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Organ Donation Bill Team
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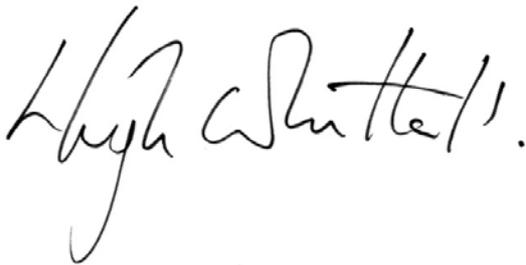
Dear Sir / Madam

Welsh Government Consultation on Proposals for Legislation on Organ and Tissue Donation

I am pleased to enclose a response to the above consultation from the Nuffield Council on Bioethics, an independent body that examines and reports on ethical issues in biology and medicine.

Please do not hesitate to contact me if you would like further information or assistance.

Yours sincerely



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Response from the Nuffield Council on Bioethics to the Welsh Government Consultation on Proposals for Legislation on Organ and Tissue Donation

Key points

- Decisions about deceased donation should be based on the known wishes of the donor, so far as these can be discovered.
- We would not oppose on ethical grounds a soft opt-out system, in which families had the opportunity (without pressure) of contributing their knowledge of the person's own views. We do, however, note some practical difficulties in implementation, and some doubts as to the impact of such a change.
- It is important that loss of trust in the system is minimised, for example by ensuring that those seeking family views are not themselves subject to targets that might be seen as leading to pressure on families.
- If an opt-out system is introduced in Wales this should be accompanied by robust research, both on the role of relatives in determining whether organs may be donated, and on the effect that the legislative change has had on the numbers of organs donated.
- The possibility of donating material for research use should be routinely raised with the person's family when authorisation for the removal and use of organs or tissue is sought after death.

Introduction

- 1 In October 2011, the Council published a report, *Human bodies: donation for medicine and research*,¹ which considers the ethical and social issues that arise when people are asked to donate bodily material (such as organs, blood, eggs and sperm) for medicine and research. The report was the result of a two-year independent inquiry led by Professor Dame Marilyn Strathern which sought to answer the question: how far should society go in encouraging people to donate their bodily material?
- 2 In coming to its conclusions, the Working Party consulted a wide range of people, including members of the public, patient and user organisations, academics and researchers, people involved in regulating donation and research, and professionals involved in transplantation and fertility services. 179 individuals and organisations responded to an open call for evidence between April and July 2010, and a deliberative workshop with 43 recruited members of the public took place in Bristol in July 2010.² More information about the inquiry, method of working and resulting report can be found at: www.nuffieldbioethics.org/donation

¹ Nuffield Council on Bioethics (2011). *Human bodies: donation for medicine and research* (London: Nuffield Council on Bioethics). Available at: www.nuffieldbioethics.org/donation

² Opinion Leader (2010) *Nuffield Council on Bioethics: human bodies in medicine and research - report of deliberative workshop on ethical issues raised by the donation of bodily material* (London: Opinion Leader). Available at: www.nuffieldbioethics.org/donation/donation-external-consultation

Public opinion on opt-out systems

- 3 Responses to our consultation, and the deliberative workshop with members of the public, showed considerable polarisation around the issue of consent, particularly in the context of organ donation after death. On the one hand, some felt that the health needs of those who require scarce organs were so great that this could justify an 'opt-out' system, or perhaps a system of mandated choice. On the other hand, some felt that in moving to an opt-out system, the state would effectively gain control over, and ownership of, individuals' bodies, and that such a shift would be quite unacceptable. All parties agree that 'consent' is important in the context of organ donation, but disagreement focuses on how that consent should be signalled.

Ethical considerations

- 4 We believe that **decisions about deceased donation should be based on the known wishes of the donor**, so far as these can be discovered. Such information should, ideally, derive from the person's own expression of these wishes before death (see paragraphs 5.57-5.61 of the full report).
- 5 In the absence of a record of the deceased's wishes (including the absence of any evidence of objection), information as to their likely wishes should be sought from those close to the deceased person, who are usually best placed to know the deceased person's wishes, and who themselves, in their bereavement, have a stake in how their deceased relative's body is treated.
- 6 We take this overall view on the basis that there is sufficient evidence that, for many people, the disposal of their bodily material is a matter of significant personal concern, and that to take material without some evidence that this is in accordance with the person's wishes risks treating the person's body as a means to others' ends.
- 7 Clearly not everyone regards their bodily material – during life or during death – in such a way, but the entrenched and opposing views on proposals for an 'opt-out' approach to deceased organ donation highlight the fundamental lack of consensus on this issue within the UK. However, we make a distinction between what is required for valid consent to an intervention during one's lifetime, and what should be required for valid consent in respect of a deceased person's bodily material. In particular, we suggest that the degree of detail required when providing information about the proposed procedure will differ significantly, and that it should be possible for a person to provide legal authority for donation after death on the basis of quite minimal information, if this is sufficient for them to be clear about their own wishes.
- 8 Finally, we emphasise the importance of consent in creating and maintaining trust in health professionals and the health care system as a whole. We note that where 'medical mistrust', or mistrust of the system, is cited as a reason for people to hold back from donating bodily material, this may be associated with concerns about consent: both that the terms of the consent may be abused (for example by using the donated material in a different way from that envisaged in the consent) and that additional

material may be taken without explicit consent. We highlight how values such as honesty and trust were raised by our consultation respondents as central in both the professional and personal relationships affected by the donation of bodily material. While we cannot make any clear findings from the evidence available to us as to the *levels* of such mistrust within the UK at present, we conclude that it is a factor that must be taken into account when considering any changes to approaches to consent.

Research on effectiveness of opt-out systems

- 9 We are aware of the ongoing discussions in the research literature as to whether increases in organ donation in countries such as Spain that have introduced opt-out legislation can be ascribed to the legislative framework, or whether other systemic factors in the way organ procurement is managed are the main contributing factor to the increase. A systematic review of studies comparing 'before and after' donation rates after legislative change in a number of countries, published in 2009, concluded that changing to an opt-out system of consent alone was unlikely to explain the variation in organ donation rates between countries, with many other factors identified as relevant. These included both factors affecting the total number of potential donors available (for example rates of motor accidents, the population's age distribution, and the country's definition of death), and factors affecting how many of those potential donors in fact went on to donate (for example the organisation and infrastructure of the transplant system, wealth and investment in health care, and underlying public attitudes and awareness).³
- 10 Another study, published subsequently, concluded by contrast that opt-out systems *are* associated with relatively higher rates of deceased donation – but also with relatively lower rates of living donation.⁴ We are also aware of research modelling the possible effects on organ supply of an opt-out system, based on differing levels of individual and family opt-out.⁵ We note that, while such models demonstrate a potential increase in the number of available organs (and hence lives saved) on the basis of particular assumptions about numbers opting out, such assumptions clearly remain to be tested.

Our recommendations

- 11 In our opinion, the importance to be attached to the person's own wishes rules out absolutely any consideration of introducing a 'hard' opt-out approach to deceased organ donation, given the impossibility of ensuring that everyone would be sufficiently well-informed to have the opportunity of opting out during their lifetime.
- 12 **We would not oppose on ethical grounds a soft opt-out system**, in which families had the opportunity (without pressure) of contributing their

³ Rithalia A, McDaid C, Suekarran S, Myers L, and Sowden A (2009) Impact of presumed consent for organ donation on donation rates: a systematic review *BMJ* 338.

⁴ Horvat LD, Cuerden MS, Kim SJ *et al.* (2010) Informing the debate: rates of kidney transplantation in nations with presumed consent *Annals of Internal Medicine* 153: 641.

⁵ Bird SM, and Harris J (2010) Time to move to presumed consent for organ donation *BMJ* 340: c2188.

knowledge of the person's own views and, where appropriate, of determining that the person would not have wished to become a donor, or indeed that donation would cause the family significant distress. We do, however, note some practical difficulties.

- 13 First we suggest that initial assumptions as to the numbers of additional organs that might be obtained in such a way should be modest, if families do indeed continue to feel genuinely free to express any objections they feel. It does not automatically follow that families who currently refuse consent to the use of their deceased relative's organs would take a different view under such a system. Indeed, if families in such cases felt coerced in any way, then this would potentially render their role meaningless. On the other hand, if the effect of any policy change were to change attitudes so that donation were seen as 'natural' or 'normal', hence increasing the likelihood that families would conclude that donation would be in line with their deceased relative's wishes, this would be ethically unproblematic. Similarly, if families felt relieved from the requirement actively to make the decision, this too might lead to fewer refusals.
- 14 Second, given the strong opposition in some quarters to the notion of any form of opt-out scheme, and the associated concerns that the state (acting through health professionals and the health care system) would be intervening to 'take' organs rather than facilitating their being 'given', there is at least a risk that some degree of trust in the system could be lost. In such circumstances, **it would be particularly important that systems should be designed in such a way as to minimise such loss of trust**, for example by ensuring that those seeking family views are not themselves subject to targets that might be seen as leading to pressure on families.
- 15 As we have already shown, there may be a significant difference between how people think or say they will act in particular theoretical situations, and what they actually do if that situation arises (see paragraph 6.19). We are therefore hesitant to rely on research reporting on how people say they would respond to the introduction of a soft opt-out system including all the protections described above. **If an opt-out system is introduced in Wales we recommend that this is accompanied by robust research**, both on the role of relatives in determining whether organs may be donated, and on the effect that the legislative change (as opposed to any confounding factors such as system changes) has had on the numbers of organs donated. Such research would provide a clear evidence base for any proposals for change elsewhere in the UK, or indeed further afield.

Donation of organs and tissue for research

- 16 The current proposals in Wales will apply to the donation of organs and tissues for the purposes of transplantation only. It will not include the donation of organs and tissues for other purposes, such as research, display or commercial use.
- 17 The Nuffield Council report highlights the importance of research using human tissue, arguing that research, and the future health benefits that research seeks to bring, are of vital public interest. The difficulties experienced in accessing tissue for research are essentially different in kind

from the 'shortages' described in other fields: the available evidence suggests that, if asked, plenty of people are more than willing to permit their tissue to be used for research purposes.⁶ The difficulties that arise relate therefore not so much to encouraging people to consider donating, but rather in the need for much better systems to be in place to ensure that consent is sought and documented appropriately; and that materials are appropriately shared (see paragraph 7.16 of the full report).

- 18 Research should not be seen as a peripheral or 'second-class' use of bodily material, but rather as a mainstream use of donations. Such an approach has implications both for the ways in which individuals are encouraged to authorise the donation of material in advance of their own death, and for the ways in which families are approached after their relative's death.
- 19 We consider that it is crucial that any change in the systems used to obtain consent should take fully into account the implications for the donation of research. In the context of the current 'opt-in' system to organ and tissue donation, our report recommends **that the possibility of donating material for research use should be routinely raised with the person's family when authorisation for the removal and use of organs or tissue is sought after death.** We also suggested that routine information about the Organ Donor Register should include explicit reference to the potential research uses of organs and tissue, and that potential donors should have the option of authorising such uses in advance.

⁶

See paragraphs 6.7 and 6.82 of the main report for further details.