

**"Comments on 'Review of Documents'"**

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Subject: Comments on

'Review of Documents'

Linda

Some comments on the latest draft - given in the order they occur, rather than by relative importance. There are a few questions that may need to be resolved before this goes to the Archer Enquiry.

On a general point, it does not appear to be very clear from just where the Department was getting its medical advice during the years in question - maybe its not clear from the papers. There is mention of a DHSS Expert Group on the Treatment of Haemophilia in the chronology, for both 1973 and 1975 but not thereafter; and there does not appear to be an obvious source of advice in the main body of the report.

Likewise the Department's response to events is also not always clear - was it solely the attempt at self-sufficiency. Were there any submissions to Ministers that may throw

some light on to DH thinking? It maybe that many of the individual decisions concerning treatment and the use of particular products were left to the treating physicians (or to advice from the Haemophilia Centre Directors), but this may be difficult to get across without appearing to shift any responsibility. [And just what was the extent of DH responsibility in this area?] Other than the work at the LSHTM, was DH promoting any work to find a test for NANBH?

[One possible difficulty which we will not be able to reconcile, is whether the Department obtained the various scientific papers contemporaneously, or in retrospect.]

Para 1.- 3rd sentence - do we need to qualify 'DH documents...' with the word "some" or something similar?

Para 3. - do we need this sentence in the summary?

Para 7. - 1st sentence - I am not sure that NANBH was thought to be the 'main cause of chronic liver disease' - perhaps this should read "the main cause of post transfusion [viral] hepatitis." OR perhaps 'the main cause of chronic liver disease in patients with haemophilia'. In the next sentence we need to make clear it is the severity of chronic hepatitis related to the NANB virus...etc.

Para 8 and 9 - there appears to be a change of tense in these two paras - perhaps both should be in the past as elsewhere in the summary. In the 1st sentence of para 8, suggest drop the word 'yet'. Given that people are likely to read the summary first, I wonder if you might drop the word 'however' from the 2nd sentence and consider altering the 3rd to something along the lines of:- "However, it was perceived [? considered] that the overall benefit of factor VIII in reducing the mortality and morbidity among patients with haemophilia outweighed the clinical risks resulting from [NANB] hepatitis. Was this a general perception, or a DH position?

Para 11. - my ignorance - was BPL Factor 8Y primarily to inactivate HIV (rather than NANBH and HIV) - see para 84

Para 13.- penultimate sentence - don't think you need to penultimate word 'also'.

Para 23. - need to check (with Denise) the definition of haemophilia - in some cases factor VIII may be severely reduced rather than missing - might it be better to say "is deficient" rather than 'missing'. You have spelt out the degree of deficiency in the categorisation later in the para.

Also pertinent to this para (again check with Denise), I thought that much of the early mortality was due to [spontaneous] intra-cerebral haemorrhage; if so, it may be worth mentioning this as well.

Comment - the ongoing payments for patients infected with HIV (paras 30 and 31) seem in stark contrast with para 32 on the ex-gratia payments for hepatitis C. These facts are not unknown, but are the paras on compensation for HIV really relevant to this report?

Para 34. perhaps this is the place to mention who produced the report

Para 43. - I know what you mean, but as read this may not be clear to those outside, and give the impression that something is being with-held.

Para 48. - there does not appear to be a table 2. Subsequent tables may need to be renumbered - (unless you change figure 1 into table 1).

Para 50. - using figures for both references and footnotes is somewhat confusing - would suggest you use either symbols or small letters for the latter. The second footnote linking aetiology with jaundice is incorrect, and probably not necessary anyway.

Para 86. - not sure what is being evaluated - what tests are they suggesting and why the delay?

Para 106 documents the prolonged gestation of the redeveloped BPL. One can't help noticing that this was just the time at which virally inactivated clotting factors were being developed and then produced. The obvious question is whether the undue delay in redeveloping BPL had any adverse effect on the development and production of inactivated clotting factors. The redevelopment of BPL has already been covered in the *Self Sufficiency Report*.

Para 110 - perhaps you should say what period the missing files cover - rather more important than when they were destroyed. I would expect these would have covered such things as consideration of the use of surrogate markers before hepatitis C was discovered, and then the introduction of an accurate anti-HCV test.

Para 113 - is the reference to a 'previous administration' in any way relevant? - perhaps best removed. I do not follow the argument of your last sentence that just because papers were not disclosed, they were considered as missing. The fact that someone decided not to disclose them, suggests quite the opposite.

Chronology - in the sixth entry you need a 1 before 975.

In the 1986 entry, I wonder whether "but progression to symptoms associated with severe disease may be very protracted" may be easier to understand, but I am not sure where this line came from.

I wonder how relevant the 1988 entry referring to the MacFarlane Trust, and the 1989 entry on the HIV litigation are.

In the first 1992 entry you could say "a retrospective study" rather than a 'retrospective hepatitis C study'.

Under 2002, it might be better to finish after the date 1991. The next entry speaks of the *Self Sufficiency report*, and mentioning it twice advertises how long it took to produce, without discussing the various stages in its genesis.

Happy to discuss with you, or with others.

Hugh