National Blood Transfusion Committee

National Blood Transfusion Committee
Annual Report (2019/20)

Executive Summary:

This annual report of National Blood Transfusion Committee (NBTC) comes at a time that could have not been predicted. The entire transfusion community from NTBC, to Regional Transfusion Committees, Hospital Transfusion Committees and clinicians on the coal face are under increasing pressure to deliver the world class service we are proud of in the face of the SARS-CoV-2 global pandemic. The ongoing liaison and two-way support with NHS Blood and Transplant (NHSBT) has never been more crucial to promote best transfusion practice within the NHS.

Despite the constraints of the pandemic the activities of the NBTC continue at pace, the working groups, national and regional meetings all now working effectively via virtual conferencing applications. We are proud that as a transfusion community we have been open and responsive in learning new ways of working and communicating. Within this report the expansive volume and range of quality work led by the NBTC is a testament to the resilience and ingenuity 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 hospital research department's determination to deploy this treatment as part of multi-centre trials has displayed exemplary collaborative working.

This brings us to the future. Although uncertain and frightening, 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 digitalisation, research and development, increased support for laboratories, enhanced education, compliance to NICE guidelines and improved accountability will bring meaningful and sustainable benefits from this keenly awaited document.

Finally, we would to thank not only to the healthcare professionals and support staff that make up our transfusion community, but also our patient representatives who play a critical role in keeping us on the right track. Their assistance is invaluable, thank you so very much.

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 report displays the now expansive activities of the NBTC; it details the flow of information and good practice between Hospital Transfusion Committees (HTC), Regional Transfusion Committees (RTC) and the NBTC. 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 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 a number of 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 following discussion with NHS England to further strengthen governance and reporting arrangements.

This annual report is for 2019/20 bringing up to date reporting from the biennial report for 2017/19.

Committee Meetings and Working Groups:
The NBTC, the Executive Working Group (EWG), the Regional Transfusion Committee (RTC) Chairs Group, all met twice during 2019/20.

Current Working Groups:

- Patient Involvement.
- National Transfusion Laboratory Managers.
- Patient Blood Management.
- Education.
- Emergency Planning – reconvened 2018.
- A National Transfusion Practitioners Working Group was convened in 2019 to strengthen the TP framework.
- The O D Negative Working Group was reconvened in 2019 in partnership between NBTC and NHSBT in response to the significant ongoing pressures on O D Neg demand.
- A Digital Working Group is being convened in Q4 2020; its remit includes national benchmarking of Transfusion Digital Maturity and developing a national Transfusion accountability index working in partnership with NHSI Model Hospital.

The Anaemia Working Group was disbanded after decision by the NBTC EWG in Jan 2019; a CQUIN had been developed and implemented nationally for pre-operative anaemia, this is currently on hold due to the pandemic.

Work of the NBTC in 2019/20:
The NBTC has an annual work plan setting out objectives and actions to support the NBTC strategy focussed to support the PBM initiative http://www.transfusionguidelines.org/uk-transfusion-committees/national-blood-transfusion-committee/business.

The Transfusion 2024 Symposium held in March 2019 was aimed at informing an updated 5-year strategy for clinical and laboratory transfusion practice. Whilst work has been underway

informed by these recommendations there have been delays in final publication of the plan as a joint NBTC/NHSBT initiative but with a publication date of 3rd Dec 2020.

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 (RTCs):
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 currently ten RTCs which were realigned in 2006/07 to reflect the boundaries of the Strategic Health Authorities; going forward we will be addressing how reporting can be 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 www.transfusionguidelines.org.uk along with updated Terms of Reference.

RTC Chairs have been active in highlighting the pressures on hospital transfusion laboratories with staffing and training challenges that impact on transfusion practice through pathology modernisation. These concerns and mitigating recommendations have been incorporated into Transfusion 2024.

NHSBT are about to complete Supply Modernisation Projects for North of England and Leeds/Sheffield. Both these projects have implications for stakeholders in the Yorkshire & Humber and East Midlands RTC regions. There has been good engagement between NHSBT and customer stakeholders, with ongoing inclusive transparent dialogue essential to ensure success of these projects for all parties.

NHSBT has highlighted significant demands on Supply of Group O D Neg blood and is working with RTCs to promote engagement and dialogue with hospitals to promote best practice in relation to appropriate use and stockholding. The COVID-19 pandemic has highlighted the need for responsive good quality data on blood use to inform NHSBT demand and supply planning.

National initiatives that the NBTC/NHSBT have led in 2019-20:

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. Avoidable and 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 Managment were endorsed by NHS England and issued to hospitals. http://www.transfusionguidelines.org.uk/uk-transfusion-committees/national-blood-transfusion-committee/patient-blood-management.

The National Institute for Health and Clinical Excellence (NICE) published guidelines on Blood Transfusion in 2015 https://www.nice.org.uk/guidance/ng24 and are these were followed by quality standards for transfusion which were published in November 2016. The guidelines provide a framework for implementation of Patient Blood Managment 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 were:

- Embed PBM into hospitals as a long term and sustainable model for the delivery of patient-centred, evidence based, high quality care.
- Implement PBM strategy through a collaborative approach between NHSBT, NBTC and hospitals/primary care.
- Develop structures, tools and processes to support the implementation of PBM.
- A revised strategy and toolkit is in development, with the aim to launch late 2020.

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 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.

Recommendations for further action have been drafted reflecting the aims of the NHS Long Term Plan (www.longtermplan.nhs.uk) 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 (https://improvement.nhs.uk/resources/patient-safety-strategy/) promoting a safer culture and systems for the benefit of patients.

The final release of the 5-year plan as a joint NBTC/NHSBT initiative was delayed in attempts to get NHSEI endorsement with intervening events including Brexit, UK elections and then the onset of the COVID-19 pandemic in early 2020. Ongoing efforts have helped release the final document on 3rd Dec 2020.

National initiatives that the NBTC/NHSBT have endorsed in 2019-20:

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 https://hospital.blood.co.uk/patient-services/patient-blood-management/

Communicate the benefits and risks – do not 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 – do not 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 < 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 http://www.transfusionevidencelibrary.com/

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 is informing research strategy https://www.jla.nihr.ac.uk/priority-setting-partnerships/blood-transfusion-and-blood-donation/

NBTC Working Groups Activities:

Patient Blood Management (PBM) Working Group.
NBTC/ NHSBT PBM survey
NHSBT and the NBTC undertook a survey in 2015 to evaluate progress towards PBM in NHS Trusts in England with a further repeat undertaken in 2018 with the final report now completed.

Further information can be found at: http://hospital.blood.co.uk/patient-services/patient-blood-management/

NBTC National TP group
A new TP competency framework has been developed and is awaiting final changes. The Transfusion Practitioner group held a successful national meeting in November 2019 that was well attended with good outputs. A further day is planned for 2021.

NBTC Anaemia Working Group
Development of CQUIN for Pre-operative anaemia
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 NBTC anaemia group had important key objectives around promoting awareness and action it struggled to deliver on these. 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. However, a CQUIN for pre-operative anaemia has now been completed. Implementation has been delayed by the onset of the pandemic but will be progressing when feasible.

NBTC PBM Self-Assessment Working Group

The aim of this newly formed group is to develop a transfusion practice self- assessment tool for hospitals to allow benchmarking as an initial step towards external accreditation. The plan for 2020 was to implement a National Comparative Audit of Patient Blood Management based around the NICE Quality Standards. This has however been delayed due to the COVID-19 pandemic. The aim will be to collect data on how sites are configured to deliver optimal PBM practice and identify barriers to improvement and what support is needed to progress and to collect data from clinical case records to provide local evidence of compliance with the 4 NICE Quality Standards and their constituent statements. The group will provide reports to sites in a way which allows them to use the data to understand what steps they can take to improve PBM and to measure the effectiveness of any interventions undertaken.

NBTC O D Neg Working Group

- National Comparative Audit – recommendations published and promoted in regional and national TLM and TP forums.
- Revised O D Neg Working group with new terms of reference commenced March 2020. Confirmed projects include the implementation of O D pos for adult males in trauma, gain insight into the use of O D neg in pre hospital care (HEMS) with the potential to produce recommendations, improving stock holding and wastage.

NBTC Indication Codes App

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 aim of the App is to provide easy access to the indication codes for those authorising blood components, ensuring that transfusions are administered appropriately. Over 12,000 registered users in 154 countries since launch in April 2017; over 60% are returning users. This app continues to exceed expectations with over 3,500 new users since the start of 2020.

NHSBT Blood Assist App: component administration App

Following wide consultation with stakeholders NHSBT are in the process of developing an app that will provide beside accessible advice and guidance on the administration of blood components. Development of the app has included a robust QA process for change management, validation and testing. Launch of the app has been delayed due to COVID-1 but revised launch date is November 2020.

Transfusion Laboratory Managers Working Group

The chair of the group resigned from this role as of March 2019. An interim chair was appointed pending the start of a successor along with a new role of deputy chair that both came into post in Sept 2019.

- The group completed a review of its Terms of Reference and continued to work on several projects including development of a template for senior laboratory staff competencies.
- The group continued to work closely with NHSBT to provide assistance and advice on the implementation of changes associated with blood component supply.

- The group has also provided laboratory representation for a number of other groups including: Patient involvement working work, UK Transfusion Laboratory Collaborative, O RhD negative working group, Emergency Planning working group and the inception of a new transfusion MSc as a collaboration between NHSBT and a university.

- The group also continues to monitor and advise on the progress of plans for Pathology consolidation and highlight concerns where needed. The group is represented on the newly formed transfusion subcommittee advising NHS Improvement on implementation of Pathology networks.
- The group has also been actively involved in the support of laboratories and NHSBT during the COVID-19 pandemic. The group provided 2 sets of frequently asked questions which were distributed to all transfusion laboratories. The chair also contributed to the review of the NBTC Red cell shortage plan. Although the pandemic has meant that it hasn't been possible to meet, the group set up a WhatsApp team to encourage communication and support of the members and other TLMs.

Emergency Planning Working Group
The objective of this group is to provide hospitals with support and guidance for transfusion emergency preparedness. It provides resources that will help teams to plan their response to Major Incidents (MI) and Mass Casualty Events (MCE).
The objective of this group is to provide hospitals with guidance for transfusion emergency preparedness and response to a wider range of potential disruptions to transfusion support.

Activity during 2019-20 focussed on education and awareness in the wider transfusion community, and seeking assurance that hospitals are acting on the NBTC emergency preparedness guidance published in 2019. A survey of hospitals was undertaken in early 2020 to explore awareness of guidance and plans for transfusion preparedness. More recently, individuals within the working group have contributed to the response to COVID-19 including the updating of existing integrated shortage plans. The working group has 'met' two to three times a year using various virtual platforms to co-ordinate activities.

Education Working Group:
The NBTC areas of interest cover 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 include:

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 the e-Learning for Health platform. This module can be used for lots of different staff 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 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, RolCOG, 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

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
    - 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 and Public Involvement Working Group*:*

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

The Working Group was involved in several patient-related activities during 2019/20: -

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 however publication of revised versions is currently on hold as we await clarification on the wording required by the NHSBT's solicitors on risks associated with transfusion. The PILs continue to be delivered within the ethos of the information standard.

During the COVID pandemic a new PIL was developed for recipients of Convalescent Plasma. The review process was carried out promptly and the response rate from reviewers was extremely high.

We are seeking more IT solutions to the management of the PILs to reduce the risk of outdated versions being used. The PILs are available here: http://hospital.blood.co.uk/patient-services/patient-blood-management/patient-information-leaflets/

Promote Transfusion awareness in collaboration with specialist societies and groups
The NHSBT PBM team continues to attend conferences held by:

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

Promote Implementation of SaBTO guidance on consent
A number of the members of the PIWG were invited to participate in the review by SaBTO of its consent for transfusion guidance. The resulting document was reviewed by several key stakeholders including the other members of the PIWG.

Promoting patient safety
Screen savers for both staff facing ("Do you know who they are?") and patient facing ("Do we know who you are?") areas have been developed to remind staff to perform I.D. checks on patients and to empower patients to ask staff to ensure that they are checked before any investigation or procedure is carried out. Attendance at teleconferences and meetings was declining however the introduction of "Teams" led to a much greater attendance and involvement.

Other activities / groups:

National Comparative Audit of Blood Transfusion (NCABT):
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: http://hospital.blood.co.uk/audits/national-comparative-audit/national-comparative-audit-reports/

Audits 2019 to 2020

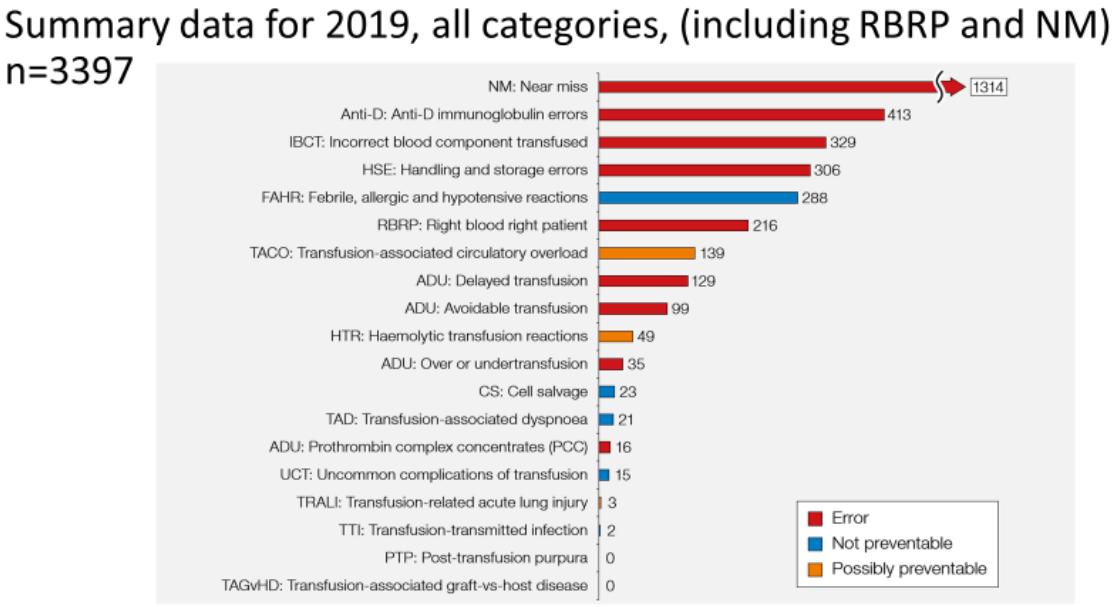
- 2018 Maternal anaemia audit (final report – additional paper)
- 2018 Major haemorrhage audit (final report) Key points
- Re-audit of the medical use of red blood cells (interim report – additional paper)
    - 62% (342/549) of asymptomatic patients were given a transfusion when their pre-transfusion 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

NHSBT Blood Components

We have established a programme of work to assess the feasibility of supplying whole blood in the pre-hospital setting following feedback from the NBTC that this was a priority area for consideration for research and development. 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 initiated a feasibility study that will also assess its safety in collaboration with Barts Health Trust and London Air Ambulance. This study is due to complete end 2020. 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 are now designing an appropriate clinical trial to assess the benefits of whole blood versus standard of care in consultation with the air ambulance community and assessing routes of funding for such a trial.

1. In response to a recent risk assessment and Ministerial direction, NHSBT has discontinued importation of plasma for the treatment of patients born after 1 January 1996, in favour of UK derived components. As an interim measure both UK and non-UK derived components are issued interchangeably whilst non-UK stocks are depleted. It is anticipated that the majority will be from UK sourced plasma by the end of 2020.
2. NHSBT is also considering the potential to supply UK derived plasma for fractionation, should risk assessment and Ministerial direction support this, in order to support domestic demand for plasma derived medicinal products.
3. NHSBT is continuing to work with commercial partners as part of a consortium to develop ABO universal plasma. We have undertaken a national survey of hospitals to understand the benefits of such a product and this will be extended with face to face follow up with a sub-set of respondees.
4. 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. As part of the work on Universal Plasma we will also gauge the need/benefits of such a product in the civilian setting.
5. NHSBT has undertaken some small-scale feasibility studies to assess whether the shelf-life of cryoprecipitate could safely be extended from the current 4 hours to enable the provision of pre-thawed plasma and reduce wastage. Further work in now ongoing to supplement this data to enable a change and shelf-life.
6. NHSBT is continuing to support the establishment of clinical trials of novel red cell products including red cells grown from stem cells, pathogen inactivated red cells and Covid-19 Convalescent Plasma.
7. The Transfusion 2024 conference was an opportunity to consider future Component Development activity in NHSBT. Improving components where there is a clinical need such as to treat major haemorrhage, and to reduce complexity through increasing component universality remain important strategic goals. NHSBT will work with NBTC to develop a 5-year strategy for Component Development that addresses patients need.

Serious Hazards of Transfusion (SHOT) Haemovigilance scheme:



These are the 4 main recommendations from the 2019 Annual SHOT Report:

1. Accurate patient identification is fundamental to patient safety. Organisations must review all patient identification errors and address the causes of patient misidentification with use of electronic systems, and empowerment of patients and staff.
2. Clinical and laboratory staff should be trained in fundamentals of transfusion, human factors, cognitive biases, investigating incidents and patient safety principles both Safety I + II.
3. All healthcare organisations should incorporate the principles of both Safety-I and Safety-II approaches to improve patient care and safety. Healthcare leaders should proactively seek signals for improvement from unsafe, suboptimal as well as excellent care.
4. Healthcare management must recognise that safety and outcomes are multifaceted, a linear view of safety does not fully acknowledge the interdependencies of resources including their leadership, adequate staffing and knowledge. Healthcare leaders should ensure these are all in place to improve patient safety

The following are the key SHOT messages from the 2019 Annual SHOT Report:

- Transfusion in the United Kingdom (UK) is generally safe and SHOT data for the last five years show the risk of death from transfusion as 0.87 per 100,000 components issued.
- Non-infectious complications, especially operational procedural errors and those related to transfusion decisions continue to be the most common causes of transfusion-related deaths in the UK. Delays in transfusion and pulmonary complications (mainly transfusion-associated circulatory overload (TACO)) were the main causes of reported transfusion-related deaths in 2019.
- Errors continue to account for majority of the reports. In 2019, 84.1% (2857/3397) of all reports (including near miss (NM) and right blood right patient (RBRP)), and 74.7% of incidents excluding NM and RBRP were due to errors.

- Near miss events continue to account for a large proportion (1314/3397, 38.7%) of the incidents reported to SHOT.
- Inadequate staffing, lack of adequate training, poor supervision and poor safety culture have been identified as contributory to numerous incidents reported to SHOT. These need to be addressed urgently to reduce the risk to patient safety.
- Trends in pathological transfusion reactions, like the febrile, allergic, hypotensive, and haemolytic reactions are similar to previous years. All staff involved in transfusions must be competent and confident in recognising and appropriately managing transfusion reactions in recipient.

Medicines and Healthcare Products Regulatory Agency (MHRA)

SABRE

After a rise in the number of reportable serious adverse events (SAEs) from 2016 to 2018, the number reported in 2019 has started to plateau. 1198 SAEs were reported in 2018 and 1197 in 2019. It impossible to quantify how many vein-to-vein process steps there are in the United Kingdom to provide an adequate denominator for error reporting. On the one hand, few donations are made and therefore fewer components in circulation, but with improved blood stock management, components may be handled and used more frequently, increasing the number of opportunities for error. In fact, with the well documented pressures on transfusion laboratories with workload, staff retention, training and education, the number of errors reported might be expected to have increased despite the number of donations reducing. The fact that it has not done so is hoped to be a reflection on a laboratory's improved quality management system achieved through the effective regulation of blood and blood components.

The types of error being reported year on year remain similar with incorrect blood component issued and sample processing errors being the most frequently reported errors. However, this is not the entire picture. The Blood Safety and Quality Regulations (BSQR) cover all process steps including the storage and collection of components in the clinical area. A detailed assessment of SAE data show that errors that typically occur in hospital laboratories has decreased, while there has been an increase in the numbers of reports from Blood Establishments and reports of storage errors and collection errors in clinical areas.

MHRA have aimed to highlight the importance of thorough root cause analysis to identify the human factors involved in errors occurring and the identification of corrective measures that seek to improve the quality management systems rather than hold individual staff members accountable for errors. Assessment of the root causes of errors in 2019 demonstrate a reduction of 10% in reports associated with individual slips and lapses with a subsequent increase of 10% demonstrating an improvement in quality system processes.

MHRA run Education Days

In response to requests for more widespread practical training on haemovigilance compliance within the BSQR, MHRA now run QMS education days for HBB and BE to help to provide advice and help, within the regulatory framework, to the whole transfusion community, on site or at the MHRA head office at 10SC. The Haemovigilance Team Manager and the Senior Haemovigilance Specialist will run these days and are open to everyone. Sites can set their own agenda in accordance with the help that they think they may need or a more generic GxP agenda can be provided.

The feedback of the haemovigilance team's assistance continues to be well received helping sites with their regulatory responsibilities and manufacturers with their understanding of how their products can impact within the regulatory framework where they are placed.

Sites and manufacturers have found that post visits/communicates direct from the haemovigilance team has been constructive and well received. Examples of advice given includes:

- Advice centred on moving a transfusion laboratory led to the trust reversing this decision and postponing the movement until a more suitable area is found.
- Obtaining the appropriate and clear and unambiguous release notes for software upgrades when they were not immediately forthcoming.
- Stopping an inappropriate LIMS system being introduced when the regulations were applied to the sites proposed plan.
- Advice on UKAS and MHRA inconsistencies leading to MHRA setting up a review with UKAS once BREXIT is completed.

Review of the performance of the NHSBT

NHSBT improved performance across many indicators and at the end of 2019/20 reported:

- 98.4% of orders (excluding R0) were issued on time and in full.
- Average age at issue of red cells was 11.9 days against a target of 11 days. This was influenced by high stock holding at the end of the year to ensure continuity of supply.
- Wastage had improved with red cells at 5.4% (target 5.8%) produced not issued and platelets 6.8% (target 8.9%)
- 97% of hospitals were very satisfied or satisfied with NHSBT's services

R0 demand continues to grow which presents a significant challenge to grow the donor base sufficiently to meet demand and reduce the number of substitutions. The majority of R0 donations are from white donors (15-18% from black donors). NHSBT performance is measured to ensure validated R0 units are issued to R0 orders; 87.5% against a target of 85%.

At the close of 2019/20 there had been 5 occasions (13 in 2018/19) where red cell stock was below the three-day alert level for three or more consecutive days and 8 (7 in 2018/19) occasions for platelets. At no time were NHSBT unable to meet demand for components on these occasions.

Next steps 2020/21 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 complete recommendations in partnership with stakeholders for circulation by end 2020.
- We will update the NBTC Terms of Reference with clarity on working arrangements and reporting to NHSEI.
- We will review the RTC boundaries and reporting structure aligning to NHSE/I regions.
- We will continue to focus actively on implementation of Patient Blood Management as an essential strand of the Transfusion 2024 recommendations. We will promote consistent implementation of key PBM measures with development of PBM self-assessment for hospitals.
- The Education Working Group will continue to focus on strengthening transfusion education content and delivery for undergraduate and postgraduate education for key healthcare professionals with greater development of web based resources and also virtual education following the pandemic.
- The Transfusion Laboratory Managers Working ~Group will actively contribute to data and intelligence to support NHSBT Demand and supply planning. The group continue to work 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 the transfusion subcommittee to be reconvened as we emerge from the pandemic, advising on implementation of pathology networks with development of defined standards for transfusion laboratories around education, workforce and transfusion IT.

- The Patient Involvement Working Group will continue to actively promote patient information and consent with contribution to update of the SaBTO guidance on consent. The group will promote sharing of best practice within hospitals together with initiatives for implementation of positive patient identification.
- The reconvened Group O Neg Working Group will focus on promoting appropriate use and stockholding of Group O Neg red cells informed by updated NBTC guidance.
- 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. The Transfusion 2024 recommendations are actively guiding further research initiatives.

Further information about the Terms of Reference, membership, and work of the NBTC can be obtained from Celina Bernstrom @nhsbt.nhs.uk or via the following link http://www.transfusionguidelines.org.uk/index.asp?Publication=NTC&Section=27&pageid=814

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.

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Dr Jon Cort
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Chair, NBTC

Glossary of Terms

BSH	British Society of 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