NBS Leucodepletion Steering Group

Minutes of the Meeting held on:
Wednesday 3 December 1997
NBS Headquarters, Watford

Present:
T Wallington (Chairman)
L Williamson (Science)
P Garwood for T Male (Operations)
K Smith (Quality)
S Morgan for J Saxton (Finance)
N Tandy (Project Administrator)

1. T Wallington welcomed his colleagues to the first co-ordinating meeting of the Universal Leucodepletion Steering Group.
This group has been established with the following Terms of Reference.

⇒ To develop a strategy which will enable the implementation of leucodepletion of blood if required by the Secretary of State.
The strategy will need to take into account the Scientific, Operational and Financial implications of leucodepletion and an indicative implementation timetable. It should also be reviewed in the context of information emerging from the DoH Risk Assessment Process.

⇒ The aim is to develop an initial plan by the end of February 1998 as it is expected that the Risk Assessment process will be completed within 3-4 months.
Tim Wallington will present the Group's Report to the NBS Executive at the meeting on 17th February 1998

2. The group wished for clarification that it was the remit of others to cover the other precautionary measures that might be taken against nvCJD transmission. It is proceeding on the basis that others will take on project work related to autologous transfusion and address the problem of unnecessary blood transfusion. The monthly Clinical Directors Meeting will act as a focus to bring together progress on the Leucodepletion Project, the other aspects and the DoH Risk Assessment. Tim Wallington will make a timely report to project Board members following each CD's meeting.

As part of the process of introduction to the project, group members felt it necessary to record that they recognised that there was considerable scepticism regarding expensive measures that might be taken to prevent a risk which with our present state of knowledge is only theoretical. The group wished to emphasise that the hypothesis that nvCJD can be spread by the transfusion of blood is based on a lot of careful science which leaves no room at all for complacency. There are many conflicting demands on the time of NBS staff but this task must be given very high priority. This may necessitate other tasks being de-prioritised; the NBS Executive will need to be made aware of this fact and take responsibility for the resetting of the services priorities.

The group discussed the day to day management of the project which would be the responsibility of Nick Tandy. It was agreed that the project should proceed according to the Prince process. Nick presented a draft project initiation document and Tim Wallington would work with Nick Tandy to ensure that each project group would document its progress correctly. It was agreed that the services of a project document controller/librarian would be needed to facilitate this. A separate document will be issued to Working Group leaders on project design by 11.12.97. (Action N Tandy / T Wallington)

2 The Group then proceeded to discuss the remit of each Working Group.

2.1 Science

Understand leucodepletion requirements, which cells, how soon after donation As soon as possible bring forward justification for any statement made.
The Group understood that Philip Minors had presented a seminar on the topic and would be willing to write a supporting paper. This work would set central objectives to the project. There was discussion of the possibility that simple buffy coat removal would be sufficient. The meeting felt that unlikely but other views would be pursued, particularly views coming from the Risk Assessment. The rejection of simple buffy coat removal would need to be justified.

2.2 In collaboration with the Operations Group, assess the capabilities of leucodepletion systems against objectives. Use data available from manufacturers and develop methods and protocols for evaluation of systems within NBS. Address problems of counting low numbers of white cells and differentiating them including the differentiation of T from B lymphocytes. Explore novel approaches including the possibility of nucleic acid based methods. It was felt that this work might be profitably performed in collaboration with SNBTS.

2.3 Assess other impacts that leucodepletion might have. Commission Dr John Barbara to bring forward a paper on the topic of bacterial contamination. Investigate the impact on the need for CMV testing. Investigate the possible impact on the need for HTLV I testing

2.4 Consider other impacts of leucodepletion, in particular the possible impact on post-op infection. Look for collaboration from hospital Microbiologists in this work in addition to colleagues in Transfusion Medicine.

3. Operations

3.1 In collaboration with Science group consider the utility of available leucodepletion systems. Would they remove the cells that should be targetted in the quantities required?

3.2 Blood will need to be collected to a high standard, thorough mixing of anti-coagulant etc., if filtration is to be efficient and quick. Address this problem with relevant co-opted colleagues from Blood Collection. Address the problem of lost units as a result of the introduction of leucodepletion and its impact on NBS Collection capacity (NB any such impact may well be balanced by the greater use of autologous techniques, it will be disappointing if at the least 5% of red cells transfused in the future are not from the autologous source).

3.3 Draw in expert advice which will impact on final solutions. E.g., impact of precautionary policy on requirement of plasma for fractionation. Would it be required at all (Action on TBW to enquire and feed back)? If it was, what level of leucodepletion would be required? If leucodepleting plateletapheresis systems such as COBE LRS produced a component of the required quality could all platelet requirement be serviced by apheresis? Once position established, consider the impact of both scenarios on Operations function.

3.4 Determine the facilities that will be required for blood filtration within the Operations function.

3.5 Consider the problems associated with and plan for the procurement of filtration systems. The Blood Pack User group is the natural focal point for supplier contracts.

3.6 In collaboration with the Quality Group consider the QC elements of the process.

4. Quality

4.1 In collaboration with the Science Group, consider the issues listed under 2.

4.2 Establish any necessary Quality Control / Quality Assurance protocol.

4.3 Participate as necessary with Operations in planning the procurement process.

5. Finance

Work closely with Operations in the costing of solutions. Recognise the Research & Development elements on this work and build them into overall costs.

6. The Group felt that progress might be considerably accelerated if relevant members could visit a facility where universal leucodepletion was already the practice. A visit to the Blood Service in Vienna was suggested and Lorna Williamson will contact its Director

7. Future Meetings

It was felt that the whole Group would need to meet thrice more before reporting to the Executive. We will keep in touch by telephone, Email etc.
The next meetings will take place at Watford on Tuesday 6th January at 2.00pm and on Wednesday 28th January at 10.00am.

Please note that TBW is required to report to the NBS Executive on 17th February, so perhaps the 4th meeting planned for Thursday 19th February is inappropriate and should be brought forward to the previous week. We can decide closer to the time but contact will be made so as to reserve a date.