



# Clinical Decision-Making and Authorising Blood Component Transfusion

A Framework to Support Non-Medical Healthcare Professionals

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**United Kingdom & Ireland Blood Transfusion Network**  
Education Working Group

2022

## Table of recommendations

A summary of recommendations from the document is below.

#	Recommendation	Ref
NMA01	Involve key stakeholders in discussions on the identified service need and value to patient care, to enable the development of an organisational structure to support non-medical authorisation in clinical practice.	3
NMA02	Ensure a local non-medical authorisation policy is in place prior to the HCP participating in clinical practice. Local policy and governance processes must be followed to ensure staff and patient safety are aligned to service provision.	3
NMA03	The job description of the HCP must reflect the scope of practice within the role, with accountability and responsibility clearly detailed.	3
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NMA05	Staff not directly employed by the organisation will need to have their own professional indemnity arrangement through an insurer.	3.2
NMA06	Confirmation of ongoing competency for authorising blood should be met as part of the appraisal process between the HCP and line manager.	3.2
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NMA08	A local policy must be in place that clearly outlines the scope of practice that the HCP must follow.	3.2
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NMA10	A prospective non-medical authoriser should meet the criteria detailed in section 3.3 of this framework.	3.3
NMA11	Each HCP should have a mentor. A prospective mentor should meet the criteria detailed in section 3.4 of this framework.	3.3
NMA12	The HCP should have a minimum period of 3 months' supervision, a locally agreed number of cases (excluding simulation), and assessment of competence using case-based discussion.	3.3
NMA13	Evidence of competence and subsequent annual reviews should be kept in the HCP's competency framework document and cross referenced in their professional portfolio.	3.3

#	Recommendation	Ref
NMA14	The HCP undertaking this role development must be supported in their practice by appropriate education and training.	3.4
NMA15	There is a prerequisite level of transfusion knowledge for undertaking a non-medical authorisation programme. The criteria for acceptable minimum prerequisite education and knowledge are detailed in section 3.4 of this framework.	3.4
NMA16	There should be an agreed ratification process of qualification and competency to practice independently.	3.4
NMA17	An organisational policy that includes NMA for delivering the service to the patient should be in place and regularly reviewed and updated, particularly in line with this national framework.	3.5
NMA18	Clinical governance procedures and risk management strategies must be in place to ensure compliance to all items detailed in section 4 of this framework.	4
NMA19	The HCP practicing as a non-medical authoriser must be aware of their individual responsibilities and accountability.	4.1
NMA20	The HCP must maintain a record of the adjustment to their scope of clinical practice in their personal portfolio.	4.1
NMA21	Organisation and department managers must be aware of their responsibilities.	4.2
NMA22	Clinical leads must be aware of their responsibilities in relation to the introduction of this service.	4.3
NMA23	Clinical mentors must be aware of their responsibilities.	4.4
NMA24	The HCP must ensure that the patient is involved in a shared decision-making process, with a view to acquiring informed and valid consent for transfusion for all patients who will be likely to, or definitely will, receive a transfusion. This should be done in accordance with the local policy and national recommendations.	4.5

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## Background

Jan Green and Liz Pirie published 'A Framework to Support Nurses and Midwives Making the Clinical Decision and Providing the Written Instruction for Blood Component Transfusion' in 2009. They were pioneers of this area of practice and laid the foundations for further development and widespread implementation. On behalf of many we would like to express our recognition and extend our gratitude to them both.

In the 12 years following publication of this original framework, roles and responsibilities for the management and care of the patient have changed considerably and continue to do so. Changing patient needs and expectations have necessitated the further extension of traditional roles and it has become necessary and appropriate for registered physiotherapists, pharmacists, paramedics, and other healthcare professionals (HCPs) to be able to authorise blood components as well.

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## Executive summary

The intention for this revision of the framework document remains to provide clearly defined guidance for experienced registered and regulated healthcare professionals who need to extend their role to authorise blood component transfusion, and their organisations.

This includes guidance around making the clinical decision for blood component transfusion and providing the written (or otherwise documented) instruction in line with national/local guidelines and recommendations.

The original framework was reviewed to embrace the expansion of staff groups for which authorising blood has an acknowledged benefit for their professional role and for the patient experience.

Throughout this document the relevant professionals, as described above, will be referred to as “HCP(s)”.

The roles and responsibilities of HCPs and their organisations involved in non-medical authorisation of blood component transfusion are included in this document.

This framework is limited to the authorisation of blood components and excludes prescribing of medicines, including blood products.

The following content represents the minimum elements required for an appropriate training programme, and governance in practice to safely achieve this, and supports a structured approach across the four UK countries.

Overall, this document supports service need development where patient care is improved, without compromising patient safety. It also recognises the importance of multidisciplinary contribution and collaboration to the development of these advanced roles.

# 1. Introduction

The framework document “A Framework to Support Nurses and Midwives Making the Clinical Decision and Providing the Written Instruction for Blood Component Transfusion” (Green and Pirie 2009) was published following a multidisciplinary workshop in October 2008. It was developed in response to the changing needs of the patient and in recognition that services to patients could be improved by more effectively using the knowledge and expertise of experienced nurses and midwives. Its intention was to provide clearly defined guidance to experienced nurses and midwives who wished to extend their role to include making the clinical decision for blood component transfusion and providing the written instruction in a safe and appropriate manner.

However, BSH guidance has more recently interpreted the situation to the effect that:

*“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)

Therefore, this document is applicable to all current non-medical registered and regulated healthcare professionals, where it conforms to their professional regulations, who wish to develop their role to include making the clinical decision and providing the written instruction for blood component transfusion (i.e., red cells, platelets, fresh frozen plasma, and cryoprecipitate). Throughout this document the relevant professionals, as described above, will be referred to as “HCPs”. HCPs who have successfully completed a non-medical authorisation of blood components programme, and are practicing, will be referred to as “non-medical authorisers (NMAs)”.

The HCP undertaking this role will require the skills to assess a patient, take a history, make a clinical decision, understand the principles of consent, and have the clinical knowledge and expertise to respond to adverse events in a timely manner. Therefore, it is considered that this role development is appropriate to experienced professionals within designated areas of clinical practice, where making the clinical decision to transfuse and authorise blood components is relevant.

It is intended that this document will support a structured approach across the four UK countries (England, Scotland, Wales, and Northern Ireland) to ensure that:

- role development is underpinned and supported by the best available evidence
- role development is planned and implemented within appropriate legal boundaries and standards stipulated by the Nursing and Midwifery Council (NMC), Health and Care Professions Council (HCPC), General Medical Council (GMC) and General Pharmaceutical Council (GPhC) as applicable
- a framework is in place that supports the HCP locally
- there are clearly defined boundaries of responsibility, accountability, and authority, which are underpinned with appropriate policies, resources, education, training, mentorship, and supervision
- patient care is improved without compromising patient safety
- the decision to transfuse is made according to sound clinical principles, in accordance with appropriate hospital/local/national guidelines and indications, and after consideration of available alternatives.
- the HCPs practice within the limits of their capabilities and the scope of their professional code of conduct/standards, and they fully understand the associated responsibilities and accountability.

## 2. Context of the framework document

In the 12 years following publication of the original framework, roles and responsibilities for the management and care of the patient have changed considerably and continue to do so. “A Health Service of all the talents: Developing the NHS workforce Consultation Document on the Review of Workforce Planning” (DH 2009) outlined the intention to break down traditional boundaries around professional practice. The range of clinical posts now held by a variety of registered professionals suggests these plans are being realised. Reflecting on these new roles, there is a growing recognition of the appropriateness for registered pharmacists, paramedics, operating department practitioners and other HCPs, caring for patients across all specialties and clinical situations, to be able to authorise blood components as part of their extended practice. There are also entirely new disciplines of the healthcare delivery workforce being created, such as physician associates (PAs) or physician assistants in anaesthesia (PAAs), who are anticipated to join a regulated healthcare professional register and once regulated, may be required to undertake a non-medical authorisation of blood components programme.

In 2019 the NHS Long Term Plan was published which supports service development “to reduce duplication in how clinical services are delivered...”, but “only where patient care is improved without compromising patient safety” (NHS,2019). This is consistent with the assertion in the original framework that role development should not be about replacing doctors but enabling other professionals to use their knowledge and expertise to ensure that the patient is treated by the most appropriate practitioner (Strachan-Bennett 2006, cited in Green and Pirie 2009). It is implicit that any expansion of non-medical authorisation needs to be supported by appropriate training and education. It is also essential that this training is recognised across the UK and that, therefore, minimum standards for course content, etc. are required.

The original collaborative project between NHS Blood and Transplant (NHSBT) and the Scottish National Blood Transfusion Service (SNBTS) was undertaken to investigate if it was feasible for nurses and midwives to prescribe blood components (Pirie and Green 2007). The initial project led to a detailed review of the 1968 Medicines Act, the amending regulations and the Blood Safety and Quality Regulations 2005 (SI 2005 no. 50 and amending regulations) which was undertaken by the legal departments of the Medicines and Healthcare products Regulatory Agency (MHRA) and the Royal College of Nursing (RCN), and was summarised as follows:

“Section 130, 1968 Medicines Act (DH 1968) has been amended by regulation 25 of the Blood Safety and Quality Regulations 2005 (SI 2005 no 50). The effect of this amendment was to exclude whole human blood and blood components from a legal definition of medicinal products and therefore cannot legally be prescribed by any practitioner. The term prescription legally relates only to medicines listed in the British National Formulary; for blood components it is a written instruction or authorisation to transfuse or administer.”



The subsequent Human Medicines Regulations 2012 (SI 2012 no. 1916) which came into force in August 2012 similarly states:

*“2. (2) These Regulations do not apply to –*

*(a) whole human blood; or*

*(b) any human blood component, other than plasma prepared by a method involving an industrial process.”*

Therefore, this framework is applicable only to blood components and not to blood products (produced by an industrial process). Blood products are classified as medicines and as such should be prescribed. All medicines are outside the scope of this framework. The following definitions in the Blood Safety and Quality Regulations 2005 are helpful here:

*“‘blood component’ means a therapeutic constituent of human blood (red cells, white cells, platelets and plasma) that can be prepared by various methods”*

and

*“‘blood product’ means any therapeutic product derived from human blood or plasma”*

In clinical practice there are several accepted terms that are widely used in relation to blood components, e.g., ordering, requesting, and prescribing. The legal opinion of the RCN is that the MHRA makes it very clear that the term ‘prescription’ legally relates only to medicinal products listed in the British National Formulary (BNF). Further clarification was sought from the RCN legal department and NMC, who emphasised that it is critically important that this framework document is explicit, and the term ‘written instruction’ and not prescription should be used. (A glossary of terminology used in the document and in blood transfusion practice is provided in Appendix I).

As previously acknowledged, there is no specific legislation which requires a doctor to carry out the activity of writing the instruction to authorise blood components, therefore: “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)

Over the 12 years following the publication of the original framework support for nurse or midwife, authorisation of blood components has grown and the benefits of extending this practice to other appropriate professionals and across clinical specialties has been acknowledged.

### **3. Developing non-medical authorisation practice**

To enable the development of an organisational structure to support non-medical authorisation in clinical practice, there is a requirement to involve key stakeholders in the discussions around service need and value to patient care. Local policy must reflect service needs, identifying the patients who may reasonably be expected to have the decision to transfuse as an integral part of their care. All organisations have a responsibility to ensure a local NMA policy is in place prior to NMAs participating in clinical practice. Local policy and governance processes must be followed to ensure staff and patient safety is aligned to service provision. In some parts of the UK, national policy has been developed which will set or direct local policy. The job description of the NMA must reflect the scope of practice within the role, with accountability and responsibility clearly detailed.

### 3.1. Scope of practice; healthcare professional practice

The multidisciplinary approach of any role governed by a regulated body (NMC, HCPC etc.), is to set clear professional standards on accountability and responsibility. The NMA undertaking the role of making the clinical decision for blood component transfusion and providing the written instruction will be working at a level beyond initial registration, exercising an advanced level of knowledge, expertise, clinical reasoning, and diagnostic skills. They will be operating at an appropriate level of professional autonomy and accountability to fulfil their role and responsibilities.

The NMA should work within their professional boundaries and within their scope of practice (NMC, HCPC, GPhC, GMC). It will be the responsibility of the individual and their line manager to ensure they have the right skills, knowledge, and experience to practice safely.

Solvent detergent pooled plasma (SDFFP) e.g. Octaplas LG® is technically a blood product by the definition above; however, it may be issued by the transfusion laboratory in response to a request for a fresh frozen plasma blood component. It is for local organisational governance to determine how NMAs might safely, appropriately, and legally authorise/prescribe plasma for transfusion in such situations.

### 3.2. Indemnity issues

Legally, the concern is not whether a task or activity was carried out by a doctor, nurse, or midwife (except where there are statutory requirements), it is whether the patient received care to an expected standard. Standards of conduct, performance and ethics for regulatory bodies can be found at:

The Health and Care Professional Council: <https://www.hcpc-uk.org/resources/guidance/professional-indemnity-and-your-registration/>

Nursing and Midwifery Council: <https://www.nmc.org.uk/globalassets/sitedocuments/registration/pii/pii-final-guidance.pdf>

General Medical Council: <https://www.gmc-uk.org/registration-and-licensing/managing-your-registration/information-for-doctors-on-the-register/insurance-indemnity-and-medico-legal-support>

General Pharmaceutical Council: <https://www.pharmacyregulation.org/professional-indemnity-requirements>

Pharmaceutical Society of Northern Ireland: <https://www.psni.org.uk/news/information-on-professional-indemnity-cover-for-pharmacists/>

To meet the needs of vicarious liability a register of approved authorisers should be maintained by the organisation as part of the risk management and governance process. The HCP must have in place an indemnity arrangement which provides appropriate cover for any practice as an HCP in the United Kingdom. It is the responsibility of the employing organisation to make sure there is appropriate cover for the role and scope of practice. However, it is the HCP's responsibility to ensure that they are appropriately indemnified under their employer's cover. This cover should be relevant to their practice.

In addition, a local policy must be in place that clearly outlines the scope of practice that the HCP

must follow, and the job description of the post holder should be amended to include any new responsibilities.

### **Staff not directly employed by the organisation will need to have their own professional indemnity arrangement through an insurer**

If there is uncertainty around indemnity, and what is covered, then this should be checked under the employer's indemnity arrangements.

Additionally, there is a requirement to ensure the annual review of competency for authorising blood is met as part of the annual appraisal process between the authorisers and line manager. Please refer to section 4.1 for further information around the governance requirements.

### **3.3. Selection for healthcare professionals**

The following criteria below must be met by HCPs to undertake the role of NMA:

- Be an HCP meeting the professional standards of their relevant governing body
- Have the support of their line manager and approval of the lead clinician and organisation, based on an identified service need to improve patient care
- Provide evidence of an appropriate level of knowledge, skills and expertise in a relevant clinical specialty and manage a caseload of patients, or work as part of a clinical team optimising the care of patients who may require a transfusion
- Have an appropriate level of clinical assessment and decision-making skills
- Have a mentor who is approved by the relevant specialty clinical lead and hospital transfusion committee (HTC) or equivalent local governance committee.

It is the opinion of the UK&I BTN that there is no requirement for the HCP to be registered as a non-medical prescriber of medicines.

### **3.4. Mentor**

The main aim of the mentor's relationship is to provide support and opportunities to develop competence in practice, and to confirm that the HCP has completed a period of learning in practice and has met and continues to meet the required standards. The mentor ensures and records confirmation of competency.

Mentor criteria:

- Must be approved by the relevant specialty clinical lead and HTC (or equivalent local governance committee)
- Must work in the same specialty
- Can be either a current experienced NMA, or a senior doctor with suitable expertise and experience
- Must maintain their own transfusion training and be familiar with the organisation's transfusion policies and protocols
- Have the capacity/time to dedicate to supervising the HCP until completion of training and competency is confirmed/ratified
- Must make a commitment to provide ongoing supervision and support.

Role of the mentor:

- To observe the HCP making the clinical decision to transfuse blood components in clinical practice
- To assess and record the competence of the HCP in relation to authorisation of blood components
- To provide opportunities for the HCP to carry out consultations and suggest clinical management options which can then be discussed
- To allow in-depth discussion and analysis of clinical management using real cases from practice to enable decision-making behaviour to be fully examined
- To facilitate learning by encouraging critical thinking and reflection with the use of the HCP's professional portfolio or learning log
- To continue to act as a clinical support and annual assessor for the NMA or to hand over to another mentor who fulfills the criteria.

The HCP should have a minimum period of 3 months' supervision, a locally or regionally (HTC/governance committee) agreed number of cases (excluding simulation), and assessment of their competence using case-based discussion. When the supervising clinical mentor 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 HCP should be able to:

- Demonstrate an understanding of ethics, the legal and professional framework for accountability and responsibility in relation to their role
- Undertake effective consultation with patients and carers that includes appropriate history taking and assessment skills to inform diagnosis and clinical decision-making practice
- Apply knowledge of available blood components
- Use evidence-based sources of information, policies, guidelines, advice, and decision support, and be able to explain how these are applied in practice
- Make the clinical decision to transfuse blood components safely, appropriately and cost effectively
- Be aware of and adhere to local policy and procedures in authorising blood
- Recognise and respond effectively to changes in decision-making practice at an individual, local, and national level, and provide evidence of continuing professional development.

### **3.5. Education and training**

HCPs undertaking this role development must be supported in their practice by appropriate education and training.

Several NMA programmes have been developed to meet the needs for provision in each country in the UK. It is recognised that much of the knowledge and skills required for this role are met in other established clinical practice courses; however, these do not constitute sufficient training to undertake the NMA role.

Evidence from the development of other non-medical extended roles demonstrated that educational needs can be addressed by identifying the competencies required and developing individual learning

plans. Assessment of parts of the competency should be carried out by an expert in the area of practice who may differ from the mentor: however, the final sign-off of overall competence should rest with the assigned mentor.

### **3.6. Essential requirements for an NMA programme**

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 LearnBloodTransfusion (LBT) modules “Safe Transfusion Practice”, and “Blood Components and Indications for Use.”

#### Knowledge and competency

The knowledge and competencies required for this role development are detailed in Appendix II 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, 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:

- Competences 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 NMA practitioner 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.

Local arrangements for this should be in place, e.g., by the HTC or equivalent local governance committee.

### **3.7. Delivering the service to the patient**

It is essential that an organisational policy is in place and is regularly reviewed and updated, particularly in line with this national framework. To achieve practice development, the need for interprofessional working and shared learning continues to be essential and investment from stakeholders at all levels remains crucial.

## 4. Clinical governance

To deliver high quality and safe healthcare, clinical governance procedures and risk management strategies must be in place to ensure that:

- The patient is placed at the centre of all decisions about delivering care
- Practice is aligned to all relevant local policies
- Planning, development, and implementation of change only happens in an atmosphere of collaboration between all members of the healthcare team, managers, and directors; appropriate governance considerations are discussed at a professional and organisational level
- There is a robust process, including clearly identified practice development, for HCPs wishing to undertake this role
- There is transparency of accountability for individuals and clinical teams for all aspects of service and clinical delivery, and this accountability is identified in each HCP's scope of practice in relation to this role
- There is a register of HCPs undertaking this role within the organisation; this register is reviewed on a regular basis to confirm continuing practice in this role. Arrangements are in place within the organisation for assessment of practice, monitoring and continuing professional development for all HCPs undertaking this role
- The HCP's annual review includes confirmation of continuing competency
- If an HCP moves to a new role, the continuation of practice must be risk-assessed, additional training and competence assessment undertaken when identified as necessary, and a new scope of practice agreed
- A risk management plan is in place within the organisation to ensure incident and near miss reporting and management, including recognition and actioning of trends.

### 4.1. Healthcare professional responsibilities

The responsibilities of the individual healthcare professional (HCP) are to:

- Explore the potential for role development with their clinical team and other key stakeholders (line manager, professional lead within the organisation, e.g., director of nursing, medical consultant), to ensure that the service development is appropriate
- Ensure that the patient's journey is improved through the role development
- Work in partnership with line manager and lead clinician to develop a proposal and business case, where required
- Identify personal learning needs and develop a learning plan
- Submit the full proposal, including the learning plan, to their HTC/governance committee for agreement
- Undertake the preparation necessary for role development, to include completion of training for this role as required by the organisation and course provider. Ensure and provide evidence they have met the required criteria for the course and have approval from their line manager
- Ensure they have identified a mentor who meets the mentor criteria
- Agree to, and work within, the scope of practice of their role, recognising the limitations of this scope.

On commencement and post-course:

- Identify personal learning needs and develop a learning plan with their mentor
- Undertake independent practice only after having been assessed as competent, this being evidenced by a signed certificate of competence by the mentor
- Demonstrate ability, knowledge, and competence to undertake the role to the same standard as the professional previously responsible for the role
- Provide documented evidence to support knowledge and competence, e.g., portfolio of learning
- Ensure the patient is receiving safe care
- Ensure, on successful completion of the competency certificate, that they inform the register holder and their line manager that they are now fit to authorise blood
- Be responsible for maintaining and updating their knowledge and skills
- Participate in relevant clinical audits or service improvement projects
- Undertake regular reflection and self-assessment of practice
- Participate in ongoing performance development and annual review to verify knowledge and competence
- Ensure they update the register holder of annual competency confirmation
- Recognise when the patient's needs are outside of their scope of practice and refer to appropriate personnel in a timely manner
- Be aware that the NMA scope covers the current specialty and if they were to change specialty they would need to refrain from authorising blood until they have completed any required training for authorising blood in the new specialty
- Receive ongoing clinical supervision and support, complete annual appraisal, and develop a personal development plan.

The HCP must maintain a record of the adjustment to their scope of clinical practice in their personal portfolio. As a minimum, this record must contain the following:

- A copy of the written notification to the line manager
- A copy of the written notification authorising NMA practice
- Evidence demonstrating how the necessary knowledge underpinning the change to clinical practice (material to this role development) was achieved
- Evidence demonstrating that their ongoing competency in this role is reviewed annually
- A copy of the competency standard statements used to assess knowledge and skill in preparation for role
- Evidence that all applicable transfusion training is maintained
- The patient group to which the NMA practice applies (scope of practice).

## **4.2. Management responsibilities**

The responsibilities of management are to:

- Ensure that a partnership approach with key stakeholders is used when developing a proposal for role development when introduction of NMA is being considered in their area
- Assist with identifying the financial and human resources required to support full implementation and continuing practice
- Agree who will undertake supervision of practice and mentorship role in collaboration with the HCP and HTC, and ensure they are suitably qualified to do so



- Confirm indemnity arrangements and regulatory frameworks
- Ensure that robust risk assessments are undertaken to maintain patient safety
- Ensure the HCP undertakes and completes the education and training required
- Support the HCP to work within agreed role boundaries as per the agreed scope of practice
- Amend the individual's job description to reflect the role change if necessary
- Establish appropriate clinical governance processes, and ensure these are adhered to
- Support and advise the HCP on strategies for evaluation of role development
- Carry out regular performance review with the HCP to verify knowledge and competence, linked to annual appraisal and a personal development plan.

### **4.3. Clinical lead responsibilities**

The responsibilities of the clinician in introducing and continuing this role development in their clinical areas are to:

- Work in partnership to identify a suitable patient group or clinical setting for this role development
- Work in partnership to develop a proposal for service change
- Work in partnership to develop a local policy which reflects the requirements of field of practice
- Agree to support, and take responsibility for, the provision of a suitable mentor, including continual annual competency assessment in authorisation
- Support and advise HCP on strategies for evaluation of blood transfusion practice, focusing on appropriate and safe use of blood.

### **4.4. Mentor responsibilities**

- Maintain their own transfusion training and competency requirements
- Be familiar with trust transfusion policies and procedures and available resources
- Proceed with mentorship only when they have assessed the HCP, who has met the NMA course and NMA policy criteria
- Complete the NMA competency framework document as the HCP successfully completes each section
- Continue to mentor the HCP, including case reviews, and provide support for the maintenance of ongoing competency
- Report onwards any concern regarding patient safety or HCP capability or competency
- Ensure updates or changes in transfusion practice in the organisation are shared with the HCP.

### **4.5. Consent for transfusion**

The HCP must ensure that whenever possible the patient is involved in a shared decision-making process, with a view to acquiring informed and valid consent for transfusion for all patients who will likely receive a transfusion. This should be done in accordance with the local policy and national recommendations (e.g., SaBTO 2020), and must include consideration of the patient's capacity to give consent (or not) and patients who refuse transfusion. Gaining consent is part of the decision to transfuse, and therefore can only be performed if within the HCP's scope of practice. In order to achieve this:



- The NMA must obtain valid informed consent for transfusion in accordance with the local policy and national guidance (SaBTO 2020) ensuring that the patient\* (\* or parent/guardian/appointed representative) are fully informed of the need for transfusion, the risks and benefits, the consequences of refusing, and any possible alternative. The patient\* must be given the opportunity to ask questions or to decline the transfusion
- The patient\* should be provided with information regarding blood transfusion and given time to consider it
- The decision and reason for transfusion must be documented in the patient case notes; where transfusion is a possible clinical option and a decision has been made not to transfuse, this must also be documented
- The NMA must update their knowledge and awareness of consent for transfusion in line with SaBTO recommendations
- Local hospital policies must also accommodate patients who are unable to give consent, e.g., patients in the ITU setting (NMC 2006, MCA 2007) and patients who refuse treatment or have an advance decision to refuse treatment.

## 5. Conclusion

There is little doubt that the original framework achieved its goal:

*“... to provide clearly defined guidance to those experienced nurses and midwives who wish to extend their role, to include making the clinical decision for blood component transfusion and providing the written instruction in a safe and appropriate manner.”*

And it is widely acknowledged that the introduction of this practice has improved the care and experiences of many patients.

This revision of the framework reflects the key changes in healthcare service provision and builds on the experience and lessons learnt over the last 12 years. It aims to provide the guiding principles for the further development of this role and to establish minimum standards of training and competency assessment to promote patient safety and facilitate staff movement across the UK.

The framework clearly outlines the roles and responsibilities of those involved in establishing and delivering the service.

The review was undertaken by representatives from all the UK countries.

## 6. Disclaimer

Whilst the information in this framework document is believed to reflect current best clinical practice, neither the authors or publisher can accept any legal responsibility for any errors or omissions.

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## Appendix I: Glossary

BSH	British Society for Haematology.
Blood components	<p>Blood components are a therapeutic constituent of human blood. Blood components are controlled under the Blood Safety &amp; Quality Regulations, 2005. They are excluded from the legal definition of medicinal products (the Human Medicines Regulations, 2012).</p> <p>Components used therapeutically are:</p> <ul style="list-style-type: none"> <li>- Red blood cells (RBC)</li> <li>- Platelets</li> <li>- Fresh Frozen Plasma (FFP)</li> <li>- Cryoprecipitate</li> <li>- Granulocytes*.</li> </ul> <p>* Availability may be limited/restricted</p>
Blood products	<p>A therapeutic product derived from plasma. Blood products are controlled under the Human Medicines Regulations, 2012 and therefore must be prescribed by an appropriate practitioner.</p> <p>These include (not exhaustive):</p> <ul style="list-style-type: none"> <li>- Human Albumin Solution,</li> <li>- The various clotting Factor concentrates</li> <li>- Anti-D</li> <li>- Therapeutic immunoglobulins.</li> </ul>
BNF	<p>British National Formulary</p> <p>Provides up-to-date guidance on prescribing, dispensing, and administering medicines.</p>
Clinical decision-making	In this context, refers to the assessment of the individual patient's requirement for a blood component transfusion.
Concomitant	Occurring simultaneously, as when 2 or more treatments are used at the same time.
Erythropoietin (EPO)	A glycoprotein hormone that controls erythropoiesis, (red blood cell production).
Erythropoiesis Stimulating Agent (ESA)	Medications which stimulate the bone marrow to make red blood cells.
GMC	General Medical Council
GPC	General Pharmaceutical Council
HCP	<p>Healthcare professional(s)- a member of a registered and regulated healthcare profession.</p> <p>Throughout this document HCP is used in reference to an individual who has not yet successfully achieved NMA status.</p>
HPCP	The Health and Care Professions Council
Mentor	A healthcare professional, already undertaking the role of blood component transfusion, with the expertise and experience in the applicable clinical specialty, who provides support and opportunities to develop competence in practice and confirm that the HCP has completed a period of learning in practice and has met the required

	standards.
MHRA	Medicines & Healthcare products Regulatory Agency. The UK competent authority for blood safety
Midwives Exemptions (distinct from non-medical prescribing)	Midwife exemptions permit all qualified and registered midwives to supply and/or administer all pharmacy and general sales list medicines and medicines listed in Schedule 5, Part I and III of the Prescription Only Midwives (Human Use) Order 1997 on registration. A Patient Group Direction is not necessary for midwives to be able to supply and/or administer these medicines.
NBTC	National Blood Transfusion Committee.
NMA	Non-Medical Authoriser: an HCP who has successfully completed a non-medical authorisation of blood components course and has been approved to practice in this role.
NMC	Nursing & Midwifery Council
Ordering or requesting	Refers to the mechanism whereby the order is communicated to the hospital transfusion laboratory to prepare and issue the component for administration.
Patient*	Refers to the patient or their parent/legal guardian or court appointed representative.
Patient Group Directions	<p>Patient Group Directions (PGDs) constitute a legal framework, which allows certain healthcare professionals to supply and administer medicines to groups of patients that fit the criteria laid out in the PGD. The healthcare professionals using the PGDs are individually named and are required to ensure that they follow appropriate professional standards and codes of conduct. Unlike nurse and pharmacist prescribing, healthcare professionals entitled to work with a PGD require no additional formal qualification. However, organisations have a responsibility to ensure that only fully competent, trained health care professionals use PGDs.</p> <p>There are still instances when the development of a PGD is the most appropriate way to meet the needs of patients. This need is likely to remain although it is expected to diminish with the further development of independent nurse prescribers (DH 2008).</p> <p>For further information please see the Department of Health website <a href="http://www.gov.uk/government/publications/patient-group-directions-pgds">www.gov.uk/government/publications/patient-group-directions-pgds</a></p>
Plasma derivative	Plasma proteins prepared from pooled human plasma under pharmaceutical manufacturing conditions (coagulation factors, immunoglobulin, albumin).
Prescription	Constitutes the legal instruction to administer a medicinal product listed in the British National Formulary.
SABRE	Serious Adverse Blood Reactions and Events. The MHRA's blood safety reporting system.
SaBTO	The Advisory Committee on the Safety of Blood, Tissues and Organs.
SHOT	Serious Hazards of Transfusion, independent, professionally led haemovigilance reporting system in the UK.
Non-medical prescriber	A range of non-medical healthcare professionals can prescribe medicines for patients as either Independent or Supplementary Prescribers (BNF).
Written instruction	The written order for authorising the blood component to be transfused.

## Appendix II: Essential educational requirements of an NMA programme

The educational requirements detailed below are intended to cover the fundamentals of clinical transfusion practice. Knowledge and competency assessment should consider the specialty and clinical setting in which the prospective NMA will practice.

Understanding of	Knowledge and competencies
Anatomy and physiology of blood	<ul style="list-style-type: none"> <li>- Explain haematopoiesis and haemostasis</li> <li>- Describe the development, structure, and function of:               <ul style="list-style-type: none"> <li>• Red cells</li> <li>• White cells</li> <li>• Platelets</li> <li>• Plasma</li> </ul> </li> </ul>
Anaemia and chronic blood loss	<ul style="list-style-type: none"> <li>- Explain the different classifications of anaemia</li> <li>- Explain the physiological processes for iron deficiency anaemia</li> <li>- Recognise when to refer patients for further investigation and treatment</li> <li>- Advise how to order appropriate investigations</li> <li>- Outline the different types of iron therapies</li> <li>- Explain the use of other haematinics, and of erythropoiesis stimulating agents.</li> </ul>
Acute blood loss	<ul style="list-style-type: none"> <li>- Explain the principles of patient assessment in relation to blood loss and how to estimate bleeding risk</li> <li>- Explain the appropriate use of universal blood components</li> <li>- Explain the risks and complications associated with emergency transfusion.</li> </ul>
Patient assessment and clinical decision making <ul style="list-style-type: none"> <li>- how to take a patient history</li> <li>- accounting for co-morbidity</li> <li>- consent issues</li> <li>- need for concomitant drugs</li> </ul>	<ul style="list-style-type: none"> <li>- Explain the requirement to accurately document all actions and conversations with the patient</li> <li>- Make appropriate referral if the patient refuses blood transfusion or has an advance decision to refuse treatment</li> <li>- Take a medical history</li> <li>- Link the clinical picture with the interpretation of blood results</li> <li>- Justify appropriate decision using the best available evidence and local transfusion guidelines</li> <li>- Explain the risks and benefits of transfusion and available alternatives</li> <li>- Evaluate the appropriateness of alternatives to blood component transfusion, e.g., intravenous iron</li> <li>- Assess the patient's fitness for a transfusion, i.e., take account of co-morbidities, day case or inpatient</li> <li>- Assess for risk factors for transfusion, in particular circulatory overload</li> <li>- Explain which concomitant drugs may be required and why.</li> </ul>
Interpreting blood results	<ul style="list-style-type: none"> <li>- Recognise normal and abnormal haematology and biochemistry blood values</li> <li>- Interpret anomalous results and initiate any appropriate treatment</li> <li>- Determine if more tests and/or further evaluation is required.</li> </ul>

<p>Blood components</p>	<ul style="list-style-type: none"> <li>- Describe the differences between blood component and blood products: <ul style="list-style-type: none"> <li>• legal definitions</li> </ul> </li> <li>- Explain blood donation and component processing: <ul style="list-style-type: none"> <li>• Whole blood/component donation</li> <li>• Donor selection and screening</li> <li>• Microbiological testing</li> <li>• Processing of components, including irradiation</li> </ul> </li> <li>- Describe allogeneic blood components for transfusion: <ul style="list-style-type: none"> <li>• Red cells</li> <li>• Granulocytes</li> <li>• Platelets</li> <li>• Plasma based components</li> </ul> </li> <li>- Demonstrate knowledge of: <ul style="list-style-type: none"> <li>• Storage - temperature control/cold chain requirements of each type of component</li> <li>• Recommended transfusion rates for each type of component</li> <li>• Safe handling</li> </ul> </li> </ul>
<p>Indications for the use of blood components</p> <ul style="list-style-type: none"> <li>- Appropriate use of blood components</li> <li>- Alternatives to blood components</li> </ul>	<ul style="list-style-type: none"> <li>- Define the indications for use of blood components and demonstrate appropriate selection of components.</li> <li>- Justify the decision for transfusion, including: <ul style="list-style-type: none"> <li>• Risk vs. benefit</li> <li>• Intended outcomes</li> <li>• Evidence base for transfusion</li> <li>• Recognised standards for transfusion</li> <li>• Use of recognised triggers, thresholds, and targets</li> </ul> </li> <li>- Explain how to calculate 'dose' required to achieve target</li> <li>- Explain the importance of reassessment and documentation of outcomes</li> <li>- Explain alternatives to transfusion to consider, and strategies for avoiding/ minimising transfusion where appropriate, including single unit strategies</li> <li>- Recognise when to consult with, or defer to, a senior clinician.</li> </ul>
<p>Consent to transfusion</p>	<ul style="list-style-type: none"> <li>- Explain the principles of consent, and recognise the professional, legal, and ethical requirements for consent to transfusion</li> <li>- Describe the patient information resources available to support the consent process, and how to use them</li> <li>- Explain the requirement for documented evidence of consent in the patient's records</li> <li>- Demonstrate awareness of the issues to discuss with the patient to facilitated informed decision-making: <ul style="list-style-type: none"> <li>• Intended benefits</li> <li>• Risks</li> <li>• Alternatives</li> <li>• Possible consequences of not having transfusion</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>- Demonstrate effective consent to transfusion: <ul style="list-style-type: none"> <li>• Information giving</li> <li>• discussion</li> <li>• shared decision-making</li> <li>• record keeping.</li> </ul> </li> </ul>
Specific transfusion requirements	<ul style="list-style-type: none"> <li>- Specific requirements can encompass both specification of the components and administration requirements</li> <li>- Define which patient groups have specific transfusion requirements and explain why</li> <li>- Explain why it is important to have a process to ensure that these specific requirements are met</li> <li>- Explain the issues when specific requirements are requested, but: <ul style="list-style-type: none"> <li>• Are not, or cannot, be met, e.g., emergency situations</li> <li>• Are not actually required.</li> </ul> </li> </ul>
Writing the instruction to transfuse the blood component	<ul style="list-style-type: none"> <li>- Explain what is required in the written instruction: <ul style="list-style-type: none"> <li>• number of units/volume</li> <li>• duration of transfusion/rate</li> <li>• route of administration</li> <li>• concomitant drugs that may need to be administered</li> <li>• any additional information relevant to safety of the transfusion, e.g., blood warmer required</li> <li>• who completed the written instruction</li> </ul> </li> <li>- Explain specific measures to be taken for certain patient groups/vulnerable patients, e.g., paediatrics dose in mLs.</li> <li>- Explain specific measures to manage risk of transfusion associated circulatory overload</li> <li>- Explain the potential interaction of blood components with other IV drugs, infusions, and transfusions</li> <li>- Demonstrate correct completion of written instruction for transfusion.</li> </ul>
Laboratory testing	<ul style="list-style-type: none"> <li>- Explain ABO compatibility and alloimmunisation</li> <li>- Demonstrate awareness of clinically significant red cell antibodies</li> <li>- Describe the importance of histocompatibility</li> <li>- Explain the principles of sample validity and historic/reference groups</li> <li>- Describe the laboratory processes for pre-transfusion testing including how long testing can take.</li> </ul>
Requesting blood components	<ul style="list-style-type: none"> <li>- Explain the laboratory requirements for: <ul style="list-style-type: none"> <li>• Full patient identification details</li> <li>• Number of units/volume of components required and any specific transfusion requirements</li> <li>• Transfusion history</li> <li>• When and where the patient is to be transfused</li> </ul> </li> <li>- Explain the potential time frames for accessing different blood components from the laboratory: <ul style="list-style-type: none"> <li>• which components to request/expect depending on the level of urgency and whether the patient is known to the</li> </ul> </li> </ul>

	laboratory.
Risks and adverse events associated with transfusion and how to manage them	<ul style="list-style-type: none"> <li>- Describe the patient monitoring requirements throughout the transfusion process</li> <li>- Explain the risks of transfusion and what to do in an emergency situation (where necessary) for: <ul style="list-style-type: none"> <li>• Transfusion Associated Circulatory Overload (TACO)</li> <li>• Febrile, allergic and hypotensive reaction, including anaphylaxis</li> <li>• Wrong blood to wrong patient</li> <li>• Transfusion-transmitted bacterial and viral infections</li> <li>• Transfusion Related Acute Lung Injury (TRALI) and other pulmonary complications</li> <li>• Haemolytic transfusion reaction – acute and delayed</li> <li>• Over-transfusion/ iron overload</li> </ul> </li> <li>- Demonstrate an understanding of the complications of long-term transfusion including <ul style="list-style-type: none"> <li>• iron overload</li> <li>• alloimmunisation</li> </ul> </li> <li>- Explain the non-emergency management of the above</li> <li>- Explain haemovigilance in the UK and the reporting of adverse events/reactions, and their responsibilities in relation to reporting</li> <li>- Explain duty of candour and professional responsibility and accountability.</li> </ul>
Transfusion guidelines and protocols	<ul style="list-style-type: none"> <li>- Discuss relevant national, regional, and local transfusion and blood conservation related programmes</li> <li>- Describe relevant clinical guidelines, e.g., BSH, NICE</li> <li>- Demonstrate awareness of the Blood Safety and Quality Regulations (2005), and amendments, including traceability and cold chain requirements.</li> </ul>
Legislation, regulation, and practice	<ul style="list-style-type: none"> <li>- Explain NMA practice in relation to their professional bodies' standards of conduct, performance, and ethics</li> <li>- Explain the legislative and regulatory background to NMA practice in the UK, and the governance of NMA practice</li> <li>- Explain what should be recorded in the patient records in relation to the decision to transfuse, and why</li> <li>- Recognise the shift in professional boundaries manifest in NMA practice, and the challenges this can present.</li> </ul>