Informed Consent for Blood Transfusion

Transfusion Camp, Day 2
Based on slides kindly provided by Dr. Katerina Pavenski

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Trillium Health Partners
Better Together

Objectives

1. Understand why informed consent for transfusion should be obtained
2. Describe the key elements of informed consent
3. Review the process of obtaining informed consent

An opportunity to reflect

Why is this important?

- Ethical obligation
  - Respect patient autonomy
  - Allow for questions and discussion
- Legal obligation
  - Mandatory in Canada
- Standards
  - Required by the Canadian Standards Association and the Canadian Society for Transfusion Medicine

Krever. Government of Canada. 1997

Canadian Standards Association. 2015

Are we good at obtaining informed consent?

- There is variability in the information provided to patients
- Healthcare practitioners do not feel they receive adequate training on informed consent
  - In a survey of 304 participants, only 60% felt their training was adequate
- Previous audits and assessments have highlighted the need to improve clinical practice in obtaining informed consent for blood

Cheung et al. Transfus Med. 2014

Vossoughi et al. Am J Clin Pathol. 2015

Booth et al. Transfusion Medicine. 2017

“I was informed about the need to transfuse…but I was just told I was bleeding but that was all.”

“I was told I needed a transfusion, but very quickly, and there was no time for me to ask questions.”

“To me there was no choice, I had to have it…I did not want to become more ill.”

Davis et al. Transfusion Medicine. 2012

Are we good at obtaining informed consent?

- Documentation is poor
  - Retrospective review of 1005 charts revealed that in 75% of charts, there was no documentation regarding a discussion around the risks, benefits and alternatives

Rock et al. Transfusion. 2007

Key Requirements of Consent

Voluntary

Properly Informed

Mental Capacity

Who should obtain consent?

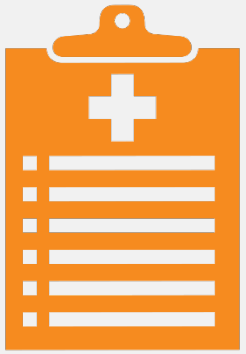
- Most responsible physician
- Residents and fellows
- Nurse practitioner
- Midwives (for Rh immunoglobulin)

What should be discussed and documented?

Date of the discussion

Patient or SDM providing consent

Indication



Possible benefit

Risks

Alternatives

Choice made by patient or SDM

Signatures

Consent Documentation

- “A consent form itself is not consent.”
- The discussion between a healthcare provider and the patient is the most crucial aspect of informed consent

Basic elements of a consent form:
Consent to investigation, treatment or operative procedure

(1) I,_____ , hereby consent to undergo the investigation, treatment or operative procedure, _____, ordered by or to be performed by Dr._____.

(2) The nature and anticipated effect of what is proposed including the significant risks and alternatives available have been explained to me. I am satisfied with these explanations and I have understood them.

(3) I also consent to such additional or alternative investigations, treatments or operative procedures as in the opinion of Dr._____ are immediately necessary.

(4) I further agree that in his or her discretion, Dr._____ may make use of the assistance of other surgeons, physicians, and hospital medical staff (including trainees) and may permit them to order or perform all or part of the investigation, treatment, or operative procedure, and I agree that they shall have the same discretion in my investigation and treatment as Dr. _____.

Dated_____
day / month / year

Patient_____

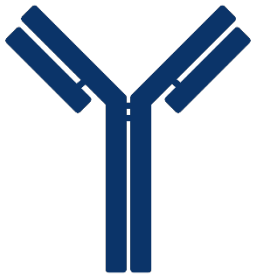
Witness_____

CMPA, 2021

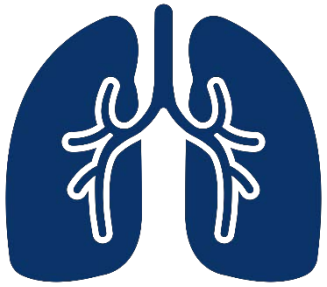
Discussing Risks

- Consider the patient’s clinical situation, personality, and aptitude for understanding medical content
- Common complications – what is most likely to happen to this patient?
- Serious and rare complications – what is the worst-case scenario?

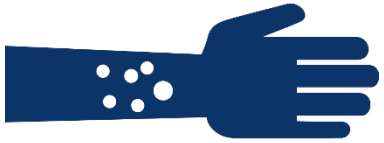
Risks that are more common



Red cell sensitization



Transfusion-associated circulatory overload (TACO)



Minor allergic reaction

Febrile non-hemolytic transfusion reaction

Risk of Event	Event
1 in 13	Red cell sensitization
1 in 100	Transfusion-associated circulatory overload (TACO)
1 in 100	Minor allergic reactions (urticaria)
1 in 300	Fever non-hemolytic transfusion reaction per unit of red blood cells
1 in 2 500	Delayed hemolytic transfusion reaction
1 in 10 000	Transfusion-related acute lung injury (TRALI)
1 in 10 000	Symptomatic bacterial sepsis, per pool of platelets
1 in 40 000	Serious allergic reaction
1 in 100 000	Post-transfusion purpura
1 in 200 000	Death from bacterial sepsis, per pool of non-pathogen reduced platelets
1 in 250 000	Symptomatic bacterial sepsis, per pool of red blood cells
1 in 500 000	Death from bacterial sepsis, per unit of red blood cells
< 1 in 1 000 000	Transmission of West Nile Virus
1 in 2 000 000	Residual risk of hepatitis B per unit
1 in 4 000 000	Transmission of Chagas Disease per unit
1 in 12 900 000	Residual risk of HIV per unit
1 in 27 100 000	Residual risk of hepatitis C per unit

Callum et al. Bloody Easy 5. 2022

Match the risk

25 F with iron deficiency	Alloimmunization to RBC antigens
85 M with CHF and CKD	Alloimmunization to HLA antigens
38 M with ESRD awaiting renal transplant	Iron overload
55 M with hemophilia A and hepatitis C	TACO
68 M with MDS requiring chronic transfusion	Hepatitis B infection

Blood Derivatives

- **Informed consent is needed for blood derivatives as well**
- Blood derivatives include:
  - Albumin
  - Intravenous immune globulin (IVIG)
  - Prothrombin complex concentrate (PCC)
  - Fibrinogen concentrate
  - Rh immune globulin (RhIg)
  - Plasma-derived factor concentrates

Tailor your discussion

- Obtain informed consent in advance and allow time for discussion
- Personalize the discussion and discuss material risks
- Engage in a dialogue
  - Ask for feedback
  - Check the patient’s understanding
  - Answer questions

Duration

- Depends on the patient's situation and location
- Generally, consent is valid during the inpatient admission
- When consent should be re-visited:
  - Change in the patient's medical condition
  - Change in the possible benefits/risks of the transfusion
  - Other treatment alternatives are available

Alternatives to Transfusion

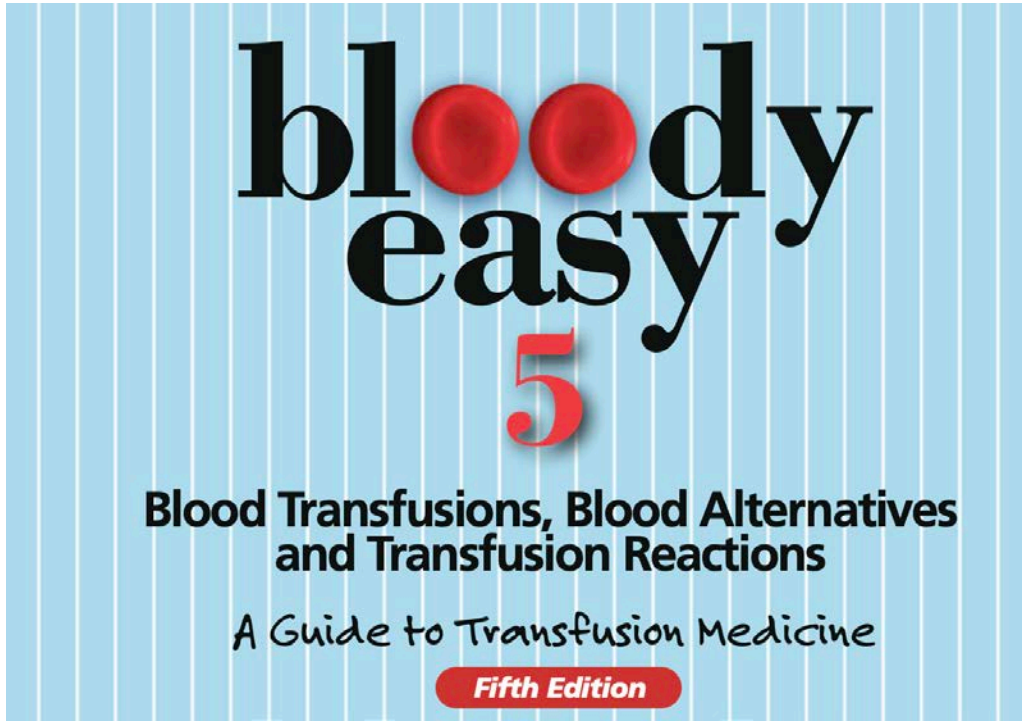
Close monitoring

Iron supplementation
(oral or intravenous)

Erythropoietin-
stimulating agents

Resources

- Patient information video:
  - https://www.youtube.com/watch?v=RxaPnLkgh-0&ab_channel=SunnybrookHospital



ORBCoN

bloody easy

INFORMED CONSENT FOR TRANSFUSION

- Responsibility for obtaining it rests with the healthcare provider prescribing the transfusion
- Is in effect for the duration of the patient's admission or course of treatment
- May be waived if the need is urgent and no substitute decision maker is available and there is no evidence that the patient would refuse due to religious/personal reasons

Healthcare Provider Responsibilities	Transfusionist Responsibilities
☑ Explain risks* and benefits	☑ Confirm that informed consent has been obtained
☑ Explain any alternatives available	☑ Verify patient identification
☑ Describe the blood component/ product to be transfused	☑ Ensure the patient has had their questions answered
☑ Give the patient an opportunity to ask questions	☑ Perform the check of the donor unit at the patient's bedside
☑ Clearly document the reason for the transfusion	☑ Check vital signs/monitor any symptoms of reaction

Any questions?

References

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