Informed Consent in Transfusion Medicine

Dr Caroline Hilton & Dr Gregory Bellairs
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Principles of informed consent

- Informed medical consent should be
  - Voluntary
  - Informed
  - Given by a person with capacity
  - Taken by a practitioner adequately trained in the procedure for which consent has been given
What is informed consent?

- Discussion between parties about a procedure or treatment
- Describes the benefits and risks of the procedure in a balanced way, avoiding bias
- Informs the person of the alternatives, including the risks and benefits of these
- Person to make an informed decision about the procedure
- Use clear, simple and consistent language
- Process must be documented
What is informed consent?

- In ideal circumstances
  - Informed consent should be obtained at a time and place that enables the person to best retain information
  - Time should be allowed for reflection on their decision
  - It should be checked that the person understands the information they have been given
Informed consent in blood donation

Benefits
• Altruism
• Health check and blood sampling
• Donor gifts and snacks

Risks
• Injury (0.38% of donations)*
• Positive test results

Donor signs informed consent section of the donor questionnaire

* 2015 South African National Haemovigilance Report, SANBS & WPBTS

Alternatives to blood donation

www.wpblood.org.za
Informed consent in patient transfusions

- Patients are not always given information on risks, benefits and alternatives to transfusion, or the right to refuse
- They are also not always made aware that they had a transfusion
- Study at Universitas Hospital, Bloemfontein (2014)
  - Of 53 patients, 20.8% had no evidence of written informed consent for a blood product transfusion
  - Four patients had written consent but had no recollection of doing so
  - 11% stated that consent was performed using unfamiliar terms
  - 83% of African patients preferred the presence of a family member during consent-taking

Ethical principles in informed consent

**Autonomy**
- Obligation to respect autonomy or ‘self rule’
- Respect the patient’s decision to accept or refuse treatment
- ‘Principle of human dignity’
- Basis of informed consent

**Beneficience**
- Obligation to bring about good in our actions
- The doctor should act in the best interests of their patient

**Non-maleficence**
- Obligation not to harm others
- Unnecessary blood product transfusions can be harmful

**Justice**
- Obligation to treat people equally, fairly and impartially
Patients unable to give informed consent

- Covered in Section 7 of the National Health Act
- Consent may be given by a
  - Person mandated by the user in writing
  - Person authorised by law or court order
  - Spouse, partner, parent, grandparent, adult, child or sibling
- Superintendent of a hospital can give consent when delay in treatment may result in the patient’s death and the patient has not expressed or implied refusal of treatment
Appropriate use of blood products

- Only prescribe blood products when absolutely necessary
- Blood is a scarce and costly resource
- Transfusions carry significant risks to the patient

Hippocrates
‘First do no harm’
Risks associated with blood product transfusions

• Incompatible blood transfusions
  • Patient receives blood product meant for someone else
  • Usually result of human error
  • Can have life-threatening consequences

• Transmission of infection from donor to patient
  • Window period risk

• Range of adverse transfusion reactions
  • Majority are minor (eg. febrile, allergic)
  • Can be lethal (eg. TRALI)
How do the blood services in South Africa ensure blood product safety?
Selective donor recruitment and screening

- Voluntary, non-remunerated (unpaid) donors
- Emphasis on recruiting regular donors
- Use of the donor questionnaire and initial interview to identify donors at risk of discernable exposure to transfusion transmissible infection
- Confidential unit exclusion - donors can notify the blood service after donation to exclude their unit
WPBTS donor questionnaire

Please make sure that you complete all required sections carefully and honestly.

SECTION 1
Lifestyle Questionnaire:
Through personal, these questions don’t want to offend, but rather to identify potential risk to the recipient.

SECTION 2
Health Questionnaire:
Your safety is as important as the safety of the recipient. Therefore, you might not be able to donate if you answer 'yes' to any of these questions. The qualified nurse will discuss your answers with you.

SECTION 3
Contact Details and Donor Enrolment Form:
These donors must complete all sections of the questionnaire. Regular blood donors should only complete section 3 if any personal information has changed.

PLEASE DO NOT DONATE BLOOD IF YOU MAY HAVE BEEN EXPOSED TO HIV/AIDS.

Your donation could save at least three lives. Remarkable, isn’t it? As a Service, we provide life-saving blood and blood products to those who need them. Please continue to make a difference by remaining a regular blood donor.
Testing of donor samples

- All individual donations are tested for the following
  - **HIV 1 & 2** (antibody and NAT testing)
  - **Hepatitis B** (surface antigen and NAT testing)
  - **Hepatitis C** (antibody and NAT testing)
  - **Syphilis** (TPHA plus RPR/VRDL, if positive)
- Two testing methods used for each infection
- Testing is done at each and every donation
Testing of donor samples

Nucleic Acid Testing (NAT)

- Introduced in 2005 at WPBTS & SANBS
- Significant reduction in window periods
- Calculated residual risk of viral transmission of HIV, HBV and HCV is less than 1 in 10 million transfusions

![Bar chart showing days of infection to detection and reduction of window by NAT for HIV-1, HCV, and HBV.]

2. Package Insert for the Procleix HIV/HCV Assay, IND57660
Leucodepletion of blood products

- White cells are the cause of many immune-mediated problems for patients in blood product transfusions
- Leucodepletion refers to the physical filtration of white cells
- Must be specifically requested at an additional cost
Leucodepletion of blood products

Sterile docking devise to join tubing to polyurethane filter and bag
White blood cells are trapped in filter
Leucodepletion of blood products

• Known benefits of leucodepletion
  - Avoidance of febrile non-haemolytic transfusion reactions
  - Filtered platelet products reduce incidence of platelet refractoriness
  - Significant reduction in cytomegalovirus transmission
  - Lessened sensitisation to transplant antigens
Gamma-irradiation of blood products

- Used to remove donor T lymphocytes from blood products
- Only recommended method for the prevention of transfusion associated graft versus host disease
- Blood products placed in an irradiator and receive a minimum radiation dose of 25 Gy
Gamma-irradiation of blood products

- Indications for irradiated blood products
  - Blood components donated by family members
  - Intrauterine or exchange transfusions in neonates
  - Stem cell transplant patients
  - Lymphocyte immunodeficiency syndromes
  - Treatment with purine analogues and ATG
Pathogen inactivation

- Refers to techniques that treat blood products to inactivate pathogens by chemical or physical means.
- Current approved methods used on platelet and plasma products only.
- Two methods being validated by South African blood services on platelet products - Mirasol® and Intercept®
- Exciting advancement in the fight on emergent infections & blood transfusions.
Limited Donor Exposure Programme (LDEP)

- Blood from a single donor is reserved for one baby who has prolonged transfusion needs
- Limits infectious risk and red cell antigen exposure
Strict Blood Bank procedures

- Careful scrutiny of blood ordering request form and crossmatch sample by Blood Bank staff
- Advanced cross-matching procedures using automated machine

Blood ordering request form

Autovue analyser
Education of healthcare workers

- Education regarding careful ordering and administration of blood products to patients and reporting of adverse transfusion reactions
Strict QA policies

- Dedicated Quality Assurance (QA) department at WPBTS
- Annual internal and external audits that monitor all processes within the service
Conclusion - Importance of informed consent

• Patients must be informed of the risks and benefits of blood transfusions
• Take consent yourself in an understandable language using simple terms
• Act in your patient’s best interests
• Avoid unnecessary transfusions due to risks involved
• Document the conversation and consent procedure
Any questions?

Please send additional comments to caroline@wpbts.org.za

Electronic version of the Clinical Guidelines for the Use of Blood Products in South Africa booklet (Edition 5) available on www.wpblood.org.za