Advancing Transfusion and Cellular Therapies Worldwide

Blood Banking & Transfusion Medicine 101

Principles of Blood Supply Safety

Presented by:
Kevin Land, MD
Vice President, Clinical Services
Vitalant
Scottsdale, Arizona

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"Blood banking has become a manufacturing industry--an industry that must conform to high standards and quality control requirements comparable to those of pharmaceutical companies or other regulated industries“

-David A. Kessler, M.D., FDA commissioner
(Nov 8, 1990 – Feb 28, 1997)

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Learning Objectives

After participating in this program you should be able to….

- Explain the steps involved in blood donor qualification.
- Recognize the two priorities: donor and recipient safety.

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Why is this important?

- **Donor eligibility factors** impact donor & recipient safety
- The **manufacture** of blood components impact shelf life & recipient safety
- **Specific modifications** of blood components to enhance safety or suitability, but may impact shelf life or efficacy

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Donor Eligibility/Screening

WHY? First layer of protection in interdicting a unit from a donor with risk factors for infectious disease

WHY? Identify and protect donors who may be at risk from losing 500+ cc of whole blood

WHY? Prevent donation by a donor taking medications that could harm recipient/in-utero fetus or reduce blood product effectiveness

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Don't forget every medical intervention has inherent risk

- Physicians must know the risks versus benefits of all therapeutic modalities, including transfusion, for each specific patient treated.
- Disproportionate emphasis is oftentimes placed on the risks and possible complications.
- Withholding transfusion may result in a greater risk to the patient than transfusion.

There is a difference in how laypeople and healthcare professionals perceive risk.
Lee DH, Mehta MD, James PD. Transfusion 2003;43:772-8.

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Doing nothing or waiting to make a decision while gathering data is not always a good idea

Birth of the precautionary principle

"… Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures…."

Declaration of Rio, 1992

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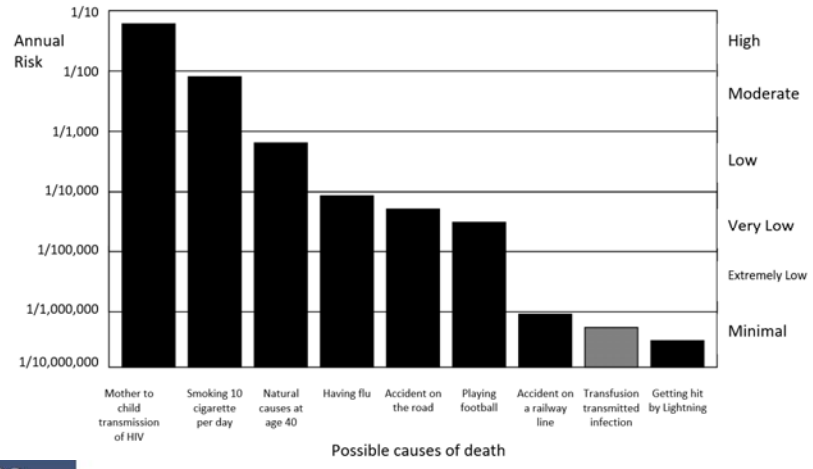
No such thing as zero risk, so caution must accompany the precautionary principle



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Blood Safety System: 5 Layers of Safety

"The heart of the blood safety system is five layers of overlapping safeguards that start at the blood collection center and extend to manufacturers and distributors of blood products." - FDA

- Donor screening
  - Educational materials and consent (Self-assessment)
  - Directed health history assessment (DHQ, mini-physical, Hgb/Hct)
- Blood Testing
  - screening followed by confirmation or additional testing
- Donor Deferral Registry
- Quarantine of untested blood
- Post-donation problems & deficiencies

Source: https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/keeping-blood-transfusions-safe-fdas-multi-layered-protections-donated-blood

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Layers of Safety

- **Donor screening**.
  - Potential donors must answer over 200 questions about their health and risk factors.
  - Those whose blood may pose a health hazard are encouraged to exclude themselves.
  - A trained health professional then interviews potential donors regarding their medical history.

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Donor Eligibility: History

- Considered essential layer of safety by FDA
- Established by multiple FDA Guidance and Memoranda documents, AABB Standards
- DHQ (donor history questionnaire) is primary tool used
  - Standardized industry questions, approved by FDA
  - Can be used as is, or made more conservative
  - New questions can be added

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Donor Eligibility: Mini Physical

- Blood Pressure (D): temporary
- Pulse (D): temporary
- Temperature (R/D): temporary
- Arm Inspection (R): temp/perm
- Hemoglobin/HCT (R/D): temporary
- Weight (D): temp/comp

D: Donor Safety Issue R: Recipient Safety Issue

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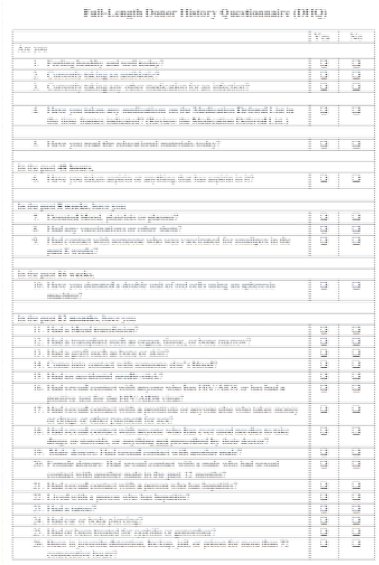
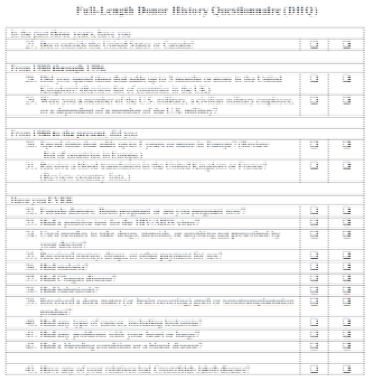
Donor Eligibility: [at least] 50 Ways to Lose a Donor

DHQ2.0
Effective Feb 2016


Full-Length Donor History Questionnaire (DHQ)


Full-Length Donor History Questionnaire (DHQ)

Just make a bad screen, Jean
or lots of deferrals, Earl
Ain't no one to draw, McGraw
If you don't listen to me!
- With apologies to P Simon

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Eligibility v Suitability

sometimes used interchangeably; not always the same

- During job interviews, candidates may be eligible for hire, but may not be suitable for a given job.
- Similarly, donors may meet general eligibility criteria, but may not be suitable for being a donor to a given patient for a variety of reasons:
  - Due to patient- or donor- specific factor
    - ABO/Rh type, incompatible antigens (red cell, HLA, etc), Sickle cell trait,
    - Even genetic sex (risk of HLA antibodies based on number of pregnancies of donor)
  - This where the laboratories help identify the best unit(s) for a patient

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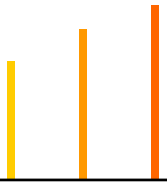
Layers of Safety

- **Blood testing**. After donation, the blood is tested for specific blood-borne agents.
- **Donor lists**. Blood establishments must keep current a list of deferred donors and check donor names against that list.
- **Quarantine of untested blood**. Blood products are not available for general use until the products have been thoroughly tested.



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Layers of Safety

- **Investigation of problems**.
  - Blood establishments must thoroughly investigate any breaches of safeguards and correct deficiencies.
  - Licensed firms must report to FDA any manufacturing problems, errors or accidents that may affect the safety, purity, potency, identity, or consistency of their products.
  - Registered firms are required to maintain accurate records for review by regulatory agencies.

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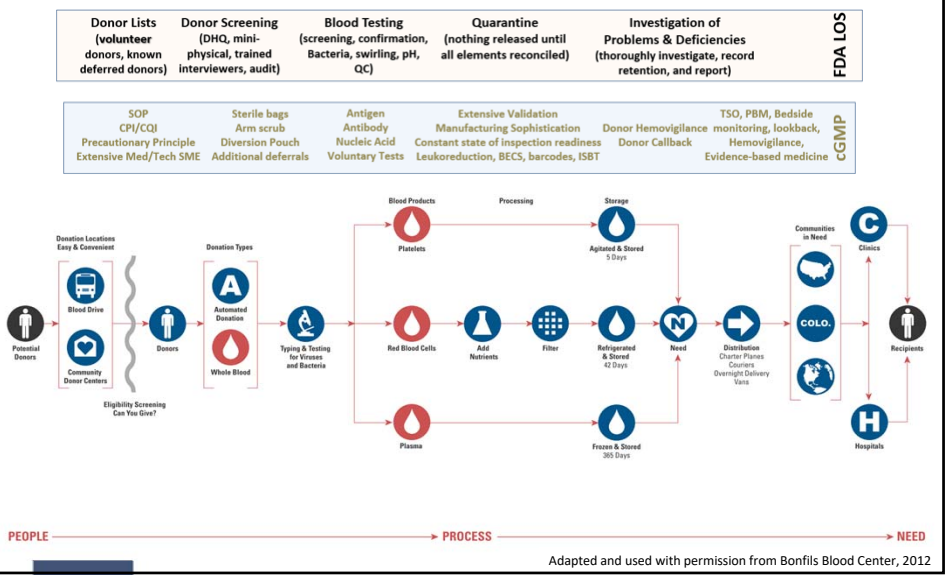
Layers of Safety & Benefits of GMP along the SQIPP Journey of Blood



Adapted and used with permission from Bonfils Blood Center, 2012

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Donor Safety

As primary donor advocate, we must vigilantly guard donor safety, even if not of immediate concern to them

- Consented to understand risk v benefits
- Generally well and healthy
  - Weigh at least 100 pounds
- Be at least 16yo
  - (parental consent may be required for 16-17yo)
  - No upper age limit
- Minimize adverse donor events
  - Take ≤10% total blood volume
  - Respond to low iron
- Negative for specific medications & conditions

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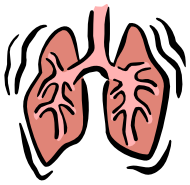
Rationale for medical history deferrals

To protect the ***donor***

- –Cardiovascular disease
- –Cancer
- –Pregnancy
- –Medications
- –Pulmonary disease
- –Abnormal bleeding condition
- –Donation frequency



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Recipient Safety & The Rights of Transfusion

Vigilant adherence to the blood center Quality System ensures products meet the Safety, Quality, Identity, Purity, Potency, and Consistency requirements of the patients we treat.

Right Outcome = Right Patient + Right Product + Right Reason + Right Dose + Right Time

Fully potent blood components
ABO/RH compatible routinely
No unexpected antibodies (red cell, plt, white cells, others)
Minimized TACO, TRALI and other AE risks
Minimized infectious disease risk including bacteria

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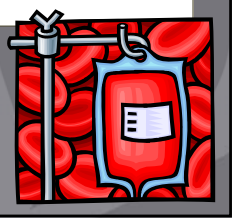
Questions to Protect the Recipient

Most questions are designed to protect the ***blood recipient*** from possible infectious diseases transmissible through blood.

We have excellent blood tests to find donors who are infected with HIV, Hepatitis B, Hepatitis C, and Syphilis.



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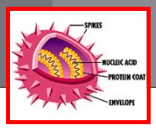
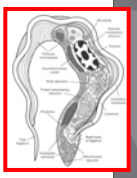
Rationale for medical history deferrals



To protect the ***recipient***

- Most questions are designed to protect the ***blood recipient*** from possible infectious diseases transmissible through blood.
  - –Big three disease concerns: HIV, HCV, HBV
    - –Emerging pathogens
    - –Bacterial infection
    - –Others: syphilis, Chagas, Babesiosis, CJD
  - –Travel: malaria, vCJD, Chagas, others
- Medications: teratogens, vCJD, platelet antagonists
- Abnormal bleeding conditions



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Questions to prevent transmission of Infectious Diseases

- Certain infectious organisms can be transmitted through blood but there is ***no test*** currently available to screen the blood.
- For those infectious agents, we try to identify donors at risk by asking questions- lots of questions!
- Questions are based on lifestyle (residence, travel, needle usage, etc) or symptoms (e.g feeling well)

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Infectious Risks of Transfusion

- HIV
- Hepatitis B
- Hepatitis C
- CMV
- Bacteria
- Chagas
- Babesia
- Malaria
- ?!? Prions ?!?

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Questions to prevent transmission of infectious disease

- The risks of HIV, Hepatitis C and Hepatitis B are exceedingly low but not ZERO
- We ask questions about life style to defer donors who may test negative to HIV or Hepatitis, but who may still be at risk because of lifestyle

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Questions to prevent transmission of Hepatitis (B and C) and/or HIV

- Exposure to blood by transfusion or needle stick?
- Bone or skin graft
- Sex with someone with hepatitis
- Lived with someone with hepatitis
- Tattoo or body piercing
- Been in a correctional institution?
- Use of needle to inject (illegal) drugs?
- History of hepatitis after age 11?
- Bleeding condition or blood disease

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Infectious Risks of Transfusion

- HIV
- Hepatitis B
- Hepatitis C
- CMV
- Bacteria
- Chagas
- Babesia
- Malaria
- ?!? Prions ?!?

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Questions to prevent transmission of Bacteria & CMV

- Are you feeling well?
- Antibiotic use?
- Recent infection?

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Infectious Risks of Transfusion

- HIV
- Hepatitis B
- Hepatitis C
- CMV
- Bacteria
- Chagas
- Babesia
- Malaria
- ?!? Prions ?!?

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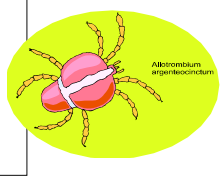
Transmission of Malaria, Chagas and other parasites

- Parasites are pathogens that live inside cells such as red blood cells
- *Malaria* lives in red cells and causes RBC to rupture; can cause death. Transmitted by mosquitoes in **tropical** areas
- *Babesiosis* is transmitted by ticks in **temperate** climates such as USA; serious infections only in immune suppressed patients



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Questions to prevent transmission of Malaria and other parasites

- Travel outside the USA or Canada?
- Ever had Malaria, Chagas', or Babesiosis?

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Infectious Risks of Transfusion

- HIV
- Hepatitis B
- Hepatitis C
- CMV
- Bacteria
- Chagas
- Babesia
- Malaria
- ?!? Prions ?!?

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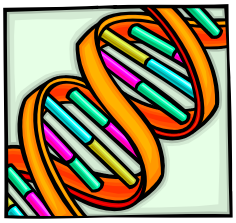
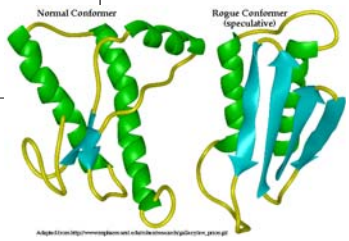
What is a Prion?



- Bare infectious protein particles
- Unlike all other infectious particles (viruses, bacteria, parasites, fungi) they do not have DNA!
- Cause disease by causing normal proteins to take an abnormal structure or form



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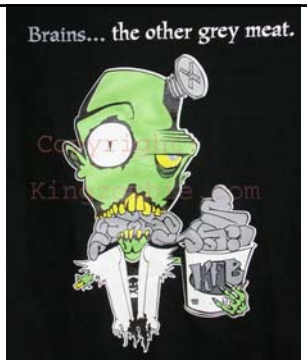
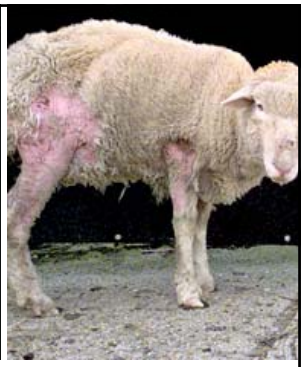
What are prion diseases?

- Mad cow disease
- Kuru
- scrapie
- Variant CJD





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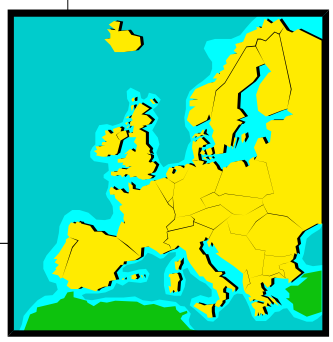
Screening questions

Ever received a dura mater transplant
- Ever received human pituitary derived growth hormone
- Used beef insulin from UK
- Europe (5 years)
- Military (6 months)
- Received blood transfusion in UK or France



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Worldwide vCJD

Since 1996, 229 vCJD
- 177 in UK
- 27 in France
- 25 across 10 other countries

6 cases in North America
- 4 US & 2 Canada
- All born outside US
  - Mainly UK & Saudi Arabia

"No, I wouldn't call you a mad cow exactly -- I'd say you're a cow with issues."

"FDA takes a conservative approach to ensure the safety of the Nation's blood supply and therefore, issues guidance relating to both known infectious diseases as well as potentially emerging diseases. This conservative approach may result in the deferral of otherwise acceptable donors.

Emerg Infect Dis. 2015 May;21(5):750-759.
https://www.cdc.gov/prions/vcjd/vcjd-reported.html
http://www.fda.gov/cber/faq/bldfaq.htm , 1/2005

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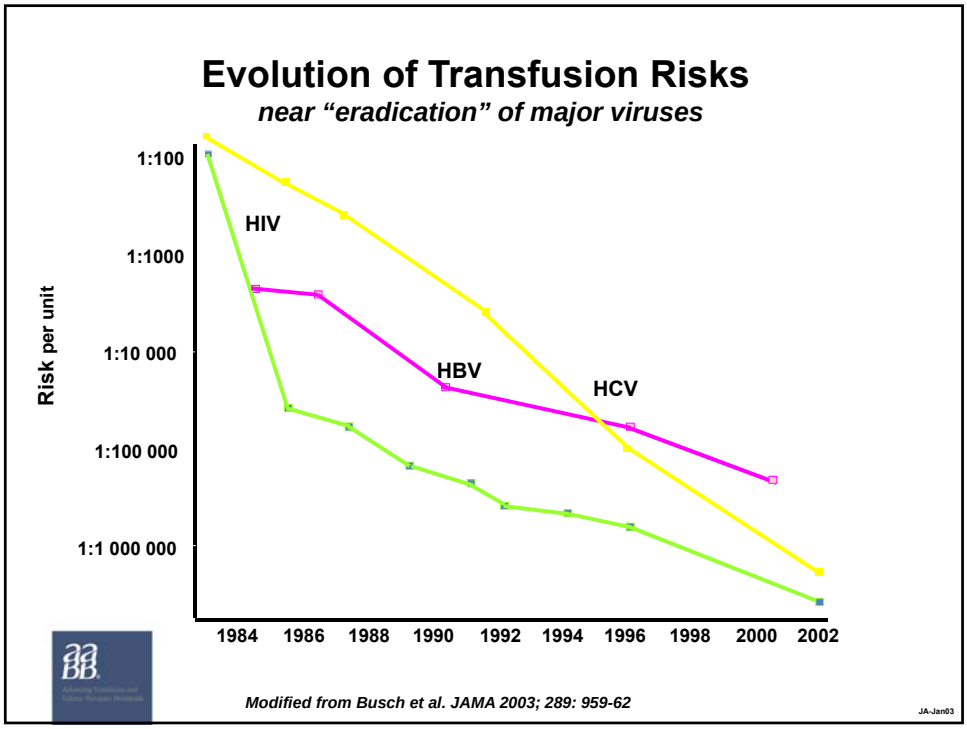

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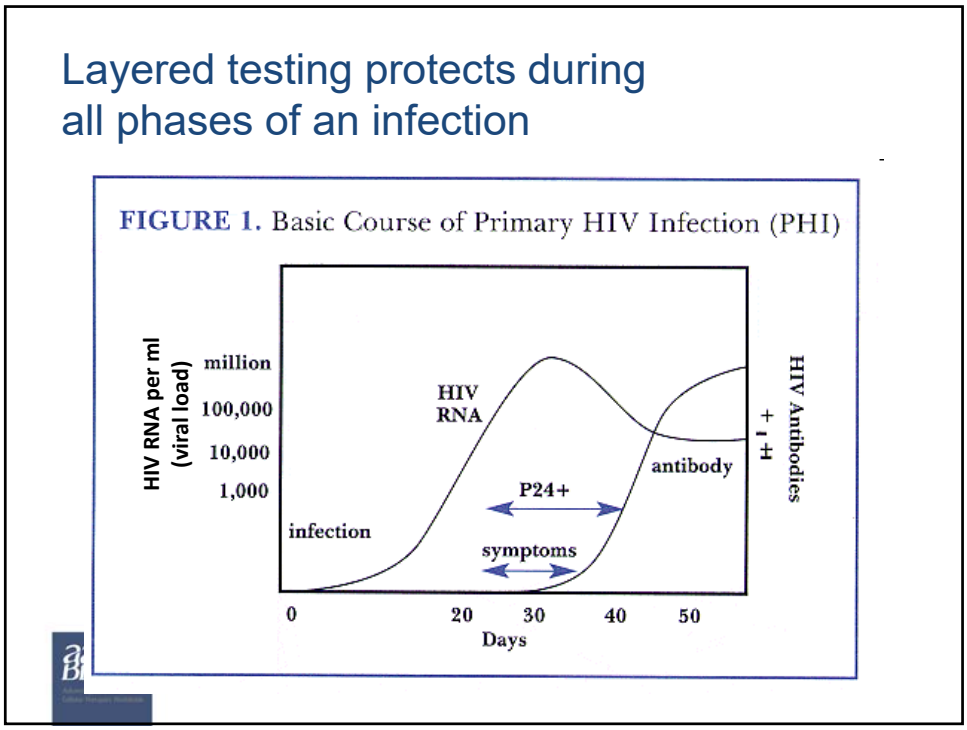

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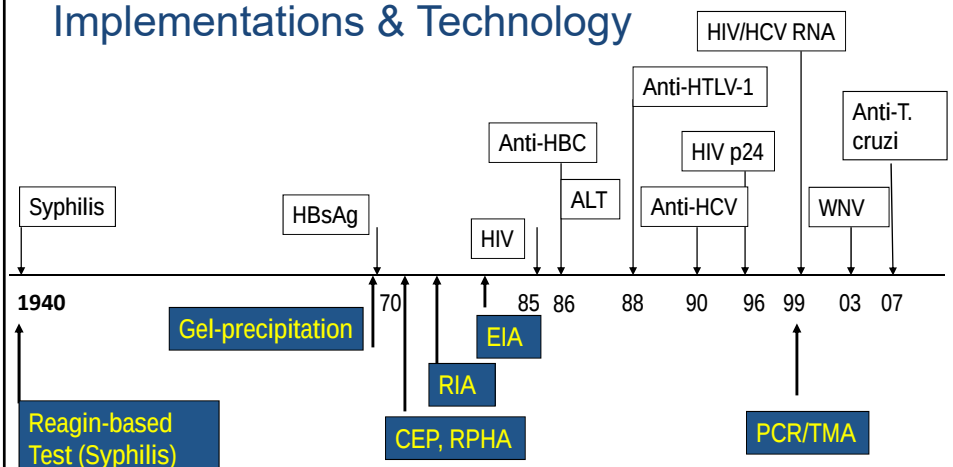
Evolution of Blood Donor Testing
Implementations & Technology



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Current Donor Screening

Antibody
- Anti-HIV 1/2
- Anti-HTLV I/II
- Anti-HCV
- Anti-HBc
- Anti-T Cruzi^

Antigen
- HBSAg
- Syphilis

Nucleic Acid Testing
- NAT (HIV-1/HCV/HBV*) RNA
- NAT (WNV)
- Anti-CMV*
- ABO/Rh
- IAT

DONOR ≠ DIAGNOSTIC
Screening/Confirmation Testing minimizes false negative test results, but does mean false positives*

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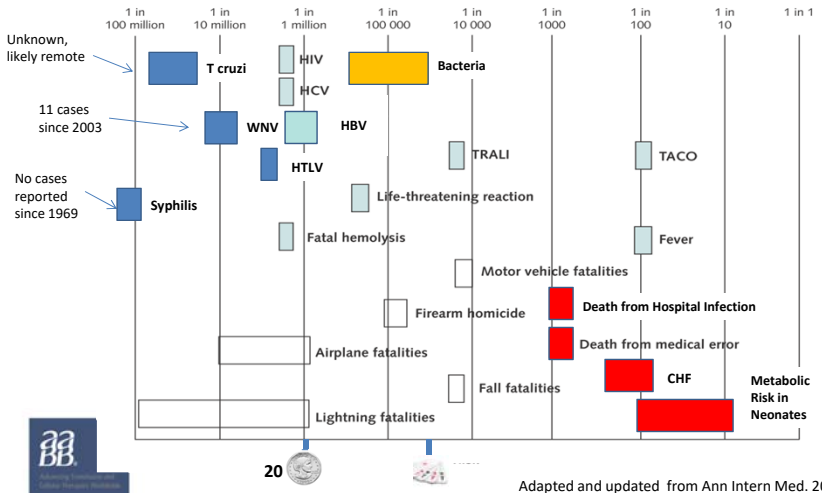
Adverse Risks of per unit transfusions in US compared to other risk



Adapted and updated from Ann Intern Med. 2012;157:49-58.

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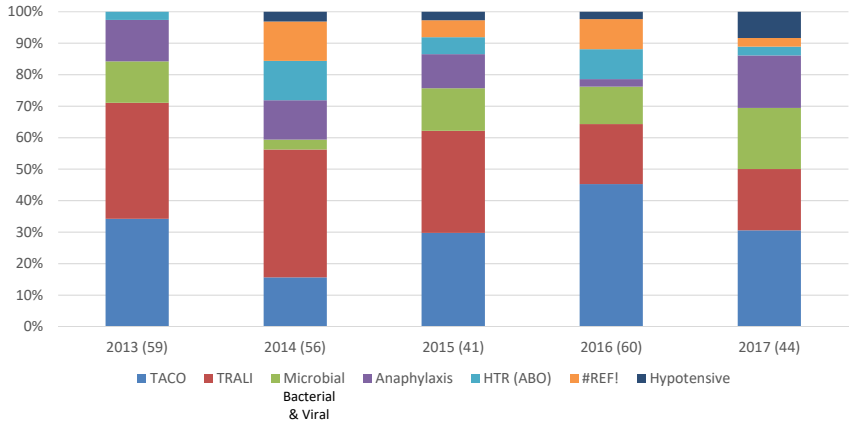
Transfusion related fatalities (10/1/16 – 09/30/17)



https://www.fda.gov/media/124796/download, accessed Jan 3, 2020

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Current Residual Risk of Infectious Diseases currently tested

Infectious agent routinely tested by blood centers	Estimated residual risk per component transfused
Human Immunodeficiency Virus	~ 1:1,930,000 One case reported in US since 1999, donor had viral load of <150 copies of RNA/mL
Hepatitis C Virus	~ <1:1,000,000
Hepatitis B Virus	~1:137,000-220,000 or less HbsAg 3.0 licensed 2003
Human T-cell Lymphotrophic Virus	~1:641,000
Syphilis	Unknown, No cases reported since 1969
West Nile Virus	Unknown, ~ 6 probable cases have been reported nationwide since July 2003 (CDC)

Stramer SL (ed.) Blood Safety in the New Millennium. AABB 2001.
Strong DM, Katz L. Trends Mol Med. 2002 Jul;8(7):355-8.

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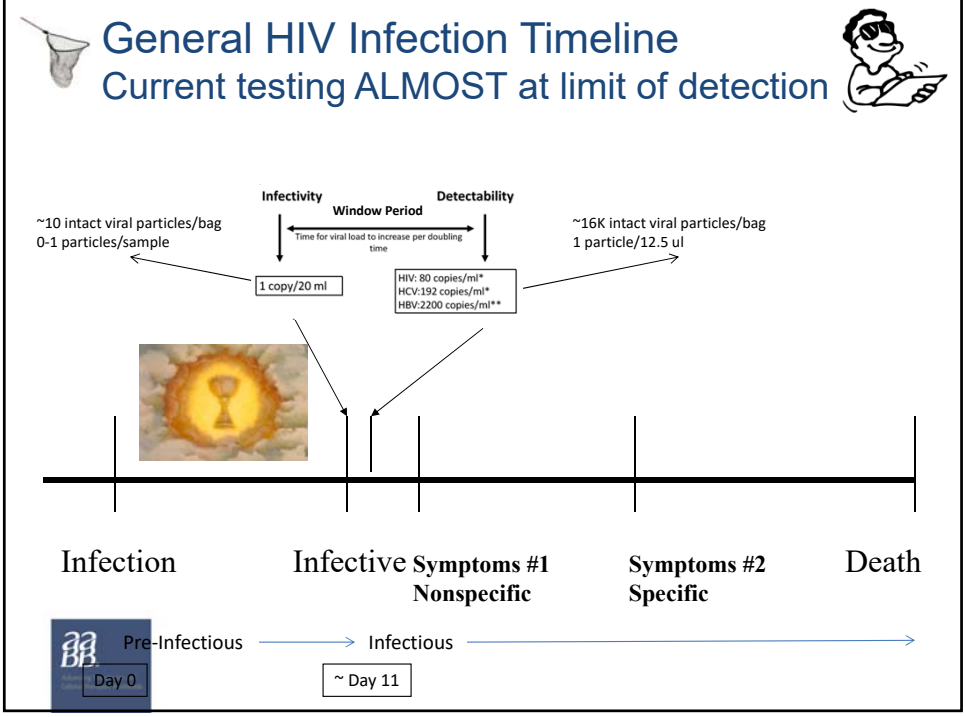
General HIV Infection Timeline
Current testing ALMOST at limit of detection



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The TTD decision matrix monitoring potential EID threats

- Tx-transmission demonstrated or "plausible"
  - Transfusion risk assessment
    - Number of transmissions
    - Number and nature of clinical outcomes
- Low-risk donor selection doable?
- Donor testing available?

- Can we inactivate/remove?
- Impact on blood supply?
- Impact on blood donors?

HEV	HGV	Rickettsia rickettsii	vCJD
Crimean-Congo Bunyavirus	Porcine endogenous retrovirus	Anaplasma phagocytophilia	Chronic Wasting Disease
HBV Mutants	Spumavirus	Erlichia sp. (HME)	Classical CJD
HIV Variants	SARS Comavirus	Rickettsia prowazekii	
SEN-V and related agents	Papillomaviruses	Babesia	
Lymphocytic Choriomeningitis Virus	St. Louis Encephalitis	Orientia tsutsugamushi	
JC/BK and SV40	Porcine Panovirus	Borrelia sp.	
Enteroviruses	Lassavirus	Chlamydia	
Avian Influenza Virus (H5N1)	Rhabdovirus	Yersinia	
Other Influenza A and B Viruses	Dengue	Other bacterial RBC agents	
HAV	Ebola Filovirus	Brucella	
HTLV Variants	Tick-Borne Encephalitis	Bartonella	
B19 Erythrovirus	Other JE Viruses	Coxiella burnetti	
Bacillus anthracis	Marburg Filovirus	Listeria	
Bornavirus	Western Equine Encephalitis	Trypanosomes (T. cruzi et al)	
Eastern Equine Encephalitis	Hantavirus	Leishmania	
HHV-8	Monkeypox	Plasmodia spp.	
Other Herpes Viruses (e.g. 6 & 7)	Variola	Filariae	
Colorado Tick Fever	Vaccinia	Toxoplasma	

EID = emerging infectious disease

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Pill nation: Medication usage

- Modern society increasingly reliant on medications
  - Polypharmacy increases directly with person's age and sedentary lifestyle
- In US, 4/5 adults & >50% of children use medication, weekly
  - Prescription, over-the-counter medication, dietary supplement, etc
- In US – 38% of population eligible to donate, <10% do annually
  - Highly mobile society
  - Blood Centers typically go about what they do in ways that don't attract young donors
  - Excessive deferrals for medications can impact donor eligibility

Mitchell A, et al. Patterns of medication use in the US 2005: A report from the Slone Survey (e-report). Boston, MA, 2006.
https://www.telegraph.co.uk/news/2017/12/13/pill-nation-half-us-take-least-one-prescription-drug-daily/

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Top medications used

PRESCRIPTION

- Levothyroxine (thyroid)
- Diuretics (hydrocholorothiazide)
- ACE-inhibitors (e.g. lisinopril)
- Amlodipine (Ca channel blocker)
- Beta blockers
- Hydrocodone/acetaminophen
- Metformin
- Atorvastatin, Simvastatin
- Azithromycin, Amoxicillin
- Metformin
- Antidepressants

OVER-THE-COUNTER

- Decongestants
- Antihistamines
- Anti-ulcer agents
- Analgesics

REFERENCE: Food and Drug Administration, NHS

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Are donors reliable witnesses of their own medication usage?

- No…but no differently than the regular population.
- Length of time taking medications (part of life)
- Success of medication (with drug, I do not have high blood pressure)
- BOTTOM LINE: Better to use specific questions about drugs of risk than open-ended questions about any and all drugs taken.

Melanson SE. Transfusion 2006;46:1402-7.
Cornish PL. Arch Intern Med 2005;165:424-9.
Tam VC. CMAJ 2005;173:510-15.

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Framework of Risk

- Is the medication a reliable predictor of donor risk (e.g. disease severity) in an otherwise healthy donor?
- Will the medication's method of action affect the safety, purity, potency, and consistency of a final product?
- Have similar medications already been considered, and if so, how have they been addressed?
- What is the likelihood that the medication will adversely impact the recipient or recipient's fetus in a dose-dependent fashion?

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Table 5-6. Risks Associated with Medication Use in the Donor

Person(s) at Risk	Type of Risk from Drug	Example
Donor center staff and other donors	May influence donor behavior, affecting, in turn, others in the immediate environment (non-recipients of transfusion).	Recent use of methamphetamine or ethanol may cause aberrant, violent behavior.
Donor	May interfere with testing or processing.	Recent hepatitis B vaccination may cause a biologic false-positive screening test for hepatitis B surface antigen.
	Is a marker for donor condition with donor risk.	Continuous oxygen required for severe emphysema puts the donor at increased risk for cardiovascular complications.

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Table 5-6. Risks Associated with Medication Use in the Donor

Person(s) at Risk	Type of Risk from Drug	Example
Donor and Recipient	Is potentially contaminated with a toxic substance or drug that affects product potency	Recent use of synthetic marijuana which has be laced with brodifacoum, a potent Vitamin K antagonist anticoagulant pesticide.
Recipient	Is a marker for a donor condition with recipient risk.	Antibiotics for active pneumonia may lead to transfu- sion-transmitted bacteria from the donor.
	May itself impart a risk of infection.	Use of bovine insulin from the United Kingdom may lead to transfusion-transmitted variant Creutzfeldt- Jakob disease from the donor.
	May alter blood component potency.	Use of warfarin in the donor may result in inactivation of critical clotting factors in donated plasma.
	Negatively affects the recipient or the recipient's developing fetus.	Etretinate (Tegison) use may cause fetal malformation

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Medical questions asked in DHQ 2.0

2	*Are you* currently taking an antibiotic?
3	*Are you* currently taking any other medication for an infection?
4	Have you taken any medications on the Medication Deferral List in the time frames indicated?
6	*In the past 48 hours, have you* taken aspirin or anything that has aspirin in it?
8	*In the past 8 weeks, have you* had any vaccinations or other shots?
9	*In the past 8 weeks, have you* had contact with someone who was vaccinated for smallpox in the past 8 weeks?

www.aabb.org/tm/questionnaires/Pages/dhqaabb.aspx

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Table 5-2. Drug Categories Addressed by the DHQ 2.0 and Associated Generic Drug Names*

1. Medications used to treat infection
2. Anti-platelet agents:
   - COX-1 and COX-2 inhibition (aspirin, piroxicam)
   - $P2Y_{12}$ inhibition (cangrelor, clopidogrel, prasugrel, ticagrelor, ticlopidine, vorapaxar)
   - PAR-1 antagonist family (vorapaxar)
3. Anticoagulants:
   - Vitamin-K antagonist (warfarin)
   - Antithrombin activator and variable thrombin inhibition (heparin family)
     - High molecular weight (unfractionated heparin)
     - Low molecular weight (dalteparin, enoxaparin)
     - Fondaparinaux (fondaparinux)
   - Novel Oral Anticoagulants (NOACs)
     - Direct Factor Xa inhibition (apixaban, edoxaban, rivaroxaban)
     - Direct Thrombin inhibition (dabigatran)
4. Medications with risk of teratogenicity or fetal harm used to treat a variety of conditions, such as acne, male-patterned baldness, prostatic hypertrophy, cancers, multiple sclerosis, and psoriasis:
   - DNA transcription alteration (acitretin, etretinate^, isotretinoin#)
   - Type II 5a-reductase inhibition (dutasteride, finasteride)
   - Hedgehog pathway inhibition (sonidegib, vismodegib)
   - Pyrimidine de novo synthesis and T-cell inhibition (lefunomide, terifunomide)
5. Human or animal-derived medications with infectious disease risk:
   - Hepatitis B immune globulin, human derived (HBIG)
   - Growth hormone derived from human pituitary glands
   - Bovine insulin manufactured in the United Kingdom between 1980 and 1996
6. Medications with unknown risk:
   - Experimental or unlicensed vaccine

*Revised November, 2017. See AABB Web site for the current version (www.aabb.org>Transfusion Medicine>Donor History Questionnaires>Blood Donor History Questionnaires).
^ removed in US September 23, 1999.
# voluntarily removed in US June 2009, still marketed in generic form as of 2018.

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Table 5-3. Common Vaccination Deferrals in the United States

Deferral Period	Vaccination (Examples)
None if symptom-free and afebrile	Killed, inactivated, recombinant, synthetic or toxoid-derived: Anthrax, Cholera, Diphtheria, Hepatitis A, Hepatitis B, Human papillomavirus, Influenza, Lyme disease, Paratyphoid, Pertussis, Plague, Pneumococcal polysaccharide, Polio (Salk/injection), Rabies, Rocky Mountain spotted fever, Tetanus, Typhoid (injection)
3 to 12 months if	Hepatitis A—food-borne outbreak: 3 months vaccine is given after exposure Hepatitis A, hepatitis B—living with or sexual contact with individual with hepatitis: 12 months
2 weeks	Live attenuated pathogens: Live intranasal influenza, tuberculosis (BCG), measles/mumps/rubella (MMR), rotavirus, measles (rubeola), typhoid (oral), mumps, yellow fever, polio (Sabin/oral)
4 weeks	German measles (rubella), epidemic typhus Chicken pox (varicella zoster), shingles* (herpes zoster)
8 weeks	Smallpox
1 year	Unlicensed or experimental vaccines Other vaccines not otherwise indicated

*Not in AABB Standards.[3]

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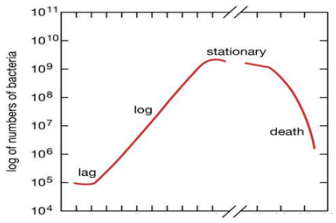
Collection Basics that Mitigate the Risk of Bacterial Contamination in Blood

- Leading microbial cause of transfusion mortality
  - Serious/fatal reactions seen due to Gram-negative organisms
    (*E coli*, *Klebsiella* sp, *P rettgeri*, *Serratia* sp)
- Residual Risk:
  - Platelets (1 in 75K)
  - Red Blood Cells (1 in 500K)
  - FFP and CRYO (extremely rare)
- Minimization Techniques?



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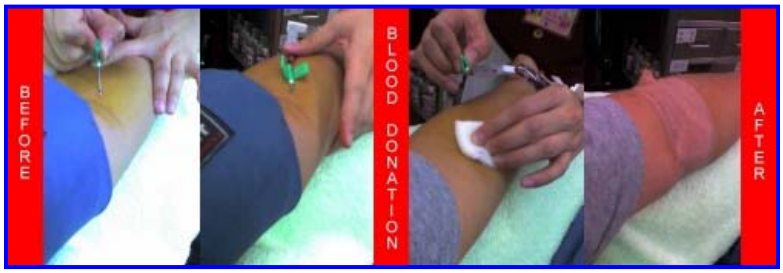
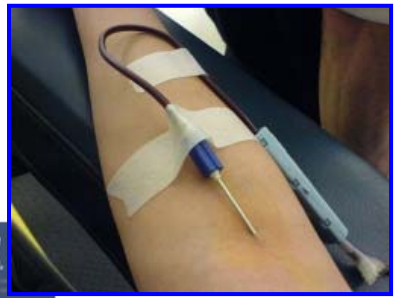
Sterilized, beveled needle used at collection





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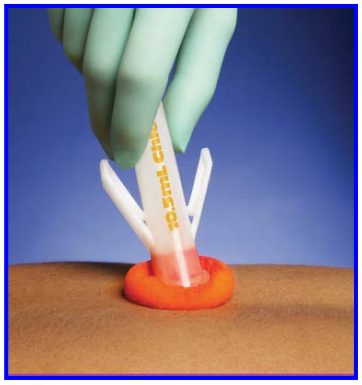
Arm Scrub



Protects both donor and recipient

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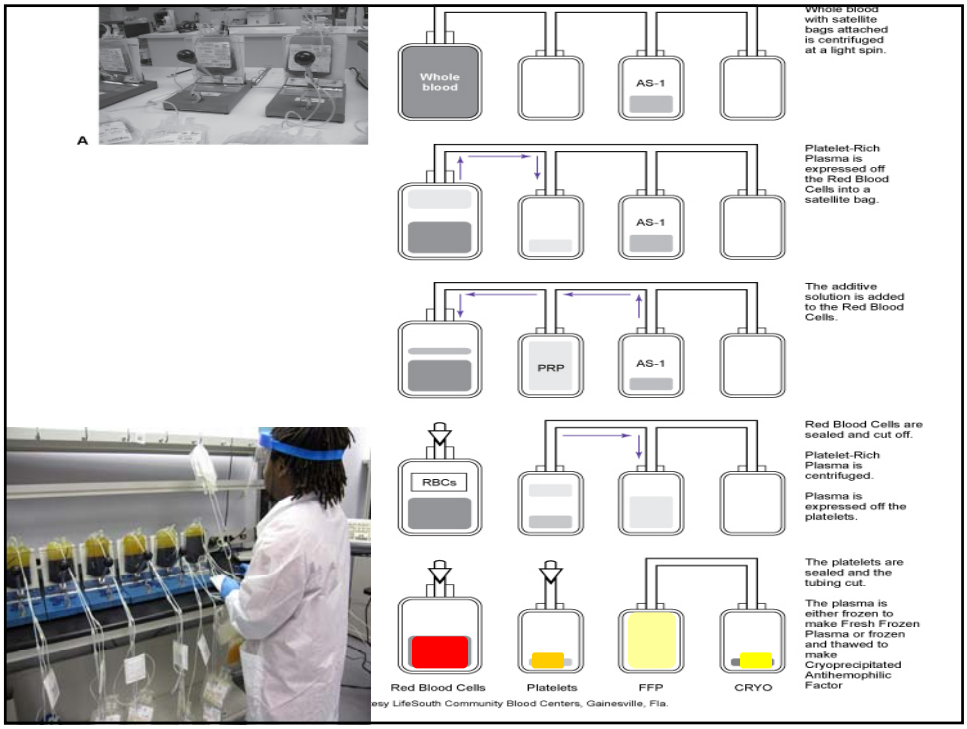

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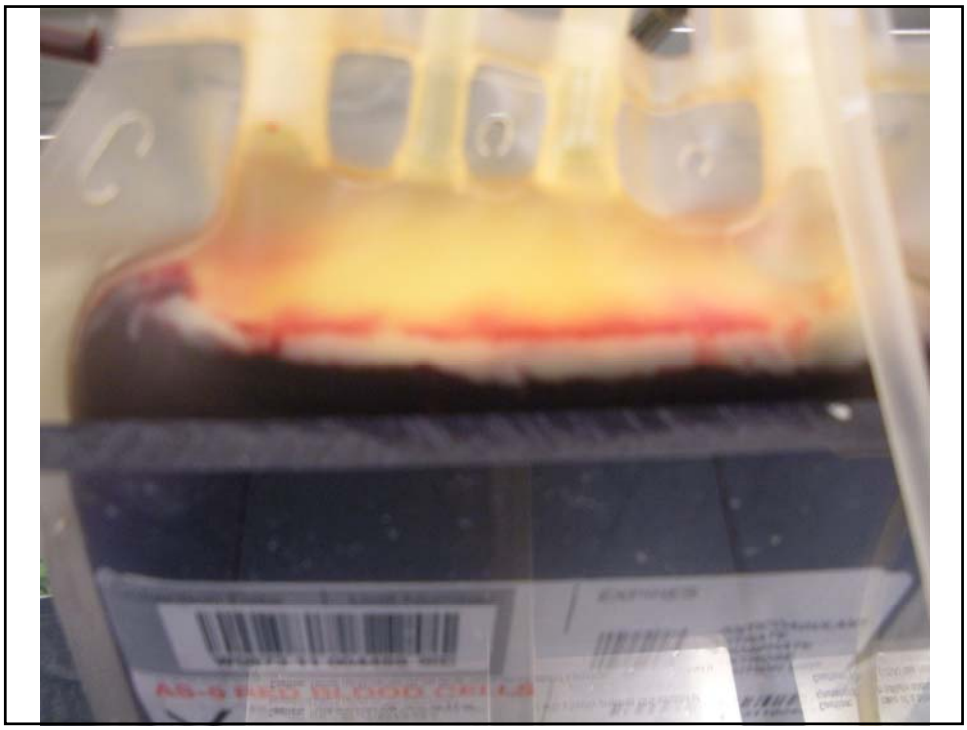

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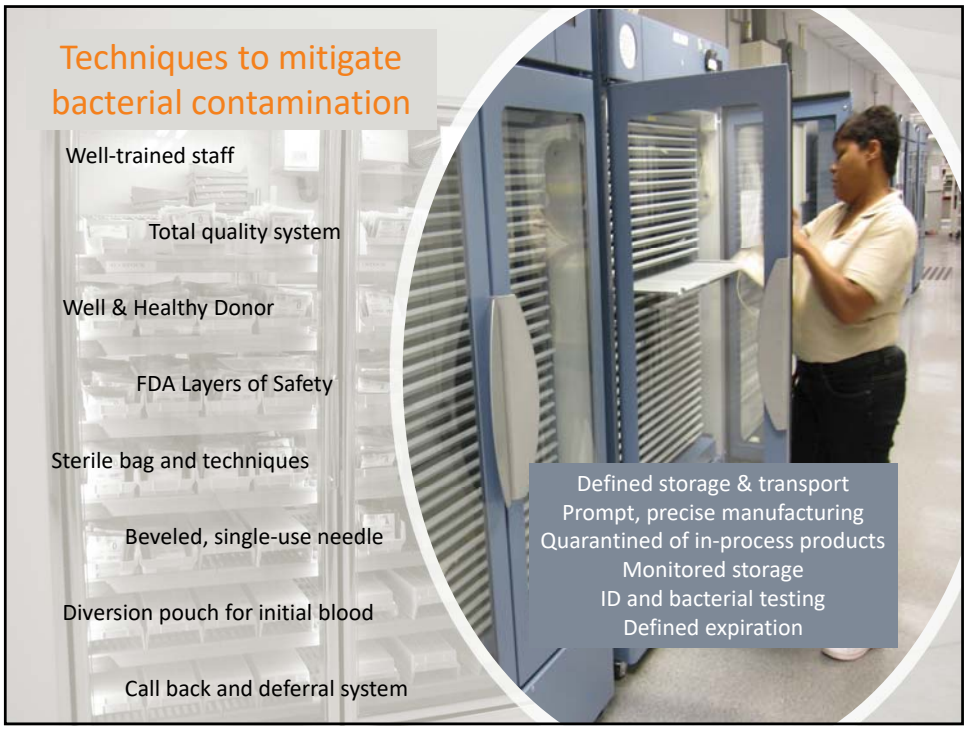

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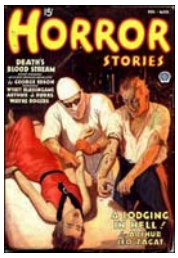
Hero vs. Horror

Perceptions of risk play a prominent role in the decisions people make, in the sense that differences in risk perception lie at the heart of disagreements about the best course of action between technical experts and members of the general public

– Slovic & Weber



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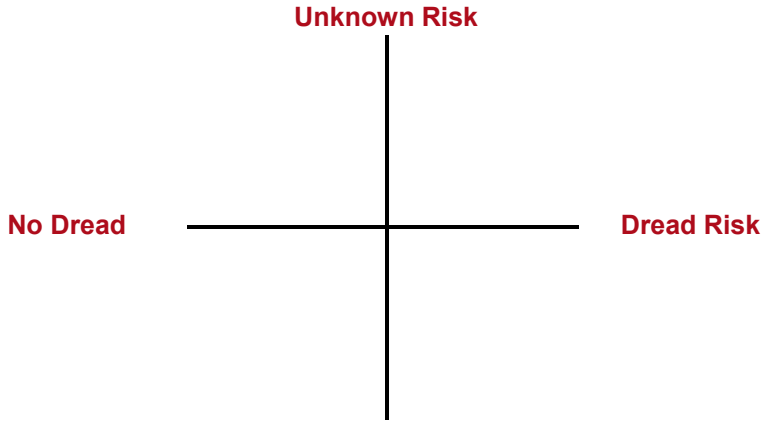
Perception of Risk



Slovic, P. Perception of Risk. Science 1987;206:280-285

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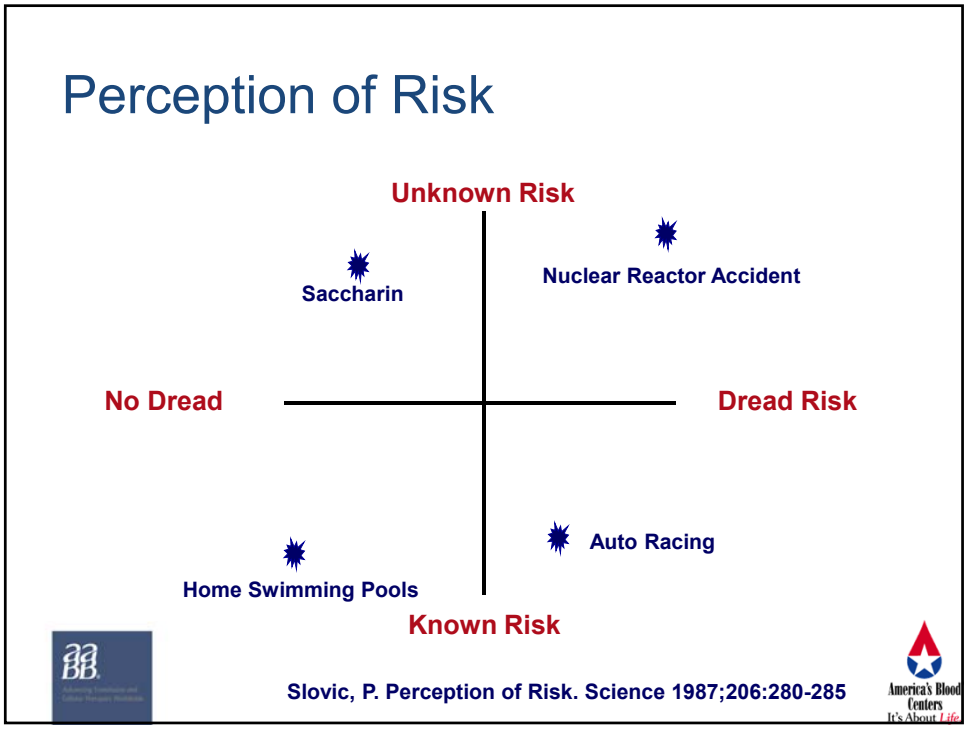

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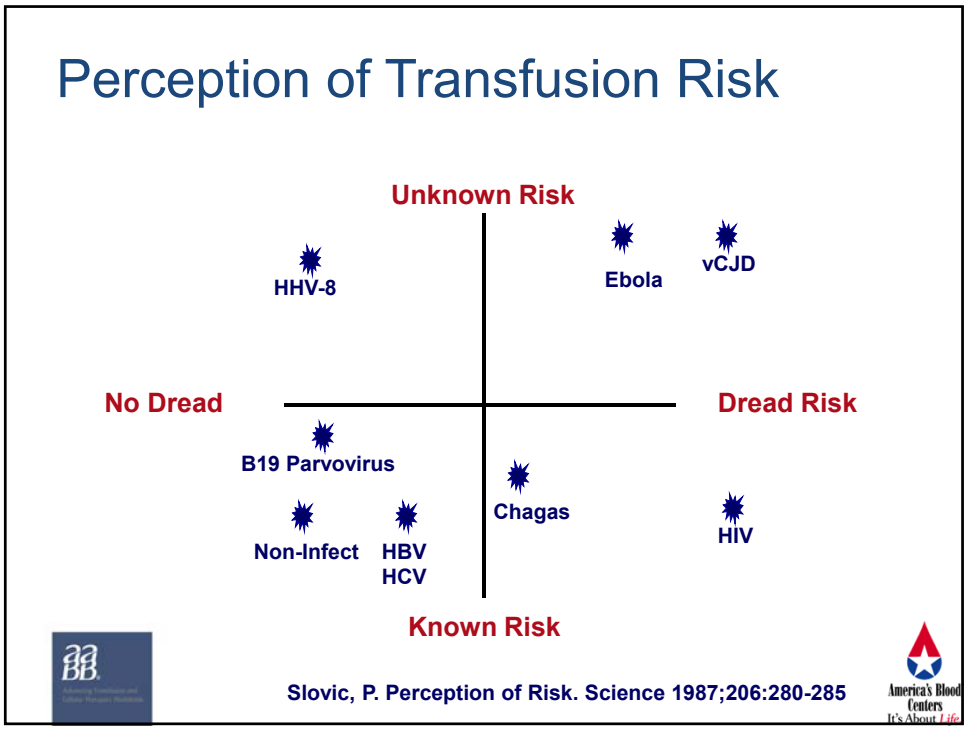

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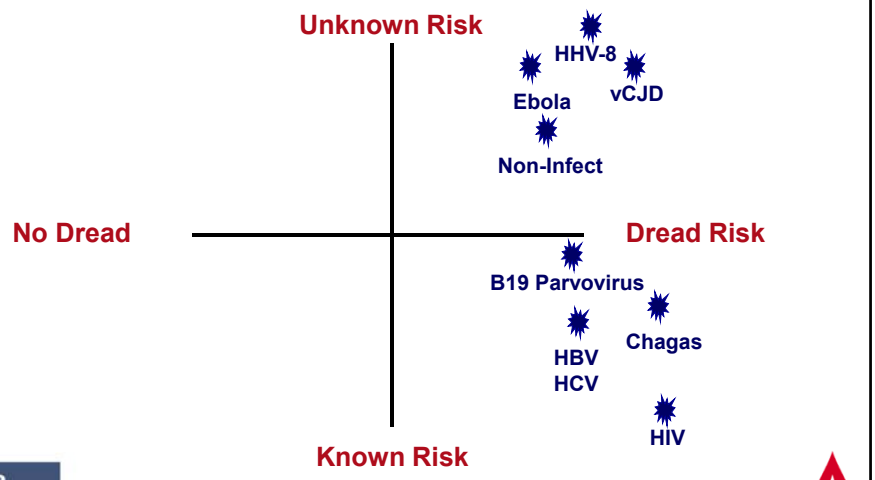
Misperception of Transfusion Risk



After Slovic, P. Perception of Risk. Science 1987;206:280-285

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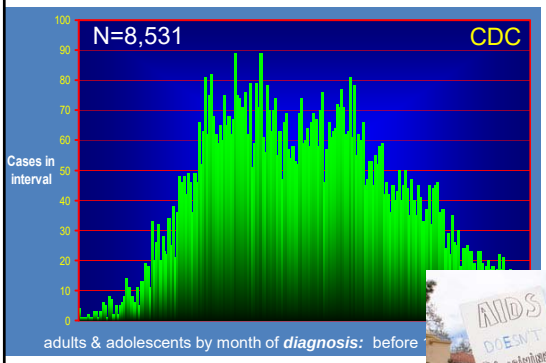
AIDS associated with receipt of blood leads to deferral strategies to protect patient rights



Which leads to deferral strategies that are interpreted by some (potential donors) as **discriminatory.**

Whose rights are more valid?

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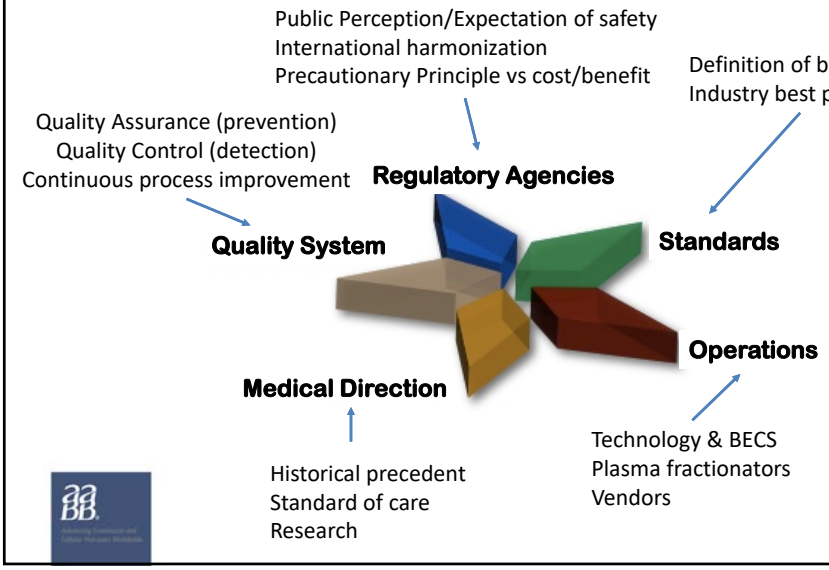
Forces Determining Donor Eligibility with primary drivers



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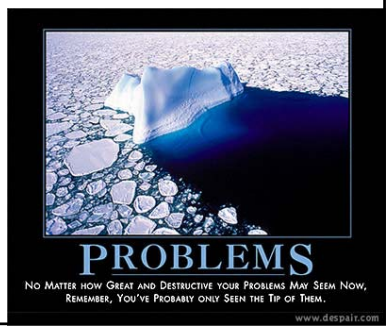
Additional influencers of the Safest Blood Possible Concept

- **Vendor reluctance** to provide innovative technologies
  - Expense and complexity of FDA licensure (510k clearance)
  - Limited competition among manufacturers, focus on short-term investment
- Donor center and FDA **competing priorities**
  - Release of "in-process" technologies (pathogen inactivation)
  - Impact of changes on donor base
  - Evolving donor base
- **Emerging pathogens** and need for unified national/international Biovigilance
  - Testing driving component disposition
  - Global Harmonization



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Avoiding risky business

- Every Medical Intervention has inherent risk, including blood transfusion.
- Infectious disease risks like HIV may be of more concern for recipient safety, but they are not the most common or lethal recipient risks.
- Donor safety is also of top concern, especially if we are to encourage a whole new generation to voluntarily donate.
- The complex interplay of the risks and benefits of both blood donation and transfusion must be understood from many perspectives to maximize not only donor and recipient safety but also maximally respect their rights.
- The FDA's Layer of Safety form the backbone of blood safety, but lots of roles and processes contribute to the overall safety.

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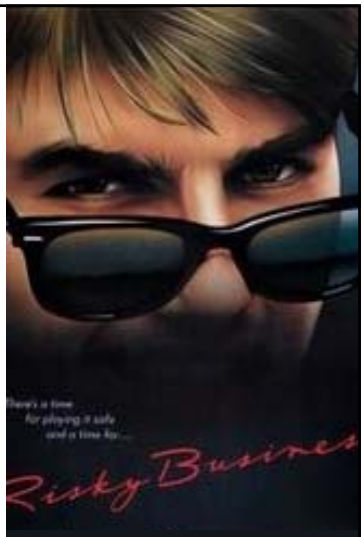

Thank you!

kland@vitalant.org

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"If donor eligibility is based on the most conservative approach, then medical professionals are no longer needed to determine policy. There are many who can choose the most conservative course. It takes wisdom and courage to use what we know to draw the deferral line a bit further back. How far back the line is drawn depends on the balance of benefit and risk and donor and recipient rights. The line then must be re-assessed with some regularity as ideas and technology change."

- Kevin Land

kland@Vitalant.org

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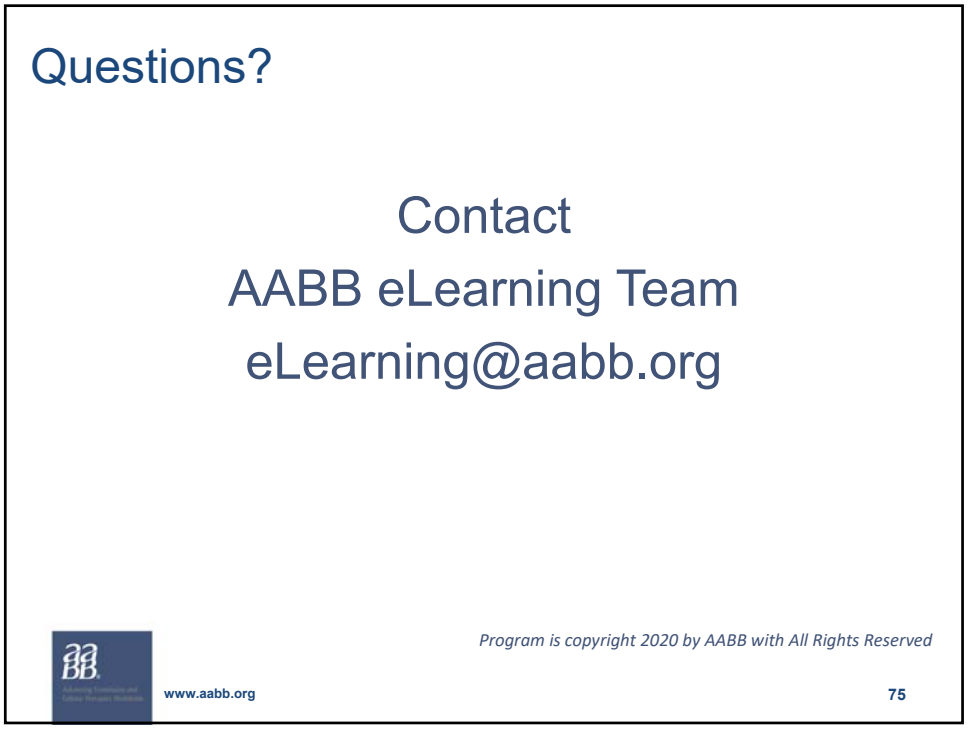

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