



Ms Sarah Sargent
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Swyddfa Ddeddfwriaeth / Legislation Office
Cynulliad Cenedlaethol Cymru /
National Assembly for Wales

10, Dallington Street
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Date: 10 January 2013

Dear Ms Sargent,

Consultation on the Human Transplantation (Wales) Bill : written evidence from the UK Donor Ethics Committee (UKDEC)

Thank you for your letter of 6 December 2012, inviting UKDEC to submit written evidence to the inquiry. I am responding as Chairman on behalf of the Committee.

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 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 and lay members.

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

Individual provisions set out in the Bill

Sections 4-8 : consent

UKDEC sees no fundamental ethical objection to a system of deemed consent or “opt out”, but we do have concerns about the practicalities involved in ensuring 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 do have concerns about the provisions in relation to adults lacking capacity. The Bill 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. The criterion of lacking capacity for a “significant period” before death is vague, and the reliance on discussion with families after death 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 Mental Capacity Act, and in order for donation to proceed it has to be established that activities to facilitate donation are in the patient's best interests. The potential for a move to deemed consent to undermine DCD schemes is discussed further under "unintended consequences", but on a practical and legislative level the Bill 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.

Potential barriers to implementation

The Bill, and its associated Explanatory memorandum, acknowledges the communications and educational challenges inherent in a switch to a system of deemed consent. From an ethical perspective, clear information about the system and the implications of opting out or not, is clearly 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.

Others will be better placed to comment on the financial costs, but we do wonder whether the impact on professionals of setting up and maintaining the new system in parallel with a different system in the rest of the UK has been fully recognised. Sections 45 to 54 of the Explanatory Memorandum set out the vision of how the scheme will work in various scenarios, for example should a person have lived in Wales but die elsewhere, or opt-out when they lived in Wales but then move elsewhere. The Bill appears to place a lot of additional burdens on staff across the UK relating to deciding about ordinary residence in Wales, checking different registers etc. Section 52 says "NHS staff across the UK will need to be aware of the law in Wales and the process will need to have a check built in to ask whether the person had ever lived in Wales, and therefore look for any recorded decision made whilst the person lived in Wales". Implementation needs to ensure all staff are fully trained and supported to help families through the process.

A key assumption is that the switch to deemed consent will lead to an increase in donations. Whilst UKDEC recognises the political imperative for introducing deemed consent in Wales, there are doubts about the evidence. 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.

We note that families will continue to be involved in decision-making under the proposals, 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 in Wales show general support for an opt-out scheme, it remains to be seen whether in practice families accept the absence of objection as 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.

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.

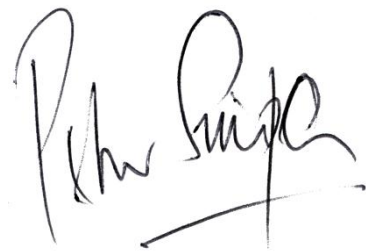
As I mentioned earlier, decisions about DCD donations need to be made whilst the potential donor is still alive. These decisions can be ethically challenging, since there are a range of interventions that might be carried out on a dying patient that will optimise the condition of organs, but have no 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 in the patient's best interests, relies heavily on the strength of evidence that the patient wants to be an organ donor.

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 Bill. We would recommend further work be undertaken on the potential impact on clinical practice in this area.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Peter Simpson', with a long horizontal stroke extending from the end of the name.

Sir Peter Simpson

Chair, UK Donor Ethics Committee