Cleveland Clinic

Blood Donation

Regulating Agencies

- **FDA-** regulates donor screening, collection, manufacturing of blood components
- **AABB-** American Association of Blood Bankers
  - Offer voluntary inspections and accreditation
- **CAP-** College of American Pathologists
  - Inspections approved by CMS and meet CLIA requirements

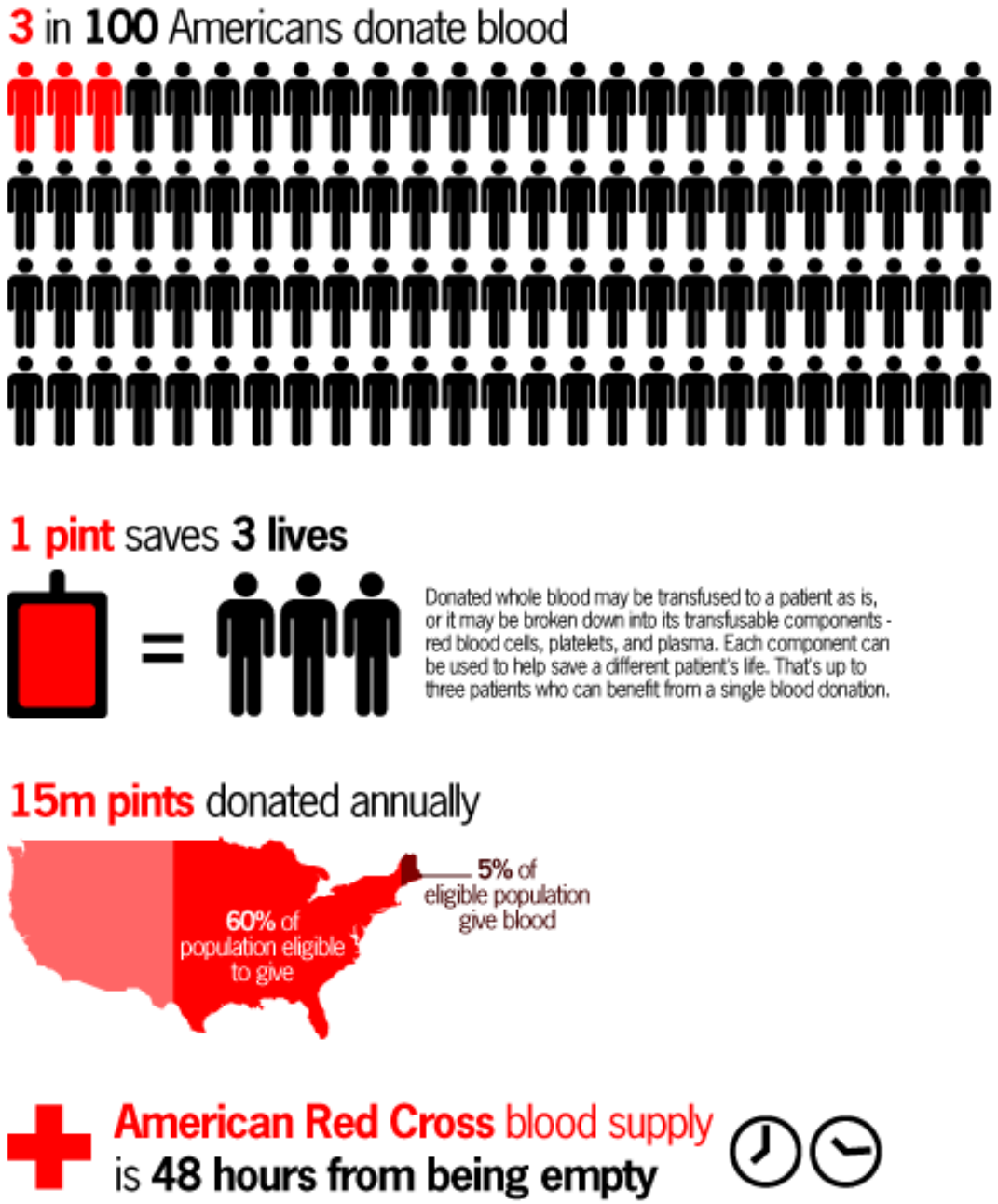
Blood Component Collection

- Made from whole blood
- Collected by apheresis

American Red Cross

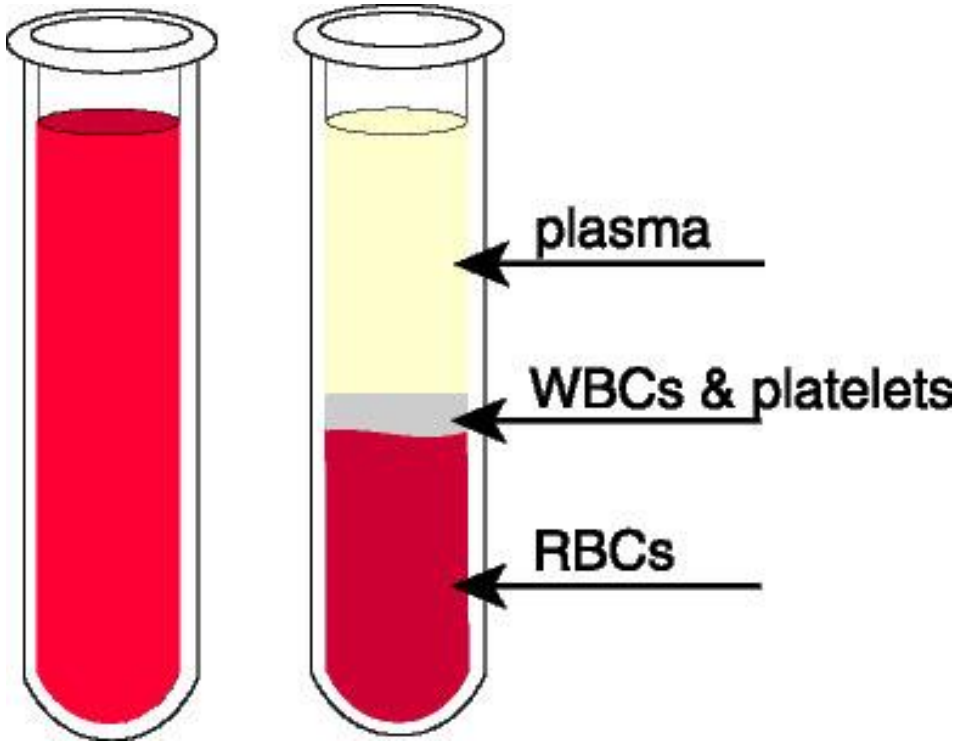
GIVE BLOOD

GIVE LIFE



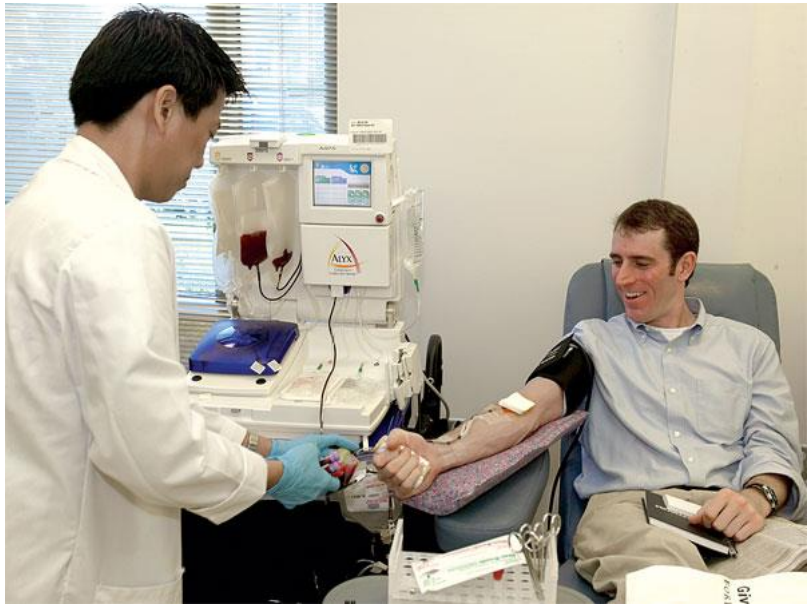
Whole blood

- Centrifuge and separate out various components
- What you normally think of when people give blood
- Mostly allogeneic donations

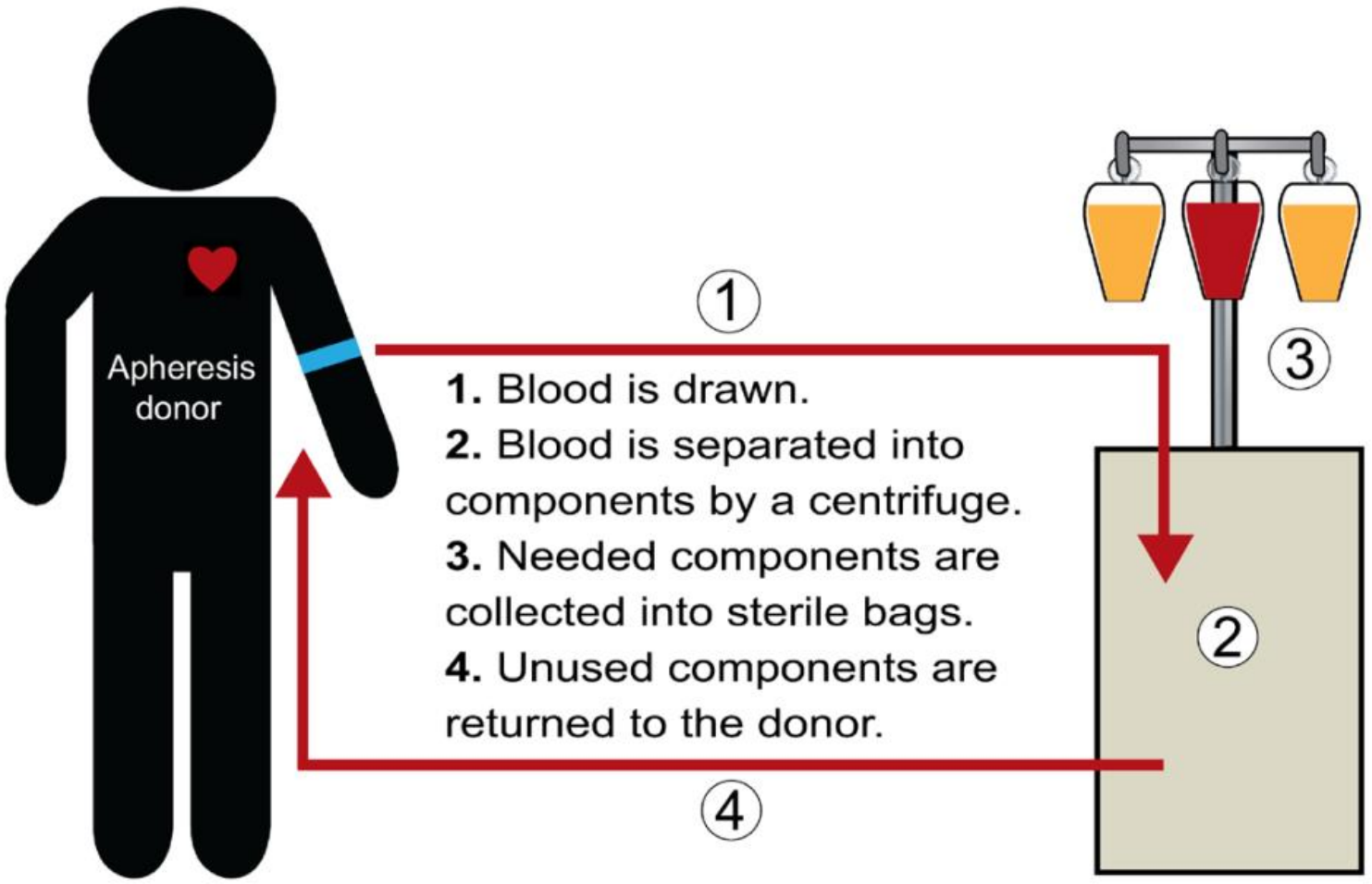


Whole Blood Collection

- Collection must be sterile!
  - Use ChloraPrep to clean draw site
  - Scrub area at least 4 cm in every direction for 30 seconds
  - Divert first 30-45mL of whole blood with any potential skin contaminants
- Mix blood with anticoagulant in bag periodically
- Collect 405-550 mL of blood
- Draw additional tubes on the donor for testing
- Store blood at 1-6° C after collection
- If platelet concentrate will be made, store at 20-24° C



Apheresis Donation



Apheresis Methods

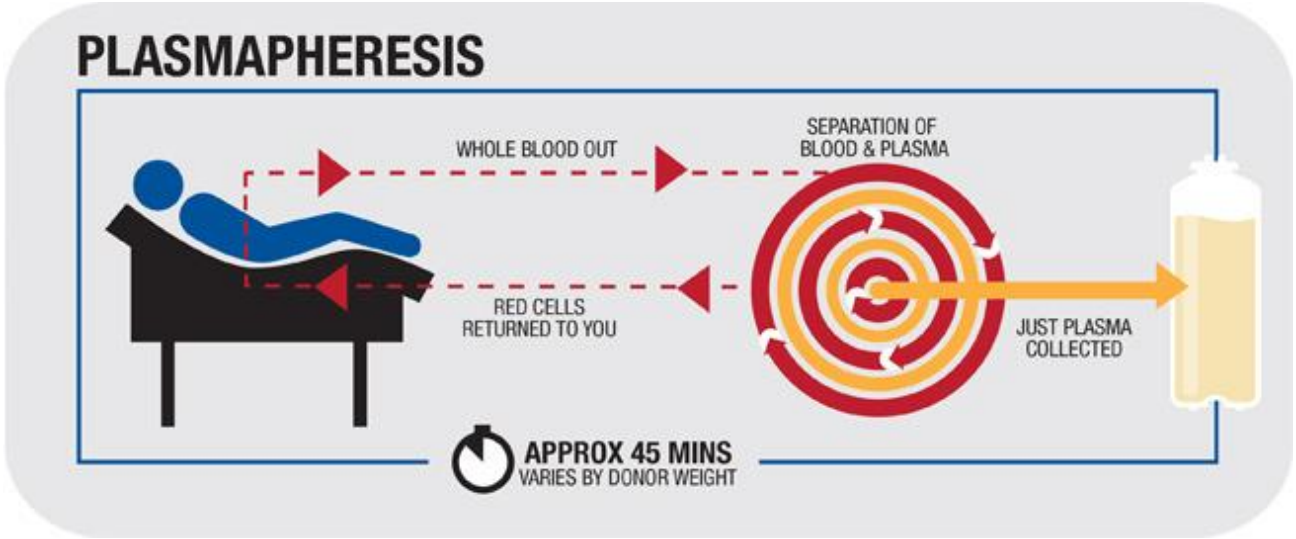
- Intermittent Flow Centrifugation
  - Blood processed in batches or cycles
  - Repeat cycles until enough product obtained
  - Only one venipuncture site needed
- Continuous Flow Centrifugation
  - Blood withdrawal, processing, and reinfusion all performed simultaneously
  - Two venipuncture sites needed

Double RBC Apheresis

- Plasma and platelets returned to the donor
- Two red cell units collected from donor instead of one
- Less exposure for the patient
- Must wait 16 weeks to donate again instead of the 8 weeks for whole blood donation

Donor Plasmapheresis

- Can take larger volumes of plasma
- Good for AB patients
- Collect for immune globulins (prophylaxis against infectious organisms)
- Can manufacture:
  - IVIG
  - RhIG
  - Immune globulins
- Max. 2 procedures in 7 days, 2 days apart



Donor Plateletpheresis

- Equivalent to 6-8 random donor platelets
- Suspended in some donor plasma
- Can yield 2-3 platelet products
- Donor criteria also include platelet count of >150,000/µL
- 24 plateletpheresis in 12 month period
- Max. 2 procedures in 7 days, 2 days apart
  - If donating a double or triple apheresis only 1 procedure in 7 days
- Cannot exceed 500 mL volume collected

Donor Screening

- Photo ID required to donate
- ≥16 years of age
- Confirm donation interval is acceptable
- Three sets of screening/testing done:
  - Medical history screening
  - Mini physical exam
  - Serologic testing of donor blood

Questions asked when determining who can donate blood:

- 1. Will donation of approx. 450 mL of whole blood be harmful to the donor?
- 2. Could blood drawn from the donor at this time potentially transmit a disease to the recipient?

Physical Exam

Exam	Required Range
Weight	Need 10.5mL of blood/kg of donor weight Minimum weight is 110lbs. <100 lbs requires modifications to be made
Temperature	≤ 37.5˚ C or 99.5˚ F
Pulse	50-100 bpm
Blood Pressure	Systolic:90-180 mm Hg Diastolic: 50-100 mm Hg
Hemoglobin	≥12.5 g/dL (women) ≥13.0 g/dL (men)
Hematocrit	≥ 38% (women) ≥ 39% (men)

Hemoglobin and hematocrit are tested with copper sulfate or point of care instruments (spectrophotometry)

Donor Reactions

- Most donor reactions will occur at the donation site
- Mild Reactions
  - Vasovagal - Syncope/fainting
  - Nausea/vomiting
  - Hyperventilation – can cause twitches and muscle spasms
  - Local injury related to needle
  - Allergic (usually local and limited to venipuncture site)
- Moderate Reactions
  - Loss of consciousness
- Severe Reactions
  - Convulsions due to hyperventilation

How often can you donate?

Blood Component	Time before next donation
Whole Blood	8 weeks (56 days)
Platelet apheresis (single)	Every 2 days (no more than 2x in 7 days; no more than 24 times in 12 months)
Platelet apheresis (double or triple)	Once every 7 days, only 24 donations per year
Infrequent Plasma apheresis	4 weeks
Serial Plasmapheresis	2 procedures in 7 days, 2 days apart
Double apheresis	16 weeks (112 days)

After pheresis donation, must wait 48 hours before donating whole blood

Medications

Reason	Length of deferral
Taking some medications	Temporary deferral based on medication
Taking some antibiotics	Temporary deferral based on antibiotic
Aspirin	2 days after last dose for platelet donation

Pregnancy and Transfusion

Pregnancy: deferred 6 weeks following end of pregnancy
(1st or 2nd trimester abortion/miscarriage not cause for deferral)

Transfusion or tissue transplant: deferred 3 months since last transfusion

Xenotransplantation: Indefinite deferral

Vaccines

Reason	Length of Deferral
Live attenuated or bacterial vaccines (measles, mumps, oral polio, typhoid, yellow fever)	2 weeks
Smallpox vaccine or contact with someone who received vaccine	3 weeks
German measles (rubella) or Chicken Pox/Shingles live attenuated vaccine	4 weeks
Hepatitis B vaccine	12 months
Viral vaccines	No deferral

Tattoos and Piercings

Coming into contact with someone else's blood: 3 month deferral

- Accidental needle stick exposure
- Muscous membrane exposure
- Unregulated tattoo/piercing
- Using needles to take drugs not prescribed by doctor

Tattoos/piercings from state-regulated organizations: no deferral

Sexual Contact

- **3 month deferral** from the date of last sexual contact for having sexual contact with:
  - Anyone who has ever had HIV/AIDS
  - A prostitute or someone who has taken money/drugs for sex in the last 12 months
  - Anyone using needles to take drugs not prescribed by a doctor
  - ~~Males having sexual contact with another male~~
  - ~~Females who have had sex with a male who have had sex with another male~~

Prison

- Incarceration for 72 hours or more consecutively

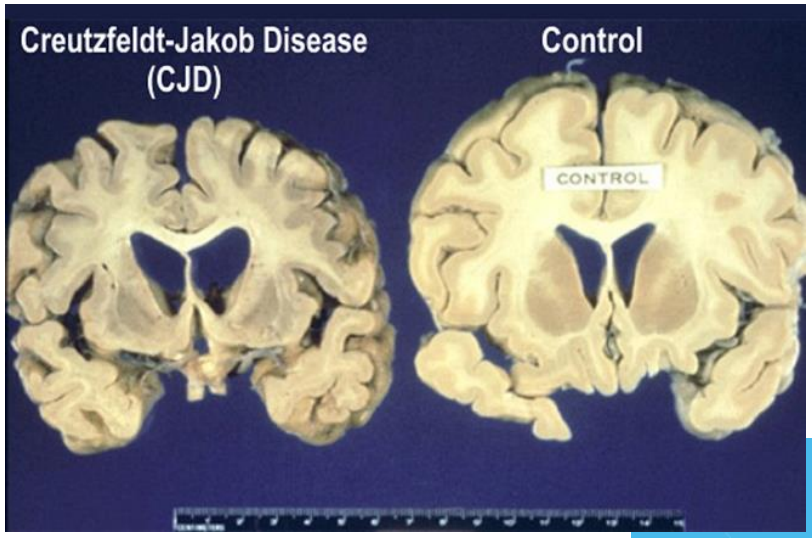
  You are deferred for 12 months

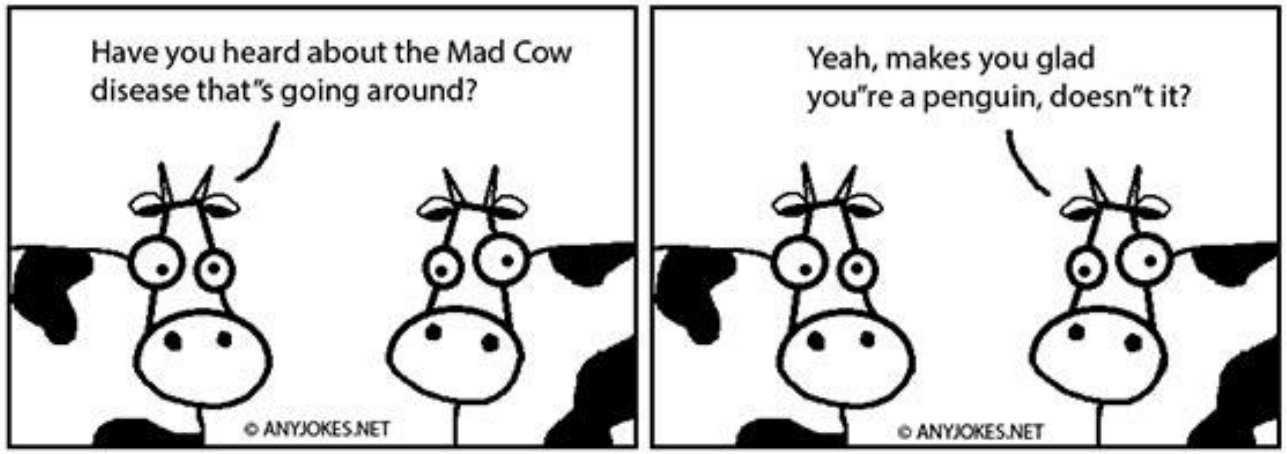
Travel to Malaria Endemic Countries

- Travel to areas the CDC considers endemic to malaria (24 hrs – 5 years):
  - 3 month deferral
- Lived longer than 5 years in area endemic to malaria:
  - 3 year deferral after departure
- Had malaria:
  - 3 year deferral after being asymptomatic

Travel to United Kingdom and Europe

- Concern for Creutzfeldt-Jakob disease (CJD)
  - Human prion disease, human equivelant of mad cow disease
  - Sponge-like lesions in brain
- Britain had an outbreak of mad cow disease and CJD from late 1980s to early 1990s





CJD Travel Deferrals

From 1980-1996 Indefinitely Deferred If:

- Spent time adding up to 3 months or more in the UK

From 1980 to 2001 Indefinitely Deferred if:

- Spent time adding up to 5 years or more in France or Ireland

1980-Present Indefinitely Deferred if:

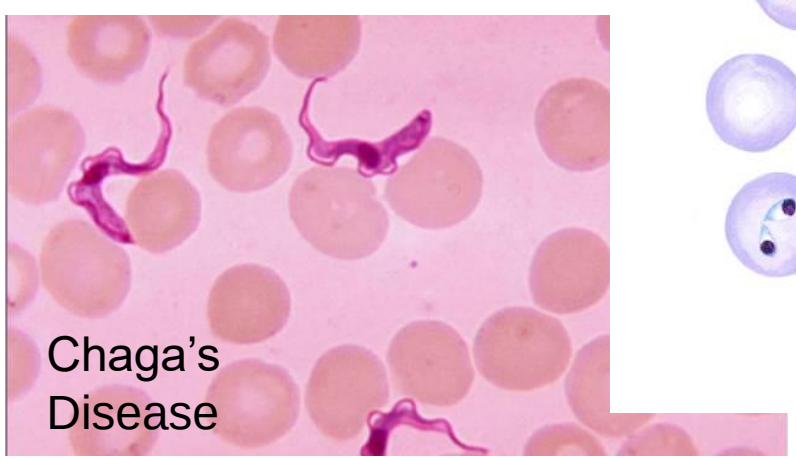
- Received blood transfusion in France, Ireland, or UK

Permanent deferral if a genetic history of CJD is present

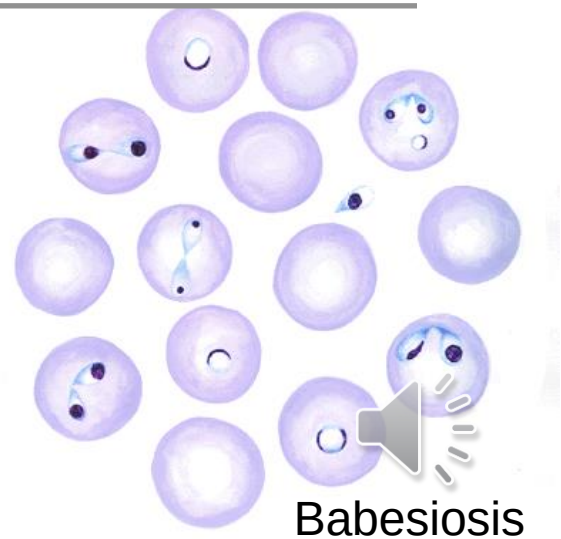
Infectious and other Diseases

- Indefinite Deferral For:
  - HIV/AIDS
  - Hepatitis B or C
  - Chaga's Disease
  - HTLV
  - Cancer
  - Bleeding Condition/blood disease
  - CJD or family history of CJD
  - Heart or Lung Problems
- 3 month deferral for:
  - Living or having sexual contact with someone who has hepatitis B or C

Disease	Deferral length
Syphilis and Gonorrhea	3 months after treatment
Babesiosis	2 years from date of last reactive test



Chaga's Disease



Babesiosis

FDA Disease Recommendations

- Zika
  - Those infected deferred for 4 weeks
  - Do not use blood from areas of active viral transmission
  - NAT testing on all plasma units
- Ebola
  - 8 week deferral – for infection or travel to area with widespread transmission

Autologous Donation

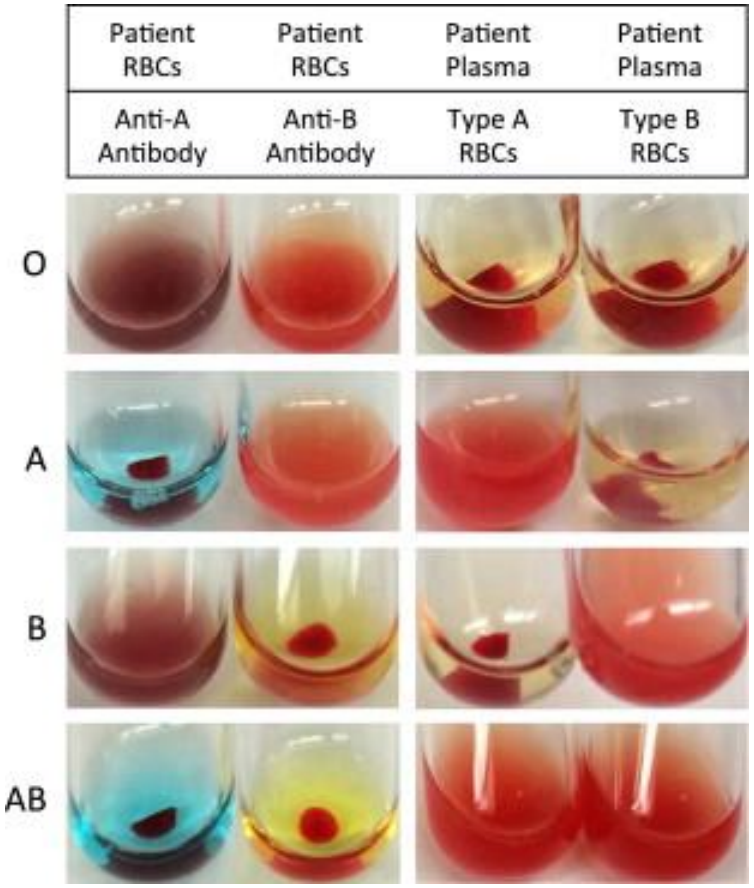
- Donation of a unit of blood for yourself usually for a future surgery
- Require doctor’s prescription
- May donate blood every 4-7 days as directed by physician
- Cannot donate within 72 hours of surgery
- No disease testing is required
- Minimum hemoglobin: ≥11g/dL
- Minimum hematocrit: ≥33%
- Unit may only be used for that specific patient

Directed Donation

- Unit is collected for a specific patient
- Follow same requirements as allogeneic donors
- Same testing is performed as allogeneic donors
- If not used for intended recipient, can be used for other donors

Serologic Testing of Donor Blood

- ABO (Forward and Reverse)
- Rh(D) Typing
  - If D positive – labeled as Rh pos
  - If D negative – do weak D testing
    - If weak D is negative – label as Rh negative
    - If weak D is positive – label as Rh positive
- Antibody Screen



Required Infectious Disease Screening

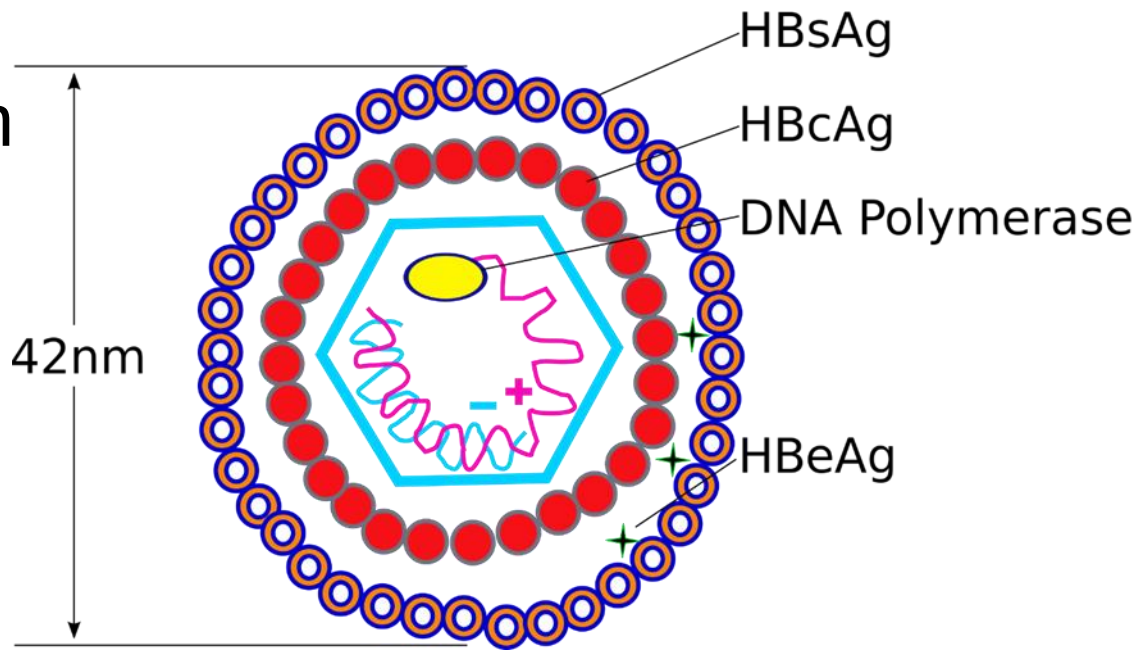
- Hepatitis B
- Hepatitis C
- HIV
- Human T-cell lymphotrophic virus (HTLV) type I and II
- West Nile Virus
- Syphilis
- T. Cruzi (Chaga’s Disease)

Hepatitis B Clinical Picture

- 15-25% develop liver diseases
- 3,000/year die from HBV
- May recover with no liver damage
- Symptoms:
  - Can be asymptomatic
  - Jaundice, dark urine, hepatomegaly, anorexia, malaise, fever, nausea, abdominal pain, vomiting

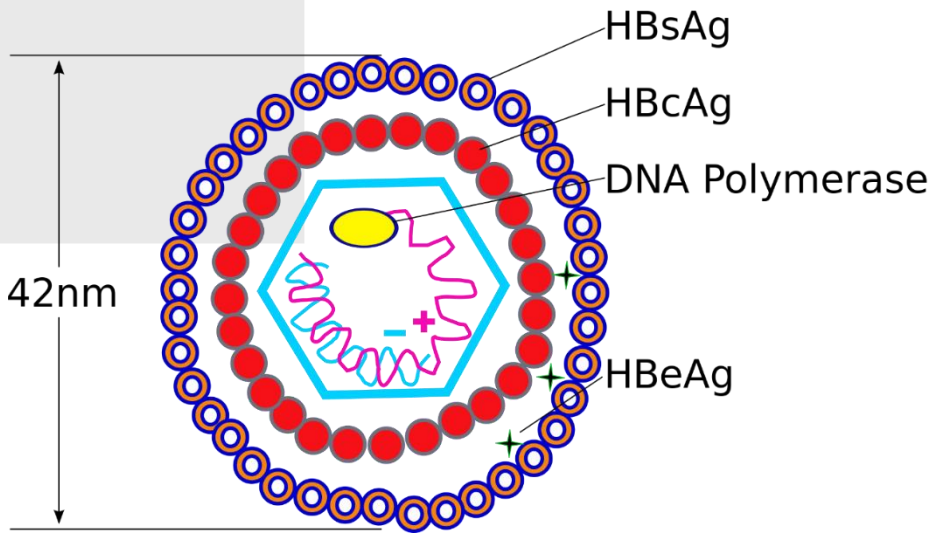
Hepatitis B *(Hepadnaviridae)*

- Hepatitis B, C, D, and G transmitted through blood (A and E transmitted through fecal/oral route)
- HBsAG- surface antigen protein on outer envelope of virus
- HBcAG- protein within the core
- HBeAG- protein within the core
- Look for antibodies to markers to determine infection



Hepatitis B Disease Screening

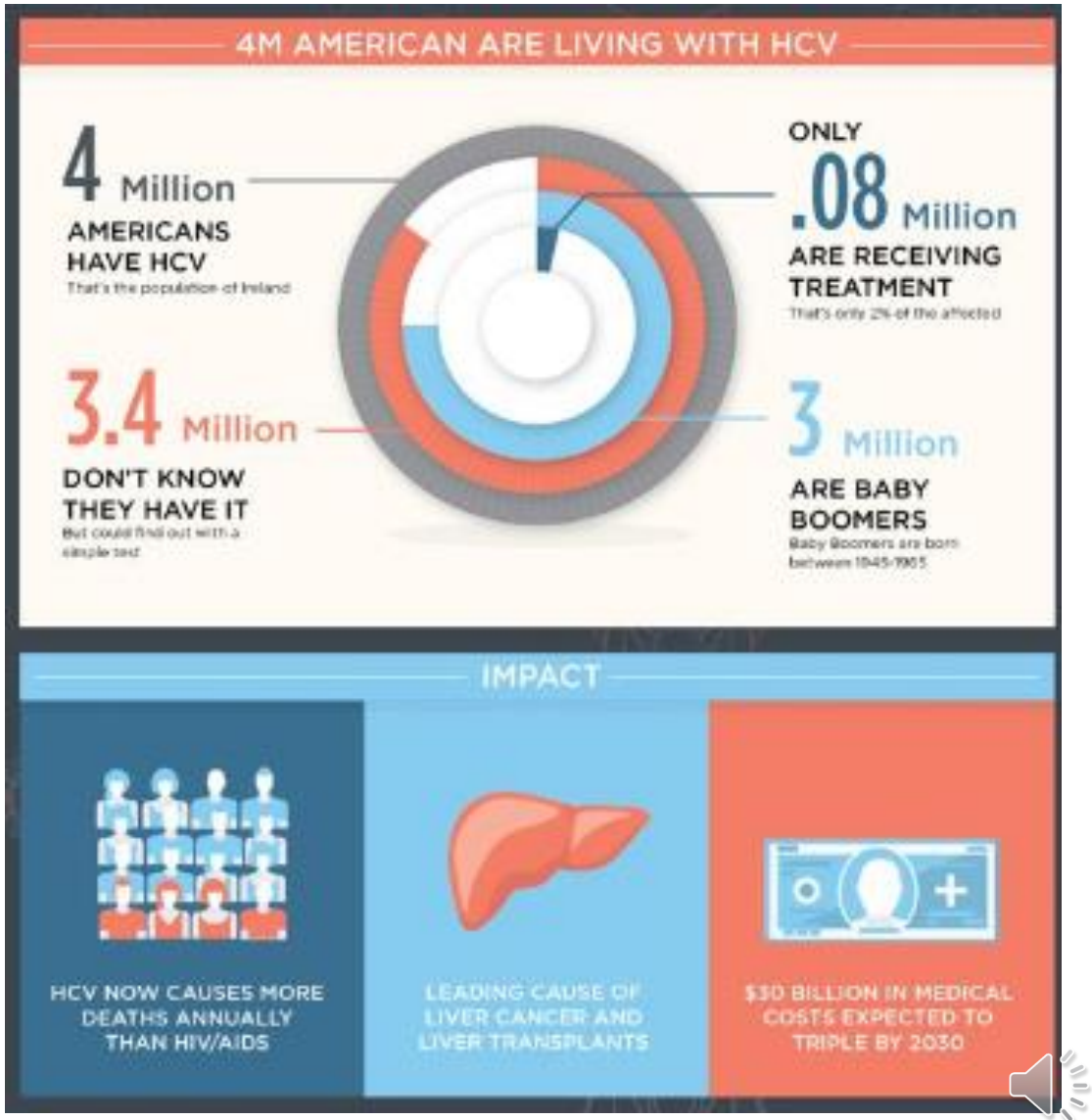
Disease	Marker Detected	Screening test method	Confirmatory test method
HBV	Hepatitis B surface antigen	ChLIA or EIA	HBV DNA neutralization
	Antibody to hepatitis B core antigen	ChLIA or EIA	
	HBV DNA	NAT (TMA) or PCR	



If confirmatory test is positive: patient is considered infected- permanent deferral
If both anti-HBc and HBsAG are positive: deferred permanently
If only anti-HBc test is positive: products discarded, deferred 8 weeks

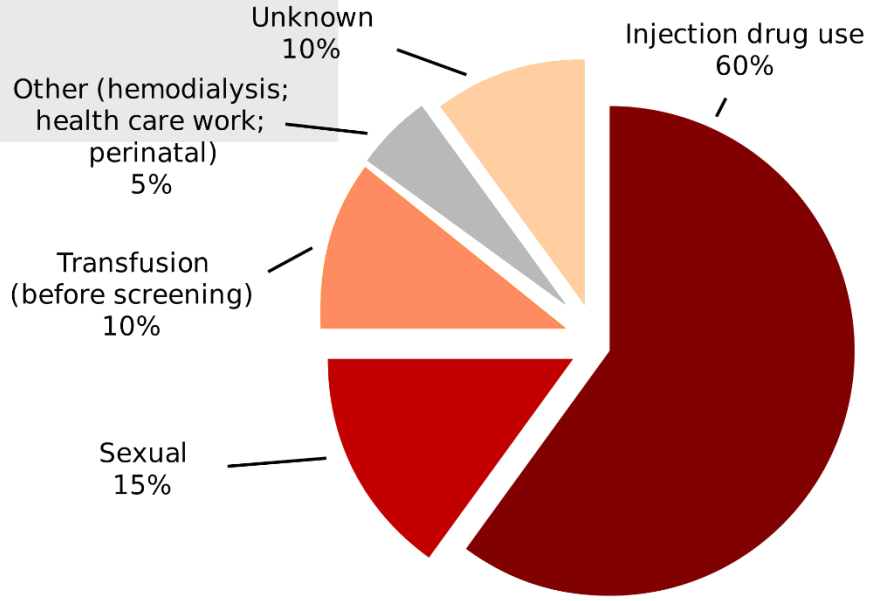
Hepatitis C Clinical Picture

- Most asymptomatic
- Symptoms: anorexia, fatigue, malaise, abdominal pain
- 75-85% become chronic carriers
- 60-70% develop chronic liver disease
- 5-20% develop cirrhosis over 20-30 years
- 1-5% fatality (highest rate of death from hepatitis)



Hepatitis C Disease Screening

Disease	Marker Detected	Screening test method	Confirmatory test method
HCV	Antibody to HCV peptides or recombinant proteins	ChLIA or EIA	HCV RNA
	HCV RNA	NAT (TMA) or PCR	

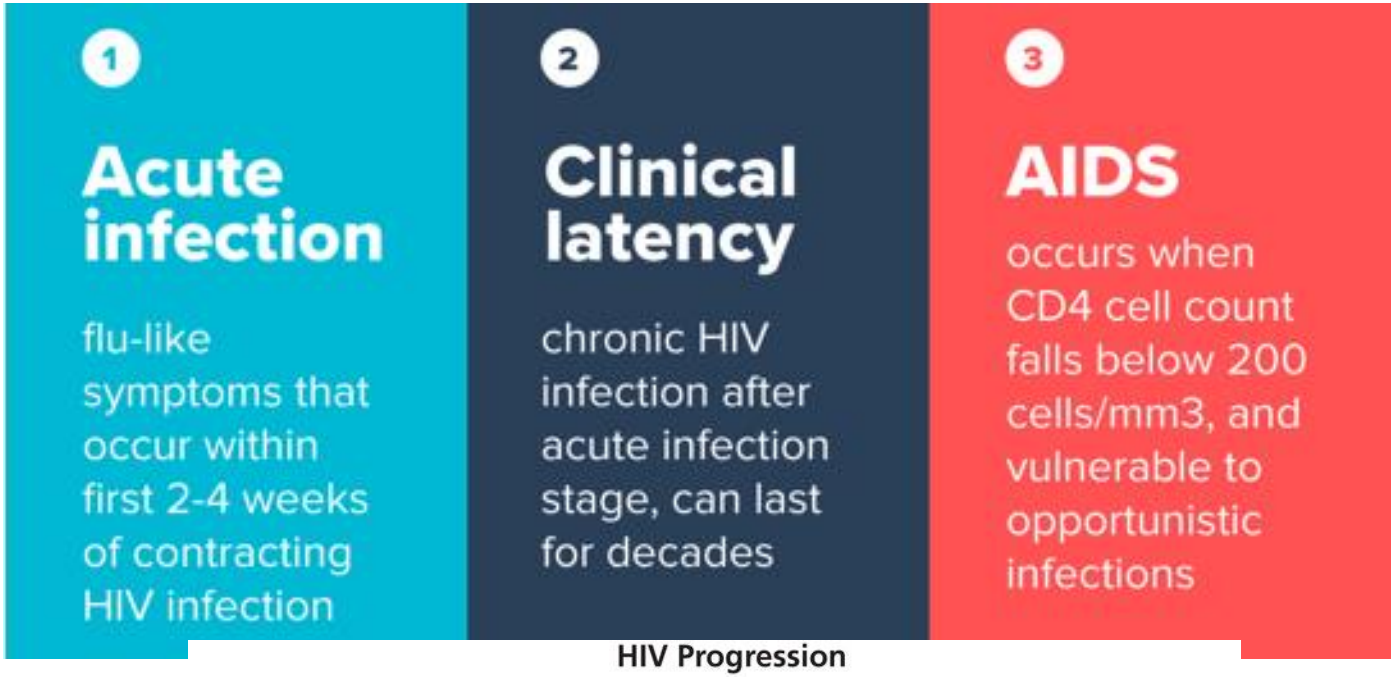


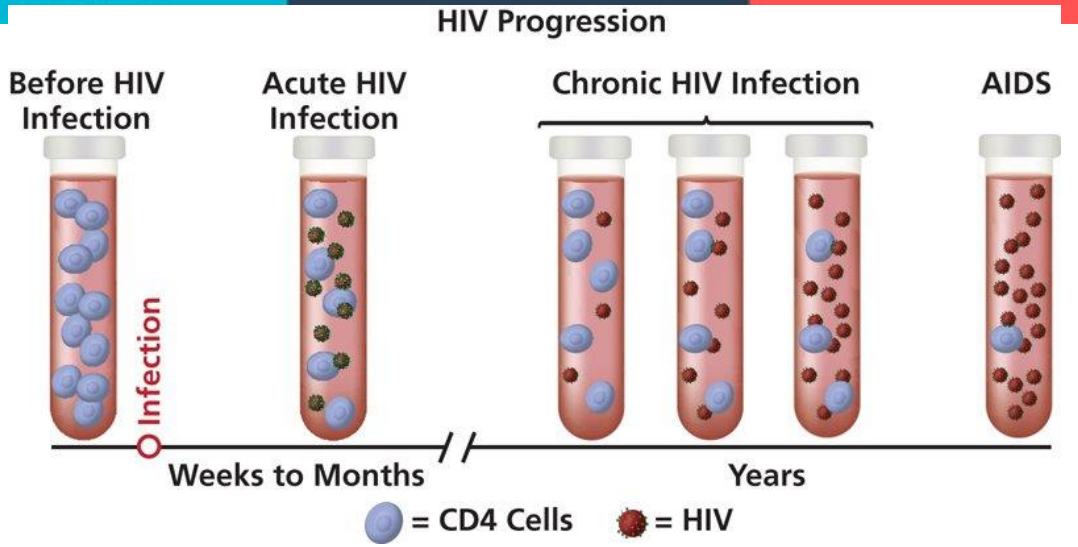
If confirmatory test positive, considered to have HCV- permanently deferred

- People infected are often asymptomatic
- Before 1992, no testing was performed on blood products
- Blood transfusions were therefore major source of Hepatitis C infection before 1992

HIV Clinical Picture

- Retrovirus causes slowly progressing immune disorder
- HIV-1: mostly in U.S.
- HIV-2: mostly in W. Africa
- Infects CD4+ lymphocytes, macrophages and other antigen presenting cells





HIV Disease Screening

Disease	Marker Detected	Screening test method	Confirmatory test method
HIV-1 & 2	Antibody to HIV-1 & 2	ChLIA or EIA	HIV-1 IFA (immunofluorescence assay) or Western Blot
	HIV-1 RNA	NAT (TMA) or PCR	

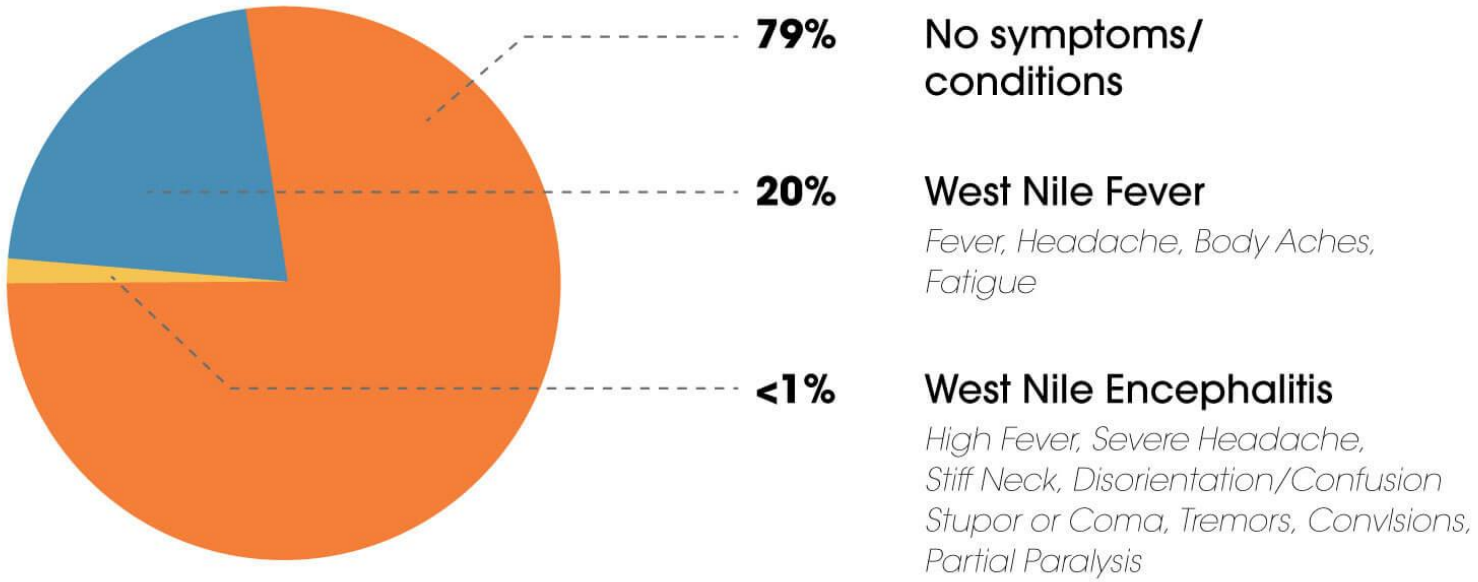
HTLV Clinical Picture and Disease Screening

- Human T-Cell Lymphotropic Virus Type I/II
- RNA retrovirus
- Type I: also called adult T-cell leukemia and HTLV-associated myelopathy
- Type II: similar to I, less severe, some neurological problems
- Only 0.25-2% of infected individuals develop a progressive neurologic disease

Disease	Marker Detected	Screening test method	Confirmatory test method
HTLV-I & II	Antibody to HTLV-I & II	ChLIA or EIA	Western Blot

West Nile Virus Clinical Picture

- Normally transmitted by mosquitoes
- Can cross blood brain barrier:
  - West Nile encephalitis, meningitis, and meningoencephalitis
- 1/150 result in severe neurological disease



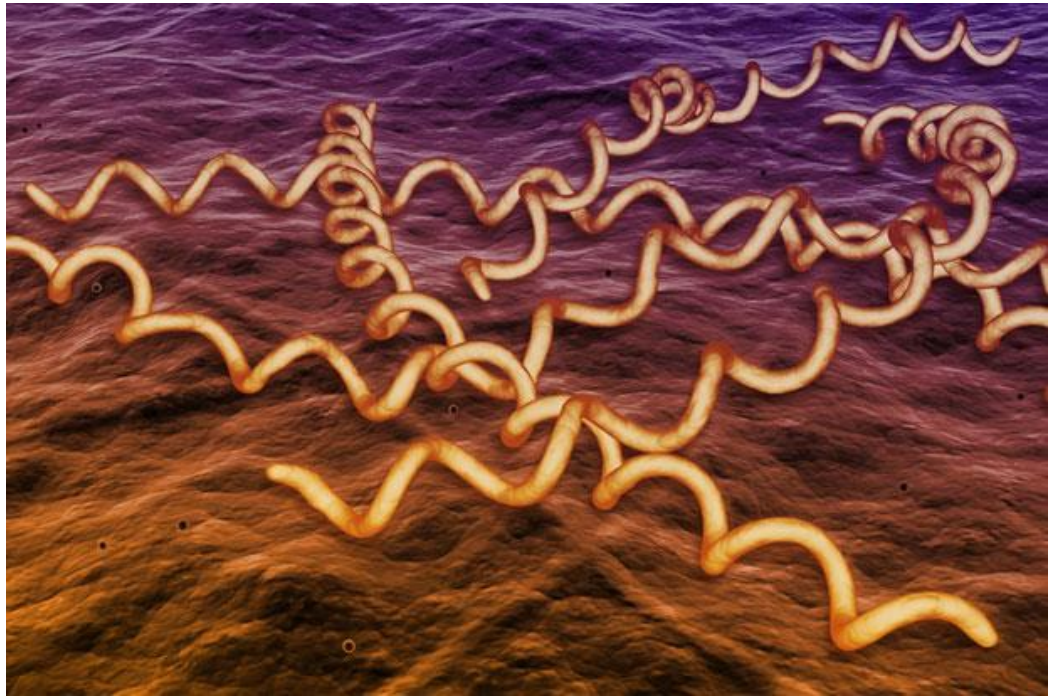
West Nile Virus

Disease	Marker Detected	Screening test method	Confirmatory test method
West Nile Virus	WNV RNA	NAT (TMA) or PCR	Repeat or alternate NAT

- Screening test: mini-pool (MP-NAT 6-16 donors at once) or individual donor (ID-NAT)
- Pool is used when risk is low (winter)
- Individual used when risk is high (summer)
- If pool is positive- retest all samples individually
- Positives: unit discarded, patient deferred 120 days

Syphilis

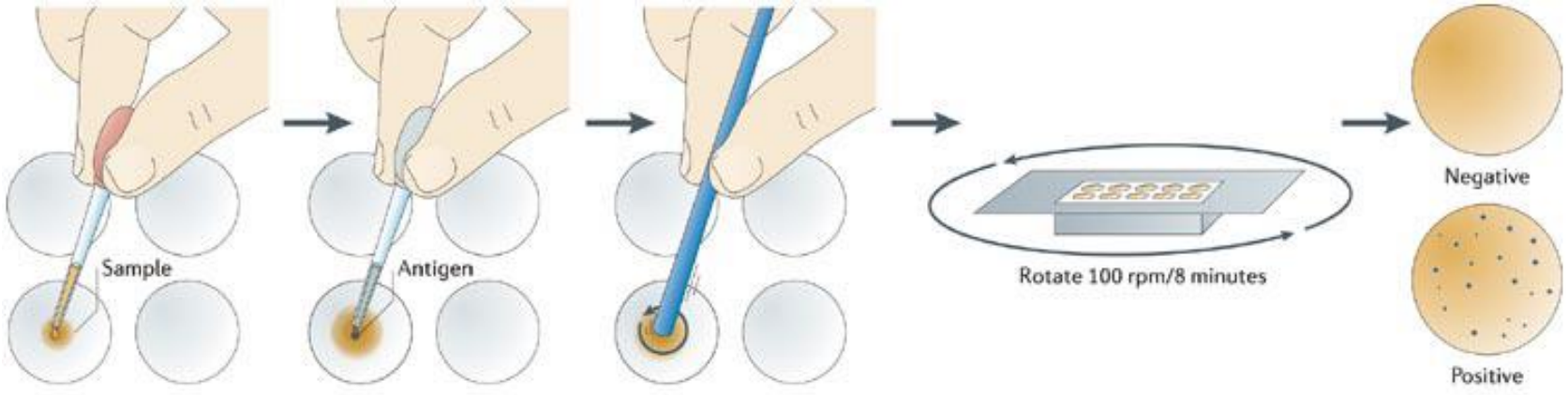
- Only survives 72 hours in red cells
- Platelets are most likely to transmit
- Because sexually transmitted- higher risk of exposure to HIV and hepatitis



Syphilis Disease Screening

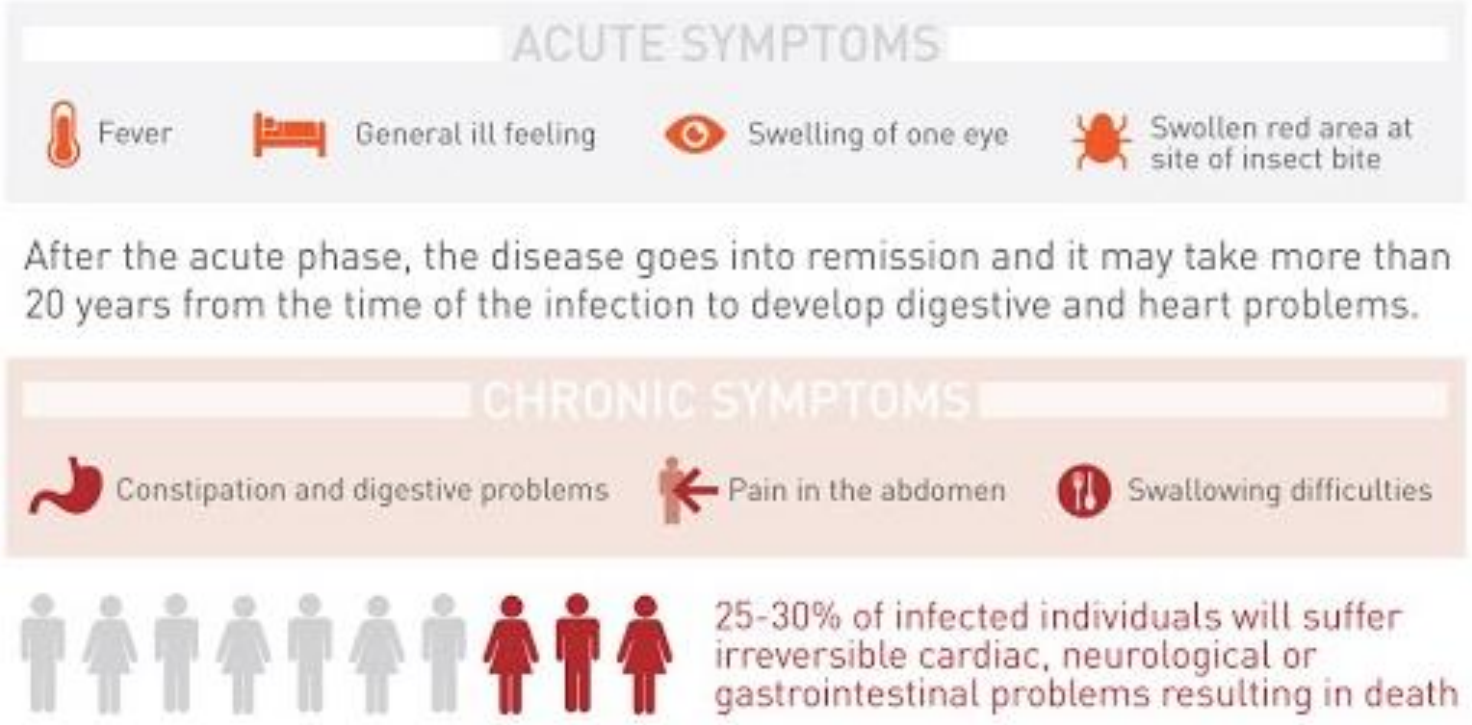
Disease	Marker Detected	Screening test method	Confirmatory test method
Syphilis	Antibody to *Treponema pallidum* antigens or, nontreponemal test for syphilis	Microhemagglutination or EIA Particle agglutination (RPR or VDRL)	Antigen specific immunofluorescence or agglutination assay

- Positive test: units discarded, donor deferred 3 months after completed treatment
- If confirmatory is negative: units discarded, donor not deferred



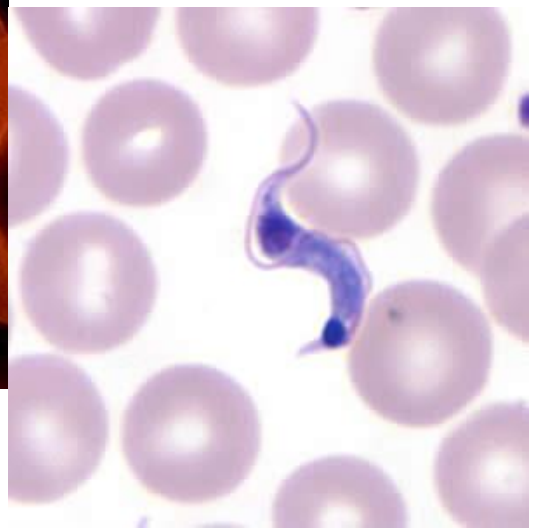
Trypanosoma Cruzi

- Flagellate Protozoan causing Chaga's Disease
- Parasitic infection endemic to Mexico and Central and South America
- From bite of reduviid bug



Trypanosoma Cruzi- Chaga's Disease

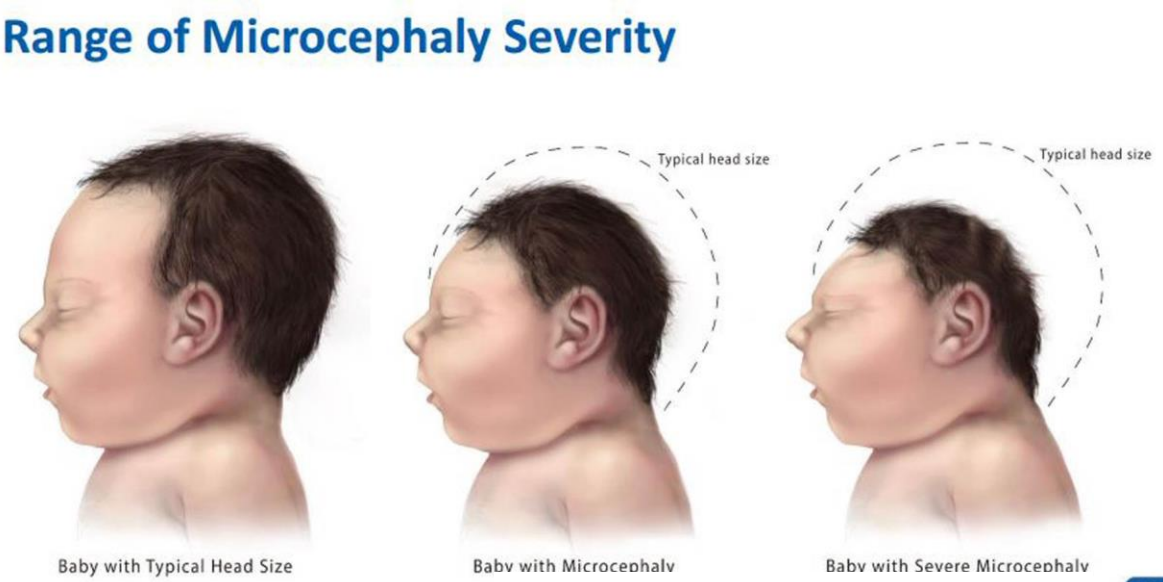
- All donors only tested once: most donors in U.S. have chronic infection from when residing in a country endemic to the disease
- Positives repeated, if still positive: units destroyed, donor deferred indefinitely



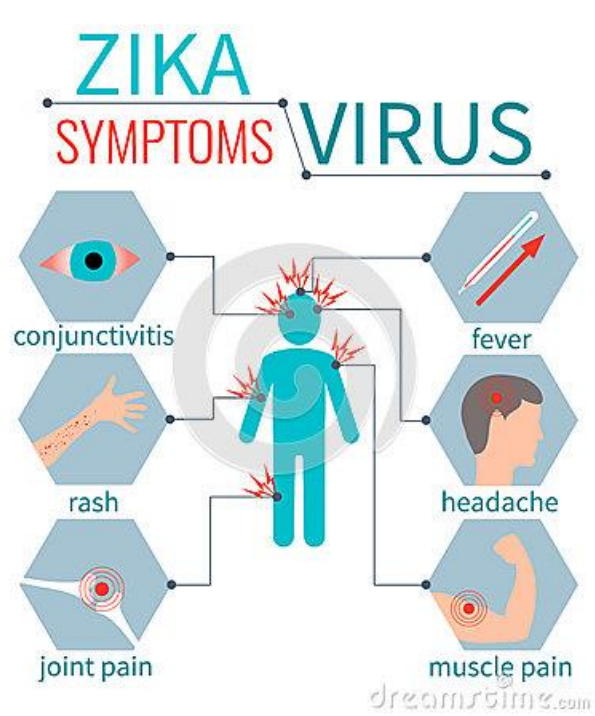
Disease	Marker Detected	Screening test method	Confirmatory test method
Trypanosoma cruzi	Antibody to *T. cruzi*	ChLIA or EIA	Enzyme strip assay

Zika Virus

- Usually transmitted by mosquitoes
- <20% experience symptoms
- Increased rates of microcephaly and fetal brain anomalies during pregnancy



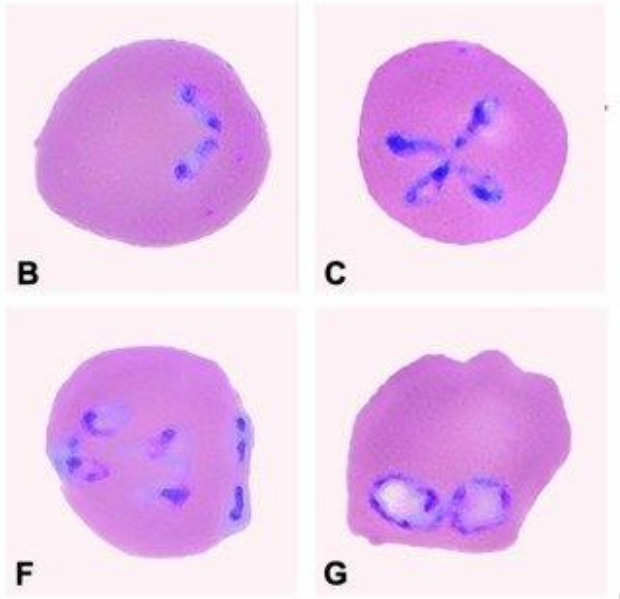
Disease	Marker Detected	Screening test method	Confirmatory test method
Zika Virus	ZIKV RNA	NAT (TMA) or PCR	Repeat or alternate NAT



Babesia spp.

- Infection caused by tick bite transmitting a parasite infecting RBCs
- Many people are asymptomatic or have mild flu-like symptoms
- Severe cases can have hemolytic anemia, thrombocytopenia, DIC, and organ failure in severe cases
- Licensed testing is required only in certain states (CT, DE, ME, MA, MD, NH, NJ, NY, PA, RI, VT, VA, WI)

Disease	Marker Detected	Screening test method	Confirmatory test method
Babesia spp.	*Babesia* spp. RNA	NAT (TMA) or PCR	Repeat or alternate NAT



Other transfusion-transmitted diseases not tested for:

- Epstein-Barr Virus (EBV)
- Cytomegalovirus (CMV)
- Parvovirus B19
- Malaria
- Prion diseases (CJD)

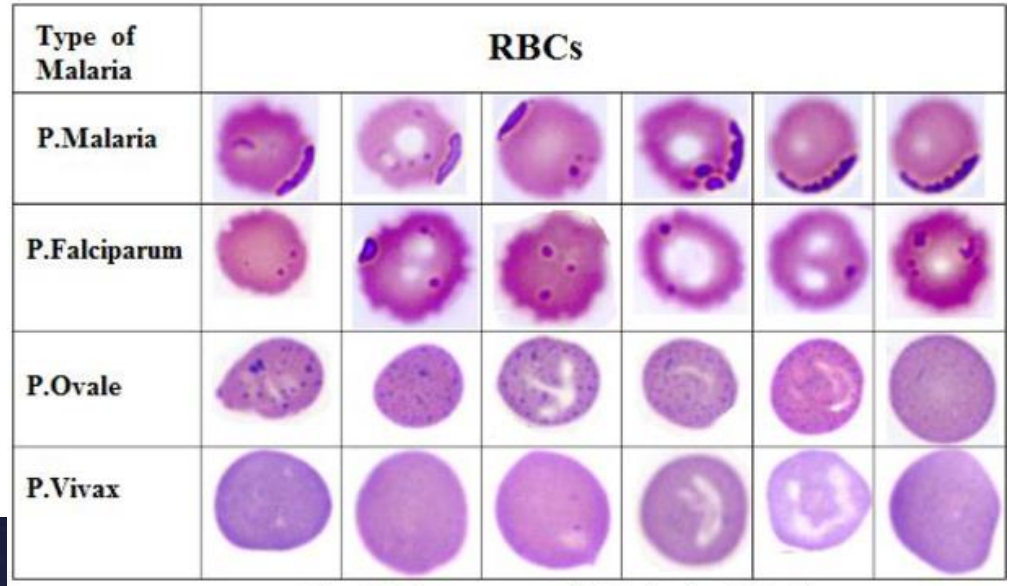
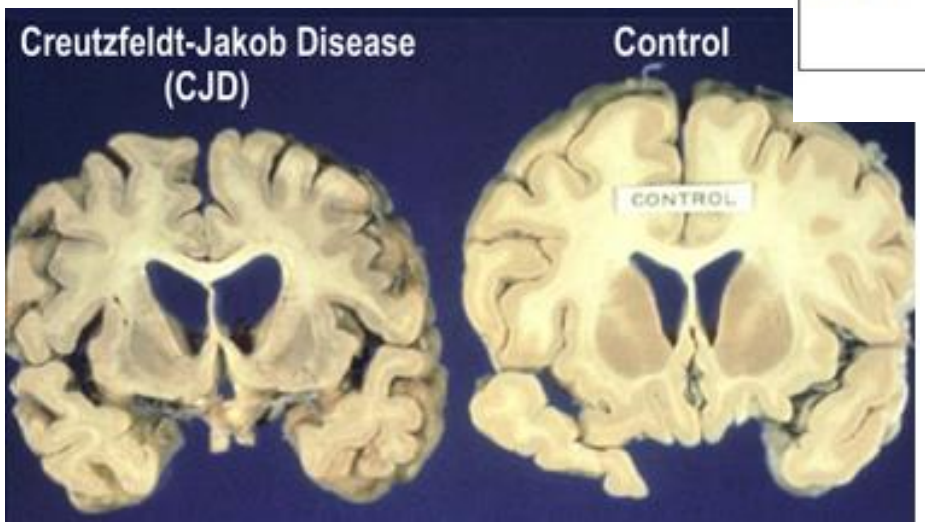


Fig 3.The type of Malaria RBCs



Platelet Bacterial Detection

- Risk of contamination due to room temperature storage
- Multiple options to reduce bacterial contamination:
  - Culture-based bacterial detection
  - Rapid detection device
  - Exposed to pathogen reduction technology
- Platelets can be issued for transfusion after the first 12 hours of culture incubation
  - Continue culture for shelf life of the unit
- Positives: unit discarded, no deferral as this is due to contamination
  - Many times patient is already transfused when culture becomes positive: requires physician monitoring
  - If it is able to be retrieved, the unit is retrieved

Sources

Information on deferrals and current testing was taken from the ASCP Certification Preparation Quick Compendium of Medical Laboratory Science (Published 2021) and may differ from the Harmening Textbook

Cleveland Clinic

Every life deserves world class care.