UKDEC
UK Donation Ethics Committee

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Welsh Government/Llywodraeth Cymru

Date: 11 April 2014

Dear Pat,

Ethical issues relating to donation after circulatory death (DCD) and deemed consent

Thank you for the paper you presented to the UK Donation Ethics Committee (UKDEC) on 21 March 2014 and for taking part in the Committee's discussion, which I hope you found interesting and helpful. I am writing to set out the key issues that arose in the discussion and UKDEC's conclusions.

Background

You asked UKDEC to consider the subject of best interests in DCD cases and how this would practically be applied in a deemed consent situation, and outlined the Welsh Government's contention that the evidence of intent in a deemed consent case will be no different to that of someone who has given express consent by recording a decision to be a donor on the register; therefore clinicians will be able to proceed safely in the knowledge that interventions may be undertaken.

You asked for UKDEC's advice on this specific issue and in particular whether the existing Ethical Framework for DCD will need to be looked at to include deemed consent. You outlined the plans for a two-year publicity campaign about the change to a system of deemed consent in Wales, and the duty placed on Ministers by the legislation to continue to keep the public informed in the future.

The Committee found it helpful to consider the implications of the Human Transplantation (Wales) Act 2013 for DCD in two categories:

- The preservation of organs after death
- Pre-mortem interventions that may be beneficial to the quality of donated organs and increase the chances of a successful donation and transplant.

Preservation of organs after death

You explained that the Human Transplantation (Wales) Act 2013 replicates the effect of section 43 of The Human Tissue Act 2004, in that it makes it lawful to retain the body of a deceased person and preserve organs in the body which may be suitable for transplantation, while the issue of consent (whether express or deemed) to the use of organs is resolved.

The Committee agreed that for interventions carried out after death the issues relating to consent under the Welsh legislation would be no different from those arising in the rest of the UK. Therefore UKDEC does not see any additional ethical issues in relation to the post-mortem preservation of organs arising from a change to deemed consent.

Pre-mortem interventions

As you say, in Wales decisions about interventions carried out before death, and where the patient lacks capacity, will continue to be governed by the Mental Capacity Act 2005 which requires decision-makers to act in the best interests of the patient.

The crux of the issue raised by the change in the legislation is therefore whether deemed consent to organ donation after death, as it will be implemented in Wales, could constitute equally strong evidence of a person's wish to be a donor as express consent, when considering (along with other evidence about the potential donor's wishes, values and beliefs) whether an intervention is in the potential donor's best interests.

There was a range of views amongst committee members. Most members felt that intrinsically deemed consent cannot constitute "*equally* strong evidence of a person's wish to be a donor" as express consent constitutes positive evidence of a wish (if perhaps a wish made without full knowledge or understanding) while deemed consent is the absence of evidence. Some members felt strongly that a positive expression of consent would provide decision-makers with more confidence that the person really wanted to be a donor than consent based on a failure to opt-out, however good the public information campaign. Balanced against this was the view that people who decide not to opt out in Wales in the context of a high level of publicity and information were making a more informed choice than people in other UK countries, and so decision-makers might feel more confident that the person really wanted to be a donor.

However, it emerged during the debate that decision-making about what is in a potential donor's best interests is complex, and in practice the donation process can involve a series of decisions that will be influenced by many factors. For example a decision about a relatively non-intrusive intervention such as measuring a patient will differ from one about whether to administer drugs that might carry a risk of harm to the patient or distress to their family. There may be a series of decisions to be made over time, each with a different balance of potential benefits and harms.

In practice, therefore, whilst establishing that a person has consented to donation after death (however this was expressed) is relevant to making decisions about whether an intervention is in a potential donor's best interests, it is unlikely ever to be the only relevant factor. Decision makers will need to explore the evidence of a person's known wishes, values and beliefs, and take these into account along with the potential benefits and harms of any proposed intervention.

This will be equally true under opt-in and opt-out systems. An individual may give either express or deemed consent without great thought or commitment, or may do so after detailed consideration, discussion with their family, and with a strong desire to donate their organs after death. It could be argued that a person who thought long and hard about donation and was a strong supporter of organ donation would be more likely to support interventions aimed at increasing the chances of a successful donation than, say, someone who had consented without thinking much about what it meant. In either case the degree of thought the person had given to the decision and the strength of their desire to be a donor after their death will not be discovered simply by consulting the ODR, and decision makers will need to explore what is known about the strength of the person's wish to be a donor in more depth by talking to those closest to them.

In summary, whilst there may be a range of views about the relative merits of deemed as opposed to express consent to donation after death, UKDEC's advice is that in practice the issues for decision makers are the same. The fact that a person has legally given consent to donation after death is only a starting point for further investigation of the evidence about their wishes, values and beliefs in relation to organ donation. The results of such an investigation will enable clinicians to make a full and considered judgement as to what is in that person's best interests.

Finally, UKDEC believes that the resources available for a publicity campaign and an information strategy in Wales present a real opportunity to raise awareness about both the donation process and what makes a successful donation, and to increase the confidence of both the public and clinicians in donation. There will clearly be lessons to be learned from the experience in Wales, and it will be important to evaluate the impact on donation rates and the real drivers for any change in donation rates – for example the relative importance of legal change and a higher level of engagement with the public resulting from the extensive communications strategy.

Thank you again for bringing this to UKDEC's attention. We will review existing and planned UKDEC guidance to see whether any amendments would be appropriate. Please let me know if you identify any other issues for the Committee's consideration.

Yours sincerely,

Professor Chris Rudge CBE FRCS

Chair, UKDEC

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UK Donation Ethics Committee

Anne McTaggart MSP,

Date: 25 September 2014

Dear Ms McTaggart,

Consultation on the Proposed Organ and Tissue Donation (Scotland) Bill: written evidence from the UK Donation Ethics Committee (UKDEC)

Thank you for inviting comments on your proposal. I am responding as Chairman of, and on behalf of, the UK Donation Ethics Committee (UKDEC).

UKDEC was established in 2010 following a recommendation of the Organ Donation Taskforce (ODTF). It is independent, hosted by the Academy of Medical Royal Colleges (with funding from the four UK Health Departments). Its purpose is to address the ethical questions that arise in organ donation, in order to remove barriers to effective decision-making in donation and transplantation. It promotes ethical practice and does not seek to increase the number of donations per se. Further information can be found at www.aomrc.org.uk/donations-ethics-committee.html. Membership includes clinicians, ethicists, medical lawyers and lay members.

Our submission therefore focuses on the ethical issues relating to the provisions set out in the proposal, including practical issues that have a bearing on good ethical practice. We also have some concerns about potential unintended consequences which are included in our response.

There are several questions where UKDEC has not discussed the issues in detail, and which we therefore have not addressed.

Consultation questions.

1. The overarching purpose of my proposal is to move from the current opt-in system to a soft opt-out system of organ donation. Do you support this move? Please indicate"yes/no/undecided" and explain the reasons for your response.

UKDEC sees no fundamental ethical objection to a system of soft "opt out", but we do have concerns about the practicalities involved in ensuring that consent under such a scheme is valid and will remain so as time moves on. We also have reservations about the impact on the relationship between professionals and donor families, and on the confidence of professionals to explore new and ethically challenging techniques aimed at increasing the number of successful donations. These issues are dealt with in more detail below, where potential barriers and unintended consequences are discussed.

On the specific provisions, we have concerns about the provisions in relation to adults lacking capacity. The proposal rightly recognises the need to protect people lacking the capacity to understand the notion of opting out. However the proposals for identifying such people do not seem very robust. Incapacity is defined in The Adults with Incapacity (Scotland) Act 2000, but we are concerned that there will still need to be a discussion with families after death that might lead to some very subjective assessments being made. Further work on how these decisions will be made in practice, and what support will be available for professionals and families, would be helpful.

A particular issue arises in the context of donation after circulatory death (DCD), which accounts for nearly 40% of solid organ donations. The decision-making about donation for a DCD donor happens while the donor is still alive, but lacking capacity. Such decisions are therefore covered by The Adults with Incapacity (Scotland) Act 2000, and in order for donation to proceed it has to be established that activities to facilitate donation are for the benefit of the patient. The potential for a move to opting out to undermine DCD schemes is discussed further under "unintended consequences", but on a practical and legislative level the proposal needs to be clear on the consent status of a potential DCD donor who may not have opted out, but is still alive and lacking capacity at the time of decision-making about donation.

2. How essential is it to change the law (from an opt-in to a soft opt-out system) in order to achieve the intended benefits (increased transplant rates, reduced waiting lists)? Are there other (non-legislative) measures that could achieve similar outcomes without the need for legislation?

A key assumption is that the switch to opt-out will lead to an increase in donations. Whilst UKDEC recognises the admirable wish to increase organ donation in Scotland, there are doubts about the evidence (recognised on page 13 of the document). Overall systems in different countries vary, and it is not necessarily possible to compare one opt-out system with another. The evidence linking opt-out systems with increased donation is equivocal or at best weakly in favour of opt-out having an effect. In order for confidence in the system to be upheld, those tasked with implementing it will need to be convinced that the time and resources involved could not be better deployed elsewhere. The NHSBT Strategy to 2020 sets out a range of measures.

A responsible way forward might be for Scotland not to move forward too quickly, and for there to be a reasonable pause of some time - maybe a few years - after December 2015 to assess the impact of the change in Wales. Indeed, some members ask whether it is ethically acceptable to proceed with this scheme when a similar model is about to be implemented in Wales, and some of the

concerns (especially relating to trust in clinicians) might be dispelled or sustained through practical experience? In particular, the fundamental assumption behind this proposal (that more transplants will take place under a soft opt out scheme, thereby justifying its costs and ethical challenges) will be tested.

3. I believe the role of the family should be limited to being consulted on whether they are aware of any (unregistered) objection by the deceased rather than asking for their consent.

Do you agree? Please indicate "yes/no/undecided" and explain the reasons for your response.

We note that families will continue to be involved in decision-making under the proposals, primarily in giving information about the deceased, albeit on the basis that in the absence of an opt-out, consent will be deemed unless the family has evidence that the person really did not want to be a donor. Whilst the surveys carried out show general support for an opt-out scheme, it remains to be seen whether in practice families accept the absence of objection as authorisation/consent to donation, and what the impact will be on family satisfaction with the process. We would recommend that implementation be accompanied by well executed social scientific research to provide an evidence base.

We are also aware of the potential undermining of families' trust in clinicians involved in the end of life care of patients who have not opted out. Support for donation is broad but shallow, and any perception that clinicians may have different priorities in caring for a dying patient could undermine that support significantly.

4. Do you think an individual should be able to appoint a proxy to the make the final decision regarding transplantation on their behalf? Please indicate "yes/no/undecided" and explain the reasons for your response.

Not discussed

5. My proposal is that only adults should be automatically opted-in to be a donor. Younger persons would have to register to be a donor, by themselves or with parental consent as they currently do. This approach is I believe the best way to safeguard children and young people. Do you agree? Please indicate "yes/no/undecided" and explain the reasons for your response.

Not discussed

6. Do you agree the age limit for an adult should be set at 16 years old? Please indicate "yes/no/undecided" and explain the reasons for your response. If you answered no, what would you consider a more appropriate age?

Not discussed

7. Do you agree the soft opt-out system should apply to people who have been resident in Scotland for a minimum period of 1 year prior to their death? Please indicate "yes/no/undecided" and explain the reasons for your response.

The proposal risks placing a lot of additional burdens on staff in Scotland relating to deciding about residence in Scotland. It is not explicit as to how this decision will be made, and what consideration will be given to those such as students attending further education institutions in Scotland. Implementation needs to ensure all staff are fully trained and supported to help families through the process. Moreover, given the need for speed in order to achieve successful donation and transplantation of some organs, there are clearly ethical implications in imposing potential additional strains on already stressed relatives, who might often be the only immediate source of necessary information.

8. If you answered no to the above how long, if any, should this period of residency last before they become subject to the soft opt-out system? Would this residency need to be for a continuous period?

See above.

9. Do you think 6 months is a long enough period to run a campaign prior to change over?

The proposal acknowledges the communications and educational challenges inherent in a switch to a system of soft opt-out. Clear information about the system and the implications of opting out or not, is a vital component of an ethically acceptable system. Training and support for professionals will also be a key element in ensuring trust in the new system – if the new system is perceived as too complicated this could undermine trust in both professionals and the public.

Whilst UKDEC has not considered the timescale in detail, the strong belief is that opt-out legislation requires a very robust process of public information and understanding to have validity. It is not clear whether this could be achieved in six months, and what steps may be taken to assess whether any campaign – or other methods used – had in fact achieved the necessary level of public awareness and understanding.

10. What is your assessment of the likely financial implications (if any) of the proposed Bill to you or your organisation? What (if any) other significant financial implications are likely to arise?

There are two possible areas with financial implications – the necessary organisational infrastructure and the educational campaigns necessary to inform the public. Others will be better placed to comment on the financial costs of the infrastructure, but we feel that the costs of an education and information campaign necessary to render deemed consent/authorisation acceptable are likely to be very significant. The validity of the process is critically dependent on the extent to which the public are made aware of any new law, and the extent to which they understand it. Information on current and future spending in Wales would be helpful to answer this question. We would also emphasise the need for any such campaigns to be on-going to cover the arrival of new residents to Scotland and young people reaching the designated age.
We would ask where that money might come from and whether spending it might impede the achievement of other healthcare targets, or even the intended aim of the bill?

Finally, we do wonder whether the impact on professionals of setting up and maintaining the new system in parallel with a different system in other parts of the UK has been fully recognised.

11. Is the proposed Bill likely to have any substantial positive or negative implications for equality? If it is likely to have a substantial negative implication, how might this be minimised or avoided?

The consultation document acknowledges that one of the main barriers to family consent is faith and cultural concerns, specifically among the BME community. Whilst the publication of information material in different languages is welcome, the experience from Wales in promoting opting-out, and in England in promoting the benefits of joining the organ donor register, suggest that structured and meaningful engagement with faith communities is necessary in order to ensure appropriate understanding of the policy changes proposed - http://www.organdonation.nhs.uk/pdfs/nhsbt_faith_action_plan.pdf

12. Do you have any other comments on or suggestions relevant to the proposal

1. Attached is a letter sent in April 2014 to the Welsh Government following their request to UKDEC to consider "Ethical issues relating to donation after circulatory death (DCD) and deemed consent".

2. Unintended Consequences

The inevitable upward trend in the demand for organs for transplantation means that clinical practice in transplantation needs to constantly evolve and find new and better ways of delivering successful donations. Donation after circulatory death (DCD) is an important potential source of increasing the organs available for transplantation, particularly hearts.

As mentioned earlier, decisions about DCD donations need to be made whilst the potential donor is still alive. These decisions can be ethically challenging, since there are a range of interventions that might be carried out on a dying patient that will optimise the condition of organs, but have no benefit to the patient other than fulfilling his or her wish to be a donor.

Therefore the justification for intervening, and the balance of benefits and burdens that need to be weighed up in deciding whether an intervention is for the benefit of the patient, relies heavily on the strength of evidence that the patient wants to be an organ donor. There are many clinical decisions to be made and the strength of authorisation/consent, and the support for donation of the family, is vital to making decisions as to which measures are to the benefit of the patient. We feel that there is a risk of over-reliance on *any* form of consent to donation after death when making decisions about interventions during life.

UKDEC recognises that there will still be an "opt in" register under the proposals, but we are concerned that a shift towards reliance on the absence of opting out as the basis of consent to donation could shift the delicate balance and undermine professionals' confidence to develop the innovative schemes that have the potential to increase the number of organs for transplantation.

Were this to happen and the unintended consequence limited new opportunities for increasing available organs, this would work against the overall aim of the proposal.. We would recommend further work be undertaken on the potential impact on clinical practice in this area.

3. It is notable that the proposal appears to use the terms “authorisation” and “consent” almost interchangeably, even though these are specific terms, with different connotations, current Scottish and other UK legislations. There is a clear potential for confusion here.

4. It should be noted that any increase in donation resulting from the change will not necessarily benefit Scottish patients in need, a factor which might well influence public opinion on the merits of the change.

5. It is important to recognise that from mid-2015 the NHS Organ Donor Register will be changed, to allow four options: Register YES All organs

Register YES Specify organs
Register NOMINATE a representative
Register NO

A different system, introduced in response to this proposal, would clearly carry a significant risk of causing confusion.

6. Whilst the proposal broadly reflects the current position on organ donation and transplantation in Scotland and the UK, we would add the following comments:

a) There are a number of statements about the necessity for an individual to register their wishes about donation, either through the current ODR or through an opt-out register. It is important to emphasise that at present, whilst a family are more likely to support donation if the positive wishes of the individual have been recorded, a significant number of donations can and do proceed on the legal authorisation or consent of the next-of-kin in a situation where the donor had not made an explicit record of their wishes.

b) The proposal contains conflicting statements about the number of people waiting for a transplant – “rising by 5% a year” on page 10, “fallen by 12%” on page 11. In fact the UK active waiting list has fallen in each of the last four financial years.

c) Whilst all would agree that there is a pressing need to increase further the number of organ donors, it is no longer accurate to say that “The United Kingdom has one of the lowest organ donation rates in Europe” (foreword). In the calendar year 2013, the UK was only marginally outside the top third of EU member states in terms of the deceased donor rate.

Yours sincerely,

Professor C J RUDGE CBE FRCS

Chairman, UK Donation Ethics Committee