Non-Medical Authorisation Course

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East Midlands Regional Transfusion Committee

Legislation

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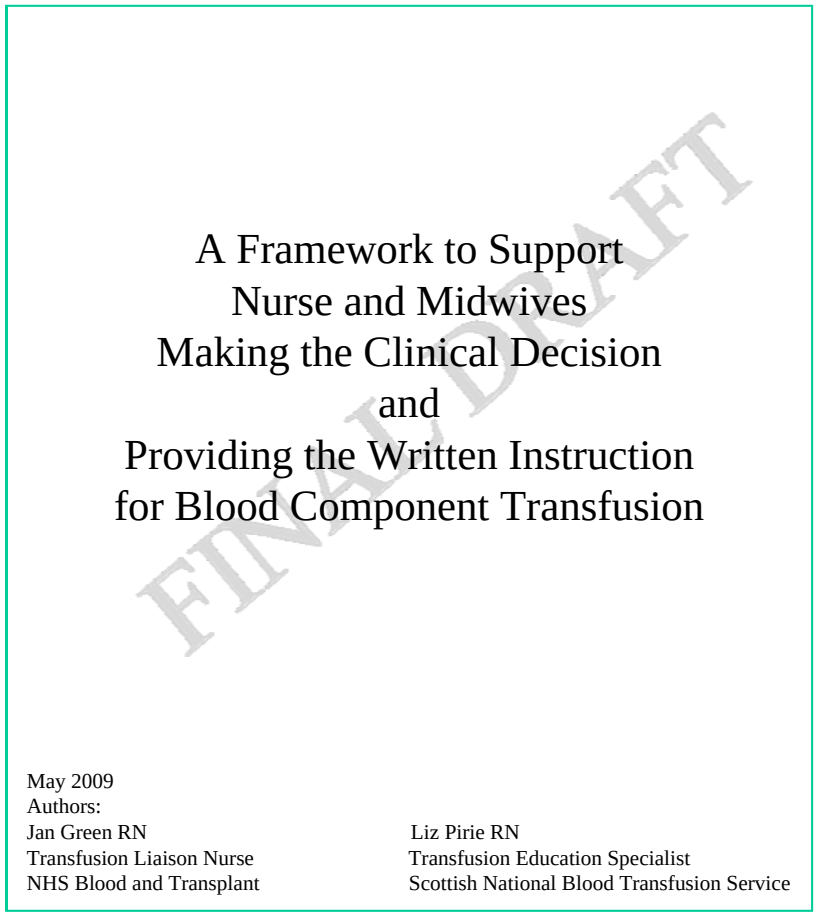
Learning Outcomes

- Awareness of the current NMC Code of Conduct and Practice
- Current legislation within the UK and how it applies to your practice
- Current recommendations from the DoH and National bodies

Why are you here today?



- Recognition that experienced RN/RM can use their knowledge and expertise to improve patient services
- Initially-review of the Medicines Act 1968
- Section 130 amended to exclude whole human blood and blood components from the legal definition of ‘medicinal product’

Blood ‘components’ vs blood ‘products’

- Blood **components** are labile human blood fractions (red cells, platelets, fresh frozen plasma, cryoprecipitate and granulocytes) and are covered by the Blood Safety and Quality Regulations 2005
- They are NOT medicines and are thus incapable of prescription in strict legal terms – but they can be ‘authorised’
- Blood **products** are produced by a pharmaceutical process and are classed as Medicines (Human Albumin, anti-D, Factor VIII, Immunoglobulin, PCC, Octaplas), so are covered by the Medicines Act 1968

The Code

1 Treat people as individuals

2 Listen to people and respond to their preferences & concerns

2.3 Encourage and empower people to share decisions about their treatment and care

2.5 Respect, support and document a person's right to accept or refuse care

The Code

4 Act in the best interests of people at all times

4.2 Make sure that you get properly informed consent and document it before carrying out any action

4.3 Keep to all relevant laws about mental capacity that apply in the country in which you are practising, and make sure that the rights and best interests of those who lack capacity are still at the centre of the decision-making process

The Code

6 Always practise in line with the best available evidence

6.2 Maintain the knowledge and skills you need for safe and effective practice.

7 Communicate clearly

7.1 Use terms that people in your care, colleagues and the public can understand

7.3 Use a range of verbal and non-verbal communication methods, and consider cultural sensitivities, to better understand and respond to people's personal and health needs

The Code

7.4 Check people's understanding from time to time to keep misunderstanding or mistakes to a minimum

10. Keep clear and accurate records

10.1 Complete all records at the time or as soon as possible after an event, recording if the notes are written some time after the event

13 Recognise and work within the limits of your competence

13.5 Complete the necessary training before carrying out a new role.

The Code

- 18 Work within the limits of the law, our guidance (NMC)
- and other relevant policies, guidance and regulations

- **YOU** are **personally accountable** for your own practice

- **YOU** must be able to ***justify decisions*** regardless of advice or directions from other professionals

legislation.gov.uk

Current Legislation and Guidance in the UK

European Directive 2002/98/EC

Statutory Instruments
2005 No. 50
HEALTH AND SAFETY
The Blood Safety and Quality Regulations –(BSQR) 2005.

Came into force on 8th Feb 2005

The ‘European Directive’ 2002/98/EC

- To set high standards of ***quality and safety*** for the collection, testing, processing, storage and distribution of human blood and blood components.

- To reassure the public that human blood and components, which are derived from donations in one member state, meet the same requirements as those in their own country

'Daughter' Directives

- **Three** daughter directives;
  - **2004/33/EC** - technical requirements for blood and components (8.2.05)
  - **2005/61/EC** - traceability and notification of SARs and SAEs (Dec 2006)
  - **2005/62/EC** - specifications relating to a quality system (Dec 2006)

B.S.Q.R. SI 2005/50 (as amended)

- MHRA appointed the ‘Competent Authority’ to monitor the regulations on behalf of the Secretary of State.

- MHRA are also the competent authority for
  - The Medicines Act 1968
  - Medical Devices Regulations 2008

What affects CLINICAL staff ?
Things we **MUST** do

- Traceability
- Quality System
  - Cold chain
  - Collecting blood
- **Mandatory adverse event reporting**
  - Promote the benefits of reporting rather than punitive aspects

Traceability

- “Vein to vein”, from the donor to the recipient - information on who has been transfused and with what - 100% compliance

MUST

- Keep record for **30** years
- Record- Donation number
  - Component type
    - Blood Establishment
    - Date provided
    - Recipient details or final fate

Traceability-additional info

- Identity of the person who authorised the transfusion
- Details of the ‘consent to transfusion’
- The reason for the transfusion
- The time, date and identity of the person who collected the blood
- The identity of the person (s) who undertook the bedside pre-transfusion checks
- The date and time of the transfusion
- Any adverse events relating to the transfusion

Cold Chain

- The requirement to ensure that storage conditions for blood and blood products are observed at all times, including during transportation.

- N.B. Remember the maximum transfusion times and take collection into account

Serious Adverse Reactions / Events

- Reactions
  - Where we ACTUALLY cause harm to a patient.
    - ABO Incompatibility
    - Transfusion-transmitted Infection
- Events
  - Where we COULD have caused harm...
    - Transfusion of an expired unit
    - Failure of “cold chain”

Things we SHOULD Do

CMO's Health Service Circulars

- BBT 1 1998
- BBT 2 2002– Appropriate Use
- BBT 3 2007– Safe and Appropriate Use
  - Appropriate use of Donor Blood
  - Promote Use of Alternatives
  - **Reporting of adverse events and feedback learning**

- PBM
  - Builds on previous BBT recommendations
  - Multidisciplinary, evidence-based approach to optimising the care of patients who might need blood transfusion**.**

Care Quality Commission

Fundamental standards

- Person-centred care
  - Patients must have care or treatment that is tailored to them and meets their needs and preferences.
- Dignity and respect
  - Patients must be treated with dignity and respect at all times while receiving care and treatment.
- Consent
  - You (or anybody legally acting on your behalf) must give your consent before any care or treatment is given to you.

Care Quality Commission
Fundamental standards

- Safety
  - Patients must not be given unsafe care or treatment or be put at risk of harm that could be avoided.
  - Providers must assess the risks to Patient's health and safety during any care or treatment and make sure their staff have the qualifications, competence, skills and experience to keep you safe.

- Duty of candour
  - The provider of your care must be open and transparent with you about your care and treatment.
  - Should something go wrong, they must tell you what has happened, provide support and apologise.

NICE / BCSH guidance

- Use of Erythropoetin
- Irradiated blood
- Investigation and management of ATR
- Use of Cell Salvage in Obstetrics
- Administration of Blood Components
- Neonatal/Paediatric guidelines