

HTA's Response to the Department of Health's Consultation on Introducing 'opt-out' Consent for Organ and Tissue Donation in England

Introduction

1. The Human Tissue Authority (HTA) welcomes the opportunity to respond to the Department of Health and Social Care's consultation on introducing 'optout' consent for deceased organ and tissue donation in England.
2. The HTA is the statutory regulator responsible for overseeing the consent provisions within the Human Tissue Act 2004 (HT Act). As noted in the consultation document, the HT Act provides part of the legal basis for the current 'opt-in' system in relation to consent for organ and tissue donation in England.
3. The HT Act establishes the concept of appropriate consent when organs and tissue are donated from deceased and living people for the purpose of transplantation. Appropriate consent is defined in terms of who may give consent.
4. The concept of valid consent is established in common law and mental capacity legislation. For consent to be valid, it must be given voluntarily by an appropriately informed person who has the capacity to consent to the intervention in question.
5. In relation to organ donation from deceased donors, the HT Act covers England and Northern Ireland. The change proposed in the consultation would only affect England. Any change to the basis of consent to organ donation in England would necessitate amendment of the HTA's Codes of Practice, which are based on the current legal foundation of valid consent.
6. In Wales, the Human Transplantation (Wales) Act 2013 introduced a system of deemed consent for organ donation from deceased donors in December 2015. The HTA wrote a supporting Code of Practice on behalf of the Welsh Government, which provides practical advice and guidance to professionals working under the Human Transplantation (Wales) Act 2013.
7. The HTA is the UK Competent Authority under the European Union Organ Directive, transposed into UK law via the Quality and Safety of Organs

Intended for Transplantation Regulations 2012. The Directive lays down the quality and safety standards for organs. It covers all steps in the transplant process from donation, through procurement, testing, and handling to distribution.

8. The HTA is also the UK Competent Authority under the European Union Tissue and Cells Directives, transposed into UK law via the Human Tissue (Quality and Safety for Human Application) Regulations 2007. These Directives lay down the quality and safety standards for tissues and cells used in patient treatment and cover all steps in the process from donation to distribution for end use.
9. When the word “organ” is used in this document, it should be read to include organs, part organs and tissue.
10. In its role as a statutory regulator, the HTA does not either support or object to Government policy proposals. However, the HTA has a duty to provide advice and guidance as required and this consultation response seeks to highlight areas that require consideration.
11. The Government will no doubt hear from others that there are strongly held views on the ethics and efficacy of an opt-out system. However, it should not be forgotten that the HT Act came about, at least in part, as a result of inquiries into the retention and use of organs without the knowledge, or active consent, of families. In the case of ‘opt-out’ consent, we are aware that while there are many who are in favour, there are some very strongly held opinions that consent must always be actively given and not assumed on the basis of inaction. For these stakeholders, the need for an active decision provides a critical safeguard against abuses similar to those that resulted in the creation of the HTA.
12. The changes being proposed in the consultation must be thoughtfully implemented, with adequate communication and appropriate safeguards, so as not to risk public confidence in the UK’s widely, and justly, respected organ donation system. Our response to the consultation tries to identify some of the key issues that may pose risks to public confidence based on our experience of regulation in this area, and on our work with the Welsh Government on the introduction of deemed consent in Wales.
13. The HTA has issued responses to previous consultations, including [a response to the Welsh Government’s consultation](#) on the introduction of a soft opt-out system for organ donation, [a response to the Scottish Government’s consultation](#) on increasing numbers of successful donations and [a response to the Northern Ireland Assembly’s consultation](#) on the

Human Transplantation Bill. All of these responses can be found on our website [here](#).

Making it easy for a decision to be known under 'opt-out' consent

Recording a decision

14. It is important to note that as a result of the changes to the law in Wales, the national Organ Donor Register (ODR) already allows UK residents in all four nations to opt-in to, or opt-out of, organ donation. We note that it will still be possible to record these decisions, and that this will not change under the proposed new system. We view this as critical, as the individual must have primacy in making the decision to consent, or to withhold consent, for organ donation after death.
15. The consultation asks whether people should have more ways to record a decision about organ donation. The importance of being able to register to opt-out means that there needs to be adequate opportunity to do so. However, the highest priority must be placed on data security and integrity, particularly when transferring data between different systems. Ensuring the accuracy of core records is a primary concern in order to avoid acting against the decision of the individual (and therefore unlawfully), and consequently undermining the system of organ donation.
16. In order for the clinical community to be certain they are acting lawfully, there should be only one place where the definitive official record is held. As such, all formal sources of consent (or objection) should link to a single repository that can be used to triangulate with information provided by the family. Multiple repositories could present barriers to checking information in a situation which is time-critical.
17. The Government has plans for every patient in England to be able to access their own medical records and complete a number of different services online, which includes registering decisions on organ donation. Should this ambition be realised, then it would be prudent to note that the provision will be limited for members of the public who do not have access to, or who would prefer not to access, a computer with access to the internet. As the ODR is not currently linked to a patient's medical record, consideration should be given to how that record will be accessed and updated by the patient and made available to the transplant services.
18. Consideration must also be given to opt-out decisions which may be recorded in different ways which are not linked to an electronic official record, for example in a will.

Public awareness

19. If the proposals go ahead, communication and public awareness are critical. The principles that underpin the HT Act point to the primacy of the decision of the individual themselves about what happens after death; in order for this principle to continue to have legitimacy individuals must understand their options, including opt-out, and the consequences of not recording a decision. Indeed, without proper communication an individual may not be in receipt of the information they require to know what their silence on the matter of organ donation after their death will mean.
20. As the consultation itself notes, “The aim is to make sure people are aware they can opt-in or opt-out, making both decisions easier to record” – public awareness of this choice is the success measure of this proposed change, and we would urge the Government to consider setting out the approach to evaluation of this measure before and after implementation. With this in mind, the HTA welcomes the proposal in the consultation that “an extensive communications campaign would be required both before and after legislation comes into effect”. Every person with capacity to make a decision in England must be made aware of the proposed system and how it will affect them. Awareness will largely be dependent on a robust campaign and having a sufficient lead-in time prior to implementation.
21. Maintaining the legitimacy of an opt-out system will require a significant, long-term commitment to communication, so that individuals will not only be aware of the choices they can make in the run up to the initial implementation of the new system, but also over their lifetime. In addition, targeted communication would be appropriate, for example, to people as they reach the age at which opt-out applies.
22. Attention should be given specifically to those groups who may have a lower awareness of changes that may affect them, such as people whose first language is not English, and also those living in more deprived areas and communities who may not have frequent contact with health and care services. It will be important to develop a communications plan that ensures people who move to England are made aware of the system soon after they become resident, in order to allow them sufficient time to make, and if necessary, record their decision. It is also vital to ensure that there is time for young people to make an active decision before they reach the age at which the opt-out system applies to them.
23. The Government must actively address any risk of a particular group or groups of individuals in England being left behind on this matter due to poor communication. Without an effective, comprehensive, targeted and continued communications campaign the proposed system cannot be said to hold the decision of the individual in life as a core principle.

Changing to an opt-out system of consent

Race and faith

24. Our interaction with stakeholders tells us that faith, religion and beliefs are hugely influential in decisions relating to the body, and what happens to an individual after they die. The HTA recognises that attitudes vary widely among cultures and religions, and welcomes the initiatives cited in the consultation to take these views into account. Our experience tells us that each case and decision is an individual and personal one, and should be treated as such. We also recognise that there is a careful balance between recognising the individual nature of decisions, and introducing increasing complexity to a system.

Family involvement in decisions to donate

25. In order for an opt-out system of consent to maintain confidence in the organ donation system, it is of critical importance that the role of the family is clearly articulated, respected by professionals and supported by the public.
26. It is perhaps instructive to consider the current legal position of the family's role in the decision to donate, before considering changes that may result from a move to opt-out consent.
27. The ODR operates throughout the UK to allow individuals to record their decision about organ and tissue donation after they have died. As long as a person registered their decision voluntarily, had the information they needed to make the decision to register and had mental capacity or competence when they registered, then the decision recorded on the ODR constitutes valid and appropriate consent at the time of registration.
28. A legally valid decision from the donor is sufficient to allow organs and tissue to be retrieved for transplantation when they have decided to donate. Similarly, in circumstances when they have decided not to donate, donation cannot proceed. There is currently no legal right for family members to revoke a legally valid decision to give or withhold consent. Further information on consent and the ODR can be found in our [Code of Practice](#).
29. We view this continued primacy of the expressed decision of the individual during their lifetime, rather than the expressed decision of a third party, as central to the legitimacy of any system.
30. However, while the existence of appropriate, valid consent permits an activity to proceed, it does not mandate that it must proceed. The final decision about whether to retrieve organs for donation rests with the medical

practitioner, with close involvement from the family. Under the current system, a donation might not proceed for a variety of reasons when valid consent is in place, including but not limited to: the family providing updated evidence of the current consent status of the donor; the family being unavailable to provide medical and lifestyle information about the donor; or the family being opposed to donation because of its implications for end of life care, for example the timing of withdrawal of treatment where donation after circulatory death (DCD) is a possibility. In these instances, this will mean the wishes of the deceased with respect to becoming an organ donor were not realised. It does not mean, legally speaking, that consent was invalidated.

31. It is our view that there is currently a great deal of misunderstanding about the legal position of the family with respect to consent, and we welcome the Government's intention to bring clarity to this issue in legislation.
32. With regard to what that role should be, it would seem very difficult to justify any lesser role for the family where consent was presumed through inaction, rather than being actively given. In particular, the same considerations set out at paragraph 30 will remain applicable.
33. Reflecting views expressed to us by our stakeholders, it would also be a very significant and divisive step to mandate that organ donation must proceed if legal consent (whatever its basis) and the medical and lifestyle conditions of the donor allow. This would be especially difficult in the case of controlled DCD donation, where individuals are highly unlikely to be familiar with end of life care pathways, the process of dying and the implications these have for organ donation and the impact on the family, when making their decision.
34. In summary, it is critical to the legitimacy and reputation of the organ donation system that the family continues to be involved in the decision making around end of life care, including organ donation.

Exceptions and safeguards in a new system.

35. The HTA agrees that suitable protections must be put in place for those who are unable to consent, or record their decision, in line with current legislation. Clear guidelines will be required for those who are not normally resident in England.
36. This also raises questions relating to cross-border issues. Operationally this poses challenges, as under the HT Act it is the decision of the individual immediately before they died which is legally effective and ,therefore, if this decision is recorded on the ODR it should be acted on, no matter where the individual dies. This means that for English residents who die outside

England, the Specialist Nurse for Organ Donation must check the ODR and act on the recorded decision, if there is one.

37. There is a real and very significant risk associated with the implementation of different consent systems for organ donation across the UK nations. This is a risk that not only has the potential to reduce public confidence in the organ donation system, but subsequent uncertainty – particularly for those living in border counties - could also result in an individual's decision not being respected as a result of these misunderstandings. This must be considered when implementing any new system to ensure there is alignment. Clear, simple guidance will be key.
38. There is a risk that members of the public will be confused, particularly those who may move from one UK nation to another. As the regulator for organ donation and transplantation, the HTA would welcome clarity on the actions and measures proposed to mitigate this risk.
39. Additionally, our experience of regulation tells us that anything that requires practitioners to consider different approaches, depending on where someone lived and died, is potentially counterproductive. Again, this will be especially acute in border counties, where an individual may be ordinarily resident in one jurisdiction but receive treatment and die in another. Uncertainty and local variations in practice could lead to a loss of professional and public confidence in donation.

In response to the request for “any opinions or evidence you have about opting out of organ donation”

40. The final consultation question asks for the submission of any further evidence about opting out of organ donation. The HTA conducted a public evaluation in 2017, and one of the topics discussed amongst members of the public in structured focus groups, and covered in an online survey, was organ donation and transplantation.
41. Organ donation and transplantation was considered a high priority area for regulation by the public in this evaluation, with 86% of respondents (n = 1000) to the online survey saying that it was the most important area that the HTA regulated.
42. The qualitative part of the evaluation told us, amongst other things, that respecting the consent of the donor, or alternatively their families (living or deceased), was perceived as particularly important.
43. As well as consent, another priority issue was ethical considerations around the sensitive handling of human tissue.

44. Those who highlighted consent were particularly concerned that consent came from the individual donor; this was felt to be more important than the family's wishes (although respondents were also able to think about consent issues from a family member's point-of-view).

45. Some illustrative comments were:

- a. 'If someone says they don't want their organs donated we should respect their wishes.'
- b. 'It's good that if an individual hasn't given consent that the authorities don't just take the body, they must ask the family.'

46. A number of respondents felt that donation after death included ethical issues around the improper use of donated organs, or not specifically respecting the wishes of the donor.

47. There was a clear diversity of opinion on whether the family has the right to override the wishes of a deceased person, although individual consent was a central theme of responses across the sample group and across the research questions:

- a. 'Once the individual has made their decision that should be respected, as long as they are of sound mind.'
- b. 'What's the point in the [consent] form if it can be overridden?'

Areas for further consideration

48. The HTA would highlight the following key areas to the effective implementation and operation of an opt-out system as requiring further consideration and development. .

Other types of donation

49. The consultation states that "Living adults must actively give their own consent on what happens to their body after death. Where an adult has not given consent, nor made a decision not to consent, a person who has been appointed as their nominated representative can decide. If there is no such person, a person in a qualifying relationship can decide." The HTA would like to make it clear, as this sentence could be misinterpreted, that this consultation on a planned move to an opt-out system of organ donation does not, and will not, affect the current consent arrangements for whole body

donation for anatomical examination. An individual who wishes to donate their whole body for anatomical examination must have given written and witnessed consent in life, and this cannot be provided after death by a relative or other representative. Information on the requirements for donation for anatomical examination is available in our relevant [Code of Practice](#). Potential donors can express a preference for either whole body donation or organ donation but can register for both, so that one or the other may be able to proceed in the event of their death. In the event of the opt-out system being introduced, those with a preference for body donation may need to opt-out of organ donation.

Impact Assessment

50. The impact assessment states that there will need to be a £2m one-off cost for managing the spike in opt-out registrations on the ODR and an on-going annual cost of £0.2m to run the ODR. The HTA urges the Government to assure itself that the IT infrastructure currently in place to support the ODR is sufficiently robust and secure to cope with the potential of several million additional people registering their donation decision.
51. Longer term planning will also be key to ensure that the health system has the capacity to transplant any additional organs that may become available, without affecting the quality or safety of individual organs.
52. Any changes to the HT Act would necessitate changes to a number of the HTA's Codes of Practice, and potentially impact on how licensable activities are superintended. In our experience, this would require significant additional resource relating to drafting, broad consultation and legal review; these considerations would also need to be factored in to any implementation plan and timetable.

Conclusion

53. It is not for the HTA itself to offer an opinion on changing the legal basis at the heart of the proposal, but rather to offer advice and guidance to ensure the Department of Health and Social Care (DHSC) and Ministers make any changes in a way that reduces risks to public confidence.
54. This response provides such advice and guidance and the HTA urges the DHSC to give further consideration to the areas highlighted in this response.
55. Communication, planning and collaboration are vital. During the development phase, this primarily means communication with all key stakeholders on the proposals and a continued dialogue with all interested parties, most notably those who oppose the proposal.

56. During the lead-in and implementation phase, communication with residents in England will need to be effective, targeted and consistent, and collaboration with organisations such as the HTA and NHSBT will be crucial to make sure all risks can be managed and addressed.
57. The HTA welcomes the Government's intention to bring clarity to the legal position with regard to the family's role in consent to deceased organ donation through legislation.
58. Finally, post-implementation, the importance of continued communication with residents in England cannot be overstated to ensure that individuals understand the implications of not registering a decision to opt out. Without such effective and continued communication, the right of an individual to decide whether to donate organs after death will not be protected.