



Review of the Organ Donor Register

*Report to the Secretary of State for Health by
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Executive summary

Organ transplantation is a life-saving procedure for patients with organ failure. Many people wish to save the lives of others by making the altruistic gift of their organs after death. There is, however, a shortage of organ donors, and three patients die on average each day while waiting for an organ transplant.

The organ donor register (ODR) is a computer database enabling people to make their wishes on organ donation known during their lives, potentially also saving their families from having to make decisions at a time of great distress. NHS Blood and Transplant (NHSBT) hold the ODR, and several outside sources, including the Driver and Vehicle Licensing Agency (DVLA), feed into it (there is an option to volunteer for organ donation on the driving licence application form).

Last year a survey of nearly 2000 people showed that 96% would accept a donated organ but only 27% had joined the ODR as potential donors. There is a pressing need to increase awareness of the ODR and the number of people on it. For this to happen, confidence in the system is a prerequisite.

In February 2010, NHSBT identified a systematic error in the recording of organ donation wishes in data received from the DVLA. The error did not affect information from other external sources, or from the DVLA source where donors had recorded willingness to give all organs, but only where DVLA registrants had indicated wishes to donate specific organs.

As soon as the error was confirmed, NHSBT suspended all registrations from the DVLA and set about defining the error, when it occurred, who had potentially been affected and what needed to be done to rectify the position. Subsequent investigation defined a transcription error when information from DVLA was entered onto the NHSBT database.

There are 17,087,646 registrants on the ODR and the error likely occurred in January 1999, potentially affecting 992,424 records, of which the details of 301,578 could not be confirmed without reference to the registrant. NHSBT wrote to each of those individuals. If they have not replied to confirm their donation wishes and subsequently become a potential donor, no reliance will be placed upon their ODR record in any discussions with their family about organ donation.

Twenty-five families were actually affected by the error when consenting to organ donation by a deceased family member. Thankfully, this number is no larger, although even one affected family would be one too many.

With the benefit of hindsight, it would seem that the transcription error might have been avoided altogether, or identified earlier by systematic data verification procedures. However, it is important to remember that the ODR was originally set up to monitor the success of awareness-raising campaigns, and not as an operational tool. In fact, the error came to light when NHSBT altered its procedures after the ODR became used as an operational tool.

NHSBT recognises an inherent systematic risk due to the time it can take to process registrations or withdrawals via a third party. It has stated that no other systematic errors have been identified, and it has rectified the transcription error that occurred with DVLA data. Appropriate actions have been undertaken aimed at ensuring the accuracy of information held on the ODR, now and in the future.

Recommendations

There is a large need for organ transplantation, with patients dying for want of a donated organ. As shown by the 17 million who have put themselves on the ODR, many altruistic people wish to record their intention to be organ donors. Public awareness of this option must be heightened, and a high level of confidence in the ODR is crucial to the ultimate aim of raising the number of life-saving transplants.

The current ODR system was not designed to fulfil the function for which it is now used, and technology for secure, interactive information management has advanced greatly since the ODR was originally set up 16 years ago.

The recommendations below are aimed at restoring and increasing public confidence in the ODR, and ensuring that it can meet broader requirements now and in the future, including a role in the process of informed consent.

Recommendation 1

The longer-term solution for the Organ Donor Register is to create a secure, interactive system designed specifically to handle projected operational requirements in relation to organ donation. With inherent data verification and cross-referencing functions, this would also allow individuals to check and, if necessary, change their own data.

It is recommended that as soon as funding permits, the design and commissioning of a new replacement ODR should be taken forward.

Recommendation 2

In the meantime, NHSBT must operate within the constraints of the existing ODR infrastructure, and the current system must be made robust in terms of the accuracy of information held.

Systematic sampling and checking of data for accuracy against source documents or cross-references should be undertaken routinely, with a frequency and scale determined by statistical modelling. Exercises should be undertaken routinely to challenge the performance of various parts of the system infrastructure.

Recommendation 3

To reduce the future risk of error in transposing data from external feeds onto the ODR, and to reduce the potential for confusion, all external forms on which people are asked to agree to donate either all or specific organs should collect the same data in a uniform way. People signing up via the Boots Advantage Card Scheme will not have been asked if they wish to donate specific organs, and should in future receive a letter from NHSBT inviting them to indicate, in a format consistent with other feeds, either their willingness to donate all organs or only specific organs.

Recommendation 4

NHSBT's current practice of writing to all new registrants giving them an opportunity to report any errors in their recorded details should continue. All reported errors should be investigated. Error rates, broken down by Partner organisation, should be closely monitored and routinely shared with Partner organisations with a view to minimising them.

If the error rate for a particular feed is significantly higher than that of other feeds, consideration should be given to suspending the transfer of data from that feed to the ODR until appropriate corrective measures have been implemented.

Recommendation 5

To provide added assurance to the action plan that NHSBT has developed to improve control and governance, it is recommended that NHSBT invites an external organisation, with experience and expertise in running a large, secure database, to review its proposed new control systems.

Recommendation 6

While it is understood that, since 2004, reference to the ODR has increasingly become the standard practice for establishing the wishes of the donor, it is recommended that in future it should always be consulted as an essential part of the process of establishing consent for organ donation.

In the context of the consent requirements of the Human Tissue Act 2004¹ (and the parallel requirements in the Human Tissue (Scotland) Act 2006²), consideration has been given to the current arrangement whereby people wishing to join the ODR express this by ticking³ various boxes on third party forms, such as the DVLA driving licence application form. It should be noted that NHSBT already plans to review the status of those forms to determine whether they are a valid record of consent. Without wishing to pre-empt that review, the following recommendations are made.

Recommendation 7

Ticking the boxes for organ donation on third party forms should trigger the sending of further information from NHSBT to the individuals concerned, drawing on the excellent Q&A section on NHSBT's website. This would give essential information about what it means to be an organ donor and it would provide the answers to frequently asked questions. Crucially it should also give people clear advice on what to do if they want to check their own record held on the ODR and, if necessary, change the wishes they have previously expressed. To avoid extra cost, this additional information could form part of the "thank you pack" already sent to new registrants.

¹ The Human Tissue Act 2004, Chapter 30

² The Human Tissue (Scotland) Act 2006, asp 4

³ The use of the word 'tick' should be interpreted to include a cross or other mark used to indicate a willingness to donate

It has been suggested that after receiving further information, individuals should be asked to re-affirm their wish to donate. Clearly, the value of the tick box system is the ease and convenience with which people can express their willingness to donate their organs. Provided that individuals are then given adequate, understandable information as well as the opportunity and means to change their earlier decisions, there seems to be no strong case for a further re-affirmation stage in the process, and the possibility of creating confusion by introducing one.

Recommendation 8

When people register on the ODR, they should be encouraged to tell their families of their wishes to become organ donors, and whether they would like to donate all organs or just specific organs. This could be done in the information pack sent to them from NHSBT after they join the ODR. It may also help stimulate consent rates in families in communities with a high level of need.

Recommendation 9

Close attention should be paid to the language used in describing the effect of ticking and not ticking the boxes in relation to specific organs. Most people will correctly assume that the effect of ticking a box against the name of a specific organ is to indicate their consent to the donation of that organ. But, in the absence of some explanation, they may be less clear about the implications of not ticking a box against the name of a particular organ. NHSBT interpret the absence of a tick as the individual's preference not to donate that organ at the time of registering. A decision not to consent to the donation of an organ has legal force under the Human Tissue Act 2004, and it is therefore important that there is no misunderstanding about the wishes of an individual whose intention when deciding not to tick a box was to indicate their decision not to consent to the donation of that organ. The use of the word "preference" in this context may not be ideal.

Foreword

This Review was prompted by the discovery that a number of registrations on the Organ Donor Register (ODR) were inaccurate, and by the decision of the then Secretary of State for Health (the Rt Hon Andy Burnham MP) that the cause of these inaccuracies must be investigated independently and measures identified to prevent a recurrence.

The ODR is a rare thing – a public sector database about which most people feel positively. It has entered into the consciousness of the public, and is associated in many minds with saving lives. Through the ODR, millions of people have willingly signed up to become organ or tissue donors in the event of their death so that other people, whom they have never met, will be able to benefit from one of the great advances of modern medicine, organ and tissue transplantation.

In the year to 31 March 2010 the lives of 3,706 patients in the UK were saved or transformed by organ transplants through the generosity of 1985 donors (of which 959 were deceased donors). A further 3,061 people had their sight restored through a cornea transplant. However, at the end of March 2010, nearly 8,000 people were on the waiting list for a transplant. Each year more than 1000 – 3 every day on average - die before an organ becomes available. Organ donation by people from Asian or African Caribbean backgrounds is low despite a disproportionately high level of need in patients from these communities.

The importance of letting those close to us know how we feel about organ donation cannot be overstated. It is important to be as explicit about our wishes as possible. If we are happy to donate all of our organs we should make this clear. If we are happy to leave some but not others, we must again be explicit and not leave our families to try to work out what we would have wanted. They will have more than enough to worry about at that most difficult of times. We know that at the end of a loved one's life, families are so much more likely to agree that the organs may be used for transplantation when they know that this is what their partner, parent, child, brother, sister wanted. The figures are striking. Permission is given in 90% of cases where someone is registered on the ODR. This contrasts with a general consent rate of only 60%.

However, these figures also demonstrate how important it is that the ODR reflects accurately the wishes of registrants and can command their confidence. This has been at the forefront of my mind while carrying out the present Review. In the time available I have necessarily confined this Review of the ODR to those areas that I perceive to be of greatest risk. I have had the full cooperation of NHSBT staff, all of whom have been most helpful in answering questions and providing information. I am also very grateful to those who wrote to me with their views, and to those who gave their time for discussions by telephone and in person.

Terms of reference

To report to the Secretary of State for Health on the mis-recording of peoples' wishes when joining the NHS Organ Donor Register.

The review will consider:

- how, when and why the error occurred and whether it could reasonably have been prevented
- how it took ten years for the error to be discovered
- how it came to light, and how it was handled once it had been identified, including communication with donor families and those on the Register
- how to ensure it has been rectified and does not happen again
- recommendations to ensure the Register reflects the wishes of those registered and that confidence in the system is maintained.

The report will be published and shared with the Devolved Administrations.

Method of working

I have conducted this Review by dividing the Terms of Reference into three key elements:

- the specific events that led to the inaccurate records, and the facts associated with how it occurred, why it took so long for it to be uncovered and the actions taken to avoid a recurrence
- the handling of the matter once it came to light, and in particular the communications with affected families and other stakeholders
- how to ensure that the ODR reflects accurately the wishes of those registered and that public confidence is maintained. This includes maintaining confidence in the future as the operational use of the ODR evolves.

For the first element, I have established the facts by asking detailed questions of NHSBT both in correspondence and in face-to-face meetings with the Chief Executive and key employees. It is a measure of the seriousness with which the senior management of NHSBT took this error that their own internal investigations, which I considered carefully, were painstaking and thorough.

For the second and third element, I wrote to and invited comment from the following groups:

- NHSBT's own stakeholders (names at Annex A)
- the families for whom the decision to donate a particular organ was likely to have been influenced by the incorrect information (for data protection reasons, the letters were addressed and posted on my behalf by NHSBT and for these reasons names are not listed in this report)
- a small sample of those who had replied to a letter from NHSBT to 300,000 DVLA registrants asking for confirmation of their donation wishes (for data protection reasons these letters too were addressed and posted on my behalf by NHSBT).

For the third element I had discussions with individuals whose background and experience would offer me valuable perspectives (names at Annex B).

1. Organ Donor Register: Historical background

1.1 The Organ Donor Register (ODR) is maintained by NHS Blood and Transplant (NHSBT), a Special Health Authority with responsibility for optimising the supply of blood, organs, plasma products and tissues and raising the quality, effectiveness and efficiency of blood and transplant services. NHSBT was set up in October 2005 bringing together UK Transplant (UKT), the National Blood Service and the Bio-Products Laboratory. It inherited responsibility for the ODR from UKT.

1.2 UKT's primary focus was the smooth running of the organ allocation system and the allocation of organs to recipients in a fair and transparent manner. It set up the ODR in 1994 not as an operational tool to be used in establishing whether a particular patient had agreed to be an organ donor, but as a tool for measuring the effectiveness of awareness-raising campaigns to encourage people to donate their organs. It was resourced accordingly.

1.3 Decisions on whether to proceed with organ donation in a particular case took place in the context of a discussion with the family about whether the deceased had expressed a view about organ donation and, if not, whether the family felt able to agree. In some cases these decisions were informed by knowledge within the family that the deceased had joined the ODR or by the evidence of a donor card. The legislative framework governing organ donation at the time was the Human Tissue Act 1961⁴ which provided that in the absence of a "request" from the potential donor expressed during their lifetime, donation could go ahead if "having made such reasonable enquiry as may be practicable", there was no reason to believe that the deceased, or the surviving spouse or other relative, objected.

1.4 The first records were from Donor Registration Forms received by UKT and keyed in by MPL (Manual Processing Limited), a company contracted to UKT. New names were added to the ODR through partnerships with organisations with which the public had contact. The first of these new "feeds" were from the Driver and Vehicle Licensing Agency (DVLA), and registrations collected in the surgeries of general practitioners. Over the years more "feed" organisations entered into partnership with UKT including Boots UK Ltd who invited their customers to join the ODR through the Boots Advantage Card scheme. Currently the ODR contains the donation wishes of over 17 million people across the UK. Through most of the feed organisations registrants can opt to donate "all organs" or they may express a wish to donate specific organs or tissues: kidneys, liver, pancreas, heart, lungs and corneas.

1.5 The Human Tissue Act 2004, which came fully into force in September 2006, changed the legal basis for organ donation. It requires "appropriate consent" (or "authorisation" under the Human Tissue (Scotland) Act 2006). In England, Wales and Northern Ireland, this consent (or decision to refuse consent) may be given by the deceased during their lifetime, or, if they

⁴ Section 1(2) Human Tissue Act 1961, Chapter 54

did not give or refuse consent, after their death by someone they have nominated for this purpose or by someone who stands in a “qualifying relationship” to the deceased. Those in a qualifying relationship are a hierarchy of individuals with a close, mainly familial, connection with the deceased, starting with spouse or partner and ending with “friend of long standing”.

1.6 The Act, and in particular the provision that people may record their wish to consent to organ donation in life, provided the impetus for UKT to change the role of the ODR. It increasingly took on an operational role. From 2004 UKT made available a service to hospital staff through which they could check a potential donor’s donation wishes with its central Duty Office in Bristol. This service was not initially used consistently but the check became, and remains, a routine step taken by the Specialist Nurse – Organ Donation (SN-OD) before discussions take place with the potential donor’s family.

1.7 In the past few years the focus of interest in the ODR has been on increasing the numbers of registrants. In January 2008 the Organ Donation Taskforce published its first report⁵ with recommendations about how the number of organ donors could be increased within the existing legislative framework. The Taskforce recommended, among a range of other measures, a UK-wide campaign to encourage people to join the ODR. In November 2008 the Taskforce published its second report⁶ examining the implications of moving to an organ donation system based on “opt-out” or presumed consent. In accepting the Taskforce’s recommendation against moving to an opt-out system, the Government set a target of achieving 25 million registrations by 2013. At that time there were 16 million registrants.

⁵ Organs for Transplant: A report from the Organ Donation Taskforce, *January 2008*

⁶ The potential impact of an opt out system for organ donation in the UK: An independent report from the Organ Donation Taskforce, *November 2008*

2. How, when and why the error occurred and whether it could reasonably have been prevented

How, when and why

2.1 I will explain in subsequent chapters how the error came to light and why it took so long to identify it. I will also express my view on whether it was preventable. However I think it is important first to explain the nature of the error and how, when and why it occurred.

2.2 The error occurred in 1999. At that time there were four active Partner feeds to the ODR:

- MPL (Manual Processing Limited) contracted to key in data from Donor Registration Forms received by NHSBT (then UKT). This service is now provided by Advanced Data Services
- registrations collected in GP surgeries and fed to UKT by the Family Health Services Authority
- registrations collected in GP surgeries and fed to UKT by the Scottish Family Health Services Authority
- the Driver and Vehicle Licensing Agency (DVLA).

2.3 None of the feed organisations passes data directly to the ODR. Since 1994 each Partner has made a file available (for collection by electronic retrieval from a secure computer server) or sends a file electronically by email to the Organ Donation and Transplantation arm of NHSBT. Each file contains records of registrant data. Within each record, along with Name, Address, Date of Birth etc, single character fields represent the wishes expressed by registrants to donate some or all of their organs. For example, a cross on a form against ‘Liver’ is converted into a character ‘2’ for ‘yes’ at the point of entry into a computer. This is a standard practice as the computer uses up less space to store a single character than it would to store the word ‘Liver’.

2.4 The organ preference fields all start off with a default character ‘1’ which means ‘No cross present’. A cross in the ‘Donate all’ box is valid only if no crosses have been entered subsequently against individual organs. A cross against an individual organ would over-rule a cross in the ‘Donate all’ box, and so a ‘2’ character meaning ‘yes’ would be recorded against the preferred organ(s) for donation and a ‘1’ or ‘no’ is recorded in the ‘Donate all’ position.

2.5 In the case of the DVLA feed, people completing a driving licence application form were (and still are) invited to complete a section headed “Organ Donation”.

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A person filling out a driving licence application form would see:

Figure 1.

Application for a driving licence
If you are applying for a car or bus licence, you need to fill in a D1 application form.
Please read booklet INF1D before filling in this form.
Do it online at www.direct.gov.uk/drivinglicence

1 What are you applying for?
Please put against all that apply:
 A full provisional (learner) licence (full or a view in passing a test)
 To drive a car or van because I have a physical disability
 Using alternative mobility equipment at the higher rate
 To change my name on my licence
 To change my address on my licence
 To replace my licence as it has been lost stolen defaced destroyed
 To exchange my paper licence for a photocard licence
 To renew my licence at age 70 or over
 To renew the photo on my licence
 To renew my licence
For medical reasons
Because it was recalled or was disqualified
If you were disqualified in the UK please give (if you know it) the date: DD/MM/YY
and the name of the court:
To change my licence
After passing a test
Enter categories passed here
To renew expired endorsement details
To add provisional motorcycle entitlement
To renew expired 12MTH motorcycle restriction
• To exchange my Northern Ireland licence
• To exchange my non-UK licence for a British one
If you are changing your country of residence, tell us the issuing country, which country did you pass it in?
If you passed your test in Canada, see booklet INF1D.
If your licence has been withdrawn, suspended or cancelled by another country e.g. because of disqualification, please state which country

2 Your details
Your GB driver number if you know it:
Title: Mr Mrs Miss Ms Other: _____
Surname: _____
First names: _____
Date of birth: DD/MM/YY
Full current address:
House No.: _____
Postcode: _____
If any of the details above have changed since your last licence was issued please give the previous details below:
Previous address: _____
Photo: _____
Photo Auth: _____
Regd Add ID: _____
Regd Soc Reg: _____
DAM Add: _____
S-Doc: _____
Non-Pres: _____
Amount: _____
Lic End: _____
Lic Issue No: _____

3 Your eyesight
Please see page A over the page.
Can you read a car number plate with places or corners blurred? (Passing) Yes No
Do you wear glasses or contact lenses? Yes No
Organ donation
I want to register my details on the NHS Organ Donor Register as someone whose organs/tissue may be used for transplantation after my death. Please put in the boxes that apply.
Any of my organs and tissue or
Kidneys Corneas Heart Lungs Liver Pancreas
An executive agency of the Department for Transport
b1-1109

Organ donation
I want to register my details on the NHS Organ Donor Register as someone whose organs/tissue may be used for transplantation after my death. Please put in the boxes that apply.
Any of my organs and tissue or
Kidneys Corneas Heart Lungs Liver Pancreas
An executive agency of the Department for Transport
b1-1109

2.6 The data provided by the person who filled out a form would be keyed into the DVLA systems through a number of screens. The screen for the donor preference data where the donor has agreed to donate all their organs looks like this:

Figure 2.

DLC9999A DRIVER LICENSING SYSTEM 11.06.10
DUPLICATE LICENCE TRANSACTION ORGAN DONOR SCREEN

Organ	Donated
All Parts	Y
Kidneys	N
Cornea	N
Heart	N
Lungs	N
Liver	N
Pancreas	N
Withdrawal of Consent	N

Enter to Accept Data
PF3 to Quit

Command => DUP Key => *.....

440 08.046

2.7 Once data has been keyed into the DVLA computer it is formatted into a record that has a prescribed layout. In the case of the DVLA, a record for someone who has agreed to donate some of their organs looks like this⁷:

SMITH401668SA2PR 101 STONEHILL GROVE ALCESTER	SMITH ST JOHNS PQ2 5PT 1965071812122211	STANLEY ALAN
---	---	--------------

2.8 The Driver Number, Surname, Forenames, Address, Postcode and Date of Birth (yyyymmdd) are fairly easy to pick out. The key part is the coding of the yes/no wishes (highlighted in the box below).

SMITH401668SA2 PR 101 STONEHILL GROVE ALCESTER	SMITH ST JOHNS PQ2 5PT 19650718	STANLEY ALAN
	1212221 1	

In this fictional case, the registrant has made specific organ choices as below.

Table 1. The highlighted characters show:

Donate all organs	1	No	I do not wish to donate all organs
Kidney	2	Yes	I wish to donate my kidneys
Cornea	1	No	I do not wish to donate my corneas
Heart	2	Yes	I wish to donate my heart
Lungs	2	Yes	I wish to donate my lungs
Liver	2	Yes	I wish to donate my liver
Pancreas	1	No	I do not wish to donate my pancreas

(The final character in the record layout - a '1', indicates the record type. 1 is a new registration record, a 2 means an update to an existing record, and 3 is a request to withdraw from the ODR).

2.9 The order or sequence of tick boxes on a form or screen need not bear any relation to the order of fields in the computer record. Provided the computer processing a record has the instructions (the programme), it will know where in each record specific information resides.

⁷ Fictional data – not a real person or address.

2.10 Between 1994 and 1999, the order of the single character fields representing the organ preferences in the four Partner feeds was:

Table 2. Organ preferences position in the files uploaded to the ODR

File from MPL	File from FHSA	File from SFHSA	File from DVLA
Donate all	Donate all	Donate all	Donate all
Kidney	Kidney	Kidney	Kidney
Heart	Heart	Heart	Cornea
Liver	Liver	Liver	Heart
Cornea	Cornea	Cornea	Lungs
Lungs	Lungs	Lungs	Liver
Pancreas	Pancreas	Pancreas	Pancreas

2.11 As long as the computer was programmed to interpret the DVLA file differently from the other files no errors occurred. In 1999 when the ODR system was moved to the new computer infrastructure and some re-programming became necessary, the DVLA file was assumed to have the same layout as the other feed files. In other words, the significant position of the 1s and 2s was assumed to be the same across all four record layouts. This meant that the wishes of donors from the DVLA feed were transposed as follows:

Table 3. Transposition between the DVLA record and the ODR (1999)

DVLA Consent to donate	Recorded on ODR
All organs	All organs
Kidney	Kidney
Cornea	Heart
Heart	Liver
Lungs	Cornea
Liver	Lungs
Pancreas	Pancreas

2.12 Therefore, where someone had consented to the categories of “All”, or “Kidney”, or “Pancreas” the records matched, but for all other preferences they did not. For example, someone who had been willing to donate a liver through the DVLA would have that decision recorded on the ODR as a willingness to donate lungs.

2.13 The error took on special significance whenever the Specialist Nurse – Organ Donation had a discussion with the donor’s family based on incorrect information on what the donor had indicated.

2.14 It is perhaps fortunate that as many as 87% of people registering via the DVLA provide consent for the donation of ‘All’, ‘Kidney’ and / or ‘Pancreas’. However, around 13% of registrations sourced via the DVLA were affected by the error.

Whether the error could reasonably have been prevented

2.15 It is clear that the move to the new computer infrastructure occurred at a time when documentation and software change management and version control was weak. Had adequate governance arrangements for the introduction of the new computer system been in place at that time, and systematic checks carried out, the error might have been detected quickly. The data feed tests that were carried out routinely at that time were limited to the data held by UKT (now part of NHSBT) and were not extended to compare data on the ODR with source data.

2.16 However, it is important to record that decisions and actions at that time were taken within an organisation that was very different in size and nature to NHSBT. UKT was a relatively small organisation and lacked the infrastructure needed to provide an adequate level of quality assurance for a database which, at that stage, was not used as part of the process of establishing consent for organ donation.

2.17 During the period from 2002 to 2007 a number of improvements were introduced to provide a greater degree of control over changes. With the benefit of hindsight, there was perhaps an opportunity in 2004, when the role of the ODR changed to a functional tool in the organ donation process, to establish a rigorous and continuing programme of testing for all aspects of the system.

3. How it took 10 years for the error to be discovered

3.1 To understand why such a serious error could have lain undetected for so long it is necessary to consider the history of the ODR. For many years the ODR was not consulted as part of the process of establishing consent for organ transplantation. As I have explained in Chapter 1, organ donation went ahead or not on the basis of a discussion with the donor family, informed by their knowledge of whether or not the potential donor had joined the ODR or carried a donor card.

3.2 Until consultation with the ODR started to become more routine it appears not to have been seen as a business critical system and consequently it seems that resources and scrutiny were concentrated on other priorities. Therefore when, in 1999, the ODR was moved to the new computer platform there was a lack of systematic data checks and end-to-end testing to confirm that registrants' wishes expressed to third party Partners were accurately transposed to the ODR.

3.3 Although some improvements in control systems were introduced in the subsequent years, systematic data checks that might have uncovered a transposition error do not seem to have been undertaken. Consultation with the ODR as a normal part of the process of organ donation became increasingly routine from 2004.

3.4 Until April 2006, when NHSBT began to write to new online and telephone registrants, there was no process in place to invite registrants to confirm their registration details. It was the extension of this contact with registrants in November 2009 that led to the uncovering of the error. Had this been introduced earlier it is logical to conclude that the error would have been uncovered earlier.

3.5 It is also more likely that the error would have been uncovered earlier if the Specialist Nurses – Organ Donation (previously known as Donor Transplant Coordinators) had been in the employ of one organisation. Until 2009 they were employed by individual hospitals as members of their transplant teams. This made it more difficult to identify any trend in potential inaccuracies of recorded donation wishes emerging from discussions with families.

4. How the error came to light, and how it was handled once it had been identified, including communication with donor families and those on the register

How it came to light

4.1 The error came to light after NHSBT introduced a new policy in November 2009 of sending new registrants who had joined the ODR through a third party (including the DVLA) a welcome pack setting out their organ donation wishes. This new policy was introduced as part of NHSBT's campaign to encourage more people to join the ODR. It extended a process started in April 2006 when NHSBT began writing to thank new registrants who had joined online or by telephone. From December 2009 an increasing number of people contacted NHSBT to report mistakes in their registration record. These comprised a range of errors, including names and addresses, confusion over their initial registration and the incorrect recording of their organ donation wishes.

4.2 NHSBT investigated each of these reports, correcting incorrect data and consulting Partners where registration was via a third party, to ascertain the wishes expressed on the individual's paper form, for example their driving licence application form. By the end of February 2010 – substantially more people had by then received the welcome pack from NHSBT - a picture was beginning to emerge that suggested a systematic error with the details of some organ donor wishes, but only those from the DVLA feed. The possibility of a mismatch between output and input was then suggested. Further detailed investigations continued throughout March 2010. These included the transfer of test files between NHSBT and the DVLA, and daily teleconferences to review and discuss the information emerging from the investigations being carried out by both organisations.

4.3 The investigating team was able to identify that the problem had arisen prior to 2000 because the original DVLA documents were still available to enable donor's wishes to be verified. The team therefore sought to establish, with a high degree of confidence, the exact point before 2000 when the critical error occurred.

4.4 NHSBT's Statistical and Clinical Audit Department team undertook a careful analysis of the donation wishes of people registering via the DVLA since 1994. By comparing those records with those on the entire ODR, the team was able to demonstrate, with a high level of confidence, that the error occurred on, or shortly after, 1 January 1999. Further enquiries

revealed that a software error had been introduced at that same time, and that errors had been made in the programme that processed data from the DVLA for inclusion in the ODR.

4.5 On 12 March 2010, when the cause of the problem was clear, NHSBT suspended the uploading of data from the DVLA to the ODR. As a precautionary measure, use of the Register for the purpose of informing discussions with families was also suspended if the donor record had been received from the DVLA.

4.6 Establishing the source and timing of the problem enabled NHSBT to group registrations by type and test whether they had been affected.

Groups included, for example:

- Sole registration via DVLA from 1999 unamended by any subsequent registration⁸
- Initial registration via DVLA from 1999, subsequent registration from another source
- Initial registration not via DVLA before 1999
- current registration not via DVLA but interim registration/amendment via DVLA

4.7 The groups were identified, the assumptions about the consequences of the incident on each group clarified and then thoroughly tested using DVLA source data and archive files where available. This enabled NHSBT to establish how many records were correct and how many were potentially affected by the problem as follows:

'Live' ODR records on the register	17,087,646
Correct records	16,095,222
Records ring-fenced as potentially incorrect	992,424
Records capable of correction without reference to the registrant (and corrected on 20 & 22 April)	491,829
Remaining records ring-fenced as potentially incorrect	500,595
Records confirmed correct, or removed from register	199,017
Records where the status could not be confirmed without reference to the registrant (added to mailing list)	301,578

⁸ Registrants to the ODR can register a number of times. Any new registration supersedes a previous registration.

4.8 Considering only those records that NHSBT was able to correct and those where NHSBT needed to write to the registrant, the position by nation was:

Country	Automatically Corrected Records	Records Added to Mailing List
England	421,599	261,954
Scotland	46,483	25,524
Wales	23,654	13,724
N Ireland	1	311
Missing or N/A	92	65
TOTAL	491,829	301,578

4.9 NHSBT also checked each group of records to determine whether any of the registrants had become organ donors. A group of organ donors was identified for whom NHSBT requested the donation record in order to determine whether the register had been referred to during the donation consent process (the ODR was not a standard part of the process prior to 2005). For each record reviewed, a judgement was made by pairs of Specialist Nurses – Organ Donation as to whether the register was: used; likely to have been used; unlikely to have been used; or not used. These judgements were recorded with the supporting evidence and these assessments further reviewed by the Associate Medical Director (ODT). As a result, NHSBT determined that in 25 cases the outcome of the donation appeared to have been influenced by the incorrect record on the register, and it was necessary to inform the donor families of the situation. This seems a reasonable approach in the circumstances, given the history of the ODR, but see recommendation 6 that reference should always be made to the ODR.

How it was handled once it had been identified, including communications with donor families and those on the Register

4.10 Once it was clear to NHSBT that the error was at its side of the data transfer process and the matter had been reported to senior managers, a Serious Untoward Incident (SUI) team was established on 10 March 2010. The SUI team – which was led by the Director of Organ Donation and Transplantation – worked to:

- establish the facts
- put in place interim arrangements for the operation of the ODR to prevent any new donation decisions being made which relied on potentially inaccurate information
- identify and implement remedial action

- support affected donor families
- contact registrants whose preferences were unclear and establish call centre support
- confirm the legal position with respect to consent and data protection
- implement a communications plan for the affected families, registrants, the media, Partners, stakeholders and staff
- manage consistent reporting to the Department of Health, Devolved Administrations and the NHSBT Board
- project manage the incident.

Communication with donor families

4.11 As explained above, the SUI team was able to determine that inaccurately recorded wishes were referred to in discussion with the families of 25 donors.

4.12 The SUI team's priority was to ensure that the families of these donors should be the first people outside of NHSBT and a small group in central government and the DVLA to know about the error. Dates were set for initiating contact with the families and a provisional date was identified for a press release.

4.13 In the event, it was not possible for NHSBT to achieve its aim of communicating with the affected families first. The media became aware of the error and it became the subject of high profile media interest from Saturday 10 April 2010. It is not within my terms of reference to investigate how the media became aware of the problem, but in carrying out this review I have heard nothing to suggest that NHSBT was itself the source of information being made available to the media before the affected families had been contacted. Whatever the explanation of the early disclosure might be, it thwarted NHSBT's admirable aim of communicating with families first and forced NHSBT to bring forward its plans which were implemented from Monday 12 April. Communication with affected families comprised:

- an initial letter alerting the family to a possible error with their relative's donation (Annex C). This letter also gave the number of a telephone helpline and explained that NHSBT would try to make contact by telephone if it did not hear from the family
- a telephone conversation to explain the error, to apologise and to offer further support, including independent counselling
- a second letter, from the Chief Executive, Lynda Hamlyn, to provide a written account of the incident, a personal apology and her contact details if the family wished to discuss matters further (Annex D).

4.14 Of the 25 families whose relatives' donation had been influenced by the erroneous data, one had not provided any contact details at the time of the donation. NHSBT therefore had no way of tracing this family.

Of the remaining 24 families:

- NHSBT spoke to relatives in 17 families in total, the majority of these within one week of the original letter. Of the 17 families, 15 were supportive and remained positive about their relative's donation, and two were distressed. Of the two, one family did not want further contact. The other family indicated that they might wish to have a face-to-face meeting with a senior Specialist Nurse or the Chief Executive, but did not respond to further requests by NHSBT to arrange this. One family that was initially positive subsequently wrote to NHSBT to claim compensation for distress.
- NHSBT was unable to speak to seven families. Six families did not respond and NHSBT has reported that all efforts to trace them have been exhausted. One family member refused to accept the letter when it was delivered.

Communication with those on the ODR

4.15 Following detailed investigations and the automated correction of 491,829 affected registrations, there were 301,578 organ donor registrants whose preferences could not be confirmed. Having checked with the NHS tracing service that each of these individuals was still living and verifying their current address, letters were sent to all of them asking them to confirm their registration wishes. The following methods have been available to registrants to confirm or correct their details:

- telephone the NHSBT National Call Centre. The call centre increased its staffing to handle the expected volume of calls and a new software application was developed which allowed call centre staff to access the Organ Donor Register details and amend them in real time – this was a positive new development which is being maintained
- email to a dedicated email address
- letter to a freepost address.

4.16 Letters to all those whose wishes needed to be checked were issued by the end of May. The records of any affected registrants who did not respond to NHSBT's letter will continue to be flagged to ensure that, in the event of their potential organ donation, the record is not relied upon in discussion with their family.

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4.17 The table below shows the number and source of responses from registrants to 28th June 2010

DATE OF MAILING	23/04/2010	05/05/2010	10/05/2010	12/05/2010	17/05/2010	19/05/2010	24/05/2010	26/05/2010
No of records mailed	19,996	49,995	49,999	50,000	50,000	25,141	22,556	32,115
No of records not mailed due to incomplete/invalid address	2	5	1	0	0	1	0	75
No of responses to mailing	3,217 (16.1%)	7,821 (15.6%)	7,727 (15.5%)	7,317 (14.6%)	7,478 (15.0%)	3,623 (14.4%)	3,364 (14.9%)	3,380 (10.5%)
No of records confirmed	1,200 (37%)	3,117 (40%)	1,914 (25%)	2,261 (31%)	2,323 (31%)	1,077 (30%)	1,026 (31%)	968 (29%)
No of records corrected/updated	1,546 (48%)	3,981 (51%)	4,987 (65%)	4,370 (60%)	4,362 (58%)	2,125 (59%)	2,091 (62%)	2,026 (60%)
No of records withdrawn/died	235/2 (7%)	594/5 (8%)	733/5 (9%)	564/3 (8%)	572/6 (8%)	301/2 (8%)	189/3 (6%)	297/20 (9%)
No of responses still to be categorised	234 (8%)	124 (1%)	88 (1%)	119 (1%)	213 (3%)	118 (3%)	55 (1%)	69 (2%)

Note: The 'No of records not mailed due to incomplete/invalid address' row under the 23rd April column heading shows a figure of 2. The mailing went to 20,000 addresses. The missing 2 mailings are accounted for as follows: one letter was included in another's envelope – a 'double envelope' error. One recipient asked to be mailed again so was subsequently removed from the count. In both cases letters were sent in subsequent mailings.

5. How to ensure the problem has been rectified and does not happen again

How the error has been rectified

5.1 The faulty data conversion script used by NHSBT to upload the data has been rewritten. The DVLA prepared test records covering all the possible combinations of organ donor wishes and NHSBT has bedded in new test procedures that include steps to compare the source record of the donor's wishes with those recorded on the ODR.

5.2 System Query Language programmes were drafted, tested and validated on test files for the task of correcting data where this was possible without the need to consult registrants. This testing was formally approved and the correction was applied in four stages.

5.3 For registrants to whom NHSBT wrote in order to confirm their donation wishes, NHSBT's National Call Centre was equipped with a new and fully tested software application so that changes indicated by registrants can be applied during the telephone conversation.

How to ensure it does not happen again

5.4 In addition to the immediate "handling" action, NHSBT undertook a Root Cause Analysis on 14 May 2010. A further workshop was held on 24 May to review the lessons that had been learned about what went wrong, and to identify what action could be taken to ensure that a similar error did not occur in future. This was the start of a process that led to the identification of the following actions designed to prevent such an error happening again:

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Immediate actions/Action	Progress at July 2010	Target completion / next steps
Identify operational "Owners" for each critical system in use at ODT (including the ODR). Owners are to be formally responsible for the management, correct operation and performance monitoring of the system and for authorising changes. Roles and responsibilities to be clearly documented in formal, approved policies and procedures	Established a steering group to address issues in relation to the ODR which will include identifying operational ownership and clearly defining and documenting roles and responsibilities.	October 2010
Put in place procedures for a periodic technical and business-led monitoring process, so that data is checked and verified every few months (timings have yet to be determined). This will include random sampling of ODR records and comparing them with Partners' original data to confirm all data matches.	Interim procedures have been signed off and implemented.	By end of December 2010
Establish new processes for feed management and ensure our Partners understand and agree to our new test procedures and our 'data supply maintenance process'	A suite of processes and supporting documentation has been drafted for review by the steering group.	September 2010
Establish new Partner Agreements between NHSBT and data supply Partners to serve as a 'baseline' from which any change becomes subject to the data supply maintenance process and change control processes.	A new feed management documentation pack has been issued to Data Services. This includes processes for bringing new feeds on-line, maintaining feeds at the Partner end, change control activities within ODT and periodic feed integrity monitoring,	Next steps: Revisit all Partner Feeds and supplant all existing documentation with this new pack by the end of the year.
Introduce an updated Change Control Process to ensure that Partners are advised of any procedural, technical or personnel changes within NHSBT with the potential to affect the data feeds.	A suite of processes and supporting documentation has been drafted for review by the steering group.	Embed the processes into Data Services Standard Operating Procedures by end of December 2010.
Bed in new test procedures which now include steps to compare the donor's original source stated preferences with those recorded on the ODR.	New test procedures are in force within ODT IT.	Complete
Implement a comprehensive audit trail of data load and subsequent modification including who, when, by what means, and why is being developed and this will greatly facilitate any future data management investigations.	The audit trail for data load and modification is implemented. We can investigate, and if necessary reverse, any changes made to the Database since June 2010.	Extend this audit trail (subject to business requirements) to capture the reason for changes and the change originator. Target is end of 2010.

Longer term actions/further recommendations from Root Cause Analysis (RCA)

Action	Progress at July 2010	Target completion / next steps
Review the end-to-end management of all the processes associated with the maintenance of an accurate, complete and secure record of the donation preferences for people wishing to donate organs. Include the sources of registration, the communication with registrants, the maintenance of the register itself and all the supporting processes. The review will identify areas of weaknesses together with recommendations for improvements.	Have established a steering group to take this forward. Will complete for the existing ODR by end of Q4. Statement of Work for scoping future operating model has been drafted.	End of December 2010 for existing ODR and definition of future operating model.
Review all IT systems in use in ODT (NHSBT's Organ Donation and Transplantation directorate) and consider their criticality based on quality, compliance and clinical care criteria.	Planned to commence by September 2010 – scope and end date to be confirmed.	To be confirmed
Define and document the policy and procedures for the management of critical IT systems. Include full development life-cycle management, independent Quality Assurance validation, procurement and out-sourcing, change control and specification.	In progress	Q1 2011.
Review internal expertise and resources for IT system development life-cycle management to effectively implement the policies and procedures for the management of critical IT systems and to have oversight of internal software development, testing and validation.	Revised internal IT structure is now in place with separate teams to support the development and maintenance of key systems such as the ODR and organ allocation schemes.	Q2 2011
Implement formal change control as part of an ODT quality management and governance of system development, to ensure that the impact and risks of all changes affecting operations are assessed and changes in practice managed in order to mitigate the risks identified.	Formal change control has been implemented. A full risk assessment is being carried out with mitigating actions identified for all file types for the ODR prior to reinstating any of the feeds. A risk based approach will be adopted for changes to all systems as part of the change management system.	Q2 2011
Review the status of the third-party forms and decide whether they are an appropriate record of	Will be picked up as part the steering group plan.	Q1 2011

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consent under the Human Tissue and Human Tissue (Scotland) Acts. If so, consider where the responsibility lies for obtaining that consent and clearly state this in formal agreements with Partners. Include the need to see copies of forms and changes to the forms before they are implemented and to input into their design including guidance on completion.		
Ensure that a formal Quality Management System is implemented to assure the effective adoption of the RCA recommendations and compliance with the EU Organ Directive due to be implemented by July 2012.	Resource identified from 1 August 2010 to commence implementation of QM system	TBC
Examine options for implementing periodic customer experience sampling across the web, call centre and Partner channels.	Steering group will develop proposals as part of stage 3 plan.	Q2 2011
Examine options for implementing SUI simulations ('fire drills') across ODT's critical systems.	No progress	A feasibility and options paper will be produced Q2 2011

6. Conclusions

6.1 Parts of the terms of reference require a simple report of the facts. I have delivered factual accounts on the following:

- how, when and why the error occurred (Chapter 2)
- how it took 10 years for the error to be uncovered (Chapter 3)
- how the error came to light, and how it was handled once it had been identified, including communication with donor families and those on the ODR (Chapter 4)
- action taken by NHSBT to rectify the error and prevent a recurrence (Chapter 5).

6.2 It is implicit in parts of the terms of reference that as well as reporting on the facts, comment should be made where appropriate on the adequacy and quality of NHSBT's actions. I have already expressed my view in Chapter 2 on whether the error could reasonably have been prevented.

6.3 Aspects on which it may be helpful to comment further are:

- the handling of the error once it had been identified, including communication with donor families and other registrants
- NHSBT's remedial action and plans for the future.

Handling after error identified

6.4 Having heard at first hand of the distressing impact it had on the families of, thankfully, a small number of donors, I do not underestimate its importance. This was a serious error, and avoidable if action had been taken at the right time.

6.5 It is, however, right to record that the error was uncovered as a direct result of action taken by NHSBT itself to check the veracity of the records. It should also be noted that having investigated the cause of the error, NHSBT's communication plans were designed with a view to transparency and openness about what happened, beginning with the families directly affected and then the wider general public. This reflects well on the organisation and its leadership team.

6.6 Overall, I consider that after the cause of the error had been identified in early March 2010 and the SUI team established, NHSBT handled the situation efficiently and with sensitivity. Although it is understandable that NHSBT staff wanted to make sense of the reports of incorrect data before they escalated matters to the senior tiers of management, I believe that there was sufficient evidence to justify such escalation at an earlier date, but probably no earlier than the preceding month. However, after the Director of Organ Donation and Transplantation and the Chief Executive became aware, I have been impressed by the

professional and systematic approach adopted by the SUI team, and the degree of personal commitment shown by NHSBT senior management and other employees to remedying as far as possible what went wrong. I appreciate what a difficult and, at times, demanding task it must have been for many.

6.7 NHSBT staff members were also painstaking in identifying those cases in which the erroneous data had, following the death of the donor, influenced discussions with their family about the donation of specific organs. Communication plans rightly made the families the first priority, and it is unfortunate that the media received information before an explanation could be given to the families in accordance with the plans.

6.8 As part of my review I wrote to all the affected families for whom NHSBT had managed to identify an address, to invite their comments on NHSBT's handling of the communications. I received a small number of responses. The general view was that the letters were polite and sensitive and that the NHSBT staff to whom they had spoken were patient, professional, sympathetic and sensitive. One family member's letter arrived on the anniversary of the death of their loved one and they felt that this was insensitive of NHSBT. Two family members, while appreciating NHSBT's moral duty to be open about what had happened, said that they would have much preferred not to know.

6.9 NHSBT has reported that most families graciously accepted its apology and were supportive. Clearly in circumstances such as these people will differ in both how much information they will want and in the way they will respond to it. Against that background, and given the difficulty of the message they were required to convey, I believe that overall NHSBT acted with sensitivity, thoughtfulness and care in their contact with affected families.

6.10 Other communications, with external stakeholders and registrants were also generally well received, although one stakeholder wrote to me in highly critical terms about NHSBT's communications but may not have been aware of NHSBT's need to bring forward its plans following unexpected media reports about the error.

NHSBT's remedial action and plans for the future

6.11 The judgements made by the SUI team in suspending the use of the suspect records, and holding back the migration of new data from the DVLA to the ODR were all sound. The task of identifying which records could be corrected without reference to the registrant and which ones required clarification of the registrant's wishes was considerable and NHSBT should be commended for that effort, and for its early decision to write to more than 300,000 registrants.

6.12 The immediate actions by NHSBT described in Chapter 5 are all designed to improve control of the current ODR infrastructure, and, so far as I can tell, as someone who is not a specialist in the security and control of large databases, they are appropriate and proportionate.

6.13 Finally I would like to make a general point about the ODR. It is clear that demands are being made on the ODR for which it was not originally designed. It was not set up to be an interactive tool integral to the organ donation process. It is now the vessel within which the names of more than 17 million people are contained. Those names have been entered from a variety of sources most of which require the intervention at some point of third party human beings to key in data, all capable of making human errors. A small number of errors continue to be made during the keying process. Indeed I heard from one person who received a letter thanking him for joining the ODR when he had not, in fact, elected to do so. For the feed in question, the estimated rate for this type of sporadic error is 0.017%. There are two “backstops” in place to mitigate the risk of a donation going ahead against the express wishes of the deceased donor. Nevertheless, a single error is one too many. The operation of the current ODR relies on the processing of data by a range of third party organisations. This does not help the avoidance of error. The scope for such errors would be greatly reduced if the ODR used 21st century technology of the type we are now accustomed to seeing in, for example, electronic banking.

6.14 This has been recognised by NHSBT managers who have plans in place to scope and cost a new ODR.

6.15 A new ODR would be designed so that registrants would have easy access to their own data with the ability to update their preferences and other details such as email addresses.

6.16 An ODR that offered this enhanced service would go a long way towards mitigating any errors remaining undetected for a long period and would enable NHSBT to establish a more interactive relationship with registrants.

7. Recommendations to ensure that the register reflects the wishes of those registered and that confidence in the system is maintained

7.1 There is a large need for organ transplantation, with patients dying for want of a donated organ. As shown by the 17 million who have put themselves on the ODR, many altruistic people wish to record their intention to be organ donors. Public awareness of this option must be heightened, and a high level of confidence in the ODR is crucial to the ultimate aim of increasing the number of life-saving transplants.

7.2 The current ODR system was not designed to fulfil the function for which it is now used, and technology for secure, interactive information management has advanced greatly since the ODR was originally set up 16 years ago.

7.3 Those advances have a great deal to offer in ensuring that the ODR reflects the wishes of those registered. They could enable people to have easier access to up-to-date and accurate information on which to base their registration decisions, and allow registrants control over their own ODR record. This in turn will help to maintain the confidence that people place in the ODR.

7.4 For many people, joining the ODR is an action that is incidental to another action, for example completing a driving licence application form or signing up for a Boots Advantage Card. The statistics on the routes by which people join the ODR indicate that despite the fact that the overwhelming majority of the public support organ donation, they need such a prompt to encourage them to act. This may mean that for some people the decision to join the ODR is based more on instinctive altruism than the outcome of a careful consideration of all the facts. The challenge for NHSBT is to encourage as many people as possible to join the ODR while at the same time ensuring that its processes achieve what is sometimes referred to as “informed consent” and which the Human Tissue Authority (HTA) calls “valid consent”.

7.5 According to the HTA’s Code of Practice on Consent , for consent to be valid “it must be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question”. I have no doubt that when ticking a box to join the ODR most people have at least a broad understanding of the implications, and that many people will regard that broad understanding as a sufficient basis for their decision. They will know, for example, that donating their heart after death will involve an invasive procedure that includes the surgical removal of their heart. Other people, though prepared to tick the box, may have unanswered questions about particular aspects of the process or about donating specific organs. If the ODR is to reflect clearly the wishes of registrants it is important that they are given:

- sufficient information to answer their questions
- access to an easy process for checking and changing the ODR's record of their wishes.

Recommendation 1

The longer-term solution for the Organ Donor Register is to create a secure, interactive system designed specifically to handle the projected operational requirements of organ donation. With inherent data verification and cross-referencing functions, this would also allow individuals to check and, if necessary, change their own data.

It is recommended that as soon as funding permits, the design and commissioning of a new replacement ODR should be taken forward.

Recommendation 2

In the meantime, NHSBT must operate within the constraints of the existing ODR infrastructure, and the current system must be made robust in terms of the accuracy of information held.

Systematic sampling and checking of data for accuracy against source documents or cross-references should be undertaken routinely, with a frequency and scale determined by statistical modelling. Exercises should be undertaken to challenge the performance of various parts of the system infrastructure on a routine basis.

Recommendation 3

To reduce the future risk of error in transposing data from external feeds onto the ODR, and to reduce the potential for confusion, all external forms on which people are asked to agree to donate either all or specific organs should collect the same data in a uniform way. People signing up via the Boots Advantage Card Scheme will not have been asked if they wish to donate specific organs, and should in future receive a letter from NHSBT inviting them to indicate, in a format consistent with other feeds, either their willingness to donate all organs or specific organs.

Recommendation 4

NHSBT's current practice of writing to all new registrants giving them an opportunity to report any errors in their recorded details should continue. All reported errors should be investigated. Error rates, broken down by Partner organisation, should be closely monitored and routinely shared with Partner organisations with a view to minimising them.

If the error rate of a particular feed is significantly higher than that of other feeds, consideration should be given to suspending the transfer of data from that feed to the ODR.

Recommendation 5

To provide added assurance to the action plan that NHSBT has developed to improve control and governance, it is recommended that NHSBT invites an external organisation, with

experience and expertise in running a large database, to review its proposed new control systems.

Recommendation 6

While it is understood that, since 2004, reference to the ODR has increasingly become the standard practice for establishing the wishes of the donor, it is recommended that in future it should always be consulted as an essential part of the process of establishing consent for organ donation.

In the context of the consent requirements of the Human Tissue Act 2004 (and the parallel requirements in the Human Tissue (Scotland) Act 2006), consideration has been given to the current arrangement whereby people wishing to join the ODR express this by ticking various boxes on third party forms, such as the DVLA driving licence application form. It should be noted that NHSBT already plans to review the status of those forms to determine whether they are a valid record of consent. Without wishing to pre-empt that review, the following are recommended:

Recommendation 7

Ticking the boxes for organ donation on third party forms should trigger the sending of further information from NHSBT to the individuals concerned, drawing on the excellent Q&A section on NHSBT's website. This would give essential information about what it means to be an organ donor and it would provide the answers to frequently asked questions. Crucially it should also give people clear advice on what to do if they want to check and, if necessary, change the wishes they have previously expressed. To avoid extra cost, this additional information could form part of the "thank you pack" already sent to new registrants.

It has been suggested that after receiving further information, individuals should be asked to re-affirm their wish to donate. Clearly, the value of the tick box system is the ease and convenience with which people can express their willingness to donate their organs. Provided that individuals are then given adequate, understandable information as well as the opportunity and means to change their earlier decisions, there seems to be no strong case for a further re-affirmation stage in the process, and the possibility of creating confusion by introducing one.

Recommendation 8

When people register on the ODR, they should be encouraged to tell their families of their wishes to become organ donors, and whether they would like to donate all organs or just specific organs. This could be done in the information pack sent to them from NHSBT after they join the ODR. It may also help to stimulate consent rates in families in communities with a high level of need.

Recommendation 9

Close attention should be paid to the language used in describing the effect of ticking and not ticking the boxes in relation to specific organs. Most people will correctly assume that the effect of ticking a box against the name of a specific organ is to indicate their consent to the donation

of that organ. But, in the absence of some explanation, they may be less clear about the implications of not ticking a box against the name of a particular organ. NHSBT interpret the absence of a tick as the individual's preference not to donate that organ at the time of registering. A decision not to consent to the donation of an organ has legal force under the Human Tissue Act 2004, and it is therefore important that there is no misunderstanding about the wishes of an individual whose intention when deciding not to tick a box was to indicate their decision not to consent to the donation of that organ. The use of the word "preference" in this context may not be ideal.

Chronology

1971	Kidney donor card introduced in the UK
1981	UK kidney donor card changed to multi-organ card including kidneys, corneas, heart, liver, and pancreas
1985	UK donor card extended to include lungs
1994	NHS Organ Donor Register established
1994	Advance Data Services (formerly known as MPL) becomes Partner feeding names of donors to the Organ Donor Register
1994	The Driver and Vehicle Licensing Agency (DVLA), and the Family Health Services Authority (FHSA) and the Scottish Family Health Services Authority (SFHA) feed names of donors to the Organ Donor Register from GP surgeries
1999	Organ Donor Register was moved to a new computer infrastructure
2000	Boots the Chemist start to collect registrations for the Organ Donor Register through the Boots Advantage Card Scheme
2003-2009	New “feeds” to the Organ Donor Register are added (Organ Donor Line telephone registrations, DVLA in Northern Ireland, Northern Ireland Central Services Agency, on-line registrations, text, Southampton City Council, Dundee City Council, Bracknell Forest Council)
2004(November)	The Human Tissue Act 2004 was enacted. It requires “appropriate consent” for the removal of organs in England, Wales and Northern Ireland for transplantation. This provided the impetus to change the role of the Organ Donor Register from a largely marketing tool to a consistent operational tool.
2004	UK Transplant made available to hospital staff a service through which they could check a potential donor’s donation preferences via a telephone call to the UK Transplant’s HQ in Bristol.
2006 (March)	The Human Tissue (Scotland) Act 2006 passed. It requires “authorisation” for the removal of an organ for transplantation.
2006 (April)	NHSBT started to write to new registrants joining the Register online or by telephone to acknowledge their registration and to help ensure the accuracy of data held.

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2009 (November)	NHSBT started to write to first-time registrants applying to join the register through a third party, eg DVLA, to thank them for their registration and confirming with them what they had registered to donate.
2009 (from November)	NHSBT received reports, in response to the letters described above, of an error or errors in individuals' registrations. Errors reported in names and addresses, incorrect recording of preferences, and confusion over the initial registration. NHSBT investigated reported errors, following up where necessary with Partners where registration was via a third party.
2010 (end of February)	A pattern in the errors had emerged pointing to a systematic error in organ preferences derived from the DVLA data feed.
2010 (March)	NHSBT conduct further detailed investigation, including the transfer of test files between NHSBT and the DVLA. Once it became clear that the error in organ preferences was associated with data from the DVLA feed, NHSBT suspended the upload of data from that source.
2010 (April)	NHSBT identified that the problem was caused by a programming error when the Organ Donor Register was moved to a new computer platform in 1999. Use of the Register for the purpose of informing consent was partially suspended.
2010 (11 April)	The Secretary of State for Health announced an independent review of the error.
2010 (from 12 April)	NHSBT began communication with families where the decision to donate a particular organ(s) may have been influenced by incorrect data on preferences.

Glossary of acronyms

DVLA	Driver and Vehicle Licensing Agency
FHSA	Family Health Services Authority
MPL	Manual Processing Limited
NHSBT	NHS Blood and Transplant
ODR	NHS Organ Donor Register
ODT	Organ Donation and Transplantation Directorate (NHSBT)
SFHSA	Scottish Family Health Services Authority
UKT	UK Transplant
UKTSSA	United Kingdom Transplant Support Service Authority

Annex A: List of organisations invited to comment

Donor Family Network
Live Life then Give Life
The Brightside Charity
British Transplantation Society
Welsh Organ Donation Committee
Northern Ireland Donation Committee
Intensive Care Society
Scottish Intensive Care Society
Welsh Intensive Care Society
Donation Ethics Committee
British Heart Foundation
British Kidney Patient Association
British Liver Trust
British Lung Foundation
Children's Heart Federation
Children's Liver Disease Foundation
Children's Transplant Foundation
Cystic Fibrosis Trust
Diabetes UK
Driver and Vehicle Licensing Agency
Kidney Research UK
Kidney Wales Foundation
Register and Be a Lifesaver
Legacy of Life
National Kidney Federation
Organ Donor Campaign
Roy Pitman Society
Transplant Kids
Transplant Patients' Trust of Great Britain
Transplant Sport UK
Transplant Support Network
Transplant Trust
ACLT
Royal College of Surgeons of England
Royal College of Surgeons of Edinburgh
Royal College of Anaesthetists
Royal College of General Practitioners
Royal Colleges of Physicians
Royal College of Nursing
Royal College of Emergency Medicine
British Association of Critical Care Nurses
National Commissioning Group
National Specialist Commissioning Group
Public Health Agency
Paediatric Intensive Care Society

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Great Ormond Street Hospital
MedicAlert
Unison
Human Tissue Authority
General Medical Council
General Nursing Council
Patient Concern
The Patients Association
Boots plc
Organ Donation Taskforce
Nuffield Council on Bioethics
Royal Society
Royal Society of Edinburgh
Wellcome Trust
Research Council UK
Academy of Medical Royal Colleges
Clinical Leads for Organ Donation in NHS Trusts

Annex B: Meetings/telephone conversations with individuals

Mr Harry Cayton – Council for Healthcare Regulatory Excellence

Sir Bob Hepple QC – University of Cambridge

Ms Vicki Chapman – Human Tissue Authority

Miss Victoria Marshment - Human Tissue Authority

Professor Gurch Randhawa – Professor of Diversity in Public Health, University of Bedfordshire

Mr Christopher Rudge FRCS – National Clinical Director for Transplantation

Annex C: First letter to families directly affected by the error

Date

Dear NAME

I am writing to you regarding the organ/tissue donation which your late relative NAME made on DATE. Firstly I would like to say thank you once again to NAME and all his/her family members for this donation.

You may remember that his/her wishes as recorded on the Organ Donor Register were discussed with you at the time when hospital staff talked to you about organ (and/or tissue) donation. We have recently identified a technical error within the Register which has affected a very small number of donors, and we believe that the donation made by your relative / NAME may be one of those affected.

In order to verify this and to explain the issue to you in more detail, I would be very grateful if you would contact us as soon as possible on 0300 123 1205. This line will be operating at the following times this week:

Monday 12th April: 12 noon – 10pm

Tuesday 13th April: 9am – 9pm

Wednesday 14th April: 9am – 9pm

Thursday 15th April: 9am – 9pm

Friday 16th April: 9am – 5pm

I realise that contacting you about this may cause distress and I would like to reassure you that there is no doubt that NAME joined the Organ Donor Register and recorded his/her wish to donate organs. However, we would like to talk to you and answer your questions at the earliest opportunity, and so will also try to contact you by telephone using the telephone number held in our records.

Yours Sincerely

Sally Johnson
Director of Organ Donation
NHS Blood and Transplant

Annex D: Second letter to families directly affected by the error

Date

Dear NAME

Following your discussion with (DTC NAME) regarding the NHS Organ Donor Register (ODR), I am writing to provide a written account of the issue, and to provide you with contact details should you have any further queries in relation to this matter.

As the Chief Executive at NHS Blood and Transplant, the organisation now responsible for organ (and tissue) donation in the United Kingdom, firstly I would like to sincerely re-state our gratitude to NAME and all his/her family members for the donation made on DATE.

You may remember that his/her wishes as recorded on the Organ Donor Register were discussed with you at the time when hospital staff talked to you about organ (and/or tissue) donation. The register held details of which organs he/she had indicated a wish to donate. As you know, we have recently rechecked this record and unfortunately discovered that (one/some of) their preferences for organ donation was/were incorrect.

We are absolutely certain that NAME did join the register and recorded his/her wish to donate organs. In the discussion we had with you, however, we indicated that he/she wished to donate (A, B, C, and D). Having verified the information provided to the register, we now know that in fact he/she had listed (A, B, and E) but not (C). In the event, you very kindly agreed that C could be donated, but we realise that you might not have agreed to this if you had been aware that NAME had not specifically stated a wish to donate this organ. We are extremely sorry for this error and apologise unreservedly for any distress this has caused.

A number of records on the Organ Donor Register were affected by this error and a small number of the affected registrants went on to donate organs. This was caused by a processing error with one our systems, which has now been corrected. When we discovered the problem we knew that although contacting you may cause upset, the right thing to do was to tell you about it.

Although you have already discussed this with NAME, I appreciate that you will probably want to reflect on the information that has been provided and possibly discuss this further. Please contact my office using the details below if you would like to arrange a time for me to call you back.

We have also arranged for an Organ Donation Support Service telephone line to be set up. If you would find it helpful to access this counselling service, please call 0800 680 0646. Please note that calls to this number are only free from landlines.

Yours sincerely
Lynda Hamlyn

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