Dr. Katerina Pavenski, Informed Consent

Key points

- Studies show that there is room to improve the informed consent process for transfusion
- Consent for transfusion is required because of
  - Ethical obligation: respects patient's autonomy, involves patient in his/her care, allows patient to "own" treatment decision
  - Legal obligation: Informed consent is legislated nationally and, in some provinces, provincially (although does not specifically address consent for transfusion)
  - Standards: consent is required by the Canadian Society for Transfusion Medicine and Canadian Standards Association

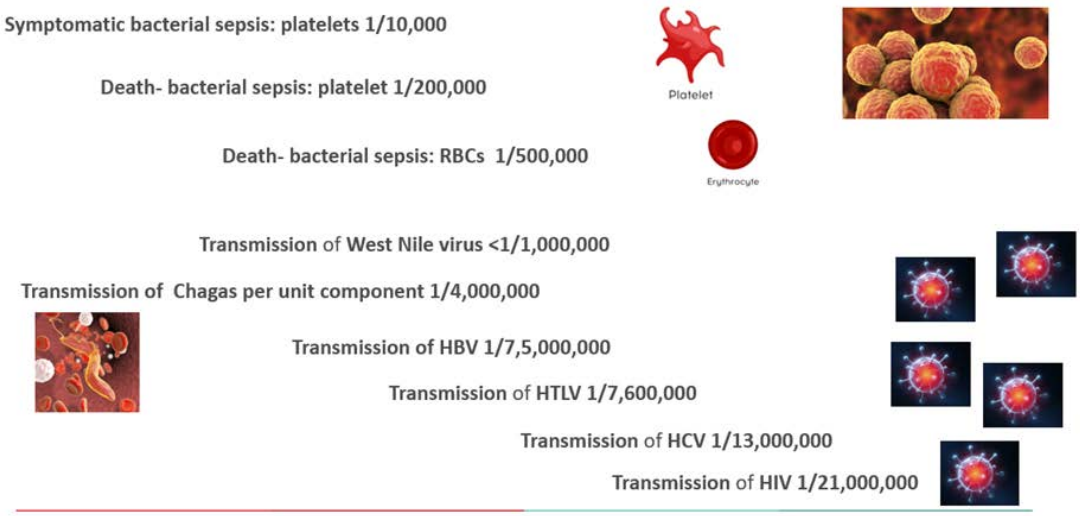
- Who should obtain consent? Obtaining informed consent is the responsibility of the *physician or a nurse practitioner* who orders the transfusion
- Process: to obtain informed consent, follow this process:
  - Determine the person's **capacity to decide** (if deemed incapable, locate a substitute decision-maker)
  - Obtain **consent** or **refusal**
  - **Document** in chart informed consent/refusal
  - **Communicate** your patient's decision to the other members of the healthcare team

- Elements of Informed Consent: Inform patient of:
  - the nature of treatment
  - What component is to be transfused? Why?
  - risks of transfusion – most common; uncommon but severe; and material to your patient
  - expected benefits
  - possible alternatives and their risks
  - the likely consequences of not having the treatment
  - right to refuse transfusion
- Obtaining consent is about giving information and receiving feedback from a patient
- Reference ORBCON informed consent pocket card: https://transfusionontario.org/wp-content/uploads/2020/06/InformedConsent2017.pdf

Dr. Steven Drews, Acute & Delayed Transfusion Transmitted Infections

Key Points

- The most common transfusion transmitted infection is Bacterial sepsis
- To reduce the risk of bacterial contamination
  - Skin disinfection
  - Diversion of the first 40mL of blood
  - Detection of bacterial contamination in ALL platelet units
- Transmission of blood borne viruses is extremely low



- To reduce risk of other infections
  - Donor health assessment questionnaire
  - Infectious disease testing

Infectious marker testing for all donations at CBS

Agent	Assay	Window Period (days)
HIV	anti-HIV-1/2 HIV-1/2 NAT	8
HCV	anti-HCV HCV NAT	4.1
HBV	HBsAg anti-HBc HBV NAT	22.4
HTLV	anti-HTLV I/II	51
Syphilis	Antibody	na

1 Mosquito season and travellers
2 At risk donors
na = not available

- serological tests are performed on individual donor samples, duplicate repeat runs on positives
- NAT is performed on pools of 6 samples from with resolution of reactive pools down to individual specimen
- all screening tests done prior to product release

Protecting the blood supply from transfusion-transmitted infectious diseases

Canadian Blood Services is nationally responsible for a secure system of life essentials for transfusion and transplantation that's reliable, accessible and sustainable. Processes, practices and systems are designed to ensure the quality and safety of our products and services. To safeguard the blood system (including stem cells) against existing, emerging and re-emerging pathogens, Canadian Blood Services undertakes a variety of processes and practices.

All blood transfused in Canada is collected from volunteer donors. They are sked about risk factors for transfusion-transmissible diseases. As laboratory tests have improved, the importance of the health assessment questionnaire in eliminating donors at risk for infectious diseases has decreased. However, currently, the questionnaire is the only means of excluding donors with a risk of Creutzfeldt–Jakob disease (CJD), variant CJD, Ebola virus, malaria, Zika virus, babesiosis, or leishmaniasis. Donors are not tested for these agents.

Antibody and antigen tests are done on individual donor samples while nucleic acid testing (NAT) is primarily done on pools of six samples. The multiplex assay used for NAT enables the simultaneous detection of HIV RNA, hepatitis C virus (HCV) RNA and hepatitis B virus (HBV) DNA. West Nile Virus (WNV) RNA testing is also done in pools of six samples. However, to enhance sensitivity, single unit WNV NAT may be used in selected geographic areas during outbreaks of WNV.

Testing on all donations occurs for HIV-1/2, anti-HBV, anti-HCV, syphilis and anti-human T-cell lymphotropic viruses-I/II (HLTV-I/II). Testing for antibodies to *Trypanosoma cruzi* (Chagas disease) is performed on at-risk donors based on the donor questionnaire. Testing for antibodies to cytomegalovirus (CMV) is performed on a small subset of donations to provide CMV-negative products for fetuses receiving intrauterine transfusions.

Platelets manufactured from buffy coat or collected by apheresis can be stored at room temperature with gentle agitation for up to seven days prior to transfusion. This storage requirement makes platelet units the blood component most likely to be associated with bacterial growth.
These platelet units are tested for bacterial contamination using an automated blood culture system incubated for up to seven days after inoculation.

Canadian blood services maintain an infectious disease matrix which is constantly updated and analysed regularly (daily for specific pathogens) as new information becomes available from a variety of sources: peer-reviewed publications, infectious disease surveillance internet reports, non-peer reviewed scientific information, news media, information from scientific meetings and teleconferences, and person-to-person discussions with peers. The scanning activities include assessing the risk to blood components, source plasma and hematopoietic stem cell products.

Canadian Blood Services also undertakes surveillance projects for agents such as *Babesia* and Hepatitis E virus. Information generated in these surveillance exercises is used for risk analysis and risk-based decision-making approaches for blood safety.

Dr. Christine Cserti-Gazdewich, Acute Non-Infectious Reactions

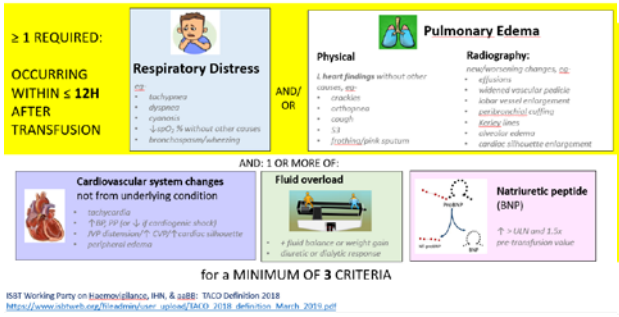
Minimum Disclosure Framework

in Layman's Terms & Logscale Frequencies

logscale		
1 2	**Common, minor events** (1 / 10^1-10^2)	non-serious **fever** non-serious **hives** make **antibodies** to donor antigens (RBC, HLA)
3 4 5	**Serious, potentially fatal events** (1 / 10^3-10^5)	**breathing trouble**: –volume-driven fluid excess –immune injury-driven fluid leaks –anaphylaxis / severe bronchospasm **bacterial contamination** of unit **botched process** (wrong sample or bag)
6	**Extremely rare events** (1 / 10^6 or less)	viral contamination of unit (**hepatitis, HIV**) **new** or **rare** (not tested-for) **bugs** fatal immune "take-over" by product

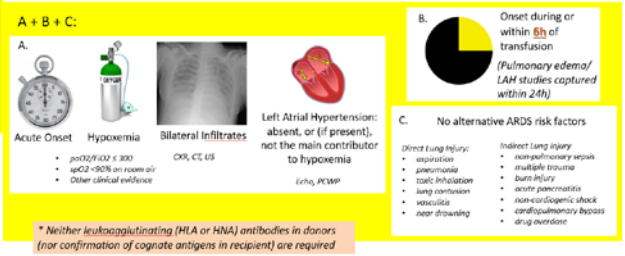
- Fever differential diagnosis
  - Low risk: FNHTR
  - High risk: bacterial contamination, bacterial sepsis, acute hemolytic transfusion reaction
- Dyspnea differential diagnosis: TACO, TRALI, Allergic, TAD

Transfusion Associated Circulatory Overload (TACO):



ISBT Working Party on Haemovigilance, IHN, & aaBB: TACO Definition 2018
https://www.isbtweb.org/fileadmin/user_upload/TACO_2018_definition_March_2019.pdf

Transfusion Related Acute Lung Injury (TRALI):



Vlaar et al. Transfusion 2019; 59: 2465-76

- Allergic reaction: ranges from cutaneous eruption to anaphylactic reaction
- Investigations:
  - Febriles: hemolysis, microbiology
  - Dyspneics: hemolysis, microbiology, CBS (donor ALA)
  - Hypotensives: hemolysis, microbiology
  - Anaphylactics: hemolysis, ?IgA/anti-IgA IgG
- Report all transfusion reactions to the blood bank and blood bank will report to outside channels (Canadian Blood Services, TTISS, Health Canada, etc.)

Dr. Waseem Anani, Delayed Non-Infectious Reactions

Review of delayed hemolytic transfusion reaction, post-transfusion purpura, and transfusion associated graft vs. host disease.