



May 2008

Guidance for British Cardiovascular Society members on the presence of representatives from commercial organisations in clinical practice.

Avoiding conflicts of interest.

Introduction:

The British Cardiovascular Society is aware of ethical concerns and potential conflicts of interest when commercial representatives are present during clinical practice. The Society considers that it would be useful to establish a set of principles of good ethical practice for its members to avoid potential conflicts of interest.

Modern health care uses and purchases large amounts of commercial products and services. Many of these have taken a long time and much expense to develop, and are often of high value. Usually there is essential support from commercial organisations for the introduction of complex or new equipments, treatments, technologies and implants; such support is a necessary part of the modern delivery of health care. This valuable support should be acknowledged in the areas of clinical teaching, training and education in new knowledge and skills. Teaching, training and education should be delivered where this is most appropriate to the educational and training content. Often this will be in a clinical setting. The British Cardiovascular Society acknowledges that there can be considerable benefit to patient care in having commercial representatives in clinical areas of practice to support appropriate use of products and services, by assisting with the use of equipments, treatments, technologies and implants, and with teaching, training and education in their use.

The presence of representatives from commercial organisations during clinical procedures could potentially result in the inappropriate selling or marketing of products and services. This could result in potential conflicts of interest to clinicians. Patient confidentiality also has to be maintained. The British Cardiovascular Society proposes the following principles of good ethical practice for its members when representatives from commercial organisations might be present during clinical procedures.

Proposed principles of ethical practice:

- 1. The British Cardiovascular Society expects that health professionals and commercial organisations should comply with their own codes of practice, professional requirements and host institute policies.**
- 2. Patient confidentiality must be maintained at all times.**
- 3. Sales or marketing staff should not be present in any clinical area where a patient is undergoing assessment or treatment.**

Relevant clinical areas include any room, clinic or space, including laboratory or imaging control rooms, where a patient is undergoing clinical assessment or treatment. As an analogy, pharmaceutical sales representatives should not be present where in-patients or out-patients are undergoing clinical assessment or treatment.

4. Personnel from commercial organisations with expertise in training about the use of a device or procedure can, where appropriate, be present in a clinical area.

Personnel from commercial organisations who are clinical specialists or training staff involved in the teaching, training and education of use of equipment or technology, or implantation or programming of a device for example, may be present in clinical areas where a patient is being treated. The principle should be that only personnel from commercial organisations who have a material contribution to the conduct of the procedure or the care of the patient should be present. Appropriate personnel from commercial organisations would be those who have specialist skills and expertise with specific equipment, treatments, technologies or devices, and whose presence is required for patients to receive appropriate treatment. Appropriate personnel from commercial organisations would also be those without whom staff would not receive appropriate teaching, training and education in the use of equipment, technologies or devices. It is good clinical practice to inform the patient of the presence and the specific role and contribution of visiting and external staff present during clinical examinations or procedures. It is also good clinical practice that there is documentation placed in the clinical records of this information provided to the patient.

The presence of personnel from commercial organisations should be subject to the local governance arrangements of the host institute for visiting staff.¹

5. Commercial representatives should not be allowed to have access to, or sight of, patient details such as patient registers, theatre or laboratory or imaging room logbooks, and clinical databases or stock details such as stock control or ordering systems and stock storage areas, etc.

This should not prevent commercial representatives from reviewing and inspecting stock, and stock levels, supplied by their own company with staff from the user institute. In cases where stock is present on “consignment” (technically owned by the supplier, but placed in a department until used, when it is invoiced by the supplier to the user institute), there should be agreed contractual arrangements for the supplier to review, inspect and list their own stock at appropriate intervals. Such reviews and inspections should not be undertaken in the presence of patients, and must not extend to review of stock present from other commercial organisations.

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1. Where local governance arrangements are uncertain or undefined, the British Cardiovascular Society suggests the following areas of good governance practice:
- The presence of visiting staff should usually require a specific request of the clinician responsible for the case, or documentation such as a letter of introduction and agreement from the clinician responsible for the case. Visits without a specific invitation or appointment should not be allowed.
 - Documentation should include written identity requirements of the visitor (such as a business card) with the name, job title and company or organisation represented, and a visitor's name badge that should be worn which clearly identifies them as non-staff and external.
 - The names, titles and organisations of all visiting and external staff present should be specifically documented in the clinical records of every case when they are present.
 - A secure, formal sign-in and sign-out register of visiting and external staff would be a useful record for the host organisation. The clinical manager or head of the unit or department would usually have responsibility for maintaining this register.

6. Sales or marketing staff should not be present when there are any clinical discussions about identifiable patients.

Sales or marketing staff should not be present during multidisciplinary or other clinical meetings when identifiable patients are discussed. Where individual cases are discussed with personnel from commercial organisations, this should be done on an anonymous basis. Live demonstrations of procedures, by video link to another room or facility for example, should be done with patient anonymity and with explicit written consent from the patient.

7. Use of products brought in by commercial representatives should be documented.

When a product (other than a medicine) is supplied by a representative of a commercial company, rather than purchased through the usual ordering systems, the cost of that product should be provided in writing together with details of the supply of the product; for example is it supplied free of charge, or will an invoice be submitted to the host institute? The use of such products should be documented in both the clinical records, and the host institute administrative, ordering and stock control systems. Commercial products may be used free of charge as part of an agreed and approved research or development study; such use should have the funding procedures clearly specified in the agreed and approved research or development protocols, and documented in the local host institute Research and Development Ethics Committees files. Local governance arrangements should document the ordering, supply, delivery and use of free-of-charge commercial products in agreed and approved research or development studies.

8. Terms of trade.

The arrangements for supply of a product should be clear and transparent. The use of a product should not be associated with payments to individuals or to departmental funds. Commercial representatives should not employ any inducement or subterfuge to gain an interview with staff of the purchasing organisation; no fee should be paid or offered for the grant of an interview. The use of a product in research should have the relevant Ethical Committee and Research & Development approvals, and be subject to appropriate and agreed contractual costs and reimbursements to the host organisation, and not to individuals.



Appendix:

Associated codes of practice:

1. BCS Code of Practice on relationships with the Biomedical Industries and other Commercial Organisations (British Cardiovascular Society, March 2007)
2. Code of Conduct for HR-UK Professionals and industry. (Heart Rhythm UK, March 2007)

Useful links:

1. **ABPI Code of Practice for the Pharmaceutical Industry 2006.**
Prescription Medicines Code of Practice Authority - Constitution and Procedure.
http://www.abpi.org.uk/publications/pdfs/pmpca_code2006.pdf
2. **Prescription Medicines Code of Practice Authority.**
Administers the Association of British Pharmaceutical Industry's Code of Practice at Arm's length from the ABPI. <http://www.pmpca.org.uk>
Guidance Notes for Health Professionals. Understanding the ABPI Code of Practice for the Pharmaceutical Industry. Controls on the Promotion of Prescription Medicines in the UK, 2006. <http://www.abpi.org.uk/%2Fpublications%2Fpdfs%2FPMPCA%2Epdf>
3. **The Association of British Healthcare Industries (ABHI).**
<http://www.abhi.org.uk/>
4. **European Federation of Pharmaceutical Industries and Associations. EFPIA Code On The Promotion Of Prescription-Only Medicines To, And Interactions With, Healthcare Professionals.** Adopted by EFPIA.
<http://www.efpia.org/Objects/2/Files/code%20medicines%202007.pdf>
5. **European Federation of Pharmaceutical Industries and Associations. EFPIA Code Of Practice On Relationships Between The Pharmaceutical Industry And Patient Organisations.** Adopted by EFPIA.
<http://www.efpia.eu/Content/Default.asp?PageID=263&DocID=3484>
6. **Eucomed Code of Business Practice.**
Association representing the interests of European medical technology & device manufacturers.
<http://www.eucomed.org/abouteucomed/ethics.aspx>
- Eucomed Code of Business Practice:
<http://www.eucomed.org/sitecore/shell/Controls/Rich%20Text%20Editor~/media/pdf/tl/2008/portal/abouteucomed/ethics/eucomedcodeofbusinesspractice.ashx>
- Eucomed Guidelines on Interactions with Health care Professionals:
http://www.eucomed.org/sitecore/shell/Controls/Rich%20Text%20Editor~/media/pdf/tl/2006/other_docs/attachment1code_of_business_practice%20pdf.ashx