
Documentation submitted by NHS Blood and Transplant to Professor Sir Gordon Duff's Independent Review

Reports by NHSBT to Professor Sir Gordon Duff

Annex 1: Extract from NHSBT Board report (May 2010)

Duff Review: NHSBT response (June 2010)

Supplementary information required by Prof. Sir Gordon Duff following a meeting on 14th June

Answers to questions raised during a meeting on 13th July

NHS BLOOD AND TRANSPLANT

27 MAY 2010

NHS ORGAN DONOR REGISTER: SERIOUS UNTOWARD INCIDENT PROGRESS REPORT

EXECUTIVE SUMMARY

In March the Board was notified of a Serious Untoward Incident relating to the accuracy of some donation preferences recorded on the Organ Donor Register (ODR). The problem was isolated to a proportion of those people who had registered specific organ preferences via our partners at the Driver and Vehicle Licensing Agency (DVLA). At the time of reporting, it was still unclear how the problem had arisen, exactly how many records had been affected and to what extent the problem applied to the families of people who had subsequently become organ donors. This report sets out the findings of our internal investigations to date; the remedial action taken; our work with affected families and our correspondence with affected registrants; the impact on donors and donor confidence; and the establishment of an independent inquiry due to report in July.

RECOMMENDATION

The Board is asked:

- To consider the progress made in investigating and managing this incident and ensure no key areas for action have been overlooked.
- To endorse the early lessons identified and support the approach being taken to review the incident fully.

BACKGROUND

Work initiated towards the end of 2009 to improve communications with people on the ODR identified a problem with the recording of some registrants organ donation preferences. Most people (87%) who join the ODR, tick the box consenting to the donation of all their organs. There is no problem with these registrations. A very small number of people register to donate just kidneys and/or pancreas and there is no problem with these registrations. There is, however, a problem with the accuracy of the registrations where only a donation of eyes, hearts, lungs or liver is selected – but only in those registrations originating from the DVLA

The partnership with the DVLA started in 1994 and covers the whole of the UK (with the exception of Northern Ireland). It is the largest single registration source, providing 8 million of the 17 million records currently held on the register.

INVESTIGATION OF THE INCIDENT

A Serious Untoward Incident team was established led by the Director of Organ Donation and Transplantation. Membership included the Medical Director, Director of Business Transformation Services, Director of Communications & Public Affairs and the Assistant Directors of Quality, Organ Donation, Transplant Support Services, IT, Public Affairs, and Internal Communications. A project manager was identified to support the process and as a result of daily teleconferences, the team 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
- Establish the legal position with respect to the Human Tissue Acts and Data Protection legislation
- Implement a communications plan for the affected families, registrants, the media, partners and stakeholders
- Manage consistent reporting to Department of Health, Devolved Administrations and the Board.
- Project Manage the incident in its entirety.

ESTABLISHING THE FACTS

The SUI team were able to identify that the problem had arisen prior to 2000 because the DVLA still held the original documents which could be used to verify donation preferences on the ODR. An initial task, therefore, was to establish, with a high degree of confidence, the likely point before 2000 when the error occurred which had led to data received from DVLA being wrongly recorded on the ODR.

The Statistics and Clinical Audit Department undertook a careful analysis of the donation preferences of people registering via the DVLA since 1994. By comparison with the registration preferences recorded on the entire register, they were able to demonstrate (with a very strong confidence level) that the problem with misrecording of preferences took place on, or shortly after, 1 January 1999. Subsequently we were able to discover that a software change had been introduced at that same time. Further investigation revealed that errors had been made in the program which processed data received from the DVLA for transfer onto the ODR. All other data feeds (both current and expired) were checked and it was confirmed that the error applied only to the DVLA feed.

Establishing the source and timing of the problem enabled us 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 registration)

- Initial registration via DVLA from 1999: subsequent registration from another source
- Initial registration not DVLA pre 1999: current registration not DVLA: interim registration/amendment via DVLA.

Each group was 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 us 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

Considering only those records that we were able to correct and those where we needed to write to 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

We 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 we requested the donation record in order to determine whether the register was referred to during the donation consent process (the ODR was not a standard part of the process prior to 2004). For each record reviewed, a judgement was made by

pairs of Specialist Donor Nurses as to whether the register was: used; likely to have been; 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, we determined that in 25 cases the outcome of the donation appeared to have been influenced by the record on the register and the donor families needed to be informed of the situation.

SUPPORT TO DONOR FAMILIES

As soon as it was apparent that some donors families were affected by this incident, our top priority was to provide information and support donor relatives. We agreed that they should be the first to know about the issue and determined a date when we would contact them to let them know there was an issue which we wished to discuss with them. In the event, the media became aware of, and published reports on, the issue before we were able to contact the families. The media reports ran from Sunday 11 April and we couriered letters to families from Monday 12 April. The families were asked to telephone a helpline staffed by Senior Nurses from both ODT and Tissue Services. Once telephone contact had been made and the situation explained, this was followed immediately by a letter of personal apology from the Chief Executive and an offer to meet the families as well as details of an independent specialist support service we had established. We also followed up families from whom we had not heard

Of the 25 families, one had not provided follow-up information at the time of donation and requested no further contact: we have no way of contacting this family. Of the remaining 24 families:

- NHSBT staff have now spoken to 17 relatives. 15 were supportive and remained positive about their relative's donation and two were distressed. Of the two, one family member remains distressed but does not want further contact. The other family member indicated that they might wish to have a face-to-face meeting with a senior Specialist Nurse or the Chief Executive, but has not followed up this offer.
- NHSBT have not been able to speak to seven families. Six families have not responded and all routes to trace them have been exhausted. One family member refused to accept the letter when it was delivered. The helpline has now been closed and no further contact with these families is planned.

CORRECTING INACCURATE RECORDS

The initial task was to establish which records on the ODR were unaffected by the error and therefore could continue in use for informing decisions about donation. We were able to use some simple and safe assumptions based primarily on the date of initial registration, source of the registration and the specific donation preferences that led to the identification of 16,095,222 out of a total 17,087,646 records as correct.

The remaining 992,424 records were subjected to an extensive series of analysis routines to determine, among other factors, the sequence of initial and subsequent registrations from multiple sources and the nature of any subsequent updates i.e. if the specific donation preferences were updated or not. The information sets used in this analysis included the ODR itself, the source data records (where these were

available) and the system audit records (where these were available). The results of each stage of the analysis were formally signed off to allow a full audit trail supporting the decisions to remediate records or not. The first stage was the remediation of the 491,829 records which were determined to be incorrect and capable of automated remediation. The second stage was to release 199,017 records which were determined to be correct and the third stage was to write to the 301,578 registrants where we were unable to determine the status of their preference from our own information sources.

CONTACTING REGISTRANTS WHOSE PREFERENCES ARE UNCLEAR

We were unable to be certain about the accuracy of the records held for 301,578 organ donor registrants and, after checking with the NHS tracing service that the individual is still living and verifying their current address, we are writing to all of them asking them to confirm their registration preferences. They can do this by calling the National Call Centre, by email or by letter. The call centre has increased its staffing to handle the expected volume of calls and we have developed a new application which allows call centre staff to access the Organ Donor Register details and amend them in real time – this is a welcome new development. Previously call centre staff have had to take details and transfer them to NHSBT for processing. All registrants in this group will be written to by the end of May. Outcomes of the mailings to date (19th May) are as follows:

DATE OF MAILING	23/04/2010	05/05/2010	10/05/2010	12/05/2010	17/05/2010
No of records mailed	19,996	49,995	49,999	50,000	50,000
No of records not mailed due to incomplete/invalid address	2	5	1	0	0
No of responses to mailing	2,801(14%)	5,249 (10.5%)	4,739 (9.5%)	3,868 (7.7%)	1,867 (3.7%)
No of records confirmed	1,050(37%)	2,086 (40%)	1,126 (24%)	1,155 (30%)	335 (18%)
No of records corrected/updated	1,341 (48%)	2,964 (56%)	3,496 (74%)	2,683 (69%)	1,523 (82%)
No of records withdrawn/died	180/1 (7%)	110/1 (2%)	69/0 (1%)	5/0 (0%)	0/0 (0%)
No of responses still to be categorised	229 (8%)	88 (2%)	48 (1%)	25 (1%)	9 (0%)

*The number of contacts without a defined outcome has dropped from 8% of the first mailing to 3% of the second mailing. The problem relates to a training issue and additional training has been provided for call centre staff.

To date, the response rate of is lower than ideal. Where people do not respond, their record will remain flagged to ensure that, in the event of their donation, the record is not relied upon in discussion with their family.

LEGAL AND REGULATORY RESPONSE: HUMAN TISSUE ACTS AND DATA PROTECTION ACT

NHSBT's legal advisers provided initial advice that was reported to the Board previously. We then asked that they review the actual case details and we were advised that:

- registration on the ODR constitutes valid agreement to donate under the Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006 in Scotland.
- where the donor did not express a wish either for or against donation of the organ then consent/authorisation for use of specific organs given by the person's nearest relative is valid under the Act.

The HTA was briefed informally and formally on the SUI. The HTA has acknowledged our reports and will be reviewing the adverse event file during their inspection of Liverpool, in June. As part of our Quality Management System a Root Cause Analysis exercise was also initiated on the 14 May, which will form a key element of the adverse incident file and the lessons learned process.

As the tissues involved were procured via licensed establishments with which NHSBT has formal Service Level Agreements, formal contact was also made with the Designated Individuals of those establishments to advise them of the issue as they carry legal responsibility under the Human Tissue Act for the consent process within their establishments.

We informed the Information Commissioner of the problems with data recording on the ODR on 12 April and there have been a number of communications with his office. On 26 April he wrote to us to ask:

- How defective software was commissioned for use with the ODR data base system.
- How such a fundamental error, resulting in the creation of thousands of inaccurate records, went undetected for a period of some ten years.
- The precise number of resultant inaccurate data sets.
- The precise number of individuals subject of 'unauthorised' organ harvesting.

The Commissioner recommended that NHSBT consider commissioning an independent external body to enquire into and report on these matters. We have now supplied the Commissioner with responses to his questions and confirmed also that these issues will be covered in the Independent Review commissioned by the Department of Health.

OPERATIONAL USE OF THE ODR

Since the problem was first identified we have ensured that any potentially incorrect information held on the ODR is not be used in conversations with potential donor families. Initially this was achieved by instituting different procedures within the duty office. We have now been able to flag potentially incorrect records on the register to warn Duty Office and Specialist Nurse staff not to rely on the preferences recorded.

The DVLA feed was quarantined at the outset and has not yet been reinstated. From 17 May we are running tests on small quantities of data to ensure that we have properly corrected the problem. Assuming this goes well, we expect to be regularly updating the register with data from the DVLA by the end of June. We are pleased and relieved that the DVLA (the largest single source of new entrants to the ODR) remain committed to this important partnership and have agreed to provide them with data about any corrections we receive from registrants after they receive their thank you letter. This will help us understand better how many people register without intending to and where data processing errors are found.

MEDIA HANDLING AND STAKEHOLDER COMMUNICATIONS

We had prepared for a proactive release of the information to the media after we had informed the families or for a reactive response should the media be alerted in advance. We had a full media handling strategy with support from an external agency in place when we were warned the story was about to leak.

Staff from the Incident team and others worked throughout Saturday evening and Sunday to respond to enquiries and to provide widespread stakeholder briefing. Following an early statement by the Secretary of State, the Chief Executive provided TV and Radio interviews on Sunday. Thereafter national media interest was low. Over 100 stakeholders (plus Clinical Leads for Organ Donation and Transplant Centres who were sent separate communications) were briefed -some personally as well as in writing. Many responded very positively to being kept informed. Two stakeholders said they were unhappy with the briefing.

We tracked comments on social media throughout the course of the issue handling. The vast majority of comments were positive and supportive, with a small number neutral or mildly negative. The majority of critical comments were posted on US sites in relation to the NHS system and proposed US policy changes.

INTERNAL COMMUNICATIONS

Both a proactive and reactive internal communications plan were in place, with the latter being actioned over the weekend of 10/11 April. This included the Chief Executive briefing the Leadership Team via e-mail on Sunday 11 April - including background, next steps, copy of intranet news item for all staff and guidance on directing any stakeholder or media enquiries received. At the same time the intranet was updated with a news item again outlining the issue and giving reassurance that it was being managed to a positive resolution. At the same time a message was sent on behalf of Sally Johnson to all ODT staff informing them of the issue and giving them key messages to share with others.

The next working week saw regular updates online plus inclusion of messages in Lynda Hamlyn's online message for all staff, Connect Briefing and Connect

Magazine. Sally Johnson also wrote to all DTCs personally addressing any professional concerns or issues. An all staff vote was held online with just over half of respondents expecting the news to put people off joining the ODR. The results of the week long vote were announced with news that registrations via the web in the week of the leak had actually increased.

IMPACT ON THE ORGAN DONOR REGISTER

Public confidence in the ODR is important for maintaining and increasing the number of registered supporters of organ donation and for ensuring that NHS staff facilitating donation can rely on its data. Anything which impacts on public confidence in the register is a matter of concern. We were therefore pleased to see the supportive public response immediately after 12 April.

Date	ODR Web Registrations	ODR Withdrawals
Sun 11 Apr	6,003	177
Mon 12 Apr	2,404	52

This compares with 4,742 registrations (final week end of campaign in March) and 1,988 registrations for the first weekend in April. Withdrawals from the register as a result of this issue have remained low: of the 220,000 people we have so far written to about their registration preferences, 364 have withdrawn from the register. The overall impact on the register will be reviewed when all mailings are complete and the incident is closed.

PROGRESS REPORTING

Throughout the incident we reported frequently to the Department of Health and provided briefings to each of the devolved administrations to inform them of progress and support any local enquiries. The Chief Executive provided routine briefings to the Board to keep members abreast with the investigation and handling of the incident.

CORRECTIVE ACTION

Although the SUI will not be formally closed until all registrants have been written to and given an opportunity to respond, we have already taken or planned some immediate corrective action and improved some of our processes. These include:

- We have carried out checks on the accuracy of all other sources of registrations to confirm that the data is accurately recorded on the ODR
- We will continue to acknowledge all registrations and organ preferences in writing, from all sources which will enable all new registrants to check (and correct if necessary) the accuracy of the information held for them on the ODR.

- We are implementing and documenting change management and maintenance procedures to capture and manage all changes to all existing and any new feeds to the ODR
- We will carry out regular checks on a sample of records from all feeds to confirm the accuracy of records held on the ODR
- We will implement routine statistical monitoring of the ODR feeds to highlight any changes in registration patterns which may indicate an error in processing
- We will review and update the service level agreements with all sources of registrations to take account of the lessons learned from this incident
- We will implement full auditing of all changes to records on the ODR from all feeds
- We have created new applications to enable customer support at the National Donor Line to check registrants' ODR entry at the time of the call.
- We will consider, as part of our project scoping the development of a modern ODR, how best to communicate with all 17m registered supporters of organ donation in the future.

All of these actions should be in place by the end of July.

IDENTIFYING AND LEARNING LESSONS

Unsurprisingly following an incident of this magnitude, there are many questions to be answered and lessons learnt. We are still identifying what we should have done differently.

There were a number of key issues noted during the Root Cause Analysis (RCA) workshop which took place on the 14th May. The headline issues and contributing factors identified were as follows:

- There was no robust software development life cycle process in place for the ODR at the time. There was therefore a lack of documentation, no requirement for agreed design specifications and a resultant lack of formal validation or parallel testing of any changes made.
- The National Transplant database was the critical focus at the time and the ODR was therefore given less priority in terms of formal development and testing.
- At its conception and until there was a critical mass of registrations (in around 2004), the ODR's focus was not on gathering consent information, it was aimed mainly at collecting numbers of potential donors and some demographic data. Its role has therefore changed with time, without a recognition and application of the regulatory controls required where consent is concerned.
- There were no end to end testing systems in place to positively review, reconcile and verify the data being collated via the ODR.
- The RCA process has identified other weaknesses which although not implicated in the SUI, need to be reviewed and strengthened, eg. ambiguity in the way the DVLA forms are completed and interpreted.

The final RCA report is in preparation and will contain the comprehensive findings of the analysis and result in a full corrective and preventive action plan to address the issues identified.

We have also scheduled a workshop for the SUI team to identify lessons from the handling of the incident for 24 May.

Before the incident, we had already identified that the need to replace the ODR on a modern technology platform and work to scope the development of a new ODR is already part of this year's strategic plan. We had also recognised that ODT is not covered by the quality system which is standard across the rest of NHSBT. We had planned to tackle this as part of the implementation of the EU Organ Directive and a quality project manager is being recruited to support this work. As an organisation we did not have a standard guide to establishing an SUI team and managing an incident: this is now in preparation and will be informed by the 'lessons learned' workshop. We are also identifying some detailed remedial action that will be required, for example, having the capability to update our websites more rapidly.

INDEPENDENT REVIEW

On the day the story appeared in the press, the former Secretary of State announced that he was commissioning an independent review into the incident. This review has superseded the external review that NHSBT had agreed to commission. The review will be led by Professor Sir Gordon Duff and the Terms of Reference are as follows:

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

The review will consider:

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

It is expected that the review will report in July.

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Supplementary information required by Prof. Sir Gordon Duff following a meeting on 14th June

Partner data reaching the ODR in 2010

A table at the end of this paper presents a snapshot of the 14 Partners actively engaged in passing data to the Organ Donation Register (ODR) as of March 2010.

Partner data reaching the ODR in 1999

Only the first four Partner feeds listed in the table (MPL, FHSA, SFHSA and the DVLA¹) were active at the time of the switch over to the new computer infrastructure in 1999, when the programming error mentioned in NHSBT's June submission to the Duff Review occurred.

The MPL data feed was the first ever partner feed into the ODR.

Representing values in a computer record for transfer

In order to pass data to the ODR each Partner makes 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. This has been in place since 1994. Each file contains records of registrant data. Within each record, along with Name, Address, Date of Birth etc, single character fields represent the preferences expressed by registrants wishing 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'.

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 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.

Capturing a registrant's preferences (using the DVLA as an example)

Those wishing to join the Organ Donor Register may elect to do so on-line, by telephone, by text, or more traditionally by filling out a paper form and marking boxes with a cross.

In the case of a person filling out a driving license application form they would see:

¹ MPL – a contracted company carrying out data entry on behalf of UKT

FHSA / SFHSA - Family Health Services Authority / Scottish Family Health Services Authority

DVLA – Driver and vehicle licensing authority

Once the data has been keyed into the DVLA computer it is formatted into a record which has a prescribed layout. In the case of the DVLA, a record looks like this²:

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

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 preferences.

```
SMITH401668SA2PR      SMITH      STANLEY ALAN
101 STONEHILL GROVE   ST JOHNS
ALCESTER              PQ2 5PT 19650718 1212221 1
```

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 cornea/eyes
Heart	2	Yes	I wish to donate my Heart...
Lungs	2	Yes	...Lungs...
Liver	2	Yes	...Liver...
Pancreas	1	No	...but not 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).

The important thing is 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 program), it will know where in each record specific information resides.

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

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.

² Anonymised data. – not a real person or address.

Hypothesis 1. That the original feed layout – from MPL - was regarded as the ‘master’ layout. In that case, and in the absence of other full and comprehensive documentation, a computer programmer charged in 1999 with producing software code to process and register data from feeds might well refer to the MPL record layout specification to inform their code development. As we now know, the DVLA format differed from the other feeds so reliance on a single specification was flawed. Under this hypothesis we are as certain as we can be that the MPL record layout specification was used as the ‘template’ for the record layout for the FSHA and the SFHSA records.

Why did the DVLA record layout differ?

To answer this question a second hypothesis is necessary. The MPL, FHSA and SFHSA Partners were acting with UKT and would have been happy to take direction from UKT on the record layout. In 1994 the DVLA organisation was prepared to send data to UKT but that data had additional characteristics that simply would not have featured in other feeds. The most obvious example is the inclusion of the DVLA Driver License Number in the record.

Hypothesis 2. On the basis that the record layout was unique to the DVLA, it is possible that a DVLA programmer wrote the file format specification on behalf of the DVLA and passed this to UKT. This would explain why the only file specification ODT could find during the SUI investigation was a copy faxed from the DVLA.

If, in 1994 the DVLA programmer got the field positions the wrong way around or chose the given order for a reason, *and* ODT conscientiously coded the DVLA upload program as per the specification even though this record layout did not match the other feeds, this would account for the difference.

Prior to the latter part of 1999 this led to no problems, but when the next UKT programmer unwittingly applied the ‘standard’ record layout processing to the non-standard DVLA records the transposition error came into being.

Table 3. March 2010 snapshot of engaged Partners passing data to the Organ Donation Register (ODR)

Partner	Transfer method	Preferences	Notes	Active since...
Advanced Data Services (used to be known as MPL. The first partner feed for the ODR)	Encrypted email attachment. Sent weekly.	Files contain (coded) donation preference expressions (e.g. Kidney '2' for yes, lungs '1' for no). This is explained fully elsewhere in this document.	Files are decrypted and loaded into a network drive. Files contain details from paper registration forms sent to our contractor, ADS, for processing	October 1994. The original and for a time only feed to the ODR
DVLA	1 file per week extracted by ODT from a location at DVLA	Donation preference expressed	Files consist of registrations and updates from DVLA in Swansea from license and application forms.	1994
GPs/Primary Care Support Agency (FHSA)	Weekly secure transfer to ODT servers.	Donation preference expressed	File consists of registrations and updates from the GPs surgeries in England & Wales.	1994
Scottish Central Services Agency (SFHSA)	Protected email attachment. Sent monthly.	Donation preference expressed	Registrations and updates from GPs surgeries in Scotland.	1994
Boots the Chemist	Encrypted email attachment. Sent weekly	No donation preference expressed. Potential donor agrees simply to being on the Register	Registrations from the Boots Advantage Card scheme.	2000
Organ Donor Line telephone registrations	Encrypted email attachment. Sent daily.	Donation preference expressed	Files contain details of people who have registered or amended details over the telephone. Weekly withdrawals file also received and dealt with manually by the ODR Team.	2003
DVLA-NI	Encrypted email attachment. Sent monthly	Donation preference expressed	Files consist of registrations and updates from DVLA in Northern Ireland from license application forms.	2004
NI Central Services Agency	Protected email attachment. Sent fortnightly.	Donation preference expressed	Registrations and updates from GPs surgeries in Northern Ireland	2004

Partner	Transfer method	Preferences	Notes	Active since...
On-line registrations	Hourly feed from 4 web servers.	Donation preference expressed	Registrations received via the Organ Donation & Transplant website. 1 withdrawal file received daily for manual processing by ODR Team.	2004
Text	Encrypted file received weekly from AdIQ	Donation preference expressed	SMS texting is used for most major campaigns in addition to web, telephone and paper sources.	Circa 2006
Southampton City Council	Monthly secure and password protected transfer to ODT servers.	Donation preference expressed	1 file transferred each month from Southampton City Council. Has password protection before connection.	Circa 2008
Dundee City Council	Secure and password protected monthly transfer	Donation preference expressed	1 file transferred each month by SFTP from Dundee City Council and loaded into the appropriate network drive. SFTP has password protection before connection.	Circa 2008
Bracknell Forest Borough Council	Secure automated transfer from the Council server to the ODR Server	Donation preference expressed		2009
Citizen Card	Secure and password protected file retrieved by ODT on 1 st of each month	No donation preference expressed. Potential donor agrees simply to being on the Register	1 file available on 1st of each month to download from Citizen Card by SFTP and load into appropriate network drive. SFTP has password protection before connection.	March 2010

Duff Review: NHSBT response

Introduction

NHSBT is 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.

The organisation 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 Organ Donor Register (ODR) from UKT. 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 as a database that largely recorded the progress of low level marketing campaigns and it was resourced accordingly.

Launched in 1994, the ODR was the first tool that provided the ability to record an individual's donation wishes in a confidential database. Today the Register records the wishes of over 17 million people, with registrations being received direct to the Register (paper form, web, telephone) or through one of ten partner organisations, for example DVLA, GP Practices, and Boots the Chemist. Registrants can opt to donate 'all organs', or select specific organs: kidneys, liver, pancreas, heart, lungs and corneas.

From 2004 UKT made available a service to hospital staff through which they could check a potential donor's donation preferences with the central Duty Office ¹ at UKT headquarters in Bristol. This service was not initially used consistently but is now a key part of the Specialist Nurse – Organ Donation (SN-OD) normal practice before discussions with the potential donor's family take place.

The Human Tissue Act 2004 and the Human Tissue Act (Scotland) 2006 changed the law to allow individuals to record their wish to consent to organ donation in life and provided the impetus to move to more consistent operational use of the Register rather than simply a marketing tool.

In January 2008 the Organ Donation Task Force (ODTF) published its report ² recommending, amongst other things, a UK wide campaign to encourage people to join the ODR. Following the second ODTF report ³ in November 2008, Government set a target of achieving 25 million registrations by 2013: in January 2008, when this recommendation was made, there were 16 million registrants.

In November 2009 NHSBT launched the first nationwide public awareness campaign to encourage more people to join the ODR and discuss their wishes with their families. To coincide with the campaign NHSBT reviewed communications with registrants. In April 2006 NHSBT had already started writing to new registrants joining online or by telephone, to acknowledge their registration and to minimise the possibility of false or malicious registration by a third party.

¹ The central Duty Office coordinates the organ allocation process for the UK

² ODTF 1 made recommendations about how the number of organ donors could be increased within the existing legislative framework

³ ODTF 2 examined whether more donors would be secured if existing 'opt in' legislation were to be changed

As part of the 2009 campaign it was agreed to extend this contact to include first time registrants joining through a third party (such as the DVLA) to thank them and provide more information about their registration. This included confirming with them what precisely they had registered to donate. This was part of a longer-term plan to introduce communications with all registrants. It was this initiative that led NHSBT to uncover the error with some registrations in the database.

At the same time as preparing and launching the campaign, NHSBT was compiling its 2010/11-2012/13 business plan. NHSBT recognised that the infrastructure supporting the ODR was not suitable to meet the demands being placed upon it, and included plans for the next business plan year to scope the development of a database and associated support processes which were more fit for purpose.

Uncovering the error

Following the introduction of thank you letters to all new registrants as part of the November 2009 campaign, an increasing number of people contacted NHSBT to report an error or errors in their registration. These covered a range of issues but included incorrect name and address, incorrect recording of their organ donation preferences and confusion over the initial registration.

NHSBT proactively investigated each of these issues, correcting inaccurate data and tracing issues via partnerships where registration was via a third party. By the end of February 2010 it became clear that there may be a systematic error concerning organ preferences, as a pattern had begun to emerge indicating such a problem, but only with the DVLA data feed.

This was the subject of further detailed investigation during March 2010, which 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. As soon as it became clear that there was an error causing the transposition of some preferences for organ donation where people had registered through the DVLA, we immediately suspended the upload of data from this source to the Register.

By April 2010 we were able to identify that the problem was due to a software programming error introduced when the Register was moved by UKT to a new computer platform in 1999/2000. As a precautionary measure, use of the Register for the purposes of informing consent was partially suspended.

The problem was identified as a mis-match between what people registering via the DVLA had consented/authorised to donate and what was being uploaded to and recorded on the ODR. This is illustrated below.

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

Where someone consented to the categories of All; Kidney; and Pancreas the records match but for all other preferences they were different. As an example of what this means, someone who had expressed a preference to donate a liver through the DVLA would have that preference recorded as willing to donate lungs on the ODR, and it would be the preference to donate lungs that would be discussed with relatives when seeking consent/authorisation for donation. 87% of people registering via the DVLA provide consent for the donation of 'All'; 'Kidney'; and / or 'Pancreas', therefore around 13% of registrations sourced via the DVLA were affected by the error.

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

- **When did the error occur?**

In order to establish this, NHSBT's statistics team analysed records since the introduction of the ODR. We were able to establish that a step change occurred in the patterns of registration preferences from DVLA registrations in January 1999, at the same time as the introduction of a new computer platform. This led to more forensic investigative work which uncovered the cause of the mis-recording of preferences.

Statistical analysis on preference trends had not previously been carried out on an individual feed basis because in the absence of end-to-end testing of records or contact with registrants, there was no indication of a problem requiring closer scrutiny of registration patterns (this is detailed under question 2).

- **How did the error occur?**

The ODR database was moved from one computer platform to another to take advantage of a more common and better supported infrastructure. This necessitated the writing of new software code for the conversion and transfer of data feeds from the various partners (of which the DVLA was one). An assumption was made at the time that the DVLA data feed was structured in the same way as other partner feeds (which it was not), which led to the incorrect mapping of data in an intermediate file.

- **Why did the error occur?**

Initially the ODR was not used as part of the donation process but simply recorded the success of campaigns to promote organ donation. It was not viewed as a business critical system in the allocation of organs and it appears that resources and scrutiny were focused on other priorities. As a result, when the Register was moved to a new computer platform, it appears that there was a lack of systematic data checks and end-to-end testing to verify the accuracy of the records as a reflection of the original documented preferences of donors. Such checks would have facilitated early detection of the software error.

2) How it took ten years for the error to be discovered

It has not been the practice to check new records on the ODR against the original registrations that partners received from registrants. The data feed tests carried out routinely were limited to the data and information held by UKT/NHSBT and were not extended to comparison with source data. As a result of this error we are now exploring options to introduce such checks with our partners.

Until April 2006 there was no process in place to confirm registration details proactively or communicate with those registering. If such a process had been in place, this may have led registrants to alert UKT/NHSBT to registration errors. In April 2006, this process was introduced only for those registering directly with NHSBT online or by phone. In the absence of registrant contact, there was no reason to suspect that there may be a programming or transposition error leading to incorrect registrations.

Discussions with families of potential organ donors registered on the ODR were carried out at local hospital level, with limited sharing of experiences across hospitals between those responsible for discussing donation preferences with families. Until 2009 Specialist Nurses (then known as Donor Transplant Coordinators) were employed by hospitals as part of their transplant teams. It was only with the recommendations of the ODTF report that these Specialist Nurses began to transfer into the employment of one organisation, NHSBT. This meant that there was no easy way to identify any trend in potential inaccuracies of recorded donation wishes emerging from discussions with families.

There was therefore no process in place for the inaccuracy of some records on the Register to surface until NHSBT started to write to new registrants at the end of 2009.

3) How it came to light, and how it was handled once it had been, including communication with donor families and those on the Register.

- **How it came to light**

The error came to light when NHSBT initiated a process through which new registrants to the ODR received a welcome pack to confirm their details and preferences for organ donation. NHSBT began to receive a number of responses to welcome packs in December 2009, stating that the organ donation preferences listed were inaccurate. Our initial investigations revealed a problem with the DVLA data feed.

- **Summary of investigations and handling**

Please see annex 1 (NHSBT Board report extract May 2010) for a full description of the investigation and handling actions.

As soon as it was clear that the error existed at the NHSBT side of the data transfer process, the team that had already been working to investigate the error was formally established as a Serious Untoward Incident (SUI) team, led by the Director of Organ Donation and Transplantation. The team 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
- Establish the legal position with respect to the Human Tissue Acts and Data Protection legislation
- Implement a communications plan for the affected families, registrants, the media, partners, stakeholders and staff
- Manage consistent reporting to Department of Health, Devolved Administrations and the Board
- Project Manage the incident in its entirety.

- **Donor Family contact**

As part of the investigation NHSBT checked whether any records affected by the error belonged to individuals who then went on to become donors. The clinical records of those identified were then thoroughly checked to determine whether the ODR was used as part of the discussion with their families. We were able to determine that inaccurately recorded preferences were referred to in discussion with the families of 25 donors.

Our first priority was to ensure the families of these donors should be the first to know about the issue and the SUI Team determined a date when NHSBT would be in a position to initiate contact. In the event, the media became aware of, and published reports on, the issue just before this planned date.

The media reports ran from Saturday 10 April and the donor family contact plan was implemented from Monday 12 April.

The plan consisted of:

- An initial letter alerting the family to a possible error with their relatives' donation, which provided a help line number for them to contact us, explaining that we would try to contact them by telephone if we did not hear from them
- A telephone conversation to explain the issue, apologise and offer further support including independent counselling
- A second letter from the Chief Executive to provide a written account of the issue, a personal apology and her contact details if they wished to discuss the issue further.

In our letters and when speaking to the families we were able to assure them that their relative was genuinely in favour of organ donation and there was no doubt as to their wanting to become donors in the event of their death.

Of the 25 families whose relatives' donations had been affected by the ODR error, one had not provided follow-up information at the time of donation and requested no further contact. We therefore had no way of tracing this family. Of the remaining 24 families:

- NHSBT staff spoke to 17 relatives in total, the majority of these within one week of the initial letter. 15 were supportive and remained positive about their relative's donation and two were distressed. Of the two, one family member remains distressed but does not want further contact. The other family member indicated that they might wish to have a face-to-face meeting with a senior Specialist Nurse or the Chief Executive, but has not followed up this offer. One of the fifteen families that were initially positive has now written to claim compensation for distress
- NHSBT have not been able to speak to seven families. Six families have not responded and all routes to trace them have been exhausted. One family member refused to accept the letter when it was delivered. The helpline has now been closed and no further contact with these families is planned.

- **Registrant contact**

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 preferences. The following methods have been established for registrants to confirm or correct their details:

- Telephone the NHSBT National Call Centre. The call centre has increased its staffing to handle the expected volume of calls and a new software application has been developed which allows call centre staff to access the Organ Donor Register details and amend them in real time – this is a positive new development which will be maintained

- Email to a dedicated email address
- Letter to a freepost address.

Letters to all those whose preferences needed to be checked were issued by the end of May and we expect to continue to receive responses from these registrants throughout June. The records of any affected registrants who do not respond to our letter will continue to be flagged to ensure that, in the event of their donation, the record is not relied upon in discussion with their family.

The table below shows the number and source of responses from registrants to date (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%)	7478 (15.0%)	3623 (14.4%)	3364 (14.9%)	3380 (10.5%)
No of records confirmed	1,200(37%)	3,117 (40%)	1,914 (25%)	2,261 (31%)	2,325 (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.

4) How to ensure it has been rectified and does not happen again

How has the error been rectified?

- **Remediation of potentially incorrect records**

The Organ Donor Register database was thoroughly examined to confirm that only records reaching the database via automated data feeds from the DVLA suffered from the data transposition error and that no other 3rd party data feeds were affected. A sample of ODR registrations that were recorded as having been sourced via the DVLA were then compared with original paper registration forms passed to NHSBT from the DVLA to assist with the investigation. Finally, System Query Language (SQL)⁴ programmes were drafted, tested and validated on test files to 'correct' the data. This testing was formally approved and the correction was applied in four stages.

Correction of the Data Feed Issue

The data conversion script used by NHSBT to upload the data (which was the source of the problem) has now been rewritten. The DVLA has prepared test records covering all the possible organ donation preference combinations. These will be loaded into a test version of the ODR and results will be checked to ensure preferences are accurately reflected under all conditions when they are uploaded from data files to the Register. In addition, independent verification and approval of the test results will be performed by NHSBT's Quality Assurance Software Validation group.

The National Call Centre has been equipped with a new and fully tested software application so that, should any registrant call them to change their donor preferences, the changes can be applied in real-time during the phone call. This has resulted in a genuine service improvement and we are currently examining opportunities for this functionality to be rolled out to the Organ Donor Register internet interface so that in future, registrants will be able to check and change their recorded preferences themselves online.

- **What steps have been taken to ensure it doesn't happen again?**

A Root Cause Analysis (RCA) investigation was undertaken on 14th May 2010. A further workshop was held on 24th May to review 'lessons learned' and identify what action can be taken to ensure that a similar error does not recur in the future.

⁴ System Query Language programs are used to extract information from databases.

Steps being taken to ensure the error cannot happen again include:

Immediate actions

Action	Action Owner	Senior Accountable Officer
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	David Shute - Assistant Director Transplant Support Services	Sally Johnson – Director ODT
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).	For technical monitoring – Clive Mangan - Head of ICTS. For business monitoring – Andrew Maxwell - Head of Data Services.	Sally Johnson
Establish new processes for feed management and ensure our Partners understand and agree to our new test procedures and our ‘data supply maintenance process’	Andrew Maxwell	Sally Johnson
Establish new Service Level Agreements (SLAs) 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.	Andrew Maxwell	Sally Johnson
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.	Andrew Maxwell	Sally Johnson
Bed in new test procedures which now include steps to compare the donor’s original source stated preferences with those recorded on the ODR.	Andrew Maxwell	Sally Johnson
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.	Clive Mangan	Neil Hogg - Assistant Director, IT Service Delivery

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

Action	Operational Owner	Senior Accountable Officer
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.	David Shute	Sally Johnson
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.	David Shute and Neil Hogg	Sally Johnson
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.	Neil Hogg	David Shute
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.	Neil Hogg	David Shute
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.	Neil Hogg	David Shute
Review the status of the third-party forms and decide whether they are an appropriate record of 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.	Andrew Maxwell	David Shute
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.	Ian Bateman - Assistant Director, Quality Assurance	Sally Johnson
Examine options for implementing periodic customer experience sampling across the web, call centre and partner channels.	David Shute	Sally Johnson
Examine options for implementing SUI simulations ('fire drills') across ODT's critical systems.	David Shute	Sally Johnson

We believe the steps detailed above provide the rigour and attention to detail necessary to prevent a repeat of the transposition error. Furthermore, the processes now in place, the improved test procedures, and the periodic technical and business led monitoring are designed not only to eliminate weaknesses in processing, but also to give early warning should an issue of any kind occur. Lastly, a full audit trail of data and the changes made to that data provide for a much more rapid remediation in the event of a processing error occurring.

NHS Blood and Transplant, June 2010

Appended:

1: Extract from NHSBT Board report May 2010

Answers to questions raised during a meeting on 13th July

1. What contemporaneous documentation do you have relating to the process of moving to the new computer infrastructure in 1999?

At the time of the SUI no documentation came to light despite a thorough search throughout the IT department. The move to the new computer occurred at a time when documentation and software change management and version control was weak.

During the period 2002 to 2007 a number of changes were implemented which mean that we now exert a greater degree of control over changes, with change request logging, software and documents version control, change histories, analysis reports, test plan approvals, release management processes and change implementation sign-off by management tiers.

2. Was it possible to identify the groups or individuals who were responsible for the programming error in 1999? If so, has disciplinary action against them been considered and what factors influenced the decision whether or not proceed with any action?

Yes it was possible to identify some individuals associated with the programming error. The case for disciplinary action was considered and rejected, taking account of advice from Human Resources experts. The reasons why there was insufficient evidence upon which to successfully pursue disciplinary action were documented. The major reason related to lack of information governance systems and inadequate management oversight rather than the omissions of one or two individuals.

3. The first partner organisation was MPL (now Advanced Data Services). What is their role?

Prior to 2001 a company called MPL (Manual Processing Limited) were contracted to key in data from Donor Registration Forms received by NHSBT (then UKT). From April 2001 that same role was performed by Cheltenham Data Services. On 1st April 2002 a Glasgow based company called Cendris was awarded the contract and in November 2007 the contract fell to Advanced Data Services (ADS), also based in Glasgow.

UKT staff used to drive the Donor Registration Forms up to Cheltenham for keying by the staff in Cheltenham Data Services. Couriers have been used since April 2002. Both the Glasgow based companies sub-contract the keying to offshore units. In the case of ADS, the current contract holder, they scan the Donor Registration Forms and send the electronic images to the Philippines on a Tuesday. The keyed data is returned to Glasgow the following Monday and NHSBT receives an emailed file that evening.

ADS are regarded as a Feed Partner even though their role is very different to other Partners such as DVLA or Boots. This feed is still often referred to as the MPL feed despite three companies performing this role since MPL.

4. Can you say more about the thinking behind the decision to start writing to first time registrants via the third party feeds in 2009. Was it primarily to check that the records were up-to-date or was it promotional? Could you supply a copy of what you sent out please?

In April 2006 NHSBT began writing to first time registrants who had registered by telephone or online, as a way to safeguard against the risk of false (malicious) registrations. In November 2009, after a change of management at the top of the NHSBT Organ Donation and Transplantation Directorate (ODT) in 2008, a new strategic direction was agreed whereby, over time we would seek to establish a connection with all registrants – building on the links we already had with those registering since 2006 online or by phone. The next phase covered all new registrants and the timing was arranged to broadly coincide with the launch of the first UK-wide organ donation public awareness campaign.

The initiative to contact new registrants was undertaken for the following reasons:

- To provide each registrant with a formal record of their registration - with the intention of reducing the number of duplicate registrations we experience;
- To provide a tangible card to carry giving details of registration - with a view to phasing out the paper donor cards which do not link to electronic registration;
- To record the registrant's specific registration details -to enable them to correct any errors and also so that they knew how to change their details at a later stage rather than re-registering;
- To thank them and to re-inforce the positive action they had taken by giving them information about the numbers of people awaiting organ transplantation;
- To remind them to tell their families of their decision; and to
- Ask them to encourage others to join the Register as well.

5. What groups of people on the ODR have not had a letter from NHSBT setting out the information NHSBT holds on their donation wishes? Do you have plans to write to them?

Anybody who registered via the telephone or online prior to April 2006, or via a third party partner feed prior to November 2009, will not have received a letter or welcome pack setting out the information held or the donation preferences registered.

Our long term aspiration is to introduce some form of contact with all those on the ODR, so that we can continue to highlight to them the importance of discussing donation wishes with family members, ensure their registration details are up to date, and perhaps ask for their help in supporting future national or local campaigns.

In time we hope to do this electronically but the cost of writing to all 17 million plus people, many of whom may have been on the ODR for many years and who may since have moved address, seemed disproportionate to the investment of public funds required. This decision was re-visited once we had seen the response rate from the 301,000 registrants we wrote to about potentially inaccurate data on their preferences. The 14% overall response rate re-inforced our feeling that this was not the best use of public money.

With the future development of the ODR, we aim to develop the register into a much more interactive database that would allow registrants to log in securely to their online record to update their personal details or donation preferences. This would significantly improve the accuracy of the data stored and would be much more cost effective than writing to all registrants. A project to scope a 'new' ODR is being progressed by NHSBT, and this initiative was contained in the next phase of the Strategic Plan before the SUI occurred.

6. Is our understanding correct that the 301,000 registrants you wrote to in May/June were all DVLA registrants?

All 301,000 registrants that we wrote to to check their donation preferences had registered at one point in time through the DVLA. For these registrations, we were not able to "reverse engineer" their records (i.e. correct them at source by working through an algorithm to correct the donation choice transposition) as all of them had registered multiple times through a number of different routes (including the DVLA), and therefore we could not assume with 100% certainty that "reverse engineering" the transposition error for the DVLA registration would change the records to reflect the wishes of these registrants. It was therefore decided that for these registrants, the best way to ensure that their ODR records reflected their current preferences, was to write to them.

7. The Human Tissue Act 2004 (S3(6)) says “appropriate consent” for transplantation and other scheduled purposes means “a decision of the deceased to consent, or a decision of his not to consent to it, was in force immediately before he died”. Where someone does not enter a tick indicating their willingness to donate all organs, you treat a tick in a box against the name of a specific organ as consent to the donation of that organ. How is the absence of a tick against a specific organ interpreted in those circumstances?

When an individual registers onto the ODR through a method that allows the registrant to choose specific organs (e.g. in the case of the DVLA), their ODR record reflects exactly which preferences they have registered. Where a registrant becomes a potential organ donor, this enables health professionals to discuss with family members the preferences for donation that were registered on the ODR. The absence of a tick for specific organs would be interpreted as that person’s preference not to donate other organs at the time of registering.

It is also important to note, however, that peoples’ preferences for donation do change, and discussions between health professionals and family members also take into account any knowledge the relatives may have of the person’s donation wishes from discussions that may have taken place more recently. In the absence of any knowledge of donation preferences, the ODR preferences usually guide family members’ decisions to agree to the donation of specifically indicated organs.

8. You say that after you began writing to third party registrants in November 2009 an increasing number of people contacted you to report an error or errors in their registration, and that these included incorrect names and addresses, confusion over the original registration and incorrect preferences. Can you explain the nature of these other errors in a little more detail please? Could you also please supply the absolute numbers who reported that their preferences were wrongly recorded, and as a proportion of the overall number of errors reported?

Amendments are received on a daily and weekly basis via post, telephone to ODT, the National Call Centre(NCC) and the website enquiries’ email service . These amendments include:

- changes to addresses or names when people move or marry
- corrections to errors made whilst registering or amending online e.g. date of birth or name
- corrections to errors made by agents at the NCC while taking telephone registrations or amendments e.g. names spelled incorrectly.

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The first letter to all new registrants was mailed on 19 November 2009. Prior to that, the number of amendments received from the NCC (people who telephoned amendments) and those we received through the mail were very small.

In the first three weeks of November we received 103 amendments from the NCC. These would have mainly been:

- changes to names and address.
- amendments to spelling mistakes made by NCC agents when taking information over the telephone
- amendments to mistakes made by people registering via the website – dates of birth etc.

The week commencing 29 November we received 178 amendments. These amendments included all the types of issues previously included above, plus additionally disputed registrations and changes to organ preferences.

October 2009	Number of amendments received	Number of changes to organ preference	February 2010	Number of amendments received	Number of changes to organ preference
	178	Approx. 12		615	Approx. 360

The above table shows the comparison between October 2009 and February 2010 and the increase in number was attributed to the fact that as well as an increase in registrations, more people were now receiving an acknowledgement letter.

9. You say that when errors started being reported you “traced issues via partnerships where registration was via a third party.” Could you explain in a little more detail what this involved please?

On receipt of any contact from a member of the public querying either their inclusion on the ODR (people often forget they have ticked a box) or their stated preferences, we checked the source of that individual’s registration or latest update. If the last update was via the web or through an agent at the National Call Centre we were generally able to resolve the query ourselves. If the registration or latest update had reached us via a feed partner then we contacted that partner to ascertain the original preferences stated on the individual’s paper form (driving licence application form, GP registration form etc)

10. When were concerns about the error first communicated to the senior management tier including the Chief Executive?

Following the introduction of contact with all new registrants in November 2009, NHSBT started to receive a number of responses from registrants related to errors in names and addresses, as well as to errors in the recording of donation preferences. As outlined above, each of these issues were investigated and in late December a trend started to emerge indicating a possible error in data received via the DVLA. This was duly investigated through detailed testing of file upload and processing within ODT and with the DVLA during January and February and everything was being uploaded and processed correctly. The possibility of a mismatch between output and input files was then suggested. The Director of Organ Donation and Transplantation was made aware of this possible problem on 10th March and immediately informed the Chief Executive and established a Serious Untoward Incident (SUI) group to take forward the detailed investigations and remedial actions that were required.

11. You say that as soon as you realised that there was an error in the transposition of data from the DVLA to the ODR you immediately suspended the upload of data from his source? When was that, and what is the latest position with data from that feed?

The DVLA feed was suspended from 12th March.

The latest position on the DVLA feed is:

1. Final testing of the DVLA feed was signed off on Friday 9th July.
2. NHSBT retrieved the file containing the backlog of DVLA records on 12th July. (842,073 records)
3. The file has been separated into batches of 50,000 records.
4. A 'backlog clearance schedule' has been drafted and aligned with the mailings plan (our schedules for issuing welcome packs to new registrants)
5. The ODR Steering Group led by a senior Programme Manager met and approved the plans on Friday 16th July.
6. Our target is to start processing the first of the 50,000 record batches from Monday 19th July subject to due diligence and risk assessments.

12. Did that suspension occur at the same time as your partial suspension of using the ODR for the purpose of informing consent?

Yes. The email carrying this note (regarding the suspension of the DVLA feed) includes an attached memo circulated to the Duty Office on the 12th March instructing staff to disregard the stated preferences if the registration source for a donor record was DVLA. Duty Office staff informed Transplant Co-

ordinators to explain to families that no preferences were known at that time and instead to confirm to the families that their relative had definitely registered to the ODR and wished to donate organs.

15 Have you considered an independent assessment of the adequacy of the new governance systems you have put in place?

We have made significant improvements in the controls surrounding any changes to the ODR and the data feeds from partner organisations with further work to be completed as set out in the action plan outlined under Q.17. These changes have been subject to review by our internal quality assurance team who will have a continuing role in reviewing further changes. We have also committed to an independent review of all the IT systems and related business processes and governance arrangements in use at ODT (items 11 and 12 in the action plan). We expect to use an external organisation to support this review and we have already had indication of support for this from the Information Commissioner's Office.

We are currently indentifying a suitable external organisation with substantial database management expertise to Quality Assure our revised processes once they are complete.

16. We haven't spoken to anyone at the DVLA to ask whether there is anything they would wish to bring to Sir Gordon's attention. Could you suggest the name and telephone number of a suitable contact please?

[details redacted]

17. Could you indicate which of the actions you have set in train are complete, and the proposed timings of other actions where this has been decided.

(see next page)

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)

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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 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.	Will be picked up as part the steering group plan.	Q1 2011
Ensure that a formal Quality Management System is implemented to assure the effective adoption of the RCA recommendations and	Resource identified from 1 August 2010 to commence implementation of QM	TBC

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compliance with the EU Organ Directive due to be implemented by July 2012.	system	
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