NHSBT Board
May 25 2016

Clinical Governance Report

1. Status – Public

2. Executive Summary

This paper reports on the key clinical governance areas discussed at the May Clinical Audit, Risk and Effectiveness Committee (CARE), progress on risk management and incident reporting, and provides an update on safety policy matters.

3. Action Requested

The Board is asked to:

- Note the contents of the paper and agree any further actions if required.

4. Open Serious Incidents Requiring Investigation (SIRI)

4.1 There have been two new SIRIs since the last report.

4.2 INC67700 Diagnostic and Therapeutic Services (DTS) Two stem cell donor transcription errors (Histocompatibility and Immunogenetics (H&I) laboratory). Human error occurred in undertaking a complex transcription which was not identified during subsequent checks, lack of a suitable environment for undertaking uninterrupted activity was identified as a contributory factor. No patient harm has occurred. One transplant was delayed by a month but has now been performed. The transcribed cumulative reports have been discontinued, an office which provides a suitable environment for reporting has been identified and it is anticipated that an automated method for producing cumulative transplant reports from Hematos will be in place by November 2016.

4.3 INC INC68445 (DTS) A patient with sickle cell disease developed a sickle crisis post-delivery and required transfusion from the rare frozen blood bank. She developed hyperhaemolysis and sadly died despite all treatment efforts. The incident was was classified in the local Trust as a 'high level incident'. Notifications were sent to the Coroner and SHOT. Initial NHSBT investigations were to confirm that the best matched products were transfused and made available as timely as possible. NHSBT were involved as clinical experts at time of treatment and is supporting the Trust investigation. Initial indications are that there is no error on the part of NHSBT and that the quality of care and advice provided was of a high standard. It is expected that post investigation the SIRI will be downgraded to a major incident.

4.4 The serious incident process and terminology is being updated in line with NHS England. A paper will come to June GAC and final recommendations to July Board .

5. Donor adverse events/reactions

A total of seven Serious Adverse Events of Donation (SAED) occurred since the last report; none were first time donors. Three SAEDs had a definite link to donation; a hospital admissions post fainting, and two donors with fractures; and the remaining four SAEDs had a possible link to donation. All donors have been withdrawn from donation.

6. Clinical Audit Programme

6.1 There were 11 overdue clinical audit actions; 7 in Blood supply (BS) and 4 in Diagnostic and Therapeutic Services (DTS) in this reporting period.

6.2 DTS- Peer Review of Surgical Donation for Clinical release (AUD 2371): The audit has highlighted very good consistency between Regional Tissue Donation Managers (RTDMs) for the clinical decision regarding outcome.

6.3 Blood Supply (BS) Audit of Session Day - Session Layout (AUD2600): This audit was undertaken to measure whether the session layout fulfils its purpose.. The layout in place at the session adhered to the layout plan in 96% of cases. However where a change to the session layout was required, it was only correctly recorded in 20% of cases, so improvement in documentation is required.

6.4 BS Audit of Extended Phenotyping (AUD2605): This audit examined whether the optimal extended testing (full phenotyping) of blood for patients with sickle cell disease and those requiring rare types of blood occurred to minimise the risk of alloimmunisation. A revision of MPD83 and has already been completed to include standards for full phenotyping of donations from all new and existing BAME ethnicity codes. Changes, including actions both proactive and reactive to address the issues identified have been implemented since the undertaking of the data collection for this audit and current practice has changed as a result. Repeat auditing is planned against the MPD later this year.

7. Clinical risks.

The number of risks on the corporate risk register, for which the dominant risk is clinical, is 46; no increase from the previous report. There is one amendment within the March 2016 register, which is the reduction to the risk score of risk X-ICT-029 (business change) which has been revised from a residual score of 12 (December 2015) to a score of 8.

8. Alerts.

A total of seven alerts were issued via the Central Alerting System (CAS); none was relevant to NHSBT. A total of 49 documents were issued by NICE; 40 required no action and 9 were considered possibly relevant and underwent review, but no required changes to practice were identified.

9. Complaints and commendations.

9.1 In BS there were no serious complaints or commendations reported.

9.2 In ODT there was an increase in complaints received during 2015/16. Total numbers received 334; the majority related to changes in Welsh Legislation. A number of complaints related to the letters sent to those who had opted out; responses to these complaints are managed by NHSBT. Any complaints relating to the legislation directly are managed by the Welsh Assembly.

9.3 In DTS the hospital complaints, both total and major, have fallen since a peak in July and remain stable. The content of reports and turnaround time of diagnostic reports were highlighted as low scoring areas in customer surveys. User group feedback has been taken into account in the wording of reports but some recent changes are based on updated national guidance and this has been fed back to users. A number of compliments have been received from hospitals about Customer Services, RCI and H&I.

10. Blood supply.

10.1 An assessment has been undertaken across BS toidentify any areas in which transcription errors could potentially occur. A collated list of aeas where transcription is undertaken will be reviewed at the next Blood Donation (BD) and Manufacturing and Logistics (M&L) SMT meetings to establish levels of risk and prioritise areas for action.

10.2 A Root Cause Analysis (RCA) has been held for an incident where air was seen in an apheresis line. There were no implications for the donor as the procedure was immediately discontinued. The risk register has been reviewed and guidance for teams will be formulated. The case will be discussed with the Chief Nurse DTS to review any similarities to a previously reported case in Therapeutic Apheresis Service (TAS).

10.3 Proposals to stop testing underweight packs for markers of infection and blood groups have been approved in principle, subject to donor acceptibility.

10.4 A switch from Chloraprep wands to Chloraprep FREPP for arm cleansing and for the removal of sterile versions of swabs and finger prick plasters have been approved.

11. Organ Donation and Transplantation.

11.1 There has been an increase in incidents reported over the past five months, largely in the Donation area. The next ODT Care will include an overview of incidents reported during the year, focussing on those classified as “amber”, to identify key themes, trends and action plans.

11.2 A recommendation from a previous incident regarding positive Candida cultures from organ transport fluid was that routine testing of the fluid be considered by the National Retrieval Group.. Consensus has not been reached, with 50% of retrieval teams currently undertaking routine testing.

Therefore the issue has been taken to the Advisory Group Chairs for timely decision making.

12. Diagnostic and Therapeutic Services.

12.1 There was been one case of Transfusion Related Acute Lung Injury reported year to date.

12.2 Recent slow functioning of the laboratory information management system Hematos has affected the efficiency of the functions that use it with a potential impact to patient care; however there have been no specific incidents. This issue has been added to the DTS Risk Register.

12.3 A new rapid automated system for typing deceased donors has been procured and will be operational in all H&I laboratories by August 2016. This will improve turnaround time substantially and reduce errors of transcription.

13. Information Governance (IG).

The IG Sub-Committee (IGSC) has approved a number of new or updated IG policies. The IG Toolkit Submission occurred on time and an overall 'Satisfactory' status was attained, along with a score of 82% compared with the target of 81%. PwC will audit the submission as part of the internal audit annual plan for 2016/17.

14. Montgomery ruling on Consent.

In March 2015 the Supreme Court decision in Montgomery v Lanarkshire Health Board [2015] resulted in a significant change to consent law. Clinicians must now ensure that patients are aware of all "material risks" involved in the proposed treatment and of reasonable alternatives. The GMC's view is that this is already enshrined in Good Medical Practice. Its applicability to living donors requires consideration, so each directorate has undertaken work to consider the impact of ruling in each function and identify any changes required. A paper will be submitted to June ET and the GAC to follow.

15. Clinical Claims.

CARE discussed the annual summary of Medico-legal work, including claims pursued against NHSBT; claims referred to the NHS Litigation Authority (NHSLA), inquests held and pending/ potential Judicial Review proceedings. A paper will come to August ET with suggested improvements in the governance arrangements regarding Clinical Claims, particularly when to refer claims to NHSLA.

16. Risk Management.

ET has approved proposals to improve risk management across NHSBT, including a new risk register, staff training and communications. The workplan with timelines will come to June GAC.

17. Nursing Revalidation.

Revalidation has been implemented and the first tranche of our nurses have submitted the requirements for revalidation. Work to support nurses in this preparation is led by the Revalidation Committee reporting to the Nursing Leadership Team, and has been regarded as supportive and successful.

18. Safety policy matters.

18.1 The English, Scottish and Welsh blood services are providing HEV tested components to hospitals. Northern Ireland will provide these after April 2016.

18.2 SaBTO had received correspondence from some hospitals and SNBTS regarding the difficulties of implementation. There were difficulties with some Laboratory Information Management Systems. There was also concern regarding MHRA compliance if errors were made during implementation. There is a statement on the MHRA website which provides reassurance and SHOT are not yet including HEV in the 'wrong component provided' data.

18.3 Richard Tedder will chair a SaBTO subgroup on HEV testing to finalise recommendations for the use of screened blood components in immunosuppressed non-transplant patients, plus the testing of living stem cell/organ donors and deceased organ/tissue donors.

18.4 There is guidance due on HEV in chronic liver disease and BSBMT are producing guidance on the chronically infected stem cell transplant patient.

18.5 A SaBTO work group, the Donor Selection Criteria group was established to review the deferral criteria for MSM, tattoos/acupuncture/ piercings, flexible endoscopy, and donors with partners from HIV endemic areas. This will call on data from the 2015 UK Blood Services/PHE Donor Survey. The group intends to present preliminary findings to SaBTO by April 2017 then invite wider consultation for a final report by summer 2017.

18.6 SaBTO heard presentations on updated microbiological guidance for transplant recipients and on the standards microbiology laboratories should adopt if undertaking testing of organ donors. SaBTO endorsed the principles, but agreed this should be managed through NHSBT commissioning.

18.7 SaBTO heard a presentation from the JPAC chair on agreed UK actions to date on Zika. SaBTO were content with the steps taken ie 28 day deferral of returning travellers for blood/tissue donation, no deferral of sexual partners, and a risk- based approach for individual organ donors. Heart valves from 2 deceased tissue donors were in quarantine because of travel to a Zika area.

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