

# Is presumed consent an ethically acceptable way of obtaining organs for transplant?

Pradeep Kumar Prabhu 

## Abstract

The near-universal acceptance of cadaveric organ donation has been based on the provision of explicit consent by the donor while alive, either in the form of a formal opt-in or informal discussion of wishes with next of kin. Despite the success of transplantation programmes based on explicit consent, the ongoing imbalance between demand and supply of organs for transplantation has prompted calls for more widespread introduction of laws validating presumed consent with facility for opt-out as a means of increasing organ availability. The Department of Health (UK) has recently concluded a consultation on the introduction of such a law for England. This article explores the debate on presumed consent from an ethical point of view and summarises the key arguments on both sides of the ethical divide.

## Keywords

Presumed consent, ethics; clinical, ethics; transplantation, tissue and organ procurement, ethics

## Introduction

The first successful human organ transplant operation was performed in 1954 and involved the transplantation of a kidney from an identical twin.<sup>1</sup> There has since been a progressive increase in the number and range of transplantation procedures performed successfully, driven by improvements in surgical technique and intensive care and the emergence of medical technologies to bridge organ function in the face of irreversible organ failure and to combat rejection. In the UK as elsewhere, a large proportion of solid (unpaired) organ transplants that are currently performed utilize organs obtained from dead donors.<sup>2</sup>

From the outset, there was widespread support for the concept of allogenic organ transplantation from the dead. Even disregarding extreme utilitarian views such as the macabre ‘survival lottery’ hypothesised by John Harris,<sup>3</sup> there is logic in a utilitarian and communitarian view that the dead cannot be harmed by removal of their organs, while the living (and society in general) stand to benefit from them. From a deontological (duty-based) perspective, it can be argued that the right to be a recipient when in need of a transplant imposes corresponding duties to be a donor.<sup>4</sup> The Catholic Church was early to realise the benefits to humanity from transplantation and supported organ salvage from the dead. The violation

of the sanctity of the dead was justified by the concept of the ‘Ultimate Gift of Charity’ that a human being could leave his fellows. Integral to this concept was the need for this ‘Gift’ to be properly endowed or ‘given’ by the donor, and not be ‘taken’.<sup>5</sup> This could only be guaranteed by a process of ‘informed consent’ by the donor allowing for the violation of his mortal remains after his death.

The earlier view (and one that still prevails in many jurisdictions) is to insist on the exclusive validity of ‘explicit’ consent, where the donor needs to have ‘opted-in’ to becoming a donor. This needs to have taken place by an act of (usually) signing into a donor register, ideally having had access to adequate information. In the event of untimely death of a potential donor with no explicit evidence of consent or dissent to organ donation, most opt-in jurisdictions accept ‘consent’ to donation being provided by his closest relatives. While there is a general acceptance that only the donor has the right to decide how his ‘private

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Department of Anaesthetics, The Royal Surrey County Hospital, Guildford, UK

### Corresponding author:

Pradeep Kumar Prabhu, The Royal Surrey County Hospital, Egerton Road, Guildford, Surrey, GU2 7XX, UK.  
 Email: [pradeep.prabhu@nhs.net](mailto:pradeep.prabhu@nhs.net)

property' is disposed of after his death, a common-sense approach is taken that his closest relatives are likely to know what his wishes would have been, and are most likely to act accordingly.<sup>6</sup> Allowing relatives to consent prevents a valuable resource from going waste, and importantly, ensures that the potential donor's wishes are adhered to as closely as possible. Most jurisdictions have tacitly extended the right of veto to close relatives claiming an individual may have changed his mind after opting in, and in some cases, using organs against strong objections by relatives (while legal) may cause distress to those left behind and may adversely impact the doctor–patient relationship and social solidarity on which transplantation systems thrive.<sup>7</sup>

In the UK, an opinion poll conducted by the organ donation task force has revealed that 90% of adults are in favour of becoming organ donors.<sup>8</sup> However, as of the last available activity report from the NHS Blood and Transplantation service, only about 36% of eligible adults have registered onto the organ donor register.<sup>2</sup> In the case of adults who die without being on the donor register, refusal rates for organ retrieval by relatives is high, with the consent rate being only 46.7%. The consent rates are high (91.2%) if the potential donor was already on the register or if their wishes are known by the relatives.<sup>2</sup> The numbers of patients on the transplant waiting list has increased by 7% between 2001 and 2013, and the gap between the waiting list size and organ availability is increasing alarmingly. The latest available statistics indicate that in the UK, there are 6388 patients awaiting a transplant as of the end of March 2017, and 457 patients on the waiting list dying while awaiting a transplant.<sup>2</sup> This is the background to the idea that alternative forms of consent such as presumed consent (opt-out) or mandatory choice should be considered as a means of increasing the supply of organs.<sup>9</sup> Other methods of obtaining organs for donation such as 'organ conscription'<sup>10</sup> or 'routine recovery'<sup>11</sup> and 'normative consent'<sup>12</sup> have been mooted, but are largely considered theoretical challenges to the existing pragmatic ethical positions. The risk of extreme policy positions alienating public opinion and reducing donation rates is accepted as being real, and this has prevented any jurisdiction from seriously considering their implementation.

### **The concept of presumed consent, deemed consent or 'opt-out'**

The concept of presumed consent for organ donation is not new and dates to an idea first mooted by Dukeminier and Sanders.<sup>13</sup> The issue had bubbled over in the field of bioethics with Cohen making the case for it and Veatch and Pitt against.<sup>14,15</sup> However, the concept was brought to the fore when Professor Ian Kennedy and his co-authors wrote in the *Lancet* arguing the case for presumed consent as a way of increasing the supply of urgently needed organs.<sup>16</sup>

The BMA's Medical Ethics Committee endorsed presumed consent for organ donation in the UK calling for a consolidated approach to organ donation for the 21st century.<sup>7,17</sup> This resulted in a report by the Organ Donation Taskforce (2008), which suggested that while presumed consent was ethically acceptable, an improved opt-in system or a system of mandated choice may be a better way of ensuring that the wishes of the donor were honoured.<sup>18</sup> The review of existing studies commissioned by the taskforce concluded that while most jurisdictions did clearly have higher donor numbers per million population (pmp) after introduction of opt-out legislation, this could by no means be conclusively attributed to the opt-out legislation in isolation.<sup>19</sup> Opt-out countries such as Spain, Austria and Belgium have among the highest donation rates, but some such as Bulgaria and Luxemburg have among the lowest.<sup>20</sup> The taskforce suggested that significant improvements in organ donation rates could be achieved by improvements in infrastructure and education, including public awareness campaigns. They indicated that the issue of presumed consent should be revisited in five years if the targets were not achieved.<sup>18</sup>

By enacting the Human Transplantation (Wales) Act 2013, the Welsh Assembly chose to introduce deemed consent for organ donation into Law from 1 December 2015.<sup>21</sup> The review on which the Welsh Assembly based its decision came to a similar set of findings, but suggested that on balance opt-out legislation was likely to increase donation rates.<sup>22</sup> The version of deemed consent chosen by the Welsh Assembly is termed 'soft opt-out', where intention is that the state will not go against refusal by the next of kin. The rationale for this (as against a hard opt-out) is to avoid giving the impression that the state was acting as though it had a 'right' to the organs from the deceased, potentially provoking opt-outs from individuals. While early data suggest an increase in consent rates, more registered donors and more live donations, there has been a decrease in actual donor numbers. Admittedly, the small size of the population makes it difficult to draw inferences this early.<sup>23–25</sup> The Department of Health (DoH) recently commenced a public consultation on the introduction of an opt-out system of organ donation for England as a means of improving organ donation rates.<sup>26,27</sup> This consultation ended on 6 March 2018 and has attracted over 11,000 responses highlighting the passionate views held by the public on this topic.

### **Ethical arguments relating to the presumption of consent**

The following discussion looks at the ethical arguments against and for an opt-out arrangement. It is not meant to add to the two excellent reviews and a critique that have looked into the issue of whether introduction of presumed consent will increase the

supply of organs in England and Wales.<sup>19,20,22</sup> An attempt will be made to draw some conclusions that bridge the chasm in normative ethics about the use of presumed consent strategies.

### The argument against presumption of consent

One of the key arguments made against the presumption of consent is the concern that informed consent would no longer be involved in the process of organ acquisition. This means that the organ is no longer a gift or donation in the true sense of the word. It appears as something that has been ‘taken’ from the dead. In Pope Benedict XVI’s words, “...In these cases, informed consent is a precondition of freedom so that the transplant can be characterised as being a gift and not interpreted as a coercive or abusive act”.<sup>28</sup> On this basis, Austriaco has urged that all catholic individuals and institutions “... must reject presumed consent and not cooperate with an unjust system of organ procurement.”<sup>29</sup> There is evidence that majority of recipients wish to be certain that the organs were only retrieved in accordance with the donor’s wishes.<sup>30</sup> This concern (among other practical considerations) was one of the factors that made the Organ Donation Taskforce argue against the introduction of presumed consent.<sup>18</sup>

The problem is that this assumes the opting-in process to entail ‘informed consent’. With behavioural economic theories (nudge theories) being applied extensively in the public policy sphere, the process of opting into a donor register involves nothing more than a tick in a box during an application for a driving licence or renewing a vehicle excise duty.<sup>31</sup> At the time the application is made, the implications of the tick box are likely far from the applicant’s mind. Similar ‘nudge theories’ are thought to lie behind the use of presumed consent in organ donor registration policy. There is clear acceptance in the domain of behavioural economics that when presented with alternatives, people who are unsure tend towards the default (status quo bias or default bias).<sup>32</sup> This is thought to be one of the reasons behind higher donation rates in presumed consent jurisdictions.

The fact remains that most potential donors in the UK are not on the donor register, and current practice in explicit consent jurisdictions entails asking relatives to ‘consent’ on their behalf. This consent has no real validity in terms of ensuring the gifted nature of the donation process. Besides, it puts an additional strain on the relatives in a situation that is already excruciating. The relatives are being asked to rule against the ‘presumption’ that the donor would not have wished to donate (which is the presumption in explicit consent jurisdictions), and consent to what they might consider as the mutilation of the deceased’s mortal remains. It is therefore not surprising that consent rates for organ retrieval are low when the wishes of the potential donor are not known. There is also the

argument that of the 90% of individuals who stated in surveys that they would wish to donate, the 54% who did not register presumably failed to do so primarily due to apathy, and not because they would not want to donate.<sup>8</sup> It could also be argued that the claims made when surveyed may reflect their values, but may not reflect their wishes, hence the disparity between survey results and donor registration rates.

The main argument against presumed consent stems from the potential for violation of the donor’s autonomy: his wish about what should happen to his body after death. Farsides states that “acknowledging and where possible acting in accordance with a person’s wishes regarding treatment of their body signals respect for that autonomy”.<sup>33</sup> The moral wrong involved in interfering with a dead person’s body against his (un)stated wish maybe seen as worse than the moral wrong involved in non-interference with the body against his (un)stated wish. Veatch and Pitt argue that the two wrongs are not morally equal, analogous to the commonly accepted view that it is better to let nine guilty individuals be unjustly freed than for one innocent to be punished.<sup>15</sup> They state that unless it is unequivocally clarified that the overwhelming majority of individuals would want to donate their organs upon their deaths, the only morally correct solution would be to adhere to an explicit consent policy. This is because removal of organs without explicit consent constitutes a blatant violation of bodily integrity (and thence autonomy), whereas failure to remove organs when it may have been desired, is ‘merely’ an unfortunate failure to help bring about a desired outcome.

A further point of objection to presumed consent policies raised by Veatch and Pitt is the view that such policies are actually a misnomer, as no one can presume consent when the person who owns the property is unable to provide such consent explicitly. They state that such policies are attempting to give ‘eminent domain’ policies (that basically state that private property is for the state to use to satisfy a public Good) a cloak of respectability to make them acceptable to a society that values the rights of the individual above everything else.<sup>15</sup>

Ben Saunders, a prominent supporter of the opt-out policy for organ donation agrees that the presumption of consent is a misnomer, as consent as we know it involves an active process with its three well known components (capacity, adequate information and ability to balance the information to come to a decision). He argues that ‘an opt-out policy without presumptions’ is ethical, as the failure to register an objection (given adequate chances to do so) can be ‘interpreted’ as implied consent.<sup>34</sup> MacKay counters this with the evidence that across Europe, surveys have shown poor understanding of existing donor registration policies.<sup>35</sup> In the backdrop of this, the assumption that silence means tacit consent would not be ethical.<sup>36</sup>

One of the fears raised by the Organ Donor Task Force was the risk of increased opt-outs as a push

back against what could be considered interference by the state. In fact, the Welsh experience has shown that about 5% of the eligible population did opt out in the three years since the legislation came into force.<sup>37</sup>

### The argument for presumption of consent

On the other side, Cohen<sup>14</sup> argues that a presumption is made in either case: either a presumption that majority of individuals do not wish to be donors or to the contrary.<sup>14</sup> In each case, a proportion will be wronged by having their autonomous will violated. He argues that violation of the autonomous will of a dead person is equally wrong: whether it involves a mistaken removal or a mistaken non-removal. The interference with the body is not the moral wrong, but the violation of autonomy. He states that “the present system, depending entirely on the expressed consent of the decedent’s family after death, thus errs in its empirical underpinning, and by that error promotes a great moral mistake”.<sup>14</sup> In this sense, even if 51% of individuals are potential donors, fewer mistakes would be committed with a presumed consent policy. This supports the ‘fewer mistakes’ claim in favour of a presumed consent system of organ donation, assuming that the mistakes are morally equal.

A system of explicit consent (opt-in) with a low uptake that relies on consent from the next of kin may leave an objector open to potential violation, as their relatives may not be aware of their objection and may have values different from the donor. In such a situation, proponents of presumed consent with opt-out argue that the provision of opt-out provides objectors with a clear path to maintain their autonomy.<sup>7</sup>

There is also the logical assumption that an individual opposed to organ donation is more likely to opt-out under a system of presumed consent, than someone who desires to donate is to opt-in under an explicit consent system. This assumption stems from the fact that “most of those opposed to organ donation have conspicuous religious or moral objections of which they themselves are very aware, and as a result are unlikely to neglect to opt-out of a system of presumed consent”.<sup>38</sup> In stark contrast, those who wish to donate are doing so out of an altruistic motive, which is “relatively unremarkable”, and are less likely to make their preferences clear before the unexpected eventuality of their death occurs.<sup>38</sup> However, in a stinging counter to this, Kluge argues that presumed consent policies with opt-out protection are akin to a person who does not wish to be violated having to inform trespassers of this fact and is a ‘reversal of polarity of the right to inviolability’.<sup>39</sup>

Spital and Taylor make a case for “entirely eliminating the consent requirement for the routine recovery of transplantable cadaveric organs”.<sup>11</sup> They equate this to a situation of total war in which most citizens would accept the concept of a draft in the

general public interest. They claim additional benefits to routine removal such as equity, avoidance of additional stress on grieving relatives and removal of potential for exploitation as reasons why this process is more ethical than explicit consent. The issue seems to boil down to whether organ retrieval (or routine salvage as Dukeminier & Sanders referred to it) is actually a ‘give’ by the donor or a ‘take’ by the state.

Gill gives this argument a completely novel dimension by defining the two types of autonomy being referred to implicitly in these two widely varying points of view. He argues this difference in the forms of autonomy being referred to as being a crucial aspect in rationalising the two arguments.<sup>38</sup>

To understand this better, it would help to use the relatively simple analogy of disposal of one’s assets. When an individual is alive, he has every right to do what he wants with his assets, and any interference with his wishes goes contrary to his autonomous will. If he dies with a will in place, his autonomous will is clearly stated, and his assets are distributed as he would have wished. This is referred to as the ‘non-interference model’ of autonomy. The two proponents do not differ in their approach to this model of autonomy. If an individual is alive and competent, an invasive procedure will only be performed with his explicit consent. Similarly, if his desires regarding organ donation are clear, the same model would apply.

The divergence happens if this individual dies intestate, or without leaving clear instructions as to his wishes regarding organ donation. The non-interference model is no longer applicable, as the state cannot leave his assets be as they are when he died. Nor can the state leave his body as it is when he dies. ‘Interference’ in some shape or form is mandatory, and the state uses a ‘respect for wishes model’ of autonomy to decide how best to interfere in these scenarios. In the case of his assets, the state takes the view (presumes) that most people would want their assets distributed among their closest relatives and acts accordingly. In so doing, it is likely that in a few cases mistakes will be made: for example, if he wanted all his assets left to charity. From a policy perspective, it makes sense to implement one that makes the fewer mistakes. Gill is categorical in his dismissal of Veatch and Pitt, and Kluge’s claim that mistaken removals violate an individual’s right to non-interference with their bodies, as these individuals when brain-dead, are no longer capable of self-determination.<sup>15,39</sup>

Gill argues that the same should apply to organ donation after death: “The duty to respect persons’ wishes about what should happen to their bodies after death implies that we should follow the policy that can reasonably be expected to lead to the fewest mistakes”. If the available evidence is right, and points to a majority wishing to donate their organs after death, an organ procurement policy that presumes consent will overall make fewer mistakes than one that insists on explicit consent. In fact, he argues that a society which institutes

a presumed consent policy is “a society that does its best to construct policy that respects individuals’ own choices” and not one that fails to adhere to the Nuremberg Code.<sup>40</sup> Mackay counters this argument by clarifying the implications of donor registration policies. Their remit is all about registering currently competent people for an intervention that will occur when they are no longer competent. In this context, autonomy will be only respected if they are asked for authorisation while they are competent rather than use a respect for wishes model when incompetent. He says that consent may not be a necessary step in organ retrieval (if society so decides), but to be respectful of autonomy, a donor registration policy should do everything possible to seek consent (opt-in).<sup>36</sup>

## Conclusion

What is clear from the arguments presented is that an individual society’s chances of making ‘fewer mistakes’ in preserving autonomy of the donor revolves around knowing for certain what the overwhelming majority of its members would want happen to their bodies after death.

Opponents of presumed consent policies argue that only if the desire to donate applies to the “overwhelming majority” could a presumed consent policy be considered morally acceptable. The proponents argue that if a simple majority emphatically desire to be donors, a presumed consent policy will be justified over an explicit consent policy. Neither disagree that from a communitarian perspective, organ donation is a moral good, and should be encouraged. Both accept that information on the process is the key to ensuring the ethical validity of either approach.

It seems incumbent upon society to ensure that this message gets across to everyone by making information on the benefits of organ donation available in a language that is simple and clear. This would eventually overcome the apathy that seemingly prevents the silent majority from signing on to the organ donor register, and thereby render the whole process almost self-fulfilling. Such a paradigm shift will also not ignore the needs of those who, for whatever reason or no reason at all, are opposed to becoming organ donors. They should be able to make their opposition clear without fear of recrimination, and with the utmost certainty that society will uphold their wishes. This seems to have been the approach taken by the organ donation task force in its report titled “The potential impact of an opt out system for organ donation in the UK: An independent report from the Organ Donation Taskforce”. The taskforce concluded that as things stand, “a presumed consent system has the potential to undermine the concept of donation as a gift, to erode trust in health professionals and the Government, and negatively impact organ donation numbers”.

A presumption of consent is also ethically sound and morally justified in organ retrieval for transplantation,

provided information on the opt-out process is readily available in easily comprehensible formats, it is ensured that as many people as possible understand the opt-out process and families are given a say in the final decision. However, the concerns that surround the implementation of such a policy are real and mandate that implementation be preceded by a public information campaign highlighting the moral justification for organ donation as a whole, changes in infrastructure that separate the clinicians involved in the clinical care of potential donors from the staff involved in the diagnosis of brain death, consent process, organ retrieval and organ transplantation and clarification of the legal standing of organ donor cards.

Until this happens in practice, policies that presume non-consent and those that presume consent will continue to make mistakes in individual cases. Society will have to decide whether a moral mistake that saves other lives (mistaken removals in presumed consent policy) is in any way preferable to an equivalent moral mistake that in addition costs lives (mistaken non-removals in a policy of explicit consent). It would be hoped that in a future where organ donation is ‘the norm’, history will not harshly judge us as a society that left its sick to suffer through a desire not to harm the potential autonomous will of its dead.

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## ORCID iD

Pradeep Kumar Prabhu  <http://orcid.org/0000-0002-6322-4971>

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