

PAPER IV

Implications of the introduction of heat-treated Factor VIII concentrates

A number of commercial manufacturers of Factor VIII are hoping to introduce Factor VIII concentrates which have undergone an additional heat-treatment step which is designed to reduce viral infectivity. Although originally aimed at reducing the risk of transmission of hepatitis, it is now being suggested that heat-treated concentrates might also reduce the risk of the transmission of AIDS.

As far as is known, there have been no controlled clinical trials to substantiate a reduced hepatitis risk from the heat-treated concentrates and nor, of course, is there any information on the transmission of AIDS. Nevertheless, should they be licensed for use in this country, it seems more than likely that there will be a heavy clinical demand for them. Not only would this have cost implications for the NHS, since the heat treatment substantially reduces the yield of Factor VIII per litre of plasma and therefore increases production costs, but the BPL may find itself obliged to manufacture heat-treated concentrates for which up to 60% more plasma might be needed simply to produce the current output of Factor VIII.

Clearly, there is a need for a controlled clinical trial of heat-treated concentrates in respect of hepatitis infectivity. However, such a trial could pose ethical problems at the present time. In earlier discussions on a protocol for such a clinical trial, Haemophilia Centre Directors had been of the opinion that a meaningful trial could only be conducted in patients who had not previously been treated with Factor VIII ie newly diagnosed mild haemophiliacs. However, this is a particular group of patients for whom the Directors have recommended that only NHS material should be used.