Friday, 24 July 2015

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For Action

1.1 Out of Sight, Out of Control: Blood Stocks Management Scheme Annual Roadshows
The Blood Stocks Management Scheme Annual Roadshows this year will focus on ways to reduce wastage through "out of temperature control" and look at various challenges around maintaining the Cold Chain for red cell components. We will also have some news about the changes to the "30 minute Rule", which is responsible for a high proportion of OTCOL wastage. The cost to attend is £30 which covers refreshments and lunch. All blood transfusion staff are welcome. Dates and venues are:

Birmingham NHSBT 7th September 2015
Sheffield NHSBT 10th September 2015
London Euston (Friends House) 17th September 2015

For more information see our website www.bloodstocks.co.uk or email bsms@nhsbt.nhs.uk

Elaine MacRate, BSMS Manager

1.2 New Credit Request Process
Following the launch of the new credit request process in June 2015 we have received valuable positive feedback from hospitals. As a result we have amended the order in which the components are shown in the drop down list (so the most common appear first) and have added the product codes.

Uptake of the new form has been successful but we are still receiving copies of the old paper request form. This may be due to the new process becoming standard practice but if you are experiencing any difficulties please let us know.

We have also received a high number of requests via the ‘manual’ rather than the ‘electronic’ option and again would appreciate any feedback on why this is the preferred option.

The new form and the user guide are available on the Hospitals and Science website at http://hospital.blood.co.uk/customer-services/request-for-credit/

If you have any questions please contact your local Customer Service Manager or nhsbtcustomerservice@nhsbt.nhs.uk

Christine Gallagher, Regional Customer Service Manager

For Information

2.1 Improvements to the Platelet & Granulocyte Immunology Service
We have made a number of changes to improve the diagnosis of key clinical conditions referred to the NHSBT H&I laboratory at Filton for platelet and granulocyte immunology investigation.

Platelet Immunology
We will be supplementing our current testing algorithm for human platelet antigen (HPA) specific alloantibodies in conditions such as neonatal alloimmune thrombocytopenia (NAIT), platelet transfusion refractoriness and post transfusion purpura with bead based technology to enhance antibody detection in selected cases.

Granulocyte Immunology
We have revised our granulocyte immunology reports to reflect our predominantly DNA based approach to human neutrophil antigen (HNA) typing. The reports now describe the alleles detected but we also provide the interpreted epitopes (antigens) as an aid to interpretation. This DNA based approach also allows us to detect newly described alleles, and interprets the resultant epitopes, which are currently being incorporated into a revised ISBT nomenclature for HNA. It is anticipated that the ability to identify these new alleles will enhance the investigation of suspected cases of neonatal alloimmune neutropenia (NAIN) and Transfusion Related Acute Lung Injury (TRALI).

Dr Andrea Harmer, National Head of H&I Services

2.2 LyoPlas
NHSBT has recently received a number of requests from UK hospitals to import LyoPlas N – w (“LyoPlas”) for general clinical use.

LyoPlas is produced by the German Red Cross (DRK Blutspendediesnt-West) predominantly for its own internal, domestic uses and not generally for other external "markets".

LyoPlas is not licensed for use in the UK and, as such, we have no plans to add this to our portfolio of components. NHSBT works closely with hospitals to ensure security and sufficiency of supply of the components that we produce and our understanding is that LyoPlas is not manufactured or produced in volumes that would meet UK or other demand.

We continue to offer Fresh Frozen Plasma (FFP) and Methylene Blue treated and removed Fresh Frozen Plasma (MBFFP) for clinical purposes.

We have also been approached to offer logistical support to procure small volumes of LyoPlas for use in defined studies. We have been happy to consider providing partnership support to these studies with our involvement being limited to offering logistics and procurement expertise only and not warehousing or ordering/supply of individual units to study participants.

We are currently examining the feasibility of a liquid/never-frozen plasma component and also to respond to the recently published Practical Guideline for the Haematological Management of Major Haemorrhage (Hunt et al Br J Haem: Article published online: 6 JUL 2015 DOI: 10.1111/bjh.13580) that will allow the use of Group A plasma as "universal" in trauma cases where the recipient's ABO group is not known.

We will provide updates on this work as matters progress.

Alastair Hunter, Frozen Component Manager

2.3 Patient Blood Management Working Group Terms of Reference Template
The Patient Blood Management (PBM) Practitioner Team have created a PBM Working Group Terms of Reference Template and guidance document which outlines the key areas that need to be considered and included when developing a PBM Working Group in your Trust. The template can be adapted for use.

Both documents are available to download from the Hospitals and Science Website at:
http://hospital.blood.co.uk/patient-services/patient-blood-management/

Denise Watson, Regional Lead, Patient Blood Management Practitioner Team

2.4 Anaemia business case template
The Patient Blood Management Practitioner Team have developed an Anaemia business case template for hospitals looking to introduce an anaemia service. This template has been developed to support hospitals with implementation of the national Patient Blood Management guidelines: An evidence-based approach to patient care (2014). It can be adapted for individual hospital practice with the option to add and remove information as appropriate to the service intended.

The template can be found at:
http://hospital.blood.co.uk/patient-services/patient-blood-management/general-resources/

Frances Sear, Patient Blood Management Practitioner, Cambridge

2.5 New guidance for nursing staff on iron deficiency and anaemia in adults
The Royal College of Nursing launched guidance for nurses on iron deficiency and anaemia in adults at their annual congress in June. This document is available for download at:
http://www.rcn.org.uk/__data/assets/pdf_file/0003/629553/RCNguide_iron_deficiency_WEB.pdf

Katy Cowan, Patient Blood Management Practitioner, Exeter

2.6 UK Cell Salvage Action Group (UKCSAG) Newsletter and updated policy templates
The 9th edition of the UKCSAG Newsletter is now available on the Transfusion Practice Toolkit at:
http://www.transfusionguidelines.org/transfusion-practice/uk-cell-salvage-action-group

Included within this edition are the results of the recent "Survey on Intraoperative Cell Salvage in the UK", details of the new quality assurance and control standards, an update on the SALVO trial, and information about swab washing.

In addition, the UKCSAG would like to advise hospitals that updated versions of the policy templates are available on the website.

Rebecca Gerrard, National Lead for PBM Practitioner Team

2.7 RCI Licensing and Accreditation
We have published the RCI license and accreditation registration references on the Hospitals and Science website at: http://hospital.blood.co.uk/diagnostic-services/red-cell-immunohaematology/

This will enable you to access these easily when you need them for internal and external audits/inspections.

NHSBT is committed to a total quality philosophy with regulatory expertise, backed by years of experience and governed by a single Quality Management System.

Our work is carried out according to:

- Good Laboratory Practice (GLP)
- Good Manufacturing Practice (GMP)
- Blood Safety and Quality Regulations (BSQR)
- Data Protection and Freedom of Information Acts

As well as relevant:

- British Committee of Standards in Haematology (BCSH) Guidelines
- Royal College of Obstetricians & Gynaecologist (RCOG) Green-top Guidelines
- ISO standards

We are regulated by:

- Medicines and Healthcare products Regulatory Authority (MHRA)
- Clinical Pathology Accreditation UK (CPA UK) and are in transition to the UKAS standard ISO15189
- Care Quality Commission (CQC).

NHSBT RCI participate in UK NEQAS (or EQAS) exercises for all relevant disciplines.

Erika Rutherford, RCI Business Development Manager

2.8 Protocol for blood transfusion management of patients in the phase I dose trial of the Humanized Anti-CD47 Monoclonal Antibody Hu5F9-G4 in Acute Myeloid Leukaemia (AML)
Hu5F9-G4 binds to red cells and may lead to erythrophagocytosis and autoimmune haemolytic anaemia. Treatment with Hu5F9-G4 may obscure assessment of ABO phenotyping and/or underlying RBC alloantibodies. This means great care has to be taken with blood grouping and red cell compatibility testing.

The document enclosed in the following link /media/27698/camellia_transfusionprotocol_v2-0_16apr2015.pdf provides the protocol for the transfusion management of patients in this trial. The protocol has been agreed between NHSBT and the trial sites which are the academic haematology units in the Oxford University Hospitals, Barts & The London, Queen Elizabeth Birmingham, Nottingham University Hospitals, Christie Hospital in Manchester, University Hospital of Wales in Cardiff, St James Hospital in Leeds and Royal Liverpool Hospitals.

It is possible that patients in the trial will be admitted to other hospitals, and if so, it is suggested that requests for information and advice should initially be directed to the blood transfusion laboratory at the relevant trial site, and then to NHSBT if further advice is needed.

Prof. Mike Murphy & Dr. Nay Win, Consultant Haematologists

2.9 NHSBT Reagents and UKAS ISO15189 Audit

NHSBT Reagents have received a number of enquiries from customers regarding the performance of products and traceability to standards. Such enquiries have arisen from comments made following UKAS ISO15189 audits. NHSBT can confirm that its *in vitro* diagnostic red cell serology reagents are produced in accordance with the following stringent legal requirements and guidelines ensuring their potency, specificity and traceability to existing international/national standards:

- 97/89/CE European In vitro Diagnostic Device Directive; compliance with the requirements of this is scrutinised annually by UL UK (MHRA designated Notified Body for CE marking) and we are licensed to apply the CE mark with products that meet the intended purpose. NHSBT also complies with the additional EU requirements ”Common Technical Specifications (CTS) for Products Referred to in Annex II List A Of Directive 98/79/EC” http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2009.039.01.0034.01.ENG

- Guidelines for the Transfusion Services in the UK Chapter 11 (internationally recognised and followed by many non-UK Blood Establishments) detailing requirements for reagent purchase and manufacture including traceability to applicable NIBSC standards. The various NBS/NHSBT Reagents Laboratories have complied with this since 1989. The antisera used to type reagent cells are validated against NIBSC standards. However, there are no internationally recognised standards that apply to the intended purpose of our (or indeed any commercially equivalent) extended portfolio of products.

- The NHSBT Quality System which is regularly updated in line with new requirements and is subject to regular inspection by Licensing and accreditation agencies including the MHRA.

Following consultation with UKAS it is not expected that the manufacture could verify fitness for purpose for use by each and every customer. Manufacturers cannot replicate the testing protocols and environment in each user Laboratory. For this reason ISO15189 requires customers/users to 'verify' that commercial reagents are fit for their intended use.

To assist with this, NHSBT Reagents produce a certificate of conformance for each lot of Reagent manufactured. These are available on the Hospitals & Science website at: http://hospital.blood.co.uk/diagnostic-services/reagents and confirms that the lot has met all of the required standards.

If you require any additional information please contact ReagentsCustomer.Services-Liverpool@nhsbt.nhs.uk

Michelle Weston, Reagents Operations Manager

2.10 Removal of date and signature on Radsure labels on Irradiated Blood Components - Update

NHSBT currently provide all irradiated cellular components with a Radsure label attached which demonstrates that the product has been irradiated.

The current label has an area for a date and initial which is manually completed by the operator at the time of irradiation.

It was previously the intention to remove this date and signature option in June 2015. In order to ensure this change process is conducted in a controlled manner, the removal of the signature and date option has been rescheduled to later in the financial year. As previously stated NHSBT will introduce an internal checking process which requires the operator to confirm the label presence and change on the central IT system before the unit can be issued.
We will confirm details of the revised timeline once finalised.

In the interim, if any users still have concerns regarding the removal of this data, please contact your local Customer Services Manager.

Graham Walters, National Hospital Services Manager

For Training

3.1 Training & Education Events and Courses

A full list of NHSBT training events, which are open to hospital personnel, is available on the our website at http://hospital.blood.co.uk/training/index.asp

If you have any queries regarding the above, please do not hesitate to contact your local Customer Service Manager, Patient Blood Management Practitioner or either of us using the details below.

For further information please visit the NHS Blood and Transplant hospitals website on:
http://hospital.blood.co.uk/

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