

# SaBTO

**Advisory Committee on the  
Safety of Blood, Tissues and Organs**

## **ANNUAL REPORT**

**2012/13**

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## Foreword

While 2011/12 saw the conclusion of a number of long-running pieces of work, 2012/13 has been, in contrast, a year characterised by the launch of new reviews by SaBTO. Ongoing work has also progressed.

SaBTO has been occupied with a wide range of topics in 2012/13. Following the recommendation made in 2011 that led to a change in the blood donor selection criterion in most of the UK for men who have sex with men, SaBTO has been considering the equivalent criteria for donors of tissues and cells, a complex and difficult task. Work has also continued to ensure the measures to reduce the potential risk of transmitting variant Creutzfeldt-Jakob disease (vCJD) are based on the latest evidence. Those born since 1<sup>st</sup> January 1996, when measures were in place to remove BSE from the food chain, are beginning to be eligible to donate blood, and SaBTO has considered a number of related issues. Discussions that began in 2011/12 about the microbiological and other risks associated with cell based advanced therapies have resulted in a new Working Group being set up. A second new Group is reviewing the risks that may prevent organs from being utilised for transplantation, building on SaBTO's advice in 2012 on the use of organs from donors with brain tumours. And finally, SaBTO members are developing advice to guide those involved in situations where organs have been transplanted from a donor subsequently found to be infected with West Nile Virus.

SaBTO has undergone some changes this year. The status of the Committee has altered, though we do not expect it to change the way we work. More significantly, a number of the Committee's members left this year, all of them founder members; and we have been fortunate enough to recruit some high calibre new members.

Further details of all these items can be found in the following pages.

SaBTO members continue to give most generously of their time and expertise to consider issues referred to them, and to develop SaBTO's advice, ensuring it is scientifically rigorous, evidence based and impartial. SaBTO members are not remunerated, and their dedication is admirable and greatly appreciated.

I would also like to pay tribute to the Health Protection Analytical Team at the Department of Health. Their data analysis and modelling has underpinned SaBTO's considerations of many topics over the years, particularly in the area of the risk of transmitting infections through transfusion or transplantation. Their contribution has been, and continues to be, invaluable.

Although SaBTO's running costs are minimal, the Committee and its Secretariat cannot remain immune to the requirement for financial stringency.

Our work programme has been carefully reviewed, to ensure the work we are undertaking is essential in order to fulfil our remit and advise UK Ministers and Health Departments on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion and transplantation.

Professor John Forsythe  
Chair, SaBTO

## Topics considered by SaBTO in 2012/13

### BLOOD

#### **vCJD Risk reduction measures**

Part of SaBTO's role is to advise on potential measures to reduce the risk of transmitting variant Creutzfeldt-Jakob disease (vCJD) through blood transfusion, and ensure that such measures are based on the latest evidence. SaBTO's Prion Sub Group, chaired by Professor Marc Turner, has been reviewing the measures in place in light of the revised approach to risk assessment developed since 2011 by the Health Protection Analytical Team at the Department of Health, which is in keeping with the number of UK clinical cases of vCJD that have been observed. This approach has been agreed by the Advisory Committee on Dangerous Pathogens (ACDP), and is described in detail in a paper published in spring 2013 at [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/186959/risk\\_assessment\\_Feb\\_2013.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/186959/risk_assessment_Feb_2013.pdf).

Another important development this year has been the completion of a research study to measure the prevalence of the abnormal prion protein associated with vCJD in stored samples of appendix tissues, removed since 2000 from patients born between 1941 and 1985. The abnormal protein was found in 16 of the 32,441 samples examined, giving a prevalence of approximately 1 in 2,000 (with a 95% Confidence Interval of 1 in 3,500 to 1 in 1,250). Taking a precautionary approach, this is taken as an indication of the prevalence of asymptomatic vCJD infection in the general population which was exposed to BSE, although it is not actually known if someone with that protein is likely to develop vCJD within their lifetime, if at all. A statement by ACDP on the occurrence of vCJD and the prevalence of infection in the UK population is published at <http://media.dh.gov.uk/network/261/files/2012/08/ACDP-statement-vCJD-occurrence-and-prevalence-Jul-2012.pdf>.

#### ***Sourcing plasma for importation***

In March 2012, SaBTO reviewed the importation of fresh frozen plasma (FFP) to treat those born after 1<sup>st</sup> January 1996 and patients with Thrombotic Thrombocytopenic Purpura (TTP), who need frequent transfusions. They concluded that this importation should continue, and agreed that the use of imported plasma should not be extended for the treatment of other groups of patients.

SaBTO also reviewed and updated advice on which countries would be suitable as a source of such imported plasma. The Health Protection Analytical Team reviewed their previous assessment of the prevalence of subclinical vCJD in other countries relative to that in the UK, in light of the revised risk assessment and any new data available. This prevalence was estimated using a number of different methods. On the basis of their work, SaBTO concluded that imported single donor plasma should be sourced from

countries with a prevalence of subclinical vCJD at least 2.5 logs lower than the UK by all assessment methods, 3 logs (ie 1,000 times) lower by some. The Health Protection Analytical Team's paper, giving the details of prevalence in various countries, is published at <https://www.gov.uk/government/publications/sourcing-blood-plasma-for-import-into-the-uk>.

### ***Prion filtration of red blood cells***

SaBTO has considered the use of a prion filtration technology to reduce the potential risk of vCJD transmission on a number of occasions. In 2009 they made a provisional recommendation that it should be introduced, depending on the outcome of a research trial to test whether its use made red cell transfusion less safe. This trial, PRISM A, concluded that prion filtration did not reduce the overall transfusion safety<sup>1</sup>, which SaBTO accepted at its meeting in March 2012. Before deciding on a recommendation, however, they decided to await the findings of the study of stored appendix samples, as well as further results of animal trials of the filter's efficacy which were under way.

One of the trials was completed in 2012, and the other is still ongoing. Full details will be published by the researchers in due course. SaBTO reviewed their findings in December 2012, along with other evidence, and updated modelling of the cost effectiveness of prion filtration as a potential vCJD risk reduction measure using ACDP's agreed risk assessment. SaBTO concluded that the evidence did not currently support the introduction of this technology, and rescinded its earlier provisional recommendation. They agreed the matter will be kept under review, however, and considered again as new evidence becomes available.

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<sup>1</sup> A summary of the report of the PRISM A trial is published at <http://www.ncbi.nlm.nih.gov/pubmed/23294293>

## **Those born after 1<sup>st</sup> January 1996**

The evidence leads us to believe that consuming products from cattle infected with BSE was the primary cause of vCJD. Measures introduced to safeguard the food chain mean that those born after 1<sup>st</sup> January 1996 can be presumed not to have been exposed to BSE through their diet, and so to be at lower risk of developing vCJD. Theoretically other routes of transmission may exist, such as surgery, dental treatment or parent to child, but there is no evidence of any such transmission ever having occurred.

This group receives imported FFP, to avoid exposing them to potential vCJD transmission from an infected UK blood donor. This continues even now some are more than 16 years old and so are treated in adult rather than paediatric services.

During 2012/13, SaBTO has considered those born after 1<sup>st</sup> January 1996 both as potential blood donors and as recipients of a blood transfusion.

### ***Those born after 1<sup>st</sup> January 1996 as blood donors***

#### **Prioritisation of recipients**

The first of this group became old enough to donate blood at the beginning of 2013. The risk that they might pass on vCJD infection in their blood is assumed to be extremely low, and the UK Blood Services asked SaBTO to advise on which patient groups should potentially be prioritised to receive it.

Three options were presented which, it was noted, were not mutually exclusive. These were:

- to supply the youngest patients first;
- to supply patients who had not previously been exposed to a blood borne risk of vCJD, such as those not previously transfused; or
- to supply those at greatest risk, such as haemoglobinopathy patients who are exposed to multiple transfusions.

SaBTO was clear that members would not want to make value judgements about the needs of the different patient groups, so practical considerations were important. It was agreed that potentially these donations should be used first for intrauterine transfusions, newborns and infants. This would be easy in practise as separate blood bags are produced for these patients, and would maximise the benefit as they are likely to live the longest after transfusion. When the supply became sufficient, those who had not yet been exposed should receive it; after that, those who need multiple transfusions and are therefore at greater risk.

## **Use of first donations**

Donated blood is tested for a range of viral infections such as Hepatitis C and HIV, but if the infection is very recent it may not be detected: this is the 'window period'. There is clear evidence that first time blood donors are more likely than repeat donors to have such viral infections, so the risk of passing on an infection in the 'window period' in first donations is also greater. For this reason, first donations are not used for transfusions to newborns and infants, who are particularly vulnerable. This measure was introduced in 1997, following a recommendation by MSBT<sup>2</sup>, although since then the introduction of NAT (Nucleic acid Amplification Technology) testing has reduced the window period.

FFP for newborns and infants is imported and treated to kill viral infections, as it is for others born after 1<sup>st</sup> January 1996, but no such process is available for red blood cells or (currently) for platelet concentrates. Components from UK repeat donors are therefore used, with a theoretical risk of vCJD infection.

SaBTO was asked to consider whether first donations from donors born after 1<sup>st</sup> January 1996 should be given to newborns and infants, as modelling showed there might be sufficient to supply components two or three years earlier than if only repeat donations were used. A detailed comparative assessment of viral risk compared to vCJD risk is being carried out, and the results will be known in 2013/14.

SaBTO agreed that samples for testing could be taken from these donors before their 17<sup>th</sup> birthday, allowing full donations to be taken as soon as possible.

### ***Those born after 1<sup>st</sup> January 1996 as transfusion recipients***

Anyone who receives a blood transfusion is excluded from donating blood. This measure was introduced in 2004, following the first report of vCJD transmission through a blood transfusion, but it also serves to stop any risk of diseases being 'recycled' within the population, and some countries have a similar ban for reasons unrelated to vCJD.

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<sup>2</sup> Advisory Committee on the Microbiological Safety of Blood, Tissues and Organs, the predecessor of SaBTO.



## Topics considered by SaBTO in 2012/13

### TISSUES AND CELLS

#### **Tissues and cells: MSM donor selection review**

In November 2011, the blood donor selection criterion relating to men who have had sex with men (MSM) was changed in England, Scotland and Wales, following a recommendation by SaBTO. A SaBTO Working Group had reviewed the evidence, and found it now supported a temporary deferral of 12 months from the last MSM contact, rather than lifetime deferral.

SaBTO then turned its attention to the donor selection criteria relating to MSM donors of tissues and cells, and any anomalies between their exclusion and that of MSM blood donors. A Working Group was set up in spring 2012, chaired by Dr Lorna Williamson. The Group included members from groups representing gay and bisexual men and relevant patient groups as well as experts in a range of medical specialties and in epidemiology.

The Group reviewed data on generic virus risks, and considered tissue-specific infection risks such as HHV-8<sup>3</sup>. Unfortunately they found that while the UK Blood Services could provide epidemiological data for tissue donors, no such data were available from other tissue banks for tissue donors or for donors of stem cells, pancreatic islets, or gametes. The Group therefore adopted a risk-based approach, and identified factors that would determine the overall risk/benefit balance. These included whether the tissue or cell transplant was life-enhancing or life-saving; supply issues; the need for donor/patient matching; the amount of detail recorded about the donor; product testing and manufacture, and practicability.

The Working Group went through three stages to develop their recommendations for different tissues and cells. First, they issued a standard questionnaire to Group members to gather information on how the factors listed above applied to each type of individual tissue/cell product. In some cases, they sought further information on current practice through professional societies. Then, based on these factors, they divided the 11 products into four groups - haematopoietic stem cells (family and friends, unrelated donors, and cord blood); pancreatic islets and hepatocytes; banked tissues (skin, cornea, heart valves, amnion, bone and tendon), and gametes and embryos for reproductive purposes (ie not for derivation of cell lines). Finally, using data from the survey, they carried out risk-based assessments on the four groups of products.

The Working Group's report and recommendations will be put to the full SaBTO committee at its meeting in June 2013.

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<sup>3</sup> HHV-8: Human herpesvirus 8. This causes cancers (eg Kaposi's sarcoma), especially in immunosuppressed people including AIDS patients. Gay and bisexual men are more susceptible to infection, though transmission routes are not well understood.

## **Cell based advanced therapies**

Questions about potential risks relating to cell derived medicinal products were raised by SaBTO members some time ago. In February 2012, SaBTO members met with representatives of the regulatory bodies that operate in this area and cover the various stages from initial donation to authorisation of cell derived medicinal products: the Human Fertilisation and Embryology Authority (HFEA), the Human Tissue Authority (HTA) and the Medicines and Healthcare products Regulatory Agency (MHRA).

SaBTO was then asked for advice by the UK National Clinical Human Embryonic Stem Cell Forum. This group is involved in the derivation and banking of human embryonic stem cells from IVF embryos, and had met with experts in transmissible spongiform encephalopathies (prion diseases such as vCJD) and tissue banking, to explore the possibilities of such infection in stem cells and other tissues intended for clinical use.

It was agreed that some of the issues raised lay outside the regulators' remit, and in late 2012 SaBTO set up a Working Group chaired by Professor Marc Turner to look into them. The Group's remit is to review those risks associated with Cell Based Advanced Therapies which originate in the starting donor material, in particular those relating to donor selection, consenting and testing; and to make recommendations to SaBTO on how these can be optimised in order to support the development of Cellular Therapies in the UK whilst maximising donor and patient safety.

The work breaks into three main areas:

- infectious agents in donors, which could cause disease in recipients of a therapy developed from their cells
- genetic risks in donors, which could cause disease in therapy recipients
- issues for donors and therapy recipients arising from traceability, and the nature of informed consent.

### ***Infectious agents in donors***

The Working Group will consider which infectious agents are relevant, both those which are currently screened for and others such as endogenous retroviruses, prion diseases such as vCJD, and infections which may be insignificant for a healthy person, but more serious for someone with a specific disease or with suppressed immunity. These risks may vary depending on the type of tissues/cells involved, the way in which the therapy is to be used, and the geographical population from which the donor comes.

The Working Group will consider donor selection procedures, taking as a starting point the procedures currently in place for donors of blood, tissue, haematopoietic stem cell and solid organ transplant donation. They will also

look at testing strategies, and consider whether testing should be applied to the donor, the donated tissue or cells, and/or the cultured product which is subsequently used to manufacture a therapy.

### ***Genetic risks in donors***

As with infectious agents, the risk arising from a genetic abnormality in the donor will vary according to factors such as its nature, the nature of the condition to be treated by the therapy and characteristics of the recipient. The Working Group will consider which genetic abnormalities could result in harm to the recipient, or could damage the efficacy of the therapy.

The Group will also look at the genetic screening of donors.

### ***Consent and traceability***

A donor must give consent for their material to be used to make a cell-based therapy, and it is a fundamental principle that such consent must be based on an informed understanding of the potential consequences. Records are kept to ensure that both the original donor of the starter material for a therapy, and subsequent recipients of that therapy, can be traced. This raises some complex and sensitive issues.

Some such issues are routinely encountered in the context of blood, organ and tissue donation and transplantation currently. Clearly there are implications for a donor if screening shows they have an infectious or genetic problem, or if a recipient of the therapy manufactured from their cells should develop an infectious or genetic disease.

Additional issues are thrown up, however, by the fact that a therapy may be used for many years after the original donation of the material used to create it. For example, the Working Group will consider the implications for a donor or their family if a recipient develops a disease years after their donation; or the implications for recipients if a donor should develop a disease years after donating, which may have a longstanding infectious or genetic basis. The disease that emerges may be one not known at the time the donation was made, so not taken into consideration when consent was given.

The Working Group expects to report to SaBTO early in 2014.

SaBTO plans to make cellular therapies the subject of the next SaBTO Open Meeting, to share information with, and gather feedback from, interested members of the public including cell-based therapy developers, patient groups, healthcare staff and others.

## **Topics considered by SaBTO 2012/13 ORGANS**

### **Risk assessment of donors and organs for transplantation**

In 2011, SaBTO published recommendations on the use of organs for transplantation from donors with cerebral tumours. The evidence showed that in most cases, using such organs gained additional years of life for patients awaiting transplants.

In late 2012, SaBTO set up the Donor / Organ Risk Assessment Working Group – known as DORA for short – under the joint chairmanship of Professor John Dark and Professor Chris Watson, to build on that earlier work. DORA is to consider a range of factors that might lead a clinician to refuse an offered organ, and review the evidence, with the aim of producing advice that will support clinicians and inform consent. The decision to accept or refuse an organ is for the transplanting surgeon, in agreement with the patient, but clear guidance on specific risks, with supporting evidence, would be of great help. It is hoped that the advice will result in fewer organs being rejected unnecessarily, and more patients being successfully transplanted.

DORA members agreed that this is not a single project, but a programme of work, with different strands being undertaken to different timescales. The Group will produce a series of Position Papers, which in time will build into wide ranging guidance. In due course it is envisaged that a web-based repository of knowledge of use to the transplant community will be available.

The first topics to be addressed are:

- The results of virological tests carried out at the time of potential organ donation, and their correct interpretation, including:
  - i. Virological reactive tests available at the time of the organ donation, not later confirmed; and
  - ii. Confirmed positive virological tests available at the time of donation. Currently test results showing low level reactivity are blocking some transplants unnecessarily;
- Drug abuse in a potential organ donor. For this, information will be needed on factors such as what drugs the donor had taken, and how recently; the effects of those drugs on the organs, and the infection risk associated with different types of drug-taking;
- Cancer in a potential organ donor. This will build on work shortly to be published on the transmission of cancer by transplantation.

In parallel, an additional paper on both “anatomical oddities” and rare pre-existing medical conditions in donated organs, drawing on the published literature rather than on data from NHS Blood and Transplant (NHSBT), will

be developed. This work will be led by the DORA Chairs, but carried through by a further set of experts, predominantly surgeons, rather than the main DORA group.

DORA is able to draw on a wealth of data from NHSBT, which supports organ transplantation for the entire UK by providing donor organ matching and allocation services and recording heart, kidney, liver, lung and cornea transplants. Detailed information is captured by NHSBT on potential donors who have given consent for donation, including on potential donors where no organ is retrieved, and on the reasons for an organ being retrieved but not used. The difficulty is how to capture data on those who never become donors (ie no consent for donation is taken) and so are not on the database.

Much of the relevant information is in free text, unfortunately, making it difficult to access and analyse. The work currently under way is to extract the relevant data. Early analysis will show the numbers of cases in the different categories, and help DORA prioritise the areas where its resources can be directed to best effect.

## **West Nile Virus and solid organ transplantation**

West Nile Virus (WNV), a blood-borne virus which is carried by mosquitoes, has been spreading across southern Europe in recent years, and was predicted to move further north and west in 2012. SaBTO was kept informed of moves by NHSBT to test donated blood rather than deferring donors who had recently returned from areas affected by WNV, because it was feared the number of donors who might have to be deferred could have an impact on the blood supply. In the event, NHSBT screened 28,973 donations for WNV from May to the end of December 2012, with no infected samples being detected.

There is evidence that WNV can be transmitted by organ transplantation as well as by blood or tissue, though the number of cases is very low even where WNV is endemic. WNV infection in most people produces few if any symptoms, but it is more serious for people who are immunosuppressed, as organ transplant recipients are: up to half of them may develop symptoms, with encephalitis and/or a poliomyelitis-like syndrome more likely than in the wider population, and more likely to be fatal.

At its meeting in December 2012, SaBTO considered the scenario of an organ donor testing positive for WNV, but the test results becoming available only after their organs have been transplanted. SaBTO decided that, although this was currently a remote possibility, circumstances might change, and it would be helpful to have advice in place about how such a situation should be managed.

A group of experts led by Professor Kate Gould accordingly is working to develop such advice. SaBTO expects to consider the final draft at its meeting in June 2013.

## SaBTO's work programme for 2013/14

SaBTO's work programme for 2013/14 includes the following:

- Ongoing consideration of the efficacy and appropriateness of measures to reduce the potential risk of transmitting vCJD and other infections through blood transfusion, both measures already in place, and any new measures proposed.
- Ongoing consideration of issues relating to those born after 1<sup>st</sup> January 1996, particularly as blood donors.
- Review of the donor selection criterion relating to men who have had sex with men, for donation of tissues and cells.
- Ongoing consideration of the microbiological and other risks relating to cellular therapy, particularly with respect to donor selection, consenting and testing.
- Ongoing consideration of risks associated with the donors of organs for transplantation, and whether those risks make the organs unsuitable for use.
- Development of advice for the eventuality that an organ donor is found to be infected with West Nile Virus, but the test results become available only after the organs have been transplanted.
- When significant new information becomes available:
  - Consideration of the deferral of commercial sex workers from blood donation, when new evidence is available on compliance with the current deferral policy and on rates of blood borne viral infection in this group;
  - Consideration of the use of prion reduction technology for red blood cells;
  - The use of cryoprecipitate and any licensed / potential alternatives;
  - Washing of femoral heads, when data are available from clinical trials.

## SaBTO membership

### Members who left

SaBTO lost some longstanding members during 2012/13.

Professor Deirdre Kelly stood down from SaBTO in September 2012. She left the Committee before the end of her second term when she was appointed as Chair of the Implementation Advisory Group for Safe and Sustainable Cardiac Surgery, overseeing the reduction in the number of cardiac units. Professor Kelly contributed significantly to SaBTO's work: most notably, she chaired the working group reviewing the blood donor selection criteria relating to sexual behaviour. Guiding this review was a task of considerable scope and great sensitivity. The report and recommendation led to a change in the deferral criterion for men who have had sex with men in England, Wales and Scotland, which is still under consideration in Northern Ireland: its scientific rigour and impartiality carried conviction, changing practice and reassuring many potential donors that deferral is evidence-based and not discriminatory.

At the end of November 2012, three other members reached the end of their appointment terms.

Professor Peter Braude contributed to a number of initiatives over the last five years, in particular to the updated and expanded *Guidance on the Microbiological Safety of Human Organs, Tissues and Cells used in Transplantation* which is used so widely in the NHS. He was also influential in raising the issue of risks associated with cellular therapies, though having helped shape the work, sadly he retired just as it was getting under way.

Mr Elwyn Nicol was SaBTO's patient representative, working most ably to keep the patient's viewpoint at the heart of SaBTO's thinking. He played a large part in the success of SaBTO's Open Meetings, and contributed significantly to the working group on valid patient consent for a blood transfusion. The recommendations on consent are increasingly being implemented in the NHS, improving patients' experience of a blood transfusion.

Professor Hamish Simpson, like the other three departing members, had been with SaBTO since its inception in 2007, and contributed to meetings and initiatives over the years. Professor Simpson was, in particular, a valuable member of the Bone and Tissues working group, reviewing new safety measures.

SaBTO had a longer standing vacancy left by Dr Mike Potter, who left in 2011, and in 2012 a recruitment exercise was carried out. A number of excellent applications were received, whose calibre reflected the importance of the work SaBTO undertakes. The new members were put straight to work, with a Committee meeting within two weeks of their appointment, and most have



already had an opportunity to contribute their expertise to SaBTO's working groups.

## Current membership

(New members are marked with an asterisk)

Professor John Forsythe	Chair
Professor John Cairns	Health economist
Professor John Dark	Solid organ transplant surgeon
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	Epidemiology/public health specialist
Dr Eithne MacMahon	Microbiologist/bacteriologist/virologist
Professor Joanne Martin	NHS management specialist
Professor Alison Murdoch *	IVF/fertility/stem cell specialist
Dr Mallika Sekhar *	Haematologist
Professor Tom Solomon *	Microbiologist/bacteriologist/virologist
Professor Richard Tedder	Microbiologist/bacteriologist/virologist
Professor Marc Turner	Haematologist
Professor Anthony Warrens	Immunologist
Dr Lorna Williamson	Medical Director, blood services

## SaBTO's change of status

With effect from 1<sup>st</sup> December 2012, SaBTO (along with a number of other bodies) changed from an Advisory Non-Departmental Public Body to a Departmental Expert Committee. This resulted from the Cabinet Office Public Bodies review, whose findings were announced in October 2010.

The review was conducted as part of the Government's ongoing commitment to increase the transparency and accountability of public services and reduce their number and cost. It looked at the committees, groups and panels that provide expert advice to the Government, among others. It was recognised that there is a clear and continuing need for the provision of independent expert advice to Ministers and the Department: the changes ensure this continues, but is provided in a more flexible and appropriate way, with a reduced administrative burden. For example, as SaBTO is no longer a public body, Ministers will not need to have a role in the appointments process.

The change is not intended to alter the way SaBTO works. The Committee's remit covers the whole of the UK, and SaBTO will continue to provide advice to all four Health Departments. Wales, Scotland and Northern Ireland will continue to play a part in the appointment of SaBTO members and in setting the topics SaBTO considers.

The Chair and Members will continue to be appointed on the basis of their individual expertise, through a rigorous, open and transparent appointment process, to ensure that SaBTO continues to consist of independent experts. However in future, appointments will be made by the Department of Health Senior Responsible Officer, currently Dr Felicity Harvey CBE, Director General, Public Health, rather than by Ministers.

In addition SaBTO, like all Scientific Advisory Committees, both Expert Committees and Advisory Non-Departmental Public Bodies, will be covered by the Code of Practice for Scientific Advisory Committees issued by the Government Office for Science, which is published at <http://www.bis.gov.uk/assets/goscience/docs/c/11-1382-code-of-practice-scientific-advisory-committees.pdf>.

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