CLINICAL DIRECTORS MEETING -

20th March 1996, 9am

Proposed Agenda

1. Transfusion Medicine as a Distinct Specialty and training issues (paper from SK)

2. HCV Lookback update
   Indeterminates
   "Bottlenecks"

3. Provision of components for non-clinical use

4. National Nursing Advisory Role

5. Transfusion Microbiology
   Kit evaluation

At 2pm Martin Coleman will give an IT presentation on Specialist Services.

A working lunch will be provided between 1pm and 2pm

Apheresis - change dates?

Clinical Directors Meeting
20th March 1996
Minutes

1. Transfusion Medicine As A Distinct Specialty And Training

PF gave a briefing of meeting of JCHMT attended by himself and SK.

Two issues identified in relation to Calmanisation due on 1/10/96: -

a) The Service felt strongly that Transfusion Medicine should be recognised as a distinct specialty.
b) There was a preference for the Royal College of Physicians to take responsibility for training, rather than RCPath

John Lilleyman was happy to accept these two issues, but felt more rapid progress required. Consequently the following actions were suggested: -

I. Production of a short paper (1-2 sides A4), forward to John Lilleyman who would forward to Professor Shaw (medical convenor of JCHMT), who would then pass on to the Specialist Training Authority (STA). John Cash (a member of STA) suggested they would be awaiting and be receptive to such a paper. The final decision as to whether Transfusion Medicine would be accepted as a Specialty would be made by the STA. (*Chair* - Professor Leslie Turnberg)
ACTION - SK to combine new paper (with suggested amendments) and previous paper, expanding into 2 pages, circulate to AR, PF, TW by end of 21st March for comment. Then to John Cash by 25th March. Final draft to be forwarded to John Lilleyman with covering letter by 27th March.

AR to send letter to Graham Winyard.

II. T o deal with the problems of how to manage the transition and how to cope with the impact of Calmanisation and the increasing responsibility of the Colleges, PF suggested that as a short term measure Transfusion Medicine was set up as a subcommittee to the JCHMT SAC in Haematology, with Royal Colleges responsible for key nominations. John Lilleyman agreed and will write to colleges in order to push for rapid progress. The suggested membership, if possible: - SK and PF to provide continuity, and the ideal nominees from the Colleges would be Bill Wagstaff, Marcela Contreras and at John Cash's suggestion, Brian McClelland and Ian Franklin (Glasgow). Additionally the college needed to be asked to identify a national advisor for Transfusion Medicine within the RCPath. The need to nominate a Chairman urgently for the RCPath Committee of Transfusion Medicine was recognised, who would drive progress forward and would probably also sit on the Joint Colleges Committee and heighten the profile of Transfusion Medicine in the College Bulletin.

ACTION - SW to order and distribute copies of "A guide to Specialist Registrar Training - March 1996" to PF, SK, TW

2. HCV Lookback

Bottlenecks
Approximately 550 LBF3 forms have now been received for entry onto the national database. AR suggested that to speed the response from some Trust hospitals a letter needed to be sent from the DoH to Chief Executives of those Trusts.

It was agreed that the letter should be general, rather than directed to specific hospitals/trusts and should result in CE's having to review their own hospitals performance. CD suggested that figures showing the progress to date may be included.

ACTION - AR to draft a proposed letter and ask for the MSBT Secretariat to arrange for this to be sent from the DoH to CE's of Trusts to try and overcome "bottlenecks".

Updated figures on progress to date would be required prior to the MSBT meeting on May 2nd.

ACTION - TW, PF, SK to provide updated figures by April 26th.

Indeterminates
AR has circulated letter to all haematologists in the Service responsible for the Lookback programme.

PF expressed concern that an inconsistent approach to how an "indeterminate" donor is defined could lead to far too many donors being identified. A careful appraisal of those initially interpreted as falling within the criteria would eliminate those who are not in reality at risk. However, this required knowledge and skill. SK suggested a zonal approach, rather than by individual centre, nominating one person from each zone who has the necessary expertise. CD suggested that to be truly consistent these three nominees should meet and discuss all identified indeterminate donors and form a joint decision on each case.

The original MSBT instruction should make it clear that the decision on inclusion should be taken on the *original* results. i.e. don't re-test.

ACTION - AR to produce letter, stressing that the exercise is to identify a small group of recipients who may be at risk, and stress the consistent approach required.

Funding
Two issues arose re funding:

1. Payment to PHLS. It had been agreed by Barry Savery that we should not allow payment to PHLS in advance of testing. Sharon van Turnhout has devised a method of carrying some funding over to next year.
   ACTION - AR to discuss with BJS how to do this
   AR to notify Philip Mortimer that he will not receive monies in advance, but in due course, when the testing has been done.

2. Funding for indeterminates. AR has received letter from Bill Wagstaff. MSBT minutes recognise that 10% additional funding will be required for inclusion of indeterminates. AR has written to Jeremy Metters on the assumption that an additional 10% funding will be forthcoming. Awaiting reply.

3. Provision of Components for non-clinical use

AR has not yet written proper Terms of Reference nor written to the 3 people suggested to form a working party to look at the ethical, moral and control aspects of this issue. AR firstly wanted confirmation that these were the correct candidates.

3 names previously suggested: - Vanessa Martlew (Chair), Gamal Gabra, Ruth Warwick. AR also suggested the inclusion of Gail Williams, which was agreed.

TW suggested the inclusion of someone outside the Service, to provide an objective viewpoint. He suggested Dame Rosalind Hurley, who had now retired and was very well respected. This suggestion was agreed, but it was felt that it would be more appropriate to ask the working party to produce a preparatory paper before contacting Dame Rosalind.

AR suggested paper should use material from the minutes of the previous Clinical Directors Meeting, plus the letters of response from Clive Dash and Ruth Warwick.

ACTION - AR would circulate to VM, GG, RW and GW (by 22nd March) all the correspondence received to date with a covering letter requesting them to produce some guidance within a two month deadline (i.e. before Clinical Directors Meeting on 22nd May).

AR quoted from the minutes of the Clinical Directors Meeting held on 12th July 1995 -

"3. NBS policy re payment for waste-surplus materials from blood collection"

3.1 There is a need to have clear definitions of what is genuine waste and what is genuine surplus material within the NBS.

3.2 It is deemed acceptable to devise a means of cost recovery between NHS organisations and universities and to provide "waste'surplus" materials at cost to hospitals and universities to support R&D work.

3.3 Commercial requests for material: -

This is a much more difficult issue and the first task is to collate centrally what commercial relationships are already in place.

It was felt important that guidelines should be drawn up as to how to handle commercial requests for NBS "surplus" or "waste" material, including whether a statistical analysis of donor responses to questionnaires regarding the use of this material should be cone before proceeding. It was also felt to be important to clarify

what use would be made of NBS waste/surplus material within the commercial sector and whether or not this was "ethically" acceptable to the NBS and justifiable to the voluntary based donor community.

The first action is to centrally collate what is happening now zone by zone, this will then lead to further discussion and recommended actions."

A decision was taken that, as an interim measure, the instruction would be that anything other than 3.1 and 3.2, until these Guidelines are produced, do not happen. Existing contracts would be honoured, but no new ones.

4. National Nursing Advisory Role

The need for, the role of, and the Job Description of a national Nursing Advisor post was fully discussed. Amendments and requirements of the post and how this role would integrate into the Zonal structures was discussed. It was agreed that communication channels needed to be set up that would compliment existing organisational structures. Rather than a national "nursing" functional group a similar arrangement to that which was now working for Quality issues would be most effective with a National "functional" group dealing with clinical collection issues with the National Nursing Advisor meeting with MB, TM and VM possibly at quarterly intervals with more regular meetings in between with designated nurses from the zones, to promote "panZonal" consistency in the delivery of PREP, the development of national standards and NVQs and to drive forward the continuation of the Blood Collection Project. Comments on the job description are awaited from MB and TM then AR to advise Lesley Jones of any proposed amendments to the job description, how and when to advertise the post and an external assessor for the interview panel. AR to discuss with LJ the type of contract to be offered. AR's view was that this should be a permanent, rather than a fixed term contract.

In the interim the current Blood Collection Project Post contract would be extended for 3 months from April 1st 1996 As the person in this post at present also acts as the Senior Nursing Advisor for the NBA and is also key to the development of NVQ's within the service, AR considered that a break in this activity during this period of massive organisational change would be detrimental to the service (Lesley Jones to arrange).

5. Transfusion Microbiology

Kit Evaluation Group

A problem had been identified in that the remit defined by the Terms of Reference for this group only allowed the approval of assays, not the de-approval. PF requested that AR change the Terms of Reference.

At present there is no consistent response throughout the service when de-approval is agreed. This group can only make recommendations, not decisions. These are then passed to AR to finally "rubber stamp". However, de-approval has implications for BPL's licence. In such

instances a time-scale needs to be determined. PF is to discuss this matter with Alan Slopecki, who needs to report back to Terry Snape by the end of March.

SK suggested that a major problem arose with the dissemination of information and that it should be passed through the Executive for appropriate dissemination. However PF felt that this would not be appropriate in all cases, as some recommendations will need to be enacted quickly with minimum bureaucracy.

SK expressed the requirement for a policy statement of the general mechanism of what happens.

PF said that there was a lot occurring at SACTTI with very poor dissemination of information throughout the country. Confusion existed as to what each National group actually did. SK suggested all such groups draw up Terms of Reference which are to be lodged with the Executive. AR commented that the Executive had already requested this to be done.

PF suggested two solutions: -

1. An update meeting for consultants interested in these aspects to be held later this year. (With invitations issued to representatives from Wales and Scotland).
2. Update letters to be sent to all consultants in the NBS (including Clinical Directors). TW suggested that in the future these may utilise the IT system to give direct access to libraries of topics of interest.

6. Any Other Business

Apheresis Strategy Meeting
As PF and TW will both be unable to attend the next meeting scheduled for 9th May, the meeting will be rearranged to take place in June, after meetings have been held between AR and Barry Savery and the manufacturers (Cobe, Haemonetics, Baxter), also this will then allow the Red Book Executive to meet and discuss regulatory aspects of Red Cell apheresis prior to the Strategy Group meeting.

ACTION - SW to arrange meeting in June

Hepatitis G
CD has been approached by David Webster, Consultant Immunologist at the Royal Free Hospital, with a request to investigate plasma pools for Hepatitis G testing. CD was asked to raise this with the Clinical Directors.

SK, TW and PF expressed concern. It was felt that either Hepatitis G should be looked at across the Service, or not at all. In particular it raised two questions -

1. What would be learnt from such a study?
2. What would the impact be of this information?

However, if the NBA produced a purely negative response, this could be deemed obstructive. PF suggested the appropriate response should state that the issues raised should be considered by the SACTTI before any decision is made.

Transfusion Medicine - Core Updates

The issue of post graduate education was discussed. The duplication of work resulting from production of 3 zonal core updates could be minimised by combining into a national consultant update. This could have two separate audiences, both internal and external to the Service.

Several suggestions were made as to how such updates could be produced on a this basis. It was decided more thought was required on this issue and the item was added to the Agenda for the next Clinical Directors Meeting.

Reintroduction of Tuta packs into the NBS

The Clinical Directors expressed the view that they did not feel sufficiently informed about the quality issues surrounding the Tuta pack incident and whether they had all now been dealt with. AR promised to provide a summary report of the Investigation and audits with respect to the whole Tuta bag incident to clarify the situation. AR affirmed that although visual inspection of the seals at the time of the incident suggested a manufacturing defect which might affect the integrity of the seal, subsequent investigation by the MCA and ourselves did not reveal any increased incidence in leaking seals i.e. it was a visual defect only, the integrity of the seals did not in fact appear to be compromised.

The NBS Executive had already accepted the report from Alan Slopecki on the quality aspects of Tuta and fully supported the reintroduction of Tuta packs on a trial basis but were concerned that the PR aspects associated with this reintroduction were handled with great care by both the NBA and Tuta. The Operations Directors were drafting an operational plan for their reintroduction which they wished to be circulated to all relevant functional groups so that any additional actions necessary could be added in particularly with regard to internal and external staff groups where good PR would be essential prior to and during their reintroduction.

SD FFP and Octapharma

PF understood that Octapharma had provided additional information to the MCA in relation to the adequacy of viral inactivation procedures. It was therefore possible that a product licence may be made available in the foreseeable future. This raised the question of what will be the position in the UK if SD FFP becomes a licensed product when the MSBT advice is that at present neither virucidally inactivated plasma or SD FFP is needed to improve the safety of the blood supply. PF felt that a UK wide position statement was needed on use or non-use of SD plasma.

Proposed way forward: -

1. PF will expedite the production of residual risk figures for known viruses. This should enable a consideration of risk versus benefit to the SD product.

2. The issue is already on the SACTTI agenda for 16th April.

3. AR will raise the issue at MSBT to identify if this potential development should influence the current approach of "cautious observation".

   Points to consider -

   a) Comparative cost effectiveness and timescales of quarantining and virucidal inactivation.
   b) Delay in trialing MB viral inactivation.
   c) Should SD plasma now become the preferred option, using UK plasma
   d) What the position is internationally and is the UK acting in isolation.

BMJ - L Kay letter
AR requested assistance from experts in the Zones on the various topics L Kay raised in order to respond appropriately to the BMJ, on behalf of the service.

7. Date of Next Meeting
17th April 1996 at 9am at NBA Headquarters