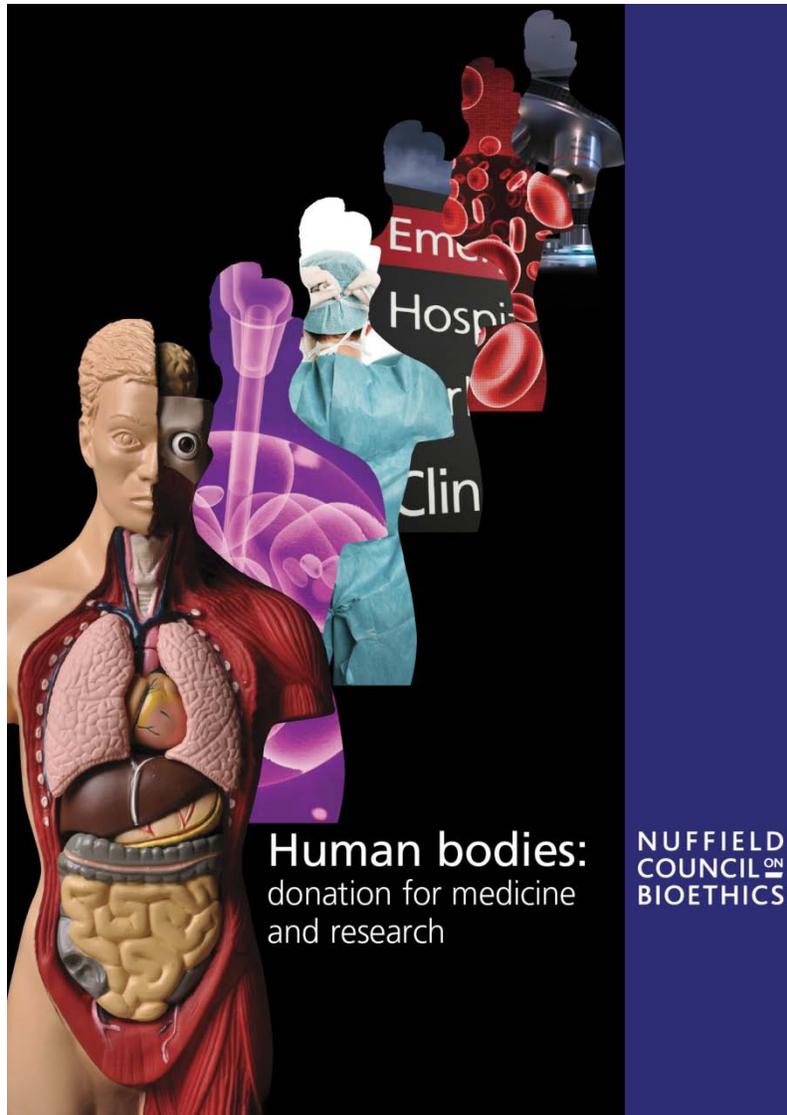


# NUFFIELD COUNCIL ON BIOETHICS

## Human bodies: donation for medicine and research



**Report developments**  
November 2012

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## Introduction

In October 2011, the Nuffield Council on Bioethics published a report entitled [Human bodies: donation for medicine and research](#). This document, published just over a year after the report's launch, highlights both general developments in areas focused on in the report, and also specific developments in relation to its recommendations and conclusions. These are addressed in chronological order.

## Developments relating to the Report's recommendations and conclusions

### **DH suggests ODR administration could be privatised** **18 October 2011**

#### **Relevant recommendations**

There is clearly a risk that, in the face of such organisational changes and pressure on budgets, valuable systemic improvements that have led in recent years to significant increases in the number of organs made available for transplantation might be lost. We recommend that the Department of Health should monitor closely the impact of these changes on organ donation services, and be prepared if necessary to act to protect systems that have been shown to work well.

The Working Party endorses this recommendation. It should not be the case that the public's willingness to donate is undermined by information technology systems that are unable to account accurately for potential donors' preferences.

The DH published a [commercial review](#) of the functions of NHS Blood and Transplant, which includes a suggestion that running the ODR could be privatised.

In its review, DH noted that "NHSBT should consider specialist solutions given the willingness and capability of the private sector to deliver systems of this nature. Therefore, DH supports the proposal to develop a business case for the delivery of a new ODR that includes the options involving any necessary private sector expertise."

### **HFEA increases compensation for gamete donors** **19 October 2011**

#### **Relevant recommendation**

We recommend that the current cap of £250 on lost earnings that may be reimbursed should be removed, and that lost earnings, where applicable, should be reimbursed in full in the same way as other expenses such as travel costs.

The Council rejects outright the concept of paying a 'purchase' price for gametes, where any

payment made is understood as payment for the gamete itself, rather than as recompense or reward to the donor herself or himself.

Shortly after the Nuffield Council's report was published in October 2011, the [HFEA](#) agreed to change its rules on the amount of compensation that gamete donors may receive from clinics.

The new scheme, which follows a consultation that ran from January to April 2011, permits the payment of a fixed sum of up to £35 per visit for sperm donors, and a fixed sum of up to £750 per cycle of donation for egg donors. Both amounts include expenses. This changes a system which has operated since 2006 where anyone who donated either eggs or sperm was entitled to travel expenses incurred and compensation for loss of earnings of up to £61.28 per day, but no more than £250 in total for each cycle of donation.

### **YouGov publishes poll results based on Nuffield Council report 3 November 2011**

#### **Relevant recommendation**

We recommend that NHS Blood and Transplant should consider establishing a pilot scheme to test the public response to the idea of offering to meet funeral expenses for those who sign the ODR and subsequently die in circumstances where they could become organ donors.

Following the publication of the Nuffield Council's report, YouGov launched a [poll](#) based on the recommendation relating to the payment of funeral expenses. The poll asked 2,640 UK participants the following question: "It has been suggested that the NHS should pay for the funeral costs of people who have donated their organs. Would you support or oppose this proposal?" The results of the poll showed that 47 per cent supported the proposal, 32 per cent opposed it, and 21 per cent did not know whether they supported or opposed.

In addition, the poll asked: "And do you think that offering to pay for the funeral costs of those who donate their organs will increase or decrease the number of people who register to donate their organs, or will make no difference?" In total, over half of participants (56%) stated that it would *increase* the number of people, 32 per cent stated it would make no difference, 11 per cent 'did not know', and just one per cent thought that it would decrease the number of people who register to donate organs.

For the 1,897 participants who were not registered organ donors, YouGov also asked: "You said that you are not currently on the Organ Donor Register. If funeral costs were paid for people who donated organs, would this make you more likely to join the Organ Donor Register, less likely to join, or would it make no difference?" The majority of participants (58%) felt that such a change of policy would make no difference to the

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likelihood of them joining the register, but 28 per cent said that they were more likely to register to donate. Three per cent stated that it would make them *less* likely to donate, and 12 per cent 'did not know'.

### **HealthTalkOnline publishes resource on deceased tissue donation for research 1 December 2011**

#### **Relevant recommendation**

We recommend that the National Institute for Health Research and the Medical Research Council should take a lead in discussing with research organisations in both academic and commercial sectors, and with NHSBT Tissue Services, whether there is sufficient demand for a more structured approach to access to tissue from deceased donors for research purposes around the country.

HealthTalkOnline, an online resource where the views of both patients and members of the public on various aspects of health care are given a forum, published a [resource](#) which focuses on the issue of using the tissue of deceased persons for research. Several accounts have been gathered from participants, and views ranged from those who put deceased donation “to the back of my mind”, “pretending I’m not mortal.” However, most people interviewed by researchers were positive about the idea of deceased donation, regardless of whether or not they had thought about the issue prior to their interview, although a few found it a difficult issue to think about.

As well as providing several very useful accounts on deceased donation, the resource also suggests that those who would like to read further discussion about the issues of deceased donation should refer to the Nuffield Council’s report.

### **Pharma industry agrees academic access to compounds 5 December 2011**

#### **Relevant recommendation**

We conclude that it is appropriate for commercial companies to make an explicit, and additional, contribution, in some way, to the costs of maintaining these public goods to reflect the value of the public's donation. We therefore recommend that any prospective sample collection for research (whether national or local) should be underpinned by a business plan that includes funding contributions from the full range of public, charitable and private sources, depending on where research users for the particular collection are likely to be located. Any such business plan should ensure that the financial value of the materials that patients and members of the public have freely donated should be recognised as being on the 'public' side of the balance sheet.

We conclude that where material is freely donated by patients or by members of the public, it is not acceptable for individual researchers or research groups to hinder, inhibit or refuse access

to other researchers for scientifically valid research, unless there are sound reasons for doing so. Indeed, we take the view that where material has been donated for research use, there is an ethical imperative to make the most efficient possible use of it.

In December, global pharmaceutical company [AstraZeneca](#) announced that it would grant academic researchers access to compounds developed by its own scientists. This announcement followed an agreement between the MRC and AstraZeneca, where the latter agreed to grant academic researchers access to 22 compounds developed by its own teams.

As part of the collaboration, the MRC invited research proposals from the UK's academic community to use the compounds in new areas. The MRC is set to judge and select the best scientific proposals, and award up to a total of £10 million to fund research based on the use of the 22 compounds.

The announcement that the two organisations would collaborate in this way came on the same day that David Cameron [unveiled a new strategy](#) designed to encourage and increase collaboration between scientists working for pharmaceutical companies and those working in the NHS.

### **New South Wales Government publishes organ donation discussion paper 6 December 2011**

#### **Relevant recommendations**

In our opinion, the importance to be attached to the person's own wishes rules out absolutely any consideration of introducing a 'hard' opt-out approach to deceased organ donation, given the impossibility of ensuring that everyone would be sufficiently well-informed to have the opportunity of opting out during their lifetime.

We would not oppose on ethical grounds a soft opt-out system, in which families had the opportunity (without pressure) of contributing their knowledge of the person's own views and, where appropriate, of determining that the person would not have wished to become a donor, or indeed that donation would cause the family significant distress. We do, however, note some practical difficulties.

We conclude that, in principle, both mandated choice and prompted choice systems present ethical options for seeking authorisation in advance to deceased organ donation.

The Government in New South Wales published a [discussion paper](#) in December 2011 which sought views on a number of questions relating to organ donation.

Recognising the shortage of organs in the State, the discussion paper focused on suggestions which would increase the number of organs available. Suggestions included switching to an 'opt out' model for organ donation, and promoting the use of

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advance care directives for people to make their wishes regarding donation known (i.e. where people are not on the national register). The discussion paper also put forward the idea of ‘designated requestors’ should be introduced to help families dealing with consent issues at the point of potential organ donation of a relative, and also recognised that the existence of a family veto for organ donation meant that a number of patients who wanted to donate were precluded from doing so because such a veto was invoked. The paper therefore suggested the policy that family members’ right to refuse donation, even if their family member is on the register, should be revoked.

Comments on these issues, and others concerning organ donation in the state of New South Wales were invited until January 2012. The Government’s official web page for organ donation is currently under construction, but will provide details about the conclusions arising from the discussion paper once the site is completed.

### **NICE launches new guidance on organ donation 12 December 2011**

#### **Relevant recommendation**

We conclude that information must be *available* to those considering donation and it must always be clear that more information is available if people desire it. If people make it clear that they wish to agree to donation, whether in advance via the Organ Donation Register, or on behalf of a deceased relative, even if they do not want to know any details about the process, this should be accepted as sufficient expression of their wishes.

In December 2011, the National Institute for Health and Clinical Excellence (NICE) published its first ever [guideline](#) that addresses the shortage of organs for transplant. NICE recommended that organ donation should be considered as a normal part of end-of-life care planning, and that each hospital should have a policy and protocol for identifying potential donors and managing the consent process. The guideline also recommends that in all cases those close to the patient should be approached in a professional, compassionate and caring manner, and be given sufficient time to consider the information they have been offered.

In addition, the guideline states that patients who are potentially suitable donors should be identified as early as possible based on two possible criteria. The first is defined by clinical trigger factors, which indicate a high likelihood of brainstem death, in patients who have had a catastrophic brain injury. The second is the intention to withdraw life-sustaining treatment in patients with a life-threatening or limiting condition which will, or is expected to, result in circulatory death. If the patient is in circumstances where they are able to make their own decisions, the health care team should seek their views on organ donation and, where appropriate, their consent.

### **Relatives overrule organ donor wishes 22 December 2011**

### Relevant recommendation

We conclude that information must be *available* to those considering donation and it must always be clear that more information is available if people desire it. If people make it clear that they wish to agree to donation, whether in advance via the Organ Donation Register, or on behalf of a deceased relative, even if they do not want to know any details about the process, this should be accepted as sufficient expression of their wishes.

In December 2011, the Royal Victoria Infirmary in Newcastle reported [research findings](#) which suggest that families regularly refuse to allow their relatives' organs to be donated for treatment. Specifically, the research concluded that, in cases where the patient is registered on the ODR, one in ten families of dead patients refuse donation.

The research did not call for changes which would allow families to be overruled, but did argue that the process should be handled with greater sensitivity, such that more families might consent to donation. The researchers also concluded that “although not wholly consistent, a large body of work suggests that teams can improve consent rates by attention to key aspects of the family approach. Increasing consent rates in the UK beyond the current rate of 60 per cent is a realistic aim and would be a major step in addressing unmet transplantation needs.”

The authors identified a number of practical steps that might help achieve this aim:

- an approach pre-planned by the coordinator/specialist nurse and healthcare team to consider specific individual circumstances—the ‘team huddle’;
- requesting donation via individuals known to the family;
- requesting donation via team members with the required training and expertise to provide the right information in a sensitive and empathic manner. In the UK, this should be the SNOD and a senior doctor;
- requesting at a time separate to that when the family are informed of the death or its inevitability, in an unhurried manner in an appropriate setting;
- use of unapologetic and positive language, emphasising the benefits of donation;
- ensuring the family are given specific information as detailed above and that in particular, concerning DBD, that the concept of brain death has been fully explained.

Concern about families vetoing relatives' decision to donate was also raised in a [Personal View](#) by David Shaw published in the BMJ on 7 August 2012. This piece argued that clinicians have a responsibility to pursue donation where the deceased person had signed the ODR, even when the family is reluctant to accept it. It stated that, “The family’s proximity increases the stress on the doctor, but does not change the ethics of the situation. Although we should treat the family compassionately, doctors do not have the same duty to the family as to dying patients or other patients who need organs”.

## **Stem cell research on donor embryos sometimes not disclosed by US fertility clinics**

**29 December 2011**

### **Relevant recommendation**

We recommend that the World Health Organization should develop appropriate guiding principles to protect egg donors from abuse or exploitation.

Research published in [Fertility and Sterility](#) investigated whether egg donors whose eggs are used to form embryos for treatment purposes are informed by US clinics when those embryos are, in fact, used for research.

The research found that 66 consent forms for egg donation were provided by 100 clinics which both accept egg donation and also provide ‘excess’ embryos for research. These consent forms indicated that, although *most* egg donor consent forms inform donors that they will not have control over embryos which result from their donation, only 30 per cent inform them that some embryos may be used for research.

Writing in an email cited in an article by [Reuters](#), the authors of the report recommended that “all IVF clinics that provide some embryos for research inform egg donors about the possibility of such research (including stem cell research, which is particularly controversial)”.

## **NHSBT unveils plans for increasing living kidney donation**

**24 January 2012**

### **Relevant recommendation**

The Working Party endorses the Organ Donation Taskforce’s focus on tackling the structural problems that have, in the past, hindered the optimal use of the organs that are potentially available.

In January 2012, NHS Blood and Transplant (NHSBT) launched the first [UK Strategy for Living Donor Kidney Transplantation](#).

The strategy will build on the existing living kidney donor programme, in which paired, pooled and altruistic non-directed donations are already possible in the UK and which are growing in popularity. Public Health Minister, Anne Milton, reported that the Department of Health was working closely with NHSBT to ensure that commissioning arrangements were in place so that the number of living donors could continue to grow. Living donor kidney transplants increased three-fold between April 2000 and March 2010, and were noted to be highly successful, with 93 per cent of living kidney

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transplants still functioning well after the first year compared with 88 per cent of those using deceased donor kidneys.

One of the ‘action points’ of the strategy arose from the fact that there are sometimes delays in the preparation of donors and recipients. The [strategy](#) notes that “multiple factors are known to contribute to delay/impact on the duration of pre-donation/pre-transplant assessment. These are primarily linked to availability of resources and infrastructure within individual centres and/or across regional networks by are also recognised as generic issues. Such structural problems were highlighted in the Council’s report, in particular when it endorsed the work of the ODT in tackling such structural issues.

### **BMA publishes report on organ donation policy 13 February 2012**

#### **Relevant recommendations**

We recommend that any system set up to document people’s wishes that mandates a response to a question about organ donation should also include the option of expressing objection; to do otherwise significantly undermines commitment to following the wishes of the deceased and even, arguably, fails to comply with the spirit of current legislation with its current focus on consent. We further recommend that *any* system set up to document people’s wishes regarding donation (including the current ODR) should be able to register objections.

We therefore recommend that, where a health need is not being met by altruist-focused interventions, the following factors should be closely scrutinised in order to ascertain whether offering a form of non-altruist-focused intervention might or might not be harmful:

- the welfare of the donor: this should be understood very broadly, including physical and psychological risks at the time of donation, physical and psychological risks in the future, and the extent to which the donor feels they have other options open to them;
- the welfare of other closely concerned individuals;
- the potential threat to the common good: for example the possible impact on existing donation systems, and the risk of increasing social inequalities;
- the professional responsibilities of the health professionals involved; and
- the strength of the evidence on all the factors listed above.

We recommend that NHS Blood and Transplant should consider establishing a pilot scheme to test the public response to the idea of offering to meet funeral expenses for those who sign the ODR and subsequently die in circumstances where they could become organ donors.

We suggest that a stewardship state has a direct responsibility to explore the reasons why some populations are hesitant to donate, and if appropriate, to take action to promote donation.

The British Medical Association (BMA) published a [report](#) earlier this year on UK organ donation policy. The contents of this report and some of the preliminary

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recommendations considered by the BMA were discussed at a meeting prior to its publication which involved staff members of both the BMA and the Nuffield Council.

The report – entitled *Building on progress: where next for organ donation policy in the UK?* – updated a previous BMA report on organ donation, which was published in 2000, and highlighted a number of recommendations made by the Nuffield Council report.

Commenting on the Nuffield Council's recommendation that people should be able to record their objections as well as their assent to donation, the BMA noted that "[c]learly, if the option to say 'no' is to be included, there must be a clear and robust mechanism in place for those objections to be registered and acted upon. This would involve either modification of the ODR to include the option to opt out of donation or a new organ donor register designed specifically to allow people to either opt into or out of donation."

Supporting the view that altruism and social solidarity should remain principal concepts of organ donation, the BMA again referred to the Council's conclusions, and particularly the importance of altruism as "underpinning important communal values that express something very significant about the kind of society in which we would wish medicine and research to flourish." Moreover, the BMA took into consideration the detail of the Council's intervention ladder, and the conclusion that "systems based on altruism and systems involving some form of payment are not necessarily incompatible", even though they are normally seen as opposing approaches. In addressing this conclusion, the BMA "agrees that an individual donor's motivation could, under such a scheme [for funeral expenses to be paid], be both altruistic and financial, and that the system would still be based on altruism – in terms of being motivated by a desire to benefit others (including the financial position of one's relatives). Nevertheless, there would be a shift away from pure altruism in the sense of an act of social solidarity, where the motivation is to help unknown recipients, to one where the motivation is to provide financial benefit to specific members of one's family and heirs." The BMA also highlighted the need for empirical evidence to support the proposal on funeral expenses. Most extensively, the BMA devoted considerable attention to the Council's recommendation for a pilot scheme to be introduced which pays the funeral expenses of those who are registered on the ODR and die in circumstances where they become an organ donor. After reviewing the arguments in the Council's report, the BMA expressed the following view.

"There are undoubtedly ethical issues, practical problems and cost-implications of this proposal that need to be thoroughly investigated. Nevertheless, the BMA does not have major ethical concerns about offering funeral expenses to those on the Organ Donor Register who go on to donate organs although we question the likely effectiveness of such a venture in increasing donation rates. Moving away from a system based solely on altruism would only be worthwhile if there is good reason to believe that it will achieve this aim. Whilst recognising the difficulty of devising a sufficiently robust study, if a pilot scheme could be devised that would measure the effectiveness of such a scheme, this would be worth exploring further. Any research would also need to address public support

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and, if possible, the broader implications, if any, of introducing a system based on financial as well as altruistic motivation.”

The BMA also underlined its policy which supports the introduction of an opt-out system across the UK. It stated: “the BMA remains firmly convinced that a system of opt-out with safeguards is the best option for the UK and the one that is most likely to be effective... [and] hopes that this report will encourage and facilitate informed debate amongst professionals, policy-makers and the public about how we take forward public policy on organ donation in the UK.”

### **HTA publishes position statement on deceased tissue research March 2012**

#### **Relevant recommendation**

We recommend that the National Institute for Health Research and the Medical Research Council should take a lead in discussing with research organisations in both the academic and commercial sectors, and with NHSBT Tissue Services, whether there is sufficient demand for a more structure approach to access to tissue from deceased donors for research purposes across the country.

The Human Tissue Authority (HTA) published a [position statement](#) on extending existing licences to cover the removal of tissue from the deceased for research. This statement seeks to clarify this issue, and notes that it has “been working with individual establishments to extend existing removal licences where there is local need... Extending existing licences is the swiftest and most light touch approach we can take while we explore options, which include the possible introduction of a new type of licence specifically for the removal of tissue from the deceased.”

### **Organ donation opt-out backed by two thirds in BBC Wales poll 2 March 2012**

#### **Relevant recommendations**

In our opinion, the importance to be attached to the person’s own wishes rules out absolutely any consideration of introducing a 'hard' opt-out approach to deceased organ donation, given the impossibility of ensuring that everyone would be sufficiently well-informed to have the opportunity of opting out during their lifetime.

We would not oppose on ethical grounds a soft opt-out system, in which families had the opportunity (without pressure) of contributing their knowledge of the person’s own views and, where appropriate, of determining that the person would not have wished to become a donor, or indeed that donation would cause the family significant distress. We do, however, note some practical difficulties.

If an opt-out system is introduced in Wales we recommend that this is accompanied by robust

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research, both on the role of relatives in determining whether organs may be donated, and on the effect that the legislative change (as opposed to any confounding factors such as system changes) has had on the numbers of organs donated.

We conclude that, in principle, both mandated choice and prompted choice systems present ethical options for seeking authorisation in advance to deceased organ donation.

A [poll](#) by BBC Wales has indicated that two-thirds of Welsh people support plans to introduce opt-out organ donation.

The poll – which sought the views of 1,000 Welsh people – was undertaken in light of plans by the Welsh Government to change its organ donation policy from an opt-in to an opt-out system. The poll asked participants the question: “The Welsh Assembly Government is planning to introduce a law to change the way organs are donated in Wales. If it’s passed, the new law would presume people want to donate their organs when they die, unless they choose to opt out by talking their names off the register. This is known as ‘presumed consent’. Are you personally in favour of a law that presumes consent for organ donation? /against a law that presumes consent for organ donation? /don’t know?” Results published after the poll was carried out suggest that 63 per cent of people were in favour of opt-out, 31 per cent were against, and six per cent responded “don’t know”.

In addition, the Northern Ireland Assembly has [recently urged](#) its Health Minister – Edwin Poots MLA – to consult on an opt-out organ donation scheme. In response to this, Mr Poots has called for a public debate on how the current system might be improved, but stopped short of any definite announcement of a formal review.

### **Welsh Government consults on ‘opt out’ organ donation 8 March 2012**

#### **Relevant recommendations**

We would not oppose on ethical grounds a soft opt-out system, in which families had the opportunity (without pressure) of contributing their knowledge of the person’s own views and, where appropriate, of determining that the person would not have wished to become a donor, or indeed that donation would cause the family significant distress. We do, however, note some practical difficulties.

If an opt-out system is introduced in Wales we recommend that this is accompanied by robust research, both on the role of relatives in determining whether organs may be donated, and on the effect that the legislative change (as opposed to any confounding factors such as system changes) has had on the numbers of organs donated.

In March 2012, the Welsh Government released a [consultative white paper](#) proposing a “soft opt-out system of posthumous organ and tissue donation”. According to the white

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paper, ‘soft opt-out’ would entail a system whereby “the removal and use of organs and tissues is permissible unless the deceased objected during his or her lifetime. Individuals will have a formal mechanism for registering that objection. After death relatives will be involved in the decision making process around donation.”

The Welsh Government explicitly stated that the motivation behind the proposed change is to increase the number of available organs for transplantation; “on average approximately one person in Wales dies each week as a donor cannot be found to enable transplantation to go ahead” and in 2010, 67 per cent of donors were not on the organ donor register. In particular, the Welsh Government envisaged a new system to operate according to the following conditions:

- It will apply to people aged 18 or over who live and die in Wales;
- those adults will have the opportunity to make an objection to donation of their organs and tissues;
- there will be an effective and secure system for individuals to make an objection to donation should they wish to, and such a system will enable objection to donation of some or all organs and tissues;
- any objection of an individual to donate organs and/or tissues will be upheld, after death;
- the system will support the opportunity for individuals to change their minds, and to include people who move to Wales or who reach the age of 18; and
- after death families will be involved in the decision making process around donation.

### **NHSBT gathers faith communities to discuss organ donation 9 March 2012**

#### **Relevant recommendations**

We suggest that a stewardship state has a direct responsibility to explore the reasons why some populations are hesitant to donate, and if appropriate, to take action to promote donation.

[A] stewardship role includes a duty to take positive action to remove inequalities that affect disadvantaged groups or individuals. In this context, the stewardship role of the state (exercised here by intermediary bodies such as NHS Blood and Transplant and individual hospitals and trusts and professionals) includes taking action actively to promote donation, in order to ensure that the NHS is able to offer fair access to donation services to *all* UK residents.

In March 2012, NHSBT gathered together representatives from all of the UK’s major religious groups for the first national [Organ Donation Congress](#).

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Leaders representing Buddhism, Hinduism, Judaism, Islam, Christianity, Jainism and Sikhism participated in a panel discussion about the social, cultural and ethnic influences on deceased donation in the UK.

The religious leaders also contributed to the drafting of a [leaflet](#) exploring religious perspectives on organ donation. This new resource gives an overview of each of the religion's views on organ donation. According to NHSBT, "it is hoped the leaflets will help people make an informed choice about joining the NHS Organ Donor Register (ODR), and encourage them to discuss the issue with their family and friends.

### **HFEA launches strategy to boost egg and sperm donation**

**5 April 2012**

#### **Relevant recommendations**

We recommend that the Royal College of Obstetricians and Gynaecologists and the British Fertility Society should work with the HFEA to review what is currently regarded as best practice in the UK with respect to measures taken to safeguard egg donors, with a view to issuing guidance that will send out a clear public signal about how the welfare of egg donors should underpin any consideration of donation.

We conclude that, in order properly to inform this debate, good quality empirical research evidence is urgently needed as to what, if any, effects financially incentivised gamete donation has on children conceived as a result of such donation and, indeed, on the wider context of how responsibilities towards children are understood.

The HFEA has launched a [national strategy](#) to raise awareness of egg and sperm donation and to improve the care of donors.

The strategy will focus on addressing a number of obstacles to donor recruitment and retention which were identified as a result of its 2011 public consultation on donation. In tackling these obstacles, the HFEA will aim to increase awareness of donation and the information that donors receive, improve the „customer service“ that donors receive when they contact clinics, and help donors to provide better information about themselves for future families.

The development of the strategy will include the appointment of a national group of 12-14 experts from within and outside the fertility sector. According to an HFEA press release, this group will be comprised of "a range of people from diverse experiences – such as blood donation, PR and unregulated sperm websites, as well as those with first-hand experience of sperm and egg donation." This group will then be expected to suggest new approaches to raise awareness of gamete donation.

### **Study suggests egg donors remain fertile following donation**

**12 April 2012**

### Relevant recommendations

We consider that the welfare of the potential donor, especially with respect to egg donors, is central in determining what constitutes acceptable practice in this area.

We endorse the good practice guidance issued by the European Society of Human Reproduction and Embryology (ESHRE) on the treatment of egg donors in the context of cross-border reproductive care, and note its potential relevance also for domestic care. In particular, we endorse ESHRE's call for national registers of gamete donors to be established, and for centres to participate in the collection of national or international data. In addition we recommend, as a matter of urgency, that action is taken by licensed clinics to start collecting data on a systematic basis (if possible retrospectively, as well as through the new registers) to track the long-term health effects of repeat egg donations.

We recommend that the Royal College of Obstetricians and Gynaecologists and the British Fertility Society should work with the HFEA to review what is currently regarded as best practice in the UK with respect to measures taken to safeguard egg donors, with a view to issuing guidance that will send out a clear public signal about how the welfare of egg donors should underpin any consideration of donation.

A [study](#) published by a team of Belgian researchers concluded that donating eggs does not appear to have a negative effect on a woman's chances of becoming pregnant.

The study aimed to assess whether there is an increased risk of infertility in 194 women that have previously undergone ovarian stimulation and egg retrieval for the purposes of donation. It concluded that, of the women who indicated having pursued conception after egg donation, 57 out of 60 – or 95 per cent – became pregnant without assistance.

### **Fertility company targets female Cambridge students for donor eggs 12 May 2012**

### Relevant recommendations

The Council rejects outright the concept of paying a 'purchase' price for gametes, where any payment made is understood as payment for the gamete itself, rather than as recompense or reward to the donor herself or himself.

We consider that the welfare of the potential donor, especially with respect to egg donors, is central in determining what constitutes acceptable practice in this area.

We recommend that the Royal College of Obstetricians and Gynaecologists and the British Fertility Society should work with the HFEA to review what is currently regarded as best practice in the UK with respect to measures taken to safeguard egg donors, with a view to issuing guidance that will send out a clear public signal about how the welfare of egg donors should underpin any consideration of donation.

The [Huffington Post](#) reported that female students at Cambridge University were targeted as potential egg donors. Leaflets were distributed, asking female students to donate eggs in order to help an infertile couple, who are believed to be graduates of the university.

The leaflets were produced by Altrui, a company which specialises in ‘altruistic egg donation’. Under existing legislation, donors are permitted to receive financial compensation (but not direct payment), with an upper limit of £750. The flyers have raised concerns that students may be enticed into donating out of financial hardship.

### **Study highlights success of TOPS June 2012**

#### **Relevant recommendation**

We welcome the voluntary accreditation scheme for units conducting phase 1 trials, established in 2008 by the Medicines and Healthcare products Regulatory Authority (MHRA), which requires that accredited units must have a procedure in place to address over-volunteering. We recommend that the MHRA should monitor closely any units that do not apply for accreditation, with a view to making requirements to guard against over-volunteering compulsory if necessary. We further recommend that the National Research Ethics Service should consult on the possibility of limiting the total number of first-in-human trials in which any one individual should take part.

A research paper published in the [European Journal of Clinical Pharmacology](#) concluded that The Over-volunteering Prevention System (TOPS) system is widely used. Specifically, it found that a total of 55 research units (29 clinical research organisations, 13 universities, eight hospitals and five pharmaceutical companies) throughout the UK registered to use TOPS, and have entered a total of 124,906 volunteers into the system. Given these findings, the study concluded that TOPS is widely used and effective, and helps research units to comply with UK clinical trial regulations.

### **Patients at Devon hospital asked to be organ donors on admission 14 June 2012**

#### **Relevant recommendation**

That stewardship role includes a duty to take positive action to remove inequalities that affect disadvantaged groups or individuals. In this context, the stewardship role of the state (exercised here by intermediary bodies such as NHS Blood and Transplant and individual hospital trusts and professionals) includes taking action actively to promote donation, in order to ensure that the NHS is able to offer fair access to donation services to *all* UK residents.

In June 2012, it was [reported](#) that Torbay hospital in Devon started asking every patient admitted if they are, or would register as, an organ donor. Torbay hospital, which is the only hospital in the county asking patients, said the answers would be recorded on patients' files but not passed on to any other body.

### **Welsh Government launch opt-out consultation 18 June 2012**

#### **Relevant recommendations**

We would not oppose on ethical grounds a soft opt-out system, in which families had the opportunity (without pressure) of contributing their knowledge of the person's own views and, where appropriate, of determining that the person would not have wished to become a donor, or indeed that donation would cause the family significant distress. We do, however, note some practical difficulties.

If an opt-out system is introduced in Wales we recommend that this is accompanied by robust research, both on the role of relatives in determining whether organs may be donated, and on the effect that the legislative change (as opposed to any confounding factors such as system changes) has had on the numbers of organs donated.

We conclude that, in principle, both mandated choice and prompted choice systems present ethical options for seeking authorisation in advance to deceased organ donation.

The Welsh Government launched a [consultation](#) on the Draft Human Transplantation (Wales) Bill. The draft Bill would introduce a 'soft opt-out system' for organ and tissue donation in Wales. A 'soft opt-out system' deems a person's consent to donation to have been given unless they objected during their lifetime but also gives those individuals with very close relationships to the deceased an important role to play in the process.

Currently, there are a number of ways 'appropriate consent' to organ donation can be provided in Wales: express consent given by donor while they were alive (for example by joining the Organ Donor Register); a nominated representative giving express consent after the person's death; where the donor had given no instructions for or against during their lifetime, the relevant next of kin can give express consent on their behalf, based on what they think or know the deceased would have wanted. The draft Bill would add 'deemed' consent as a new form of consent to donation for those over the age of 18 who live and die in Wales. There "will be safeguards for children, people who 'lack capacity' and those who do not live permanently in Wales". The explicit purpose of the proposed change in policy is to increase the number of organ and tissue donors.

The draft Bill, which, if passed, would come into effect in 2015, would be the first opt-out scheme in the UK. The consultation is open until 10 September 2012.

### **Transplant Alliance publishes strategic plan 13 July 2012**

#### **Relevant recommendations**

We suggest that a stewardship state has a direct responsibility to explore the reasons why some populations are hesitant to donate, and if appropriate, to take action to promote donation.

[A] stewardship role includes a duty to take positive action to remove inequalities that affect disadvantaged groups or individuals. In this context, the stewardship role of the state (exercised here by intermediary bodies such as NHS Blood and Transplant and individual hospitals and trusts and professionals) includes taking action actively to promote donation, in order to ensure that the NHS is able to offer fair access to donation services to *all* UK residents.

In July 2012, the Department of Health's announced the publication of a [strategic plan](#) which sought to address the underrepresentation of black, Asian and minority ethnic (BAME) people on whole organ and bone marrow recipients.

The plan, which was authored by the National BAME Transplant Alliance, a new group which aims to bring together people and organisations with in-depth knowledge of their communities to address the problem of low donor and transplant rates.

The introduction to the strategic plan notes that "a raft of recent reports, from the UK Stem Cell Strategic Forum, the Organ Donation Taskforce, the All Party Parliamentary Kidney Group and the Nuffield Council on Bioethics, have all raised this as an issue and its consequences for equality of access to healthcare.

The objectives of the group are stated as:

- To establish the group as the authoritative voice for BAME donation, built on a reputation for sound advice, guidance and leadership.
- To facilitate discussion and agree strategies to increase representation on donor registries of individuals from BAME or mixed parentage backgrounds.
- To provide high level coordination and advice on awareness campaigns covering the donation of stem cells and whole organs from BAME and mixed parentage populations.
- To facilitate better networking to support work at a local and national level.
- To promote the implementation of joint initiatives covering different types of donation wherever possible.
- To identify and support initiatives and projects that help overcome the barriers that exist in preventing the conversion of willing donor to successful transplant.

**NHSBT launch organ donation survey  
27 July 2012**

**Relevant recommendations**

We therefore suggest that a stewardship state has a direct responsibility to explore the reasons why some populations are hesitant to donate, and if appropriate to take action to promote donation.

The Working Party endorses the Organ Donation Taskforce's focus on tackling the structural problems that have, in the past, hindered the optimal use of the organs that are potentially available.

There is clearly a risk that, in the face of such organisational changes and pressure on budgets, valuable systemic improvements that have led in recent years to significant increases in the number of organs made available for transplantation might be lost. We recommend that the Department of Health should monitor closely the impact of these changes on organ donation services, and be prepared if necessary to act to protect systems that have been shown to work well.

NHS Blood and Transplant (NHSBT) published a survey which aimed to gather opinion from both members of the public and stakeholders about how arrangements for organ donation in the UK should progress after 2013.

The survey asked a range of questions, including how NHSBT might maximise the use of every organ through organisational changes; how to ensure that everyone with the potential to donate has the opportunity to do so; how to increase the donor pool; and how to make organ donation “a normal part of UK culture”. Among the options offered to respondents to the survey are: giving people registered on the Organ Donor Register priority as transplant recipients (a system which currently operates in Israel); and the introduction of new financial rewards for intensive care units that provide organs. In addition, the question of moving to a system of ‘presumed consent’ for organ donation – as is currently being tried in Wales – is also raised.

As part of its follow-up activities, the Nuffield Council submitted a [response](#) to this survey. [Results](#) of the survey were published in November 2012, and will inform a new strategy document that is expected to be published in April 2013.

**JME article notes research opportunity following Organ Directive  
8 August 2012**

**Relevant recommendations**

We suggest that routine information about the Organ Donor Register should include explicit

reference to the potential research uses of organs and tissue, and that potential donors should have the option of authorising such uses in advance.

Should such a pilot scheme prove successful, we recommend that the possibility of donating for research purposes (distinguishing between research as part of the transplantation process, and research undertaken with material that would otherwise not be used for transplantation) should be included within the standard consent/authorisation documentation for deceased donation.

An article published in the [\*Journal of Medical Ethics\*](#) suggested that opportunities for translational research to be further supported may arise as a result of the EU Organ Directive (2010).

The article – written by Antonia Cronin, James Douglas, and Steven Sacks – noted that the provisions of the Human Tissue Act 2004, and specifically its requirements for a system of licencing for transplantation research, meant that opportunities for research were being missed. Conversely, regulations introduced as following the European Organ Directive (2010), impose a compulsory licencing system, similar to that for research, on the *whole* transplantation process. This, argued the authors of the paper, goes beyond what is required by the Directive and may have an inhibitory effect similar to that already seen in research. However, following a public consultation, the DH has stated that all sanctions under the new regulations were to be decriminalised. This, it was suggested, highlights “an awareness of the DH that excessive regulation unnecessarily harms the transplantation process. An opportunity thus arises for the Human Tissue Authority...to end the current illogical and harmful separation of transplantation and transplantation research by ensuring that all centres licenced for organ donation, retrieval and transplantation are also fully licenced for related research.”

### **ASRM finds egg donor recruiters ignore ethical standards 9 August 2012**

#### **Relevant recommendations**

We consider that the welfare of the potential donor, especially with respect to egg donors, is central in determining what constitutes acceptable practice in this area.

We endorse the good practice guidance issued by the European Society of Human Reproduction and Embryology (ESHRE) on the treatment of egg donors in the context of cross-border reproductive care, and note its potential relevance also for domestic care. In particular, we endorse ESHRE’s call for national registers of gamete donors to be established, and for centres to participate in the collection of national or international data. In addition we recommend, as a matter of urgency, that action is taken by licensed clinics to start collecting data on a systematic basis (if possible retrospectively, as well as through the new registers) to track the long-term health effects of repeat egg donations.

We recommend that the World Health Organization should develop appropriate guiding

principles to protect egg donors from abuse or exploitation.

We conclude that there should be a coherent and managed infrastructure for egg and sperm donation, on the lines of the structures currently in place for organ donation.

The way that US egg donors are recruited by fertility clinics and other groups was examined by the Society for Assisted Reproductive Technology (SART), an organisation affiliated with the American Society for Reproductive Medicine (ASRM).

In a paper published in [Fertility and Sterility](#), SART highlighted the results of a survey of the websites of over 100 egg donor ‘agencies’ or IVF clinics that recruit donors online and display the amount that donors could expect to be paid in what the authors describe as ‘compensation’ for their donation.

The survey found that a significant number of websites were non-compliant with the ASRM’s guidelines. For example 34 per cent varied the amount of compensation they offered according to the donor’s traits (e.g. the (perceived) ‘trait’ of prior donation success), and 41 per cent did not have a specific requirement that donors should be over the age of 21, both of which are specified by ASRM guidelines. In light of these findings, SART recommended that the ASRM should consider changes to its guidelines, along with improvements to monitoring and action by the ASRM in relation to compliance.

### **MEPs oppose paid donation of tissues and cells** **11 September 2012**

#### **Relevant recommendations**

We endorse the current position that no payment, over and above the direct reimbursement of costs incurred in being a donor, should be made to living organ donors. We also conclude that systems assigning priority to those who have earlier expressed a willingness to donate are inappropriate, given the wide range of circumstances in which people are held to be ineligible to donate different forms of bodily material.

We do, however, endorse the current guidance by the Department of Health that the costs incurred by living organ donors (including actual lost earnings) should be fully reimbursed by their local Primary Care Trusts. Given the current organisational changes within the NHS in England, under which both Primary Care Trusts and the Human Tissue Authority will be abolished in their current form, we urge the Department of Health to ensure that this guidance is given proper weight within the new organisational structures. Possible ways of achieving this would include through legally binding Directions or through the Code of Practice issued under the Human Tissue Act.

We have already argued that the state has a stewardship role in maximising the donation of bodily materials, where these have the potential to contribute to improved health, and within ethical limits. To that extent, and no further, the aim of national self-sufficiency is clearly laudable. However, where this national self-sufficiency cannot be achieved without taking

action that would otherwise be regarded as unethical, the fact that people may still choose to travel abroad should not force a change of policy.

A non-binding [resolution](#) adopted by MEPs stated that the donation of tissues and cells should be voluntary, unpaid and – in most cases – anonymous.

In a [press release](#) from the European Parliament, the contents of the resolution were summarised, and it was noted that MEPs also supported the proposal that, while healthcare remains mainly a national responsibility, they recommended that EU countries should cooperate better on cross-border donations.

The resolution was drafted by Marine Yannakoudakis, and adopted by 551 votes to 14, with 81 abstentions. Among the key points of the resolution was the call by MEPs for all EU countries to ban financial incentives for donation and to clearly define the conditions under which financial compensation may be granted, for example to reimburse travel expenses or loss of earnings. Moreover, the MEPs also called on the European Commission to propose legislation designed to guarantee the principle of unpaid donation.

### **Funeral expenses recommendation cited in *National Post* article 25 September 2012**

#### **Relevant recommendation**

We recommend that NHS Blood and Transplant should consider establishing a pilot scheme to test the public response to the idea of offering to meet funeral expenses for those who sign the ODR and subsequently die in circumstances where they could become organ donors.

The [National Post](#) cited the Council's recommendation in relation to the payment of funeral expenses, in an article that focused on shortages in organs for donation in Canada.

The article endorsed the Council's recommendation that a pilot scheme should be introduced by the Department of Health which pays funeral expenses of registered organ donors who die in circumstances where their organs may be used for transplantation. Specifically, the article states: "A British ethics body called the Nuffield Council of Bioethics suggested that the UK's National Health Service should start paying for organ donors' funeral costs. It would be a small step, but a relatively safe one. Access to organs would not be affected — rich people awaiting transplants would not be given any advantage since the costs would be borne by the government, not the would-be recipient.

And the prospect of a potential donor being unduly enticed to give up his organs seems unlikely given that the reward for the decision would not accrue to him. On the other

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hand, the promise of funeral payments might make the very common instance of a grieving family overruling a donor's previously stated intent to give up his organs, less likely to occur.

After all, it's the family that must deal with the funeral arrangements.”

## General developments

### **Longest organ donation ‘chain’ recorded in the US 23 February 2012**

In February, the [Independent](#) reported that the longest ever kidney transplant chain had been carried out in the United States. The transplant chain began with a non-directed altruistic donation – also known as ‘altruistic donation’ – and resulted with 30 patients receiving kidneys from 30 living donors. The operations were carried out over a period of four months in 17 hospitals across 11 states.

### **China to phase out prisoner organ donation 23 March 2012**

A piece in the [Guardian](#) newspaper reported that a Chinese health official announced that the Chinese Government intends to abolish “the transplanting of organs from executed prisoners within five years and try to spur more citizens to donate”.

Vice Health Minister Huang Jiefu was quoted as stating that the high rates of infection in the prisoner’s bodies meant that “the long-term survival rates for people with transplanted organs in China are always below those of people in other countries”.

### **US court will not reconsider bone marrow payments ruling 28 March 2012**

In March 2012, [AP reported](#) that the 9<sup>th</sup> US Circuit Court of Appeals declined the Obama administration’s request to reconsider a ruling the court gave in December 2011 that allows bone marrow donors to be paid for their donations like blood donors. The court ruled that technological developments had made the process of donating bone marrow similar enough to giving blood plasma such that the procedure does not now amount to an organ transplant.

The administration had 90 days to petition the US Supreme Court, but [declined to do so](#). This means that some bone marrow donors could soon be compensated for their donation.

### **Facebook enables users to indicate organ donor status 1 May 2012**

The social networking website, Facebook, announced the inclusion of a [feature](#) which allows its users to indicate their organ donor status on their individual member profiles. The feature, which is currently only available in the US and the UK, also presents a link to a Facebook webpage which explains how to register as an organ donor.

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The new feature appears to have had some success: on the first day of its launch, 6,000 people in the US reportedly registered as organ donors through links provided by the Facebook website. This is in comparison to a typical daily figure of 400 new registrations.

### **Recipients of donor eggs barred from donating blood 16 July 2012**

An article in [The Times](#) reported that women in the UK who received donated eggs during fertility treatment will be barred from donating blood in order to help prevent the spread of vCJD. The ban was implemented following a recommendation from the UK Standing Advisory Committee on Care and Selection of Donors. The committee made the recommendation on the basis of a [2010 paper](#) showing prion infection in the uterus of a US woman who had died of vCJD, which demonstrated the possibility of onward transfer of the disease. The ban does not apply to people conceived as a result of egg or embryo donation or women who have used donated sperm.

### **Research shows that tax breaks haven't increased organ donor rates 31 August 2012**

An article published in the [American Journal of Transplantation](#) has suggested that the policy of some US states to offer tax breaks to living organ donors has not increased the rate of donation.

In total, 15 US states passed tax deductions, and one passed a tax credit, to help recompense donors for potential medical, accommodation and wage losses that might eventuate from their decision to become living donors. Researchers assessed data from each of the states which had passed these tax policies and found there to be no statistically significant effect on donation rates. They suggested that there may be several reasons why this policy proved ineffective at raising the level of living donation: the cash value of the tax deduction was too low to offset costs to donors; there was a lack of public awareness about the tax scheme; and states that were proactive enough to pass these tax policies may have already depleted their donor pools with previous interventions.

### **'Matching donors' website launched 31 August 2012**

A [website](#) which aims to match living donors with potential recipients of their kidneys was launched in the UK in August 2012.

A press release from the HTA noted that "The HTA is aware of the launch of the matching donors website in the UK. We are not yet clear how it will operate here and the legal implications, and we have not had a conversation with the charity about these issues. Once we have more information, we can advise members of the public considering the possibility of arranging a donation through this route. Our initial review

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suggests that the UK site, like the US one, charges up to \$595 for organ recipients to register. The US site does not appear to provide information on how many successful organ donations have taken place after the 'matching' process. This is something that potential recipients may want to know in order to make an informed choice."