NHS Blood and Transplant

NHSBT Board
28 January 2016

Update on Serious Incident Requiring Investigation (SIRI) INC63390

Review of deceased organ donor typing processes following HLA type transcription error in the Birmingham Histocompatibility and Immunogenetics laboratory.

1. Status – Public

2. Executive Summary

This paper supplements reports previously provided to the GAC[1], Executive[2] and Board[3]. It provides an update on the actions undertaken to remediate the issues and risks identified in the course of investigating an HLA typing transcription error transmitted to Organ Donation and Transplantation (ODT) in September 2015.

3. Action Requested

The Board is asked to scrutinise the completed and ongoing actions in light of the risks and issues associated with this serious quality incident.

4. Background

At 20.15 hours on 15/09/15 a member of staff working alone and on-call in the Histocompatibility and Immunogenetics (H&I) laboratory in NHSBT Birmingham completed tissue typing on two deceased donors. The typing was completed correctly but, for one donor, HLA A*01 and A*31 was erroneously written on the form to be faxed to ODT; the correct result was HLA A*03 and A*31. The following day, in accordance with normal practice at the Birmingham laboratory, the raw data from the laboratory tests was checked, but the data entered onto the ODT form was not checked. On 25/09/15, NHSBT was informed of the error because of repeat testing at the NHS recipient centre laboratory. No harm occurred to the recipients; fortuitously they had all received compatible organs. The revised type did not affect the allocation sequence so no other potential recipients were disadvantaged. The incident was a near miss, investigated as a SIRI and reported to the Board.

The HLA typing process requires 3½ - 4 hours of laboratory work. The last half an hour involves interpretation of results and completion of documentation. Three

[1] Serious Incident Requiring Investigation INC63390: Organ donor transcription error in the Birmingham Histocompatibility and Immunogenetics laboratory. Report for the NHSBT Governance and Audit Committee, November 2015.

[2] Briefing Note. The Standardisation of Laboratory Procedures in Specialist Services, November 2015.

[3] Serious Incident Requiring Investigation INC63390: Organ donor transcription error in the Birmingham Histocompatibility and Immunogenetics laboratory. Summary report, NHSBT Board, November 2015.

transcriptions of data occurred per donor during the final half an hour, firstly from the analyser printout on to protocol sheets, secondly from the protocol sheets into the NHSBT laboratory information management system (LIMS, Hematos), and finally on to a form used by the ODT duty office. The data has to be entered onto the ODT form in a different order to that used for entering data into Hematos. The completed form is then faxed to the ODT duty office where staff in turn transcribe the data from the form into the National Transplant Database (a fourth point of transcription).

Until recently, the technologies available for the rapid HLA typing for deceased donors did not permit seamless data transfer, and therefore manual transcription is an unfortunate necessity. NHSBT is currently in the process of purchasing equipment that will remove the need for transcription (described later) for this type of testing, as part to a strategy to avoid manual transcription across its laboratories.

Contributory factors to the error included:

- The process has more than one transcription point per donor with the layout of the transcriptions being different (the order in which the results are recorded is different when entered into the laboratory information management system compared with the form transmitted to the ODT duty office).
- The operator was working on two donors simultaneously.
- The work was being undertaken out of hours by a lone worker who was working an additional session as a result of a staffing shortfall.
- While working on the testing process for the donors, the operator was asked by telephone by a Specialist Nurse in Organ Donation to provide the results as swiftly as possible for the potential heart donation.
- At the time, the operator was aware of the need for rapid provision of results but also of the risk of error which was stressful.

As an immediate remedial action the deceased donor typing processes in all 4 NHSBT laboratories have been reviewed. In addition, at the time of the incident, and pursuant to an earlier clinical audit of transcription errors[4], the Tooting H&I laboratory was piloting the effectiveness of a new approach for real-time checking of data entered onto forms to be faxed to ODT.

5. Update

Table 1 summarises the key lessons learned from this incident, and the actions investigated and/or implemented to mitigate associated risks.

[4] Audit of discrepancies in Histocompatibility and Immunogenetics reporting to Organ Donation and Transplantation (AUD2610). D Sage *et al* (2015)

Table 1

Key risks and issues identified		Mitigations investigated and/or implemented	Status	Note
Technology and process	H&I's rapid HLA typing technology requires manual interpretation and transcription and, hence, manual data entry onto ODT forms	Explore technological solutions to immediately automate the transmission of data to Hematos and/or ODT	Discounted as an feasible option following investigation by a senior IT solutions architect	1
		Bring forward a business case to procure and implement one or more platforms for rapid automated HLA typing; these platforms to be capable of transferring data to Hematos without human intervention.	EU tender and platform evaluation exercise completed; business case approved by ET in January 2016. Implementation to complete end Q2 2016/17.	2
		Make software changes to Hematos to allow ODT forms to be automatically completed.	In progress for May 2016 Hematos software release.	
	H&I laboratories did not have a "real-time" national approach for checking data entered onto ODT forms	Review the effectiveness of the checking system being piloted at H&I Tooting and, if effective, close pilot early and implement nationally. This involves a "real-time" double-entry data check of typing results by the operator at the time of testing. This process is supplemented with "next day" checking by an independent member of staff.	Implemented October 2015	3
	Staff in the ODT duty office transcribe data from faxed forms into the national transplant database (NTxD)	Use of double blind entry has resulted in no reported errors in the last 5 years; this will continue in the short term.	The ability to remove this final transcription step will be appraised as part of the ODT Hub programme with potential implementation by 2017.	
	There are no national standards for donor typing processes or reporting conventions	An expert group from NHSBT and non-NHSBT laboratories has been convened to assess donor typing processes nationally and to agree acceptable standards and reporting conventions.	The group's first meeting is on 6 January 2016 with a report due by mid-year.	

Human factors	Staff working alone and on-call may feel under pressure to type multiple donors concurrently to meet turnaround times; this may increase the likelihood of making an error	Staff have been reminded to type donors sequentially, that achieving accuracy is paramount, and to refer customers impatient for results to the on-call consultant scientist if necessary.	Completed November 2015	
	Working alone and on-call is stressful for some H&I staff; this may increase the likelihood of making an error	Seek staff-side support for a review of on-call rotas to ensure workload is shared equitably among qualified staff	Agreement secured, revised rotas to be considered by end January 2016.	
		Undertake review of working practices in H&I, giving consideration to extending the working day to reduce the amount of work performed on-call (i.e. as per RCI)	Working group recommendations due Q1 2016/17	
	There may be scope to introduce novel approaches to further reduce the likelihood of human error	Work with other organisations, especially air traffic control, to train staff in observational techniques and human factors and to identify opportunities for future error.	First workshops and training planned for Q4 2015/16.	

Notes.

1. The automated platforms currently in use in NHSBT's H&I laboratories are not capable of completing HLA typing of deceased donors within three hours; hence more manual but more rapid techniques have been used to date.
2. Several new automated platforms capable of typing deceased donors within three hours became available during 2014 and 2015.
3. The checking step developed at Tooting requires the lone worker to a) print the report destined for ODT, b) to compare the report with the raw data from the test platform (ticking each result as correct in turn), then c) re-printing a clean report to fax to ODT. This process is supplemented with "next day" checking by an independent member of staff. An internal control is also included in each assay to provide assurance that the tests have worked correctly. NHSBT also partakes in an external assay assurance scheme (NEQAS) for test calibration.

Two reviews will be conducted during 2016 to further assess the effectiveness of current and proposed processes. First, an internal clinical audit will be performed towards the end of 2016 to confirm the performance of the new rapid HLA typing platforms due to be implemented by July 2016. Second, Professor James Neuberger has asked for a review with the aim of ensuring the safe, efficient and effective HLA typing (from NHSBT and non-NHSBT laboratories) of donors in the UK.

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