NHS BLOOD AND TRANSPLANT

28 MAY 2015

CLINICAL GOVERNANCE REPORT

1. INCIDENTS AND ADVERSE EVENTS

1.1 Serious Untoward Incidents

There have been two new Serious Untoward Incidents (SUIs) since the last report. One occurred in the Bristol Eye Bank (BEB) prior to its transfer to NHS Blood and Transplant (NHSBT) Tissue Services. The second SUI occurred in the Blood Supply (BS) Directorate and relates to a needlestick injury.

Diagnostic and Therapeutic Services SUI:
On the 1st April 2015, managerial and legal responsibility for BEB transferred from the University of Bristol to Tissue Services, as the University no longer wished to provide the service. Prior to this date, BEB was commissioned by Organ Donation and Transplantation (ODT) to receive, process, store and assess ocular tissue for transplantation. On the 21st March 2015 the Designated Individual for BEB informed NHSBT's Tissue Services of a decision to cease the processing and issue of ocular tissue following a series of episodes of microbial growth identified as a result of routine monitoring of corneas. There were three instances of contamination detected by routine microbiological testing of the dextran medium which corneas are transferred into shortly prior to transplantation. The same fungal species, *Scopulariopsis gracilis*, was subsequently isolated by Public Health England's (PHE) Mycology Laboratory in all three samples.

In one case, the contamination was evident before the cornea was despatched to the recipient hospital so the cornea was not transplanted. In the other two cases, the contamination became evident only after the corneas had been transplanted. The surgeons were informed as soon as contamination was detected. One of the patients developed an infection and the surgeon decided to remove the graft. The infection has been successfully treated and the patient will receive a new graft once they have been infection-free for six weeks. NHSBT will provide the new graft free of charge. There have been no signs of infection in the second patient, and no growth in the routine samples sent at time of surgery.

All corneas (72) in BEB that passed repeat microbiological testing were sent to Manchester Eye Bank (MEB) following a risk assessment to increase their stock availability. Staff from NHSBT Tissue Services and BEB were transferred to Manchester to supplement local processing capacity. The BEB site was handed over to contractors for remedial works to commence. It was anticipated that BEB will re-open during the week commencing 9th May 2015; however, this was delayed due to issues identified in environmental monitoring. It is now anticipated the site will re-open week commencing 18th May 2015.

Approximately 50% of the corneas sent from BEB to MEB to bolster their stocks failed the final Quality Control check prior to release (cell count). The reason for an increased failure rate at this stage is unclear; however, it is likely to be attributed to the movement from Bristol to Manchester. Due to this increased failure rate, MEB had insufficient supply to meet demand for orders week commencing 26th April

2015. However, stocks are now sufficient to meet future demand. Nine operations had to be postponed.

The governance of the supply of ocular tissues from BEB has been streamlined and as of 1st April 2015 it became the responsibility of NHSBT Tissue Services. The licensing and management of the BEB and MEB has been transferred to Tissue Services with the Director of Quality becoming the Designated Individual for this activity. The MEB will be remaining in its current location in Central Manchester Foundation Trust. The BEB will remain in its current facility until it is moved to Filton in September/October this year.

Blood Supply SUI:

On the 16th April 2015, NHSBT were informed that a ten year old child acquired a needle stick injury after finding a needle in a school hall during a PE lesson. A blood collection session was held at the School on the 10th April 2015 and therefore it was thought to be a needle used by NHSBT left behind after the session. After several discussions with the School's Head Teacher it has been confirmed the needle found had both caps present and the needle guard was not engaged (i.e. it is very unlikely the needle had been used).

NHSBT has been in contact with PHE regarding the incident and advised them of the belief the needle was unused. PHE have completed their own risk assessment and advised the child's GP that the child should receive a course of Hepatitis B vaccinations.

The incident has been reported to the Health and Safety Executive due to an injury to a member of the public resulting in treatment. A written apology has been sent to the School and to the family involved, via the School; with an offer to meet with the family and the School.

The root cause of the incident was the local process used to decant haemoglobin testing material into a box that was not fit for purpose; allowing a needle to fall out of a box unnoticed. This practice has now been discontinued, with immediate effect, across all teams that were still practising in that way. A new process, which was already planned, is being implemented over the next week. The School has been informed of the new process, and has granted permission for NHSBT to collect blood there again as planned on 17th May 2015.

Serious Incidents overview

The total number of serious incidents reported during the financial year (2014/2015) is six. A breakdown of the category applied to the incidents reported is presented below. A full annual report will be presented to the June Governance and Audit Committtee (GAC).

Period	Serious Untoward Incident (SUI)		Never Event		Potential Significant Harm Incidents (PoSHI)		Recognised Serious Complication Incidents (RSCI)	
2014 / 15	1	▼	0	►◄	4	▲	1	▼
2013 / 14	2		0		3		9	

Table 1: Total number of serious incidents reported in 2014/15

Directorate in which serious incidents occurred during 2014/15

Directorate	SUI	Never Event	PoSHI	RSCI
BS	0	0	0	0
DTS	0	0	3	1
ODT	0	0	1	0
Clinical – International Blood Group Reference Laboratory (IBGRL)	1	0	0	0
TOTAL	**1**	**0**	**4**	**1**

Table 2: 2014/15 Serious incidents by Directorate

1.2 *Donor and patient adverse events/reactions*

The numbers of Serious Adverse Events of Donation (SAEDs) and Patient Adverse Events (PAEs) are reported below for the most recent 16 months up until the end of March 2015. No unusual trends have been noted.

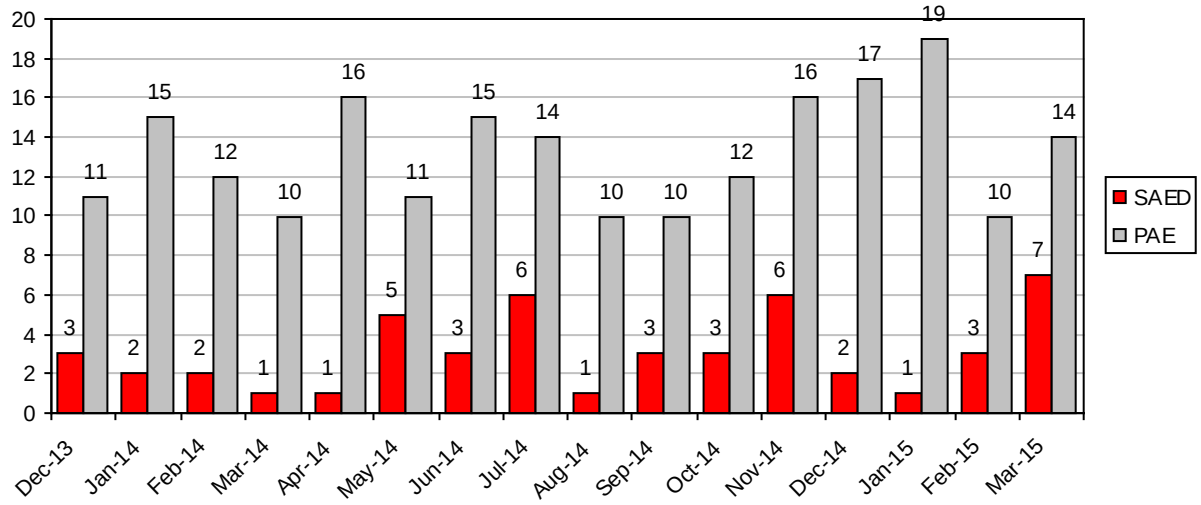


Figure 1: Numbers of SAEDs and PAEs

1.3 *Never Events*

The Department of Health (DH) has updated the list of never events for 2015/16. The changes that impact NHSBT, are the removal of air embolism as a never event, and the merger of two previous never events into one; Transfusion or transplantation of ABO incompatible blood components or organs. In 2014/15 no never events were reported by NHSBT.

2. CLINICAL AUDIT

2.1 Summary of annual programme

The annual clinical audit programme is informed by high risk areas on the risk register. All links to the risk register are listed in the annual programme and within each audit report. A system to risk assess the outcomes of clinical audits has been piloted and will be incorporated into all clinical audits on the 2015/16 programme;

ensuring a focus on risk throughout the clinical audit process. In 2014/15 there were 66 programmed audits in total; 31 were new audits added, and 35 were carried over from the previous year. At the end of 2014/15; ten clinical audits had been completed, eight were on hold, one had been removed, eight had not started, and 39 remained in progress. For those clinical audits which have been completed there are currently no overdue actions.

Development of the clinical audit annual programme for 2015/16 has been delayed; the programme will be finalised and submitted to July Clinical Audit, Risk and Effectiveness Committee (CARE). It has been agreed the programmed audits will in future be prioritised, with one being the highest priority; with a commitment those will be completed within year and have full support of the clinical audit team. It was agreed going forward new annual clinical audit programmes will be developed and submitted to March CARE meetings for approval.

2.2 Clinical Audit Final Reports

One clinical audit report has been approved by DTS Care since the last report; Audit of Patient Identification (ID) within Bristol Therapeutic Apheresis Service (TAS). The Bristol TAS unit provides a variety of therapeutic procedures with each nurse providing care for multiple patients. It is important all patients are identified correctly to avoid errors which have the potential to cause any harm to patients. The aim of the audit was to provide assurance that medical error and patient harm relating to misidentification is well mitigated, and that identification wristbands are removed with appropriate disposal. The key findings of the audit were:

- In all cases patient ID was confirmed on arrival and at each administration of medication / treatment
- In all cases the patient was wearing a correctly completed ID wristband
- In all cases the patient's preferences, medication, or allergies were identified
- In all but two cases the ID wristband was disposed of on leaving the unit; in both cases where that did not happen, the patient returned the following day for a second procedure after which the wrist band was removed appropriately.

The audit was undertaken to seek assurance, and full assurance was provided.

3. CLINICAL RISKS

The number of risks on the corporate risk register, for which the dominant risk is clinical, is 40; this is an increase from 36 reported in the previous report. Of those, nine continue to have a residual risk of 15 or above. The reason for this increase in the number of risks is due to an error rather than an actual increase in the number of risks. A column had been left blank on the corporate risk register which led to the following four risks not been included in the figures in the last report:

- Incompatible product transfused / transplanted (A-PS-08)
- Blood donors will be harmed through NHSBT activity (BSC-01)
- Failure to supply blood product (BSC-02)
- A transfused product will result in the transmission of disease (BSC-03)

One risk has reduced the residual risk from twelve to eight; there is a risk that additional savings may need to be found over-and-above existing cost improvement plans in ODT operational budgets in 2015-6

A risk relating to the supply of Human Albumin Solution (HAS) had been placed on the DTS Risk Register and was raised at CARE. The issues surrounding supply are complex, however, the current risk centres on the decision of Bio Products Laboratory (BPL), as of the 29th April 2015, to not accept any further orders for 4.5% HAS until October 2015. This particularly affects NHSBT's TAS Units in the North, as units in Bristol and Oxford are supplied by CSL, which can continue to provide supplies. The Chief Nurse, DTS, has worked closely with BPL, CSL, and the DH Commercial Medicines Unit (CMU) to better understand the situation, and to ensure NHSBT's host Trusts have contingency plans in place to minimise the risk of plasma exchange treatments being affected. This situation is being closely monitored by the Chief Nurse, DTS. It should be noted that plasma exchange for the most urgent indication is not affected, as Octaplas (solvent-detergent fresh frozen plasma) or standard fresh frozen plasma are the products of choice in this situation.

4. ALERTS, GUIDANCE AND REGULATIONS

Since the last report, guidance from the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) has been published which is relevant to NHSBT; 'Current measures to reduce the risk of Variant Creutzfeldt-Jakob Disease (vCJD) transmission by blood'. This is a position statement on current measures and no new actions are required.

The National Institute for Health and Clinical Excellence (NICE) have issued a total of 34 documents since the last report; no specific action is required from NHSBT in relation to the guidance published. However, BS CARE are considering how NHSBT can support the NHS with the wider health promotion strategy in relation to:

- Physical activity: encouraging activity in all people in contact with the NHS
- Smoking: reducing tobacco use
- Maintaining a healthy weight and preventing excess weight gain among adults and children.

No alerts issued by the Central Alerting System (CAS) required action from NHSBT.

Duty of Candour (DoC) Audit

The audit, as requested by the Board, has now been completed and presented to May CARE. Three incidents which occurred during 2014 were reviewed as part of the audit; however, only one of the incidents occurred after the commencement of the statutory DoC; the other two incidents were included to increase the learning opportunity from the audit.

Compliance with six elements of the regulation were audited. Four of the areas were rated as green, and two rated as Amber. The elements rated as Amber were, the requirements to provide reasonable support to the relevant person, and to provide an accurate account about the incident as at the date of the notification. The amber ratings were based on the information recorded within the written correspondence and within the investigation report. Following subsequent discussions with the investigation lead, it is understood the requirements had been met but not sufficiently well recorded within the investigation reports. After discussion at CARE, the following actions were agreed:

Requirement	Recommendation	Timescales
Support organisational awareness of the DoC requirements and process	The Clinical Quality and Compliance Manager to develop and implement a Being Open policy document which includes compliance with Duty of Candour.	Draft to go to July CARE for approval
Clarify the steps to be taken within directorates, when the need to inform a donor or hospital of an error is identified or suspected	The Clinical Quality and Compliance Manager to communicate with directorates, via CARE Groups and reinforce NHSBT's approach to managing notifiable safety incidents, ensuring the requirements of notification, documentation and gaining adequate assurances when communication is shared with other clinical teams, are addressed.	June CONNECT
Highlight and discuss the complexities unique to NHSBT with regard to some elements of the Duty of Candour, with CQC and other responsible organisations. This specifically relates to NHSBT's contact with a patient always being via their clinician	The Assistant Director - Governance and Clinical Effectiveness engages in discussions with the Department of Health, NHS England and the Care Quality Commission, clarifying the potential complexities for NHSBT and agrees an accepted way forward. This agreement to be included in the Being Open Policy and communicated to the directorates.	End of July 2015

It was agreed at CARE the Assistant Director (AD) of Governance and Clinical Effectiveness will work with the directorates to understand how they currently operate regarding DoC, and agree across the organisation an appropriate and pragmatic way to be open and honest, and ensure compliance with DoC; allowing for individual directorate requirements. This will then be presented to the Care Quality Commission (CQC) as the proposed approach, and the discussions with the CQC will focus on regulated activity within NHSBT. The approach agreed will form the basis of the Being Open Policy.

5. CLINICAL CLAIMS AND INQUESTS

5.1 Clinical Claims

An update of the new, settled, and on-going clinical claims is shown in table 3 below. The clinical claims annual report was presented to May CARE.

	2013/14 01.04.13 - 31.03.14	2014/15 01.04.14 - 31.03.15
Ongoing at start of period	16	19
New claims	16	16
Settled claims	9	5
Withdrawn claims	4	3
Active claims at end of period	19	27
Total damages paid (£) (NHSLA)	272,000	22,500 (2,000 pending)
Total damages paid (£) (NHSBT)	23,700	21,318.54
Total claimant legal costs paid (£) (NHSLA)	nil	20,950
Total claimant legal costs paid (£) (NHSBT)	31,600	11,000

Table 3: Clinical claims for 2013/14 and 2014/15

In 2014/15 NHSBT were notified of five new clinical claims, three in ODT (one was subsequently withdrawn) and two in BS. No new notifications were received in DTS. At the end of 2014/15 six clinical claims remain on-going in ODT, three in BS, and one long-standing claim in DTS. A full report will be presented to the September GAC.

5.2 Inquests

Cardiff (Ref: INC 423)
The H. M. Coroner's report in this case has now been published on the Courts and Tribunals Judiciary website: https://www.judiciary.gov.uk/subject/prevention-of-future-deaths

A summary of NHSBT's response to the report is as follows;

The coroner raised concerns that the Core Donor Data Form (CDDF) contained insufficient clinical information regarding ongoing donor investigations, and that NHSBT had failed to pass on relevant microbiology results to the transplanting team; which could have aided their decision making process. In response, NHSBT advised the coroner of its firm view that all relevant information known at that time was transmitted to the transplanting centre.

The coroner also recommended that NHSBT employ systems to ensure the capture and transmission of all relevant clinical information, and that all Senior Nurses – Organ Donation (SNODs) should certify, if required, that all relevant information has been transmitted. In response, NHSBT advised of the January 2015 Board approval of expenditure to change the way in which donor data is recorded and transmitted. This aims to reduce the risk of transmission error and will be fully operational by April 2016. NHSBT advised that the SNODs are not able to provide certification as suggested and that problem could only be overcome by a UK-wide single unified system.

Human Leucocyte Antigen (HLA) Error (Ref: ODT INC 218)
The patient who received a heart transplant following mis-communication of HLA results in the Duty Office has sadly died. The inquest on this death is listed to take place on 20th and 21st May 2015. H. M. Coroner has called three NHSBT employees to provide evidence in person; the duty officer, the duty office manager and Director ODT. Concerns have been raised by the family's solicitor that NHSBT failed to adequately investigate this incident, having classed it as a PoSHI rather than a SUI (classed as such because no immediate harm arose). NHSBT refute the allegation. In light of this, H. M. Coroner has also requested a statement from the HTA's Director of Regulation, which supports the action taken by NHSBT.

6. COMPLAINTS AND COMPLIMENTS

6.1 Complaints

a) Blood Supply

Two complaints have been received during this period. A donor was upset they had been retired due to age criteria, and following further discussions with the donor, it also became clear they were unhappy regarding the lack of sessions in their area, and the lack of communication regarding the retirement. The donor has been contacted and apologies and explanations provided. The donor remains withdrawn.

A donor was upset at a standard letter they received informing the donor of the fact their recent platelet donation had a technical problem in which not all white blood cells were filtered out. The donor has been reinstated but as a whole blood donor.

b) Diagnostic and Therapeutic Services

Blood component related customer service issues were assessed in conjunction with voice of the customer surveys and a number of actions are planned to address the issues raised, particularly in relation to logistics**.** The Manufacturing department are amending their processes to reduce the number of complaints received that cryoprecipitate is found to have lumps in it on thawing in hospitals.

c) Organ Donation and Transplantation

There were eleven complaints in February and 9 in March; ten complaints were associated with the Organ Donor Register, and two regarding the Welsh opt out, which are fed back to the Welsh Government. No significant trends were identified.

An organisation-wide review of complaints is being led by the Communications Department; this will ensure donor complaints with a clinical element are seamlessly handled.

6.2 Compliments

BS received a thank you from a donor who was taken to hospital following donation, noting the first rate care and attention they received, and friendly nurses who showed real concern at a busy session.

Therapeutic Apheresis Services received thirteen compliments, nine from patients, one from a donor, two from service users (hospital clinicians), and one from a person who was given a work experience opportunity.

7. KEY ITEMS FROM DIRECTORATES SINCE THE LAST CLINICAL GOVERNANCE BOARD REPORT

7.1 Blood Supply

a) Medicines and Healthcare Products Regulatory Agency (MHRA) inspections:

The Blood Donation teams were commended by MHRA inspectors at both Leeds and Brentwood for their skill and knowledge. One major finding was received at the Colindale inspection for NHSBT's temperature mapping procedures across many departments in BS.

b) Serious Adverse Blood Reactions and Events (SABRE):

Two SABRE reportable events have been recorded in the reporting period:

1. A hospital was issued with a red cell pack with a radsure label indicating it had been irradiated but as it did not go through the correct PULSE stages, therefore, the product description was not shown as irradiated. There was no patient impact
2. Platelets sent to Southampton were packed using cooled phase change material instead of warm phase change material. A total of 43 units were implicated and discarded. This was caused by the task was not being carried out in designated area and the fact that there is no single defined process for completing this task, a contributory factor was that it occurred at the end of a 12 hour shift. A national committee was held and it was decided the units should be discarded.

c) Transfusion Transmitted Infections

The probable bacterial transmission from platelets previously reported has now been confirmed as coming from the platelets.

A case previously discussed at CARE (INC55555) has now confirmed the transmission of Hepatitis E Virus (HEV) through Fresh Frozen Plasma (FFP) given to a recipient with underlying chronic liver disease. The patient has recovered.

d) Approved research projects

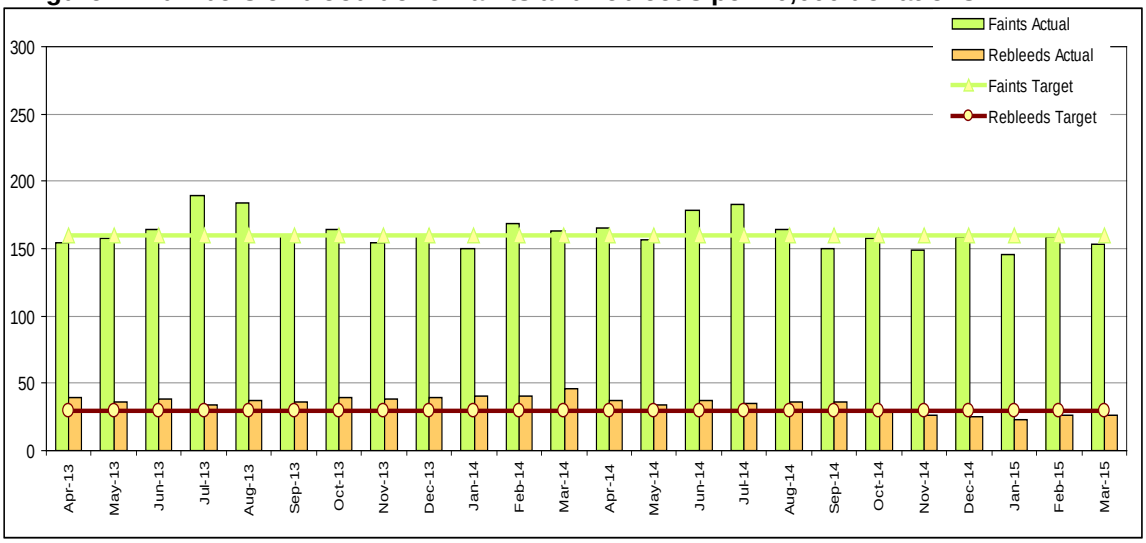
Approval has been given to two research requests; University of Oxford: Development of novel diagnostics and cellular therapies, and the University of Cambridge: INTERVAL participants to NIHR BioResource.

e) It was highlighted that the majority of SAEDs were due to delayed faints and they were all female donors. It was agreed to follow up if we fully understand the number of people who donate and then don't re-attend due to the fact they feel unwell after donation.

7.2 *Donor Adverse Events*

Numbers of blood donor faints and rebleeds per 10,000 donations are shown in figure 2 below. The incidence of rebleeds continues below target, and the faint rate continues to be monitored carefully. The need to reinforce muscle tension exercises at sessions was agreed at CARE.

Figure 2: Numbers of blood donor faints and rebleeds per 10,000 donations



Some adverse reactions are reportable to the MHRA and some to the HTA. These adverse reactions are reported in the Management Quality Review.

7.3 Diagnostic and Therapeutic Services

a) The stock from the Heart Valve bank in Bristol University which closed earlier this year, was transferred to Liverpool and stored by NHSBT. The valve tissue is being reviewed for suitability of issue. The Bristol Heart Valve bank used to provide pulmonary patches, a tissue that NHSBT has not previously provided, and appropriate approvals are being sought from the HTA to provide this tissue.

b) The IBGRL Reference Services and Diagnostic Development moved into the Diagnostic and Therapeutic Services Directorate on 1st April 2015. This will facilitate improved marketing including new services.

b) During an extracorporeal photopheresis procedure, the machine appeared to fail to detect air in the line. The procedure was aborted immediately and the patient was seen by the consultant and the registrar who explained what had happened. There was no harm to the patient who attended again the following day for another procedure. It has since been confirmed by the Manufacturer that the air detector was in fact fully functional, and the air observed was a combination of a very small pocket of air and very clear fluid, and there wasn't a risk to the patient. This has been communicated to staff and the staff member who identified the perceived risk has been praised for their vigilance and swift action. This incident has been reported to and closed by the MHRA.

c) DTS participated in a multi-agency Serious Incident Review facilitated by the Yorkshire and Humber Clinical Commissioning Group following the death of a 52 year old patient with Thrombotic Thrombocytopenic Purpura (TTP). Whilst there had been no fault/error with NHSBT's actions leading up the tragic incident, this was an opportunity to learn from the incident in partnership with other organisations, and share that learning across NHSBT and those partner organisations. There has now been a further TTP death in the same Trust at the commencement of plasma exchange. Again we are working with the Trust to investigate.

7.4 Organ Donation and Transplantation

a) No SUIs or PoSHIs have been reported since the last ODT CARE meeting.

b) Following full review by both ODT and the HTA, 10 Serious Adverse Events (SAEs)/ Serious Adverse Reactions (SARs) have been reported to the HTA under NHSBT's assisted function role (please note not all SAE/SARs implies there was an error by NHSBT or other staff). The majority of these were related to organ damage during retrieval leading to the organ being deemed as untransplantable. This number has increased, possibly as a result of greater awareness of the need to report, however, this trend will be closely reviewed.

c) There was a significant decrease in incident reporting during February 2015. This decrease will be monitored; however it is felt, this may be associated with a reduction in organ donation, retrieval and transplantation activity.

d) The incident reporting on-line form has been revised to improve ease of use and improve trending.

e) A risk was raised regarding the difficulties in providing the transplant centres with the patient assessment documentation. Due to the need to avoid transmission of data by fax, which is soon to be removed as an option, a solution has been proposed to include this document in the transplant boxes at the time of transplantation; however, this practice needs to be revised as it is associated with numerous risks. An interim measure, which is being rapidly evaluated, is to use a scanning application via the iPad to scan the patient assessment and send it to the transplant centres via email. This interim measure will commence on the 1st June 2015. Options regarding including the documentation within the Electronic Offering System (EOS) are currently being explored. Whilst the risk of not sending the patient assessment documentation at all to the transplant centres is of course a significant risk, the above solution and interim measure is felt to also contain significant risks.

8. OTHER

a) Information Governance (IG)

In 2015 NHSBT scored 88% on the IG Toolkit compared to a score of 94% in 2014. A workplan is being developed which will be based on the key priorities to be identified for IG across the organisation, and the key risks. This workplan will be developed in partnership with IT, to support the delivery of the wider IT change programme.

b) A Human Factors workshop, facilitated by an external provider, is being held on the 8th June, which will include representatives from all the directorates.

c) The Nursing Leadership Team has been linking with PHE, with the aim of learning from them as an early adopter of Nurse Revalidation, and work is underway to prepare for its introduction in April 2016. A gap analysis has been undertaken regarding the revised NMC code of practice. NHSBT Chief Nurses are hosting a visit from the Chief Nurse of PHE this month.

d) Penrose Inquiry. A draft of the key points made by Penrose and current practice in relation to them has been completed and, following consultation will be signed off by CARE and reported to the July Board.

9. SAFETY

9.1 SaBTO

A. Hepatitis E Working Group

The SaBTO working group on HEV presented its report, conclusions, and recommendations to SaBTO in April 2015. It emphasised that in the UK, and internationally, the situation and knowledge of the virus were evolving rapidly. It is estimated that up to 400 transmissions/year may be occurring; most of these cause no harm and are rapidly cleared. However, HEV may become chronic in immunosuppressed patients, and can progress to liver damage; the frequency with which this happens is not clear yet. A major issue is that most infections in donors and recipients come from ingestion of infected pork products; therefore transplant patients need dietary advice for as long as they are on immunosuppressive drugs. A cross- government meeting is planned in June to consider these issues.

The committee agreed that further work was needed to formulate costed option plans to test donated blood (both universal and selective screening), organ/stem cell donors and/or transplant patients. It was agreed that this should be progressed before the next planned meeting in September, led by Professor John Cairns, the Health Economist on SaBTO. Additionally SaBTO agreed with the working group's recommendations that:

a) Awareness of HEV needs to be increased amongst clinicians treating transplant patients, pregnant women, neonates and transfusion-dependent patients
b) No specific mitigation steps are needed for recipients of tissues (consider pancreatic islets and hepatocytes as organs), gametes or embryos
c) A plan with timelines should be prepared by NHSBT/other UKBS/PHE and clinical teams to gather information on:
    - HEV acquisition, chronicity and clinical sequelae in transplant recipients
    - Feasibility and effectiveness of testing of transplant recipients e.g. by testing all living recipients once
    - The changing epidemiology in blood donors
    - HEV acquisition in transfusion-dependent patients and transfused neonates/ children
    - Effectiveness of pathogen inactivation methods for platelets and FFP.

Work being undertaken within NHSBT is largely in support of SaBTO:

i) Work to develop costed options to test donated blood, led by Assistant Director – Manufacturing Development, Dr Stephen Thomas. This group includes representatives from other UK and international blood services
ii) Testing of transplant/stem cell transplant recipients and/or donors co-led by Professor James Neuberger
iii) Research studies as outlined above are being led by NHSBT/PHE Consultant Virologist, Professor Richard Tedder

In addition, NHSBT are seeking legal opinion regarding our liabilities if SaBTO does not recommend blood donor screening, and are using our safety framework to consider options.

B. Donor Compliance Study

Initial analysis of results was presented to SaBTO at the April 2015 meeting. Due to the volume of data gathered, detailed analysis will continue over coming months, a further update will be presented to SaBTO at a later meeting. Of particular interest were questions related to travel history, drug use, and sexual practice. Data gathered relating to policy e.g. travel and piercings will be fed back to JPAC

for consideration. The full report will be considered by JPAC and individual Blood Services.

8.2 Bacterial Risk Reduction

Since bacterial screening of platelets began in 2011, there have been 3 near-miss events and one confirmed non-fatal bacterial transmission. This transmission rate of approximately one in one million units tested is in the expected range. Since our contract for bacterial screening is due for renewal, we are considering pathogen inactivation of platelets as an alternative and obtaining costings for both screening and inactivation. Options will be assessed using the Safety Framework to demonstrate the costs and benefits of moving to an alternative bacterial risk reduction method, before a recommendation to the Board.

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