PFC Report

UK TO NON-UK PLASMA EXCHANGE PROJECT

PROJECT UPDATE

Following the UK Government statement of 13 May 1998 that UK plasma should not be used for the manufacture of therapeutic products, the SNBTS secured supplies of non-UK plasma from Bavaria and the United States of America. An exchange of non-UK products for existing stocks of UK plasma derived products on a product by product basis has since been planned and carried out as and when sufficient stocks of each product becomes available.

The aim of this exercise is to ensure that, as far as possible, when non-UK derived products become available, they are supplied for use to all customers on the same day, regardless of location.

The exchange plans were discussed with, and agreed by SNBTS Regional Transfusion Centre staff, local hospital consultants and blood banks, the Haemophilia Directors for Scotland and Northern Ireland, and the Primary Immunodeficiency Association.

Current Status

Non-UK stocks of all non-hyperimmune products (i.e. Factor VIII, Factor IX, Intravenous Immunoglobulin, DEFIX, Human Normal Immunoglobulin, 4.5% Albumin and 20% Albumin) were issued to all hospitals by 31st March 1999. All UK derived products were quarantined and returned to PFC during April 1999.

Non-UK plasma derived Anti-D was issued on 28 June 1999 and all stocks of UK plasma derived batches have now been returned to PFC.

Non UK-sourced manufacture of the remaining intramuscular and intravenous hyperimmune products is now at an advanced stage. It is planned to exchange the intramuscular hyperimmune products by the end of September 1999, with the intravenous products to be exchanged before the end of December 1999. The only exception to the above timetable may be Anti-Rabies IgG. SNBTS will not be manufacturing a non-UK version of this product, but will instead purchase this from BPL. A firm date for availability of this product is awaited.

Elspeth McIntosh
Project Manager
7/9/99

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Elspeth McIntosh
Project Manager
7/9/99

NBA Report

Universal Leucodepletion Update Report
8 September 1999

The NBS examined the feasibility of the implementation of Universal Leucodepletion (LD) between December 1997 and March 1998 reporting to the Department at the end of March. The NBS Working Group had determined:

- a feasible specification for LD, 99% of blood components will contain $<5x10^6$ leucocytes with 95% confidence;
- that using available methods, a combination of filtration and increased plateletpheresis, universal LD could be achieved. The minimum time this might take to implement was estimated as 12 months;
- that leucocyte counting at the low concentrations left following LD presented a major challenge but by using a Statistical Process Control approach it would be possible to demonstrate the quality of components produced;
- that LD would cost £77.4 million over a full year (within a 10% margin). Initial capital requirements for the Project were estimated at £4.8 million.

In the light of its expert advice and the NBS report, the Government decided that LD as specified should be implemented, the process to be finished by 1 November 1999. By that time all blood components issued from NBS Blood Centres will have been through an LD process. The remit emphasised that any risk to current blood safety or supply to be a prime consideration and minimised.

The LD Implementation Project was established in July 1998 across the three NBS Zones and has subsequently proceeded largely to plan:

- all changes to buildings and facilities have been completed;
- the bulk of new staff required have been recruited. Recruitment is no longer on the critical path to completing the Project;
- after a painstaking process of evaluation the mix of procedures that will be used for LD and the NBS Processing Centres in which they will be used is decided and contracts with Suppliers are close to being signed. These will cover the first 12 months of activity. In line with NBS policy on security of supply and reasonable competition, three Suppliers are being used;
- all of the procedures that will be used are currently in routine use and being ramped up across the Service. All platelets have been LD since January 1999. Presently approx. 70% of red cells are LD, red cell ramp-up will be completed in most Centres by the end of September, in all by 15 October 1999. Where they are LD these products are issued to Hospitals as LD. Frozen products are not

issued as LD as suitable bag labels are not yet available. However, processes for these products are in place and the ramp-up underway. All FFP and Cryoprecipitate will be processed through LD filters by mid-October 1999 and appropriately labelled;

- quality assurance has proved a major challenge. All problems are not yet solved. Counting the low numbers of leucocytes left after LD is proving to be just within the capability of the machines available. Machines have been evaluated and purchased. Problems are being experienced with the validation and introduction to routine use of certain of these machines. We expect to solve these in good time. Contingency has been addressed in case we do not. Much experience has been gained with Statistical Process Monitoring (SPM). It is now being rolled out across the Service in time with Project needs. External quality assurance, both a NEQAS Pilot and a scheme internal to the NBS is organised so that we have control of the reliability of our counting procedures;
- LD does add complexity both to blood collection and processing. There is a risk that processes will fail. Comprehensive contingencies have been worked up and operating procedures will be in place;
- while implementation has been in planning the processing systems available have improved significantly, both their ease of use and price. This will impact significantly on total cost of LD, calculated at £59 million for the financial year 2000 - 2001. This is an early estimate requiring further work;
- research and development projects have been established as follows:
    - ◊ investigate the clinical impact of LD, studying post-operative infection rates before and after LD. The pre-LD phase is complete;
    - ◊ provide effective external quality assurance programmes;
    - ◊ provide a better approach to leucocyte counting across the relevant concentration range;
    - ◊ investigate the presence of prion and prion bearing cell fragments in filter eluates. These may be important to disease transmission

Thus we regard this as a Project that is being successful carried through. We hope this short report justifies our confidence that its objectives will be successful delivered on time.

T B Wallington
Chairman NBS LD Project Implementation Board.

SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE
INTRODUCTION OF LEUCODEPLETION
PROJECT UPDATE

1. Introduction

Universal leucodepletion is the process of removing white cells from all blood donations which, *inter alia*, reduces the risk of infectious agents (inc. the theoretical risk of variant Creutzfeld Jacob Disease) being passed on through blood transfusion.

Following the UK Government's decision in July 1998 an Outline Business Case (OBC) was submitted to the Management Executive. This was followed by an approved Final Business Case (FBC) in December 1998.

2. Implementation Timetable

In the FBC, the earliest possible date identified for full implementation was 31 August 1999 and this was the target for the Project with an absolute end date of 30 September 1999.

The Project is on target to meet the September deadline. The final implementation phase is underway and expected to be in full operation by the middle of September.

This represents an excellent achievement for the many staff involved in the Project, particularly so for the laboratory teams who have introduced this major change in working practices whilst bedding in the major restructuring which SNBTS have recently undertaken. The main features of SNBTS' leucodepletion project are :-

- new temperature control processes from donor to production laboratory
- new transport logistics
- new laboratory working practices
- new quality assurance systems and equipment
- products meeting spec throughout the transition process

John Francis
Project Director