

# Advisory Committee on the Safety of Blood, Tissues and Organs: code of practice

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## Introduction

The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) advises Ministers of the UK Government and the Devolved Administrations as well as UK Health Departments and the UK Blood and Transplant services.

This Code of Practice should be read in conjunction with the Code of Practice for Scientific Advisory Committees revised and republished following a public consultation by the Government Office for Science in 2021.

This Code of Practice also reflects the [seven principles for public life as set out by the Committee on Standards in Public Life](#).

Members of SaBTO are required to accept the principles set out in this Code of Practice, and to follow them in carrying out their responsibilities as members of SaBTO.

This Code of Practice also applies to members of any working groups or sub-groups established by SaBTO.

## **The committee**

SaBTO's Terms of Reference are published on the [SaBTO webpage](#).

SaBTO has no executive function. Its role is to provide high quality, up to date and well-considered advice and recommendations on matters within its remit as set out in its Terms of Reference, to Health Ministers in England, Wales, Scotland and Northern Ireland; to the UK Health Departments; to the UK Blood services and Transplant services, and to the NHS more widely. This includes giving advice and making recommendations both on matters of a 'routine' nature and on any specific matters referred to the Committee by the Department of Health and Social Care (DHSC) or by the health departments of Wales, Scotland or Northern Ireland.

Members of the Committee must at all times be accountable for their activities and for the standard of advice they provide. DHSC is responsible for the framework within which SaBTO operates.

SaBTO provides its advice via the sponsoring department, DHSC. Any legal challenge to any action taken on SaBTO's advice or recommendations will be the responsibility of DHSC rather than of SaBTO.

SaBTO was set up as an advisory non-departmental public body (ANDPB), but with effect from 1st December 2012 it became a Departmental Expert Committee. This change was not intended to alter SaBTO's independence or the principles that guide its conduct.

## **Membership**

SaBTO comprises the Chair and appointed members only. It is supported by the Secretariat and members of the Secretariat attend meetings.

Representatives of DHSC, the Welsh Government, the Scottish Government and the Northern Ireland Executive, representatives of other government departments and other advisers known as Observers may also attend SaBTO meetings.

The Chair and Members are appointed by DHSC, with the endorsement of the Health Departments of Wales, Scotland and Northern Ireland.

## **Secretariat**

The Secretariat for the Committee is comprised of officials from the Department of Health with scientific support from NHS Blood and Transplant.

These officials should at all times respect SaBTO's independence.

## **Observers**

Observers attend meetings for the purpose of providing information and advice as required by SaBTO, and in order to provide liaison between SaBTO and the organisations they represent.

## **Working groups and sub-groups**

Where SaBTO requires additional relevant expertise to consider an issue fully, appropriate experts may be co-opted to the Committee, to serve on a specialist working group or sub-group established on an 'ad hoc', time-limited basis to consider the issue. The Chair of such a working group or sub-group will usually be a SaBTO member.

To avoid any potential or perceived conflict of interest, a person who holds a position on the Board of their employing organisation, or a similarly senior policy-making position in that organisation, shall not act as the Chair of a working group if the topic under consideration directly relates to their employing organisation's interests or activities. They may, however, serve as a member of that working group.

# **Roles and responsibilities**

## **The Chair's role and responsibilities**

The Chair of SaBTO is accountable to DHSC for ensuring that SaBTO observes the highest standards of propriety including impartiality, integrity and objectivity in the execution of its role and responsibilities.

The Chair is expected to provide effective leadership for SaBTO and to promote rigorous, impartial consideration of the matters before it. In particular, the Chair should:

- ensure SaBTO has the right balance of skills in its membership
- ensure that all views are captured and explored

- be responsible for ensuring that the minutes of meetings, produced by the Secretariat, accurately record the decisions taken and advice given
- represent SaBTO's views to DHSC, and to the general public if required
- provide an assessment of Members' performance annually
- ensure that new SaBTO members are briefed upon appointment
- take appropriate action to progress SaBTO's work and on proposals for action

## **SaBTO members' role and responsibilities**

Members are appointed to SaBTO as individuals to fulfil the role of the Committee, not as representatives of any organisation. Members with a particular expertise have a responsibility to make SaBTO aware of the range of opinion within their discipline on a particular matter. However, a Member's role is not circumscribed by the expertise they bring to SaBTO and Members should feel able to comment on an issue or question information provided even if it does not relate to their own area of expertise.

Members of SaBTO (including the Chair) have a collective responsibility for the operation of the Committee. Members should engage fully in the collective consideration of issues before SaBTO, taking account of the full range of relevant factors and of guidance provided by DHSC.

Members of SaBTO are expected to:

- act in good faith and in the best interests of SaBTO in undertaking their Committee duties
- comply with this voluntary Code of Practice, and ensure that they understand their duties and responsibilities and are familiar with the role and responsibilities of SaBTO
- not misuse information gained in the course of their Committee service for personal gain or for political purpose, nor seek to use their position on SaBTO to promote their private interests or those of persons, firms, businesses or other organisations connected to them
- avoid premature or selective disclosure of SaBTO's deliberations. Where papers or information presented to SaBTO include confidential material such as unpublished internal documents and reports, pre-publication copies of research or information of commercial significance, these must be treated as strictly confidential

- refrain from accepting hospitality or gifts offered to them in their capacity as a Member of SaBTO if this might be construed as being in conflict with SaBTO's independence, objectivity and integrity

The membership of SaBTO is in the public domain. If a representative of the media should ask a Member to comment in their capacity as a SaBTO member, or to state the Committee's views or recommendations, they should refer the enquiry to the Secretariat, who will normally handle media enquiries through Departmental press offices.

In accordance with Government policy on openness, Members should comply fully with the Ministry of Justice Code of Practice on the discharge of public authorities' functions under Part I of the Freedom of Information Act 2000 (FOIA), the Freedom of Information (Scotland) Act 2002 and the Code of Practice on the discharge of the obligations of public authorities under the Environmental Information Regulations 2004 (EIR). These all came into force on 1st January 2005. Members should also comply with the Data Protection Act 2018.

## **The Secretariat's role and responsibilities**

The Secretariat supports SaBTO through organising meetings and other matters and by bringing issues of concern to SaBTO's attention.

The Secretariat will produce accurate and impartial minutes of SaBTO committee meetings, in unattributable form unless the views or statements of individual members need to be recorded in particular circumstances. Minutes will be presented to the Chair and circulated to Members for approval. They will be published when they have been accepted as being an accurate record of the meeting.

Communications between SaBTO and DHSC will be through the Secretariat, except where it has been agreed that an individual Member should act on SaBTO's behalf.

The Secretariat is responsible for ensuring that SaBTO does not exceed its remit. It will also ensure that appropriate guidance on the functioning of scientific advisory committees is followed.

## **Observers' role and responsibilities**

SaBTO's discussion represents the development of its collective view and Observers are asked to note that comments made by individual Members during discussion should not be regarded as the collective view of the Committee. Additionally, as a topic may be considered over several meetings, Observers are asked to note that the conclusions of the Committee are not finalised until the full range of information has been discussed and a formal statement or line published.

Observers may participate in SaBTO's discussions if invited by the Chair or the Secretariat, though they may intervene to correct or add information which is relevant and/or vital in assisting SaBTO to reach a conclusion or decision. Observers should at all times respect SaBTO's independence.

## **Appointment of SaBTO members**

DHSC will manage the process of recruiting members to the Committee in a way that is open and fair to all applicants, and appointments will be made on merit.

Appointment will initially be for a period of up to three years. This may be followed by re-appointment for additional terms of up to three years, up to a maximum total of ten years, subject to satisfactory appraisal and SaBTO's needs. Appointments may be terminated by DHSC in the event of unsatisfactory attendance at meetings or conduct that renders the member unfit to remain in office.

Appointments to SaBTO are unsalaried and not pensionable. Members are asked to seek reimbursement for reasonable travel and subsistence expenses incurred in the performance of Committee duties from their employing organisations: where this is not possible, Members may seek reimbursement from DHSC, at rates determined by DHSC.

## **Declaration of interests**

It is important that there can be no real, possible or perceived conflict between Members' private interests and their responsibilities as Members of SaBTO. Members must declare when they or a close family member may have a personal, business, private pecuniary or other interest likely to conflict with their responsibilities as a SaBTO member and notify the Secretariat of any changes to their interests as they occur.

The Secretariat will maintain a register of Members' interests. The register will be updated at least annually and published on the SaBTO website.

A Member should declare an interest at any SaBTO meeting where it relates specifically to a matter under discussion, and refrain from participating in discussion or determination on that matter unless the Chair, as guided by the Secretariat, rules this is not necessary. The Member may be asked by the Chair to withdraw from the meeting whilst the matter is discussed.

Guidance on the declaration of interests, including what constitutes an 'interest', is given at Annex A. Members may approach the Secretariat if they have any queries.

# The conduct of business

SaBTO will hold at least four committee meetings a year. As members and attendees are based across the UK, whenever possible, meetings will be hybrid. For those attending in-person, DHSC will usually host at their London offices (39 Victoria Street, London). One meeting per year will occur outside London, either in Scotland, Wales or Northern Ireland.

Meetings will not be open to the public because SaBTO routinely considers sensitive and confidential information. SaBTO may hold open meetings if discussing matters of strong public interest as part of a stakeholder engagement process.

In exceptional circumstances, the Chair may need to act on behalf of SaBTO to ensure a timely response. If time permits, Members would be consulted via telephone conference, email or by holding an extraordinary meeting. The devolved administrations would also be informed. In the rare event of the Chair acting on behalf of SaBTO, the decision/action taken will be circulated to members for information following the event.

SaBTO will maintain a high level of transparency in the conduct of its business and be as open as possible given the confidential nature of some items of business.

## Formulation of SaBTO's advice

In formulating its advice, SaBTO will:

- first and foremost, recognise that patient safety is the paramount, guiding principle
- consider the UK as a whole and, by default, make recommendations that apply across all 4 nations - there may be exceptions to this principle, such as where there is a different epidemiology of infections, or different legal frameworks
- take account of the scientific evidence available, including the nature of uncertainties and assumptions used to reach conclusions
- consider the application of statistical modelling techniques and specific expertise in risk assessment
- use the [Alliance of Blood Operators Framework](#) to help streamline the process of assessing blood safety risk and make informed blood safety decisions
- acknowledge any gaps and uncertainties that influence any judgements reached. Where uncertainties occur, the Committee will follow the precautionary principle: that is, where there is lack of evidence or there is uncertainty about the extent of risk, the

Committee will assume a 'worst case' scenario to produce advice, and review and revise recommendations, as appropriate, when more evidence is available

- indicate the degree of scrutiny given to the topic and the degree of certainty that can be attached to the judgements given, acknowledging that decisions may be required before absolute certainty is achieved
- assess cost-effectiveness, using the model laid out by the [UK government Green Book](#), appreciating that cost, though a relevant factor, should not be the starting point
- consider the impact of its advice on all stakeholders, and take account of the risk of policies being perceived as unfairly discriminatory
- consult with patients, patient groups and other stakeholders, as appropriate, and encourage lay member representation in each working group
- take account of any legal requirements, and any other SaBTO recommendations

SaBTO will aim to reach decisions by consensus. Where there is significant difference of views or interpretations, however, this should be reflected in any report or advice or, if at a meeting, in the minutes.

Once recommendations have been accepted by SaBTO, the chair of the relevant Working Group and the Chair of SaBTO will formulate a letter to Ministers, Departments of Health, or others, where relevant. This letter will include as appropriate:

- the recommendations
- a brief background to the issues that led to the formation of the working group
- a brief outline of the evidence base for the recommendations
- areas of uncertainty and controversy
- assessment of cost and cost-effectiveness
- any patient, professional or lay consultations
- implications of implementation and non-implementation
- any other comments to help Ministers/others decide whether to accept the recommendations



## **Publication of SaBTO's advice**

SaBTO's advice will normally be published on SaBTO's website as a detailed Committee statement or report. This will be in terms that can be understood by a layperson; include a transparent account of how the advice was formulated including sources of data and any assumptions underlying the advice, and identify the nature and extent of any scientific uncertainty. Where there is a need to convey a decision urgently, oral advice may have to be given but should be followed up with written confirmation.

When SaBTO's advice is published, the Secretariat will agree with the Chair, other Committee Members (for example, the Chair of any relevant working group), the devolved administrations and others additional steps to disseminate the advice to interested groups such as clinical professional organisations, Royal Colleges and patient organisations and promote its adoption.

## **Publication of meeting papers**

Agendas and minutes of SaBTO committee meetings and the papers considered by the Committee will be published on the SaBTO website (subject to considerations of confidentiality: see below).

SaBTO routinely considers information that is confidential or sensitive, including the following:

- unpublished data, such as scientific results prior to publication in the scientific literature. As premature disclosure of unpublished research may prejudice publication, there is a generic requirement to treat such material as confidential unless the researchers give permission for pre-publication release
- information that is commercially confidential or sensitive
- confidential patient information or other personal data
- draft versions of guidelines, reports, position statements, risk assessments etc. There may also need to be a delay in making public the assessment of risks until DHSC has developed appropriate risk management policies

Papers containing confidential or sensitive information will not be published, or will be published with relevant sections edited / redacted, in line with the principles of the Freedom of Information Act 2000, the Freedom of Information (Scotland) Act 2002, the Environmental Information Regulations 2004 or the Data Protection Act 2018. Where the material considered confidential is later published, or the particular reasons for the sensitivity no longer apply, the information will be placed in the public domain.

## **Annual report**

SaBTO will publish an Annual Report covering the period of the financial year. The report will be drafted by the Secretariat and will include details of SaBTO membership, and a summary of issues considered throughout the year. This will be circulated to Members for comment prior to its publication. The annual report will be published on the SaBTO website.

## **Liaison with other advisory committees**

SaBTO will liaise with other committees whose work relates to SaBTO's areas of responsibility, to ensure that decisions are taken by the appropriate committee, that work is not duplicated and that the boundaries of each committee's responsibilities are respected. In the event of disagreement between SaBTO and another committee about the scope of their remit, or the validity of decisions taken, the matter shall be referred to the committees' sponsor departments for resolution.

# **Annex A: guidance on declarations of interests**

## **Introduction**

This guidance reflects the advice of the Committee on Public Appointments.

The following is intended as a guide to the kinds of interests which should be declared. Where members are uncertain as to whether an interest should be declared, they should seek guidance from the Chair or the Secretariat or, where it may concern a particular matter that is to be considered at a SaBTO meeting, from the Chair at that meeting.

When an interest is not of a direct pecuniary kind, members should consider whether it could be perceived as influencing their participation in the discussion or determination of a matter by SaBTO and if so, declare an interest or approach the Secretariat or Chair for clarification. The final decision on whether any particular interest could be seen as being in conflict with a particular Member's duties rests with the Chair, as guided by the Secretariat.

If members have interests not specified in these notes but which they believe could be regarded as influencing their advice they should declare them.

However, members are not under an obligation to search out links between one company and another, for example where a company with which a member is connected has an interest in another company of which the member is not aware and could not reasonably be expected to be aware.

## **Types of interest**

In the following, 'industry' means any commercial company, partnership, trade association or individual, an interest in the affairs of which or whom, members of the public might reasonably think could conflict with the responsibilities incumbent on a member of SaBTO.

References to 'member(s)' include the Chair.

### **Personal interests**

A personal interest involves payment to a member personally. The main examples are:

- consultancies - any consultancy, directorship, position in or work for the industry which attracts regular or occasional payments in cash or kind
- fee-paid work - any work commissioned by the industry for which the member is paid in cash or kind

- shareholdings - any shareholding in or other beneficial interest in shares of the industry. This does not include shareholdings through unit trusts or similar arrangements where the member has no influence on financial management

### **Non-personal interests**

A non-personal interest involves payment which benefits an organisation, for example a university department for which a member is responsible, but is not received by the member personally. The main examples are:

- fellowships - the holding of a fellowship endowed by the industry
- support by the industry - any payment, other support or sponsorship by the industry which does not convey any pecuniary or material benefit to the member personally but which does benefit their position or department; for example:
  - a grant from a company for the running of a unit or department for which the member is responsible
  - a grant or fellowship or other payment to sponsor a post or a member of staff in the unit for which the member is responsible. This does not include financial assistance for students
  - the commissioning of research or other work by, or advice from, staff who work in a unit for which the member is responsible

Members are under no obligation to seek out knowledge of work done for or on behalf of the industry within departments for which they are responsible if they would not normally expect to be informed.

## Annex B: guidance for SaBTO working groups

The secretariat has drafted some brief guidance on operation and governance of committee Working Groups which is intended to:

- help frame a common approach to the way in which Working Groups operate
  - promote consistent use of the SaBTO safety framework, providing a systematic approach to development of recommendations
  - ensure consideration is given at an early stage to how best to involve stakeholders in any piece of work
  - ensure members understand the routes by which Working Group outputs can be ratified
1. Where relevant to the issue under consideration, Working Groups should follow the SaBTO safety framework as far as possible, and ensure a completed copy of the framework accompanies their recommendations to the main committee.

Responsible owners: Working Group Chair and secretariat.

2. Where a Working Group is drafting clinical guidance, the Working Group Chair should, where possible, have a professional background relevant for the audience to whom the guidance is primarily directed.

Responsible owners: SaBTO Chair and members.

3. As well as co-opting external experts to Working Groups on a time-limited basis to assist with a particular piece of work, Working Group Chairs should consider with members whether/how to involve wider stakeholder input. This could be through inviting stakeholder representatives to join a Working Group, contacting stakeholder organisations by correspondence to ask for their input or by circulating draft guidance to the intended audience for information and/or comment before final ratification by SaBTO. Additionally, lay representatives should also be considered for membership in all SaBTO Working Groups.

Responsible owner: Working Group Chair.

4. Working groups should present their recommendations/advice to the main committee for ratification before publishing. This includes clinical guidance. Ratification should ideally be via committee discussion at a full SaBTO meeting, but in circumstances where it needs to be expedited, it can be sought via correspondence, or exceptionally

by Chair's action. Working Group Chairs should plan the most appropriate route for ratification of their group's work with the secretariat.

Responsible owners: Working Group Chair and secretariat.