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PROPOSED PFC RESPONSE TO POTENTIAL VIRAL CONTAMIANTION (HTLV III) OF IGG PRODUCTS

Intravenous Immunoglobulin

1. Test all current batches at issue for HTLV III Ab.

2. Test all library samples of consumed batches for HTLV III Ab with the proviso that library samples are not completely depleted.

3. With immediate effect, all IV IgG will be manufactured only from screened plasma.

4. Screen all immunocompetent recipients of IV IgG (where possible) for seroconversion. In particular, detailed reports of antibody status, batches used and dose should be obtained from Dr R Crawford in respect of patients treated under his co-ordination.

5. Implement heat treated IV IgG product as a high priority as follows:

   Short term - 68°/24 hrs subject to satisfactory in vitro characterisation of 'new product' and satisfactory clinical trial.

   This material could be at issue by mid-February '86 but should be used after existing batches (unheated) have been consumed.

   Long term - 80°/72 hrs product involving significant process modification.

6. Implement experimental programme to establish the efficacy of existing manufacturing processes to inactivate HTLV III.

   Programme may include:

   (a) Cohn fractionation.

   (b) Freeze drying.

   (c) pH 4/pepsin.

   (d) Heat treatment.

   This work will be performed in collaboration with Professor Weiss.

Intramuscular Immunoglobulin

Existing supplies of IM IgG (normal and specific) are derived from unscreened plasma. In the case of specific IM IgG products, this will continue to be the case for a considerable period of time if existing and intermediate stocks are consumed prior to fractionation of screened plasma.

Action which may have an immediate effect on perceived product quality is

therefore limited. With the exception of normal immunoglobulin and anti-D, attempts to replace specific immunoglobulin products in stock with product derived from tested plasma may take a considerable period of time in respect of:

(a) Collecting plasma.

(b) Establishing sensible working stock levels of finished product.

Such an exercise may not be justified in the absence of any reports of HTLV III transmission from IM IgG products worldwide - many such products are almost certainly manufactured from plasma with a higher level of viral contamination than might be expected in Scotland.

However, the following action is proposed:

1. Test all current and previously issued batches for HTLV III Ab.

2. Investigate the feasibility of donor identification in all existing batches and testing of donation samples for HTLV III.

3. Produce all future batches from screened plasma only.

4. Investigate the feasibility of conducting viral inactivation experiments on IM IgG manufacturing process.

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