Informed Consent and Informed Refusal

September 20, 2023

Saint Luke's

1

Objectives

- Understand why informed consent is necessary for blood transfusions for ethical, regulatory and legal reasons
- Understand what an effective informed consent process includes and review challenging situations with arise with consent
- Discuss the concept of an informed refusal of consent

2

Informed Consent: Why do we do it?

Ethics

Regulatory

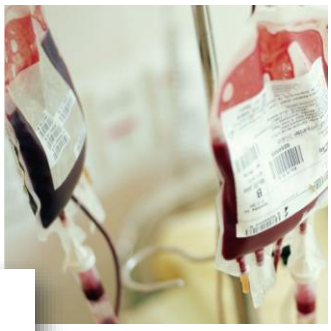
Legal

AABB

SAINT LUKE'S

3

Know your policy



1. **Consent**

   a. General: The **Ordering Provider/Physician** will obtain Informed Consent from the patient before transfusing any blood components. The consent process must include a conversation with the patient to disclose the risks, benefits and alternatives of transfusion. The receipt of informed consent can be documented on the system consent form one of three ways.

      i. The provider/physician can document receipt of informed consent by signing the "Consent to Receive Transfusion of Blood or Component form" (SYS-368). The RN caring for the patient will act as witness.

      ii. The provider/physician has a conversation with the patient witnessed by an RN (via phone or in person) but does not sign the (SYS-368) form. The provider will indicate in the EMR that they have spoken with the patient and obtained consent for blood transfusion. RN signs (SYS-368) consent form as witness and writes "verbal consent obtained by provider" in signature for provider space.

      iii. The provider/physician indicates in the progress note or elsewhere in the EMR that they have spoken with the patient and obtained consent for blood transfusion. RN reviews the provider's note and validates with the patient that the provider has had this informed consent conversation. The RN will then sign (SYS-368) as the witness and writes "verbal consent obtained by provider per provider note" in signature for provider space.

SAINT LUKE'S

4

Informed Consent:
It is a process, not a piece of paper

The provider

- Explains the transfusion.
- Benefits
- Risks
- Alternatives
- Opportunity for questions/clarification

5

SAINT LUKE'S

5

Blood Informed Consent: Risks

- High-frequency complications (fever, urticaria)
- Low-frequency complications (HIV infection, mistransfusion)
- Patient-specific complications (volume overload, hypersensitivity)

TACO (transfusion-associated circulatory overload)

TRALI (transfusion-related acute lung injury)

- Hypothetical/controversial complications (immunomodulation, Creutzfeldt-Jakob

6

SAINT LUKE'S

6

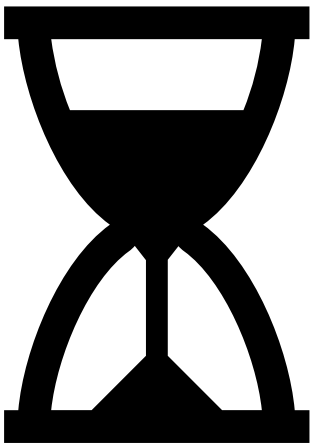
Informed Consent Considerations

- Reading level
- Language barriers
- Cultural norms
- Telephone consent

SAINT LUKE'S

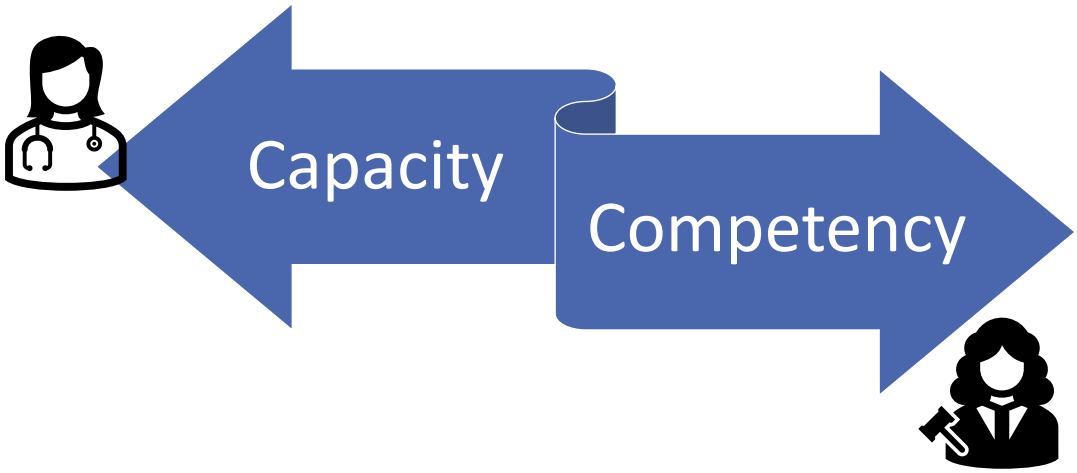
How long is consent good for?

It depends…



SAINT LUKE'S

Informed Consent: Competency v Capacity



SAINT LUKE'S

Informed Consent: Surrogate Decision Makers

- DPOA (Durable Power of Attorney for Healthcare)
- Advance Directive
- Guardianship
- Minors

SAINT LUKE'S

Lack of Consent legal consequences

Cause of action of lack of informed consent

Elements

- Procedure was done without with informed consent and an injury occurred
- Had the patient known of the risks, they would not have undergone the procedure

Civil Battery

Unwanted touching without permission

SAINT LUKE'S

11

Informed Refusal

Patient refuses a recommended medical treatment based on a full understand of the facts and implications of not following the recommendation.

SAINT LUKE'S

12

Thank you!

SAINT LUKE'S

13