

The potential impact of an opt out system for organ donation in the UK

An independent report from the Organ Donation Taskforce



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Organ donation occurs at a time of great emotional distress. The terminology and phraseology in this report are necessarily factual and might appear unsympathetic to those most closely affected by organ donation. This dispassionate reporting of events and outcomes should not be taken as disrespectful to deceased donors or their families, or to the amazing gift they make.



INTRODUCTION BY THE CHAIR OF THE ORGAN DONATION TASKFORCE

I am pleased to present the Organ Donation Taskforce's report on the potential impact of introducing an opt out system for organ donation in the UK.

During its discussions and engagement with academics, health professionals, members of the public, organ recipients, families of donors and faith leaders, the Taskforce has come across an enormous range of views and opinions on this matter, often strongly held. Everyone, on whichever side of the opt in/opt out debate they stand, has engaged constructively. I am grateful to those who took the time to write to us, speak to us or engage in debate at public events for their contribution to our consideration of this finely balanced question.

The report itself is deliberately concise, but this should not disguise the wealth of evidence that has been accumulated and carefully considered since we began our work. Therefore we are making available, as a separate set of annexes to the report, all the background information and research that we have drawn on in reaching our conclusions.

Finally, I would like to express my thanks to all the members of the Taskforce and its various working groups, and pay tribute to their humanity, knowledge, energy and commitment.

A handwritten signature in black ink, which reads "Elisabeth Buggins". The signature is fluid and cursive, with a long horizontal stroke at the end.

Elisabeth Buggins CBE DL
Chair, Organ Donation Taskforce

1

A FINELY BALANCED QUESTION

1.1 The question of whether or not changing to an opt out system for organ donation is right for the UK is a finely balanced one, generating impassioned debate and a wide range of opinions.

1.2 When the Taskforce began its deliberations, members had a variety of views. By the end of the process a clear consensus had been reached, but only after an extensive range of evidence had been considered along the way, with much powerful and well considered opinion expressed on both sides of the equation.

1.3 Everyone agrees that there is an urgent need to do something to help the thousands of people in need of transplants every year. It is clear that the current system is not doing enough to translate the high degree of public support for organ donation into actual donations of organs. This message came through particularly plainly at the events we held with members of the public.

1.4 On the face of it, several factors support a change to an opt out system.

1.5 The systematic review of research evidence commissioned by the Taskforce revealed an apparent correlation between high donation rates and opt out systems in countries around the world. However, the reviewers found that presumed consent alone does not explain the variation in organ donation rates between the different countries. Many other factors affect donation rates.

1.6 In working with the public we found that the majority – around 60% – would support a change to an opt out system, as long as it was properly implemented to ensure that the rights of vulnerable groups were protected and there was sufficient information to back it up. This is consistent with previous surveys carried out by others.

1.7 The expert working groups set up by the Taskforce to consider the legal and ethical implications of changing to an opt out system advised that there are no fundamental legal or ethical barriers to introducing a ‘soft’ opt out system, in which, as a safeguard, family members would be consulted about donation.

1.8 On the other hand, we found considerable evidence highlighting the potential downside of such a move.

1.9 The Clinical Working Group heard persuasive arguments from health professionals about the potentially negative implications for clinical practice, especially the potential to damage the vital relationship of trust between clinicians caring for people at the end of life, their patients and their families. Some intensive care staff in particular fear that a move to an opt out system would make critical care more difficult and could lead to some intensive care practitioners themselves opting out of participation in donation programmes. This would be disastrous for the future of organ donation in the UK since many of the recommendations made by the Taskforce in its earlier report, *Organs for Transplants*, are dependent on the active support of intensive care practitioners.

1.10 The working group considering clinical implications also heard powerful evidence from recipients of organs who stressed their need to know that organs had been freely given by donors and their families, and from donor families who often find great comfort in being an active part of the decision to donate.

1.11 It became increasingly clear that it would be both complex in practical terms and also costly to put in place an opt out system that could command the trust of professionals and members of the public. There would need to be a significant and sustained communications programme to ensure that all members of society knew about the new system and what it would mean for them. Real concerns were

expressed about the security of information on an opt out register; this issue would need to be addressed by using a robust and secure IT system.

1.12 We heard support from members of the public and patients' groups for the principle of informed consent, and a perception that assuming consent from silence belongs to a more paternalistic era. Some felt that an opt out system could be 'dehumanising'. Given that current trends in healthcare place great emphasis on choice and responsiveness, this is an important consideration.

1.13 Many people have reservations about a change to an opt out system, including some who are currently on the Organ Donor Register (ODR). Some faith leaders we spoke to warned of the potential for provoking anti-donation feelings and even active anti-donation campaigning. We heard considerable concerns about the impact on some groups, for example those who might be less comfortable using the 'opting out' process. However, the Taskforce established that there is great willingness to donate under the present system, including within faith groups.

1.14 On balance, the Taskforce feels that moving to an opt out system at this time may deliver real benefits but carries a significant risk of making the current situation worse.

1.15 Nevertheless, some clear messages emerged from our findings about priority action for improving consent rates for donation, the most striking of which was the need to address the extremely low awareness of the ODR. If a person's name is on this register, 90% of families consent to donation, compared with a general consent rate of about 60%. There is a clear need to publicise the register and to make the process of registering easier and more widely understood.

1.16 Other areas for development include the following:

- Many people have fears or misgivings about organ donation based on misconceptions or 'myths' that need to be dispelled.
- We need to encourage people to talk about organ donation with their families and friends, as recommended in the draft NHS Constitution.

1.17 Implementation of the recommendations in *Organs for Transplants* is under way, promising at least a 50% increase in donation over five years. The recommendations already have widespread support and may make a change in the law unnecessary. Progress should be closely monitored and the question of changing to an opt out system revisited only if we need to.

2

SETTING THE SCENE

2.1 There are not enough donated organs to save people's lives in the UK. Although over 3,000 people in the UK received an organ transplant in 2007/08, another 1,000 died after having waited in vain on the waiting list, which currently numbers over 8,000 people. This figure does not reflect the true extent of need: many who could have their lives transformed by a transplant never even reach the waiting list. Need is, at minimum, 50% more than is currently available. It is a desperate situation.

2.2 The Organ Donation Taskforce was established in 2006 and asked to identify obstacles to organ donation and suggest ways of overcoming them. In its report *Organs for Transplants*, published in January 2008, the Taskforce made 14 recommendations. It was persuaded that if these were fully implemented, a 50% increase in donations could be delivered within five years. All the recommendations were accepted by UK Health Ministers. The recommendations are currently in the process of implementation across the UK in a programme that is being led by Sir Bruce Keogh, Medical Director of the NHS in England, and overseen by the Programme Delivery Board.

2.3 Some countries – such as Spain and, increasingly, the USA – have high rates of organ donation. This success has not been achieved by changing one single aspect of their organ donor system in isolation, but rather by addressing each piece in the complex jigsaw of interdependent elements that make up a successful donation programme.

2.4 The Taskforce, which is a UK-wide initiative, was able to rigorously review all elements of the UK system for its first report, excepting those that would require legislative change. This meant that the Taskforce did not consider presumed consent. The Taskforce members were therefore pleased to be invited by the UK Health Ministers to bring similar rigour to considering this piece of the jigsaw.

The Taskforce was asked what measures might be required to introduce a system of presumed consent and whether this would increase the number of organ donors. It was also asked to consider public attitudes to presumed consent.

2.5 Those who have first-hand experience of the desperation of those on the waiting list for donor organs and who have been frustrated by the lack of progress in increasing donor numbers understandably wish to do everything they can to increase the availability of donor organs. This passion is shared by every member of the Organ Donation Taskforce.

2.6 From the outset, the Taskforce has approached the issue of presumed consent or opt out with an open mind, with many members sympathetic to a change to the current system, should the evidence support it. All Taskforce members were grateful that the issue had been given such a high profile by the Prime Minister, the Chief Medical Officer for England, UK Health Ministers, the British Medical Association and others, because it has stimulated and enhanced public debate and this has already been of benefit to transplant services.

2.7 Those who promote presumed consent do so for the best of reasons, expecting that it will increase the number of donors. The Taskforce has sought to test those expectations against the widest available evidence to check whether the intuitive answer is, in fact, correct.

3

METHODOLOGY

3.1 For this new undertaking, Taskforce membership was expanded to include, among others, ethicists and medical lawyers as well as clinicians, together with further representation from the devolved administrations. A list of members is at Annex A.

3.2 The Taskforce adopted a rigorous approach that included:

- the formation of six working groups (clinical, communications, cultural, ethics, legal and practical), each recruiting additional expertise from outside the Taskforce membership. Over 70 people were involved in this way from right across the UK, reflecting the fact that increases in organ donor numbers can only be addressed by the United Kingdom as a whole. Each working group had specific terms of reference that are detailed, together with their membership, at Annex B. The reports of the groups are contained in Annexes C to F and M;
- the commissioning of an initial analysis of the costs of setting up a new consent system, as detailed at Annex G;
- the commissioning from the University of York of a systematic review of international literature on presumed consent systems across the world. The full terms of reference for the review are at Annex H and the report itself is at Annex I;
- the commissioning of a comprehensive series of deliberative events in seven regions across the UK. The events involved over 350 members of the public, representing a statistically valid sample of the UK population, and were carried out by Opinion Leader. A report of the findings is at Annex J;
- the views of a wide range of stakeholders. A summary of their views is at Annex K. There were also many unsolicited letters received from members of the general public, whose views are summarised at Annex L;
- the commissioning of one-to-one interviews with leaders of 17 different faith and belief groups. A report of the findings from these interviews is included in the Cultural Working Group's report at Annex M; and
- for information, a summary of progress made on each of the recommendations in the Taskforce's first report, *Organs for Transplants*. This is included at Annex N.

We believe that this approach has enabled us to carry out a thoughtful, comprehensive, detailed and rigorous investigation of presumed consent.

All of the information in the annexes is available separately at www.dh.gov.uk/organdonationtaskforce

4

THE CURRENT SITUATION – ISSUES AND LIMITATIONS

4.1 Most people find it very difficult to discuss their death, even with those closest to them. If such conversations do take place, they are more likely to do so in the context of serious illness or advancing age. Those who are younger and healthy may feel such conversations with their families are unnecessary, morbid or ‘tempting fate’. Yet it is previously reasonably healthy under-50s who form the greatest proportion of organ donors, although donation can, and does, occur from people over 80 years old. Unless someone has registered with the ODR or carries a donor card, their family and those close to them may not know their views on organ donation when they die. Given this uncertainty, and faced with a decision at a time when they are feeling vulnerable and distressed, next of kin may feel that the ‘safest’ course of action for them is to refuse permission for donation.

4.2 With regard to organ donation, the recorded wishes of the deceased are given legal primacy by the Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006, although the legislation is ‘permissive’, i.e. there is discretion not to proceed with the donation if doing so would cause deep distress to family members. According to the UK Transplant Potential Donor Audit (PDA) summary report for the 24-month period from 1 April 2005 to 31 March 2007, at present 90% of families consent to donation if the deceased was registered on the ODR compared to a general consent rate of 61%. Where ethnicity was recorded, consent rates were 67% for white potential donors and 24% for non-white potential donors.

4.3 It has been reported in surveys that between 65% and 90% of the UK population are in favour of donating their organs, yet only about 25% have registered their wishes on the ODR. Some of this gap may well be the result of an artificially high response rate to poll questions, but even if the lower response figure is taken, it points to at least 40% of the UK population failing to register their wishes to donate on the ODR. This illustrates a problem of inertia familiar to us all: always meaning to get round to doing something that

is not top of the ‘to do’ list. A system of presumed consent is often described as consent for the disorganised. Many argue that having such a system would more accurately reflect majority wishes, allowing donation to become the default position. This is a powerful argument for the introduction of presumed consent. On the other hand, some people are concerned that a proportion of the 10% to 35% of the population who would not have wished to donate their organs, but never got round to registering an objection, could mistakenly be considered as willing donors under an opt out system.

4.4 The gap between intent and action illustrated by the number of people registered on the ODR (approximately 25% of the population) compared with those who say they are prepared to donate an organ after their death (about 65%) or those who say they support donation (up to 90%) exposes the many inadequacies of the current system of registration of preference. These include lack of awareness about the ODR; a low budget for promotion of the ODR; confusion among individuals as to whether they have actually registered or not; the incorrect assumption that having a donor card is the same as being on the register; and inadequate control over data input. The Taskforce is clear that the current system is far from ideal.

Over 15 million people have registered with the Organ Donor Register, but this represents only 25% of the population compared to the 65% or more that say they are prepared to donate organs after their death. This strongly suggests that the current system is inadequate and playing a part in this disparity.

4.5 The Taskforce was deeply impressed by the generosity of the British people – by the families of those who had donated organs and who spoke of organ donation as a gift, and by the many, many people who spoke of organ donation as an opportunity to fulfil either their own or their loved one’s choice to help others in need. This generosity should not be a

surprise. The UK consistently appears in the top five when countries are ranked according to individual charitable giving.¹ The population of the UK is overwhelmingly generous but also wants to be given the opportunity to express freedom of choice in their giving.

4.6 Running as a leitmotif throughout the Taskforce's discussions has been the issue of trust: in government, in the NHS and, to a lesser extent, in doctors and other clinical staff. The public have become less trusting and more questioning of authority over recent years. Ipsos MORI has documented the decline in trust in government information, beginning with *Who Do You Believe?* in 2005² and subsequently in responses to specific trust and influence questions in the UK Government Delivery Index. Trust, however, is key to the success of the organ donation system in the UK. If public trust is shaken, organ donor numbers are likely to fall rapidly and could take many years to recover. The need to maintain the confidence of the public has been a key consideration in the Taskforce's deliberations.

4.7 Like all debates, that on presumed consent is set within the landscape of the moment, and it is worth outlining where the UK finds itself in 2008 on two particular issues of relevance, both of which relate to trust. The issue of consent is one that was brought to the fore by the events at Alder Hey and the Bristol Royal Infirmary, and these are still fresh in the minds of many. These events were in part responsible for the subsequent Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006, which have been in operation since 2006. The legislation makes consent a fundamental principle in the removal, storage and use of body parts, organs and tissues. The concept is expressed as 'authorisation' in the Scottish Act, and applies to children from the age of 12.

4.8 The issue of data protection and privacy is one that has attracted many headlines recently. A series of incidents involving the loss or breach of government data has undermined public confidence and has made the public feel concerned about the security of key pieces of personal information. For some, there are few more sensitive items of information than one's wishes for one's own body after death.

4.9 A move away from requiring explicit consent would put organ donation out of step with prevailing practices and would be inconsistent with the Human Tissue Authority's (HTA's) guidance on consent. It would also challenge commonplace assumptions about consent and individual decision making at a time of greater expectation of individual autonomy among the public. This expectation has been encouraged by the move towards a choice and personalisation agenda within the NHS, which gives people a greater sense of control over what happens to them.

1 Charities Aid Foundation (2006) *International comparisons of charitable giving*. CAF briefing paper, November 2006. West Malling, Kent: Charities Aid Foundation.

2 Ipsos MORI (2005) *Who Do You Believe? Trust in government information*. London: Ipsos MORI.

5

DIFFERENT FORMS OF CONSENT

5.1 There are a number of variations of consent systems for organ donation. These are set out in Table 1 below.

Table 1: Different consent systems in use around the world

Option	Details
1: A 'hard' opt out system	Doctors can remove organs from every adult who dies – unless a person has registered to opt out. This applies even if relatives know that the deceased would object to donation but had failed to register during life. Example: Austria.
2: A 'hard' opt out system which does not cover some groups	Doctors can remove organs from every adult who dies – unless a person has registered to opt out OR the person belongs to a group that is defined in law as being against an opt out system. Example: Singapore where Muslims chose to opt out as a group.
3: A 'soft' opt out system	Option 3a: No need to consult relatives Doctors can remove organs from every adult who dies – unless a person has registered to opt out OR the person's relatives tell doctors not to take organs. It is up to the relatives to tell the doctors because the doctors may not ask them. Example: Belgium.
	Option 3b: Relatives should be consulted Doctors can remove organs from every adult who dies – unless a person has registered to opt out. It is good practice for doctors to ask the relatives for their agreement at the time of death. Example: Spain.
4: A 'soft' opt in system (current system in the UK)	Doctors can remove organs from adults who have opted in. It is up to each person to decide if they want to opt in. It is normal practice to let relatives know if the person has opted in and doctors can decide not to proceed if faced with opposition from relatives.
5: A 'hard' opt in system	Doctors can remove organs from adults who have opted in. It is up to each person to decide if they want to opt in. Relatives are not able to oppose the person's wishes.
6: A choice to opt in or opt out	Option 6a: People can register their choice to opt in or opt out.
	Option 6b: People must register their choice to opt in or opt out.

5.2 ‘Presumed consent’ is something of a misnomer in medical care because consent is in fact an active process in which permission is given by a patient for a procedure to be carried out on their body, thereby avoiding any possibility of clinical staff being guilty of an assault on the patient. Should a patient lack capacity and be unable to give consent for vital invasive procedures, doctors act on their judgement of the patient’s ‘best interests’, not on ‘a presumption’ of consent. The Taskforce prefers to use the term ‘opt out’ to describe what is often called presumed consent. Opt out will be used throughout this document, except when reporting the words or systems of others.

5.3 The UK, North America, Australasia and most of Asia (excluding Singapore) have explicit consent systems (what we might call opt in systems) in place. Many European countries have a form of opt out system. In practice, the ways in which these systems – even the same types – function differs between countries and even within regions.

6

LEGAL ISSUES

‘Hard’ forms of opt out

6.1 The Legal Working Group was asked to advise on the legal viability of a system of opt out and quickly established that a ‘hard’ opt out system that did not seek evidence from families about the deceased’s own opinions or wishes could be open to a potentially successful challenge under the European Convention on Human Rights (ECHR).

6.2 Furthermore, the legal group concluded that simply having a register where people could record their decision (opting either in or out) during their lifetime, without involving families at the time of death, would probably be insufficient to ensure compliance with the ECHR because:

- in an opt out system, it could result in organs being taken from those who had not yet managed to register an objection, perhaps because they were simply busy or disorganised. They might also have learning difficulties or other problems with communication, such as English as a second language; and
- in an opt in system, the deceased may have registered a wish to donate a long time ago and since changed their mind, but had not got round to taking their name off the register.

Therefore, any system must allow for taking evidence from family members about the deceased’s wishes and beliefs. If the law were to be changed to an opt out system, this would be necessary to enable the presumption of consent to be rebutted if there was evidence that the deceased did not wish to be a donor, even though they had not recorded this decision on a register. If this were not provided for, the Legal Working Group considered that there would be a significant risk of successful legal challenge. There would also need to be provision relating to minors and those lacking capacity.

6.3 Having no reference to family members at the time of death would also be problematic clinically, because details obtained from relatives about the patient’s medical and behavioural history can play an important part in the success of a transplant.

6.4 The views expressed by members of the public in the deliberative events suggest that most people would not support a ‘hard’ form of opt out. A hard opt out system polarised opinion among participants. While some strongly supported such a system, others were staunchly opposed. While a fifth ranked a hard opt out system as their preferred system overall, roughly double this number chose this as their least preferred system, indicating the extent to which some people have serious concerns. Examples of concerns expressed included the following:

“As a mother I am opposed to the hard opt out system as it takes the choice away from families and I think they need to be included.”
(participant, London)

“I don’t believe in a hard opt out system. People can change their minds right up to the moment they die, and they might have confided in a close family member.”
(participant, London)

A major reason given for supporting a hard opt out was the belief that an individual’s wishes should take precedence, with some preferring that relatives are not consulted in cases where wishes have been clearly defined.

“It seems a nonsense that if you carry a donor card and are on the register that your relative can override your wishes in reality, even if legally the doctors were allowed to take your organs. If you are on the list, you should have your organs taken.” (participant, Belfast)

The Taskforce does not recommend a ‘hard’ form of opt out (presumed consent) in which family members are not consulted because it would polarise public opinion, would create difficulties clinically and might be open to successful legal challenge under the European Convention on Human Rights.

Mandated choice

6.5 There is some support for the concept of ‘mandated choice’, in which people would be legally obliged to opt in or opt out of organ donation at some point in their lives, with their expressed views on donation taking precedence over the wishes of relatives in the event of their death. The Royal College of Physicians submitted a paper to the Ethics Working Group, setting out the advantages of mandated choice over an opt out system. The Ethics Working Group noted that mandated choice was not a consent system in itself, but a possible adjunct to consent systems. It concluded that a system of mandated choice was likely to mean greater engagement by families in organ donation and would help provide greater clarity about the wishes of the deceased, removing the need to make assumptions.

6.6 However, it would not resolve all potentially difficult issues; for example:

- where a person dies having changed their mind but not having registered a revised decision;
- where a person fails to comply with the requirement to choose, but nevertheless wished to donate; and
- whether the feelings or views of the donor’s family should carry any weight.

6.7 In general in the UK, we do not require people to make choices. For example, we do not make voting mandatory as it is in Australia. We encourage UK

citizens to make choices but also allow them the right not to make choices. A system of mandated choice on organ donation would be a significant departure from established UK norms. Mandated choice is also associated with some formidable practical problems (for example, with whom would people have to register their decision; at what point in their life should this choice occur; how do people register a change of mind; how do people opt out of donating some organs but not others?).

6.8 It is debatable whether such a system would be effective in practice, since it would be difficult to force people to make a decision if they do not want to. The Taskforce was uncomfortable with the idea of a legal sanction if people did not make a choice. If sanctions were imposed, enforcement would raise difficult issues, especially for clinical staff. Moreover, the Taskforce was concerned that if people were forced to choose, this might cause resentment and have a negative impact on organ donation rates.

6.9 There was considerable support for mandated choice by participants in the deliberative events. The main advantages were seen to be that it removed doubts about people’s wishes and would make people ‘come off the fence’. A mandatory opt in/opt out system was ranked in the top three by nearly half of participants and ranked first by just over a fifth. However, many people also recognised the practical difficulties involved and the difficulty of enforcing the system in practice. Examples of comments are included below:

“Opt out or opt in is highly commendable – it says we take responsibility for our own actions – it says we can’t all agree but we can make a decision.” (participant, Birmingham)

*“There are always going to be people who won’t fill in the form and won’t make the decision – what happens then? I think it will complicate the system even further.”
(participant, Birmingham)*

At the present time, the Taskforce does not recommend a system of mandated choice for opt in or opt out because it has significant practical problems and would be difficult to enforce.

Family involvement in an opt out system

6.10 The Legal Working Group, subject to a number of caveats laid out in its report (Annex C), supported the proposition that it would be legally possible to introduce an acceptable opt out law as long as the system allowed opportunities for people to change their mind and that there were safeguards relating to children, those lacking capacity and those whose identity is unknown. Families would need to be involved to provide or corroborate evidence of the deceased’s wishes and there should be a sufficient period of time following legislation to ensure that people have enough time to register their wishes.

6.11 Given this clear legal steer, and the necessity of involving families for clinical reasons, in all its subsequent deliberations the Taskforce working groups concerned themselves with considering the impact, practicalities, other legal, ethical, cultural and clinical considerations and communication requirements of a ‘soft’ form of opt out only, comparing and contrasting these with the status quo.

7

ETHICAL ISSUES

7.1 Members of the Ethics Working Group included medical ethicists, clinicians and philosophers. Their full report is at Annex D. They were unanimous in their belief that a society has an opportunity to do something morally significant by improving donation rates, as it is an opportunity to remove suffering and bring about substantial benefits for many people. Yet, despite this overwhelming moral good, the means of achieving this end still need to be independently scrutinised because it is also important that systems under which organs are removed for transplant are seen as morally acceptable. In other words, the end cannot be seen to justify the means. Rather, the ethical goal in terms of organ donation is to acquire the maximum number of organs via a system that is seen to be morally acceptable and consistent with a society's values.

7.2 Given that there is a strong moral presumption in favour of donation, the group felt that there is also a strong justification for reinforcing and promoting a societal message that donation is 'the right thing to do', through education and effective forms of social engagement. However, the final decision on whether to donate is a private one, based on personal beliefs and circumstances.

7.3 Having said this, the Ethics Working Group felt that it is important to engage people with organ donation in a way that helps them make the 'right choice'. Thus it would be appropriate to highlight donation as an opportunity to do good, and to assure potential donors of the willingness and ability of both the Government and the NHS to support those who wish to take advantage of this opportunity for altruism. The group felt that the opportunity to do good through donating organs could be more appropriately promoted within a system that gave people the means to positively opt in than through one that invited them to opt out if they wished to do so.

7.4 Having encouraged individuals to donate, it is then important to be able to demonstrate that each and every donation has been properly authorised; key to this is the need to be able to determine that an individual's wishes (or those of their families, where appropriate) have been honoured. This is of importance because, even though we wish to actively promote donation, we ideally want to know that people have clearly chosen to donate.

7.5 The group recognised that there were problems with the current system. It is hard to argue that signing the ODR is an act of 'informed consent', as the term is more broadly understood, but it is clearly intended as an act of authorisation. If a person has not registered their wishes formally, in the absence of a clear conversation taking place, a family can only do their best to establish what someone would have wanted. If there is uncertainty, the family carry the responsibility for deciding what to do on an uninformed basis, which is unsatisfactory regardless of the choice they make.

7.6 Uncertainty about a potential donor's wishes is at the heart of difficulties with the current system, yet uncertainty could remain an issue with an opt out system. It may not be appropriate to assume that all those who have failed to opt out have no objection to becoming donors, given the real possibility of apathy and/or disorganisation preventing them signing the opt out register. The group was not convinced that evidence of widespread support, as expressed in opinion surveys, could necessarily support a claim that all those who fail to opt out actively intend to donate.

7.7 To sum up, the group did not have any fundamental moral objections to a system of authorisation based on checking an opt out register. However, they felt that an improved opt in system, or possibly even a system where people were required to make the choice to opt in or opt out, would provide a basis on which to proceed with a greater degree of certainty about an individual's wishes and would therefore be more acceptable.

7.8 Having said this, given the significant benefits to be gained by increasing donation, if an opt in system continues to fail in delivering an increased number of organs for donation despite thorough attempts at public engagement and improvements to the organ donation system more generally, a society might have to consider other possible forms of authorisation, particularly if evidence were available to suggest that those systems would result in significantly more organs being donated.

There is no fundamental moral objection to opting out as a means of recording individual wishes regarding donation, but there are reasons to prefer an improved opt in system as a means of removing uncertainty and thereby facilitating donation.

8

HOW AN OPT OUT SYSTEM WOULD OPERATE IN PRACTICE

8.1 At present, authorisation for organ donation is dependent on there being a robust relationship between clinical staff and the family of the potential donor, with the best interests of the potential donor being at the centre of all decision making.

8.2 The Clinical Working Group heard from a number of clinicians from intensive care (where the majority of deaths leading to donation occur) who were persuasive in articulating the view that a presumption of consent might make families feel that they were being pressured and erode the relationship of trust between clinician and family. These views were echoed in a recent survey of its members conducted by the Intensive Care Society.³ Views expressed at the deliberative events by members of the public suggest that this concern is shared by many non-professionals as well. It became clear that many people at these events had concerns that their best interests might be jeopardised if they were seen to be potential organ donors. The fear that you might not actually be dead, with doctors ‘jumping in too quickly’ before ‘someone is definitely gone’, was one that was widely expressed. A system of decision making which is based on respecting the known wishes of the patient is the one that is most likely to maintain the integrity of the relationship between doctors and patients and between doctors and the wider public, and maintain trust and confidence in the donation system.

8.3 According to the Intensive Care Society’s survey, intensivists are evenly split as to whether an opt out system should be introduced, but the strength of feeling among those who are opposed is considerable. Some practitioners are very concerned that the vital relationship of trust between doctors, their patients and patients’ families might be eroded by an opt out system, since it could be perceived as shifting the balance of power in decision making away from families. There are also risks that introducing an opt out system at this time might serve as a distracting and confounding influence on the medical workforce, which

needs to play a key role in implementing the recommendations of the Taskforce’s first report.

8.4 There is an argument, advanced by some, that a system of presumed consent would relieve families of the burden of making a decision in the absence of any indication as to the deceased’s wishes. The Taskforce finds this a somewhat paternalistic view, at odds with the ethos of today’s NHS. Further, our evidence from donor families was that they stressed the importance to them of being involved in the decision to donate and of being allowed to make the decision that was right for them at the time. The Taskforce found the evidence from donor families compelling.

8.5 Recipients of transplants reported that it was important for them to know that the family of the donor had been involved in the decision and were comfortable with it. They also stressed the importance of knowing that organs had been freely given. These families spoke movingly of the concept of organ donation as a gift, and were concerned that an opt out system might undermine the principles of organ donation as a gift.

8.6 Evidence from donor family representatives, recipients and health professionals suggests that the way donation is broached and handled with families is a critical issue in determining donor rates. Research carried out at the University of Southampton⁴ on the reasons families refuse organ donation showed the importance of focusing on families’ bereavement issues. Further information about this is detailed within the Clinical Working Group’s report at Annex E.

An opt out system has the potential to erode the trust between clinicians and families at a distressing time. The concept of a gift freely given is an important one to both donor families and transplant recipients. The Taskforce feels that an opt out system of consent has the potential to undermine this concept.

³ Intensive Care Society, 2008.

⁴ Sque M, Long T (University of Southampton) and Payne S (University of Sheffield) (2003) *Organ and Tissue Donation: Exploring the needs of families*. Southampton: University of Southampton.

9

LEGISLATIVE IMPLICATIONS

9.1 Following extensive consultation with the HTA, it has become clear that there would need to be a revision to the Human Tissue Act 2004 in order to accommodate an opt out system. Similar issues arise with the Human Tissue (Scotland) Act 2006. These Acts have only been in operation since 2006.

9.2 Such a legislative change would also require a thorough assessment of the implications for the system of consent for other activities governed by the Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006. Effectively there would be different systems of consent or authorisation for different purposes involving human organs and tissues. This clearly has the potential to cause confusion to patients, their families and clinical staff at a time when clarity and sensitivity are of the utmost importance.

9.3 The HTA's guidance is clear that consent is a positive rather than a passive process, which equips the prospective donor with the information needed to make a decision. Therefore, the change from opt in to opt out for transplant purposes could risk undermining the 2004 Act's consent provisions, which safeguard the rights of individuals or their families to be asked if tissue can be used for a variety of other purposes. The HTA was very concerned that a change to the consent requirements for one activity could result in the destabilisation of the consent provisions for other activities. There would be similar concerns about the 2006 Act in Scotland, which also covers post-mortem examinations and the donation of bodies for medical science.

A move to an opt out system would require primary legislation to revise the Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006 only two years after they came into force. It would also require a review of the Human Tissue Authority's remit in relation to consent for activities involving human tissue, and a recasting of their guidelines.

THE PRACTICAL ISSUES THAT WOULD NEED TO BE ADDRESSED TO IMPLEMENT AN OPT OUT SYSTEM

10

10.1 The Practical Working Group looked in detail at what systems and infrastructure would need to be put in place to support different consent systems. The group's report is at Annex F. The Taskforce considered opt out information to be more sensitive in nature than information provided for opting in. Opting in is seen to be 'a good thing' by society, whereas opting out might potentially be seen as socially stigmatising. With the current opt in system, the consequence of not registering wishes is that the potential pool of donors is decreased, but it is not personally harmful. With an opt out system, not registering may mean that someone's organs are taken when they had serious objections to this happening. The current ODR is based on an open access website and an electronic register, which is available to hospital staff. Although there is no evidence to suggest that this is happening on a wide scale, it is currently theoretically possible for a third party to enter someone's name on the ODR without their knowledge. This is a risk that is considered to be outweighed by the benefits of accessibility conferred by the current system. Some would argue that an opt out register requires a far greater level of security because the consequences of non-registration are greater for the individual and because of the sensitive nature of the information. For these reasons, there would need to be more certainty about the identity of the person registering.

10.2 A mirror of the current ODR, in which people register their decision to opt out rather than to opt in, might therefore require more safeguards than there are in the current system because of the greater sensitivity of the information.

10.3 It might be possible to accommodate opt out data within the Personal Demographics Service (PDS), which forms a key element of the forthcoming NHS Care Records Service. If this were the case, opt out data would need to be entered by NHS staff following an appropriate conversation. If someone changed their mind, this too would have to be recorded via a member of NHS staff. There are three foreseeable difficulties

here: entering data would be a drain on NHS resources, particularly at the start of an opt out system that might involve capturing the data of several million people; secondly, the value of inclusion in the PDS would be limited by the fact that it only has application in England, whereas the transplant programme covers the whole of the UK; and thirdly, if donation is the socially acceptable decision, those who wished to opt out might not feel able to make their wishes known to NHS staff, unless they felt particularly strongly. This suggests that a more secure version of the current easy-access ODR would be needed, so that citizens could register their wish to opt out with confidence.

10.4 The Taskforce does not believe that an electronic opt out record is the only acceptable evidence of someone's decision. Other written wishes, such as those in a will or on an opt out card, should be considered valid, although practically speaking, these might be very hard to access in the difficult circumstances surrounding death.

10.5 There would need to be a mandatory requirement to check the opt out register at death if organ donation was a possibility. The scheme would also need to ensure that those who were responsible for organ donation would have to make other reasonable enquiries to ensure that the deceased had not laid down their wishes clearly in another form or changed their mind. For example, if someone's name was on the opt out register and no conversations were initiated with the family, there would be no opportunity for the family to give evidence of a change of mind on the part of the deceased. Framing this requirement would be complex.

10.6 As they do at the moment, people may wish to opt out of donating certain body parts – for instance, eyes are an issue for some – while being content that others are used. As medicine advances, people may wish to be increasingly specific about the organs or tissues they will donate; they might refuse their face for a face transplant, for instance. Equally, tissues not dreamt of

as transplantable now may become so in the future. This poses many challenges. If a list is comprehensive it will be long, with potential for a high 'yuk' factor. The default might be that people opt out altogether rather than go through the list body part by body part, thereby increasing the percentage of those opting out. A blanket 'all body parts' opt out would be simpler. However, as a matter of principle, the Taskforce feels that comprehensive information on all body parts that could be donated should be provided. If it were not, it might lead to a damaging loss of confidence if the public were later to feel that something had been concealed from them. It might also occasion later legal action. Contacting those who had opted out many years earlier with information about new uses of tissues or organs for their consideration would be problematic.

The Taskforce considers it essential that people have definitive information about the organs or tissues that can be donated and that any opt out system should be able to accommodate specific wishes. This would require a significant ongoing investment in information and recording systems to ensure it was as effective as the public deserves.

10.7 There are issues about recording the wishes of those who do not engage with the UK's institutions and systems, including those with limited capacity and hard-to-reach groups. Visitors to the UK are another concern. A further group with entitlement to NHS treatment, including transplantation, is non-UK European Union residents.

10.8 There is an assumption that those with strong objections to organ donation are likely to register their wishes, but this is not an assumption backed by evidence, and the disorganised may be as disadvantaged in an opt out system as in an opt in system.

10.9 Introducing an opt out system would require very considerable costs for a suitable infrastructure. There would need to be an initial public awareness programme, targeted so that it reached every UK adult. In addition, an ongoing education and public awareness programme would be essential. Capital expenditure would be required on the development and establishment of a secure database, plus running costs, the cost of initial inputting of data, and the ongoing training of a wide range of healthcare professionals, from GPs and practice nurses to staff in secondary care. Only a very small proportion of these costs would be offset by closing the current ODR, and in any event there are strong reasons to retain the opt in register, even in the event that it is decided to adopt an opt out policy in the future. Various opt out jurisdictions, such as Belgium, have both opt in and opt out registers operating in tandem.

10.10 A lead time sufficient to ensure that everyone had been contacted and was aware of the new system would be required. This might involve a period of at least three years following enactment of legislation.

10.11 Findings from the public engagement events revealed that awareness of the organ donation registration system is low in the UK. Many people were aware of donor cards but few knew where to obtain them. Only a minority were aware of the ODR, and usually only because they had recently obtained a driving licence (which includes a question about being on the ODR on the application form). Feedback from work with faith leaders suggests that faith-specific donor cards might be particularly helpful and would serve a dual purpose, since such cards would also remove doubts about whether a particular faith supports donation or not.

10.12 Willingness to donate is high, and participants showed interest in finding out more about donation generally. They identified a number of barriers to donation – for example, lack of awareness, laziness, unwillingness to think about death, a lack of trust in

medical professionals and concerns about how donors are treated – but they felt that these are surmountable within the current legal system. There is a call for better publicity and education to dispel misconceptions and to encourage families to discuss the issues surrounding donation more openly. There is also strong support for making registration easier and more visible and for GPs to raise donation as a matter of course with their patients. Participants, particularly families with direct experience of organ donation, felt that more could be done with regard to how medical professionals broach the concept of organ donation with bereaved families. Examples of comments included the following:

“I have actually never heard of the Organ Donation Register, although I was aware that you could donate your organs.” (participant, London)

“I have not got a card. It never occurred to me. I would not use my day off to go and get a card.” (participant, London)

“Where do you get a card from?” (participant, Newcastle)

“Only when I was asked to come here have my sons and I discussed organ donation – they thought I might have been on my way out!” (participant, Birmingham)

10.13 A number of participants mentioned the importance of involving schools in the education process:

“We need to bring it into the national curriculum, perhaps as part of personal and social education issues. I think if we get children thinking about it when they are young, then at least they will have an opinion on it.” (recipient family)

10.14 This suggests that the most pressing need, regardless of the consent system in operation, is to raise the level of awareness and understanding of organ donation, and to encourage people to let their families know their views.

10.15 Given the lack of awareness about organ donation among the general public, the Taskforce believes that there are simpler and easier ways of substantially increasing the numbers of organs available for donation, without the complexity and difficulties of trying to implement an opt out system. An analysis of the likely costs of putting the necessary infrastructure and communications strategies in place to implement an opt out system was commissioned. The full findings are set out at Annex G, but, in broad terms, the costs are approximately £45 million in set up costs for IT and communications. There would be £2 million per year in IT running costs and an additional £5 million every few years to refresh public messages.

Given the current lack of awareness about organ donation among members of the public and the complexity, difficulties and costs of implementing an opt out system, the Taskforce considers that at this time resources would be better prioritised if they were directed towards raising public awareness and understanding about organ donation.

IMPACT OF THE INTRODUCTION OF AN OPT OUT SYSTEM ON THE NUMBER OF ORGAN DONORS

11

11.1 It is assumed that there must be a correlation between the enactment of opt out legislation and an increase in organ donation. As part of its evidence gathering, the Taskforce commissioned a systematic literature review from the University of York to assess the impact of opt out legislation on organ donation rates in other countries. There are five ‘before and after’ studies involving two countries in particular (Austria and Singapore, both of which have a ‘hard’ form of presumed consent). These show an increase in donation rates of up to 25%. The reviewers note, however, that in each country many other changes were introduced at the time of legislation, such as better infrastructure or increased funding for transplant programmes. Awareness of the need for organ donation was also raised. This makes it difficult to assess the exact contribution of presumed consent legislation alone.

11.2 Eight studies comparing different countries were also reviewed. Direct comparison between countries is difficult because of the wide range of other factors that influence organ donation rates within countries, for example mortality rates from road traffic accidents, overall health expenditure, religion, education and transplant infrastructure. The reviewers concluded that:

“The evidence identified and appraised is not robust enough to provide clear guidance for policy.”

11.3 The high organ donation rate in Spain (34.4 per million population in 2007 compared with 13.2 per million population in the UK) is often presented as a consequence of its system of presumed consent. Dr Rafael Matesanz, president of the Spanish National Transplant Organisation, gave evidence to the Taskforce during the preparation of its first report. He

was explicit: presumed consent was not the reason for the success of the Spanish system. He reiterated this at a briefing on presumed consent held more recently in September 2008 at the Science Media Centre, which was reported in the *British Medical Journal*.⁵ When asked if a presumed consent law was the reason for the success of the Spanish system, he said:

“Is it because of the law? Not likely. We have always had the same law. The families are always approached. They always have the last decision, and there are great variations from region to region.”

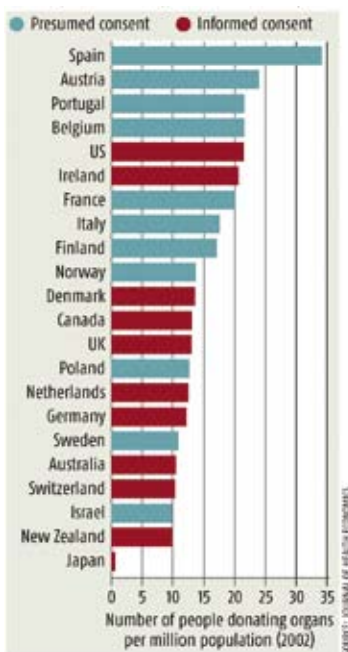
He pointed instead to the many other changes in infrastructure that had been made, underlining the point made in paragraph 2.3 that many elements have to be right if an increase in organ donor rates is to occur. Dr Matesanz said that when Britons living in Spain are approached in Spanish hospitals, the family refusal rate falls to 9%, compared with 43% in the UK.

11.4 It is worth noting that presumed consent legislation was passed in Spain in 1979 but it was only a decade later, in 1989, when their national transplant organisation was founded, putting a new infrastructure in place, that donor rates began to rise. In Italy presumed consent legislation was passed in 1999, but before it was fully enacted some regions, notably Tuscany, adopted the Spanish organisational model and saw organ donation rates double to 26.9 donors per million population.⁶ On the other hand, not all countries that have presumed consent legislation have high organ donor rates. Sweden switched to presumed consent in 1996 but continues to have one of the lowest rates of organ donation in Europe (see Figure 1).

⁵ *British Medical Journal* 2008; 337: a1614.

⁶ Simini B (2000) Tuscany doubles organ donation rates by following Spanish example. *Lancet* 355; 9202: 476.

Figure 1: Different consent systems and donation rates



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11.5 There are two examples of a negative impact of presumed consent policies. Brazil adopted a ‘hard’ presumed consent law in 1997, with opt out denoted by a note on an ID card or driving licence. The law had to be repealed in 1998, principally because of mistrust of government and accusations of body snatching. In France, which has a variation of presumed consent, there was an incident in 1992 in which corneas were taken from a 19-year-old road traffic accident victim whose parents had consented to only limited organ retrieval. This resulted in a great deal of negative press coverage of the medical profession, despite the clinicians having complied with the strict letter of the law, and damaged public trust in the organ donation system for some time.

The Taskforce is not confident that the introduction of opt out legislation would increase organ donor numbers, and there is evidence that donor numbers may go down.

12

ATTITUDES OF THE PUBLIC TO AN OPT OUT SYSTEM

12.1 As part of its review of the available evidence, the Taskforce also commissioned the Centre for Reviews and Dissemination at the University of York to review the published literature on public attitudes to presumed consent. The terms of reference and full review are available at Annexes H and I. Among the eight UK surveys reviewed, there was considerable variation in the level of support for presumed consent, ranging from 30% to over 60%. The survey evidence is incomplete, and the variation in attitudes between surveys may reflect differences in methods and the phrasing of the question. The reviewers concluded that:

“The limited and incomplete evidence available from surveys suggests variable levels of support. In addition consideration needs to be given to potential variation in attitudes between different socio-demographic sub-groups.”

Of note are the views of younger people, who are consistently less supportive of presumed consent than older people.

12.2 The Taskforce engaged an independent research company, Opinion Leader, to carry out a series of regional public deliberative events to seek views from the general public on different systems of consent for organ donation. Events took place in Belfast, Birmingham, Exeter, Glasgow, London, Manchester and Newcastle. Over 350 members of the public, representative of the UK demography, were recruited to these events. In order to capture their views, the representation of minority faiths was upweighted by 100% and that of black and ethnic minority groups by 150%. In addition, a series of 12 family interviews took place, which included the families of donors and those of transplant recipients and patients. A full report is at Annex J. The Welsh Assembly Government is conducting its own consultation and educational programme and, at the time of writing, is planning a series of events within the Principality with the aid of the Community Health Councils.

12.3 There were several clear messages from this work. Willingness to donate is high. At the outset, 50% of those involved in the deliberative sessions said they would definitely donate their organs and a further 36% thought they might possibly do so. By the close of the sessions, 61% were definite and 26% said it was a possibility. The proportion of those who said they would not do so or did not know remained almost static (14% compared with 13%).

12.4 Awareness of the current organ donation system was low. Most participants knew about donor cards but there was little awareness of a registration system, even among those who had donor cards. Of those who did know about the ODR, awareness was driven primarily through the driving licence and the Boots Advantage Card. There was considerable confusion between the cards and the register; many assumed that having, or ever having had, a donor card meant that they were registered on the ODR, which is not the case.

12.5 Participants assumed that introducing an opt out system would increase organ donor numbers and that the reason for the deliberative events being held was to affirm this.

12.6 A number of barriers to donation were identified, including lack of awareness, laziness, unwillingness to think about death and concerns about donation in practice. Many felt that these could be overcome within the current legal system with better publicity and education (including in schools) to dispel myths about organ donation, to encourage families to discuss the issues and to make registration easier. There is strong support from all for such changes.

12.7 Those who did not wish to register voiced a number of concerns, the chief of which were that you might not actually be dead when organs were retrieved and that there would be less effort to keep you alive if it was known that you were a potential donor. Older people thought it was not worth them registering as their organs would be ‘worthless’.

Myths about organ donation revealed by the deliberative events

You’re not dead

Absolutely false. Exactly the same tests are used to establish death in those who donate as in those whose organs cannot be donated.

They make less effort to keep you alive if you are critically ill and could be an organ donor

Absolutely false. Intensive care doctors do everything possible to treat every patient.

The same doctors look after you and do the transplants

Absolutely false. Different teams of doctors are responsible for transplants from those treating patients in intensive care.

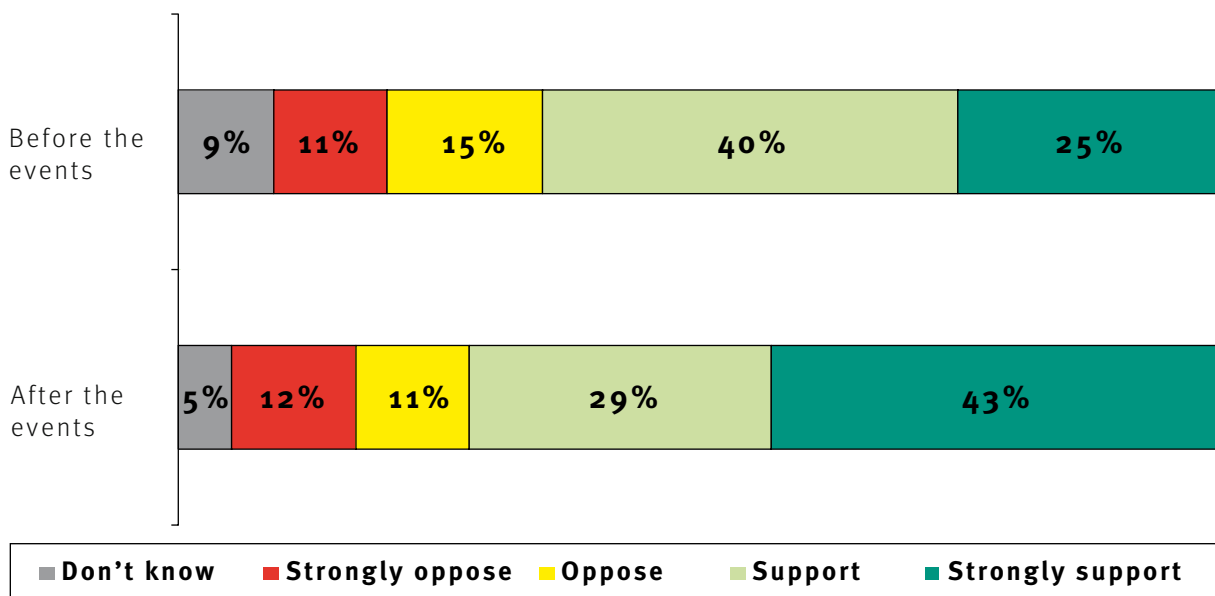
Only the organs of young people are any good for transplants

Absolutely false. Nearly half of UK organ donors are over 50 years of age. Organs are frequently suitable for transplants from people in their 70s and occasionally their 80s.

12.8 Concerns identified about the current system included a feeling that families are given disproportionate ‘power’ to override wishes. This issue polarised opinion among participants. It is worth noting that participants (including those who felt strongly about families not being involved) had firm views about the primacy of family wishes where children were concerned, probably because many could better imagine themselves being in this situation. There was considerable debate about what the ‘age of consent’ should be. This suggests strongly that people’s views about family veto are not fixed but depend on the situation.

12.9 There was considerable support for ‘soft’ opt out systems among members of the public participating in the deliberative events. According to the post-workshop questionnaire, around three-quarters of participants said they would support the law on organ donation changing from an opt in system to an opt out system (see Figure 2).

Figure 2: Participants’ stance on opt out before and after the public deliberative events



And to what extent would you support the law on organ donation changing in the UK from an ‘opt in’ to an ‘opt out’ system?
 BEFORE THE EVENTS Base: 340 AFTER THE EVENTS Base: 341

The main perceived advantage of an opt out system was that it was likely to increase the number of donors. Indeed, some participants considered that they would not have been assembled for such an exercise if this had not been the case. Many participants felt that only people with strong convictions would be likely to opt out, which would mean that the majority of people would be registered as donors. Examples of comments are shown below:

“The majority want to donate, so the opt out makes sense.” (participant, Glasgow)

“The opt out system simplifies everything and would increase the amount of transplantations.” (participant, Exeter)

12.10 There was an assumption among many participants that a change in the legal framework would necessitate considerable investment in communications. These people thought the publicity that would be required to promote a move to an opt out system would be the factor that increased levels of donation, rather than the change in the system per se. They were less concerned about the legal framework and more interested in publicising organ donation – therefore, if a change to an opt out system would bring an increase (and keeping the current system would not), they would want to move to an opt out system for this reason. For some, support for a move to an opt out system was contingent upon improved communications; they would not want a change without this. For example:

“I don’t think the opt out system will make that much difference. The publicity involved in changing the legislation will make the difference.” (participant, Newcastle)

12.11 However, there was a sizeable minority of people who were strongly opposed to a system of opt out, and even those who supported it in theory had reservations about certain issues. While people recognised that an opt out system might result in greater donation rates, for some such benefits were outweighed by the human rights implications. Many people felt that the system would take away individual choice – as a result of apathy, donation would become the default position – and disliked the idea of that choice being taken away. They felt that it would give the state too much control and ‘ownership’ over people’s organs, rather than giving individuals the right to choose what to do with their own bodies. Comments included:

“I feel that with the opt out system people might feel as though they have lost all their rights. It’s as though they have been disempowered.” (participant, London)

12.12 There were also concerns that people might not opt out who would have wanted to, either because they did not fully understand or because they were not aware of a change in the system.

12.13 A small number believed that there was even a danger that donation rates might actually go down, for example if people opt out because they resent government interference, or to be on the ‘safe side’ if they have not fully understood the system. For example:

“Please do not force people to feel as though they are losing their individual rights as extreme cases may hurt your campaign in the long run.” (participant postcard, Newcastle)

The evidence shows that most people would accept a move to an opt out system on the basis that they assume this would lead to an increase in organ donation rates. However, there is a sizeable minority who are strongly opposed to a system of opt out, and even those who support it in theory have reservations around certain issues.

12.14 The issue of trust was raised frequently. There were concerns over the ‘power’ being given to doctors if an opt out system is introduced, and a lack of trust in systems that are used to collect and store data vital to support donation decisions.

12.15 Participants recognised that some cultural and religious groups may have different attitudes. These were not known in detail by participants, but they felt strongly that whole groups should not opt out or be opted out because of the societal divisions this would create. There was a strong consensus that opting out should be a matter of individual choice. The one exception to this view on ‘block’ opt out was for children and people unable to take decisions for themselves, who some thought should be considered for automatic opt out.

12.16 During these discussions, it became clear that a substantial minority of participants felt that individuals who opted out should not have the same priority in receiving organs as those who had not done so, provoking heated debate among participants at some of the events. However, most felt that healthcare should be available to all. There was also some concern about the possible victimisation of people who opt out, and it was generally agreed that people should not be forced into donating organs if they do not want to. As one participant put it:

“Just because you don’t want to give your organs, you should still be able to receive other people’s organs. It’s about personal choice. Also you don’t give to receive.” (participant, Exeter)

12.17 The overwhelming message for the Taskforce related to the lack of awareness about the current organ donation system and the opportunities that this creates. Participants suggested many ideas for ways to increase the number of organ donors, including having a national donors day and GPs being mandated to ask all patients about their organ donation preferences.

The deliberative events revealed a considerable lack of awareness about the current organ donation system. Addressing this should be seen as a major opportunity. There is a great deal more that we can do to increase registration and donation within the current system.

12.18 The Taskforce also sought views from a number of key stakeholders on an opt out system of consent. In line with the findings from the public events, at least half of the respondents specifically mentioned the need for increasing and improving overall public awareness and knowledge of organ donation. Around one-third of respondents expressed support for an opt out system of consent and a significant number supported the recommendations contained in the Taskforce's first report and supported their implementation. There was wide recognition that a change to the consent system alone might not bring about increased donor rates – improved infrastructure and communications were among a number of factors involved in increasing donor rates. A summary of the themes raised by stakeholders is at Annex K.

12.19 In addition, many individual members of the public, as well as charities and other organisations, wrote expressing their views on an opt out system of consent for organ donation. The need to enhance (or create new) donor registration schemes was a general theme, along with the need to increase knowledge about and raise awareness of organ donation and the donor registration scheme. While not all correspondents expressed a view, in keeping with the findings from the deliberative events, considerable support (around one-third of correspondents) was expressed for an opt out system of consent. The main reason given for this was that people believed it would significantly increase the number of donors. However, around one-third of correspondents also expressed concerns about such a system, citing human rights issues and access to information and difficulties in registering choice as reasons. A summary of the themes raised by the public is at Annex L.

ATTITUDES OF DIFFERENT FAITH AND BELIEF GROUPS TO AN OPT OUT SYSTEM

13

13.1 Data relating to organ donor waiting lists and organ donors highlights significant disparities between ethnic groups. For instance, UK Transplant data shows that people of Asian or African-Caribbean descent are three to four times more likely than white people to develop end-stage renal disease, largely because of the higher prevalence of type 2 diabetes. UK Transplant data shows them to make up 23% of the kidney waiting list but 8% of the population. A further concern is that only 3% of donors are from these communities. Empirical studies have shown that cultural issues are important influencing factors when making a decision about organ donation. The influence of belief and faith systems is less clear. The Department of Health therefore commissioned one-to-one interviews with senior representatives of faith and belief groups. A total of 17 interviews were conducted. A full report of this work is contained within the Cultural Working Group's report at Annex M.

13.2 From the interviews, it is clear that, while the majority of faith and belief groups interviewed tend to allow organ donation, diverse views exist not only between but also within these groups. Some groups have core beliefs that support organ donation, and few tend to forbid it. A potentially significant finding is that religion per se is not described as a key influence on people's decision to opt in. The influence of culture may have been attributed to faith or belief systems in the past, and it can, of course, sometimes be difficult to disentangle one from the other.

13.3 Many of those interviewed felt strongly that the decision to donate is a personal choice for the individual to make. For example:

"The benefit is that it is a more informed decision and doesn't put the person in a quandary." (Jasdev Singh Rai, British Sikh Consultative Forum)

"The question is of personal autonomy, and being able to make decisions for yourself. So

for me, we should stay with the opt in." (Mufti Zubair Butt, Muslim Council of Britain)

"Advantage is that people have choice, and I think that if there are some deeply held religious views that the body or organs should not be tampered with, then I suppose it is an issue of human rights laws that they should have that right to refuse to donate." (Khurshid Ahmed, British Muslim Forum)

The majority were opposed to the introduction of an opt out system, with only two in favour of a change in legislation and two who raised no issues with either the current system or an opt out system. A key concern with a move to an opt out system was the potential lack of certainty that a failure to opt out was equivalent to an informed decision to donate:

"How do we know it's been done with appropriate and informed consent? If it is opt in, then consent is there automatically." (Debbie Hodge, Churches Together in England)

13.4 As with the deliberative events, the majority assumed that the opt out system would result in more organs being available. Faith leaders saw this as the key – and in many cases the only – advantage. Some suggested that introducing an opt out system could trigger a backlash in some communities:

"I would think that you may see a backlash with increased opt out, not only in the Jewish community but also from other communities." (David Katz, Board of Deputies of British Jews)

"By default we could create a promotion campaign that says 'opt out' and for this reason opt out is worrying." (Katei Kirby, African Caribbean Evangelical Alliance)

“There is a danger of people overreacting because they see it as becoming not human anymore. This danger is not overstated.” (David Jones, Catholic Bishops’ Conference of England and Wales)

“It would up the stakes for people who are sceptical. Currently, those who are sceptical are happy to grumble on sidelines. It is likely to precipitate an anti-organ transplant movement that doesn’t exist now.” (David Jones, Catholic Bishops’ Conference of England and Wales)

13.5 Other concerns expressed about moving to an opt out system included the following:

- ‘Hard-to-reach’ groups would not have the information they needed to opt out.
- It was a lazy way to achieve more organ donations, and may make people feel uncomfortable about opting out.
- It would alter the relationship between state and individual and potentially provide the Government with a level of control that could be abused.
- Removing the gift element was dehumanising.

13.6 For many faiths the one-to-one interviews, which were conducted at times and in places convenient to them, were the first opportunity that they had had to engage with the issue of organ donation. The low level of donations from within certain groups was of particular concern to them, given the higher level of need. There was widespread recognition of the extent of work required at grass roots level within their communities to encourage donation and a willingness

to engage with the Government in this work. There was little prior awareness among the interviewees of the leaflets published some years ago setting out the views of some prominent faiths on organ donation. This was underlined by a recent study carried out in Birmingham,⁷ in which 60% of Muslims, from a wide variety of ethnic backgrounds, said that organ donation was contrary to their faith, when it is not. This suggests that written leaflets alone may be ineffective and that other methods of engagement need to be found.

13.7 In order to achieve better engagement on organ donation with members of faith and belief groups in the future, it will be important to continue the dialogue that has begun with these interviews. A multifaceted communications strategy is essential.

The Taskforce strongly recommends that the Programme Delivery Board builds on the foundations of the interviews with faith and belief groups, reported in Annex M, to ensure that the valuable dialogue that was established is maintained.

While the majority of faith and belief groups interviewed were positive about organ donation, most were opposed to the introduction of an opt out system. All set considerable store by personal choice, and many did not see a failure to opt out as the equivalent of a choice to donate.

⁷ Razaq S and Sajad M (2007) A Cross-sectional Study to Investigate Reasons for Low Organ Donor Rates amongst Muslims in Birmingham. *Internet Journal of Law, Healthcare and Ethics*, Volume 4, Number 2.

COMMUNICATIONS REQUIREMENTS WERE AN OPT OUT SYSTEM TO BE INTRODUCED

14

14.1 Were an opt out system to be introduced, a communications strategy would need to be devised to ensure that all those people who wished to opt out entirely, or to opt out of the donation of particular organs or tissues, knew how to do so. In addition, communications would be needed to outline arrangements for special groups such as children, those lacking capacity and visitors to the UK. Consideration would need to be given to the information needs of ethnic minorities, those with English as a second language, and hard-to-reach groups, such as the homeless. The media campaign would need to be extensive both in its use of different forms of media and in its duration (over at least two years, prior to and after enactment of legislation). Such a campaign would require considerable resource (at least £45 million initially, with further reminder campaigns every few years and as new transplants become possible). The effectiveness of this campaign would need to be evaluated on a regular basis to identify any deficiencies. A lack of information would disadvantage those who wished to opt out but did not know how to do so. This might conceivably lead to legal challenge in the future.

14.2 Of concern is the fact that communications would necessarily involve highlighting the negative aspects of donation rather than the positive. The consequence might be an unintended increase in the opt out rate beyond that anticipated. The Taskforce was concerned that if an opt out system were run with a strong societal message in favour of donation, people might feel reluctant to record an opt out, fearing that it would make them subject to unequal healthcare if they became ill. A consequence of a poorly executed or resourced campaign might be inclusion of those who did not wish to donate among those presumed to have consented.

Changing to an opt out system would require a complex, extensive and well resourced communications strategy using a wide range of media outlets. By concentrating on negative aspects of donation, the numbers opting out might increase.

14.3 Trust is central to confidence in the organ donation system, no matter what the legal status of the consent system. The Communications Working Group considered there to be several conflagratory issues that have the potential to inflict major damage on confidence in a system where consent is presumed:

- those relating to equity and opt out;
- inadvertent removal of organs of those who had opted out;
- stories about body snatching by the state if there was a case in which futility of care became an issue of dispute between a family and the clinical staff caring for their relative; and finally
- headlines if there was a breach or loss of data on the ODR.

As the case in France detailed in paragraph 11.5 demonstrates, a single incident is enough to produce a major dent in confidence if that case attracts sufficient media interest, even where there is no actual breach of either the law or professional practice guidelines.

14.4 A strong message from the deliberative events was that few people were aware of organ donor promotion, while all were aware of campaigns promoting blood donation. Many were concerned that organ donation was not given as high a profile as blood donation. It is difficult to make direct comparisons since, unlike organ donation, the promotion of blood donation is about motivating people to donate on a regular basis over a period of time. However, it is worth noting that currently annual

expenditure on publicity relating to blood donation is at least three times the £900,000 spent on organ donation promotion in England.

14.5 The Communications Working Group also considered the communications implications of the key messages arising from the deliberative events, regardless of the legal system for consent in place. These were:

- dispel myths about organ donation;
- encourage early discussion about donation;
- provide sufficient accessible information to make an informed choice;
- ensure that the registration system is easy to access, regularly updated, confirmed and secure; and
- respect the views of the individual but do not ignore families.

14.6 There is clearly considerable scope for communications work in respect of the first three items above. The communications aim should be to make donation usual – not unusual – so that every family expects to be asked about donation as a routine part of end-of-life care and has confidence in the integrity of the donation system.

14.7 It is interesting that 25% of those currently on the ODR have been recruited through the driving licence application form; there is clearly considerable scope for extending this sort of initiative to applications for other government documents, for instance passport renewals. The recently announced initiative in the US state of New Jersey (the ‘New Jersey Hero Act’, S755/A2083), which would make opting in or out a requirement of driving licence renewal, was noted. The Boots Advantage Card (which asks about organ donation) was mentioned often at the deliberative

events. Since the UK Transplant partnership with Boots began in July 2000, over 1 million Advantage cardholders have opted to join the ODR (this is over 6% of those currently on the register). Other commercial partnerships should be sought that would raise awareness of the importance of registration.

14.8 The Communications Working Group was struck by the numbers that have been quoted several times in this report:

- Permission for organ donation is given by families in 90% of cases where the deceased has registered on the ODR.
- Only 25% of the population is registered on the ODR, compared with the 65% or more who say they support donation.

The public engagement work undertaken suggests that numbers on the ODR could be increased at a relatively modest cost through a more extensive publicity and engagement programme, perhaps akin to that for blood donation.

14.9 A key message, identified by both Taskforce members and members of the public, is the need to encourage people to let their family and friends know their wishes in relation to organ donation. The Taskforce is therefore pleased to note that the draft NHS Constitution includes making those closest to you aware of your wishes about organ donation in its proposed patient responsibilities, as something we can all do to help the NHS carry out its work more effectively. We are also pleased that the Welsh Assembly Government has sponsored an organ donation awareness-raising campaign called ‘Donate Wales: Tell a Loved One’. The main thrust of the campaign is to encourage people to firstly discuss organ donation intentions with loved ones, and secondly to register as an organ donor.

Given that 90% of organ donations are approved if a person's name is on the Organ Donor Register, there is a substantial opportunity within the current legal system to drive up donor numbers through increased awareness of, and registration on, the Register.

14.10 The Communications Working Group concentrated on communications involving the public, but communications strategies also need to be developed for a wide range of other groups, such as intensive care clinicians, donor co-ordinators, GPs and coroners. Implementation of the recommendations in the Taskforce's first report to improve training for clinical staff, and to develop guidelines for coroners, will be a vital part of addressing this.

15

CONCLUSION

15.1 The raising of presumed consent by the Prime Minister, the Chief Medical Officer for England, Health Ministers across the UK, the British Medical Association and others, all of whom have a common commitment to improving organ donor numbers, has had a very positive impact. It has raised the profile of organ donation, to its benefit, and has led to a thorough review of the evidence base. A significant opportunity to engage with faith leaders on organ donation has been created, and this has led not only to the emergence of some important insights that could make a considerable difference to communities that are currently disadvantaged, but has also laid a firm foundation for future engagement activity with those communities.

15.2 The Taskforce's members came to this review of presumed consent with an open mind, with many sympathetic to the view that presumed consent seems an obvious step forward. However, the more the Taskforce examined the evidence, the less obvious the benefit, and the more multifaceted and multidimensional the issue of increasing donor numbers was revealed to be. It became clear that what appears to be a simple idea to increase numbers may not in fact generate additional donors in sufficient numbers to justify the significant investment needed to put a new system in place. Moreover, there are risks in going down the opt out route which could impact negatively on organ donation. The Taskforce reached a clear consensus in their recommendation that an opt out system should not be introduced in the UK at the present time.

Taskforce members had a wide range of views at the outset. However, after examining the evidence, the Taskforce reached a clear consensus in recommending that an opt out system should not be introduced in the UK at the present time. The Taskforce concluded that such a system has the potential to undermine the concept of donation as a gift, to erode trust in NHS professionals and the Government, and negatively impact on organ donation numbers. It would distract attention away from essential improvements to systems and infrastructure and from the urgent need to improve public awareness and understanding of organ donation. Furthermore, it would be challenging and costly to implement successfully. Most compelling of all, we found no convincing evidence that it would deliver significant increases in the number of donated organs.

15.3 During the next five years, major changes will be made to the transplant infrastructure as the 14 recommendations of the Taskforce contained in its report *Organs for Transplants* are implemented by the Programme Delivery Board. The Taskforce strongly believes that successful implementation will deliver a 50% increase in organ donor numbers within five years (i.e. by 2013). Initial progress will be slow while the new training and systems are put in place, with the major increase in numbers being expected towards the end of this period.

15.4 The Taskforce has been greatly encouraged by the successes achieved by innovative practice since its first report was published. Examples of this include the following:

- In Royal Bolton Hospital NHS Foundation Trust, the Liverpool Care Pathway for the dying patient includes organ donation as a step in the pathway. A 100% referral rate has been achieved by ensuring that donation is considered as a routine part of end-of-life care. It is worth noting that the Trust

Board produced a positive statement on donation which is displayed Trust-wide in support of this activity. Increasing organ donation needs a commitment of support from everyone, not just from donor co-ordinators.

- Another approach has been initiated by the University Hospitals Birmingham NHS Foundation Trust. Using clinical triggers as minimum notification criteria for referral, 100% of patients diagnosed as brain stem dead at University Hospitals Birmingham were referred to the in-house donor co-ordinator and all families were approached.
- The in-house donor co-ordinator model for donor transplant co-ordinators has now been introduced in the UK by NHS Blood and Transplant's directorate of donor care and co-ordination. The strategy is based on international literature regarding donation and practice in both Spain and the USA and is part of the structure that allows the early referral of all possible donors to trained donor personnel so that efforts at all levels in the hospital can be co-ordinated to best support the possibility of consent and donation. It also enables contact with potential donor families before the subject of donation is broached, which supports the building of trust and better meets the needs of all families of potential donors. Data obtained from the potential donor audit over the four-year period from April 2003 to March 2007 demonstrates the effectiveness of this strategy: an increase in the conversion of potential donors into actual donors from 45.3% to 48.1% has already been seen.⁸

15.5 These developments do not mean that the Taskforce is complacent about the current situation. It is clear that there is considerable work to be done in increasing the numbers registered with the ODR. Some suggestions have already been outlined. While additional resource may be required to augment that currently spent on promoting the ODR, it is likely to be significantly less than that required to implement a change in legislation, and is less risky in terms of alienating public opinion.

The Taskforce recommends that the Government considers working with NHS Blood and Transplant to agree target increases in numbers on the Organ Donor Register and a suitably expanded budget for promotion of the Register.

The Taskforce recommends that, in developing a strategy for raising awareness and addressing misunderstanding about organ donation, the Programme Delivery Board builds on the evidence from members of the public contained in the report at Annex J.

15.6 A clear message from participants in the deliberative events is that people who want to be donors feel very strongly that their wish should be carried out wherever possible. This suggests that when a patient dies in appropriate circumstances, all families should be given the opportunity to have a discussion with a trained donor co-ordinator. We recognise that there are some legal issues on which clinicians are unclear – such as the weight that can be given to a decision by an individual to place their name on the

⁸ UK Transplant potential donor audit, available at www.uktransplant.org.uk/ukt/statistics/potential_donor_audit/potential_donor_audit.jsp

ODR or to carry an organ donor card – and that these issues could present a barrier to donation in some circumstances. We doubt that these issues require any amendment to the legislation, but clinicians would benefit greatly from clear guidance. We recommend that the Departments take urgent steps to clarify the legal position in this area, and we see a pressing need for guidance for clinicians covering the legal aspects of organ donation, showing how the legal framework supports donation policy and thus removing some perceived obstacles to increasing donation rates.

15.7 The Taskforce shares the same passion for increasing the number of organ donors as those calling for presumed consent. It simply concludes that there is a way of getting to the same place by a different, less risky route. Only if donor numbers have not grown by 50% by 2013 should the question of opt out be revisited. Meanwhile, every effort should be made to deliver the potential for increase within the current legal system.

The Taskforce recommends that opt out systems should be reviewed in five years' time in the light of success achieved in increasing donor numbers through implementation of the 14 recommendations of the Taskforce in its report *Organs for Transplants*.

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