NHSBT Board
Clinical Governance Report
25 July 2019

1. Status – Official

2. Executive Summary

- There were no new Serious Incidents (SIs) within this reporting period. All previous SIs are now closed
- Two serious adverse events in research led to the Quality in Organ Donation (QUOD) Biobank and the Pre-Implantation Trial of Histopathology In renal transplant Allografts (PITHIA) study being paused in Organ Donation and Transplantation (ODT) to review biopsy techniques. These have been revised and both studies are now live again.
- The SHOT Report 2018 is featured as the focus item for this report

3. Action Requested

The Board is asked to note the contents of the paper.

4. Clinical Governance

Clinical Governance was first described by Scally and Donaldson in the British Medical Journal (BMJ) in 1998 as “a system through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish."

Five key themes appear repeatedly in policy documents about healthcare quality (rcn.org.uk):

- Patient focus - how services are based on patient needs
- Information focus - how information is used
- Quality improvement - how standards are reviewed and attained
- Staff focus- how staff are developed
- Leadership - how improvement efforts are planned

In NHSBT Clinical Governance covers the following areas

- Clinical effectiveness
- Clinical risk and incident management
- Information Governance including the remit of the Caldicott Guardian and incidents reported to the Information Commissioner’s Office (ICO)
- Clinical Audit
- Research and Development
- Clinical Training and Education
- Clinical guidelines, safety policy and haemovigilance

This report is a new format designed to report issues in the above areas that the Board should be aware of. Feedback is welcomed on whether or not this allows the Board to be more aware of issues in these areas. It is planned that each report will have a single area of focus that will vary to allow the Board to understand an area in more depth. This month’s focus is haemovigilance, but future reports may include

areas such as serious adverse events of (blood) donation, Cautionary Tales in ODT, clinical audit, Caldicott Guardian activity, policy making overview, or indeed other areas you may wish to suggest. We will work with colleagues in Quality Assurance (QA) to ensure that there is minimal duplication between this report and QA reports

5. Overview of relevant events this reporting period

- There were no new SIs within the reporting period, all previously reported incidents have been closed.
- Following a successful feasibility study, BSCARE granted approval for the main STRategies to Improve Donor ExperienceS (STRIDES) trial to commence in November. The aim of the trial is to evaluate interventions to prevent vasovagal reactions among whole blood donors. This study will also recruit donors into the NIHR BioResource
- We are acting as a contract manufacturing organisation for Cerus in the SCient study. This is a Phase 2, randomized study designed to evaluate the efficacy and safety of INTERCEPT treated RBCs in patients undergoing exchange transfusion for sickle cell disease. The block to signing the contract for this study is now resolved and work will start on the validation phase in the near future.
- There were two serious adverse incidents which related to ODT; where patients were impacted post kidney transplantation because of receiving a kidney that had a QUOD biopsy taken at organ retrieval. One patient lost their kidney graft and one required a large transfusion of blood. A decision was made to pause the practice of taking a kidney biopsy for both QUOD and PITHIA until the biopsy size was reviewed. The biopsy size for both QUOD and PITHIA have been reviewed and the size reduced for each. Additionally, only one biopsy will be taken for either QUOD or PITHIA, but not split for both. Both QUOD and PITHIA are now live again.
- Jamie Lomas has been appointed as NHSBT's local Freedom to Speak Up (FTSU) Guardian and has now commenced in post.
- The ICO has recently proposed significant fines for British Airways (£183m) and Marriott (£99m) following their data breaches. This action serves as a reminder that it does not matter how or why personal data was lost, if companies lose data then they will be held responsible under the law, if they have not taken 'appropriate technical and organisational measures' to protect those data.

6. Safety Policy Matters

The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) held the first meeting of the risk tolerability working group. This has been set up to examine and try to define what the UK blood services consider to be acceptable and tolerable levels of risk to patients from blood transfusion, tissue and organ transplantation and what costs are reasonable to mitigate these risks. The primary focus will be blood risk with the hope that some general principles could be extended to tissues and organs. The first meeting focused on risk tolerability and there will be at least one further meeting in the Autumn to try and establish a broad cost/benefit framework.

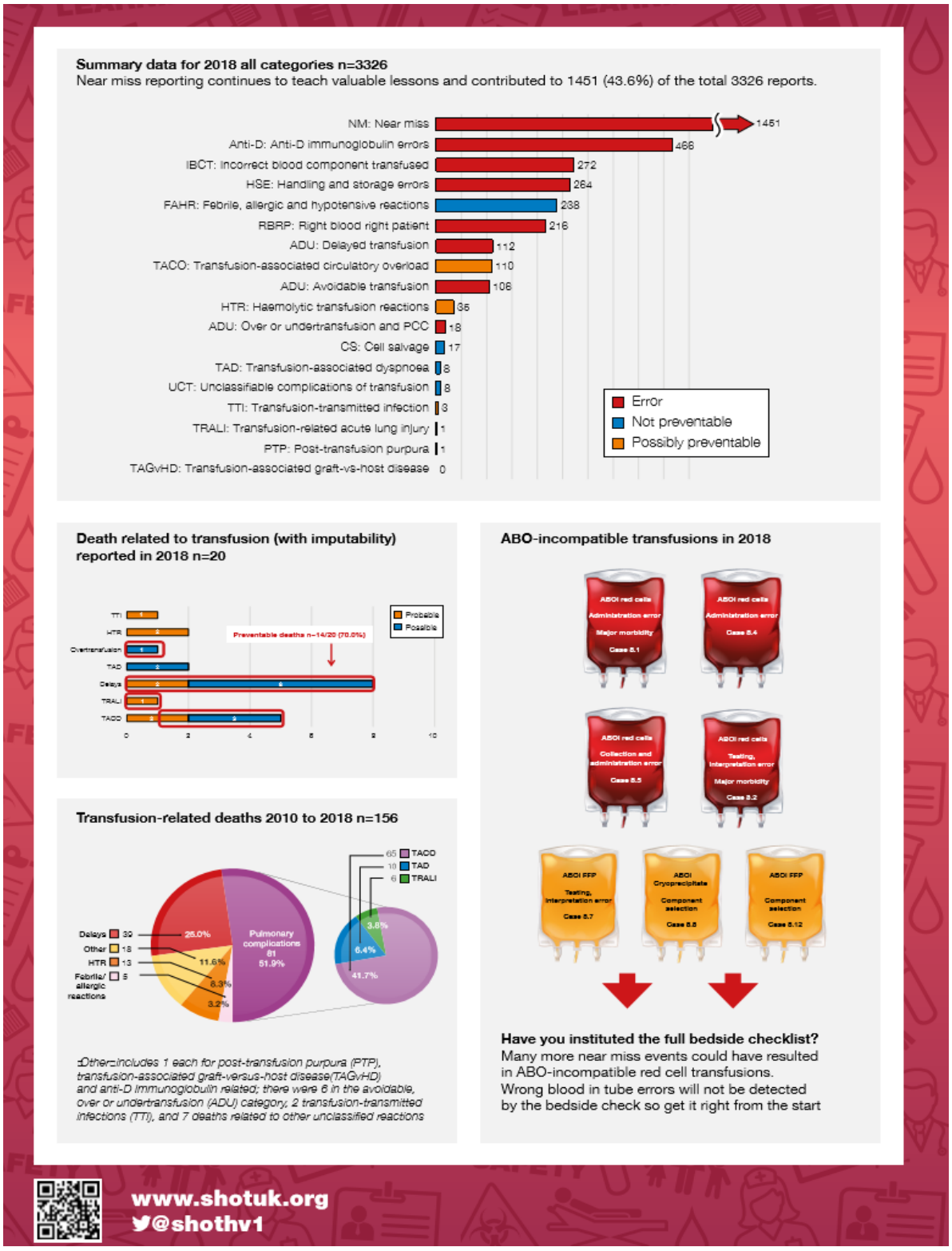
NHSBT will be submitting a review of Hepatitis E testing since implementation of the universal screening policy (this will include the previously reported confirmed HEV transmission) to the September SaBTO meeting for review.

A review of Occult Hepatitis B Infection (OBI) in donors is ongoing following the previously reported case of occult HBV transmission has been started to quantify the risk and the effectiveness of current donor screening procedures.

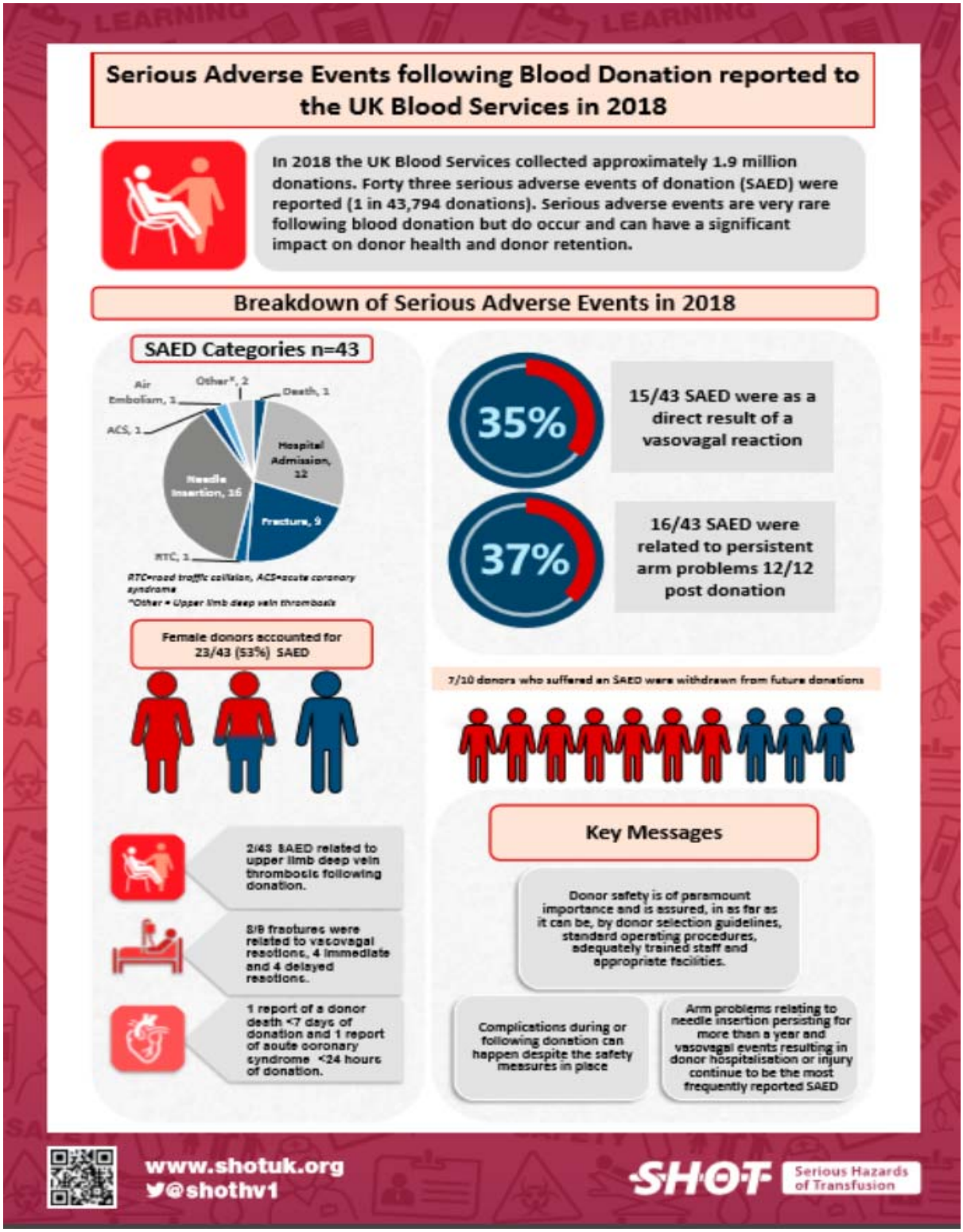
7. Report Focus - Serious Hazards of Transfusion (SHOT) Report 2018

SHOT produced their annual report this month. Three of the four summary infographics are re-presented below. The key recommendations and messages below apply to all organisations involved in the transfusion and will be reviewed. The figures are largely comparable with last year's numbers.

Of the 20 deaths probably or possibly attributed to transfusion, eight were due to pulmonary complications, the second most important cause is delays to transfusion. These are consistent with reports from previous years. This year fourteen cases were considered to be preventable.



This year is the second year that a chapter on donor adverse events is included and next year there is anticipation that this will also include a chapter on incidents in blood manufacturing establishments for the first time. This will complete the aim of having haemovigilance of the entire vein to vein blood supply chain.



https://www.shotuk.org/wp-content/uploads/myimages/130584.03-SHOT-REPORT-SUMMARY-2018_v6.pdf

Authors
Louise Cheung, Assistant Director, Governance and Clinical Effectiveness
Olive McGowan, ODT AD Governance and Education
Gary Mallinson, Safety Coordinator
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Responsible Director
Dr Gail Miflin
Medical and Research Director