

## **National Blood Transfusion Committee**

# National Blood Transfusion Committee Annual Report (2020/21)

## **Executive Summary:**

This annual report of National Blood Transfusion Committee (NBTC) covers an unprecedented time-period for the NHS and for all of us. The entire transfusion community from NTBC, to Regional Transfusion Committees, Hospital Transfusion Committees, Transfusion Laboratory staff and clinicians on the coal face have been under increased pressure to deliver the world class service we are proud of in the face of the COVID-19 global pandemic. The ongoing liaison and two-way support with NHS Blood and Transplant (NHSBT) has never been more crucial to promoting best transfusion practice within the NHS.

Despite the constraints of the pandemic, NBTC activities continue at pace with the working groups, national and regional meetings working effectively via virtual conferencing applications. We are proud that as a transfusion community we have adapted quickly and shown the agility, resilience and innovation that marks the very best of organisations during a time of unexpected challenges and pressures. This report showing the expansive volume and range of quality work in spite of and in response to the COVID-19 pandemic is a testament to the robustness and talent of healthcare professionals involved in transfusion across the country.

The close working relationship we have forged and tightened between NHSBT and the NBTC over recent years has truly delivered in these testing times. The achievement of instigating the Convalescent Plasma capability from NHSBT and the determination of hospital research departments and transfusion laboratories to deploy this treatment as part of multi centre trials has displayed exemplary collaborative working.

This bodes well for the future. Although uncertain times lie ahead, we can be certain that the completed Transfusion 2024 publication will be read with far greater interest, both within the NHS and internationally. We recognise and appreciate the opportunities this brings in terms of more digitalisation, more research and development, better education and compliance to NICE guidelines and how improved accountability can also bring meaningful and sustainable benefits for patients.

Finally, none of the achievements described in this report would have been possible without our dedicated multidisciplinary transfusion workforce. We thank you all along with our patient representatives and will continue to keep shining that spotlight on your vital work as the NHS hopes to build back better from 2020-21. We will also not forget to continually nurture the next generation of transfusion champions to grow this world-leading service into the future.

#### The Report:

The National Blood Transfusion Committee (NBTC) was established in 2001, with the primary purpose of promoting safe and effective transfusion practice in hospitals.

This annual report showcases the wide activities of the NBTC covering clinical and laboratory transfusion practice; This is based on strong two-way communication between Hospital Transfusion Committees (HTC), Regional Transfusion Committees (RTC) and the NBTC. Key targeted work has been achieved through the many NBTC working groups with education and audit strongly supported via the RTCs.

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 remit 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 several Royal Colleges.

The Committee 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 Regional Transfusion Committees (RTCs) have been updated in 2020 following discussion with NHS England to further strengthen governance and reporting arrangements.

This annual report is for 2020/21 bringing up to date reporting from the annual report for 2019/20.

#### **Committee Meetings and Working Groups:**

The NBTC, the Executive Working Group (EWG), the Regional Transfusion Committee (RTC) Chairs Group, all met twice during 2020/21. These meetings have been virtual during the COVID-19 pandemic.

#### **Current Working Groups:**

- Patient Involvement Working Group (PIWG)
- National Transfusion Laboratory Managers Working Group (TLM)
- Patient Blood Management (PBM)
- Education
- Emergency Planning Working Group
- National Transfusion Practitioners Working Group reconvened in 2019
- O D Negative Working Group reconvened in 2019

The previous Anaemia Working Group was disbanded after decision by the NBTC EWG in January 2019; a CQUIN had been developed and implemented nationally for pre-operative anaemia though on hold during the pandemic. A further refocussed Anaemia Working Group has been reconvened.

## Work of the NBTC in 2020/21:

The COVID-19 pandemic has a had major impact on priorities and ways of working of the NBTC, RTCs and various working groups. All meetings have been conducted virtually.

Despite the constraints of the pandemic, the Transfusion 2024 Plan was published on 3<sup>rd</sup> December 2020 and circulated to key stakeholders. The recommendations are based on a collaborative symposium organised by the NBTC and NHSBT that was held in March 2019 with a subsequent updated 5-year strategy for clinical and laboratory transfusion practice.

The Terms of Reference and working arrangements of the Working Groups are also available on the NBTC website www.transfusionguidelines.org.uk.

## **Regional Transfusion Committees:**

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

The ten RTCs previously related to the Strategic Health Authorities as designated in 2006/07 are now being aligned to the 7 NHS Regions to facilitate transfusion accountability and reporting.

Details on the wide range of ongoing activities and output of all RTCs can found at <a href="https://www.transfusionguidelines.org.uk">www.transfusionguidelines.org.uk</a> along with updated Terms of Reference.

RTC Chairs working with Regional Transfusion Teams have maintained key activities supporting safe transfusion practice during the pandemic together with actively assisting NHSBT with addressing ongoing demand challenges with an ongoing focus on appropriate use and stockholding.

The COVID-19 pandemic has brought into stark relief the need for responsive good quality data on blood use to inform NHSBT demand and supply planning.

The RTCs have been active in highlighting the pressures on hospital transfusion laboratories including staffing and training challenges together with the impact of pathology modernisation. These concerns and mitigating recommendations have been incorporated into the Transfusion 2024 Plan.

#### National initiatives that the NBTC/NHSBT have led in 2020-21:

**Transfusion 2024 - A Five-year Plan for Clinical and Laboratory Transfusion Practice**The Transfusion 2024 Plan was published on 3<sup>rd</sup> December 2020 as a collaboration between NBTC and NHSBT despite the constraints of the pandemic <a href="https://www.transfusionguidelines.org/uktransfusion-committees/national-blood-transfusion-committee/transfusion-2024">www.transfusion-committees/national-blood-transfusion-committee/transfusion-2024</a>

The recommendations are based on the Transfusion 2024 symposium organised jointly in March 2019 by NBTC and NHSBT with support from NHS England (NHSE) towards defining 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 across the NHS.

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 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 provide an overall direction of travel for hospitals, RTCs, NBTC and its working groups, NHSBT and other key stakeholders. Ongoing progress will be reviewed on a regular basis at the six monthly NBTC meetings and the interim NBTC Executive Working Group meetings.

## National initiatives that the NBTC supported in 2020-21:

#### 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. The link to various key messages relevant to transfusion have been posted on the NHSBT website <a href="https://hospital.blood.co.uk/patient-services/patient-blood-management/">https://hospital.blood.co.uk/patient-services/patient-blood-management/</a>

**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).

**Give iron to iron-deficient patients**. Don't transfuse red cells for iron deficiency anaemia without haemodynamic instability.

**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.

**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.

Only considering transfusing platelets for patients with chemotherapy induced thrombocytopenia where the platelet count is  $< 10x10^9$  /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 <a href="http://www.transfusionevidencelibrary.com/">http://www.transfusionevidencelibrary.com/</a>

The James Lind Alliance published recommendations on priority setting for further studies in blood transfusion and blood donation from patients, carers and healthcare professionals and continues to inform research strategy <a href="https://www.jla.nihr.ac.uk/priority-setting-partnerships/blood-transfusion-and-blood-donation/">https://www.jla.nihr.ac.uk/priority-setting-partnerships/blood-transfusion-and-blood-donation/</a>

#### **COVID-19 Convalescent Plasma Trials**

The NBTC and RTCs actively supported NHSBT in promoting awareness and hospital participation in two large trials looking at the role of convalescent plasma in the treatment of COVID-19 namely REMAP-CAP and RECOVERY.

The REMAP-CAP trial was an international adaptive trial including convalescent plasma for patients with COVID-19 in intensive care for less than 48 hours. The RECOVERY trial studied the effectiveness of convalescent plasma for treating patients with COVID-19 who were in hospital, but not in intensive care.

Whilst analysis from both trials has shown no overall benefit for people in hospital care there are still questions being considered around the benefit of plasma in subgroups of patients, such as those with low natural antibody levels. Moreover, international collaboration is also being considered for possible further trials of plasma use much earlier in the disease before people get to hospital. Early use could help some of the most vulnerable people, such as the elderly or those with weak immune systems.

#### NBTC Working Groups activity:

#### Patient Blood Management (PBM) Working Group

The PBM Working Group provides a forum for the following working groups. It also allows the NHSBT PBM function to report on its activity and gain stakeholder engagement

## **NBTC Anaemia Working Group**

- NHSE Preoperative Anaemia CQUIN update. Pre-pandemic activity largely focused on preoperative iron deficiency anaemia CQUIN (CCG10, 2020/21 scheme). Under NHS Standard Contract terms for 2021/22 this remains in place for the first 6 months of 2021/22. The group awaits clarity yet on future direction.
- This group's activity has been severely disrupted by the COVID pandemic. The intention is to reform a group in 2021/22 with the continued focus on pre-operative anaemia

# **NBTC PBM NICE Quality Standards Audit Working Group**

- The Transfusion 2024 strategy identified an action to assess the implementation of Patient Blood Management (PBM) in hospitals.
- This working group was established to provide benchmark data on the implementation of PBM and identify any barriers to its implementation.
- The first part of this process will be to assess compliance of hospitals with the NICE Quality Standards for Blood Transfusion (2016): -
  - Treatment of preoperative iron deficiency.
  - Use of tranexamic acid for patients undergoing moderate blood loss surgery.
  - o Reassessment of patients after each unit of blood.
  - Provision of information for patients receiving transfusion.
- This work is being conducted in collaboration with the National Comparative Audit programme.
- Data collection for the audit has been delayed until late 2021 because of the hospital pressures associated with the Covid-19 pandemic

## **NBTC O D Neg Working Group**

- A revised O D Neg Working Group with new Terms of Reference commenced March 2020.
- Confirmed projects include: -
  - The implementation of the use O D pos red cells for adult males in major haemorrhage.
  - O Gain insight into the use of O D neg in prehospital care (HEMS) with the potential to produce recommendations, improving stock holding and wastage. Survey to evaluate "Blood Component support in the prehospital setting" completed. The group will be producing good practice guidance for laboratories supplying prehospital vehicles.
- The group have supported the production of additional O D neg red cell laboratory infographics to support key messages and education in this area. These are now available on the NHSBT Hospitals and Science website

# **Emergency Planning Working Group**

The Objectives for the Emergency Planning Working Group are to meet 3-4 times a year to provide hospitals with support and guidance for transfusion emergency preparedness by providing resources to help teams to plan their response to Major Incidents (MI) and Mass

Casualty Events (MCE) and wider range of potential disruptions to transfusion support i.e., total power outage.

Activity during 2020-21 has focussed on education and awareness in the wider transfusion community through publications and presenting at national and international meetings with contributions to the response to COVID-19, including the updating of existing documents on lessons learnt during COVID-19, producing transfusion resources for Nightingale hospitals, updating the existing NBTC guidance and triage tool for massive haemorrhage in severe blood shortage.

#### **National Transfusion Practitioners' Working Group**

The Transfusion Practitioner group has held successful national education meetings virtually during the pandemic. Progress has been made in defining tasks and roles for different bands which will support further development of a TP competency framework.

The group also worked with the Transfusion Laboratory Managers' Working Group to pull together lessons learnt by hospitals during the COVID-19 pandemic with a view to publication of findings.

## **Transfusion Laboratory Managers' Working Group**

The group is made up of Transfusion Laboratory Managers representing each RTC along with representatives from NHSBT and the MHRA. The overall objectives are to promote good laboratory practice and to provide a framework to assist in various laboratory aspects of transfusion including improving safety, promoting the highest laboratory quality standards and to assist in improving the appropriateness of transfusions to patients.

The group continued to work closely with NHSBT to provide assistance and advice on the changes to blood component demand due to the COVID-19 pandemic. We are having weekly video calls with the team working on demand management.

The group published several documents including: -

- Appropriate specification of emergency red cells this document was aimed at assisting
  hospital laboratories ensure they are selecting the most appropriate units to use as
  emergency stock.
- Advice on good stock management this document was aimed at providing advice to hospital laboratories on good practice regarding the management of blood component stocks.
- A set of managerial competencies for Senior Transfusion Laboratory staff this document was aimed at helping laboratories ensure senior staff competencies were recorded appropriately and provide some standardisation.

The group also worked with the Transfusion Practitioner Working Group to record and publish a paper on the lessons learnt from the first spike in the COVID-19 pandemic. We are looking to revise this document in light of further spikes.

The group has continued to provide laboratory presentation for a number of other groups including: Patient Involvement Working Group (PIWG), UK Transfusion Laboratory Collaborative, O D neg Working Group, Emergency Planning Working Group and the National Comparative Audit Group.

#### **Education Working Group:**

This group has 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

- Basic e-learning modules for anaemia completed (funded by HEE).
  - o Anaemia the only introduction you need
  - Anaemia in primary care patients
  - o Anaemia in hospital patients
- More advanced anaemia modules being developed with Health Education England (HEE) funding.

#### Core medical training

• Transfusion Education Initiative in collaboration with BSH. Developing on-line content with BSH on their new platform.

#### Postgraduate core medical and higher speciality training

- Continuing to raise profile of transfusion medicine across clinical disciplines.
  - Transfusion camps being run in Oxford (Prof Murphy) and Birmingham (Dr Morton).
  - Participation and leading on National Comparative Audits.
  - Contribution to professional guidelines.
- Updated curriculum for haematology trainees in effect from August 2021.
  - o Slides on new curriculum.
  - o <u>Haematology Training Curriculum.</u>

## 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.
- Development of e-learning modules started in 2020 to 2021
  - Essential Transfusion Medicine online content developed. Has received very positive feedback from trainees.
  - Intermediate Transfusion Medicine on-line content being developed funded by HEE.
    - Microbiology virtual content completed.
    - 2021-2022 haemoglobinopathy and advanced blood group education being developed.
    - 2022-2023 plan to develop H&I and neonatal and paediatric transfusion modules (subject to HEE funding).
- Supporting transfusion attachments in partnership with Trusts, deaneries and NHSBT at 8 centres, funded by HEE at Bristol, Leeds, Manchester, Newcastle, and Oxford. Funded by the local deaneries in Cambridge, Liverpool, and Sheffield.
- Supporting NHSBT strategy for international placements with Royal College of Pathologists.

## Scientific training

- Ongoing Contribution to HSST Transfusion Medicine training. First HSST NHSBT trainee has completed training.
- The Practical Introduction to Transfusion Science course has been running as a virtual course with course development funded by HEE. Practical aspects of the course have now restarted.
- MSC in Transfusion and Transplantation Science has been

#### Nursing & Midwifery training

 Non-Medical Authorisation courses (NMA). Successful, highly rated courses run 5 to 6 times a year. Annual review of content – due to be reviewed Autumn 2019. Development of e-learning for midwives – maternal anaemia module – to be ready by Spring 2020.

# Multidisciplinary training

- Created short educational videos funded by HEE
  - o 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

#### **Patient Involvement Working Group (PWIG)**

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

The group held four meetings over the year April 2020 - March 2021. Although the pandemic had some impact on attendance, there was sustained support from a core of dedicated members, enabling us to contribute to a number of valuable projects. This was the last year in post for the present chair, who has nominated a successor to take over from summer 2021.

# Organisation and membership

The PIWG finalised updated terms of reference and introduced a standing review of outcome measures to better capture the output of the group. The PIWG are aiming to widen representation on the group by inviting new members from the Royal Colleges and Specialist Societies and developing closer collaboration with the Sickle Cell and Thalassemia societies. These efforts will renew once the demands of the pandemic ease.

#### Contribution to SaBTO guidance on consent

The group was part of the consultation process for the new SaBTO guidance on consent for transfusion and all members were invited to contribute individual feedback. The PIWG gave support to the concept of a single information resource for patients having a transfusion anywhere in the UK, and for this to include all blood components and to be relevant for both adults and children.

#### Review of Patient Information Leaflets (PILs)

The PIWG provided input on the following publications for patients:

- Anaemia update of a popular existing resource.
- **Convalescent Plasma** a new leaflet providing information for recipients of plasma in the RECOVERY and REMAP-CAP trials.
- Receiving a Blood Transfusion the new single UK-wide information resource as recommended by SaBTO.

The June meeting was attended by representatives from the Patient Information Forum, an independent organisation which provides guidance on the production of high-quality health information for patients and the public. They signposted a number of resources as well as discussing their PIF TICK - which they have developed as a UK wide quality mark for health information.

## Resources for patients receiving anti-D immunoglobulin

NHSBT has discontinued its leaflet on anti-D immunoglobulin for RhD negative women in pregnancy. The group felt strongly that these patients still need a reliable and accessible information source, and we approached the Royal College of Obstetricians and Gynaecologists

and the Royal College of Midwives to invite expressions of interest in developing an alternative. A positive response was not received and so have offered their assistance to CSL Behring, the UK supplier of anti-D immunoglobulin, to improve their existing information for patients, and we look forward to developing this collaboration in the coming year.

## **Projects for 2021-2022**

Following completion of the Receiving a Blood Transfusion leaflet in July 2021, the group will be working to ensure this is publicised and disseminated as widely as possible.

Another recommendation of SaBTO was for a centralised resource for healthcare professionals to facilitate discussions during the consent process. We hope to contribute to this as it is developed, helping to ensure it has a patient-centred perspective.

## Other Activities / Groups:

#### **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 can be found here: <a href="http://hospital.blood.co.uk/audits/national-comparative-audit/national-comparative-audit-reports/">http://hospital.blood.co.uk/audits/national-comparative-audit-reports/</a>

#### Audits 2020 to 2021

- Re-audit of the medical use of red blood cells 2019 (final report available Sept 2021)
  - 62% (342/549) of asymptomatic patients were given a transfusion when their pre-transfusion Hb exceeded 70 g/L.
  - Only 20% (327/1600) of people who were not bleeding or on a chronic transfusion programme had their Hb checked in between units given, and 27% (433/1600) were clinically reviewed in between units given
  - 51% (2545/5018) of patients there was evidence that the risks, benefits and alternatives to transfusion were discussed.
- Paediatric and neonatal audit of plasma and cryoprecipitate use (final report available Sept 2021).

Future audits 2021 and 2022 are the audits that had been planned for 2020

- PBM in paediatric surgery (Spring 2022 specialist paediatric hospitals).
- Audit of NICE quality standards (Autumn 2021).
- Potential re-audit of upper GI haemorrhage to be performed by gastroenterologists in association with the British Society of Gastroenterologists (Spring/Summer 2022).
- Audit of blood sample collection and labelling (Autumn 2022).

Due to the ongoing situation with COVID-19 future plans are subject to change

## **NHSBT Blood Components**

#### NHSBT & NBTC component workshop

In September 2020 a joint workshop between NHSBT and NBTC was held to consider priorities for new blood components in clinical transfusion practice. This builds on strategic priorities presented as part of Transfusion 2024 and will help inform NHSBT's corporate and blood supply strategy.

A brief survey was sent to participants beforehand to gauge opinions on areas of need and priorities, the results from the survey were presented along with presentations on the current state of the art with respect to developments internationally. The overall conclusion from the workshop was that there were three patient groups where the need for change was the greatest: treatment of major haemorrhage, transfusion dependent and haematology/oncology patients. Characteristics that were highly desirable included more universal products and increased shelf-life (especially cryoprecipitate and platelets). The rationale for these were reduced decision making, ease of use/reduced time to administration, improved safety/effectiveness.

The output from the workshop is being fed into groups within NHSBT who are currently developing NHSBT's strategy, representatives from these groups will be in contact with NBTC as this develops.

#### Whole Blood

We established a programme of work to assess the feasibility of suppling whole blood in the pre-hospital setting following feedback from the NBTC that this was a priority area for consideration for research and development, which was re-affirmed at the workshop. In phase 1 of the study, we assessed the product which would be simplest to provide: leucocyte depleted whole blood that does not contain platelets (red cells and plasma) and have completed a feasibility and safety study in collaboration with Barts Health Trust and London Air Ambulance. In parallel we have undertaken a laboratory study to assess platelet function in whole blood that contains platelets, which has enabled approval of a provisional component specification for the product for use in clinical trials in the UK. We have designed an appropriate clinical trial to assess the benefits of whole blood versus standard of care, discussed this with the MHRA and have secured most of the funding for the trial. Subject to securing the remaining funding, the trial will commence Spring next year. Due to the increased donor selection requirements and reduced shelf life of the product compared with standard red cells, supply of whole blood is challenging. We are currently assessing two options to ease this issue: 1) increase the shelflife to 21 days from 14 and 2) whether RhD positive rather than negative blood could safely be used. We are currently performing comprehensive risk modelling on the latter, and when this is complete will solicit NBTC's view as to whether this is acceptable.

#### ABO universal plasma

NHSBT is continuing to work with commercial partners as part of a consortium to develop ABO universal plasma. We have undertaken national and international surveys of to understand the benefits of such a product. We are establishing a project and seeking funding to extend this work to platelets. We have collated national data on anti-A/B levels in UK donors and together with Australia will now use this data to model risk associated with a number of options for moving towards a more universal product. This includes assessing whether pooled cryoprecipitate and pooled platelets in additive solution are sufficiently low risk to be considered safe to transfuse across ABO groups.

#### UK derived and manufactured dried plasma

NHSBT are also considering the feasibility of producing a UK derived and manufactured dried plasma product in response to a request from the UK military to consider this. We are currently seeking external funding to support this programme of activity. We would like to understand the potential benefits and demand of such a product in the civilian setting. We have drafted two brief surveys; one aimed at transfusion lab managers and another at treating physicians. The former will be sent out via our usual customer services route, but we would appreciate NBTC's help in reaching the right people for the latter.

We are continuing to work on whether the post-thaw shelf life of cryoprecipitate could safely be extended from the current 4 hours to enable the provision of pre-thawed cryoprecipitate and reduce wastage. We have summarised the available data to enable a provisional change in the shelf-life from 4 hours to 5 days (if stored at 4°C followed by brief re-warming) to permit extended trials with a small group of hospitals. As part of these trials, we have observed some technical issues with the product and are now working to try and resolve these.

During COVID a number of clinical trials had to be paused, including starting our phase 1 first in man study of red cells grown from stem cells. We are now re-engaging to get this trial up and running.

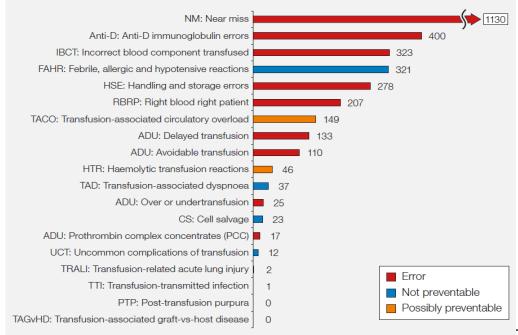
## Serious Hazards of Transfusion (SHOT) Haemovigilance scheme:

<u>Serious Hazards of Transfusion</u> (SHOT) is the UK's independent professionally led haemovigilance scheme collecting and analysing anonymised information on adverse events and reactions in blood transfusion from all healthcare organisations that are involved in the transfusion of blood and blood components in the United Kingdom. Where risks and problems are identified, SHOT produces recommendations to improve patient safety. The recommendations are put into its annual report which is then circulated to all the relevant organisations.

The 2020 Annual SHOT Report was released on the first day of the 2021 Annual SHOT Symposium on 14<sup>th</sup> July and can be accessed <u>here</u>.

# Key highlights from the 2020 Annual SHOT Report:

In the calendar year 2020, a total of 4063 reports were received by SHOT with 3214 reports analysed and included in the 2020 Annual SHOT Report. Here is the summary of all the data analysed in the 2020 Annual SHOT Report:



The following

are the main recommendations from the 2020 Annual SHOT Report:

- Transfusion delays, particularly in major haemorrhage and major trauma situations, must be prevented. Delays in provision and administration of blood components including delays in anticoagulant reversal, particularly in patients with intracranial haemorrhage, can result in death, or serious sequelae. Every minute counts in these situations.
- 2. Effective and reliable transfusion information technology systems should be implemented to reduce the risk of errors at all steps in the transfusion pathway, provided they are configured and used correctly.
- 3. Effective investigation of all incidents and near miss events, application of effective corrective and preventive actions, and closing the loop by measuring the effectiveness of interventions should be carried out to optimise learning from incidents.

A gap analysis tool to help transfusion staff review gaps in local practices and processes in various NHS Trusts/Health boards and implement the SHOT Recommendations is available at this <u>link</u>.

All the learning cases and related educational materials from the 2020 Annual SHOT Report can be accessed via the 'Current Resources' section on the SHOT website and the SHOT App.

The following are the key messages from the latest SHOT report:

- Ensuring transfusion teams are well resourced: Clinical and laboratory teams can function optimally only if adequately staffed and well resourced. Healthcare leaders and management must ensure that staff have access to the correct information technology (IT) equipment and financial resources for safe and effective functioning.
- Addressing knowledge gaps, cognitive biases, and holistic training: Transfusion training with a thorough and relevant knowledge base in transfusion to all clinical and laboratory staff along with training in patient safety principles, understanding human factors and quality improvement approaches are essential. It is important that staff understand how cognitive biases contribute to poor decision making so that they can be mitigated appropriately.
- Patient safety culture: Fostering a strong and effective safety culture that is 'just and learning' is vital to ensure reduction in transfusion incidents and errors, thus directly improving patient safety.
- Standard operating procedures (SOP): SOP need to be simple, clear, easy to follow and explain the rationale for each step. This will then ensure staff are engaged and more likely to be compliant and follow the SOP.
- Learning from near misses: Reporting and investigating near misses helps identify and control risks before actual harm results, thus providing valuable opportunities to improve transfusion safety.
- **Learning from the pandemic**: The learning from the pandemic experiences should be captured in every organisation, by everyone in healthcare and used to improve patient safety.

## Other updates from SHOT:

- The 2021 Annual SHOT symposium took place on a virtual event platform (VEP) (provided by Conference Compass) due to restrictions imposed by the COVID-19 pandemic. The event was held over 2 days (14th and 15th July) and ran 07:30-15:00 on both days. Each day began with 1 hour 'Meet the experts' (MTE) virtual discussion rooms for each chapter (platform allowing 15 participants only) followed by a full lecture programme and finishing with a 1-hour slot for networking, visiting exhibitors and viewing posters. The virtual event was very well attended with 272 unique users, from 17 countries.
- Since the start of the pandemic, SHOT have been organising free educational webinars which have been very well received with 300-500 attendees at each webinar. All webinar recordings can be accessed <a href="here.">here.</a>
- Several educational resources to support staff involved in transfusion have been developed by the SHOT team in various formats (easy to digest documents, videos, podcasts) and are all freely available and accessible via the <a href="SHOT website">SHOT website</a> and the SHOT App.
- The SHOT App launched in Oct 2020 can be downloaded on iPhone and Android phones and allows easy access to all resources on the SHOT website. It can be downloaded by scanning one of these barcodes or searching for 'SHOT UK' in the Apple App Store or Google Play Store. There have been 2748 downloads since release (last checked 03<sup>rd</sup> August 2021).
- SHOT team worked closely with the NHSBT Clinical Trials Unit on Convalescent Plasma clinical trials (REMAP-CAP and RECOVERY) in the UK during the COVID-19 pandemic. Reports to SHOT relating to transfusion serious adverse events and serious adverse reactions help inform trial decisions regarding transfusion safety. SHOT have also been

- able to pick up any inappropriate practices like using convalescent plasma as FFP replacement and contact reporters with the right safety message.
- SHOT team continue to work collaboratively on several projects with various stakeholders
  nationally and internationally to promote transfusion safety and improve transfusion
  knowledge. SHOT have produced a <u>safe transfusion aide memoire</u> during the pandemic
  working with NBTC and RCPath Transfusion SAC. A <u>Safety Notice</u> was also issued relating
  to emergency preparedness and members of the NBTC Emergency Planning Group were
  involved in reviewing and refining the document.
- SHOT continue to deliver and support educational sessions contributing to the objectives
  of the NBTC undergraduate and postgraduate education in Transfusion Medicine across
  many healthcare professionals, including the Non-Medical Authorisation courses, piloting a
  Human Factors in transfusion course in the South West region with a view to further UK
  wide rollout, transfusion link nurse education events, Specialist transfusion Science
  Practice courses and educational courses for haematology registrars.
- In 2022 SHOT will reach 25 years of haemovigilance reporting. This is a major milestone and planning is well underway to mark and celebrate our work and contribution to transfusion safety since our launch and our development into a globally respected haemovigilance scheme. Activities will include a joint Symposium with the International Hemovigilance Network (IHN) planned for July 2022 which will see contributions and attendance from the transfusion community around the world.
- SHOT submitted more than 20 successful abstracts that were presented in various formats in national and international conferences, and had articles published in Bloodlines, Pathology in Practice, Transfusion and Transfusion Medicine.
- SHOT has collaborated with NHSEI reviewing the new Systems Engineering Initiative for Patient Safety (SEIPS) model for linking with the SHOT HFIT – an ABO incompatible case has been reworked using SEIPS and released along with the 2020 Annual SHOT Report as supplementary material and can be accessed here.
- The SHOT UK Collaborative Reviewing and reforming IT Processes in Transfusion (SCRIPT) group aims to improve transfusion safety through improved IT systems and practices. A separate webpage on the SHOT website has been created to capture updates regarding work in this area. An online survey was sent to all registered SHOT reporters from November 2020 February 2021 to begin data gathering from transfusion professionals working in hospitals. The survey about IT systems used in transfusions across UK is now completed and the results are available this highlights the gaps in IT implementation and guides our future activities. SHOT will work collaboratively with everyone involved in transfusions to improve existing systems. An IT provider survey is now being undertaken and will enable us to engage with all LIMS providers in UK
- UK transfusion guidance for safe transfusions during period of blood sample tube shortages
  has been developed collaboratively by NBTC Emergency Planning Working Group, SHOT
  and RCPath Transfusion SAC, with input from BSH Transfusion Task Force and can be
  accessed <a href="here">here</a>. This guidance document should be used in line with local arrangements for
  risk assessment and concessionary release.
- A separate webpage has been created for information and updates from <u>UK Transfusion</u> <u>Laboratory Collaborative</u>. The 2014 UKTLC standards are being updated currently.
- SHOT now produce a monthly newsletter called SnapSHOT which is distributed by email.
   <u>SnapSHOT</u> includes information on current trends in SHOT reporting, signposts to upcoming SHOT and other related transfusion events, links to new SHOT resources and more.

## Medicines and Healthcare Products Regulatory Agency (MHRA)

It was a difficult year for everyone coping with the effects of the COVID-19 pandemic. Changes to clinical focus and practice, processes affecting the quality and safety of blood and blood component, workloads, staffing levels, skill-mix and education and training mean that

comparison of data from 2020 to previous years is difficult. Lower blood usage would inevitably affect the numbers of reports made.

Although the number of SAE reports was less than last year, rather than all categories of reports reducing, some stayed the same as the previous year or even increased from previous years. This may indicate that unplanned changes to processes had an adverse effect on quality and safety in some areas. Categories where numbers reduced may be a reflection on less blood usage but may also be an indication of the robustness of the processes involved that they were able to cope with the many challenges faced.

Specific data on storage errors shows that overall, the number of reports was similar to previous years. There was a decrease in the MHRA sub-categories for component and sample expiry categories that probably reflect the lower usage of blood and blood components. However, this was balanced by an increase in the category Incorrect storage of component. As hospitals adapted processes to cope with the effects of the pandemic, storage locations were either moved or became inaccessible as areas of the hospital were adapted into "hot" or "cold" areas. Staff were also redeployed to unfamiliar areas. Therefore, errors in the incorrect storage of components were likely to be the result of inadequately planned changes to storage processes with a lack of thought to how the changes made might affect how components might be correctly stored and ensuring that these changes had been notified to staff through update training and ensuring shifts were covered by staff with the correct access to storage locations and adequate re-training. It is accepted that coping with the pandemic presented hospital staff with many challenging circumstances and staff should not be criticised for the increase in Incorrect storage errors, but it does demonstrate how errors can be prevented using robust change management controls.

Assessment of the "other" category shows the effect of the pandemic in laboratory areas. The reduction in the overall number of reports received is probably a reflection of the reduction in blood usage during the pandemic as can be seen in a reduction of Incorrect blood component issued and sample processing errors. However, not all categories of event have reduced, with some categories remaining similar to last year or even increasing. Although workloads in laboratories reduced as fewer components were used, laboratories were not immune to the effects of the pandemic with reductions in staffing levels as staff were sick, isolating or redeployed. Even without the pandemic laboratories are still affected by other factors including staff vacancies and loss of experienced staff, training of new staff and inexperienced members of staff trying to cope with reduced supervision.

Along with SHOT, MHRA continue to encourage reporters to investigate incidents to identify the most likely root causes of events and to consider human factors when implementing corrective and preventive action (CAPA). MHRA will liaise directly with reporters if it feels that the investigation is not as in-depth as it could be, or if the CAPA proposed is not adequate. Working with reporters in this way has ensured that 60% of all events reported to MHRA have identified quality management system (QMS) improvements. Of the other 40%, it is assumed that either the QMS improvements have not been identified, or that they were genuinely the result of slips and lapses in concentration by an individual. Improved investigation techniques by reports could be used to identify further improvements to their QMS.

#### **Review of the performance of the NHSBT**

NHSBT continued to improve performance across a range of indicators and at the end of 2020/21 reported:

- 98.6% of orders (excluding R0) were issued on time and in full, up 0.2% from 2019/20
- Average age at issue of red cells was 11.5 days against a target of 12 days, up 0.4% from 2019/20.
- Waste and production losses met the red cell target at 5.8% for units produced but not issued. Platelet losses were 7.6% against a target of 7.7%.

• 100% of hospitals were very satisfied or satisfied with NHSBT's services showing an improvement from 97% in 2019/20.

#### Next steps 2020/21 and beyond

- The NBTC will continue to foster a strong partnership between hospitals and NHSBT in focussing on the needs of patients needing transfusion. The Transfusion 2024 Symposium held in March 2019 was highly successful in bringing together a multiprofessional group to highlight key priorities for clinical and laboratory transfusion practice. We have now published the recommendations and will promote and monitor implementation in partnership with stakeholders highly relevant in post COVID-19 practice.
- The NBTC Terms of Reference have been updated.
- We are making good progress in aligning RTC boundaries and reporting structure to NHSE/I regions.
- We will continue to focus actively on implementing Patient Blood Management as an essential strand of the Transfusion 2024 recommendations. We are promoting consistent implementation of key PBM measures with good progress with a PBM selfassessment project for hospitals.
- The Education Working Group has focussed on strengthening transfusion education for all key healthcare professionals with greater development of web-based resources and also virtual education following the pandemic.
- The Laboratory manager's group actively continues to contribute data and intelligence to support NHSBT Demand and supply planning. Work will continue with NHSEI on development and implementation of standards for transfusion for Pathology networks.
- The Patient Information Working Group (PIWG) has supported the development of the "Receiving a Transfusion" leaflet as a UK resource with work around translations of Patient Information Leaflets (PILs) into other languages.
- The Group O Neg working group is focussing on promoting appropriate use and stockholding of Group O Neg red cells.
- The NBTC is supporting the reconvened National Commissioning Group with clinical and laboratory input from hospitals to review ongoing blood pricing arrangements.
- The Transfusion 2024 recommendations have directly informed the key research aims
  of the NIHR and NHSBT funded Blood and Transplant Research Unit (BTRU) on data
  driven transfusion practice. We will continue to promote innovation with new component
  development. Good progress has also been made in projects supporting use of red cell
  genotyping to provide matched donor blood for multi-transfused patients.

Further information about the terms of reference, membership, and work of the NBTC can be obtained from Celina Bernstrom (Celina.Bernstrom@nhsbt.nhs.uk) or via this link.

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**Dr Shubha Allard** Secretary, NBTC

**Prof Cheng-Hock Toh** Chair, NBTC

#### **Glossary of Terms**

**BSH** British Society for Haematology

**FFP** Fresh Frozen Plasma

**FRCPath** Fellowship of the Royal College of Pathologists **Haem SAC** Haematology Specialist Advisory Committee

Haem SpRs Haematology Specialist Registrars
HSST Higher Specialist Scientific Training

JRCPTB Joint Royal Colleges of Physicians Training Board

LGIB Lower gastrointestinal bleeding

MHRA Medicines and Healthcare Regulatory Agency

NBTC National Blood Transfusion Committee

NCABT National Comparative Audit of Blood Transfusion

NCG National Commissioning Group NHSBT NHS Blood and Transplant

NICE National Institute for Health and Clinical Excellence

NMA Non-Medical Authorisation
PBM Patient Blood Management
PI Pathogen inactivation
PIL Patient Information Leaflet
RCPath Royal College of Pathologists

**Ro Units** Red cell units with the blood group Ro RTC Regional Transfusion Committee

SaBTO Advisory Committee on the Safety of Blood, Tissues and Organs

SAEs Serious Adverse Events

SHOT Serious Hazards of Transfusion

**UKAS** UK Assessment Service

**UKTLC** UK Transfusion Laboratory Collaborative