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## **Responses to Professor Sir Gordon Duff's Consultation**

### **Written responses to Sir Gordon Duff's consultation**



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17/06/2010 11:22

To ODR Review/OIS/DOH@DOH

cc

bcc

Subject ODR Review - Issues with the FAQs

History:

This message has been replied to and forwarded.

Dear Sir Gordon Duff,

As an Intensive Care Consultant I have actively supported organ donation for many years and in recent times have taken on roles as my Trust's Clinical Lead in Organ Donation and also Chair of the SW Network of Clinical Leads (the first of its kind in the UK). I wish to provide you with feedback, not about the incident that occurred, rather it is about the information provided to the public on the ODR and the NHSBT website.

ODR registration is accepted as being, in effect informed consent, therefore it is very important the information provided to the potential registrant is correct and complete. I believe that the supporting information provided to the public that underpins the registration process could be improved or updated.

I enclose a document describing my views as I thought it would be more useable than just sending a long-winded e-mail. I am, of course delighted to respond further or clarify anything to you if needed. I have also enclosed a pdf of the information as an easy reference for you.

Yours faithfully,

Dr Martin Walker  
Consultant in Intensive Care Medicine & Anaesthesia  
Clinical Lead in Organ Donation  
Chair SW Network of Clinical Leads in Organ Donation

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## ODR Review Feedback – Dr Martin Walker

### Information lacking in FAQs

In reality no information is given on the extra treatment an organ donor may be given prior to retrieval to optimise the condition of the donated organs. This is perceived by the clinical team as being in the patient's best interests so that their wishes to be a donor can be followed, however it would be sensible to provide some information on this in the FAQs

### Incorrect or confusing information within the FAQs

#### 7. How do they know you are really dead?

Organs are only removed for transplantation after a person has died. Death is confirmed by doctors at consultant level who are entirely independent of the transplant team. Death is confirmed in exactly the same way for people who donate organs as for those who do not.

Death is not always confirmed by Consultants, perhaps it would be better to describe as "experienced". Brain Stem Death tests have to be performed by two experienced doctors, one of whom has to be a Consultant. But increasing numbers of donors are controlled non-heart beating donors who are often confirmed dead by trainee doctors on duty at the time.

Patients who die in hospital but are not on a ventilator can, in some circumstances, donate their kidneys, and in certain circumstances, other organs. They are called non-heartbeating donors.

Non-heart beating donors are almost invariably on a ventilator prior to withdrawal of multi-organ support, and so this statement is inaccurate.

#### 19. Can I be a donor if I have an existing medical condition?

Yes, in most circumstances. Having a medical condition does not necessarily prevent a person from becoming an organ or tissue donor. The decision about whether some or all organs or tissue are suitable for transplant is made by a healthcare professional, taking into account your medical history.

There are only two conditions where organ donation is ruled out completely. A person cannot become an organ or tissue donor if they have been diagnosed with HIV or have, or are suspected of having, CJD.

This is currently incorrect HIV positive patients can rarely donate, but it is not an absolute contraindication. In reality for a lay explanation the only 100% absolute contraindication is CJD.



16 June 2010

Dear Sir Gordon

Error on Organ Donor Register

Patient Concern is not qualified to judge how the error occurred, save to say that computer records are more hazardous than paper records, in that substantial bodies of information can be transferred, so that when mistakes happen they affect large numbers of people, as in this case. Over-reliance on computers without a satisfactory checking procedure makes such errors only too likely.

We were disappointed to learn that the error was made by NHSBT (a service we regard highly) rather than the DVLA. This inevitably leaves people thinking that their most sensitive data can be treated so carelessly, it is impossible to have the necessary confidence in the operation of the register. We have certainly heard from individuals who are left feeling that it is safer to keep well clear.

Though it was pointed out frequently at the time that families are always consulted before organs are removed, the families involved may have based their consent on erroneous information, which may be the source of extra grief.

Patient Concern's submission to the Organ Donation Taskforce suggested 50 ways of increasing the donor register but many of them involved ticking boxes on other forms, applications etc, which would then have to be transferred. This unfortunate event raises fundamental questions over the reliability of such schemes, unless some effective checking procedure is involved.

One of the assurances given at the time by NHSBT was that no one had been registered as a donor against their wishes. However, we were contacted by a man who had not offered himself as a donor on the DVLA form, yet received a letter from NHSBT thanking him for donating his organs. He informed them of the error, so this assurance seems to have been untrue. Had he wished for publicity, this would have severely undermined public confidence in what we were being told. I have permission to pass on his e-mail address [redacted] – in case you should wish to make further enquiries. He tells me that he has since signed up to the register – his objection was having this happen without his knowledge.

Once the story broke it attracted enormous world-wide attention. We tracked the use of Patient Concern comments across scores of countries. In view of this exposure we felt that the NHSBT response was inadequate. Certainly they gave assurances that they were investigating urgently and that they were contacting the families of those affected. They made no effort to assure us of the steps they would be taking to ensure that this could not happen in the future.

We have the same criticism of their current website, where we feel that the section on the error is not nearly robust enough and centres far more on reassurance than the situation warrants. They state that those who have not heard from them can be confident that their record is accurate and that the rest of the 17 million need take no action. However they are talking about an error that apparently remained undetected for a decade. We cannot be sure that every past transfer or input of data is safe.

The best way to ensure this would be to write to everyone on the register to confirm details. Realistically, we appreciate that this will probably be ruled out on the grounds of cost.

We suggest that in the absence of such desirable blanket coverage, the following steps should be taken:

- ❖ the NHSBT should give assurances that in future they will be writing to every new registrant to confirm their preferences.
- ❖ those already on the register should be urged to ring or e-mail to ensure that correct details have been recorded (the website gives a number for this purpose but gives the strong message is that no one should bother.)
- ❖ instead of simply telling people to ensure that their family is 'aware of your wish to donate' NHSBT should urge every potential donor to tell their family whether they wish to donate all their organs or, if not, which specific organs or tissue they do not wish to donate.

This should be stated boldly on the website and publicised further in hospitals, doctors waiting rooms etc. There may well be objections that this would raise further doubts and suspicions but we believe that, on the contrary, it would send a clear and essential message that action has been taken to prevent such a mess-up in future.

We realise that consideration of a move towards presumed consent is beyond your terms of reference but there is a link here that is of enormous significance. It was worrying that supporters of presumed consent used this serious error as a persuasive reason for changing the system – apparently so that we need no longer concern ourselves with such details as people's preferences over their donated organs.

If we cannot be certain of the accurate reporting of our wishes under a system of direct consent, how can we possibly rely on the safety of an opt-out register in protecting those who are not willing for their organs to be taken?

Our history of organs routinely taken without consent in the UK - i.e. Alder Hey report (100,000 organs) and the Isaacs report (20,000 brains) - means that it would only take a couple of mistakes where someone's objections were overlooked to spark

a media feeding frenzy and a subsequent backlash that could ruin the UK transplant programme. The current hasty push towards presumed consent in Wales, where the Health Minister is ignoring the recommendations of her own health committee's report, brings the possibility of such a debacle worryingly close.

Thank you for giving us the opportunity to comment.

Yours sincerely,

Joyce Robins  
Co-Director, Patient Concern

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21 June 2010

Dear Sir Gordon

### Organ Donor Register independent review

I am writing in response to your letter of 9 June 2010, addressed to Dr Hamish Meldrum. The British Medical Association (BMA) is pleased to have been consulted in relation to the independent review of the processing error that led to the recording of incorrect data on the NHS Organ Donor Register (ODR).

The Association wholeheartedly supports the review process you are undertaking on behalf of the Secretary of State for Health. Having seen your terms of reference, we consider them to be comprehensive. Unfortunately, the BMA does not have any specific information relating to the serious untoward event in question, or any personal experience of the issues relevant to the terms of reference.

It is vital to maintain public confidence in the accuracy of the ODR and, in turn, the wider integrity of the organ donation programme. An understanding of how and why the relevant error occurred is essential to restoring any trust in the system that has been lost. The BMA is therefore happy to support your review in any further way it can, in order to ensure that processing and recording errors of this kind can be avoided in the future.

Yours sincerely  
Vivienne Nathanson

Professor Vivienne Nathanson  
Director of Professional Activities

Chief Executive/Secretary: Tony Bourne

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Mr Keith Rigg, President British Transplantation Society, Renal Transplant Unit, City Hospital Campus, Nottingham  
University Hospitals NHS Trust, Hucknall Road, Nottingham, NG5 1PB

8 July 2010

Sir Gordon Duff  
By email

Dear Sir Gordon

### **Independent Review of ODR SUI**

Thank for inviting the views of the British Transplantation Society on this important topic.

There is no doubt that this was a significant event which had the potential for great harm by weakening public confidence in the Organ Donor Register (ODR) at a time when much good work had been done to increase the profile of Organ Donation and Transplantation.

The Society is not in a position to comment on the reasons as to why this happened and why it took ten years to be discovered and acted upon. We hope that your inquiry will help to clarify the facts, not to apportion blame, but rather to try and prevent a further occurrence.

From the perspective of the British Transplantation Society the error was managed well when released into the public domain - within the transplant community, with the families involved, with the media and the general public. I received emails from the senior management team of ODT at NHSBT which detailed the facts of what had happened, the scale of the problem and what actions were being put in place to deal with the issue. I then forwarded this to the membership of the British Transplantation Society so that they were fully informed. I believe it was testimony to the effectiveness of the process that the BTS received no media enquiries at all, when we would normally be approached about transplant related issues.

It would be helpful to hear about the progress and response NHSBT have had to their strategy to deal with this problem.

There has been an ongoing promotion of, and encouragement to join, the Organ Donor Register. In moving forward it is vitally important that the public and professionals have full confidence in the systems and processes that support the ODR. It is also recognised that the ODR has a different status under the Human Tissue Act, than it had before.

The ODR therefore needs:

- To fully reflect the wishes of those registered
- To be secure so that individuals can only register themselves, whatever portal they use for registration
- To be an online system to enable registrants to check and amend their details

I hope these comments are of help, but please get back to me if you require any further clarification.

With best wishes

Yours sincerely

A handwritten signature in black ink, appearing to read 'Keith Rigg', is written over a horizontal line.

Keith Rigg  
President  
British Transplantation Society





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**Stephen J Wigmore**  
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10/06/2010

Dear Sir Gordon,

Re Organ Donor Register review.

Thankyou for your email and the opportunity to comment on the miscoding incident relating to the ODR, which came to light earlier this year. In this letter I will relate my personal experiences and recommendations which you are welcome to take or leave as you wish.

I became aware of this incident very soon after it became apparent and before the story was leaked to the press through a confidential contact with a colleague. At that point it was believed that a very substantial number of people might have been involved. The story first run on online media and in newspapers was that many tens of if not hundreds of thousands of individuals may have been involved. It was extremely regrettable that the news was leaked before the detail was established because this meant that NHSBT were placed in a position where they had to explain what had occurred without understanding the scale of the problem. It was clearly in the public interest to explain and apologise for this error and had this been done with full information the potential impact on public confidence would have been far smaller. *Recommendation: security and handling of data on the ODR and information regarding this should be restricted or traceable and the responsibility for disclosure in the public interest should lie with the Director of Organ Donation and Transplantation, NHSBT.*

In terms of how the incident was dealt with by NHSBT, I think this was done very well. A number of key stakeholders around the country were contacted by Professor James Neuberger by email and personal telephone call. The email that was sent out

contained a useful briefing paper which detailed the scale of the problem and gave some information about how this was thought to have occurred. This proved very useful given that the media frequently approach individuals directly for comment rather than going through conventional 'channels' of societies or organizations. The information was factual and there was no 'spin' from NHSBT about how media enquiries should be dealt with other than they were keen to stress that no individual had been placed on the ODR against his or her wishes. In my personal view this was an appropriate way to behave.

I was also contacted by Will Scott from the Scottish Government, who also provided more detailed information about the incident and how it related particularly to Scotland.

*Comment: I was personally very grateful for this information as I would have felt very uncomfortable if I had been approached by a journalist without any prior knowledge. I think NHSBT should be congratulated for the rapidity with which they provided information, the honesty with which this was presented and the clear acceptance of responsibility which they demonstrated.*

I accepted an invitation to participate on a live phone in radio show on BBC Radio Scotland to talk about the incident which is the subject of your enquiry. By the time I did this I was in possession of an updated briefing paper prepared by the Scottish Government containing information provided by NHSBT. I was able to explain the small scale of the actual errors and also to explain more about how it might have occurred and this was I believe very useful to the listeners.

- People who called in were concerned that their wishes were not accurately represented particularly if they did not wish to donate and so the earlier reassurance from NHSBT that no individual had been added to the ODR who did not want to donate was particularly helpful.
- A sector of the public expressed their mistrust in doctors and the Alderhey incident was specifically mentioned as an example of why doctors should not be trusted.
- The misconception that if you are a potential organ donor doctors treat you differently was vocalized.
- A number of people could not understand why more people did not want to donate but this is clearly a separate issue.
- Others wanted to know how to join the ODR and complained that access was quite difficult.
- Interestingly I was told by reliable sources that immediately after this incident removals from the ODR were relatively small compared with the increased number of members of the public who joined the ODR.

*Recommendation: Public confidence in doctors is easily damaged and difficult to repair. The public misconception that doctors know about patients' registration on the ODR before death and alter their treatment because of this needs to be put to bed. Every attempt should be made to restore public confidence in the integrity and accuracy of the ODR. Perhaps if clear daylight was placed between the ODR and doctors this might restore some confidence.*

*Suggestions :*

- *Improve public education about organ donation and in particular make clear the process.*
- *Make it clear that the ODR is not accessed by the **transplant team** but by the **donor team** and that this is only done **after** a decision has been made to withdraw treatment because life is not sustainable.*
- *The ODR could be embedded within a clearly demarcated Organ Donation Sector of NHSBT. i.e. separate the component **organ donation** from **transplantation**, this is in the spirit of the Organ Donor Taskforce Report of 2007*
- *Maintain a policy of complete transparency and honesty between the Directorate of Organ Donation and Transplantation and the Public.*

By complete co-incidence I received a letter from NHSBT around 2 weeks ago informing me that my data may have been miscoded and requesting that I check the details that I had registered. My details were actually correct but I found it reassuring that I was being asked to check. Accessibility to the ODR is however an issue and not every household has a computer. This is something that I have alluded to above.

#### *Recommendation*

- *Provide better information on how to access the ODR including a FAQ section covering key issues such as: how do I check my information is correct? How do I change my information? etc*
- *Provide different routes into the ODR. GP practice registrations, dentists advertise through other routes eg schools, retirement clubs etc*
- *Provide evidence of accuracy. Many people liked having a donor card. When someone registers **why not provide them with a card which has printed the information that is stored on the ODR** there could also be a number or mechanism for changing incorrect information. This would provide a system of personal validation of accuracy.*
- *Provide evidence of validation of transfer of information from DVLA or other routes. i.e. a published audit of validation of accuracy of samples of data.*
- *Why does data need to be recoded from for example the DVLA to the ODR? Why can the data not remain 'transferred' untouched from one to the other(I understand the problem was not with DVLA but with NHSBT.)*

#### Conflicts of Interest:

I am Professor of Transplantation Surgery and Professional Lead for Transplantation at the Royal Infirmary of Edinburgh, I am a member of the Scottish Transplantation Ethics Group (Government) and the National Specialty Advisor on Organ Donation and Transplantation to the Chief Medical Officer (Scotland). I was a member of the Clinical implementation Advisory Group to the Organ Donation Taskforce on **The potential impact of an opt out system for organ donation in the UK, DOH 2008**. I am an advocate for organ donation and transplantation and support the concept of the ODR.

I hope you find my comments helpful and would be happy to fill in any gaps if you should require further information.

Yours sincerely

A handwritten signature in black ink, appearing to read 'SJW', with a long horizontal flourish extending to the right.

Stephen J Wigmore