Informed Consent for Blood Transfusion

Transfusion Camp, Day 2

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St. Michael's

Inspired Care.
Inspiring Science.

Objectives

- List 3 reasons why informed consent for transfusion should be obtained
- Describe the process of obtaining informed consent
- Describe the key elements of informed consent

- Out of scope: approach to a patient who objects to a blood transfusion – covered in today's seminar

Time for reflection

How good are we at informed consent for transfusion?

- Rock et al Transfusion 2007
  - retrospective review of 1005 patient charts
    - 75% of charts: MD had not documented that any discussion had occurred regarding the risks and/or benefits or alternatives
- Davis et al Transfusion Medicine 2012
  - cross-sectional qualitative survey
    - 67/110 (60%) patients said that they were just told that they needed a transfusion
    - 83/123 (67%) healthcare professionals felt that patients were often not given sufficient information
- Moog Transfusion Aph Sci 2016
  - audit of 47 patient charts
    - informed consent was identified most often as inappropriate, and this was a critical point with respect to medico legal aspects

Why are we not good?

- 94% of study participants reported getting training on informed consent
  - Only 60% felt that training was adequate
- 35% indicated difficulties with informed consent
  - The most frequently cited problems:
    - insufficient time
    - insufficient knowledge base: unable to answer questions; unaware of risks/benefits; unaware of consequences if treatment declined; unaware of alternatives

Vossoughi et al Am J Clin Pathol 2015

Informed Consent: Why?

- Ethical obligation: respects patient's autonomy, involves patient in his/her care, allows patient to "own" treatment decision
- Legal obligation
  - Canada
    - Informed consent is legislated nationally and, in some provinces, provincially
    - However, neither federal nor provincial legislations specifically address consent for transfusion
  - UK
    - No legislation, "accepted principle"

Informed Consent: Why?

- Commission of Inquiry into the Blood System, recommendations 26-29, Krever 1997
  - *Patients be **informed of the risks** of blood transfusion and the **available alternatives** to blood...*
- CMPA lists transfusion as intervention requiring informed consent
- Required by standards from the Canadian Society for Transfusion Medicine and Canadian Standards Association

Informed Consent: Why?

- Required by transfusion societies, guidelines and standards of many countries:
  - International Society for Blood Transfusion
  - UK: Advisory Committee on Safety of Blood, Tissues and Organs (SaBTO), National Institute for Health and Care Excellence (NICE)
  - USA: The Joint Commission, American Association of Blood Banks

Informed Consent: Whose responsibility is it anyway?

- Obtaining informed consent is the responsibility of the *physician or a nurse practitioner* who orders the transfusion

Informed Consent: Process

- Determine the person's **capacity to decide** (if deemed incapable, locate a substitute decision-maker)
- Obtain **consent** or **refusal**
- **Document** in chart informed consent/refusal
- **Communicate** your patient's decision to the other members of the healthcare team

Informed Consent: Elements

- Inform patient of:
  - the **nature of treatment**
    - What component is to be transfused? Why?
  - material **risks** of transfusion – what would a reasonable patient need to know
  - expected **benefits**
  - possible **alternatives** and their risks
  - the likely **consequences** of not having the treatment
  - **right to refuse** transfusion

Informed Consent

How much/what to disclose?

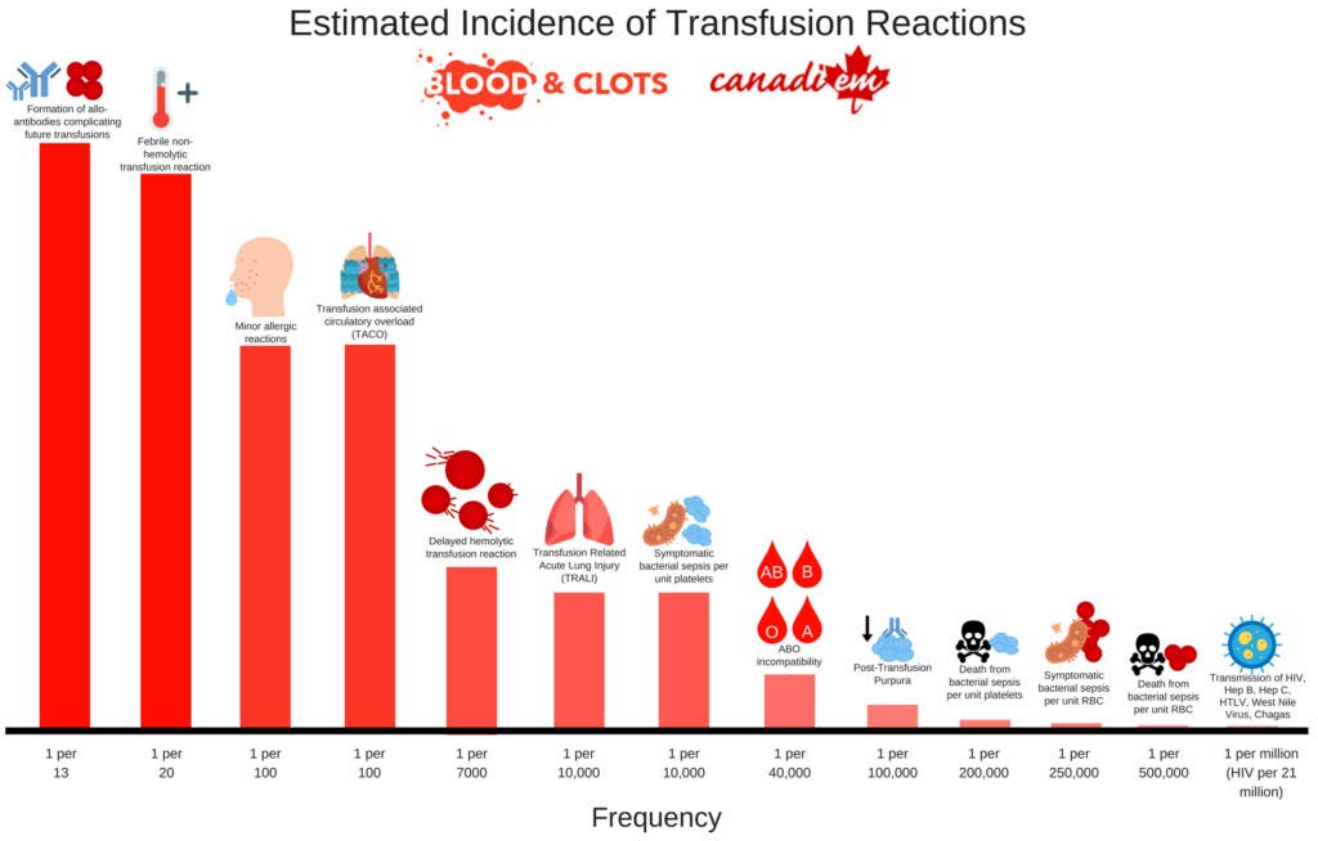
ESTIMATED RISKS OF TRANSFUSION

NON-INFECTIOUS COMPLICATIONS	ESTIMATED RISK
Red cell sensitization	1 in 13
Minor allergic reaction (hives, urticaria)	1 in 100
Transfusion-associated circulatory overload (TACO)	1 in 100
Febrile non-hemolytic transfusion reaction per unit of RBC /per pool of platelets	1 in 300/1 in 20
Delayed hemolytic transfusion reaction	1 in 7,000
Transfusion-related acute lung injury (TRALI) per unit of component transfused	1 in 10,000
ABO- incompatible transfusion per unit of RBC	1 in 40,000
Serious allergic reaction per unit of component	1 in 40,000
Post transfusion purpura	1 in 100,000

INFECTIOUS COMPLICATIONS	ESTIMATED RISK
Symptomatic bacterial sepsis per pool of platelets	1 in 10,000
Death from bacterial sepsis per pool of platelets	1 in 200,000
Symptomatic bacterial sepsis per unit of RBC	1 in 250,000
Death from bacterial sepsis per unit of RBC	1 in 500,000
West Nile virus	<1 in 1,000,000
Hepatitis B virus per unit of component	1 in 7,500,000
Human T-lymphotropic virus (HTLV) per unit of component	1 in 7,600,000
Hepatitis C virus per unit of component	1 in 13,000,000
Human immunodeficiency virus (HIV) per unit of component	1 in 21,000,000

COMPARISON OF NON-TRANSFUSION RISK EVENT	ESTIMATED RISK
Annual risk of death in a motor vehicle crash	1 in 10,000
Death from anesthesia in fit patients	1 in 200,000
Annual risk of death from accidental electrocution in Canada	<1 in 1,000,000

How Much/What to Disclose?



https://canadiem.org/what-are-the-complications-of-transfusion-what-symptoms-signs-should-i-worry-about/

How much/what to disclose?

- Consider patient's clinical situation, personality, and aptitude for understanding medical content
  - **Material** risks (of particular concern or relevance to the patient)
  - The **most common** complications (most likely to happen)
    - Fever, rash, etc.
  - **Uncommon but not rare AND serious** complications (most likely worst case scenario)
    - Ex. Volume overload, TRALI, major allergic reaction, etc.

Match material risk to patient or SDM: patient is to receive RBC transfusion

Scenario

- 22 yo female with IDA
- 93 yo female with CHF
- 42 yo male with ESRD and awaiting kidney transplant
- 62 yo male with hemophilia A and Hepatitis C
- Wife of a 37 yo male with leukemia, sepsis and MOSF
- Mother of a 5 yo female with SCD and acute chest crisis

Risk

- Alloimmunization to RBC antigens
- Alloimmunization to HLA antigens
- Hepatitis B infection
- TRALI
- Bacterial contamination
- Iron overload
- TACO

Consent: Make it about your patient

- If possible, obtain informed consent in advance and give yourself plenty of time
- The primary purpose of informed consent is to inform patient
  - Be prepared (ex. Bring a booklet, card, etc.)
  - Make it personalized – discuss material risks
  - Engage in a dialogue
    - Ask for feedback. Does patient understand the information?
    - Give patient time to digest the information and ask questions
    - Answer questions

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

*See reverse for estimated risks of transfusion

Monitor for Signs of a Reaction

Symptoms of adverse reaction to transfusion
Fever (38 °C or > 1 °C over baseline)
Chills or Rigors
Dyspnea or Shortness of Breath
Rash, Hives, Swelling
Anxiety or Agitation
Pain in Head, Chest or Back
Hypotension/Shock/ Nausea/Vomiting
Hypertension

What to do if transfusion reaction occurs
1. STOP THE TRANSFUSION IMMEDIATELY
2. Maintain IV access and notify physician
3. Check vital signs every 15 minutes
4. Re-check patient and blood unit identification
5. Contact Transfusion Medicine Laboratory (TML)
6. Follow instructions for further specimen collection
7. Return blood unit and IV tubing to TML if requested

CONSENT or REFUSAL for TRANSFUSION OF BLOOD COMPONENTS and / or PRODUCTS

A copy of this form MUST be on the patient's chart

I was given a copy of "Benefits and Risks of Blood Transfusions" Booklet (Form 61880). ☐ Yes ☐ No

The Physician or Health Care Practitioner has fully explained to me:

- What is a blood transfusion
- The reason for the blood transfusion
- How the blood transfusion will benefit me
- What are the possible risks and side effects
- What may happen if I do not have a transfusion
- What other choices of treatment I have and their risks and side effects

I have had the chance to ask questions, which were answered to my satisfaction. ☐ **Yes** ☐ **No** **Initial** _____

TO BE COMPLETED BY PATIENT OR SUBSTITUTE DECISION-MAKER

☐ **I *AGREE* to receive blood components and / or products**

☐ **I *AGREE* to receive *ONLY* those blood components / products / procedures checked on the "OPTIONS FOR PATIENTS OBJECTING TO BLOOD TRANSFUSIONS" form (see back of consent)**

_____ _____

Signature of Patient *(or Substitute Decision-Maker)* ***Date*** *MM/DD/YYYY*

_____ _____

Print Name of Patient *(or Substitute Decision-Maker)* *Relationship to Patient*

☐ **I *REFUSE* to receive *any* blood components and /or products.**

_____ _____

Signature of Patient *(or Substitute Decision-Maker)* ***Date*** *MM/DD/YYYY*

_____ _____

Print Name of Patient *(or Substitute Decision-Maker)* *Relationship to Patient*

TO BE COMPLETED BY PHYSICIAN / HEALTH CARE PRACTITIONER

I confirm that I have explained the nature of the treatment(s), expected benefits, side effects, material risks, alternative courses of action as well as the likely consequences of not having the treatments to the above patient/substitute decision maker and answered all questions.

_____ _____

Signature of Physician / Health Care Practitioner // PRINT Name ***Date*** *MM/DD/YYYY*

Transfusion Consent Type:

☐ **Specific procedure or event** (valid for specific procedure, event or duration of admission)

☐ **Ongoing transfusion therapy** - is part of the disease treatment plan (valid for duration of disease treatment)

EMERGENCY TRANSFUSION, NO CONSENT:

I certify that, due to the urgent need for transfusion, I am unable to obtain informed consent prior to therapy and that I have no advance directive indicating that transfusion in reasonable circumstances is rejected.

As mandated in the HEALTH CARE CONSENT ACT, Section 25.5, the Physician / Health Care Practitioner must promptly note on the patient's health care record the opinions that are held by the practitioner on which he or she relied.

OPTIONS FOR PATIENTS OBJECTING TO BLOOD TRANSFUSIONS

	(Patient should check ☑ and initial each item) ACCEPT	REFUSE
BLOOD COMPONENTS		
Red Blood Cells	☐ _____	☐ _____
Plasma (Frozen Plasma)	☐ _____	☐ _____
Platelets	☐ _____	☐ _____
Cryoprecipitate	☐ _____	☐ _____
Autologous Red Blood Cells	☐ _____	☐ _____
BLOOD PRODUCTS		
Albumin	☐ _____	☐ _____
Plasma-Derived Clotting Factors (Fibrinogen, PCC, FEIBA)	☐ _____	☐ _____
Plasma-Derived Proteins (C1 esterase inhibitor)	☐ _____	☐ _____
Immune Globulins (IVIG, RhIg, Hepatitis B Ig, CMV Ig, etc)	☐ _____	☐ _____
Topical Fibrin or Thrombin	☐ _____	☐ _____
RECOMBINANT BLOOD PROTEINS		
Recombinant Clotting Factors (FVIII, FIX, FXIII, rVIIa)	☐ _____	☐ _____
Erythropoiesis stimulating agents (do NOT contain albumin)	☐ _____	☐ _____
PROCEDURES INVOLVING BLOOD		
Cell Salvage	☐ _____	☐ _____
Cardiopulmonary Bypass	☐ _____	☐ _____
Hemodialysis	☐ _____	☐ _____
Therapeutic apheresis	☐ _____	☐ _____

Specify other treatment: _____

_____ _____

Signature of Patient *(or Substitute Decision-Maker)* ***Date*** *MM/DD/YYYY*

_____ _____

Print Name of Patient *(or Substitute Decision-Maker)* ***Relationship to Patient***

STATEMENT OF PHYSICIAN / HEALTH CARE PRACTITIONER

I confirm that I have explained the nature of the treatment(s), the expected benefits, side effects, material risks, and alternative courses of action and likely consequences of not having the treatment(s) to the above patient/substitute decision maker and answered all questions.

_____ _____

Signature of Physician / Health Care Practitioner // PRINT Name ***Date*** *MM/DD/YYYY*

Form No. 66880 Rev. Oct.07/2015

Heart of England NHS
NHS Foundation Trust

Adult Blood Transfusion Care Pathway (BTCP)

For administration of blood components/products

Patient Details – Affix label	
Name:	
Date of Birth:	**PID:**
NHS no:	**Gender:**
Consultant:	Ward:

Medical staff to complete

- Unless otherwise agreed locally*

EVIDENCE OF INFORMED VERBAL CONSENT FOR BLOOD COMPONENTS/PRODUCTS.

(To comply with Blood Transfusion Policy, SABTO, NBTC and NICE recommendations and requirements)

Following key issues *must be discussed and agreed* with the patient when obtaining valid verbal consent. All boxes must be either ticked, marked as not applicable (N/A) or circle yes or no.

1. **Type of blood components/product to be administered** (e.g. red cells, platelets, plasma, cryoprecipitate, PCC, Anti-D, Factor VIII) ☐
2. **Indication for the component/product** (e.g. low Hb, symptomatic, low platelet count, sensitisation) ☐
3. **Predicted benefits of having the component/product** (e.g. no longer symptomatic, desired Hb) ☐
4. **Risks associated with the component/product** (e.g. transfusion of incorrect blood component, transfusion reaction, transmission of infections, such as Hepatitis B, Hepatitis C, HIV, vCJD) ☐
5. **Is the patient at risk of Transfusion Associated Circulatory Overload (TACO)?** (If yes, record the risks and actions on the prescription chart and add an alert onto Concerto) Y / N / NA
6. **Possible alternatives to transfusion if any** (e.g. Oral / IV Iron, Intra-operative cell salvage, withhold transfusion with possible prolonged recovery) ☐
7. **Discussed route of blood transfusion/product** (e.g. intramuscular, IV) **and duration of the transfusion** (e.g. 2 or 3 hours for Red cells, 30 minutes for FFP, Cryoprecipitate or Platelets) ☐
8. **Patient informed of the correct personal identification process** (visual and verbal) ☐
9. **Patient** (must be) **informed that he/she cannot be a blood donor following blood transfusions** Y \ NA
10. **Written information provided** (NHSBT leaflet or print off from Concerto) ☐
11. **Does the patient need more time to consider or requires further information?** Y / N / NA
12. **Has the patient given verbal consent if able?** Y/ NA
13. **Unable to complete all of the above** as the patient falls under the mental capacity act, confused, ventilated, emergency situation, sedated or other_____ Y / NA
14. **Retrospective information has been given** Date_____ Y/ NA
    (Information must be given to the patient when able or given to the next of kin, legal guardian or carer.)

Note: Specific blood component/product must be prescribed along with special requirements if applicable (e.g. Irradiated, CMV neg, HLA matched). If blood warming device required, please specify.

Check all points above have been discussed and marked appropriately before printing and signing your name below

Print Name:_____Signed:_____Grade:_____

Speciality:_____Date:_____

**Any member of staff who have been competency assessed in the administration of blood/products may complete this informed consent if happy to do so and locally agreed with medical staff.*

Informed Consent Checklist for Patients

Informed consent checklist

Before any medical procedure is carried out, you (or a family member) will be asked to give your permission or *consent*.

To be involved in decisions about your transfusion, you must have enough information about your condition and the options you have. Be sure to ask questions if there is any part of your treatment that you do not understand.

When providing consent for blood, use the checklist to help you make an informed decision about your treatment.

- ☐ I am aware of which blood products will be transfused
- ☐ I am aware of how the transfusion will be given and how long it will take
- ☐ I am aware of the expected benefits of a transfusion
- ☐ I am aware of the potential risks and side effects
- ☐ I have been made aware of potential alternatives

Other questions to ask my doctor:

1. .....
2. .....
3. .....
4. .....

In an emergency, there may not be time to discuss your transfusion. However, the reasons for the transfusion should be explained to you when you are recovering. Where possible your transfusion will be discussed with your next of kin at the time.

https://mytransfusion.com.au/sites/default/files/Informed__checklist.pdf

Resources

- Materials on informed consent for transfusion
  - Ontario, Manitoba, Alberta, British Columbia
  - UK (nhsbt.nhs.uk)
  - Australia (transfusion.com.au)
- Transfusion consent video (Canada)
- http://www.youtube.com/watch?feature=player_detailpage&v=RxaPnLkgh-0
- Blood transfusion video for patients (UK)
- https://www.youtube.com/watch?v=sWlEON8Z9U0&feature=youtu.be
- Informed consent and other topics in medical ethics (Dirty Medicine)

Questions and Parting Thoughts

With my renewed focus, informed consent – the ritual by which a patient signs a piece of paper, authorizing surgery – became not a juridical exercise in naming the risks as quickly as possible, like the voiceover in an ad for a new pharmaceutical, but an opportunity to forge a covenant with a suffering compatriot: Here we are together; and here are the ways through – I promise to guide you, as best as I can, to the other side.

Paul Kalanithi “When Breath Becomes Air”