

**MINUTES OF THE 47<sup>TH</sup> MEETING**  
**1<sup>ST</sup> FEBRUARY 2022**  
**TEAMS MEETING**

**Present:**

Prof James Neuberger

Chair

**Members**

**Area of expertise**

|      |           |                |                                    |
|------|-----------|----------------|------------------------------------|
| Dr   | Stephen   | Thomas         | Blood Service Management           |
| Dr   | Gail      | Miflin         | UK Blood Services Medical Director |
| Dr   | Susan     | Brailsford     | Epidemiology Public Health         |
| Prof | Yacoub    | Khalaf         | Reproductive Medicine and Surgery  |
| Ms   | Andrea    | Head           | Nursing                            |
| Prof | Jean      | Manson         | Prion Diseases                     |
| Dr   | Akila     | Chandrasekar   | Tissue Transplantation             |
| Mr   | Roger     | Graham         | Lay Organ Representative           |
| Dr   | Lynn      | Manson         | Haematology                        |
| Prof | Peter     | Simmonds       | Virology                           |
| Prof | Mike      | Murphy         | Transfusion Medicine               |
| Prof | Will      | Irving         | Virology                           |
| Prof | Marc      | Turner         | Regenerative Medicine              |
| Dr   | Effrosyni | Grania-Klotsas | Infectious diseases                |

**Secretariat**

|    |           |           |      |
|----|-----------|-----------|------|
| Dr | Gary      | Mallinson | JPAC |
| Ms | Katherine | Evans     | DHSC |

**Observers**

Attending for all or part of the meeting were:

Betty Bassis, NHSBT; Janet Birchall, Welsh Blood Service; Dr Sheila MacLennan, JPAC; Shruthi Narayan, NHSBT; Prof Derek Manas, NHSBT; Amy Shackell, HTA; Lauryn Anderson, DHSC; Dr Carol Beattie, DoHNI; Emma Stapley, DHSC; Barnaby Roberts, DHSC; James Riley, DHSC; Laura MacKay, Scottish Government; Catherine Cody, Welsh Government; Chantal Ball, DHSC; David Olszowka, MHRA.

**1. Welcome and Apologies**

- 1.1 The Chair welcomed all to the meeting.
- 1.2 No new conflicts of interest were declared.
- 1.3 Apologies were given for the SaBTO members: Chris Callaghan, James Mason and Charlotte Silver.
- 1.4

## **2. Review of Minutes and Actions, Workplan and Provisional Meetings Schedule**

- 2.1 Members accepted the minutes from the meeting in October 2021 with minor changes.
- 2.2 Actions on the FAIR recommendations, HEV working group, Pathogen Inactivation, donor selection criteria and the lookback working group were on the agenda.
- 2.3 The action for the chair to discuss further with DHSC legal team as part of a review of current blood and tissue guidelines was closed as the legal position of tissue guidelines was provided.
- 2.4 The outstanding action from the previous meeting was to coordinate a meeting to assess whether SaBTO should revise the risk reduction measures for variant Creutzfeldt-Jakob disease (vCJD) . This action had been paused to allow the progression of other workstreams. Members agreed this action should be resumed and a meeting convened.
- 2.5 An update was provided on progress of the Occult Hepatitis B report to UK health ministers. Recommendations had been accepted in full in Scotland. The report was due to be sent imminently to ministers in Wales, England and Northern Ireland. Members were informed that an UK-wide implementation group had been created.
- 2.6 Members stressed the importance that communications plan should be prepared to the implementation of anti-HBc screening. This should be co-ordinated between all the blood services and health administrations. The chair asked for an update for the next SaBTO meeting.
- 2.7 Members agreed the SaBTO workplan with some amendments, including the addition of the vCJD working group, the inclusion of a meeting schedule and a timetable for of key agenda items.
- 2.8 The secretariat would organise scheduling for meetings in May, September and November.

**ACTION: Secretariat to amend the SaBTO October 2021 minutes and publish online.**

**ACTION: Secretariat to include an update on the implementation OBI on the next meeting's agenda.**

**ACTION: Secretariat to coordinate a meeting to assess whether SaBTO should revise guidance around CJD transfusion risk.**

**ACTION: Secretariat to circulate dates of provisional meetings.**

**ACTION: Secretariat to revise the workplan and circulate to Members for comments.**

## **3. Introduction of new Members and induction materials**

- 3.1 The chair welcomed new SaBTO members, Yacoub Khalaf (YK) as the fertility specialist and Marc Turner (MT) as the regenerative medicine specialist.

3.2 The chair proposed an induction meeting for new members and health administration staff. The previous meeting, hosted by Dr Steve Thomas at the Colindale blood centre, had been very useful. An in-person meeting would be preferred and the secretariat would explore the feasibility of conducting a meeting later this year, subject to guidelines.

3.3 The secretariat is reviewing the induction materials; these will be circulated and members asked to comment and suggest improvements.

**ACTION: Chair and secretariat to explore feasibility of an in-person induction meeting.**

**ACTION: Chair and secretariat to update the induction pack and circulate the revised version for comments.**

#### **4. Appraisals of Members**

4.1 Appraisals had been delayed due to the pandemic but the chair will now be contacting members to conduct appraisals.

**ACTION: Secretariat to coordinate the Chair's appraisals of Members.**

#### **5. SaBTO Website Update**

5.1 The chair highlighted that the website needed updating. This would include an update to the SaBTO Terms of Reference (ToR). The current ToR would be circulated to members for comment. The chair asked members to consider if the SaBTO remit required review. For example, the safety of xenotransplantation using genetically manipulated porcine organs. Members agreed that SaBTO should consult UK health departments and regulatory bodies such as the MHRA on the role of SaBTO on this issue.

5.2 Other website updates required included the membership list, the code of practice and registry of interests. The secretariat will contact members to collate updated records in due course.

**ACTION: Secretariat to contact DHSC and MHRA for comment of inclusion of xenotransplantation in the remit of SaBTO.**

**ACTION: Secretariat to circulate the SaBTO ToR for comments.**

**ACTION: Secretariat to request updated information from Members, including a registry of interests.**

#### **6. Lookback Proposals**

6.1 The chair presented this item (paper 4). Following the previous SaBTO it had been agreed to establish a working group to examine the wider issues of recipient lookbacks to try to produce general principles and guidance for conducting these investigations. Members were invited to comment on the remit and scope of the working group and to join the group when established.

6.2 Members discussed whether lapsed donors could be included in the scope of the guidance. It was agreed that this could be considered.

6.3 The Chair confirmed that the infected blood inquiry has been made aware of the new workstream.

- 6.4 Members agreed that the costs of undertaking lookback investigations, for blood services, hospital and other health organisations should also be considered by the working group.
- 6.5 Members flagged the importance of reviewing infrastructure of lookback investigations, including IT and donor archives.

**ACTION: Secretariat to set up a working group and arrange meeting ahead of the next committee meeting.**

## **7. Donor Organ Risk Assessment (DORA)**

- 7.1 Rachel Hilton gave an update on the work of the Donor Organ Risk Assessment (DORA) working group. The last meeting was held in December, the next meeting is planned for mid-April.
- 7.2 RH highlighted that the aide memoire had been available as an app since the summer to provide summary advice for transplant clinicians on the safety of organs offered for transplant. There was a commitment to ensure the aide memoire and the microbiological safety guidelines remained up to date as standing items on the DORA agenda.
- 7.3 George Greenhall, NHSBT clinical research fellow has been linking data from the UK transplant registry and the National Cancer Registries to determine:
- the reliability of cancer recording in the transplant registry,
  - how likely was an organ from a donor with a history of cancer to be transplanted,
  - what were the risks of transmitting cancer and what factors influence this risk,
  - how are donor transmitted cancers diagnosed and treated and what is the outcome.
- The linkage has been established with English cancer registry and data transfer and analysis is in progress. Work remains ongoing to source data from the cancer registries of Wales and Scotland.
- 7.4 Other current items include the risk of infection from a potential organ donor. DORA noted that the SaBTO virology review subcommittee had looked at HHV-8 and were currently looking at West Nile virus. Other infections or risks under review by DORA or others were Hepatitis C virus (HCV), Herpes Simplex virus, the increased infection risk due to lifestyle, geographical specific infections and donor travel history recording and interpretation.
- 7.5 Recent publications include a paper on abdominal abnormalities with the study of thoracic abnormalities to follow. The group continued to determine opportunities to improve organ utilisation such as the risk to transplants from donors with endocarditis. Similarly, the group has completed a review of clinical outcomes of deceased donors with albuminuria and submitted this for publication.
- 7.6 It was agreed that the DORA terms of reference would be reviewed and circulated to SaBTO members.
- 7.7 The chair thanked DORA for their work and highlighted their ongoing collaboration with Virology Review Subcommittee.



**Action: DORA to review DORA ToR and secretariat to circulate to SaBTO members**

## **8. FAIR Recommendations on Tissues and Cells**

- 8.1 Su Brailsford provided a verbal update. The FAIR steering group is currently conducting an appraisal of possible options for the application of relevant FAIR recommendations to tissue and cell donation.
- 8.2 The steering group have continued to review the safety and practical implications of implementation. For living tissue donors, implementation of all FAIR recommendations is relatively straightforward and would be the preferred option. However, for deceased there are potential issues as relatives may not be able to provide answers to some questions. This potential impact on supply is being investigated.
- 8.3 Consideration is also being given to alignment of safety standards with other countries to ensure there are no problems with importation or export of tissues for transplant.
- 8.4 The report should be presented at the next SaBTO meeting in May. Members noted the possibility of an extraordinary committee meeting if required.

**ACTION: Secretariat to include FAIR Recommendations on the next agenda.**

## **9. Pathogen Inactivation**

- 9.1 The committee discussed the ongoing work to review the previous guidance on pathogen inactivation in 2014 ([SaBTO report:Pathogen inactivation of platelets \(publishing.service.gov.uk\)](#)). This report had considered introduction of pathogen reduction technologies for platelets was not cost effectiveness.
- 9.2 After discussion, members concluded:
  - Haemovigilance reports from the Serious Hazards of Transfusion (SHOT) team had shown bacterial screening of platelets to be safe and effective in preventing infections,
  - Other blood services had carried out recent appraisals on cost effectiveness of pathogen reduction. The chair would ask if these appraisals could be shared with SaBTO.
- 9.3 Members agreed that this issue would remain on the agenda until it was clear if it could use data from other blood services or further work was required by SaBTO

**ACTION: Expert members to meet to review non-UK cost benefit analysis and draft a position statement for the committee to agree.**

## **10. HEV Working Group Update**

- 10.1 Peter Simmonds (PS) provided an update on the Hepatitis E virus (HEV) working group.
- 10.2 With the support of DHSC analysts, the group continued to consider several proposed options in assessing whether current mitigation measures were sufficient in reducing the transmission risk to recipients of blood.

- 10.3 One option, enhanced screening of platelets produced by apheresis for a limited number of severely immunocompromised patients was not supported by members. Selective screening, prior to introduction of universal screening had led to operational difficulties for blood services and hospitals in maintaining a dual platelet inventory. PS advised that the working group would take this view on board.

**ACTION: HEV working group to draft a preliminary report for the next SaBTO**

## **11. Donor Selection Criteria Review**

- 11.1 The chair presented an overview of paper 5 & 6. The SaBTO donor selection criteria (DSC) review in 2017 had made recommendations on body piercing and intravenous drug use which required legislative change before they could be applied.
- 11.2 The EU blood, tissue and cell directives were being revised. It was expected that the directives would be configured to allow technical changes, which could include recommendations similar to those proposed by the DSC review, to be made more easily. The proposed revisions were due to be published in Spring 22 but it would take time for them to become law and would include an implementation period.
- 11.3 A representative from the DHSC legal team explained that the Common Frameworks for blood and safety could be used to facilitate UK-wide discussions and collaboration. Following a risk assessment, final decisions would require collective sign-off by all Ministers across the UK.
- 11.4 Maintaining a compatible minimum set of safety and quality standards across the UK will make it easier for blood, organs, tissues and cells to continue to be shared across the UK. The Framework will allow for necessary divergence by one or more governments as required, to respond to needs such as location dependent public health concerns.
- 11.5 The chair asked members if they wished to begin the process of reviewing guidance or wait until the changes to the EU directives were published. Members considered that further discussion was needed and the chair would continue discussion with stakeholders and bring the issue back to the next meeting.

**ACTION: SaBTO chair to continue discussions on the donor selection criteria review recommendations with members and the blood services.**

## **12. Virology Review Subcommittee Update**

- 12.1 Effrossyni Gkrania-Klotsas (EKG) provided a verbal update on the Virology Review Subcommittee.
- 12.2 The subcommittee is currently reviewing guidance on West Nile virus (WNV). Another meeting is scheduled in the next week to review an updated draft of the 2013 SaBTO guidance, which may include a threshold mechanism to trigger re-assessment. An updated draft should be presented at the next committee meeting.

- 12.3 The final report of the Human Herpes Virus-8 (HHV-8) in solid organ transplantation report, prepared by Ines Ushiro-Lumb, had been circulated in August 2021. The report had noted that, following the recommendation of SaBTO that solid organ donors should be tested for HHV-8 in principle, implementation of testing would take some time as technical aspects such as test validation were not complete. Also, key staff were deployed to COVID related projects. An internal NHSBT working group was working on test implementation. It is hoped that an update will come to the next SaBTO.

**ACTION: Subcommittee to finalise draft guidance and present before the committee at the next meeting.**

**ACTION: Secretariat to include HHV-8 on the agenda for the next committee meeting.**

### **13. Organ Donation and Transplantation Adverse Events**

- 13.1 Derek Manas (DM) provided a verbal update on the Adverse Events Annual Report. The latest report is delayed but should be ready for the next SaBTO meeting.
- 13.2 Between April 2020-March 2021 820 incidents were noted, and most were related to transplant transport services.
- 13.3 Of the three noted viral infections, one was a fatal Herpes simplex virus 2 transmission to a liver recipient, the other two were transmissions of HHV-8 to liver recipients, one fatal.
- 13.4 The transmission of malignant melanoma to liver, kidney and pancreatic islets recipients had already resulted in changes to the SaBTO guidance.
- 13.5 A first recorded transmission of Fabry disease had occurred from a liver transplant.
- 13.6 SaBTO members requested that the written adverse events annual report be circulated to SaBTO when finalised for discussion at the next meeting.
- 13.7 The chair commented that organ transplantation was not without risk and some disease transmission was inevitable.
- 13.8 There was some discussion about how disease transmission in stem cells was reported to SaBTO or the blood services. Members commented that currently there was no systematic reporting system. The Human Tissues Authority was responsible for collating this data and Amy Shackell was prepared to provide a tailored report for SaBTO.

**ACTION: Secretariat to circulate the finalised report and add to the agenda for the next meeting**

**ACTION: Secretariat to liaise with Amy Shackell for a stem cell adverse events report for the SaBTO meeting**

### **14. Any other Business (AOB)**

- 14.1 Collection of plasma for fractionation: Gail Miflin briefed members on the current position for plasma collection. Funding for three permanent clinics in

England for collection of plasma for fractionation was in place. Discussion of NHSE was taken place with fractionators. The REMAP-CAP convalescent plasma trial had restarted on a small scale for immunosuppressed patients.

14.2 Members enquired if the SaBTO ToR should include the collection of plasma for fractionation. The chair commented that SaBTO remit should be clarified and he would discuss this with plasma regulators and report back to the committee.

14.3 Shruthi Narayan highlighted the recent publication of the SHOT Central Alert System report on preventing transfusion delays in bleeding and critically anaemic patients

<https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103190>

**ACTION: Chair to discuss SaBTO remit on plasma collection with regulators for inclusion in the ToR.**



## **CODE OF PRACTICE**

### **Index**

|   |    |
|---|----|
| Introduction .....                                  | 2  |
| The Committee .....                                 | 2  |
| Membership .....                                    | 3  |
| Secretariat .....                                   | 3  |
| Observers .....                                     | 3  |
| Working groups / Sub-Groups .....                   | 3  |
| Roles and Responsibilities .....                    | 3  |
| The Chair's role and responsibilities .....         | 3  |
| SaBTO members' role and responsibilities .....      | 4  |
| The Secretariat's role and responsibilities .....   | 5  |
| Observers' role and responsibilities .....          | 5  |
| Appointment of SaBTO Members .....                  | 6  |
| Declaration of interests .....                      | 6  |
| The Conduct of Business .....                       | 7  |
| Formulation of SaBTO's advice .....                 | 7  |
| Publication of SaBTO's advice .....                 | 8  |
| Publication of meeting papers .....                 | 8  |
| Annual Report .....                                 | 9  |
| Liaison with other Advisory Committees .....        | 9  |
| Annex A: The Seven Principles of Public Life .....  | 10 |
| Annex B: SaBTO's Terms of Reference .....           | 11 |
| Annex C: Guidance on Declarations of Interest ..... | 12 |
| Annex D: Guidance for SaBTO Working Groups .....    | 14 |

## Introduction

- 1 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.
- 2 This Code of Practice should be read in conjunction with the Scientific advisory committees: code of practice - GOV.UK ([www.gov.uk](http://www.gov.uk)) published by the Government Office for Science in 2011.
- 3 This Code of Practice also reflects the seven principles for public life as set out by the Committee on Standards in Public Life (**Annex A**).
- 4 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.
- 5 This Code of Practice also applies to members of any working groups or sub-groups established by SaBTO.

## The Committee

- 6 SaBTO's Terms of Reference are attached at **Annex B**.
- 7 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 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 or by the Health Departments of Wales, Scotland or Northern Ireland.
- 8 Members of the Committee must at all times be accountable for their activities and for the standard of advice they provide. The Department of Health and Social Care is responsible for the framework within which SaBTO operates.
- 9 SaBTO provides its advice through the sponsoring department, the Department of Health and Social Care. Any legal challenge to any action taken on SaBTO's advice or recommendations will be the responsibility of the Department of Health and Social Care rather than of SaBTO.

- 10 SaBTO was set up as an advisory, non-departmental public body (ANDPB), but with effect from 1<sup>st</sup> 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***

- 11 SaBTO comprises the Chair and appointed members only. It is supported by the Secretariat and members of the Secretariat attend meetings. Representatives of the Department of Health, the Welsh Government, the Scottish Government and the Northern Ireland Executive, representatives of other government departments and other advisers known as Observers are also invited to attend SaBTO meetings.
- 12 The Chair and Members are appointed by the Department of Health and Social Care, with the endorsement of the Health Departments of Wales, Scotland and Northern Ireland.

### ***Secretariat***

- 13 The Secretariat for the Committee is comprised of officials from the Department of Health with scientific support from the UK blood services. The secretariat will ensure that there is close liaison between SaBTO, national Departments of Health and other relevant stakeholders.
- 14 These officials should at all times respect SaBTO's independence.

### ***Observers***

- 15 Observers attend meetings for the purpose of providing information and advice as required by SaBTO and will provide liaison between SaBTO and the organisations they represent.

### ***Working groups / sub-groups***

- 16 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.
- 17 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***

- 18 The Chair of SaBTO is accountable to the Department of Health and Social Care for ensuring that SaBTO observes the highest standards of propriety including impartiality, integrity and objectivity in the execution of its role and responsibilities.
- 19 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 the UK Departments of Health, 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***

- 20 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 are encouraged to comment on an issue or question information provided even if it does not relate to their own area of expertise.
- 21 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 the Department of Health and Social Care.

22 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, prepublication 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.

23 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.

24 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 1998.

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

25 The Secretariat supports SaBTO through organising meetings and other matters and by bringing issues of concern to SaBTO's attention. Members of the Secretariat will also provide liaison with other relevant Government and Health Departments committees and structures.



- 26 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.
- 27 Communications between SaBTO and the Department of Health and Social Care will be through the Secretariat, except where it has been agreed that an individual Member should act on SaBTO's behalf.
- 28 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***

- 29 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.
- 30 Observers are encouraged to take an active part in the work of the Committee by advising Members on areas of their own expertise and the views of the organisation they represent.. Observers 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. Observers should also ensure close liaison between SaBTO and their organisations and draw to the Committee's attention any concerns about the working and recommendations of the Committee.

### **Appointment of SaBTO Members**

- 31 The Department of Health and Social Care 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.
- 32 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 the Department of

Health and Social Care in the event of unsatisfactory attendance at meetings or conduct that renders the member unfit to remain in office.

- 33 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 the Department of Health and Social Care, at rates determined by the Department of Health and Social Care.

### ***Declaration of interests***

- 34 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.
- 35 The Secretariat will maintain a register of Members' interests. The register will be updated at least annually and published on the SaBTO website.
- 36 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.
- 37 Guidance on the declaration of interests, including what constitutes an 'interest', is given at **Annex C**. Members may approach the Secretariat if they have any queries.

### **The Conduct of Business**

- 38 SaBTO will usually hold up to four committee meetings a year. These will not be open to the public because SaBTO routinely considers sensitive and confidential information. SaBTO may hold public meetings on specific issues which may attract a wide public interest.
- 39 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.

40 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***

41 In formulating its advice, SaBTO will:

- 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;
- acknowledge any gaps and uncertainties that influence any judgements reached;
- indicate the degree of scrutiny given to the topic and the degree of certainty that can be attached to the judgements given;
- consider the impact of its advice on all stakeholders, and take account of the risk of policies being perceived as unfairly discriminatory;
- take account of any legal requirements, and any other SaBTO recommendations.

42 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.

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

43 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; provide 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.

44 When SaBTO's advice is published, the Secretariat will agree with the Chair, other Committee Members (e.g., 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***

- 45 Agendas, minutes of SaBTO committee meetings, position statements and working group reports will be published on the SaBTO website (subject to considerations of confidentiality: see below).
- 46 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 the Department of Health and Social Care has developed appropriate risk management policies.
- 47 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 1998. 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***

- 48 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 and organisations***

- 49 SaBTO will liaise with other committees and organisations 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**

### **The Seven Principles of Public Life**

#### **Selflessness**

Holders of public office should act solely in terms of the public interest. They should not do so in order to gain financial or other benefits for themselves, their family, or their friends.

#### **Integrity**

Holders of public office should not place themselves under any financial or other obligation to outside individuals or organisations that might seek to influence them in the performance of their official duties.

#### **Objectivity**

In carrying out public business, including making public appointments, awarding contracts, or recommending individuals for rewards and benefits, holders of public office should make choices on merit.

#### **Accountability**

Holders of public office are accountable for their decisions and actions to the public and must submit themselves to whatever scrutiny is appropriate to their office.

#### **Openness**

Holders of public office should be as open as possible about all the decisions and actions that they take. They should give reasons for their decisions and restrict information only when the wider public interest clearly demands.

#### **Honesty**

Holders of public office have a duty to declare any private interests relating to their public duties and to take steps to resolve any conflicts arising in a way that protects the public interest.

#### **Leadership**

Holders of public office should promote and support these principles by leadership and example.

## **Annex B**

## **Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) Terms of Reference [when agreed]**

The Committee will advise Ministers of the UK Government and the Devolved Administrations as well as UK Health Departments on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion / transplantation. Its remit includes providing advice on the microbiological safety of gametes and stem cells, in liaison with the relevant regulatory authorities. The Committee will provide independent advice on risk management for Ministers and UK Health Departments to consider.

In formulating its advice, the Committee will:

- take into account sufficiency of supply, and the need to maintain adequate supplies of blood, cells (including gametes and stem cells), tissues and organs of appropriate quality;
- consider the efficacy of transfusion / transplantation and consider the cost-effectiveness of interventions, including the introduction of new safety measures and/or the reduction, phasing out or withdrawal of current measures;
- interpret and where appropriate, commission risk assessments from a wide range of sources, including Department of Health and Health Protection Agency Analysts, UK Blood Services, other advisory committees such as the Advisory Committee on Dangerous Pathogens, and independent researchers;
- take full account of scientific uncertainty and assumptions used in reaching conclusions, and clearly convey the nature and extent of such uncertainties with its advice;
- identify where research to reduce uncertainty is most urgently required, and where possible identify specific research needs;
- monitor and influence the EU Directives on blood, cells, tissues and organs to ensure that the guidance of the Committee is consistent with the directives in conjunction with the relevant competent authorities;
- consider the potential impact of its advice on both donors and recipients.

## **Annex C**

### **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.

#### **Note**

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.

#### **Types of Interest**

##### ***Personal Interests***

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

- (a) consultancies -- any consultancy, directorship, position in or work for the industry which attracts regular or occasional payments in cash or kind;

(b) fee-paid work -- any work commissioned by the industry for which the member is paid in cash or kind;

(c) 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 eg a university department for which a member is responsible, but is not received by the member personally. The main examples are:

(a) fellowships -- the holding of a fellowship endowed by the industry;

(b) 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:

(i) a grant from a company for the running of a unit or department for which the member is responsible;

(ii) 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;

(iii) 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 D

### Guidance for SaBTO Working Groups: annex to the code of practice

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

- Help frame a common approach to the way in which WGs 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 WG 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: WG Chair and secretariat**

2. Where a WG is drafting clinical guidance, the WG 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, WG chairs should consider with members whether/how to involve wider stakeholder input. This could be through inviting stakeholder representatives to join a WG, 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.

**Responsible owner: WG 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. WG Chairs should plan the most appropriate route for ratification of their group's work with the secretariat.

**Responsible owners: WG Chair and secretariat**