UK BTS/NIBSC

Working Group on Microbiology

Minutes of the second meeting at 11.00am 15 January 1988 at the Edgware Transfusion Centre.

Present:

Dr J A F Napier	Cardiff RTC
Dr D R Bangham	NIBSC
Dr J Barbara	Edgware BTS
Mr A Barr	Glasgow & W Scotland BTS
Mr P Harrison	BPL Elstree
Dr T Wallington	Bristol BTS

Precirculated Papers included:

1. Minutes of 1st Meeting
2. Agenda
3. Letters of comments on proposed December 1987 amendments to WHO Requirements, from Dr Wallington and Dr Barbara
4. Draft paper: Microbiology - Environmental testing from Dr Barbara and Mr Barr
5. Quality control review procedures (Dr Napier)
6. Objectives for microbiological tests in transfusion centres

Tabled:

- Requirements for the Control of Plasma Fractionation (Mr Harrison)
- Draft specification for viral inactivation during freeze-drying and heating of clotting factor concentrates manufactured in the UK (Mr Harrison)
- Extract on microbiological testing of blood grouping reagent sera and reagent red cells (from WG/BG.87/3).

1 Minutes - accepted

2 Matters arising:

2.1 December meeting at WHO to revise WHO Requirements. The meeting at Geneva had been aimed mainly at agreement on updating microbiological tests; it had not included several other respects in which it was thought revision was needed. The final draft had not yet been received from WHO. There will be opportunity to comment on it before it goes for ratification to the next meeting of the Expert Committee on Biological Standardization in October 1988.

The comments on the proposed Requirement amendments from Dr Barbara and Dr Wallington were discussed, but were received too

late for transmission to Dr D P Thomas, for the meeting at WHO.

2.2 The need for recognised quality control officers with adequate training, status, experience and independent authority in each RTC was emphasized.

2.3 There is also a need for a central authority/body/institution to collect and coordinate information on, and give guidance on, quality control matters.

Such a centre could record and provide information on data on supplies and quality of products in various RTCs; on reactions and diseases (eg. malaria) developing in recipients of blood, blood components or plasma fraction products.

Advice on special matters such as how to take blood from infected persons could be provided. It is not clear at present where the responsibility for checking the quality of blood packs, or for the quality of bulk plasma lies. In large measure this must be at the Transfusion Centres where plasma is collected, but the Plasma Fractionation Centres had also to check their bulk source material in whatever respects were possible.

A central scientific authority to audit all such work and quality control is desirable.

2.4 These points in 2.2 and 2.3 should be raised for discussion at the next meeting of the BTS/NIBSC Liaison Group (proposed for March 2).

3 Microbiological Environment Testing (Draft paper by Dr Barbara And Mr Barr)

Various amendments were discussed and will be incorporated by the authors. Certain general points made were:-

3.1 Plastic packs for blood collection and handling require systematic quality control and licensing. It is believed that in some centres no steps were taken to check their quality. An efficient system to collect and disseminate reports of blood pack equipment defects was needed.

3.2 Central guidance on the method to clean skin before phlebotomy was needed; comments on current practice from other BTCs could be collected.

3.3 Guidance was required on criteria of acceptability and of rejection for bacterial counts obtained in the monitoring of areas where 'open' handling of blood and blood components was

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carried out in RTCs. (Advice on this might be obtained from the Inspectorate).

Preparations of platelets were thought to be at special risk of contamination during their handling. Should samples of fresh blood components be tested for sterility from time to time ? Should this be undertaken systematically for a while so as to build up a data base ?

3.4 There is believed to be much disparity in the sensitivity of test kits for Hepatitis antigen (HBsAg) and for AIDS antibody: moreover the relation between manufacturers' quantification in terms of micrograms and international units defined by the International Standard needs clarification.

Should NIBSC provide national working standards for the intermittent checking of potency of kit standards (including ad and ay subtypes) ?

4 The other documents were not discussed due to shortage of available time.

5 The next meeting will be on Wednesday, February 17, at 11.00am, at the Edgware Transfusion Centre.

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