Copy → John Aldridge
Mike Palmer

I've just rec'd this revised copy of Ian Franklin's letter – partly has been changes. I would welcome an opportunity to discuss how best we resolve the various elements of this issue.

GRO-C
11/3

SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE

HEADQUARTERS

IMF/DM

5th March 1999

PRIVATE AND CONFIDENTIAL

Dr Aileen Keel
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Dear Aileen

Please accept my apologies but it is unlikely that I will be able to get to the Scottish Office meeting with Angus and other SNBTS staff next Wednesday.

I thought I should send you a note however regarding some important points and some for information.

You wrote to me about being able to identify donors who may have received blood or blood components from patients who have subsequently became diagnosed as having new variant CJD. At present we have had three or four notifications of patients with a history of residence in Scotland who subsequently developed new variant CJD (or have strongly suspected nvCJD). None of these people have shown up on any of SNBTS donor records either on computer or hard files for blood, plasma, or tissues. Therefore there is no issue for these patients having contributed to transfused products.

Under the current terms of notifications only the Medical Director in countries where the patient had a history of residence is informed. Therefore I am not informed about patients who have proven or strongly suspected new variant CJD but who did not have a history of residence in Scotland. Therefore there is no way that SNBTS can exclude people who may have received such products (I understand there are four patients who were donors) from contributing to the blood supply. I would add that even if there were such a case in Scotland it is unclear whether we would be able to flag up such a person if they were not already a blood donor. If they had been a blood donor there would be no problem putting a flag on to ensure that the donation was not used. However, if they had never been a blood donor we would need to take advice from CLO and as to whether it was permissible to enter them as a donor (even when they had not come forward to donate) and put a flag that their blood will not be used. Even then the ethical issues around not informing them that their donation would not be used is troublesome to me. We have just revised SNBTS policy such that after

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The SNBTS is a division of the NHS in Scotland Common Services Agency

3 donations a donor who is reactive, but remains unconfirmed, to one of the mandatory markers will be taken off service and told why. Perhaps ethically we could do this with this tiny group who have received blood from a person subsequently developing nvCJD, but clearly we could not do this indefinitely. Would you like me to seek advice from CLO on this issue?

I think that is the most important operational issue that I need to reply to you about.

CORD BLOOD

There is a draft report being circulated amongst the Working Party and I trust it will be agreed soon and then issued to Departments of Health. This will recommend that Scotland collaborates with Northern Ireland with regard to Cord Blood Banking and the English will sort out their own affairs. I have had a number of informal discussions with Chitra Barucha in Belfast and will be meeting with her on Monday 8th March to discuss how we might collaborate. At present the idea is to marry-up the existing expertise in processing and storage, consent etc, that exists in Northern Ireland with the potentials for clinical use and research and development in Scotland. I am personally determined that we should collect Cord Blood within Scotland but whether ultimately this is stored long-term in one place i.e. Belfast is of less concern and may be the most cost effective way of proceeding. However I will keep you informed.

Liberate HT

We spoke on the phone about this and it would be helpful to have confirmation that the Scottish Office sees no objection to SNBTS proceeding to use a contract research organisation (CRO) to conduct these trials in countries where plasma derived factor VIII remains the major form of treatment. I believe the issue of indemnity can be dealt with satisfactorily through the CRO process.

VI Plasma

We are having a number of queries about toxicology but there is little data at the low doses of Methylene Blue used in our current process. I will ask Chris Prowse to provide chapter and verse on who is using VI Plasma treated by Methylene Blue.

SNBTS Budgets

We have discussed this. I have some concerns that the current financial plan will make it very difficult for us to make the service developments that we planned in the strategy. It is fortuitous that some of these will be going ahead because of implementation of leucocyte depletion etc but from a professional prospective it would be most disappointing if we were unable to proceed with the strategy development proposals because of significant downturns in the overall SNBTS budget. It would help if the definition of what was ring-fenced were publicly (ie. At SNBTS and CSA Board levels) known.

MRC

As a final point and nothing to do with SNBTS I did mention to you that I have considerable reservations about whether the MRC Trials will be continuing. I think if there is further erosion of the trial system over the next year we would need to look within Scotland at some system for insuring that the benefits that have accrued to patients with leukaemia over the last 2 decades are not lost because of fragmentation. If the proposed managed clinical networks being set up are half as successful as the MRC Trial system has been, then they will make a massive contribution to patient care. I do not believe that the MRC structure should be lost even if the MRC itself is no longer interested. I have made some notes on the last meeting and will send these through to you when they have been amended and corrected so that you can get a flavour of what is going on.

With kind regards

Yours sincerely

GRO-C

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