University Hospitals of Derby and Burton NHS Foundation Trust

Policy for the Authorisation of Blood Component Transfusion by Non- Medical HCPs

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1. Summary

This document is a Policy for the introduction of the authorisation of blood component transfusion by Health Care Professionals (HCP) caring for adult / paediatric patients requiring transfusion within a designated clinical speciality.

An amendment of Section 130 of the 1968 Medicines Act by regulation 25 of the Blood Safety and Quality Regulations 2005 (SI2005 No.50) resulted in blood components being excluded from the Medicines Act 1968 and the subsequent Human Medicines Regulations 2012. The effect of the amendment is to exclude blood components from the legal definition of medicinal products. Therefore, although the authorisation of blood components has traditionally been regarded as the responsibility of a medical practitioner, there are no legal barriers to other trained, competent, registered HCPs ordering, authorising, and administering blood components.

BSH Guidance:
"There are no legal barriers to any appropriately trained, competent, locally designated and approved registered regulated HCP being able to authorise blood component administration." (Robinson et al., 2017, p.9)

Blood components consist of red cells, fresh frozen plasma, platelets, and cryoprecipitate.

Consideration should be given to which blood components will HCP be allowed to authorise.

A collaborative project was undertaken by NHS Blood and Transplant and the Scottish National Blood Transfusion Service to investigate the authorisation of blood transfusions by nurses and midwives. Following wide consultation, a Governance Framework was developed to support the authorisation of blood components by non-medical prescribers and nurse specialists (Green & Pirie 2009). This framework was updated in 2022:

Clinical Decision Making and Authorising Blood Component Transfusions: A framework to support Non-Medical Healthcare Professionals

2. Introduction

- HCPs provide high quality individualised care to their patients and can make the clinical decision and give written instruction for appropriate blood component transfusions. This Policy is intended to clarify the process of introducing the authorisation of blood component transfusions for HCPs caring for adult and / or paediatric patients
- HCPs who wish to develop their role to include authorisation of blood component transfusions will need to achieve relevant training and competency assessment

- HCPs will need to be able to take a history, assess the patients need for transfusion, make a clinical decision to transfuse, understand and undertake the consent process, and possess the clinical skills to respond and manage adverse events such as suspected transfusion reactions
- HCPs who take on the role of the authorisation of blood components will need continued support and mentorship with a period of supervision and a programme for revaluation. Terms of responsibility, accountability and authority must be defined and documented in local Policies
- The authorisation of a blood transfusion must only occur when the patient is in clinical need according to the local Policy and when all alternatives to transfusion have been considered
- The role of non-medical authorisation of blood components is not suitable for all HCPs and should only be taken on within the agreed governance structures of the Trust after careful consideration of service and clinical need.

3. Aims and Objectives

The purpose of this Policy is to support clinicians in responding to the changing needs of patients and developing the role of HCPs to include authorising blood component transfusions.

This Policy outlines the criteria and assessment framework required for the authorisation of blood components by HCPs. It enables them to make clinical decisions and provide written instruction for blood component transfusion for patients within their own speciality.

The aim is to:

- Ensure that the decision to transfuse will be made by experienced HCPs who have an in-depth knowledge of the transfusion process
- Ensure that HCPs authorising transfusion have an in-depth knowledge of their patients' needs
- Provide a high standard of care that will be effective, efficient, and safe, prevent delays in the decision to transfuse and in the authorisation of transfusion thereby improving the patient's quality of care and potentially reducing their length of stay
- Ensure that the HCPs undertaking the role are aware of their professional and legal responsibilities
- Clarify the boundaries of the role undertaken by the HCPs and identify clear lines of accountability.

4. Responsibilities

- The Trust must identify a service need within the specific department
- A local Policy must be in place that clearly outlines the scope of practice that the HCP must follow

- The Trust must provide adequate support for the relevant staff including clear governance structures with supporting documentation to protect patients, and individuals
- Applicants must meet the selection criteria (see section 5) and be supported by a Designated Medical Supervisor / Assessor
- The Designated Medical Supervisor / Assessor is required to meet an agreed criteria (see section 7) and is responsible for supporting the student(s) throughout the work-based learning and assessment. They will also contribute to the final agreement to practice
- The HCP is responsible for maintaining accurate documented evidence of training and practice
- The HCP is responsible for ensuring that they are familiar with current national and local guidelines and Policies by accessing relevant courses and maintaining training and competency
- The Trust must agree to release the trained HCP for updates as required
- The HCP has a responsibility to keep training and skills up to date throughout their working life and a duty to work within their own area of competency and expertise
- The HCP must comply with their professional body's code of practice
- The patient's lead Clinician retains ultimate responsibility for treatment and devolves responsibility to the identified HCP through the patient's Clinical Management Plan
- The Hospital Transfusion Committee (HTC) is responsible for monitoring the use of this framework and final agreement to practice
- It is advised that consideration is given to what processes will be put in place to ensure that the authoriser of blood component transfusions, who has been deemed competent, uses the skill, and keeps up to date
- It is the individual practitioner's responsibility to ensure they are fit to practice.

5. Selection Criteria and Training Required for HCP

The HCP:

- Must be a current registered HCP with at least 3 years post registration experience and have at least 1 year working in the Trust within the relevant specialty
- Must have the support of their Clinical Consultant and line manager
- Must manage a clinical caseload or work as part of a clinical team managing the patient's needs
- Must be up to date with mandatory training and / or e-learning as per their organisations mandatory training requirements
- Must be deemed competent by assessment for pre-transfusion blood sample taking, collection (if applicable) and administration of blood and blood components
- Will have a consultant or specialist registrar for their speciality as a Designated Medical Supervisor / Assessor for the period of education, training and revalidation
- Must have documented approval from their line manager and Designated Medical Supervisor / Assessor.

6. Training Programme for the HCP

The HCP must have successfully completed a Trust approved training programme such as the NHS Blood & Transplant Non-Medical Authorisation of Blood Components course or The Midlands RTC Non-Medical Authorisation Course.

There is a prerequisite level of transfusion knowledge for undertaking such a course. Therefore, evidence of compliance with local mandatory training requirements is necessary, and completion of additional learning to a standard equivalent to e-lfh modules: Safe Transfusion Practice, Blood Components, Consent, SHOT and Transfusion Reactions.

Knowledge and competency
The knowledge and competencies required for this role development are detailed in Document 3 (Midlands RTC Portfolio of Evidence and Competencies) and the NMA programme should cover the content indicated.

Supervisory learning log and portfolio of evidence
A supervisory learning log and portfolio of evidence is required (candidate is supplied these on completion of the NMA course by Transfusion Practitioner or member of HTC team), which accommodates a flexible approach to learning and draws on a range of sources to provide a structured record of the HCP's:

- Learning requirements
- Training received
- Reflective practice
- Assessment outcomes
- Individual development in clinical practice.

This helps to ensure that:

- Competencies and the performance level required to make the clinical decision and write the instruction for blood component transfusion are clearly identified
- A robust training needs analysis is conducted before the individual learning plan is developed
- Strategies for methods of education and training delivery, work-based learning, assessment, and supervision arrangements are agreed locally
- An agreed strategy is in place for maintaining and updating skills, knowledge, and competence.

Ratification of qualification and competency to practice independently.

The conclusion of this role development is formal recognition and documentation of successful completion of the NMA programme, and approval to undertake NMA within the agreed scope of practice. This process should be completed within a timeframe considered appropriate locally. This final step in the HCP's NMA development process should:

- Stand as evidence of agreement of candidate's accomplishment
- Include participation from all key stakeholders
- Be the mechanism for registering the NMA practitioner's status for future reference.

Clinical Decision Making and Authorising Blood Component Transfusions: A framework to support Non-Medical Healthcare Professionals (2022)

Training must include a full understanding of:

- Blood components, the indications for transfusion and thresholds for transfusion
- Transfusion reactions inclusive of recognition and management
- The significance of antibodies and the effect on sample validity and suitable blood component selection
- The British Society for Haematology transfusion guidelines
- The legal responsibilities associated with the transfusion process
- How to make the decision to transfuse and what further investigation may be required
- Information about how to reassess patients following blood transfusion.

Although it is not a requirement to be a Non-Medical Prescriber to authorise blood components, this may restrict practice, i.e. unable to prescribe concomitant drugs.
Note: Consideration should be made about the length of the supervision. This period and the number of reviewed blood component authorisations to be completed should be determined locally. An extended period of supervision may raise concerns about the suitability of the area / department for this practice.
Consideration should be given to the grade of staff / level of experience your Trust / Organisation requires to be non-medical authorisers. A suggestion would be 3 years post registration and 1 year in speciality.

7. The Designated Medical Supervisor / Assessor

The Designated Medical Supervisor / Assessor has a critical and highly responsible role in educating and assessing the HCP undertaking authorisation of blood transfusions.

The Designated Medical Supervisor / Assessor has a key role in assuring competence of the HCP by providing them with supervision, support, and opportunities to develop competence in authorisation of blood transfusions during the work-based learning element of the programme.

It is essential that every participant identifies a Designated Medical Supervisor / Assessor who will be asked to sign a declaration of support for the student at the commencement of the student's period of authorisation of blood transfusion study.

When the Designated Medical Supervisor / Assessor has witnessed practice and is satisfied with the evidence provided, the HCP can be 'signed off' as competent in the relevant section in the HCP's competency framework document. The evidence of competence and subsequent annual reviews should be kept in the practitioner's competency framework document and cross referenced in their professional portfolio.

The Designated Medical Supervisor / Assessor must be a registered practitioner who:

- Is a Consultant or Specialist Registrar who has ideally had at least three years clinical responsibility for a group of patients in the specialist area in which the HCP is employed that includes the authorisation of blood transfusion
- Has the support of the employing organisation to act as the Designated Medical Supervisor / Assessor who will provide supervision, support, and opportunities to develop competence in authorisation of blood components
- Is up to date with mandatory training and transfusion training including e-learning as per the Trustsmandatory training requirements
- Is deemed competent by assessment for pre-transfusion blood sample taking, collection (if applicable) and administration of blood and blood components
- Regularly authorises blood transfusions and with whom the HCP can work alongside for learning and assessment purposes
- Has time to support and guide the HCP through their learning experience and assess their competency during the training period
- Has experience or training in teaching, assessments and / or supervising in practice
- Will be appraised of the programme before the programme commences and be given the opportunity to ask questions and / or clarify any areas of concern.

8. Authorisation Practice

The HCP may only authorise blood components in their specific clinical area and are responsible for their own actions. The HCP will undertake the extended role solely within the clearly defined clinical transfusion guidelines for their area of practice. This area of competence is not transferable to any other areas within the Trust. They must ensure they keep themselves up to date with the Policies and procedures associated with blood transfusion and maintain their competency to authorise transfusions.

It is essential to:

- Explore alternatives to blood component transfusion
- Only authorise blood components if it will be of benefit to the patient and ensure the transfusion is safe and effective
- Ensure the patient has given informed consent for transfusion and that this is documented in the patient notes
- Document the reason for authorising the blood component transfusion
- Refer cases to Clinical Teams with the relevant expertise where there is doubt or concern about authorising the transfusion

- Contact a registered medical practitioner without delay if any adverse reaction or event is suspected and comply with local Policy and procedure.

9. Record Keeping and Documentation

The written instruction must be legible and include:

- A record that informed consent has been obtained before transfusion
- The date of the transfusion
- A description of the component to be given e.g., Red Blood Cells, Fresh Frozen Plasma, Platelets or Cryoprecipitate
- A separate written instruction line for each unit
- The exact volume (millilitres) for paediatric transfusion
- The duration of the transfusion of each unit
- Special requirements e.g., irradiated blood components
- Any additional information e.g., use of diuretic in red blood cell transfusions
- The authorisers signature
- The authorisers name and contact number.

10. Reviewing and Monitoring Practice

- Competency of the HCP must be reviewed every three years in line with NMC guidance
- All incidents must be fully investigated, and re-training initiated where appropriate as detailed in the Trust Policy
- The Trust should ensure that patient safety and clinical effectiveness is not adversely affected by introduction of extended practice by monitoring of patient safety incidents and clinical audit
- The HCP must inform the organisations Transfusion Practitioner / Blood Transfusion Specialist if they intend to leave the Trust or transfer to another department within the Trust by completing relevant exit / transfer documentation (Appendix 2).

A register of non-medical authorisers of blood components should be kept within the trust and kept up to date.
On successful completion of the approved period of study by the individual, the Trust is responsible for the final agreement to practice and for recording the qualification.
The HCP should consider recording their practice and outcomes.
Review of competency could be in the form of an audit or red cells and platelet transfusions within in the Trust. Results could be discussed at the HTT and HTC.
***Note:** This extended practice may not be transferable between Trusts or departments. The non-medical authoriser must seek advice from Transfusion Practitioner or Consultant when starting a new position.*

11. Revalidation

- Revalidation should take place every three years in line with NMC guidance
- It is considered good practice for the HCP to maintain a clinical log of patients for whom they authorised transfusion. This will contribute to ongoing reflective practice and continual professional development
- The HCP must provide the evidence to show they have kept up to date with national / local developments that could influence their practice
- It is recommended that the HCP completes a minimum of 12 authorisations over the three-year period
- If the HCP has a period of abstinence e.g., maternity, sick leave then their competency must be re-assessed at least every 2 years .

12. Equality Impact Assessment

This Policy has been screened for relevance to equality. No potential negative impact has been identified so a full equality impact assessment is not required.

13. Acknowledgements and References

J. Green RN and L. Pirie RN. *A Framework to Support Nurses and Midwives Making the Clinical Decision and Providing the Written Instruction for Blood Component Transfusion. 2009*

Denise Watson Regional Lead: Patient Blood Management Team NHSBT Newcastle upon Tyne. *Implementing Nurse Authorisation of Blood Components Blood and Transplant Matters information for hospitals served by NHS. Blood and Transplant May 2013 issue 39 p 5*

Kirsty Dalrymple Jill Martin, Kerri Davidson and Elisabeth Pirie. *Extending the role of a senior haematology or oncology nurse.* October 2011; Cancer Nursing Practice: volume 10 number 8.

All Wales Policy for Non-Medical Authorisation of Blood Component Transfusion. September 2013.

London Regional Transfusion Committee

Clinical Decision Making and Authorising Blood Component Transfusions: A framework to support Non-Medical Healthcare Professionals (2022)

Appendix 1

HCP Application Form for Blood Component Authorisation

Section A: *To be completed by the applicant:*

Applicant:

Name (Please print):

Ward/Department/Division:

Band/Job Title:

Professional Registration Number: Year of registration:

Date of Application:

Rationale: (Provide details of how this service development will improve patient care without compromising patient safety)

Signature of Applicant: ……

Section B: *to be completed by Line Manager and/or Lead Nurse*

I confirm that I support: (insert name of candidate)

- ……. as suitable for extended practice
- This application as a service development that will improve patient care without compromising patient safety

Name (Please print): ……

Signature: …… Date: ……..

Section C: *to be completed by the candidates' named assessor*

Name (Please print): ……..……

Ward/Department: ……..……..……

I confirm that (Insert name of candidate) …….....…….

has sufficient knowledge and competence in:

- history taking
- physical examination
- advanced communication
- clinical reasoning and decision making

I support this application for extended practice.

I confirm that I have current, documented competency for the Blood Transfusion process as required by the Trust to fulfil the National Patient Safety Agency Safer Practice Notice 14.

Signature:…….Date:…….

Section D: *to be completed by HTC representative/Transfusion Practitioner*

Name…….

I agree to the above candidate undertaking education and training for the authorisation of red cell and platelet transfusions.

Signature: …… Date: ……..

Appendix 2

NOTIFICATION OF CHANGE/CEASING THE AUTHORISATION OF BLOOD COMPONENTS

To be completed by Non-medical practitioner/ Specialist Nurse
Name: ……

I will no longer be authorising blood components within this trust as I am leaving the trust/moving department/failed to maintain competence (delete as appropriate).
OR
I am moving departments/job title/or hospital site and I would like to continue to authorise blood components.

Signature: ……

Clinical Area / Speciality: ……....

Date: ……

Please send a copy of this form to: - Your clinical manager/ The Transfusion Practitioner.
Keep the original for your own records.