Foreword

The National Blood Transfusion Committee (NBTC) acts as a central liaison point between clinical users and the blood service (NHSBT). Our role is both to help and encourage clinicians to use best practice when considering transfusion, and to monitor, consult and feedback on the service provided by the NHSBT. The success of the NBTC, its associated Regional Transfusion Committees (RTCs) and fellow bodies such as Serious Hazards of Transfusion (SHOT) is evident through the dramatic changes in blood use over the last 20 years.

Although the committee concentrates on clinical matters there have been increased concerns regarding hospital transfusion laboratory safety due to problems with staff training and staff recruitment. With this in mind the NBTC in association with the NHSBT organised a symposium to take place in March 2019 and the outcome of this is hoped to set a further agenda for clinical blood transfusion but also for hospital laboratory aspects of transfusion. We are also pleased to have initiated, with the NHSBT, some studies looking at more integrated methods of working between hospitals and the transfusion services.

We have a number of important working groups and are grateful to the chairs of these groups and their members for their additional work, and in particular to our patient representatives who give up their own time to contribute actively to our deliberations and decisions. Although our remit is for England, we are also pleased to have colleagues from the devolved administrations as observers and contributors.

I am most grateful to the hard work of the secretary of the NBTC, Dr Shubha Allard, to all the Regional Transfusion Committee chairs and their chair, Dr Youssef Sorour as well as the administrative support provided by Celina Bernstrom.

The report below gives some detail about the activities over the past two years.

Dr Jonathan Wallis
Chair, National Blood Transfusion Committee
15.10.19
The National Blood Transfusion Committee (NBTC) was set up in 2001, with the primary purpose of promoting safe and effective transfusion practice in hospitals.

This report provides evidence that the remit of the NBTC to provide a conduit for the flow of information and good practice between Hospital Transfusion Committees (HTCs), Regional Transfusion Committees (RTC) and the NBTC is being fulfilled. Further focused work is achieved through the NBTC working groups and education and audit is supported via the RTC symposiums.

The NBTC monitors the performance of NHS Blood & Transplant (NHSBT) and receives reports on areas of activity in transfusion which have an impact on its work, such as the Serious Hazards of Transfusion (SHOT) scheme, the National Comparative Audit (NCA) programme and the National Commissioning Group (NCG). There are also close links with other stakeholders such as SaBTO and MHRA and representation from a number of Royal Colleges.

The NBTC currently reports to NHS England via the Chief Scientific Officer (CSO) and the Deputy CSO is a standing member. The Terms of Reference for the NBTC and RTCs will be updated in 2019 following discussion with NHS England to further strengthen governance and reporting arrangements.

This report is a biennial one for 2017/19 bringing up to date reporting from the last annual report for 2016/17.

Committee Meetings and Working Groups

The NBTC, the Executive Working Group, the Regional Transfusion Committee (RTC) Chairs Group, all met twice during 2016/17.

Current Working Groups:

- Patient Involvement
- National Transfusion Laboratory Managers
- Patient Blood Management
- Education
- Anaemia – disbanded after decision by EWG Jan 2019
- Emergency Planning – reconvened 2018

A new National Transfusion Practitioners working group is being planned in 2019 to strengthen the TP framework.

The O D Negative working group is being reconvened in 2019 in partnership between NBTC and NHSBT in response to the significant ongoing pressures on O D Neg demand.

Work of the NBTC in 2017/9

The NBTC has an annual work plan setting out objectives and actions to support the NBTC strategy focussed to support the PBM initiative.

The Transfusion 2024 Symposium held in March 2019 has informed an updated 5-year strategy for clinical and laboratory transfusion practice to be completed and be available by end 2019.

The Terms of Reference and working arrangements of the Working Groups are also available here on the NBTC website.
Regional Transfusion Committees

The RTCs are key to the promotion of better transfusion practice acting as a focus for activity and a conduit between the Hospital Transfusion Committees and the NBTC.

There are 10 RTCs which were realigned in 2006/07 to reflect the boundaries of the ten Strategic Health Authorities, and these boundaries have continued in the face of further NHS reorganisations since HTCs greatly value the current structure and they strongly feel this is needed to promote wide engagement. Going forward there will be a need to consider how reporting can be aligned to the 7 NHS Regions.

Ongoing concerns expressed by RTC Chairs from their membership include significant pressures on hospital transfusion laboratories with staffing and training challenges and impact on transfusion practice through pathology modernisation initiatives focussed on high throughput pathology services and cost saving, and the challenge of engaging hospitals in PBM. These concerns were further discussed at the Transfusion 2024 symposium (see below).

NHSBT have undertaken Supply Modernisation Projects for North of England and Leeds/Sheffield Estates Review. Both these projects have implications for stakeholders in the Yorkshire & Humber and East Midlands RTC regions. There has been good engagement between NHSBT and stakeholders, at a regional and local level, with ongoing inclusive transparent dialogue essential to ensure success of these projects for both parties.

NHSBT has highlighted significant demands on Supply of Group O D Neg blood and is working with RTCs to promote good engagement and dialogue with hospitals to promote good practice in relation to appropriate use and stockholding.

National initiatives that the NBTC/NHSBT have led in 2017-19

Patient Blood Management (PBM)

PBM is an evidence-based, multidisciplinary approach to optimising the care of patients who might need transfusion. It puts the patient at the heart of decisions made about blood transfusion to ensure they receive the best treatment and avoidable, inappropriate use of blood and blood components is reduced. It represents an international initiative in best practice for transfusion medicine.

- In June 2014, the initial recommendations from the NBTC about how the NHS should start to implement Patient Blood Management were endorsed by NHS England and issued to hospitals. PBM Recommendations.

- The National Institute for Health and Clinical Excellence (NICE) published guidelines on Blood Transfusion in 2015 and are these were followed by quality standards for transfusion which were published in November 2016. The guidelines provide a framework for implementation of PBM and cover recommendations on: alternatives to transfusion for patients having surgery, thresholds, targets and doses for blood and blood components, patient safety and patient information.
In 2015, NHSBT produced a PBM Strategic Workplan 2015-2018 in collaboration with the NBTC. The strategic objectives included:

1. Embed PBM into hospitals as a long term and sustainable model for the delivery of patient-centred, evidence based, high quality care
2. Implement PBM strategy through a collaborative approach between NHSBT, NBTC and hospitals/primary care
3. Develop structures, tools and processes to support the implementation of PBM
4. A revised strategy is in development, with the aim to launch late 2019

Transfusion 2024 - A Five-year Plan for Clinical and Laboratory Transfusion Practice

*Transfusion 2024 symposium* was organised in March 2019 by the National Blood Transfusion Committee (NBTC) and NHS Blood and Transplant (NHSBT) with support from NHS England (NHSE). The aim was to define a clinical and laboratory blood transfusion strategy for England over the next five years. The areas covered included Patient Blood Management (PBM), Transfusion Laboratory Safety and Harnessing Technology and Innovation, focusing on the importance of these to the needs of patients in the NHS.

The symposium highlighted the need to build on successes of the initial Better Blood Transfusion Health Service Circulars that led onto Patient Blood Management initiatives and emphasised key actions needed to maintain and improve transfusion safety and further optimise patient care. These include the development of PBM self-assessment for hospitals, improved support for the Transfusion Practitioner role and key initiatives essential to strengthen Hospital Transfusion Laboratory safety including robust staffing and training, underpinned by advanced information technology with exploration of integrated models between NHSBT and hospitals. Furthermore, key areas were identified by user groups as important areas for continued research and innovation e.g. use of big data, new component development and donor genotyping with a need for translation into practice for patient benefit.

The recommendations for further action are currently being drafted and will reflect the aims of the NHS Long Term Plan including emphasis on a skilled and trained workforce, better use of data and technology and seeking integrated models of working while fully supporting the principles of the NHS Patient Safety Strategy promoting a safer culture and systems for the benefit of patients.

The conference provided an opportunity for the NBTC and NHSBT to work collaboratively with various hospital teams, Royal Colleges and professional bodies, regulators and healthcare providers and above all patients to help determine priorities and future strategies for transfusion care in line with key NHS strategic direction.

**The Choosing Wisely campaign**

This is an international initiative looking at ways of avoiding ‘too much’ medicine and led by the Academy of Medical Royal Colleges. Further key messages were developed with a total of 5 messages as below:

1. Communicate the benefits and risks - Don’t give a patient a blood transfusion without informing them about the risks and benefits (although do not delay emergency transfusions).
2. Give iron to iron-deficient patients - Don’t transfuse red cells for iron deficiency anaemia without haemodynamic instability.
3. Save O D negative blood - Only transfuse O D negative red cells to O D negative patients and in emergencies for females of childbearing potential with unknown blood group.

4. Review after each unit - Use restrictive thresholds for patients needing red cell transfusions and give only one unit at a time except when the patient has active bleeding.

5. Only considering transfusing platelets for patients with chemotherapy induced thrombocytopenia where the platelet count is < 10x10⁹ /L except when the patient has clinically significant bleeding or will be undergoing a procedure with a high risk of bleeding.

**The Transfusion Evidence library**

This is a database of systematic reviews and randomised controlled trial relevant to transfusion medicine. It is possible to set up a regular Transfusion Evidence alert to ensure users keep up to date.

**The James Lind Alliance**

This initiative requested feedback on blood transfusion and blood donation from patients, carers and healthcare professionals to support the priority setting of future research questions in this area. The exercise has now been completed with results published

**Changes in Demand for Blood**

**Red Cell Demand:**

- The Moving Annual Total (excluding Military and Other Blood Services) has been decreasing steadily from c. 1,440K at the end of 2017-18 to 1,413.6k at the end of 2018-19
- Red Cell demand decreased by -1.7% from 2018/19.
- O D negative red cell demand had a downward trend until July 2018, and started increasing from November 2018
- Supply of O D negative red cells remains a challenge due to changes in care of sickle cell patients requiring automated red cell exchange and the necessity to substitute O D neg red cells when Ro red cells are not available. Recent increases in O D neg red cell demand have provided further pressure to supply.
- An audit of O D neg practice in hospitals highlighted areas that laboratories could improve particularly with regards to stockholding and wastage
Platelet Demand:
- Overall platelet demand appears to have levelled, but recent weekly demand data has indicated an increase in demand
- Demand for platelet A neg steadily increased from April 2017 with a peak at c.40k ATDs from Feb-18 to Apr-18. Since then, it has been decreasing and dropped below 39k in March 2019.
UK plasma

- Demand for UK plasma has continued to fall, opposed to demand for UK Cryoprecipitate approx. 57% increase in issue of Cryoprecipitate over same time period

Working Groups:

1) PBM Working Group

NBTC/ NHSBT PBM survey

In 2018, NHSBT and the NBTC undertook a survey to evaluate progress towards PBM in NHS Trusts in England. A further survey has been undertaken in 2018 and the final report is imminent.
NHSBT PBM projects reported to the NBTC PBM working group

<table>
<thead>
<tr>
<th>Project</th>
<th>Current Status and Key Outcomes</th>
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<tr>
<td>Single Unit Transfusion</td>
<td>- 5 hospitals across England have been identified (or self-identified) as needing support to implement a single use policy for red cells and one for platelets  &lt;br&gt;- Project plans have been drawn up for these hospitals and project groups have been assembled with key stakeholders and bespoke resources/approaches needed.  &lt;br&gt;- Individual KPIs have been agreed locally  &lt;br&gt;- 2 of the projects are complete and the others are nearing completion  &lt;br&gt;- When the reports have been written up the results will be shared  &lt;br&gt;- The approach and initial success of these projects are being shared locally and another 14 hospitals in 2 regions have asked for similar support</td>
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<tr>
<td>Objective:</td>
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**NBTC Indication Codes App**

**Objective:**
To support the development of an App that will provide easy access to NBTC indication codes for clinical staff.

The NBTC Indication Codes for blood transfusion were updated to bring them into line with latest evidence and were agreed following consultation with NBTC members in June 2016.

The NBTC is funding the development of an ‘app’ which will provide easy access to the indication codes for those in the clinical environment. The app will provide further support in the decision to transfuse the component.

- Since launch in April 2017 the app has had over 11,500 users over 156 countries. Initial expectation was between 500 and 1000 users in its lifetime.
- Each user has viewed 4.52 pages a session. Users are looking at more than one screen on each visit and navigating to the information they require.
- Average Time that a user stayed on the app 1m:31s This indicates that users are finding the content useful.
- 62% of users returned to the app. Users must be finding the content useful and are actively using the app again to help them in their role.
- Most Popular Pages (not including home screen)
  - Adult – RBC 29,162 views,
  - Infants and Children – RBC 14,142
  - Adult – PLT 13,952
  - Neonates – RBC 13,844
  - Adult FFP- 11,506

Further information can be found on Patient Blood Management.

2) **Education and training**

Covers a wide remit maintaining oversight of undergraduate and postgraduate education in Transfusion Medicine across many healthcare professionals. Multidisciplinary membership with defined project groups tackling key objectives.

**Medical Undergraduate Training**

- Active collaboration with British Society for Haematology Education Committee
- Contributed to update of RCPath pathology undergraduate curriculum

**Foundation Training**

- Application for basic e-learning module for anaemia. To be completed 2020/2021 if bid successful. Planned to be hosted on e-LfH. This module can be used for lots of different groups once developed.

**Core medical Training**

- Transfusion Education Initiative in collaboration with BSH pilot course completed Spring 2018 aiming to improve transfusion training of junior doctors using Team Based Learning and social media to enhance participation and maximise learning opportunities with two single day events, with online tutorials using social media and Interactive lectures.
- Participants will be encouraged to undertake a transfusion-related Quality Improvement Programme within their own Trust.
Postgraduate core medical and higher speciality training

- Continuing to raise profile of transfusion medicine across clinical disciplines via various activities such as participation and leading on National Comparative Audits, contribution to professional guidelines (e.g. BSH Guidelines, RCOG, NICE), publications.
- Liaising with JRCPTB on updated curriculum for haematology trainees.

Haematology Specialist Registrar training

- Annual meeting to review course content and evaluation of NHSBT delivered Transfusion courses for Haematology trainees. Input from NHSBT and hospital teams and trainees with a view to further strengthening courses. Ongoing updates to JRCPTB Haematology SAC with upload of 2017/18 dates on JRCPTB website.
- Development of e-learning modules starting in 2020 to 2021 to slowly change the Essential and Intermediate Transfusion Medicine Courses from completely face to face to blended learning.
- Supporting Transfusion attachments in partnership with Trusts and NHSBT at 7 centres with further meeting to review training content in November 2019
- Supporting NHSBT strategy for international placements with Royal College of Pathologists.

Scientific training

- Ongoing Contribution to HSST Transfusion Medicine training. First HSST NHSBT trainee passed new FRCPath Part II exam.
- Explore development of International framework for Transfusion scientist trainees within RCPath Medical training initiative.
- The Practical Introduction to Transfusion Science course was a 1-week face to face course for band 4 or 5 biomedical scientist trainees. Now it will become a mixture of face to face and online learning (HEE funded for transformation to blended learning in 2019).

Nursing & Midwifery training


Multidisciplinary training

Created short educational videos funded by HEE

- Blood administration
- Pre-transfusion blood sampling
- Laboratory errors (in association with SHOT)
- Pulmonary complications of transfusion (in association with SHOT)

Further videos will be created

- In association with SHOT
- Manual red cell exchange
3) Patient and Public Involvement

The Patient Involvement Working Group was established to promote patient and public involvement in blood transfusion.

The Working Group was involved in several patient-related activities during 2017/19:

Further develop information on blood transfusion for patients and the public

- Partnership work continues between the NHSBT PBM team and approximately 20 patient organisations and charities that are associated with patients that are often transfused, to promote patient information on their respective websites and link to the Hospitals and Science and blood.co.uk websites. Approximately 8 organisations have agreed to this and show links from their website.

Ensure patient information leaflets (PILs) relevant and up to date

- The PILs continue to be reviewed on a 3-yearly basis. The PBM team that prepare the leaflets attained the “information standard” however the DH has since stopped the scheme. The intention is to continue to produce the PILs with the ethos of the information standard. The information standard will be applied to the leaflets produced that meet the criteria up until the time that the scheme is withdrawn.

Promote Transfusion awareness in collaboration with specialist societies and groups

The NHSBT PBM team continues to attend conferences held by the:

- Royal College of Nurses
- Royal College of Midwives
- Royal College of Pathologists
- National Science week
- SHOT

Promote Implementation of SaBTO guidance on consent

Following the publication of the NCA Patient Information and Consent report an action plan was drawn up by members of the PIWG. This has taken on more relevance in the light of the Montgomery ruling. The PIWG hosted a consent workshop at the September 2017 NBTC meeting and showcased a consent video produced with University Hospitals Birmingham and the PBM team. The Informed Consent Action Group (ICAG) pad developed by the South East Coast RTC was put forward as an example of good practice and has been made available nationally. Further information on Consent and the PBM Toolkit.

Patient Safety

- A bedside check video has been developed by SHOT with the PBM team.
- A further bid for funding for a blood sampling video has been submitted to Health Education England.
- A survey of Trusts’ use of positive patient identification was carried out in 2017. It appears that the take up of barcoded wristband technology has not accelerated and that many respondents are struggling to achieve Trust buy in to the systems available.
Attendance at teleconferences and meetings is declining and we have continued to try and increase the public and patient involvement in the working group however it is noted that increased work pressures within Trusts are impairing people’s ability to contribute to the group.

**Lay membership - comments from representatives**

For many years, the NBTC has had patient/lay members. Moreover, such participation is encouraged, not just tolerated and, if we do not offer contributions, we are asked for them. Between us we serve on most NBTC working groups, though not the executive working group. There is room for still wider lay participation, so that we are not constantly reporting back to ourselves. The NBTC has now increased the number of lay/patient participants from one to four members.

We have no formal role. We think we are there to ensure that patients’ views are represented by saying what patients would want to know and asking questions they would like asked, and by pressing for the language of all communications to be understandable, rather than medicalised. We aim to keep abreast of current developments in transfusion by attending meetings and educational events. We regularly comment on documents and policies and try to bear in mind what patients would want to know and have explained to them.

Formalising the role would also assist future recruitment of lay/patient representatives. Neither of us joined NBTC via a formal process; any future members should be recruited in a more transparent way.

4) **Transfusion Laboratory Managers Working Group**

The Chair and the co-Chair of this group are in the process of updating the Terms of Reference.

The group continues to support the RCI ASSIST project in collaboration between NHSBT and hospitals. The proposed pilot studies at two sites focusses on evaluating the potential benefits of adopting a more algorithmic approach to testing across RCI and hospital transfusion laboratories. In this model, small networks of hospital transfusion laboratories agree testing protocols with NHSBT; this includes triggers for referring investigations to RCI. In this way, hospital-based testing would be standardised and optimised to fit the resources available in each laboratory. By adopting agreed and standardised testing protocols, NHSBT would support hospital-based activities such staff training, validation, change control, documentation, and compliance.

The group also continues to monitor and advise on the progress of plans for Pathology consolidation and highlight concerns where needed; 29 networks have been proposed by NHS Improvement with aim of implementing hub and spoke model over the next three years. The group is represented on the newly formed transfusion subcommittee advising NHS Improvement on implementation of Pathology networks.
5) Emergency Planning Working Group

Transfusion Emergency Planning is essential as part of an integrated healthcare response to Major Incidents.

The NBTC Emergency Planning Working Group was originally set up as a short-lived group to review the lessons learned in relation to organisation of hospital transfusion services following the July 7th London Bombings in 2005. The focus was to meet the potential surge in demand for blood components and hospital transfusion support associated with a Mass Casualty Event (MCE).

More recent Mass Casualty Events across Europe and the United Kingdom, together with Major Incidents such as the wide scale disruption of computer services and adverse weather have necessitated a broadening of scope and a commitment to ongoing guidance. Accordingly, the Emergency Planning Working Group was re-established to produce on-going EP guidance to hospitals on behalf of the NBTC. The objective from this group is to provide hospitals with guidance for transfusion emergency preparedness and response to Major Incidents and Mass Casualty Events in consultation with a range of stakeholders.

Updated guidance has been issued together with an updated Gap Analysis tool for hospitals.

6) Anaemia Working Group

A key pillar of patient blood management is the timely recognition, investigation and management of anaemia. The 2011 National Comparative Audit of transfusion in medical patients highlighted the fact that many patients with reversible anaemia (mainly due to iron deficiency) were being transfused unnecessarily but were also not being investigated adequately. NICE blood transfusion guideline (NG24), National Blood Transfusion Committee (NBTC) Patient Blood Management (PBM) recommendations, and British Society Haematology (BSH) guidelines for pre operative anaemia and anaemia in pregnancy all recommend effective anaemia management. Whilst the newly formed group had important key objectives summarized below it struggled to deliver on these.

1. Produce overarching patient blood management guideline for management of anaemia
2. Raise awareness of importance of anaemia recognition, investigation and management with clinicians, patients and public
3. Develop tools to support implementation of anaemia management across primary and secondary care
4. Work with commissioners to commission pathways that support best practice
5. Develop KPIs to monitor compliance with quality standards in anaemia management

Accordingly following discussion at the NBTC EWG meeting in January 2019 this group was disbanded with discussions on incorporation of above activities within existing PBM initiatives.

Other groups/members

National Comparative Audit of Blood Transfusion

The focus of the NHSBT/Royal College of Physicians National Comparative Audit of Blood Transfusion (NCABT) programme is to conduct audits of the safe and appropriate use of blood. Audit reports.
Audits 2017 to 2019

2017 Audit of red cell and platelet transfusion in adult haematology patients.
  - Improvement in single unit red cell transfusion policy from 27% of inpatients in 2016 to 43% of inpatients in 2017

2017 Audit of Transfusion Associated Circulatory Overload
  - 29% of inpatients with a fluid balance recorded were more than 1000mls positive prior to the transfusion
  - 4.3% of inpatients developed acute or worsening respiratory distress
  - 33% of inpatients diagnosed with TACO by the hospital were reported to SHOT

2018 Audit of the use of FFP and cryoprecipitate in children and neonates

2018 O negative red cell survey (main report and key findings - additional papers)

2018 Maternal anaemia audit (interim report – additional paper)
  - 26% (221/848) of women were diagnosed with anaemia during pregnancy. Only 22% (49/221) were started on iron.
  - 71% (35/49) of those started on oral iron were followed up within 2 to 4 weeks.

2018 Major haemorrhage audit (interim report – additional paper)
  - 84% (117/140) of trauma patients were given tranexamic acid. 51/117 (43.5%) met the standard by being given an initial 1G IV bolus followed by an 8-hour infusion.
  - 62% (132/212) of women with postpartum haemorrhage were given tranexamic acid.
  - Major Haemorrhage Protocol was activated during the care of 80% (712/885) of patients, but the protocol was stood down in only 49% (350/712) of activations.

Future audits 2019 and 2020
  - Re-audit of the medical use of red blood cells (Starting October 1st, 2019)
  - Where does FFP, cryoprecipitate and PCC go in adults? (Spring 2020)
  - PBM in paediatric surgery (Spring 2020 – specialist paediatric hospitals)
  - Audit of NICE quality standards (Autumn 2020)

RTCs to feedback about which re-audit is to be performed in Spring 2021.

NHSBT Blood Components

Following an active Components workshop organised by the NBTC in 2016 there was considerable interest expressed by hospital representatives in the use of whole blood for major haemorrhage. The NHSBT is now providing a leucodepleted whole blood component to Barts Health NHS Trust for a feasibility study on the treatment of traumatic haemorrhage, especially preadmission. Initial results are encouraging but the high specification of the component and the high risk of wastage may limit the extent to which this component may be offered in the first instance. The leucodepletion process removes platelets from the whole blood, so work is ongoing on a platelet-replete version where the effect of cold storage on platelet function and shelf life require consideration.

The NBTC also strongly supported the application for funding to pursue the development of universal plasma. NHSBT is collaborating with Nonwovens Innovation and Research Institute, and MacoPharma to develop an anti-A and B removal filter. The consortium has received a National Institute for Health Research grant to develop the prototype to a stage where commercialisation may follow. The system would remove antibodies from plasma, creating a ‘universal’ plasma component. Further development
might allow removal of A and B antibodies from platelet concentrates and RBC containing plasma e.g. for exchange transfusion or whole blood.

The NBTC was an active stakeholder in discussions within SaBTO on the provision of imported fresh frozen plasma, and UK sourced apheresis platelets, for recipients born on or after 1st January 1996 as risk reduction measures for vCJD. SaBTO’s recommendations have been made to Health Ministers and an announcement is awaited.

NHSBT will be supporting three other clinical trials on red cell components. The first is as the supplier of pathogen reduced red cell concentrates for a clinical trial in sickle cell patients at UCLH, sponsored by Cerus. The second is assessing at the effect of rejuvenation of stored red cells in preventing organ damage following cardiac surgery. NHSBT is also undertaking a first in man study of red cells grown from stem cells to assess whether these cells survive longer than standard red cells once transfused.

Serious Hazards of Transfusion (SHOT) Haemovigilance scheme

This section covers the recommendations and key messages from the last two annual SHOT reports.

Annual SHOT Report 2017 - Headline data: -
- The total number of reports analysed and included in the 2017 Annual SHOT Report is 3230. This is an increase of 139 from the 3091 reports analysed in the 2016 Annual SHOT Report. This number does not include 66 reports of anti-D immunisation
- Errors account for 85.5% of all reported incidents
- There were 21 deaths reported related to transfusion, and of these, three were definitely linked to transfusion: 2 deaths due to TACO and one due to delayed transfusion

Recommendations from Annual SHOT Report 2017: -
- Training in ABO and D blood group principles is essential for all laboratory and clinical staff with any responsibility for the transfusion process. This should form part of the competency assessments
- All available information technology (IT) systems to support transfusion practice should be considered and these systems implemented to their full functionality. Electronic blood management systems should be considered in all clinical settings where transfusion takes place. This is no longer an innovative approach to safe transfusion practice, it is the standard that all should aim for
- A formal pre-transfusion risk assessment for transfusion-associated circulatory overload (TACO) should be undertaken whenever possible, as TACO is the most commonly reported cause of transfusion-related mortality and major morbidity

Key SHOT messages from 2017: -
- Do not assume, verify: At each step in the transfusion process, do not assume that no errors have been made in previous steps; verify each step, particularly patient identification
- Human factors: Failure of communication, distractions, interruptions, wrong assumptions, poor handovers and overriding alerts in the laboratory information systems are all important contributory factors
- What went wrong? Thorough root-cause analyses are essential and must identify attributable system-related and human factors so that appropriate actions can be instituted
- Is your staffing adequate? Inadequate staffing, lack of training and poor supervision are all likely to be associated with an increased risk of error
- Do not delay: Emergency transfusion saves lives. Do not let the patient bleed to death or die from anaemia
• Guidelines or rules? Guidelines must not be translated into inflexible rules which may put patients at risk. Proportionate application of knowledge and experience may lead to a different course of action in individual circumstances. However, the final bedside check is a rule and must be completed in full

• TACO alert: Patients who develop respiratory distress during or up to 24 hours after transfusion where transfusion is suspected to be the cause must be reported to SHOT. The national comparative audit of TACO in 2017 demonstrated that risk factors are being missed. It is the clinician’s responsibility to know the patient’s specific transfusion requirements

Annual SHOT Report 2018 - Headline data: -

• The total number of reports analysed and included in the 2018 Annual SHOT Report is 3326. This is an increase of 96 from the 3230 reports analysed in the 2017 Annual SHOT Report (published 2018). This number does not include 39 reports of anti-D immunisation as these are part of a separate study. The number of reports excluding ‘near miss’ and ‘right blood right patient’ is 1659, a small reduction from 1671 in 2017

• Errors account for 87.3% (2905/3326) of all reports (including near miss (NM) and right blood right patient (RBRP); Figure 3.1), and 74.7% of incidents excluding NM and RBRP

• Near miss events continue to account for a large proportion (1451/3326, 43.6%) of the incidents reported to SHOT and have increased again this year, n=1451 in 2018, compared to n=1359 in 2017

• Deaths related to transfusion (with all degrees of probability) reported in 2018 were 20 and there were no deaths which were attributable to transfusion

Recommendations from Annual SHOT Report 2018: -

• All NHS organisations must move away from a blame culture towards a just and learning culture

• All clinical and laboratory staff should be encouraged to become familiar with human factors and ergonomics concepts

• All transfusion decisions must be made after carefully assessing the risks and benefits of transfusion therapy. Collaboration and co-ordination among staff is vital

Key SHOT messages from 2018: -

• Learning from near misses is vital to prevent future incidents

• Investigating incidents should be thorough, systematic and identify systemic issues

• Staffing challenges, including staff shortages and gaps in skill mix, need to be addressed to improve safety

• Rethinking transfusion education, including more technology-enhanced learning, learning in teams, non-technical skills training, patient safety training and human factors awareness

• Standard operating procedures need to be simple, clear, easy to follow and explain the rationale for each step—this will help engage staff and improve compliance

Further details and full report including all chapters.

Medicines and Healthcare Products Regulatory Agency (MHRA)

The number of SABRE reportable serious adverse events has risen steadily from 2016. The reasons are varied and complex but should be reviewed with an open mind. Where evidence from SAE reports does back up evidence from MHRA inspections, SHOT, UKTLC and other sources, of staffing, education and workload pressures, it should also be remembered that as the concept of incident reporting “matures”, barriers and fears to reporting are being overcome and quality systems develop an open culture of learning through incident reporting.
Analysis of SAEs reported to SABRE demonstrate that the most common error is “Incorrect blood component issued”. These are reports where the laboratory has failed to issue blood to a patient that meets the patient’s specific requirements, including ABO and Rh group, irradiation, CMV and other requirements, or the wrong type of component. The next most common error is “Sample processing error” where samples that should be rejected by the laboratory are incorrectly accepted for processing.

Assessment of the root causes of error shows that around half of reports are reported to be failure to follow procedures. However, the quality of investigation and incident reporting varies. Evidence from inspection backs up the view of the MHRA Haemovigilance team, that investigation reporting needs to be improved to identify preventable causes in the quality system. When procedural errors are discounted the majority of reports are demonstrated to be caused by weak or poorly designed processes, ineffective training and issues relating to staffing, workload and skill-mix.

For the 2018/19 inspection cycle there were 3 HBBs referred to CMT, 1 that remained at IAG and 3 that remained at CMT from the previous year.

- Senior management not fulfilling their responsibilities
- Self-inspection
- Non-conformances/incidents/events and CAPA implementation
- Document Control
- QMS Failures - Change control management, Validation and Risk Management
- Resourcing and training
- Failure to complete previous commitments
- Data integrity failures
- Capacity
- Traceability

The Haemovigilance Team Manager post has been introduced to provide the following:

- Provide a central POC for the Transfusion Community
- Provide advice and help within the regulatory framework to the whole transfusion community including manufacturers.
- Create a communication flow where everybody can share success and failure
- Manage expectations of both the MHRA and the Transfusion Community
- Remove cultural and fear factors associated with the regulatory process
- Understanding the reporter’s barriers and frustrations to the regulatory process

This service is open to everybody involved with transfusion services, including manufacturers of blood transfusion technologies, and comprises of site visits and education days that provides an educational interface between the inspectorate and the whole transfusion community but remains independent of the inspectorate. The feedback has been extremely positive from all parties that have taken the opportunity to use this facility.

Resource issues and BREXIT has meant that the running of another phase of Blood Workshops has been problematic, but the running of such events will be explored in the future.

**Review of the performance of the NHSBT**

NHSBT improved performance across many indicators and at the end of 2018/19 the following targets were met:
Components issued, on time and in full  
Average age at issue of components  
Red Blood Cell and Platelet wastage  
Customer Satisfaction

Ro units supplied at 51.24%, did not meet the 55% target - Demand has continued to increase over the past few years due to changes in treatment for sickle cell anaemia patients. Donor recruitment strategies are in place to address this in the longer term.

At the close of 2018/19 there had been 13 occasions where red cell stock was below the three-day alert level for three or more consecutive days and 7 occasions for platelets. In the last eight months of 2018/19 this performance improved markedly.

Further information about the terms of reference, membership, and work of the NBTC can be obtained from Celina.Bernstrom@nhsbt.nhs.uk

Next steps 2020 and beyond:

- The NBTC will continue to foster a strong partnership between hospitals and NHSBT on focussing on the needs of patients needing transfusion. The Transfusion 2024 Symposium held in March 2019 was highly successful in bringing together a multi-professional group to highlight key priorities for clinical and laboratory transfusion practice. We will aim to complete recommendations in partnership with stakeholders for circulation by end 2019.

- We will aim to strengthen support received from NHS England/ NHS Improvement for the activities of the Committee with a stronger reporting structure.

- We will continue to focus actively on implementation of Patient Blood Management. A survey in 2018 highlighted progress made but also further improvements needed in the infrastructure within hospitals to improve practice and compliance with the NICE Clinical Transfusion Guidelines and Quality Standards. We will continue to promote further work to promote consistent implementation of various PBM measures with scoping of a PBM self-assessment initiative.

- The Education Working Group will continue to focus on strengthening transfusion education content and delivery for undergraduate and postgraduate education with greater development of web-based resources.

- The Laboratory manager’s group will work closely with NHSBT in the further development of the RCI ASSIST pilot with scope for wider application based on results. We will continue to work with NHSi via a newly formed transfusion subcommittee advising on implementation of pathology networks and support development of defined standards for transfusion laboratories around education, workforce and transfusion IT.

- The Patient Involvement Working Group (PIWG) will continue to actively promote patient information and consent with sharing of best practice within hospitals and support initiatives for implementation of positive patient identification.

- We have also reconvened the NBTC Emergency Planning Group in collaboration with NHSBT and other key stakeholders with updated guidance issued for hospitals including lessons learnt from past major incidents.
• We will focus on promoting appropriate use and stockholding of Group O Neg red cells informed by a further survey of practice within hospitals with updated NBTC guidance issued and a reconvened Group O Neg working group targeting this area.

• We will continue to promote research and innovation in transfusion with projects around use of Big Data and new component development together with further high quality randomised controlled studies increasing evidence base in transfusion. We are also keen to see translation of benefits to patient care including implementation of genotyping for multi-transfused patients.

Acknowledgements

We are grateful to Louise Sherliker, National Lead, PBM Practitioners team at NHSBT for the active support her team provides to support RTC and NBTC activities and for her assistance in compiling this report. We are grateful to all the members and co-opted members of the committee for their work, and to the NHSBT for allowing secretarial assistance and time. We thank our observers from Scotland, Wales and Northern Ireland for their attendance and contribution.

Dr Shubha Allard  
Secretary of the NBTC

Dr Jonathan Wallis  
Chair of the NBTC
### Glossary of Terms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>BSH</td>
<td>British Society of Haematology</td>
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<tr>
<td>FFP</td>
<td>Fresh Frozen Plasma</td>
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<tr>
<td>FRCPat</td>
<td>Fellowship of the Royal College of Pathologists</td>
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<tr>
<td>Haem SAC</td>
<td>Haematology Specialist Advisory Committee</td>
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<td>Haem SpRs</td>
<td>Haematology Specialist Registrars</td>
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<tr>
<td>HSST</td>
<td>Higher Specialist Scientific Training</td>
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<tr>
<td>JRCPTB</td>
<td>Joint Royal Colleges of Physicians Training Board</td>
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<tr>
<td>LGIB</td>
<td>Lower gastrointestinal bleeding</td>
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<tr>
<td>MHRA</td>
<td>Medicines and Healthcare Regulatory Agency</td>
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<tr>
<td>NBTC</td>
<td>National Blood Transfusion Committee</td>
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<tr>
<td>NCABT</td>
<td>National Comparative Audit of Blood Transfusion</td>
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<td>NCG</td>
<td>National Commissioning Group</td>
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<tr>
<td>NHSBT</td>
<td>NHS Blood and Transplant</td>
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<td>NICE</td>
<td>National Institute for Health and Clinical Excellence</td>
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<td>NMA</td>
<td>Non-Medical Authorisation</td>
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<td>PBM</td>
<td>Patient Blood Management</td>
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<td>PI</td>
<td>Pathogen inactivation</td>
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<td>PIL</td>
<td>Patient Information Leaflet</td>
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<td>RCPath</td>
<td>Royal College of Pathologists</td>
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<tr>
<td>Ro Units</td>
<td>Red cell units with the blood group Ro</td>
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<tr>
<td>RTC</td>
<td>Regional Transfusion Committee</td>
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<tr>
<td>SABTO</td>
<td>Advisory Committee on the Safety of Blood, Tissues and Organs</td>
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<tr>
<td>SAEs</td>
<td>Serious Adverse Events</td>
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<tr>
<td>SHOT</td>
<td>Serious Hazards of Transfusion</td>
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<tr>
<td>UKAS</td>
<td>UK Assessment Service</td>
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<tr>
<td>UKTLC</td>
<td>UK Transfusion Laboratory Collaborative</td>
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