

**REPORT OF UKBTS/NIBSC EXECUTIVE COMMITTEE MEETING
HELD ON 19TH DECEMBER 1996
AT THE ROYAL COLLEGE OF PATHOLOGISTS**

Present:

Mr J Adey	Dr M McClelland
Dr T Barrowcliffe	Dr A Napier
Dr M de Silva	Dr P Phillips
Dr P Flanagan	Dr A Robinson
Dr V James	Dr G Schild
Mr S Janisch	Dr W Wagstaff
Dr M Kavanagh	Dr R Warwick
Dr E Love	Dr L Williamson
Dr B McClelland	

1. Dr Wagstaff explained that the purpose of the meeting was to address two topics as follows:

1.1. The Future Organisation of "Red Book" Activities

- relationship with competent authorities
- funding of meetings
- publication of guidelines and amendments

1.2. Status of Guidelines and Legal liability of Standing Advisory Committees

2. Background

Although the UKBTS/NIBSC guidelines are well accepted in the United Kingdom, they have no formal legal status because the Committee is an ad hoc organisation which was formed originally at the request of Regional Transfusion Directors which was also a body without official status. The guidelines were originally introduced as a response to Product Liability Laws. The MCA draws upon the Red Book for its standards but also pays attention to Council of Europe guidelines. However, there are few points of conflict at present between the two sets of guidelines which are both professionally produced documents. Documents produced by the European Union under DG5 are likely to have a different approach and will have legal status.

3. Current Status of Guidelines : Mr Steven Janisch

Mr Janisch reinforced the statement that the UKBTS/NIBSC Guidelines do not have formal legal status. Pronouncements by a professional body do not

normally have direct legal effect unless the body producing them has legal power to do so, usually conferred by statute.

The Guidelines contain statements of good practice and, within the blood transfusion service, are authoritative. As such, they would be taken into account by a Court seeking to apply the *Bolam* principle: in the practice of medicine or some other situation involving the use of some special skill or competence, the standard of care required “is the standard of the ordinary skilled man [or woman] exercising and professing to have that special skill”. A medical practitioner is not guilty of negligence if he or she “has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art”.

European Union Guidelines which have the force of law “trump” the existing UK Guidelines in the event of any conflict between them.

The question of legal liability of advisory bodies was mentioned. Mr Janisch confirmed that advisory bodies and their members could be legally liable under certain circumstances. Advisory bodies should therefore ensure that they give the best advice available and should be formally accountable to an appropriate authority. If so, the authority may be vicariously liable for advice given by individual members of the body concerned. By analogy, Health Authorities are responsible in law for decisions made by members of District Research Ethics Committees.

The UKBTS/NIBSC is a complex Committee representing England, Wales, Northern Ireland, Scotland and NIBSC and there is no single responsible authority although Dr Wagstaff has received in the past affirmation of acceptance of the Guidelines from three of these authorities. There is a need for a more formal arrangement for corporate liability of sponsoring organisations. It is also not clear at the moment whether “Red Book” and indeed other Committee activities constitute normal professional activities within the scope of employment of individual Committee members and are therefore covered by these authorities. This point does not appear as yet to have been raised by Defence Societies.

Mr Janisch referred to NHS Executive circular HSG(96)48 entitled “NHS Indemnity: Arrangements for Handling Clinical Negligence Claims Against NHS Staff”, issued on 18 November 1996. It makes clear the previously unwritten policy that NHS bodies take full responsibility for claims in clinical negligence cases, without seeking to recover any proportion of settlement costs from health care professionals employed by them. Similar responsibility should be taken by sponsoring organisations for any liability arising out of membership of advisory bodies.

4. Relationship of “Red Book” to Other Guidelines

The “Red Book” is mainly for internal guidance for the Transfusion Service and is responsible for the definition of standards not policies. However, policies need to be available to it. These are determined by the appropriate authorities.

With reference to clinical practice, there is no formal link with BCSH and Transfusion Medicine handbook although these documents should be consulted in drawing up the “Red Book” standards. More formal links with the bodies drawing up clinical practice guidelines and policies would be desirable.

5. Summary

5.1. There was general consensus that the “Red Book” should continue but it will increasingly have to take account of interactions with Europe. Policy documents such as those produced by BCSH and Transfusion Medicine handbook should be consulted by SACs in drawing up standards.

5.2. Chairpersons of SACs should look afresh at representation and ensure that it is expert and appropriate with particular emphasis on user representation.

ACTION
Chairpersons of SACs.

5.3. The BCSH and Transfusion Medicine handbook should be approached about more formal links.

ACTION WW

5.4. Chief Executives of sponsoring authorities should be approached about the adoption of a more formal “umbrella” for corporate liability of members of the Executive and SACs.

ACTION WW

5.5. Chairpersons of SACs should ask their members of sponsoring organisations to produce letters of authority for their activities.

(This does not apply to other members e.g. hospital representatives)

ACTION
Chairpersons of SACs

5.6. Defence organisations should be asked whether membership of committees, advisory bodies etc. constitute normal professional activities for which the sponsoring authority should accept liability.

ACTION WW

- 5.7. Archiving of Minutes. These and all associated documents should be kept by Chairmen of SACs and passed on to their successors. This item to be brought up at the next Executive meeting.

ACTION WW

- 5.8. No further progress made regarding separate funding of meetings or formation of a secretariat.
- 5.9. The latest version of the “Red Book” will be printed in Leeds in the near future and distributed via the BPL network or courier. If relevant authorities accept these standards, they should be promulgated via the Quality Assurance network.

There will be an annual updating mechanism utilising loose-leaf inserts. The new “Red Book” will contain a registration page to ensure comprehensive updating.