

Catholic Medical Association (UK) and Catholic Union of Great Britain.

Response to the Consultation on introducing 'opt-out' consent for organ and tissue donation in England

The Catholic Medical Association (UK) represents Catholic doctors, nurses, pharmacists, hospital chaplains and other healthcare professionals within the UK. It celebrated its centenary in 2011. The CMA has its own charity, the Catholic Medical Missionary Society, to support medical projects in the Developing World.

The Catholic Union of Great Britain was founded in 1870 and is the leading lay organization whose primary objective is to champion the moral and social teaching of the Catholic Church in the public sphere.

The CMA (UK) and CU welcome this opportunity to respond to the consultation of the proposed 'opt-out' system for organ donation in England.

Introduction

In the UK over 50,000 people are currently known to be alive as a result of organ transplantation. There is widespread support for organ donation and over 80% of the population support donation in principle. In the last 10 years the number of organ donors has increased by 75% and the number of cadaveric transplants by 56%. However, there are currently around 6,500 people awaiting transplants in England.

Currently donors can 'opt in' by signing up on the NHS Organ Donor Register (ODR) or by appointing a representative to make decisions on their behalf. In practice, families can also give consent.

Organ donation is currently lawful if there is 'appropriate consent'. If there is no explicit consent from the potential donor, a person in a qualifying relationship can decide.

Organ donation after death is seen as a generous and meritorious act which is to be encouraged. However, it is not morally acceptable if the donor or their proxy have not given explicit consent. Consent ought to be obtained from the donor or their representative which could be a member of the family, acting on their behalf.

Q1. Do you think people should have more ways to record a decision about organ and tissue donation?

Yes. However, it is important that there is sufficient publicity about organ and tissue donation so that potential donors can make well considered and informed decisions in a timely fashion. These may be initiated by clinical staff for example at the time of registration with a GP. It is hoped that the increased publicity about transplantation will be enhanced by the public debate which is now occurring. However, the numbers of donors on the Organ Donor Register has increased steadily over the years from 15.1 million in 2008 to 23.6 million in 2017 without changes to the legislation. The number of deceased and living donors in the UK is shown below.

Deceased and living donors in the UK from 1st April 2007 to 31st March 2017

| Year | Deceased donors | | Living donors |
|---------|-----------------|-----|---------------|
| | BDD | CDD | |
| 2007/8 | 609 | 200 | 858 |
| 2008/9 | 611 | 288 | 961 |
| 2009/10 | 624 | 335 | 1062 |
| 2010/11 | 631 | 373 | 1046 |
| 2011/12 | 652 | 436 | 1055 |
| 2012/13 | 705 | 507 | 1101 |
| 2013/14 | 780 | 540 | 1148 |
| 2014/15 | 772 | 510 | 1092 |
| 2015/16 | 785 | 579 | 1018 |
| 2016/17 | 829 | 584 | 1043 |

BDD = Brain Dead Donors.

CDD = Circulatory [cardiac] Dead Donors

It is important that potential donors discuss their decisions with close family members. The issue of transplantation arises when the donor has died and is at a time that the family is suffering bereavement which is often sudden and unexpected. Whilst discussions with the clinical teams will also occur at this time, it is not the best time to initiate discussions for the first time. Requests for organs at the time of bereavement might appear intrusive and even insensitive.

Lack of family consent is an important factor that determines whether potential donations go ahead. In 2016 to 2017, 53% of families refused to allow donation to take place where it was unclear if their relative had expressed a decision to donate or recorded their decision on the NHS ODR. However, 90% of families agreed to donation if they knew that this was what their loved ones wanted. Nevertheless, this still means that around 100 families per year did not support the decision as recorded on the Register and the donations did not proceed.

Q2. What do you think are the advantages or disadvantages of including personal information on someone's organ donation decision?

It may be of some advantage for the personal information to include discussions regarding transplantation that have taken place and who has been involved. Contact details of family members or other 'qualifying persons' who can be contacted in the event of death and organ donation would also be useful. The donor may wish to specify which organs were for donation and those which have not been donated and should not be transplanted.

Whilst live organ donation is often for specified recipients for example siblings, the situation with cadaveric donation is more difficult. Following cadaveric donation, the recipients will be selected by the transplant team on the basis of clinical need so that it would be inappropriate to allow potential donors to specify who should receive the organs. There is also a possibility if donors were permitted to specify the recipients, it could breach equalities legislation if the selected recipients were excluded on the basis of a protected characteristic.

Q3. How can we make people more aware of the new rules on organ donation?

The increasing number of donors suggests that there is already widespread publicity around donations which can only be enhanced by the current public debate. However, there is some confusion about the meaning of the soft 'opt-out' system in practice and in relation to the proposed legislation that needs to be clarified.

In the Welsh law and the proposed English legislation, "deemed consent" is where a person is considered to have given consent because there is no direct or indirect evidence of their wishes. Therefore in the absence of a refusal ('opt-out') the person is deemed to consent. **Logically "deemed consent" is no consent.** The justification of "deemed consent" is that the person would have known that they had to 'opt-out' otherwise it would be held that they had consented to donation. The new default is that consent is assumed unless there is clear evidence to the contrary. Paradoxically, this could mean that if there was less public awareness of the issues around organ donation, individuals might genuinely be unaware that they must positively refuse donation otherwise their organs would be harvested for transplantation. Donors would then fall into two categories – those who had positively consented and those who were considered in law to have given "deemed consent" i.e. had not given their consent at all. Positive consent cannot be given by default.

Notwithstanding any changes in the law it is difficult to imagine how transplant teams would harvest organs where it was clear that no consent had actually been given. Since the harvesting of organs must occur shortly after death, situations would arise when bereaved families subsequently learned that the organs of their loved ones had been removed without any consent at all. Organ donation should be promoted by widespread publicity. Ignorance about donation should not be used as a means of obtaining organs through “deemed consent.” People should not be forced to donate by default and **the State should not assume a legal right to obtain organs** where the views of potential donors and their families have not been made clear.

There is no evidence of benefit in the comparable Welsh legislation which was enacted through the Human Transplantation (Wales) Act in 2013 which came into force in 2015 as the following figures show.

Cadaveric organ donation for transplantation in Wales for 2013 to 2017

| Category of donor | 2013/14 | 2014/15 | 2015/16 | 2016/17 |
|--------------------------------------|----------------|----------------|----------------|----------------|
| Organ Donors | | | | |
| Donors after brain death (DBD) | 32 | 32 | 36 | 40 |
| Donors after circulatory death (DCD) | 22 | 28 | 28 | 21 |
| Total deceased donors | 54 | 60 | 64 | 61 |
| Living donors | 37 | 34 | 30 | 36 |

Overall the number of post mortem donations has changed little or even fallen (for DCD) in the two years after the new legislation came into force.

Nevertheless, there has been an increase in those awaiting transplantation in Wales as the figures below show. The numbers of transplants from deceased donors has not increased whilst those from living donors has remained constant. There is no information available for the numbers of deceased donors with “deemed consent.”

| | 2013/14 | 2014/15 | 2015/16 | 2016/17 |
|-------------------------------|----------------|----------------|----------------|----------------|
| Total patients on active list | 211 | 220 | 192 | 243 |
| Organ Transplants | | | | |
| Deceased donor transplants | 158 | 128 | 168 | 135 |
| Living donor transplants | 50 | 44 | 46 | 52 |
| Total organ transplants | 208 | 172 | 214 | 187 |

Prior to the legislation coming into force in 2015, potential donors could only 'opt in' if they agreed to consent to transplantation and register on the Organ Donor Register (ODR). In the last two years the ODR is also the means whereby individuals may register their 'opt out' of donation.

The relevant figures are as follows:

| | 2014 | 2015 | 2016 | 2017 |
|------------------------------------|-----------|-----------|-----------|-----------|
| People opted-in to the ODR | 1,005,213 | 1,047,039 | 1,113,090 | 1,171,300 |
| % opted-in to the ODR | 32% | 34% | 36% | 38% |
| People opted-out from the ODR | 0 | 0 | 165,218 | 174,886 |
| % of population opted-out from ODR | 0 | 0 | 5% | 6% |

Q4. If the law changes, would this affect your decision about organ donation?

The proposed changes in legislation would have a significant effect upon decisions (or lack of decisions) about organ donation. The proposed legislation currently before Parliament in the Organ Donation (Deemed Consent) Bill is based upon the Welsh legislation. In the proposed Bill, "deemed consent" is where the person has not consented to, or refused, donation and there is no credible evidence or witness available to state what the wishes of the potential donor would be. Currently, presumed consent is where there is credible evidence that the person would have wanted to be an organ donor in the circumstances that have arisen. For example, the person may have talked favourably about donation but not registered their views on the Organ Donation Register. Under the circumstances, it would be reasonable to presume the consent of the patient. A similar, though distinct situation arises where the family admit that they do not actually know what the person would have wanted but that they would be happy to agree with organ donation. It would be possible for the legislation to consolidate current practice and allow qualifying persons (as defined in the Transplantation (Wales) Act 2013) including close family members to authorise the organ donation. In practice, there is little practical difference between presumed consent and authorisation. Where the family can identify what the person would have wanted in the circumstances it is very likely that their wishes would coincide with those of the deceased person. In practice there is likely to be little distinction between presumed consent which is verified by the family and authorisation by the family. Conversely, the use of the term "deemed consent" where there is no actual consent is a contradiction in terms and likely to cause confusion. If the Organ Donation (Deemed Consent) Bill were passed there would be no legal distinction between actual consent by the donor or a legally recognised attorney (donee of lasting power of Attorney in England and Wales or Welfare Attorney in Scotland) and "deemed" consent. However, the first is where actual consent has been given and the second is where actual consent has been expressly excluded. "Deemed consent" is actually the absence of consent.

Q5. If the law changes, people would be considered willing to be an organ donor unless they have opted out.

Do you think this change could have a negative impact on people from some religious groups or ethnic backgrounds?

As Catholic organisations we would not wish to comment on the views of other Faiths. From a Catholic point of view organ donation is seen as a praiseworthy act when performed in an ethically acceptable manner with a view to offering a chance of health and even of life itself to the sick who sometimes have no other hope. Organ donation is considered to be altruistic and should not be taken for granted, nor should organs be obtained on a commercial basis. However, from a Catholic perspective it is well established that organ transplants are not morally acceptable if the donor or those who legitimately speak for him have not given their informed consent. There are also moral issues with the donation of gametes although this does not form part of the current consultation and are not considered further here.

Post mortem donations engage the moral issues around the definition of death, although this is not strictly a matter for the current consultation, or legislative proposals. Suffice it to say that for a post mortem donation to be morally acceptable, those involved must be certain that death has occurred. The determination of the time of death must be made in accordance with responsible and accepted scientific criteria. In accordance with current medical practice, to prevent any conflict of interest, the dying patient's doctor or doctors should ordinarily be distinct from the transplant team. If this were not the case then it would violate the prohibition on removing vital organs from living persons. The removal of vital organs from persons in persistent vegetative state and patients with severely disabling conditions violates the natural right to life. Furthermore, a false diagnosis of death in a person in a persistent state of unconsciousness could result in the actual death of a person who could later have achieved consciousness. It could progress to include the removal of organs from patients in severely disabling conditions.

To protect against these dangers three conditions must apply to justify post-mortem organ donation:

1. The donor must be verifiably and legitimately dead.
2. Proper, informed consent must have been given by the deceased donor or the donation authorised by a next of kin, provided the deceased would not have opposed it i.e. had not 'opted out'.
3. The remains of the donor must be treated with respect.

Q6. If the law changes and someone has died, and they have not opted out of organ donation, should their family be able to make the final decision?

People may fail to 'opt out' of organ donation for a variety of reasons. It could be that the patient has never got round to registering their refusal on the Organ Donor Register, did not consider that it was urgent or felt the decision could wait or required further discussion or clarification. Patients might be unaware of the need to 'opt-out' or be unclear as to how to register their refusal to donate. Presumed consent is where there is reasonable evidence that the person would have wanted to be an organ donor. However, where there is no positive indication of this the family should be able to make the final decision. This is fully in accordance with Catholic teaching. The Catechism of the Catholic Church states: "Organ transplants are in conformity with the moral law if the physical and psychological dangers and risks to the donor are proportionate to the good sought for the recipient. Organ donation after death is a noble and meritorious act and is to be encouraged as an expression of generous solidarity. It is not morally if the donor or his proxy has not given explicit consent. Moreover, it is not morally admissible to bring about the disabling mutilation or death of a human being, even in order to delay the death of other persons." [Paragraph 2296].

It would be possible to amend the current legislation so that the family could legally authorise the donation on behalf of the deceased. Under the current proposals organs could be removed from a non-consenting deceased donor on the basis of "deemed consent" i.e. without consent and against the wishes of the family. If the family, or other suitable qualifying person, could authorise the donation, this would permit a soft 'opt-out' whilst still maintaining the requirement for consent, albeit from the family or other 'qualifying person'.

Q7. Do you think someone's family should be able to decide if their organs are donated, if it is different to the decision they made when they were alive?

No. If the deceased had refused to donate, that decision should not be overridden by the family. Conversely, the family ought not to refuse donation when the deceased had given consent. However, in practice the circumstances of their refusal may be emotionally charged and difficult because of their recent bereavement. Whilst the family might change their mind about donation, it is unconscionable that organs would be taken in the face of ongoing objections by the family. This would be regarded as grossly disrespectful of their feelings regarding their loved one. Furthermore, it is difficult to imagine a transplant team removing organs in the face of objections from the family. Such behaviour would almost certainly lead to serious complaints. Donation should be altruistic and never forced. It is easy to appreciate that a willing family might experience considerable consolation that the organs of their loved one were helping to save lives. Conversely a grieving family with severe reservations or strong objections to donation would experience further upset if organs were removed without their agreement. These feelings would be compounded if

there was any complaint as to how the deceased had been managed prior to death or if there was any question of negligent care.

Organ donation after death is a noble and meritorious act and is to be encouraged as an expression of generous solidarity. It is an altruistic act of free giving and a genuine expression of charity that looks beyond the death of the donor towards the gift of life to others. It offers a chance of health and even of life itself to the sick who sometimes have no other hope. However, it is not morally acceptable if the donor, or his proxy, have not given explicit consent

Q8. Which of the following should not be included in the proposed new rules about organ donation?

- **children under 18 years old**
- **people who lack capacity**
- **visitors to England**
- **people living in England for less than 12 months (for example, students from overseas, armed forces personnel)**

Are there any other groups you think should not be included? Please say why you think this.

The above exceptions are those considered within the Human Transplantation (Wales) Act 2013. It is reasonable for those under 18 years of age not to have seriously considered, or indeed, to be able to consider, the question of organ donation. However, where this is the case, if authorisation by the family were permitted, it would not present a problem for those under the age of 18 who had made a mentally competent decision to donate their organs.

Those who lack capacity, including those with learning disability or mental impairment, such that they never had capacity, cannot give consent therefore it would be unreasonable to ascribe “deemed consent” to them. However, it is possible for a person with mental competence to make a decision to donate, who subsequently loses mental capacity. Such individuals, having made a decision to donate their organs whilst mentally competent should not be debarred from donation simply because they subsequently lost their mental capacity after the decision had been made.

Visitors to England who had not been resident for at least 12 months should not be included in the legislation. Visitors from abroad or students living in England whilst studying might not be aware of the legislation and the need to ‘opt-out’ of organ donation. This could affect visitors from abroad or students living in England whilst undergoing studies who might not be aware of the legislation.

Q9. Please tell us about any opinions or evidence you have about opting out of organ donation.

The terminology and approach to the 'opt out' system of donation is somewhat difficult to understand. The proposed Bill describes its purpose as "to enable persons in England to withhold consent for organ donation and transplantation; and for connected purposes." However, clause 1 states that for the purposes of organ transplantation the person concerned [potential donor] will be deemed "to have consented to the activity [in relation to transplantation] unless a person who stood in a qualifying relationship to the person concerned immediately before death provides information that would lead a reasonable person to conclude that the person concerned would not have consented." In other words, whilst the Bill purports to facilitate refusals of organ donation, its effect is different. As the title suggests, the Bill regards the person as having given "deemed consent" unless a qualifying person can provide information to the contrary. "Presumed consent" is generally taken to be consent which can be reasonably deduced about the would-be wishes of the person derived from evidence from family or other qualifying people. Therefore, the difference between "presumed consent" and "deemed consent" is that the former presumes consent on the basis of some supportive collaborative evidence whilst the latter presumes consent in the absence of evidence to the contrary from those who know the person.

The danger with the 'opt out' system is that by introducing the concept of "deemed consent" i.e. no verifiable evidence of a refusal, that this will reduce the incentive to encourage active organ donation through actual consent from donors. In the absence of a successful campaign to encourage donation, it would then be sufficient to "deem" consent in the absence of a refusal. The default position then becomes that the deceased wanted to donate whether or not there is any positive evidence. We do not find this acceptable.

An alternative strategy would be to encourage authorisation of donation by the family or other qualifying persons where it is unclear what the deceased would have wanted but where there is a desire for the family to consider and facilitate donation.

As indicated in response to question 3 there is no clear evidence that the situation in Wales has increased the number of cadaveric organ donations in the last two years. The crucial evidence as to the number of donors who have given organs on the basis of "deemed consent" is lacking, though should be available. Nevertheless, since the numbers are small and if anything the number of deceased donors has tended to fall in the last 2 years, the advantage of "deemed consent" to select organ donors without their positive consent is lacking. Nevertheless, there has been a steady increase in the number and percentage of the population that have 'opted-in' to organ donation in the last 2 years. However, the number of those who have indicated that they do not wish to donate has also increased and is now 6% of the population, compared to the 38% who wish to donate (see response to Q3).

In countries that have adopted an 'opt-out' system it is not clear if the increase in the number of donor is because of the legislation or can be attributed to additional changes in

relation to better infrastructure, increased funding and staffing level, or better publicity and campaigns to encourage donations. Despite the legislative changes, harvesting does not occur in the face of opposition from the families. Whilst Spain is identified as a successful 'opt-out' system, the scheme in Sweden which has had such a system since 1996 remains one of the lowest-ranking countries for organ donation in Europe. Luxembourg and Bulgaria also operate 'opt-out' systems and have low donation rates.

P Howard

President of CMA (UK) and Chair of the Joint Medical Ethics Committee of the CMA and CU

A handwritten signature in black ink, appearing to read 'N. Karlen', with a large, sweeping flourish underneath.

Director of the Catholic Union of Great Britain