SaBTO

Advisory Committee on the
Safety of Blood, Tissues and Organs

ANNUAL REPORT

2013/14

Contents

Foreword

SaBTO has held slightly fewer full Committee meetings in 2013/14 than in previous years, but has undertaken a substantial and wide-ranging work programme nonetheless.

In the field of tissues and cells, SaBTO completed its complex review of the selection criteria relating to men who have had sex with men as donors of tissues and cells, to remove inconsistencies with the selection of blood donors where possible; and has a near-final draft of its report on issues raised by the donation of starting material for cell-based advanced therapies, which also involved technical complexity and challenging issues. In the field of organs SaBTO has again built on earlier work, to develop advice on the use of organs from donors with cancer or a history of cancer; and has also advised on what should be done following an organ transplant if the donor is subsequently found to have been infected with West Nile Virus. Relating to blood for transfusion, SaBTO considered whether pathogen inactivation technology for platelet concentrates should be introduced by the UK Blood Services. The Committee also completed its review of measures in place to reduce the potential risk of variant Creutzfeldt Jakob (vCJD) disease being transmitted through a blood transfusion, by considering the target to collect 80% of platelet donations by apheresis; and published a summary of all such measures, for completeness and clarity. SaBTO also identified a new topic, hepatitis E in the blood donor population, on which work will begin when the evidence from an ongoing study becomes available.

SaBTO has also provided evidence to the House of Commons Health and Technology Select Committee Inquiry into the screening of blood, tissues and organs, with particular reference to vCJD, a subject on which it has done extensive work over the years.

SaBTO members do all the work on this wide range of issues for no reward except the knowledge that it will improve the care of patients, and external members of working groups do the same. These are people at the top of their profession, recognised experts in their field, with demanding professional commitments, and yet they continue to give generously of their time and expertise to develop SaBTO's advice and guidance. Their dedication is admirable, and much valued.

SaBTO members are, nevertheless, subject to a system of annual review, as employees would be. SaBTO membership is no sinecure, and all members make a real contribution to the work of the Committee. The range of their expertise ensures that well rounded consideration is given to the topics that come before it.

The co-option of external experts in a particular subject to SaBTO working groups is one aspect of the inclusive approach SaBTO adopts. It is also common practice for a report to be shared in draft with key organisations and

individuals with an interest, to gain their feedback. This helps to ensure that SaBTO's advice is authoritative and comprehensive, and has buy-in from those in the NHS and others who will implement it.

SaBTO also aims to be transparent about its work. The published reports give information about how the working group reached its conclusions, but further details are contained in the meeting papers put to SaBTO, and the minutes of SaBTO meetings. All these are published on the SaBTO section of the GOV.UK website.

Professor John Forsythe
Chair, SaBTO

Topics considered by SaBTO in 2013/14

BLOOD

vCJD Risk reduction measures

SaBTO has continued to consider measures to reduce the potential risk of transmitting variant Creutzfeldt-Jakob disease (vCJD) through blood transfusion, in the light of the revised approach to risk assessment developed by the Health Protection Analytical Team at the Department of Health and agreed by the Advisory Committee on Dangerous Pathogens. This approach is consistent with the number of UK cases of clinical vCJD that have been observed, and with the results of a recent research study which found around 1 in 2,000 of the UK general population is likely to have the abnormal prion protein associated with vCJD infection, which could potentially be passed on in donated blood (though it is not known how likely it is that someone with that protein might develop vCJD within their lifetime, if at all). SaBTO's Prion Sub Group is chaired by Professor Marc Turner, who has had a long involvement in the subject both with SaBTO and the UK Blood Services.

Collection of 80% of platelet donations by apheresis, and use of platelet additive solution

In September 2013, SaBTO reviewed the current requirement that UK Blood Services should collect at least 80% of platelet donations by apheresis, a process that makes it possible to collect a dose of platelets from a single donor rather than from a pool of donations from several donors. (Platelet transfusions are usually used to treat, or prevent, the effects of serious blood loss.) This 80% target was set by SaBTO's predecessor committee, the Advisory Committee on the Microbiological Safety of Blood, Tissues and Organs for Transplantation, to reduce the number of donors to whom platelet recipients were exposed, and so their potential risk of vCJD infection. The underpinning assumptions reflected understanding at the time, and these have now changed.

In September, SaBTO considered new modelling of the effectiveness and cost effectiveness of the use of apheresis and additive solution in the production of platelets as a measure to reduce the risk of transmitting vCJD infection. A large number of scenarios were modelled, using varying assumptions about factors such as vCJD prevalence, incubation periods and infectivity, to calculate the number of life years that might be saved by preventing potential future cases of vCJD through the use of apheresis and platelet additive solution. This modelling showed that using additive solution saved life years in all scenarios, while combining it with a lower level of apheresis was more cost effective in all scenarios, and in a number of scenarios resulted in life years saved and cost savings in comparison to current practice. SaBTO therefore endorsed the Prion Sub Group's recommendation that the requirement to produce 80% of platelets by

apheresis should be removed and platelet additive solution should be used for the suspension of platelets.

It is estimated that, for other clinical reasons, around 20% of platelets will continue to be collected by apheresis. The UK Blood Services greatly value the dedication of the platelet donors, who attend special centres to donate by apheresis.

***Note**:* Due to information that has since become available, SaBTO will review this recommendation on the use of platelet additive solution at its meeting in December 2014.

Measures to reduce the risk of vCJD transmission via blood

This use of apheresis was the last of the measures currently in place to reduce the potential risk of transmitting vCJD through blood which SaBTO has reviewed in light of the new risk assessment approach. Other measures, such as leucoreduction, are not being reconsidered as they have many beneficial effects over and above that of reducing potential vCJD risk. SaBTO considered a summary of these measures in December 2013, and confirmed that they should continue unchanged.

For convenient reference, SaBTO has published a summary of the current measures to reduce the potential risk of vCJD transmission by blood on its page of the GOV.UK website.

Use of blood from those born after 1st January 1996 for very young recipients

It is believed that the primary cause of vCJD infection was eating beef and other products from cattle infected with BSE (a degenerative brain disease of cattle and other species). Measures introduced to prevent infected meat from entering the food chain mean that people born after 1st January 1996 are unlikely to have been exposed to BSE through their diet, and so to have a much lower risk of developing vCJD. While other routes of transmission are possible in theory, such as surgery, dental treatment or parent to child, there is no evidence that any such transmission has ever taken place.

The first of this age group became old enough to donate blood at the beginning of 2013. SaBTO had previously recommended that their donations could be used for the transfusion of unborn babies initially, when supplies became available, and then for newborn and young babies. There were concerns, however, that while these donations are thought to carry an extremely low risk of transmitting vCJD, they might carry infections which are common in teenagers and which are not routinely tested for, such as cytomegalovirus, Epstein Barr virus or B19 parvovirus.

A study is therefore being carried out by the Public Health England Blood Borne Virus Unit and NHS Blood and Transplant, funded by the UK Blood Services Forum, to measure the prevalence and attack rate of those infections (that is, the proportion of infected donations and the rate of new infections) in archived blood samples from donors who were 17 years old at the time of donation, and from the general donor population.

As the results of that study will not be available until late 2014, SaBTO decided in June 2013 that the use of blood from donors born after 1st January 1996 for unborn and young babies should not begin until it had been able to consider the findings of the study. These results will be taken into account in a new risk assessment, together with the findings from a study of the prevalence of the abnormal prion protein associated with vCJD in tissues from those born after 1st January 1996, and tissues collected before 1980, which will be available in late 2015.

Use of new donors' first donations

At the same meeting, SaBTO considered whether the current restriction should be removed, to allow the use of first donations for the manufacture of components for the transfusion of unborn babies and infants under one year old.

This restriction was introduced in 1997, because the risk of an infection in the 'window period' being transmitted in a donation from a previously untested donor is slightly higher than from a previously tested donor. There is a very short period (the 'window period') between a donor becoming infected and the infection being detectable, when it could be passed on in that donor's blood. As babies are very vulnerable, they are transfused with components made from second or subsequent donations.

Routine NAT (Nucleic acid Amplification Technology) testing for a range of infections had been introduced since that restriction was put in place, and significantly reduced the window period. Modelling was done which showed the risk of using donations from all donors was only marginally higher than the risk of using only repeat donations.

SaBTO concluded that as there was no particular reason to lift the restriction at that time, such as a shortage of supply, the question should be included in, and considered as part of, the overall risk assessment of the use of blood donated by those born after 1st January 1996 when the study referred to above has been completed.

Pathogen inactivation of platelet concentrates

SaBTO reviewed the pathogen inactivation of platelets in 2010 and, on the basis of the information then available, concluded that it should not be introduced at that time. NHS Blood and Transplant subsequently introduced bacterial screening of platelets in 2011.

In 2013, new evidence was available. The Cochrane systematic review of clinical trials of pathogen reduced platelets was published in March 2013; and in addition, data were now available from all four UK Blood Services on the efficacy of bacterial screening.

SaBTO therefore convened a working group, chaired by Dr Lorna Williamson, to review the three systems for pathogen inactivation of platelets which were then CE marked. One was not yet on the market; the other two were in routine use in a number of countries worldwide, so clinical data on them was available (although only Switzerland had adopted pathogen inactivation nationally, having had no bacterial screening system previously).

The working group reviewed evidence on:

- The efficacy of current infection screening methods, especially for bacteria
- Regulatory and operational considerations
- The efficacy of pathogen inactivation for bacteria, parasites and viruses
- The efficacy and safety of pathogen inactivation treated platelets
- The efficacy of pathogen inactivation in preventing transfusion associated graft-versus-host disease
- Cost effectiveness.

Details of the working group's findings can be found in their report, which was published in April 2014. Broadly, they found that the current measures were extremely effective, and though pathogen inactivation would have a number of benefits, there were some concerns, and cost effectiveness was currently poor. Some of the benefits of pathogen inactivation would not be fully realised until systems for treatment of red cells, as well as platelets, became available.

The recommendation adopted by SaBTO at its meeting in December 2013 was as follows:

"The driver to recommend pathogen inactivation for platelets, in the absence of systems for red cells/whole blood, would be to provide enhanced safety with regard to bacterial transmission. Clear evidence of overall clinical benefit, however, is not apparent at this time:

- Current bacterial screening, combined with diversion pouches and enhanced skin cleansing, is already providing a high degree of bacterial safety, with no reported cases since 2009

- The limitations of pathogen inactivation with regard to certain strains of pathogenic bacterial species remain to be clarified through further studies
- The estimated increase in demand will increase donor exposure and hence potential risks from complications not reduced by either pathogen inactivation or Platelet Additive Solution
- System benefits, such as removal of irradiators and travel deferrals, cannot accrue until there are pathogen inactivation systems suitable for either red cells or whole blood. Under the current circumstances, therefore, the cost-effectiveness of pathogen inactivation remains very low.

For these reasons, implementation of pathogen inactivation of platelets is not currently recommended for the UK Blood Services. The issue should be reviewed again if significant new information becomes available with respect to the issues mentioned above, and/or if costs compared to bacterial screening are significantly reduced."

The working group also made a number of detailed recommendations to the UK Blood Services, which can be found in their published report. One of these was that, given the rapid developments in this field, the UK Blood Services should develop a structure and criteria for evaluating new and existing CE-marked systems to pathogen inactivate blood components, taking account the evidence presented in this review, to remove the need for SaBTO to consider further specific systems in future.

Hepatitis E

In December 2012 SaBTO received information about an increase in the reporting of hepatitis E, associated with the appearance of a new variant of the infection. A study was being carried out jointly by NHS Blood and Transplant and the (then) Health Protection Agency to determine how many of those in the blood donor population might have the infection at the time of donating, and the implications for blood recipients.

In December 2013 SaBTO considered the subject again, in light of the early results of the joint study. It was decided that when the final results of the study became available, SaBTO should set up a working group to review them and consider what action, if any, might need to be taken; options could range from continuing current practice unchanged, through testing patients at increased risk, to selective or universal screening of all donors.

TISSUES AND CELLS

Tissues and cells: MSM donor selection review

(MSM: men who have had sex with men)

In 2011, following a review of the evidence, SaBTO recommended that the lifetime ban on MSM blood donors should be replaced by temporary deferral. SaBTO then turned its attention to MSM donors of tissues and cells, both living and deceased, with a view to removing inconsistencies between donor selection criteria as far as possible.

The working group, led by Dr Lorna Williamson, found their task to be wide-ranging and complex. Apart from the multiplicity of tissues and cells to be considered, and the various organisations involved, the group found a lack of evidence in comparison to that available for the review of blood donors. For example, epidemiological data on donors in the UK was available only for tissue donors handled through the UK Blood Services; no comparable data existed for tissue donors handled through other tissue banks, nor for donors of stem cells, pancreatic islets, hepatocytes or gametes. And calculations of residual virus risk according to different MSM deferral periods were not possible because of the small numbers of donors and because most donors donate only once.

The working group therefore adopted a risk-based approach, and identified factors that would determine the overall risk/benefit balance. These included whether the transplant was life-saving or life-enhancing; supply issues; the need for donor/patient matching; how detailed a donor history was taken; the opportunity to discuss the risks of an individual donor with the potential recipient's clinician, with or without the recipient; product testing and manufacture, and practicability. The group also took account of current legislation, guidance from different sources, and practice in other countries.

Fourteen different tissue and cell products were identified, which were considered in four groups. The recommendations adopted by SaBTO were as follows:

Group 1: Haematopoietic stem cells, whether from family and friends, or unrelated adult donors, or from cord blood. (This included related products from similar donors, such as donor lymphocytes and virus-directed T cells.)

- For family and friends, no deferral (this is current practice)
- For unrelated donors joining a registry, no deferral (this is current practice for Anthony Nolan, but requires a change by the British Bone Marrow Registry)
- For cord blood donors, no deferral (a change for both Anthony Nolan and the British Bone Marrow Registry)

Group 2: Pancreatic islets and hepatocytes

- No deferral (this is current practice)

Group 3: Banked tissues (corneas, heart valves, bone, skin, amnion, tendon)

- Men may donate 12 months after the last MSM contact
- Women may donate 12 months after the last sexual contact with a man who has ever had sex with another man. (This is a change from the current lifetime deferral of both men and women, and is consistent with the deferral of blood donors)

Group 4: Sperm, eggs and embryos

- No deferral (this is current practice).

Full details of the evidence and the working group's considerations for each type of tissue, together with the recommendations, can be found in the published report.

The working group also made a series of observations to help achieve consistency across provider organisations; and noted the value of collecting data on incidence and risk factors of virus positive donations, and samples, as is done for blood donation.

Donation of starting material for cell-based advanced therapies: a SaBTO review

The development and manufacture of cell-based advanced therapies is closely regulated, but discussion between SaBTO and the relevant regulatory bodies identified some open issues relating to the donation of starting material. The Cell-based advanced therapies working group, chaired by Professor Marc Turner, was set up to consider these issues, which concerned donor selection, consenting and testing, and to make recommendations which would maximise donor and patient safety while supporting the development of cellular therapies.

The working group focused on the potential risks of an infection or genetic abnormality being transmitted from a donor to the recipient of a therapy developed from their cells, and how those risks could be mitigated. They looked at CJD among other infections, and concluded that the possibility of a cell line being contaminated by prion disease is a global issue, not one particular to the UK. The group considered that genetic screening of donors would not be productive given our current understanding of the relationship between genetic variation and disease, but that relevant specific genetic tests on the product, related to its intended use, would be sensible.

The group also considered the challenges of a donor giving informed consent, that would remain valid in the face of change and development, given the pace of innovation in this field; and the implications of traceability (which is a regulatory requirement), when information might emerge years after donation, perhaps when a new test was developed, which could have significance for a donor or their family. They concluded it was essential that donors should have full information at the time of donation about what might happen in the future, including the limits to how far that could be foreseen, to enable them to make properly informed decisions.

In developing their recommendations, the group took account of the rapid development of this field, and sought to identify principles which would remain relevant in the light of change, rather than giving detailed guidance which would soon be out of date.

The working group took a very inclusive approach to developing their advice. The membership of the group included expertise in a range of scientific and medical specialties, patient and donor representatives, industry, ethics, research and regulators. The details are in their report. A first draft of their report, including their recommendations, was shared with key groups with an interest in the field, such as commercial and academic therapy developers and researchers, regulators, relevant medical professional organisations and ethicists. The feedback received was considered in detail, and the draft was amended in light of the points raised.

A further opportunity for feedback was the SaBTO Open Meeting scheduled for 28th April, on the topic of Cell-based advanced therapies. SaBTO was due to consider the working group's draft report and recommendations, together with points raised and views expressed at the Open Meeting, at its meeting on 29th April 2014. The final report was subsequently published.

ORGANS

West Nile Virus and solid organ transplantation

West Nile Virus (WNV) infection is spread by mosquitoes, but it can also be transmitted from person to person through blood or tissue, and there is evidence that in a small number of cases, it has been transmitted by solid organ transplantation. WNV has been spreading north and west across southern Europe in recent years, and there was some concern that the UK risk of transplant-transmitted infection might increase. Although this remains a remote possibility, in December 2012 SaBTO decided that it would be helpful to provide advice on what should be done if a donor whose organs had been transplanted was subsequently found to have been infected with the virus. A group led by Professor Kate Gould drew up this advice, which was published in July 2013.

For most people, WNV infection produces few if any symptoms. Around 1 in 150-200 of those infected, however, develop a more severe form of the disease, potentially causing fatal encephalitis, especially if they are elderly or (as transplant recipients are) immunocompromised.

There is no effective treatment for WNV, and therapy is largely supportive. In some cases alpha interferon and immunoglobulin have been beneficial, but alpha interferon needs to be used with caution in the early transplant period, and not all kinds of immunoglobulin contain sufficient antibody to be effective.

The group found no evidence that removing the transplanted organ, if the donor is found to have been infected with WNV, would prevent the development of encephalitis. Equally, there was no evidence to show that a temporary reduction of the recipient's immunosuppression would be effective in allowing the restoration of natural immunity to WNV. Therefore, on the basis of our current knowledge and until an effective treatment is found, the group concluded that careful clinical and virological monitoring, with early diagnosis and supportive therapy, were the best available options.

Transplantation of organs from deceased donors with cancer or a history of cancer

The Donor / Organ Risk Assessment working group – DORA for short – is jointly chaired by Professor John Dark and Professor Chris Watson. It was set up to build on the work by SaBTO published in 2011 which showed that, with some exceptions, organs from donors with primary brain tumours should be used. This broke new ground in analysing data on the outcomes of such transplants to establish the risk/benefit balance of tumours being transmitted via the donated organ in comparison with the risk to a patient of remaining without a transplant.

The DORA group is able to draw on a wealth of data held by NHS Blood and Transplant, which supports organ transplantation throughout the UK, as well as the evidence in published papers. NHS Blood and Transplant collects information on the outcomes of transplants that have taken place, and on those who have consented to be donors, including where no organ is retrieved, or an organ is retrieved but not used.

A prospective organ donor is assessed as fully as possible, but the constraints of the donation process mean that the risks can be minimised but not abolished. The recipient surgeon then has the responsibility of deciding whether to accept a particular organ for a particular patient; and in order to give an informed consent, it is important that the patient is fully aware of both the risks and the benefits. DORA reviewed the evidence and analysed the data relating to deceased donors with cancer or a history of cancer in order to draw up a series of recommendations, and categorise a number of cancers according to their risk of transmission to a transplant recipient. SaBTO endorsed this advice, commending its pragmatic and helpful approach, at its meeting in December 2013.

SaBTO's advice will help clinicians and patients to make their decisions on whether to accept an organ on the basis of evidence. It could enable them to use with confidence some organs they might otherwise hesitate to accept. It will also make it easier for clinicians and patients to consider the issues involved at the time a patient goes onto the waiting list, rather than when an organ becomes available and the time for making decisions is short.

The DORA group's detailed recommendations, together with their advice on the level of risk posed by different cancers, were published in April 2014.

The DORA group is continuing to work on a number of other topics.

GENERAL

House of Commons Science and Technology Select Committee Inquiry

In December 2013, the House of Commons Science and Technology Select Committee began an inquiry into blood, tissue and organ screening. Their particular focus was the potential transmission of vCJD through blood transfusion or the transplantation of organs or tissues, or through medical procedures, as they had received evidence suggesting that vCJD continued to pose a significant risk to UK public health.

SaBTO has an important role in this area given its remit to provide independent scientific advice on the safety of blood, tissues and organs, and issues relating to the risks of vCJD transmission have formed a significant part of its work programme since its inception. The Committee's advice and guidance has been influential in shaping the policies of the government, UK Blood Services and tissue and cell providers, and NHS practice relating to the sourcing, management and use of blood, tissues and organs. In addition a significant programme of research, surveillance, risk assessment and expert consideration has been, and continues to be, undertaken by the Department of Health and a number of other organisations.

The Select Committee asked for written submissions to be sent by mid January 2014, and SaBTO responded. SaBTO considered that an appropriate balance was being struck between taking measures to minimise the potential risk of infections such as vCJD being transmitted through blood transfusion or tissue or organ transplantation, and restricting donation excessively in a way that would impact on supply – while recognising that the underlying assumptions used remain precautionary. SaBTO noted that if use of a blood test for vCJD were proposed, the Committee would wish to consider amongst other issues the levels of sensitivity and specificity of the test, the availability of a confirmatory assay and the views of donors and recipients, particularly of patient groups who require frequent transfusions.

In February 2014 Professor Marc Turner appeared before the Select Committee representing SaBTO, to give oral evidence. Professor Turner is Chair of the SaBTO Prion Sub Group, and also chairs the UK Blood Services Prion Working Group. Then in March Professor Richard Knight gave evidence in his capacity as Director of the National CJD Research and Surveillance Unit; and in April Dr Lorna Williamson, Medical and Research Director of NHS Blood and Transplant, appeared. Both Professor Knight and Dr Williamson are also SaBTO members.

The Select Committee expects to publish its report later in 2014. Meanwhile detailed information, including copies of the written evidence submitted and transcripts of the oral evidence given, are published on the UK Parliament website.

Revised SaBTO Code of Practice

In June 2013, SaBTO approved a revised version of its Code of Practice. This supplements the generic Code of Practice for Scientific Advisory Committees published by the Government Office for Science, which was updated in 2011.

The SaBTO Code of Practice drawn up in 2007, when the Committee was set up, was slightly shortened, simplified and updated, but no material changes were made to members' responsibilities or the conduct of Committee business. The revised Code is published on the SaBTO website.

SaBTO's Work Programme for 2014/15

Current / ongoing topics

- **Use of future donations from those born after 1st January 1996** – including results of risk assessment of vCJD vs other risks, and use of first time donations.

- **Donor / Organ Risk Assessment Working Group (DORA)** – developing Position Papers on a series of subjects as resources allow.

- **Hepatitis E Working Group** – to consider the risk of hepatitis E transmission via blood and what action, if any, should be taken.

Work to begin in 2014/15

- **Review of *Guidance on the microbiological safety of human organs, tissues and cells used in transplantation*** – due in 2014 (ie 3 years after publication in 2011).

- **Donor Deferral** –SaBTO to review blood donor deferral and exclusion criteria related to sexual behaviour, other than MSM and CSW. Suggested next topic: those who have (had sex with a partner who has) been sexually active in areas where AIDS/HIV is common (especially sub-Saharan Africa).

Note: due to overlap in working group membership, the Review of guidance will need to follow the Hepatitis E work, with the Donor deferral work after that (possibly in 2015/16).

Topics on which SaBTO has a watching brief

- **Cryoprecipitate and alternatives** – any alternatives that become licensed, and use of fibrinogen in place of cryoprecipitate.

- **Washing of femoral heads** – the Bone and Tissue Working Group is to report back when data are available from clinical trials of the process developed by NHS Blood and Transplant and the Scottish National Blood Transfusion Service.

- **Testing deceased donors for abnormal prions using splenic / ocular tissue** – testing the feasibility of an alternative approach to a blood test.

SaBTO MEMBERSHIP

Members who left during the year

Several members' terms of appointment ended on 30th November 2013, and not all wished to continue for a further term. The following members left SaBTO:

- Professor John Dark (Solid organ transplant surgeon)
- Professor Joanne Martin (NHS management specialist).

Professor John Dark had been a member of SaBTO since it was established in 2007. His expertise in transplantation was at the heart of SaBTO's remit, and as a result he was involved with a number of working groups over the years. Among these, Professor Dark co-chaired the complex work to update and expand the *Guidance on the microbiological safety of human organs, tissues and cells used in transplantation* in 2011, a document widely used in the NHS; and he was a key member of the working group considering the use of organs from donors with tumours of the central nervous system. Building on this latter work, Professor Dark was co-chair of the DORA working group, whose work is described earlier in this report. Happily for SaBTO, Professor Dark is remaining in this role for a while longer.

Professor Joanne Martin's expertise in NHS management proved helpful in shaping the recommendations of the working group on patient consent for a blood transfusion, and contributed to their successful implementation. Like Professor Dark, Professor Martin was a founder member of SaBTO, and in addition to her working group role, she provided helpful insight to its discussions and consideration of a wide range of topics over the years.

Membership of SaBTO as at 31st March 2014

- Professor John Forsythe (Chair)
- Professor John Cairns (Health economist)
- Dr Paul De Sousa (Regenerative medicine specialist)
- Dr George Galea (Blood/transplant service manager) **
- Professor Kate Gould (Microbiologist/bacteriologist/virologist)
- Mrs Gill Hollis (Patient representative)
- Mrs Catherine Howell (Nurse)
- Professor Richard Knight (Prion disease specialist)
- Dr Harpreet Kohli (Epidemiologist/public health specialist)
- Dr Eithne MacMahon (Microbiologist/bacteriologist/virologist)
- Professor Alison Murdoch (IVF/fertility/stem cell specialist)
- Dr Mallika Sekhar (Haematologist)
- Professor Tom Solomon (Microbiologist/bacteriologist/virologist)
- Dr Glyn Stacey (Stem cell banking)
- Professor Richard Tedder (Microbiologist/bacteriologist/virologist)

- Professor Marc Turner (Haematologist) **
- Professor Anthony Warrens (Immunologist)
- Dr Lorna Williamson (Blood Service Medical Director).

** These members' terms of appointment ended on 31st November 2013, and they did not wish to be re-appointed, but they kindly agreed to be co-opted as members for long enough to complete the work on Donation of starting material for cell-based advanced therapies.

New member

One new member, Dr Glyn Stacey, was co-opted to SaBTO for 2014. Dr Stacey, a member of the Cell-based advanced therapies working group, is Director of the UK Stem Cell Bank at the National Institute for Biological Standards and Control. It was felt that he would strengthen SaBTO's expertise in this area, especially when Professor Marc Turner stood down on completion of the work on Donation of starting material for cell-based advanced therapies.

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