

Provincial Clinical Laboratory Blood Transfusion Service Informed Consent for Blood and Blood Products

Recommendation #1:

The PEI Blood Transfusion Committee recommends the adoption of the Health PEI Form 14HPE15-40540 entitled Consent for Treatment with Blood or Blood Products. This consent form would replace the jurisdiction / hospital specific forms in use. It is important to note that a consent form "is merely documentation; the form is not 'informed consent' in and of itself. Forms should be used only if there is contemporaneous explanation by a person who is qualified to explain risks and alternatives, and who is able to answer questions."

Recommendation #2:

Given that "a single [consent] process will not be applicable in all situations and jurisdictions"², the PEI Blood Transfusion Committee recommends that the particular requirements of individual facilities and departments be considered in the development of informed consent for blood transfusion guidelines. In general, the following principles apply (adapted from Burch and Uhl):

- 1. Informed consent should be obtained, if possible
 - The person making the decision must have a substantial understanding of the choices available and the advantages and disadvantages of each
 - o note that while the patient must receive all the information needed to consent knowledgeably, this does not equate to "all the information that is"
 - the professional standard requires the physician to inform the patient what a competent physician would have told any other patient; the patient-oriented standard requires the physician to tell the patient what an average patient facing the same situation would wish to know
 - o specifically, consent information includes:
 - The nature and purpose of the proposed treatment
 - The risks of the proposed treatment
 - Nature
 - Magnitude
 - Probability
 - Imminence
 - Not every risk need be disclosed. Suggest disclosure of common risks and severe risks. Use of a pocket guide (such as the ORBCoN Informed Consent Card³) is suggested to ensure consistent risk data is being provided, as well as providing an opportunity to give

¹ Berkman EM (July 10, 1986). Memo to AABB Institutional Members. Informed consent for blood transfusion. Arlington, VA: AABB.

² Burch JW and Uhl L (2006). Guidelines for Informed Consent in Transfusion Medicine. Bethesda, MD: AABB.

³ http://transfusionontario.org/en/cmdownloads/categories/bloody_easy/

context (e.g. comparing the risk of transfusion adverse events to other common risks).

- The benefits of the proposed treatment
- Alternatives to the proposed treatment, including the possible consequences of declining the proposed treatment
- o The probability of success of the proposed treatment
- The person making the decision must be free from any substantial outside controlling influence
- It should be noted that the patient may consent with restrictions (for example, the patient may elect to accept some components / products and refuse others)
- 2. In the context of emergency medical consent, the patient's right to consent to a blood transfusion may be waived temporarily
 - Such a waiver is pertinent for the patient's immediate needs only
 - As soon as possible, consent should be sought
 - Waiver during emergency should not be construed as consent where the physician has prior knowledge of the patient's wishes (e.g. in the case of a Jehovah's Witness known to be opposed to receiving blood transfusion under any circumstance)
- 3. Duration of effective consent may vary
 - In general, "a single informed consent may be sufficient for any course of therapy which may include one or more transfusions, during one or more treatment episodes"⁴
 - For example, a patient receiving regular infusions of IVIG
 - For example, a patient with bone marrow failure who receives regular infusions of red cells and platelets
 - Re-consenting the patient is suggested in the event that:
 - The consent form on the patient's chart is >12 months old
 - o The type of blood component / product changes (for example, a hemophilic who has consented to receive Factor VIII now requires red blood cells)
 - The circumstances change substantially (for example, a patient who receives red cell transfusion for bone marrow failure in the outpatient department now may require red cell transfusion in surgery after a car accident)

⁴ Informed consent for blood transfusion. Association Bulletin #94-3. (September 1, 1994). Bethesda, MD: AABB, 1994.