BLOOD POLICY HANDOVER NOTES

Key Contacts:

A list of key contacts is attached.

Programme Budgets

Zubeda has a list of these for the next three years. I can fill you in with more detail if you wish.

National Blood Authority

Business Planning - Key Contact: Terry Male (Director of Corporate Development)

A 2003/04 Business Plan and a new 3 year Strategic Plan was signed off by the NBA Board in April. Zubeda has copies.

Accountability Reviews

We hold these twice a year. The end of year review for 2002/03 is on 20 June.

The Senior Departmental Sponsor is Professor Lindsey Davies.

The NBA contingent is usually:

Mike Fogden – Chair
Martin Gorham – Chief Executive
Angela Robinson – Medical Director
Barry Savery – Finance Director
Terry Male – Director of Corporate Development.

For the meeting on the 20th, the DH line up will be:

Lindsey Davies (chair)
Ann-Marie Millar
Graham Bicker
Denise O'Shaugnessy
plus you, me and Zubeda.

An agenda has been agreed and papers commissioned. Zubeda has the details.

Past meetings under Lindsey's predecessor (Ron Kerr) tended to focus on looking forward rather than spending much time reviewing the past year. Lindsey is moving towards meetings that mirror the NHS Performance Assessment Framework. At this meeting, for the first time, she is also involving Ann-Marie Millar (Finance Director at the Midlands and East of England DHSC) to probe the financial issue at bit deeper.

Other meetings

Lindsey has monthly telephone conferences (1:1s) booked with Martin Gorham. She also speaks with Mike Fogden every quarter. Lindsey's PA, Christine Edwards, will be able to give you dates. I usually book in a telephone conversation with Lindsey a couple of days ahead to brief her on current issues. Martin and Mike are always happy to let us know what they plan to raise.

We have also set up quarterly Sponsor Branch meetings with Martin, Angela, Barry and Terry to have more informal updates. Zubeda has the dates.

Martin is also due to meet Nigel Crisp in October. Ask Zubeda to show you Martin's letter from late last year to Nigel Crisp and NC's response.

The other key NBA meeting is the Blood Safety and Tissue Safety Assurance Group, chaired by Martin Gorham. This meets monthly at the West End Donor Centre to coordinate NBS initiatives on blood and tissue safety. It's a good way to keep up to speed with developments and to meet key players in NBA. Linda Lazarus attends where possible from DH (Linda also supports the blood team on MSBT) but I would recommend that you go (as well?) at least initially to get to know what NBA are up to.

Change of Name – Key Contact Liz Reynolds (Director of Customer Services)

We agreed some time ago with Ministers to amend regulations to change NBA's legal name to the National Blood Service. We then sat on it for a while whilst dealing with more pressing issues. I attempted to get the regs laid before I left but didn't make it. The current position is that the regs are drafted and with the Welsh Assembly to agree wording relating to Wales (NBA is also a Welsh body). I have also drafted a submission to PS(PH) to sign off the regs prior to laying. Zubeda has a copy.

NBA Board Meetings

I used to try to attend all NBA Board meetings as an observer. They are usually on the 3rd Thursday of each month, either at the West End Donor Centre near Oxford Circus or at one of the NBA's main centres around the country. Jane Minifie (Martin Gorham's PA will be able to give you dates for the rest of the year). The next meeting is on Tuesday 24 June at 11am at BPL. It will be followed by a tour of BPL.

Appointment of Board Members/New Chair

Zubeda should be able to let you have a current list of Board members and appointment dates. We are now going to leave the NHS Appointments Commission to manage all

NED appointments to NBA, with the possible exception of the Chair. I think it is highly likely that Ministers will want to retain a say in this appointment, but you may wish to confirm this with PS(PH). This is immediately relevant because Mike Fogden retires as chair at the end of March 2004. We therefore need to begin the selection process now with the aim of confirming the appointment by the end of this calendar year, to allow for a decent handover.

Bio Products Laboratory

BPL is part of NBA but is operationally very distinct. The key issues are BPL's immediate financial problems and the need for action to safeguard the future of BPL. You have already seen a briefing note on the former issue and are aware of the initiative that Richard Lawes in the PFU has kicked off on the latter.

Key contacts are:

Chris Hadfield (Chief Executive)
Jane Martin (Marketing) Very helpful on issues such as BPL's sales;
Tim Lecour (Finance).

EU Blood Directive

This was adopted in January 2003 and should be introduced into UK law by 8 February 2005. Article 29 of the Directive gives power to the European Commission to introduce a series of technical requirements through the comitology process (the regulatory procedure). The first set of proposals was issued by the Commission in March and we have two expert committee meetings in Luxembourg to discuss these. I have attended both of these with Dr Angela Robinson as the UK's expert. The result is a text that the UK can live with from an operational point of view but which includes some provisions which are strictly outside the Commission's legal competence under Article 152(4)&(5) of the Treaty.

The next meeting is the formal meeting of the regulatory committee on [10 & 11 July – Zubeda please check dates] which will conclude with a vote on the proposals on a QMV basis.

Article 152(5) states that the EU cannot legislate on matters affecting the donation of blood. The technical requirements includes provisions such as donor age limits which are perfectly standard but which arguably do not impact on the safety of blood only on the health of the donor. This therefore puts them outside 152(5) competence – in our opinion but not in the opinion of the Commission. I personally think we can live with these provisions, as they are really very minor incursions into competence. Also, it seems clear from the last meeting that the only support we are likely to get is from Finland and Sweden, nothing near enough for a blocking minority.

IB advise that we should clear our position with Ministers. A submission is therefore needed fairly quickly in case Ministers want us to oppose the proposals (in which case we will have a lot of canvassing of other Member States to do before the meeting).

National Commissioning Group on Blood

Key NBA Contact – Liz Reynolds.

This group was set up in 1999 as a DH/NBA/NHS consultative forum to agree national blood prices and a national service agreement between NBA and NHS Trusts. It's remit also includes developing national pricing strategies for other NBA services, eg tissues and diagnostics. The NCG usually meets twice a year. Lindsey Davies chairs. All papers are prepared by NBA but agreed with us.

Zubeda can give you the current membership and remit and this year's meeting dates. It would also be helpful for you to see the minutes of last year's meetings and the outcome letter which Lindsey Davies sent to Trusts at the beginning of this year.

I can fill you in, if you like, on the background and history of the NCG and recent developments/issues.

MSBT (Advisory Committee on Microbiological Safety of Blood and Tissues for Transplantation)

MSBT advises the Department on new blood and tissue safety developments. It was chaired until recently by Pat Troop but Lindsey Davies will chair the next meeting, on 10 June. Jill Taylor and Linda Lazarus are the secretariat.

We agreed some time ago to extend the remit of MSBT to make it a Blood Safety – not just microbiological safety – Advisory Committee, with common membership with SEAC and the National Blood Transfusion Committee. Tissues would be covered by a sub-committee and, eventually, a separate tissues group. This still needs to be actioned. Zubeda has the papers prepared by Jill Taylor before her sick leave.

As you know, we have also set up a sub group of MSBT, chaired by Professor Don Jefferies, to make recommendations on action needed to prepare for the marketing of a vCJD blood screening test. This will report at the 10 June MSBT.

CMO's National Blood Transfusion Committee

Key NBA contact – Dr Mike Murphy

Information on the NBTC, including remit and membership, is on the DH website: http://www.doh.gov.uk/blood/nbtcommittee.htm

It meets two or three times a year. Denise O'Shaugnessy is the DH rep but you may also wish to attend at least once to get a feel for it and to build up contacts.

CJD Incident Panel

This looks, as part of its remit, at incidents involving possible exposure to vCJD via blood transfusion or blood products. There are a number of people who have received blood transfusions from donors who went on to develop vCJD. NBA have identified them as part of an epidemiological study in collaboration with the CJD Surveillance Unit (the Transfusion Microbiology Epidemiological Review or TMER study) As yet, the individuals themselves don't know that they have been exposed although the existence of such a group is in the public domain. Key contact at NBA on the TMER study – Dr Pat(ricia) Hewitt.

The Incident Panel has proposed that all the surviving transfusion recipients exposed to vCJD through blood transfusion should be informed and told that they cannot themselves give blood or donate organs or tissues and that special precautions (eg single use instruments) might be needed if they require some types of surgery (eg involving the CNS). This recommendation is currently with the four CMOs and it is unclear when a decision will be made. In the meantime, NBA have confirmed that none of the recipients are or have been blood donors and their names have been included on the donor database so that if they turn up to give blood it won't be used.

Another issues is that – before the switch to US plasma for BPL products in 1998 – plasma from people who went on to develop vCJD has been used by BPL in plasma pools. There have been two such cases to date – pre Incident Panel - both of which have been made public. As a result, a number of haemophilia patients and others have been told by their clinicians that they have received vCJD implicated products. There is a third such report currently with the Incidents Panel for advice. This is not public knowledge. Once the Panel has give their advice, you will need to be heavily involved in managing the communications exercise with patient groups and clinicians – the Haemophilia Soc, the UK Haemophilia Doctors Org and the Primary Immunodeficiency Association. The key concern will be that patients don't hear the news first from the press.

I suggest you get an update from Dr Phillipa (Pip) Edwards in the CJD Team. Pip has been involved with a lot of work recently to get some consensus around the assumed vCJD risk in the various plasma fractions. These are the assumptions that the Panel will use in giving advice on what to tell patients who will have received the latest batch of implicated blood products.

Fresh Frozen Plasma

This is a complex area which will be easiest for me to explain over the phone.

Recombinant Clotting Factors

We have £88m over the next three years to roll out recombinant clotting factors for haemophilia patients still receiving plasma derived products (largely those over age 21/22). I have set up a working group with all the stakeholders to help the Department agree a phasing strategy. This has met three times so far. You will need to take over the Chair of this. The next meeting would have been on 10 July but this clashes with the Commission's meeting on the Directive. Zubeda was trying to re-arrange.

Information on the group – remit, membership, minutes etc are on the DH website: http://www.doh.gov.uk/blood/rcfwg/index.htm

Again, it's probably easiest if I bring you up to date on where we have got to – and what needs to happen next - by phone.

Compensation for Haemophiliacs with Hepatitis C

You already know the background to this.

The current position is that Ministers here are sticking strongly to the no compensation line but Scottish Ministers have weakened. Political pressure in Scotland forced them to set up an expert group which recommended a fairly generous compensation scheme. After the expert group reported, Malcolm Chisholm, the Scottish Health Minister, went public with a lesser offer of cash. SofS asked us to see if a way could be found to stop this. The result was a legal challenge saying that any payment scheme to haemophiliacs would be a social security scheme and therefore outside Scotland's devolved powers. This issue is currently with the law officers for a determination and we are expected them to give a view very soon. If they decide in Scotland's favour, DWP will then need to decide whether to disregard such payments for social security purposes (as is the case with the Macfarlane Trust scheme).

Bone Marrow Registries

There are three UK registries:

the Anthony Nolan Trust – a charity;
the British Bone Marrow Registry, run by the National Blood Authority;
the Welsh Register, run by the Welsh Blood Service.

PS(PH) has said that she wants us to find a way for the Nolan and the NBA registry to work in partnership. Dr Julia Watson in EOR has agreed to undertake a project to investigate the scope for this and to make recommendations. However, Julia still needs formal instructions from us before she can start. Again, this is something we can discuss.