NHSBT has reviewed the proposals to change the legislation regarding authorisation of deceased organ donation in Scotland. As the Organ Donor Organisation for the UK, we wish to make it clear that we will work within the legislative systems set out by each of the four UK governments. We have worked closely with policy officials in Wales to make sure that the Human Transplantation (Wales) Act is implemented smoothly and we would expect to provide the same level of support for any legislative change in Scotland.

The comments that follow therefore are limited to three areas:

- Will it be possible to implement the proposals operationally?
- Will implementation increase costs?
- Will the proposals achieve their objective of providing more deceased donor organs for transplantation?

**Will it be possible to implement the proposals operationally?**

**NHS Organ Donor Register**

A new Organ Donor Register (ODR) has been built to meet the requirements of the Human Transplantation (Wales) Bill and therefore allows anyone in the UK to register:

- A decision to donate some or all organs
- A decision not to donate any organs
- The names of up to two representatives to make the organ donation decision for the registrant.

This broadly supports the proposed Scottish legislation but with some important differences.

If you choose to donate only some organs then the presumption is that you have refused to donate those which you have excluded. If you appoint a representative then they can make a decision about all organs: it is not possible to make your own decision about some organs and leave it to your representative to decide about others either for transplantation or other purposes.

Consequently the new ODR cannot currently accommodate all the provisions in the proposed Scottish legislation, specifically recording the names of three proxies and enabling the registrant to make a decision about some organs and leaving it to proxies to make decisions on others. We do not believe it can easily be changed to enable these provisions without disabling functions required by legislation in other parts of the UK.
Proxy decision making

The terminology used in the rest of the UK is for an appointed representative rather than a proxy and it would be simpler if the same terminology were to be used throughout. More importantly the Register and NHSBT’s supporting systems, which were developed in collaboration with representatives from all four Health Departments, are set up so that anyone who wants to appoint a representative must do so in writing and have this witnessed before the names are entered onto the Register. Only two people can be appointed as the NHS ODR can only accommodate two names and each proxy/representative has equal status. Unless the appointment provides that they are appointed to act only jointly, the default position is that the Appointed Representatives can make the decision jointly or separately. This means that they do not have to agree, so one can give consent regardless of what the other representative decides.

Under the Data Protection Action, NHSBT needs authorisation from the representative to store their details on the Register and, for this appointment to be binding, it needs to be witnessed by an independent person. We do not believe we are able to hold personal data (i.e. that of the proxy) unless the individual has authorised us to do so and therefore it would not be possible for someone to enter the personal details of their desired proxy on line without advance authorisation in writing.

We note that should it be impossible to contact the proxies in a reasonable time, the Authorised Investigating Person (AIP) can proceed without their contribution. We are concerned that should the proxy then appear before the retrieval operation has started and say that the individual did not wish to be a donor then it is very unlikely that the retrieval team would be prepared to operate, even if authorised to do so by the AIP. If the operation is already underway when the proxy makes it known that the person did not wish to donate then there may be negative publicity, undermining trust in the system.

Authorised Investigating Person

It would be helpful to clarify the role and objective of the Authorised Investigating Person. Are they there to:

1. Prevent unauthorised removal of organs (as in the New South Wales model)?
2. Ensure organs are removed when authorisation exists?

In this response we have assumed their role is to ensure organs are removed when authorisation exists.

Organ donation and transplantation systems throughout the world are heavily reliant on public trust and confidence. For example, although both the Human Tissue Act and the Human Tissue Act Scotland allow an individual to consent/authorise organ donation for themselves without reference to their family, in reality, if the family object to organ donation, it is exceptionally rare for their wishes to be ignored. Very occasionally in the US legal opinion has been obtained to uphold the wishes of the individual and this tends to attract
considerable and adverse publicity. In the UK, the family’s wishes have always been taken into account unless there is clear evidence that the donor has had no contact with family members since joining the Register.

We believe that the role of the AIP is inconsistent with the role of Hospital Clinicians and Specialist Nurses and there is a potential for a conflict of interest. If the Hospital Clinicians and Specialist Nurses were to perform the role of the Authorised Investigating Person this might put them into conflict with the potential donor’s family. For the doctors and nurses in intensive care, their care of the patient who has become a potential donor will have included care for their family during their time in intensive care. Specialist Nurses are responsible for securing authorisation for organ donation, whether that be asking families to honour an intention to donate as recorded on the Register or asking families to make a donation decision on behalf of their relative. Once authorisation is secured working closely with families to gather information about the medical, social and behavioural history of the donor is critical to reducing the risks associated with transplanting donated organs. Specialist Nurses also provide care for the family during the period of donation.

It is not clear who might be appointed to perform the AIP role. It appears to require the application of various legal tests to determine whether donation can proceed regardless of what the family want, either seeking views from a proxy or authorising donation by law. We think that hospital clinicians and nurses are unlikely to be comfortable performing the AIP role if there is a risk that it may bring them into conflict with families.

We think the role of the AIP in relation to the Procurator Fiscal needs clarification. It also needs to be clear what their role and responsibilities are in relation to the family of the potential donor.

Whoever is to perform the AIP role, they will need to be available in sufficient numbers to provide a rota to cover the whole of Scotland at all times without creating delays in the donation process. We note that the AIP will determine what is a reasonable time for the proxies appointed to respond and, if they cannot do so, will authorise removal of organs by ‘operation of the law’. We are concerned that families, excluded from the process, may challenge what is a reasonable time for the proxies to respond if they believe that their relative did not wish to donate some or all organs. We know that currently some families will withdraw authorisation because of delays in the donation process: we are concerned that the law as currently drafted will add to the length of the process.

As we understand it there are six pre-conditions the AIP needs to test:

1. was the individual resident in Scotland at time of death
2. had the individual recorded no decision to opt in
3. had the individual recorded no decision to opt out
4. contact any named proxies for a decision
5. ask individual’s nearest relative if there was a reasonable opportunity to record an objection
6. ask individual’s nearest relative about whether the person was unwilling for
the organ to be remove for transplantation.

Under test number 6, it is not clear what level of evidence of ‘unwillingness’
would be required. It is also not clear how a conflict between a proxy and
family might be resolved. For example, if a proxy appointed say two years
before the individual dies, approves donation but the family member says that
the person had told them two weeks before the death that they didn’t want to
be a donor, how will this be resolved? As currently written it appears that the
relative’s information would be disregarded. This could lead to negative
publicity for donation and an undermining of public trust.

We note that if the AIP has concluded that removal for transplantation under
section 6B is not authorised, the nearest relative can approve removal of the
organs for other scheduled purposes. We think that practically it is unlikely
that relatives will allow removal for research, training and education or audit if
there is no authorisation for transplantation.

Consideration needs to be given to which organisation will employ, train and
manage the AIP service.

Duty of Ministers

We note that the duty of Ministers to publicise the changes to the law could at
its minimum be a single campaign of six months duration. It seems unlikely
that this would be adequate and arrangements need to be in place to ensure
that 15 year olds and those coming to live in Scotland, particularly those
coming temporarily such as students and those on business for six months or
more, are aware of the law and their responsibilities.

We note that while the law does not apply to tourists, there is no mention of its
relevance to people who may be in Scotland for over six months at the
direction of someone else, e.g. members of the Armed Forces.

Will implementation increase costs?

Although the changes to the ODR have already been made to allow people to
record a decision not to donate or to record names of two proxies, any further
amendments to accommodate the provisions of this law will incur a cost to
change the Register. Changes will also need to be made to public facing
websites which may also have a cost. We would also note that there will be
additional costs associated with increasing numbers of registrations on the
ODR (communications confirming details of registrations, administering the
proxy system etc.) It is too early to estimate these costs.

We note that the expectation is that NHSBT will absorb the operational costs
of increased donor numbers within the existing baseline as we have been able
to do in Wales. The expected increase in donor numbers in Wales was 15:
using the same methodology the expected increase in Scotland could be 70
or more donors. We cannot be certain that this number of donors can be
facilitated by the existing staffing. More specifically we have two Specialist
Nurses on call in the central belt and one in the North of Scotland: if we need to facilitate more donors than can be covered by the existing rota, then on-call costs will increase.

We expect that there will be ongoing costs associated with publicising the new law: for example Wales intend to communicate with every citizen as they approach their 18th birthday so they are aware of their responsibilities under the law.

If those undertaking the AIP role are new staff, or existing staff undertaking new responsibilities with new on-call requirements, then providing a 24/7/365 rota will require considerable investment to recruit, train, pay and manage these staff.

**Will the proposals achieve their objective of providing more deceased donor organs for transplantation?**

Although NHSBT’s statisticians have estimated that the new law could result in an extra 70+ donors in Scotland, a prize well worth pursing, we have concerns that the law as currently proposed may result in conflict with the families of potential donors. If this should happen and the public lose trust in the UK organ donation and transplantation system, there may be fewer donors in Scotland and elsewhere in the UK. We would strongly urge that the Scottish Government test that the proposed operation of the law as well as the concept is acceptable to the general public, with families of those who have already gone through the donation process and with potential transplant recipients.

**NHS Blood and Transplant**