RESPONSE TO HOUSE OF LORDS SCIENCE AND TECHNOLOGY COMMITTEE CALL FOR EVIDENCE

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 on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion / transplantation. Its remit includes providing independent advice on the microbiological safety of gametes and stem cells, in liaison with the relevant regulatory authorities, and risk management options for Ministers and UK Health Departments to consider.

SaBTO does not fund research; however, we are actively interested in research with a direct relevance to the work of the committee, and to the safety of recipients of blood, tissues, organs and cells. As such, we have asked for preliminary and final results of research from government agencies such as NHSBT and HPA as well as relevant research from major academic institutions that are involved in relevant research. This information forms the basis of our decision-making platform.

Much of SaBTO’s focus over the first two years of its existence has been on protecting the blood supply from vCJD. Nearly three million units of blood components are issued annually in the UK, and it is well established that vCJD can be transmitted through blood transfusion if the donor is infected.

The challenges of protecting the blood supply for vCJD are many and complex.

1. We do not know the prevalence of vCJD in the population;
2. We do not know if carriers of the disease who may be pre- or sub-clinical can pass it on through blood donations;
3. We do not know if different people have different susceptibility to developing vCJD following exposure to the abnormal prion;
4. We do not know how much of the abnormal prion the recipient would have to receive in order to develop clinical vCJD.

These uncertainties make management of this potential problem very challenging. For any intervention, SaBTO must consider its scientific basis, its potential clinical benefits, the effect the measure may have on blood supplies, and the cost-effectiveness of such an approach. With so many unknowns, decision-making can be very difficult. Many of the recommendations on vCJD and blood, taken by SaBTO and its predecessor committees, have therefore been on a precautionary basis. It may be that some measures are unnecessary; however, while so many uncertainties
exist, it is unlikely that any will be relaxed. This of course has a high financial cost. SaBTO may therefore be making hugely complex recommendations on public health without having complete fundamental information.

The HoL STC intends to focus on:

- How decisions are made to fund research to meet societal needs
- The balance of funding for targeted versus unsolicited response-mode curiosity-driven research and
- How research is commissioned in Government departments and agencies

On these points:

- **SaBTO**, as a scientific advisory committee, must be seen to be making decisions based on robust scientific information whenever possible. Departments asking for advice from scientific advisory committees must, where possible, identify and provide information to aid the committee’s deliberations. This requires sourcing and assessment of the information in relation to the questions asked by the scientific committee;

- “Societal needs” must be clearly defined. The make-up and terms of reference of advisory committees should dovetail with these needs and therefore the research that is being prioritised. In SaBTO’s case, the committee’s priority is the safety of those receiving blood, tissues and organs, not least as such treatment is generally necessitated by illness. Beyond this, general public safety (for example, in relation to a disease such as vCJD) must be taken into account by a committee where an intervention recommended for a small number of individuals has an impact on the whole community;

- Direct research into patient safety is challenging;

- Identifying areas of economic importance for research may not be straightforward. For example, a lack of knowledge on the various aspects of vCJD may result in precautionary measures that divert money from other important areas of healthcare;

- Certain aspects of research relevant to SaBTO have been developed by the private sector; as such the research may need full independent verification before implementation of an intervention. Private companies have a legitimate interest in the outcomes of advisory committee deliberations but decisions should lie with the committee alone;

- Government agencies (such as NHS Blood & Transplant and Health Protection Agency) must have the resource to carry out research at the behest of advisory committees if those committees are to base their decisions on a sound scientific platform;

- SaBTO’s terms of reference states that the committee will “identify where research to reduce uncertainty is most urgently required, and where possible identify specific research needs”. It is quite right that independent advisory committees are empowerment to do this, but it is important that there is a mechanism in place to monitor progress.
In summary, independent advisory committees are important stakeholders for research. Their involvement at an early stage of commissioning research is important in ensuring that such research is relevant to areas of interest as identified by such committees. This approach would ensure that the advice from such committees is based on the best possible evidence. Committees like SaBTO are well-placed to comment on research needs. Departments often seek advice from such expert committees on research needs and in turn feedback to committees on progress with studies should be an important part of the process.

John Forsythe
SaBTO Chair