUs) Assuming, as you say, (in your response to Question 5 – 28 February 2012), that 3% of Scottish HCV infected individuals were attributable to blood transfusion then in 2003, 3% of 47,666 – c. 1,430 individuals with PT chronic HCV would be alive, and 470 would be aware of the diagnosis.

This figure is comparable to the 406 PT HCV registrants who were alive after 2003 from the Skipton Fund.

If the figure of 1,430 individuals alive in 2003 were accepted and assuming mortality of c. 75%-80%+ since transfusion (see lookback data), then this would imply 5,720-7,150+ individuals infected from blood transfusions, almost all prior to 1991.

ASSUMPTION 3

“This policy (of deferral for those belonging to “high risk” groups) was assumed to have reduced the HCV prevalence in the donor population constantly by 66% during 1984-1991 – an assumption based on SNBTS expert opinion.”

We believe that this assumption may be based upon the following statement from Feinman’s group in Canada:

“This drop in the HCV hepatitis rate from 31.3/1,000 to 12.6/1,000 between 1985 and 1988-1990 appears to have been associated with improved methods for the screening of blood donors.” (Blajchman MA et al, Lancet 1995 345, 21-25).

We are a little concerned about applying the assumption that in 1984 the figure dropped by 66% and remained the same from 1984-1991 for reasons:

1. While pioneering work from Brian McClelland in Lothian did produce the first efforts to help “high-risk” donors to defer, starting in about June 1983,, this was probably not really effectively promulgated throughout Scotland until 1985. The Inquiry heard that, at least in some areas, these initial efforts were relatively ineffectual.
2. As is implied in the above statement from Blajchman, actually efforts at improving “self-deferral” were continuously improved and updated from 1984/85 until 1991 (in Scotland).

Hence, while there may well have been a c. 66% drop in the prevalence of HCV among donors between 1983/85 and 1991 we suggest that a better model would be to smooth this 66% over the whole period, rather than assuming that it all occurred stepwise in 1984. If “SNBTS expert opinion” has other information to justify the 66% assumption on a stepwise basis then obviously we would bow to their greater knowledge.

3. During his evidence (Day 64 – Page 59.25 and 60.1) in respect of the estimates carried out by Blajchman, I asked Dr McClelland “In summary, you can’t make any estimation as an analogy with the sort of estimations they were making in Canada and the United States”? He replied “Unfortunately we can’t because we don’t have any of the data because we didn’t do the studies.”

Earlier Dr McClelland had stated (quoted Page 54.7-14):

“I mean, certainly, as the Inquiry has already seen, there were progressive modifications and refinements and some extensions of the donor criterion in relation to HIV ... Unfortunately, of course, we don’t have any direct evidence of the effect that that had on either the prevalence of hepatitis C in the donations that were collected or on the role of non-A non-B hepatitis in recipients.”

Dr McClelland also stated (Day 58 – pages 1-19):

“Are you asking whether I think it’s possible that the prevalence 10 years – say 1980 would have been substantially higher than it was in 1991”

Professor James:

“Yes, in the general population and, in particular, in the donor population.”

Dr McClelland:

“I think it would be pure speculation ... I think the only modestly reliable prevalence data we have is in the 1991 figure.”

ASSUMPTION 4

We are not sure of the basis for this assumption. We wonder if assuming a constant proportionality between HCV prevalence in the donor population and the IVDU HCV positive population takes into sufficient account that the donor population is very different from the IVDU population. So, for example, in 1980, before the exponential rise in “deprived classes/needle sharing IVDUs”, virtually none of whom would ever attempt to become blood donors, there was nonetheless a population of HCV positive individuals who had acquired HCV by a variety of means (“middle class” drug experimentation in the relatively remote past, tattoos, blood transfusions, immigration from areas of higher endemicity, prisoners), the proportion of this “donor population” to the total HCV positive populations was very possibly much higher in the late 1970s and the first part of the 1980s than it was to become when the ballooning of the needle sharing IVDUs took off in the mid 1980s and beyond.

The assumption made in Dr Hutchinson’s 2006 paper in the Scottish Medical Journal (2006) was undoubtedly valid by 2006, and doubtless had been so since the early 1990s but, we suggest, not nearly to the same extent in the earlier part of the relevant period for the Inquiry.

Conclusion

We feel that it may not be justified to use the kind of calculations with which you have exemplified this assumption – “(For example, the estimated number of HCV-infected IDU in 1985 was approximately 56% of the estimated number of HCV-infected IDU in 1991. Therefore, the estimated HCV prevalence in the donor population during 1984 to 1991 was predicted to be 56% of the estimated prevalence in the donor population in 1991)” (bottom para P4 of Professor Goldberg’s calculation – Letter 28 February 2012).

Professor Oliver James F.Med.Sci 22 March 2012

