Title	Provision of Specific Requirements of Blood and Blood Components
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Reviewed by	*Hospital Transfusion Team 06/2021*
Significant resource implications (financial/workload)	
Approved by	*Hospital Transfusion Committee 06/2021*
Health Inequality Impact Assessment (HIIA) (only statutory for policies)	*06/2021*

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1. STATEMENT OF INTENT AND AIM OF PROTOCOL

This protocol outlines the provision of specific requirement needs of patients requiring a transfusion of blood or blood components. The development of the protocol is designed to:

- Ensure irradiated and CMV requirements are documented in the clinical alert section of the patients' notes highlighting the need for such components
- Act as a resource and inform staff working within the clinical transfusion environment

The protocol is developed by the Hospital Transfusion Team based on national guidelines (BSH 2010, SaBTO 2012, SaBTO 2015) and is approved by the NHS Borders Hospital Transfusion Committee and NHS Borders Clinical Executive Group. The protocol is distributed to all internal stakeholders within NHS Borders. NHS Borders committee members will initiate the cascade and the distribution of the protocol to clinical areas. It is the responsibility of the individual Heads of Clinical Services and Senior Charge Nurses to oversee the distribution of the protocol within their own departments/services and to keep a record of the document holders for updates and redistribution.

The Hospital Transfusion Team on behalf of the NHS Borders Transfusion Committee will facilitate the co-ordination and maintenance of the protocol by:

- Reviewing and updating protocol every two years
- Continually reviewing effectiveness of protocol based on any adverse clinical incidents

The protocol will be hyperlinked as a resource in the NHS Borders Transfusion Policy. All incidents and near miss events **MUST** be reported through Datix. The Hospital Transfusion Team will report incidents and near miss events to Medicines and Healthcare Products Regulatory Authority (MHRA) and Serious Hazards of Transfusion (SHOT) national reporting scheme.

2. BACKGROUND

Annually, SHOT (1996- 2017) continue to identify the risks at every stage of the transfusion process, which contribute to incidents or near miss events. Within the category of incorrect blood component transfused the provision of irradiated blood is a key feature. SHOT continue to recommend robust systems for identifying patients' specific requirements needs is a fundamental aspect of patient care which should be developed within a transfusion policy supported by patient empowerment. The evidence from SHOT is used to make recommendations to inform policies, improve standards and support the development of clinical guidelines (Gerard 2006).

3. TRANSFUSION ASSOCIATED GRAFT VERSUS HOST DISEASE (TA-GvHD)

Transfusion Associated Graft Versus Host Disease (TA-GvHD) is a potential but very rare complication of transfusion, associated with a high degree of mortality (BSH 2010). Organs or tissues that can be affected include skin, thymus, gastrointestinal tract, liver, spleen and bone marrow.

Clinical features

As suggested by BSH (2010) onset of clinical symptoms may be delayed for 1 – 2 weeks after the transfusion. In view of this careful monitoring of the patient is required. Major target tissues include skin, thymus, gastrointestinal tract, liver, spleen and bone marrow. Early signs and symptoms include fever, maculopapular rash, diarrhoea and hepatitis with or without jaundice. Neonates may demonstrate early hepatosplenomagaly and lymphadenopathy followed by lymphoid regression. The risks of TA-GvHD are highest in recipients with immunodeficiency or immunosuppression. BSH (2010) has provided guidelines on gamma irradiation of blood components for prevention of TA-GVHD for clinicians to develop local protocols for practice. The recommendations from BSH (2010) have supported the development of the categorisation of patients with specific requirement needs which can support the decision making process.

Please refer to Appendix 1 for guidelines on the requirement for irradiated blood

4. CYTOMEGALOVIRUS (CMV)

CMV is an ubiquitous DNA virus, which causes widespread infection. Transmission occurs through infectious body fluids including blood. The prevalence of CMV seropositivity in healthy blood donors ranges from 40-90%, increasing with age. Seroconversion may be asymptomatic and CMV remains latent in tissues and leucocytes for many years.

Clinical consequences of CMV infection

Infection may be clinically silent, with no specific symptoms. Primary infection or reactivation may mimic infectious mononucleosis with sore throat, lymphadenopathy, lymphocytosis and fever. CMV infection may lead to serious complications in immunosuppressed patients. Specific examples are given below:

- Intrauterine infection: If a seronegative mother contracts CMV in the 1st two months of pregnancy the rate of transplacental infection is approximately 50%. The baby may develop jaundice, thrombocytopenia, cerebral calcification and motor disabilities.
- CMV infection in early neonatal period from an infected mother causes mental retardation and deafness, and may be fatal.
- Premature neonates and low birth weight <1.2 kg are at increased risk of CMV
- CMV infection or reactivation in adults with immunosuppression e.g. post marrow or organ transplantations may cause pneumonitis, hepatitis, retinitis, and multisystem failure.

Risk of transmission of CMV in Blood Transfusion

CMV is transmitted by leucocytes in blood. Universal leucodepletion of all blood components may be as effective in reducing CMV transmission as provision of CMV seronegative units. At this time it is still advised to offer CMV negative components to specific patient groups.

Please refer to Appendix 1 for guidelines on the requirement for CMV negative blood

5. DARATUMUMAB

Daratumumab (Darzalex®- Janssen-Cilag Ltd.) is an Anti-CD38 therapeutic monoclonal antibody and is approved in Scotland, England and Wales as treatment of relapsed and refractory myeloma.

Daratumumab (Anti-CD38) binding to red cells **may** cause a false positive antibody screen in pre-transfusion testing. It also affects antibody Identification and crossmatching. Daratumumab does not affect ABO and D blood grouping.
The blood bank **must** be made aware of any patient **prior** to them commencing on Daratumumab.

6. COMMUNICATION STRATEGY

Effective and early communication of special requirement needs of patients is a fundamental and integral aspect of patient care throughout the transfusion process. A multidisciplinary approach to communication is essential to improve patient safety and reduce the risk of receiving an incorrect blood component. A notification of special requirements form (Appendix 2) **MUST** be completed as soon as a patient has been identified with a need for irradiated or CMV negative components and sent to blood bank. This can be supported by verbal communication.

A Specific Requirements for Transfusion: Decision Support Tool app developed by SNBTS is available for free download from all three stores, apple, android and windows. The app will guide you through the decision making process which will enhance the understanding for specific transfusion requirements in key patient groups.

6. ROLES AND RESPONSIBILITIES DETAILED BELOW:

- The Consultant responsible for the patient is accountable for notifying blood bank and completing the specific requirement form
- Need for irradiated or CMV negative components must be documented in the clinical alert section of the patient's notes as

soon as the specific requirement need has been identified and a clinical alert sticker applied to the patient's notes

- The Consultant responsible for the patient is accountable for documenting the specific requirement on the clinical alert section of the patient's notes at the point of identifying the need (sticker from Irradiated Patient Information leaflet can be used)
- Pharmacy will furthermore support the communication strategy and inform blood bank of any patient commenced on purine analogue drugs. Ultimate responsibility for communication however, is the Consultant in charge of the patient's care.
- Transplant Co-ordinator will email Borders/Lothian/Fife Blood Banks of any patients who are placed on the transplant waiting list via the bts.labs@borders.scot.nhs.uk inbox to support the communication for patients in the 'at risk' patient group
- Specific requirement notification forms (Appendix 2) will be available in clinical areas and outpatient departments
- Irradiated blood patient information leaflets https://nhsnss.org/services/blood-tissues-and-cells/clinical-services/patient-resources-for-clinicians/ (SBNTS 2017) must be given to the patients as part of the treatment plan. This is available from SBNTS in languages other than English if required and can be obtained by telephoning SNBTS on 0141 357 7752.
- Patient information card (incorporated as part of above leaflet) must be completed as directed by Consultant responsible for patient's care at the time of the provision of the patient information leaflet and issued to the patient
- Patients with cards noting special requirements should be educated about their meaning and importance, in particular always to show these to clinical staff on admission to any hospital
- Requesting Medical Practitioner or Specialist Nurse is responsible for detailing specification on the request form
- Authorising Practitioner is responsible for completing the specific requirement section of the NHS Borders Transfusion Pathway

- Blood Bank staff will enter data as per special flags system attached to patient record in Laboratory Information System as per laboratory standard operating procedures
- Blood Bank staff will enter data on the Clinical Alert section on TRAK as per laboratory standard operating procedure

N.B Blood Bank staff can only issue irradiated or CMV negative components if they have been informed of the need for either irradiated or CMV negative components

REFERENCES

Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO2012) *Cytomegalovirus tested blood components* – position statement, available at https://www.gov.uk/government/news/provision-of-cytomegalovirus-tested-blood-components-position-statement-published

British Society for Haematology (2012) *Addendum: Guidelines on the use of Irradiated components* prepared by the British Committee for Standards in Haematology blood transfusion task force, available at http://www.bcshguidelines.com/documents/BCSH_TTF_addendum_irradiation_guidelines_final_6_11_12.pdf

British Society for Haematology (2010) *Guidelines on the use of irradiated blood components* prepared by the British Committee for Standards in Haematology blood transfusion task force, available at http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2141.2010.08444.x/pdf

Norfolk (2013) *Handbook of Transfusion Medicine*, 5th Edition, Norwich, The Stationery Office

Scottish National Blood Service (2017) *Information for patients needing irradiated blood*

Scottish National Blood Transfusion Service (2015)Special Requirements for Transfusion: Decision Support Tool

Serious Hazards of Transfusion Annual Report (1996 –2017) *Annual reports*, available at http://www.shotuk.org/home/

NHS Lothian (2016) *Blood Transfusion Clinical Policies and Prcocedures*, special requirements appendix C

Appendix 1

GUIDELINES FOR SPECIFIC REQUIREMENTS BLOOD/BLOOD COMPONENTS

IRRADIATED BLOOD/ BLOOD COMPONENTS

- Intra-uterine transfusion
- Exchange transfusion
- Top-up transfusion in premature or term infant where there has been a previous intra-uterine transfusion
- DiGeorge Syndrome
- Congenital immunodeficiency state
- Patient undergoing autologous bone marrow or peripheral blood stem cell transplant for the 7 days before the harvest continuing indefinitely thereafter
- Patient undergoing allogeneic bone marrow or peripheral blood stem cell transplant prior to planned transplant continuing indefinitely thereafter
- Patient with Hodgkin's disease indefinitely
- Patient treated with all purine analogue drugs indefinitely such as Fludarabine, Deoxycoformycin, Cladribine, Clofarabine and Bendamustine
- Transfusion from first or second degree relatives
- HLA matched platelet transfusion
- Patient treated with **ALG**, **ATG**, or **Alemtuzumab** (CAMPATH) indefinitely or any other T cell depleting agents (which can be used in non – hematological indications including solid organ transplantation, multiple sclerosis and vasculitis)

CMV NEGATIVE BLOOD/BLOOD COMPONENTS

- Women who require elective transfusion during pregnancy. If CMV negative components are not readily available and a delay will compromise the mother or baby, CMV random components are considered to be an acceptable alternative.
- CMV seronegative red cell and platelet components should still be used for Intrauterine transfusion irrespective of the CMV status of the mother and neonatal transfusion (including exchange transfusions) up to 28 days post expected date of delivery, where CMV monitoring and treatment of the patient is more difficult.
- In rare occasions at BGH granulocyte components will also continue to be provided for CMV seronegative patients, this must be discussed with SNBTS via consultant Haematologist.
- SaBTO recommends that CMV PCR monitoring should be considered for all at risk patients to allow early detection and treatment of any possible CMV infection (whether transfusion-transmitted or primary acquired infection)

PATIENTS TREATED WITH DRUGS THAT MAY AFFECT BLOOD GROUPING

- Daratumumab (Darzalex ®)

Appendix 2 **PLEASE ENSURE THIS IS DOCUMENTED IN THE CLINICAL ALERT SECTION OF PATIENTS NOTES AND CLINICAL ALERT STICKER APPLIED**

NHS BORDERS BLOOD TRANSFUSION LABORATORY: NOTIFICATION OF SPECIFIC REQUIREMENTS

Please complete this form when you identify a patient that has specific requirements for blood components

Requested By Date

Patient and Request Details	
Surname	
Forename	
D.O.B.	
CHI NUMBER	
Sex	
Patient Number (if applicable)	

IRRADIATED BLOOD/ BLOOD COMPONENTS (please tick reason)

- ☐ Intra-uterine transfusion
- ☐ Exchange transfusion
- ☐ Top-up transfusion in premature or term infant where there has been a previous intra-uterine transfusion
- ☐ DiGeorge Syndrome
- ☐ Congenital immunodeficiency state
- ☐ Patients undergoing autologous bone marrow or peripheral blood stem cell transplant for the 7 days prior to harvest continuing thereafter indefinitely
- ☐ Patient undergoing allogeneic bone marrow or peripheral blood stem cell transplant prior to planned transplant continuing thereafter indefinitely
- ☐ Patients with Hodgkin's disease indefinitely
- ☐ Patients treated with any purine analogue drugs indefinitely (please select: Fludarabine/Deoxycoformycin/Cladribine/Clofarabine/Bendamustine)
- ☐ Transfusion from first or second degree relatives
- ☐ HLA matched platelet transfusion
- ☐ Patient treated with **ALG, ATG,** or **Alemtuzumab** (CAMPATH) indefinitely or any other T cell depleting agents

CMV NEGATIVE BLOOD/BLOOD COMPONENTS (please tick reason)

- ☐ Intrauterine and neonate transfusion (up to 28 days post EDD)

Women who require elective transfusion during pregnancy. If CMV negative components are not readily available and a delay will compromise the mother or baby, CMV random components are considered to be an acceptable alternative.

PATIENT TREATED WITH DRUGS THAT MAY AFFECT BLOOD GROUPING

- ☐ Daratumumab (Darzalex ®)
- ☐ Other (please name) _____

Signed:_____ Print: _____ Date: _____

For Lab use only:

- ☐ Recorded as Critical Note on Laboratory Information System
- ☐ Recorded as Clinical Alert on TrakCare
- ☐ SNBTS informed by email (RIE & WGH)
- ☐ IRD or DTM flag added to Patient's record
- ☐ Amend 'Stock Allocation', 'Stock should be' on Laboratory Information System

Signed: Date: