Dear Ms Lovell, 24 September 2011

thank you for your letter of 1st September and the Preliminary Penrose Report. I have focussed my attention on the two questions you pose. I didn't personally keep a record at the time, but my views were, and broadly remain, in line with what I then contributed to EAGA and NBTS deliberations, and the recommendations made in the 1985 PHLS evaluation of anti-HIV kits.

In answer to your question(a): I can make an informed guess about the change to ELISA though I don't know the answer for certain. I think you will find that UK transfusion labs were still using RIA for HBsAg testing in 1985 and that the radio-reagents were both prepared and distributed within the blood services-you would need to check. That meant that their labs were familiar with and equipped to do RIA. However, by then commercial companies had or were developing ELISAs for HBsAg testing and saw the most advantage in developing ELISAs for anti-HIV. When PHLS evaluated their kits in 1985 the companies were willing to lend the equipment that allowed us to run their ELISAs, and presumably they would have done that for the blood services too.

Prior to then Richard Tedder, and with some assistance from him and Robin Weiss we as well, were using RIA to test for anti-HIV in 1984 and 1985. That RIA had the same 'competitive' format as the Wellcozyme ELISAs kit that became available for evaluation in mid 1985. During 1985 other European and US manufacturers also came forward with 'indirect' ELISAs. In principle these were formatted like the immunofluorescence anti-HIV assays which we had been using from 1984 onwards, an experience that led to the expectation that the competitive ELISA might be more specific than indirect ELISA though the latter perhaps slightly more sensitive. Generally that proved to be the case, though evaluation showed the differences were mostly not great. Since then both formats have been superseded by so-called sandwich ELISAs.

To answer your question (a), then: I suggest that the choice of ELISA was, on Wellcome's part, a commercial decision reflecting the inconvenience to customers of using a radioisotope, and on the blood services' part reflecting an urgent need to test for anti-HIV that could only be met through commercial suppliers.

To answer question (b) demands a bit of background. Other than blood donation screening, there were by early 1985 three precautions to protect blood supplies in place or under urgent consideration. First, 'advice to donor' leaflets required recognised risk groups not to donate. Second, following the work of John Craske and of US researchers heat treatment of Factor VIII concentrates was being given high priority in procurement for UK haemophilia patients. Third, efforts were being concentrated on getting anti-HIV tests available in GUM clinics and other Health Service facilities.

It became known that anti-HIV screening was to start in US in April 1985, but given that many other countries were also seeking to screen there was scepticism about continuity of supply to UK as well as the accuracy of the first wave of anti-HIV ELISAs. The first ELISAs to be offered included the Abbott kit, and in hindsight it *might* have been possible to set up continuing UK wide screening with it a few months before it actually began; but this is not certain and the gain would not have been great as other precautions, as mentioned above, were by then coming into play. A more rapid introduction would have given rise to some problems of donor management (false positives) and logistic difficulties.

It would be worth investigating how many repeat donors UK-wide were found to be anti-HIV positive once national donation screening did begin. Presumably this is discoverable from the blood services' records for late 1985 to early 1986, and would indicate how many HIV transmissions may have occurred as a consequence of the perceived delay in starting to screen.

yours sincerely,

Philip Mortimer.