PATHOGEN REDUCED BLOOD COMPONENTS:

Standard of Care and a Matter of Homeland Security

MABB Transfusion Symposium
The enVision Hotel
Tuesday April 4, 2023
Mansfield, MA

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Conflict of Interest Statement

Dr. Snyder:

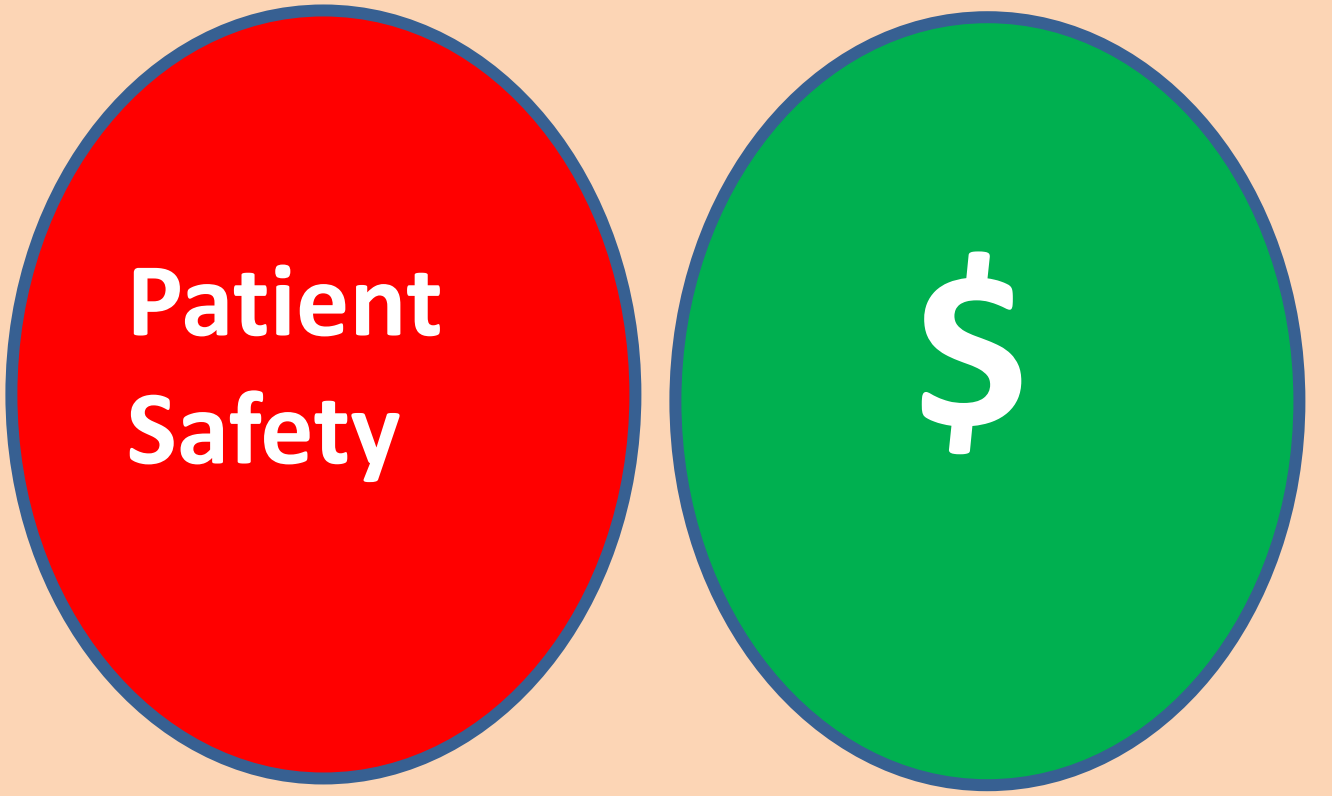
Cerus Corporation : PI - PR Platelet Clinical Trial [PIPER]
PI - PR Red Cell Clinical Trial [ReCePI]
PI - PR Red Cell Clinical Trial [RedeS]

NO personal honoraria received from Cerus

Haemonetics : Scientific Advisory Board

- **Ms Morales:**
  - **Nothing to disclose**

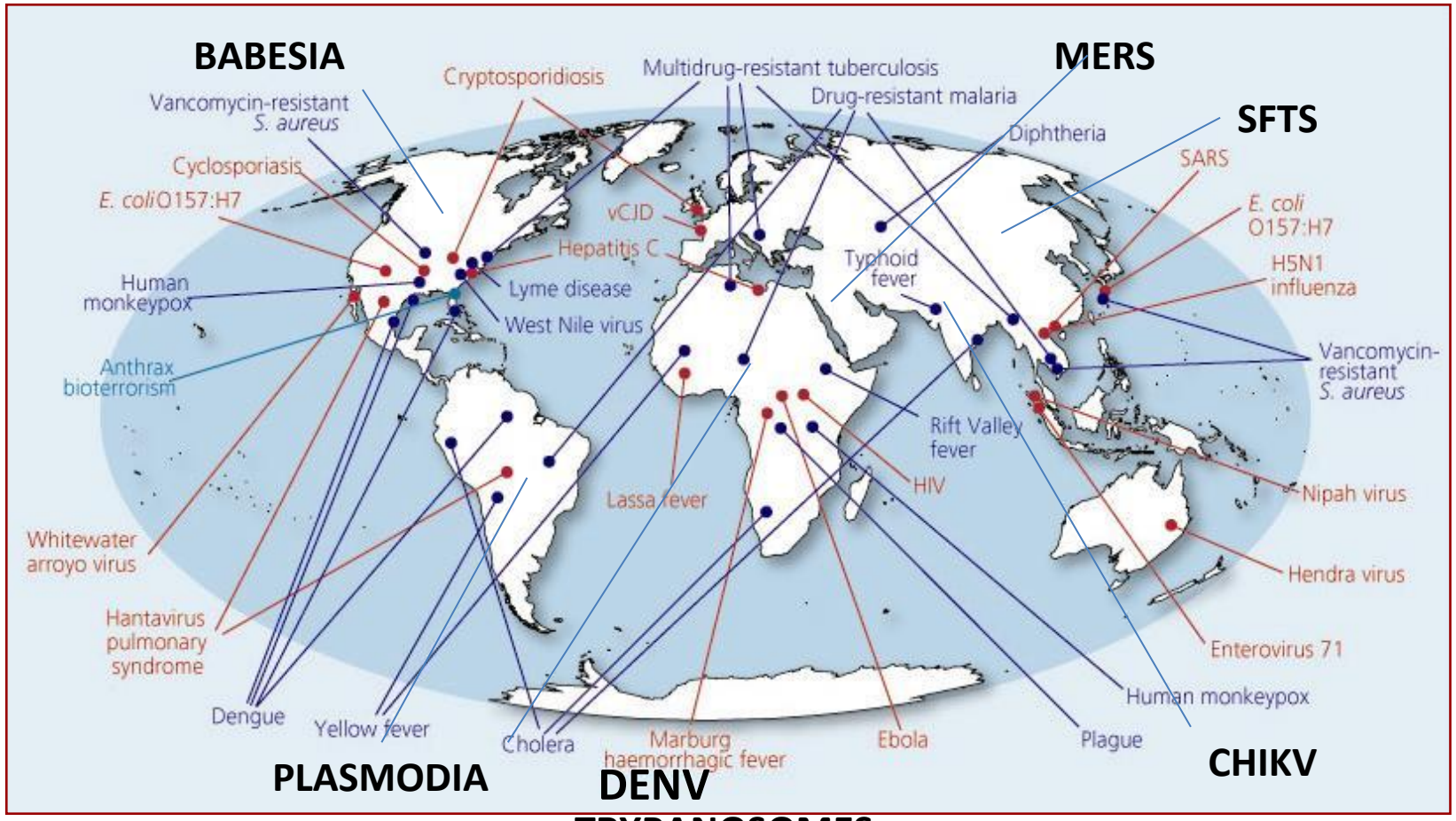
Hospital Economics c.1990



Hospital Economics 2023

Safety of Blood Transfusion is A Global Problem

~ 5 New Viruses Discovered Each Year



Adapted from Morens DM. *Nature.* 2004;430:242–9.

FDA

Homeland Security

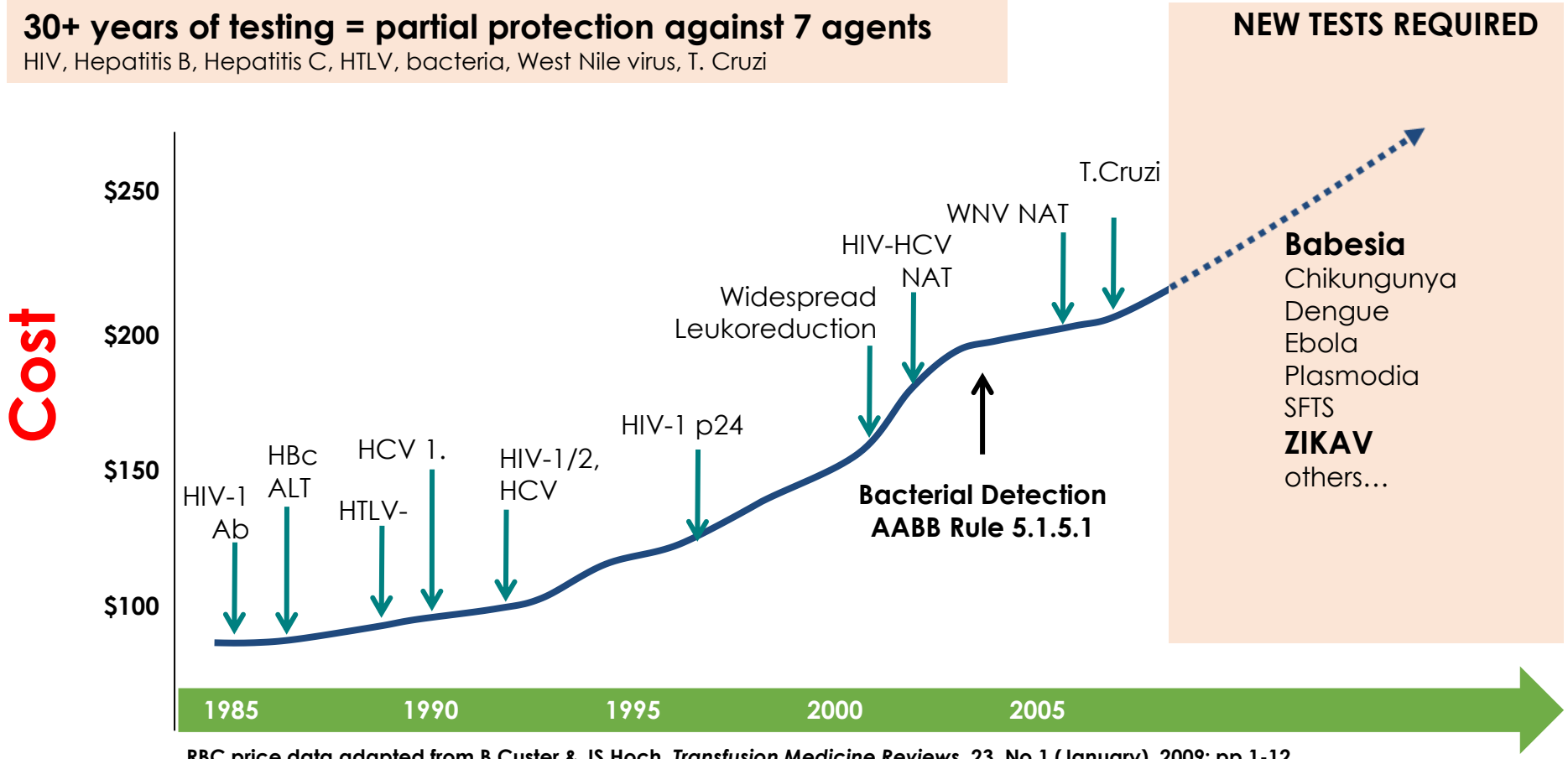
American Red Cross

Bio-Terrorism

Reduction In Risk of TTD Has Required Continual Addition of New Tests

A Reactive Expensive Approach

30+ years of testing = partial protection against 7 agents
HIV, Hepatitis B, Hepatitis C, HTLV, bacteria, West Nile virus, T. Cruzi



RBC price data adapted from B Custer & JS Hoch, *Transfusion Medicine Reviews*, 23, No 1 (January), 2009: pp 1-12

ARC No Longer Tests for CMV

In December, the American Red Cross provided notification of its intent to discontinue CMV testing of its platelet products.

In support of this decision, we shared that all Red Cross platelets are leukoreduced and almost 94% of all platelet distributions are pathogen reduced (PR).

PR platelets have been shown to be effective at reducing the risk of transfusion- transmission of many pathogens, including CMV.[1,2]

With sufficient PR platelet inventory to meet CMV-seronegative needs, effective March 8, 2023, the Red Cross will no longer supply CMV-negative LVDS platelets and will be removing this ordering option from Connect.

Scheduled orders with CMV neg requested as a substitute will be modified to remove this option from the order.

Reactive vs Proactive Scenarios

REACTIVE APPROACH [NO LONGER A SUSTAINABLE MODEL]

- -Identify an emerging blood-borne pathogen
- -Develop an assay kit for said pathogen
- -Manufacturers consider whether to commercialize the kit
- -Hospitals consider whether to use tested product if not mandated
- -Blood Centers consider whether to subsidize cost of testing
- - FDA considers Draft Guidance
- - Accrediting agencies consider whether to require a testing Standard
- - CMS considers whether to reimburse when FDA requires the test
- - While all this is occurring ---- new pathogens likely have emerged
- - REPEAT

PROACTIVE APPROACH

- - *Mandate* Pathogen Reduction – Octaplas; Intercept; Mirasol; Theraflex

Pathogen Reduction

- Pathogen Reduction (PR) is a proactive approach to prevent transfusion-transmission of pathogen-infected blood & components
- It consists of addition of reagents into blood component containers after donation, but before blood storage, which interdict transfusion-transmission of arbo- and myriad other viruses, bacteria, fungi, protozoa and other human pathogens
- PR technology also inactivates lymphocytes – mitigating TA-GVHD
- PR proactively ensures safety of the domestic blood supply
- Its adoption supports Homeland Security

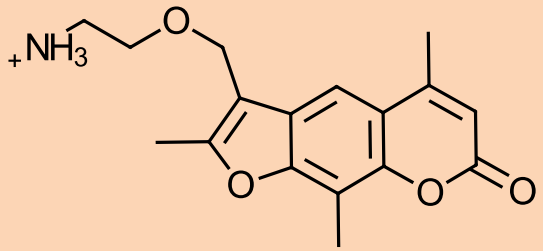
Snyder EL, Benjamin R and Stramer S. N Engl J Med 2015;372: 1882-1885.

Pathogen-Reduction Technologies Approved and in Development in the United States and Europe.*

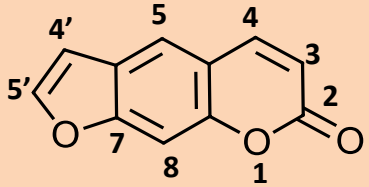
Component and Source	Manufacturer and Technology	Treatment Process	Manner of Inhibiting Replication	Regulatory Status
Platelets				
Individual volunteer donors	Cerus Intercept Blood System	Psoralen (amotosalen) and UVA light exposure	Formation of DNA and RNA monoadducts and cross-linkage	FDA approved; CE marked
	Terumo BCT Mirasol Pathogen Reduction Technology (PRT) System	Riboflavin and ultraviolet light exposure	Direct DNA and RNA damage and guanine modification	Phase 3 study planned in the United States; CE marked
	Macopharma Theraflex ultraviolet platelets	UVC light exposure	Direct DNA and RNA damage and thymine dimer formation	CE marked
Plasma				
Pools of volunteer and paid donors	Octapharma Octaplas	Plasma pools treated with solvent, tri-*n*-butyl phosphate and detergent (octoxynol)	Lipid membrane disruption of enveloped viruses	FDA approved; CE marked
Individual and minipools of volunteer donors	Cerus Intercept Blood System	Psoralen (amotosalen) and UVA light exposure	Formation of DNA and RNA monoadducts and cross-linkage	FDA approved; CE marked
Individual volunteer donors	Macopharma Theraflex MB Plasma System	Filtration, methylene blue treatment and visible light exposure	DNA and RNA damage by type I and type II redox reactions	CE marked
	Terumo BCT Mirasol PRT System	Riboflavin and ultraviolet light exposure	Direct DNA and RNA damage and guanine modification	CE marked
Whole blood				
Individual volunteer donors	Terumo BCT Mirasol PRT System	Riboflavin and ultraviolet light exposure	Direct DNA and RNA damage and guanine modification	Phase 3 studies planned in the United States, completed in Africa
Red cells				
Individual volunteer donors	Cerus Intercept Blood System	Frangible Anchor-Linker Effector (S303) and glutathione	Formation of DNA and RNA monoadducts and cross-linkage	U.S. phase 2 and European phase 3 studies complete

* The downsides of pathogen reduction vary by technology and include relative loss of component yield and reduced functionality, unknown residual infectivity of agents with pathogen loads that exceed validated inactivation efficacy, and resistance by certain pathogens (e.g., non-enveloped viruses, for certain technologies, and spore-forming bacteria). Short-term and long-term clinical adverse events have not been reproducibly documented. A listing of countries using each technology is available at www.aabb.org/tm/eid/Pages/pathogen-reduction-systems.aspx. CE (Conformité Européenne) denotes compliance with requirements in the European Union, FDA Food and Drug Administration, UVA ultraviolet A, and UVC ultraviolet C.

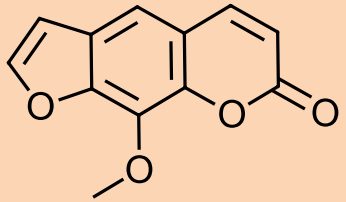
Psoralens with Medical Properties



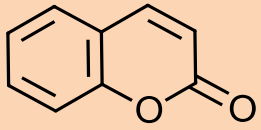
Amotosalen



Psoralen



8-MOP, or Methoxsalen

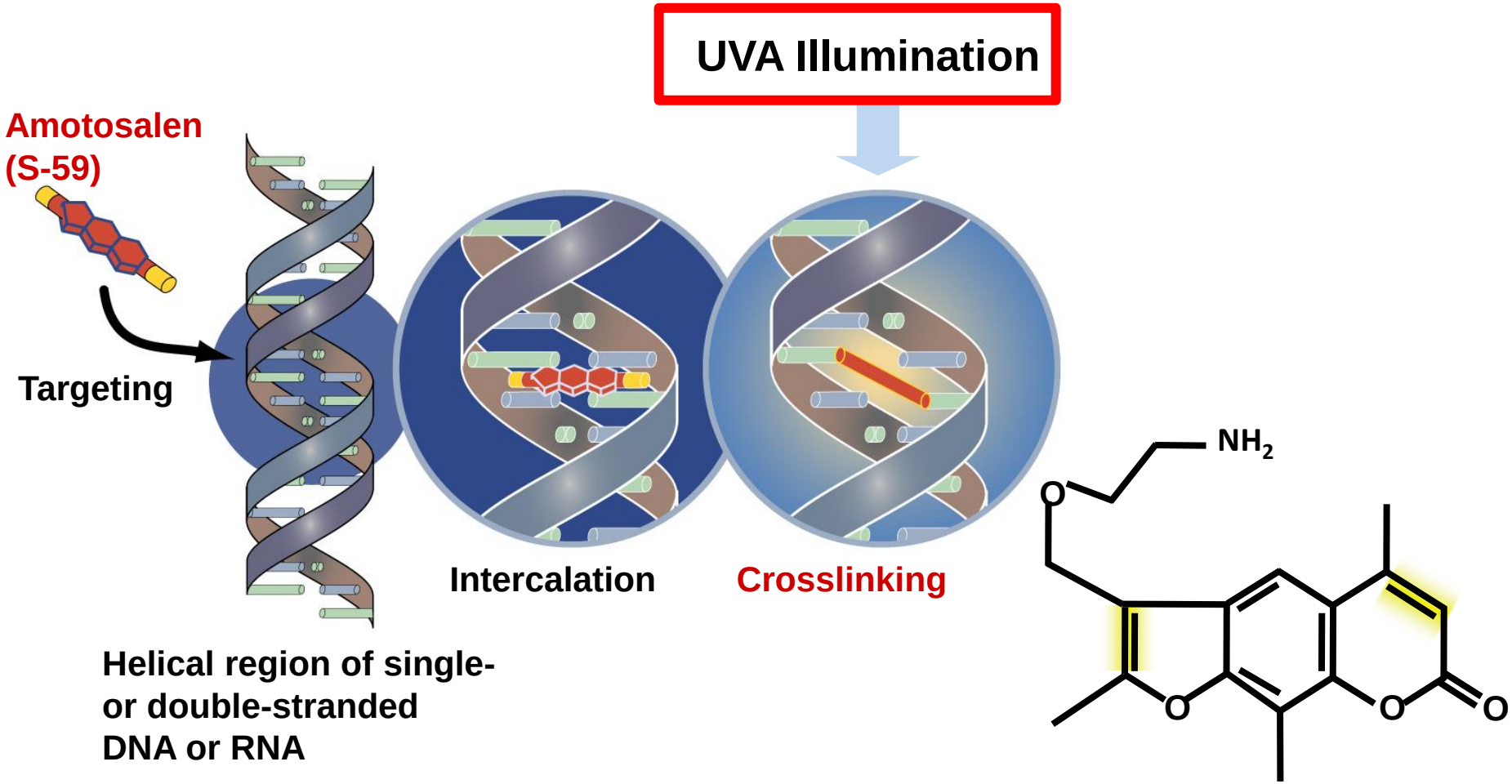


Coumarin

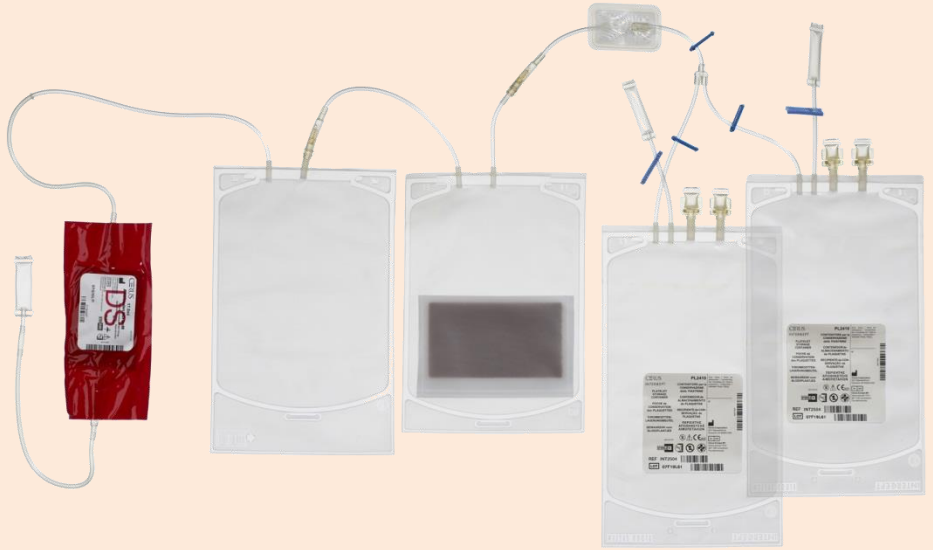
Cimino *et al., Ann. Rev. Biochem. 1985.54:1151-93*

IBS Mechanism of Action:
Nucleic Acid Targeting

FDA LICENSED – ~75% of Platelets are Pathogen Reduced Nationally



Blood System (IBS) for Platelets



Step 1 Amotosalen
Step 2 Illumination
Step 3 CAD
Process Complete Storage

Blood System (IBS) for Plasma

IBS Components Have Undergone Extensive Regulatory Review – 10 years of use

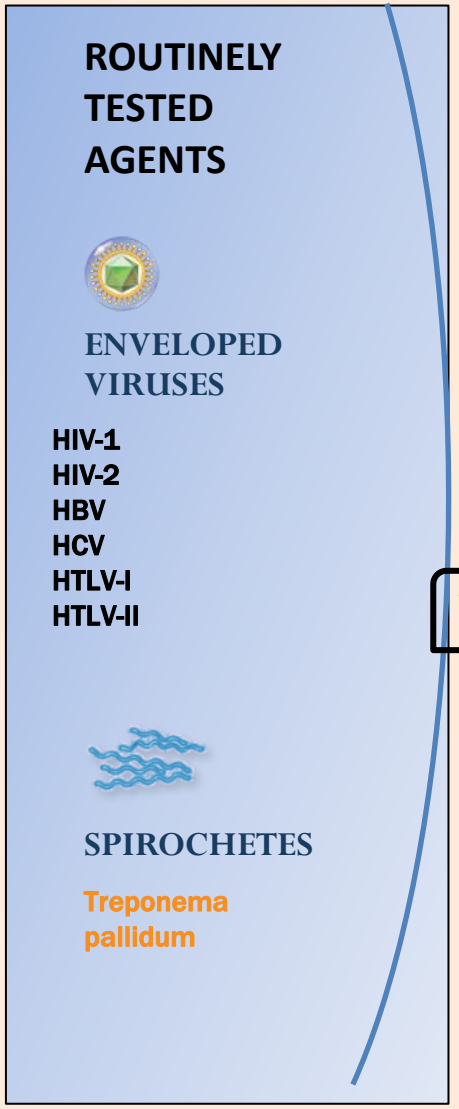
PLATELETS

2002	2003	2007	2009	2010	2014
Class 3 CE Mark Approval	Afssaps Approval	PEI Approval	Swissmedic Approval	Austrian AGES Approval	FDA Approved

PLASMA

2006	2007	2010	2011	2014
Class 3 CE Mark Approval	Afssaps Approval	Swissmedic Approval	PEI Approval	FDA Approved

IBS Pathogen Inactivation Efficacy Is Broad and Robust



VS.

NON-ENVELOPED VIRUSES

- Bluetongue virus, type 11
- Simian Adenovirus-15
- Feline calicivirus
- Parvovirus B19
- Human adenovirus 5

ENVELOPED VIRUSES

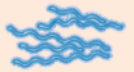
HIV-1	DHBV
HIV-2	BVDV
HBV	CMV
HCV	WNV
HTVL-I	SARS
HTLV-II	Vaccinia[1]
	Chikungunya
	Dengue[2]
	Influenza A

GRAM-NEGATIVE BACTERIA

Klebsiella pneumoniae
Yersinia enterocolitica
Escherichia coli
Pseudomonas aeruginosa
Salmonella choleraesuis
Enterobacter cloacae
Serratia marcescens
Anaplasma phogocytophilum
Orientia tsutsugamushi[3]

GRAM-POSITIVE BACTERIA

Staphylococcus epidermidis
Staphylococcus aureus
Streptococcus pyogenes
Listeria monocytogenes
Bacillus cereus (vegetative)
Bifidobacterium adolescentis
Clostridium perfringens
Corynebacterium minutissimum
Lactobacillus sp.
Propionibacterium acnes



SPIROCHETES

Treponema pallidum
Borrelia burgdorferi

PROTOZOA

Trypanosoma cruzi
Plasmodium falciparum
Leishmania sp.
Babesia microti

LEUKOCYTES

T-cells

(1) Sampson-Johannes A, et al. 2003. *Transfusion*. 43:83A; (2) Lam S, et al. *Transfusion* 2007;47:131A;
(3) Rentas F. *Transfusion* 2004;44:104A.

IBS Resistant Organisms

- **HAV**
- **HEV**
- **B19**
- **Polio**
- **B. cereus spores**

RIBOFLAVIN-BASED PR PLATELET PRODUCT *

- **Riboflavin is the photosensitizing agent in combination with UVB light**
- **Riboflavin intercalates into nucleic acids; post UVB promotes oxygen radicals**
- **Riboflavin- based PR Platelet product in use in ~18 countries as of 3/15**
- **Plt system is CE-marked and in routine use in Europe and Middle East**
- **Phase III Clinical Trial cancelled in US**
- **Not FDA approved**

***Jacquot C, Delaney M. PI blood products for pediatric patients: blood safety, patient safety, or both? Transfusion 2018;58:2095-2101**

UV-C BASED PR PLATELET PRODUCT*

- UVC light (254 nm) used as the photoactive agent and there is no photosensitizing agent added to system
- UVC acts directly on nucleic acids to induce pyrimidine dimers which blocks DNA replication
- Studies continuing *in vitro*
- Not currently FDA approved

*Jacquot C, Delaney M. PI blood products for pediatric patients: blood safety, patient safety, or both? Transfusion 2018;58:2095-2101

War of the Worlds [v 1953]

Contaminated Platelets

Classical EDS

Reproduced with permission. 2004.

Relative Bacterial Detection Level Cut-Offs

- **Gram stain bacterial detection occurs at ~ 10E6-10E7 cfu/mL**
- **Safety Measure detection at about 10E5 cfu/mL**
- **Yomtovian and Jacobs data cut-off for septic reactions ~10E5 cfu/mL**
  - **<10E5 cfu/mL less likely to produce septic transfusion reaction**
  - **>10E5 cfu/mL more likely to produce septic transfusion reaction**
- **Blood Culture for 1 day vs gram stain**
  - **Sensitivity: BC>>>GS (higher – lower)**
  - **Logistics: GS>>>BC (easier – harder)**
  - **Cost: BC>>>GS (costly – inexpensive)**
- **Concern for "looks fine vs EDS" – (Acinetobacter baumanii vs E coli)**

SAFETY MEASURE

FDA Issues New Monkeypox Information for Blood Establishments

In response to concerns about the increase in monkeypox cases, the Food and Drug Administration released a new safety and availability communication today for the blood community, reiterating that existing safeguards provide sufficient protection against the potential for transfusion-transmission of monkeypox and ensure the continued safety and security of the blood supply.

"Given the robustness of the existing safeguards for blood safety FDA does not recommend that blood establishments ask donors additional, specific questions about possible exposure to monkeypox virus," the agency stated. "Further, FDA does not recommend using laboratory diagnostic tests to screen blood donors for monkeypox virus."

FDA reiterated that there have been "no reports of transmission of monkeypox virus through blood transfusion" and that "the risk of transfusion-transmission [of monkeypox] remains theoretical."

FDA said it will continue to monitor cases of monkeypox both in the U.S. and throughout the world and will provide updates to the blood community if needed.

Viruses detectable by LVDS and/or Safety Measure = 0

Covid-19 Monkey Pox Langya henipavirus (LayV) HIV 1/ HIV 2 HTLV I/ HTLV II

Managing Editor: Drew Case

4th Generation Solution to Bacterial Contamination at Yale

Kills 99.9%

[Only 3 Log Kill]

Pathogen Reduction has a 4-6 Log kill

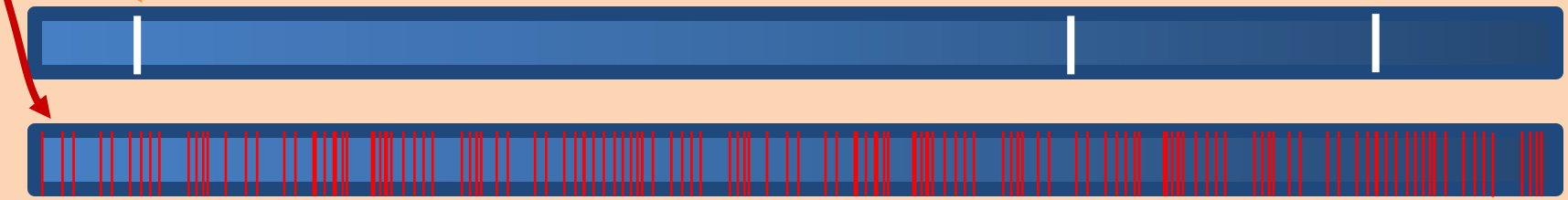
Leukocyte nucleic acid damage more efficient for PCT than with gamma irradiation

Adducts:

Gamma irradiation **1/37,000 base pairs (Oxidative)**

Amotosalen + UVA **1/83 base pairs (Adducts)**

Inhibition of APC function (MLR)
Inhibition of cytokine production



Grass JA et al. Blood 1998; 91(6):2180-2188
Slide adapted from the original provided by Dr. J Aubuchon

Irradiated Blood

ACCEPTABLE INDICATIONS:

- Congenital immune deficiency
- Acute leukemias
- Chronic leukemias
- Lymphomas / Hodgkin's Disease
- Sarcomas; GBM; Neuroblastoma; Rhabdomyosarcoma
- BMT / HSCT Pre transplant – post transplant – allo or auto
- MDS
- Patient on high dose chemotherapy; ATG; immunosuppressive therapy
- Aplastic Anemia / ITP

PRODUCTS TO IRRADIATED:

- All directed-donor cellular products
- All cellular products for NBICU
- All cellular products for children < 4 months
- All cellular products for patients on ECMO
- All PMNs and HLA-matched platelets

PRODUCTS NOT IRRADIATED

Plasma Products

Cryoprecipitate

NOT INDICATED FOR:

- Epithelial malignancies (liver; renal; breast; lung; prostate)
- Trauma / Burns
- TTP
- Musculoskeletal disease ; arthritis; Sickle Cell anemia; Thalassemia; Hemophilia

Blood Utilization and Transfusion Reactions in Adult Patients Transfused with Conventional or Pathogen Reduced Platelets

Burak Bahar, Wade L. Schulz, Amit Gokhale, Bryan Spencer, Eric Gehrie, Edward L. Snyder

BRITISH JOURNAL OF HAEMATOLOGY

Brit. J Haematol 2020;188(3):465-72

DOI:10.1111/bjh.16187 ; PMID 31566724

Table 2. Transfusion reaction rates in patients receiving CONV or PR platelets.
CI: Confidence interval; Inf: Infinite; N/A: Not applicable; [1]Febrile non-hemolytic transfusion reaction; [2]Transfusion associated circulatory overload; [3]Transfusion-associated dyspnea; [4]Transfusion-associated graft-versus-host disease; [5]Transfusion-related acute lung injury

Reaction Type	Conventional (N=8,912 units)	Pathogen reduced (N=12,995 units)	Relative risk (95% CI)	P value
Allergic	34	42	1.18 (0.73 – 1.90)	0.485
FNHTR[1]	26	37	1.02 (0.60 – 1.74)	1.000
Hemolytic	0	2	0.00 (0.00 – 7.76)	0.517
Hypotensive	0	1	0.00 (0.00 – 56.9)	1.000
Septic	**5**	**0**	**Inf (1.34 – Inf)**	**0.011**
TACO[2]	3	5	0.87 (0.14 – 4.50)	1.000
TAD[3]	2	2	1.46 (0.11 – 20.1)	1.000
TA-GvHD[4]	0	0	N/A	N/A
TRALI[5]	0	0	N/A	N/A
Total	70	89	1.15 (0.83 – 1.59)	0.420

Blood Utilization and Transfusion Reactions in Pediatric Patients Transfused with Conventional or Pathogen Reduced Platelets

Wade L. Schulz, MD, PhD, Jacob McPadden, MD ,Eric A. Gehrie, MD, Burak Bahar, MD, Amit Gokhale, MD, Rebecca Ross, MT (ASCP), Nathaniel Price, BS, Bryan R. Spencer, PhD, and Edward L. Snyder, MD

J Pediatr 2019;209:220-5

The PIPER Phase 4 Study: Pathogen Inactivated Platelets Entering Routine Practice

TRANSFUSION

Comparative risk of pulmonary adverse events with transfusion of pathogen reduced and conventional platelet components

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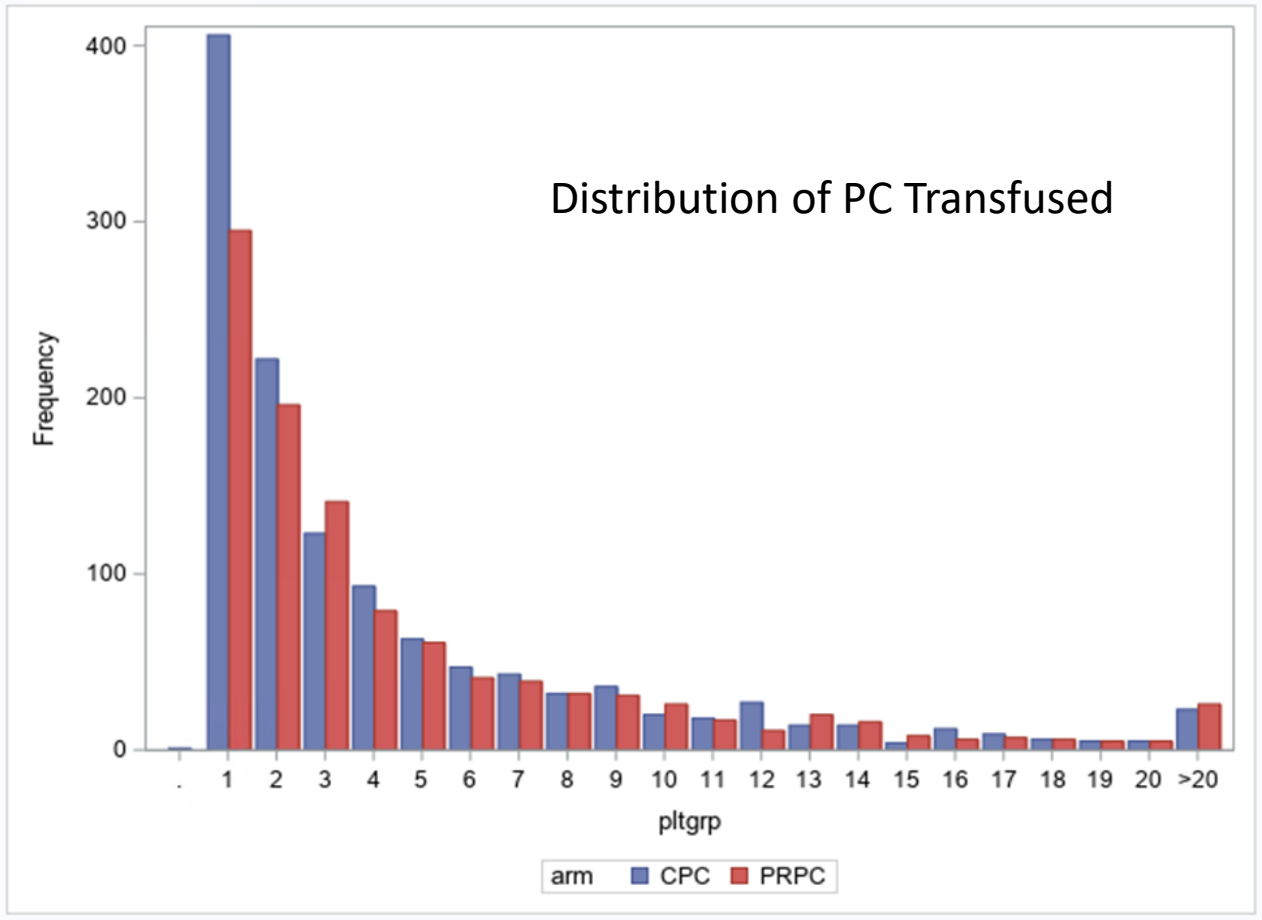
Transfusion 2022;62(7):1365-1376. July 2022
doi: 10.1111/trf.16987 ; PMID: 35748490

022;

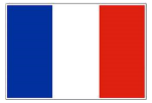
PC and RBC Transfusion Exposure (mITT)



Modified Intention-to-Treat Patients			
Parameter	**Total**		**P- Value**
	PRPC	**CPC**	
Patients (n)	**1068**	**1223**	
PC Transfused			
Mean	**4.9 ±6.1**	**4.5 ±5.1**	***0.046****
Median	**3**	**2**	
Days PC Support[2]			
Mean	**6.4 ±6.3**	**6.7 ±6.8**	**0.447**
Median	**4**	**4**	
RBC Components Transfused			
Patients: n (%)	**639 (60)**	**716 (59)**	
Mean	**3.0 ±2.7**	**3.3 ±3.1**	**0.146**
Median	**2**	**2**	

- **Overall PC use was slightly more for PRPC, but with large range consistent with minimal impact over days of PC support**

Impact of IBS On Transfusion Transmitted Bacterial Infection



	Conventional PC			INTERCEPT-PC		
Year	PC (n)	TTBI*	TTBI / 10^4 PC	PC (n)	TTBI	TTBI / 10^4 PC
2006	231,849	4 (0)	0.17	6,420	0	0
2007	232,699	9 (2)	0.39	15,393	0	0
2008	239,343	6 (1)	0.25	15,544	0	0
2009	241,625	9 (0)	0.37	21,767	0	0
2010	253,145	2 (1)	0.08	22,632	0	0
2011	267,782	3 (1)	0.11	22,392	0	0
2012	275,979	7 (2)	0.25	24,849	0	0
2013	278,230	4 (1)	0.14	25,089	0	0
Total	2,020,652	44 (8)	0.22	154,086	0	0
2005-10	151,889	16 (3)	1.1	0	0	0
2011	6,613	0	0	26,587	0	0
2012	0	0	0	34,265	0	0
2013	0	0	0	34,663	0	0
Total	158,502	16 (3)	1.0	95,515	0	0
TOTAL	2,179,154	60 (11)	0.28	249,601	0	0

- **Transfusion Transmitted Bacterial Infections (Fatalities)** France: p = 0.039 / Combined p = 0.006

Summary and Conclusions

- PRPC were non-inferior to CPC for TEAMV
- Cumulative incidence of TEAMV was statistically less for PRPC
- Incidence of ARDS was low and numerically less with PRPC
- No increased incidence of CSPAE with PRPC
- No increase in PC or RBC utilization with PRPC
- No significant difference in safety
- Decreased incidence of allergic transfusion reactions with PRPC

Conclusion: PRPC demonstrated safety in routine use with the benefit of reduced risk of Transfusion Transmitted Infection

PR CRYOPRECIPITATE FIBRINOGEN COMPLEX

Prepared from Pathogen Reduced FFP

Stored frozen – contains fibrinogen, F.XIII, vWF

When thawed, has a FIVE-DAY Shelf Life at RT vs Conv cryo 4-6h

Approved for treatment & control of bleeding D/2 fibrinogen deficiency; uremia

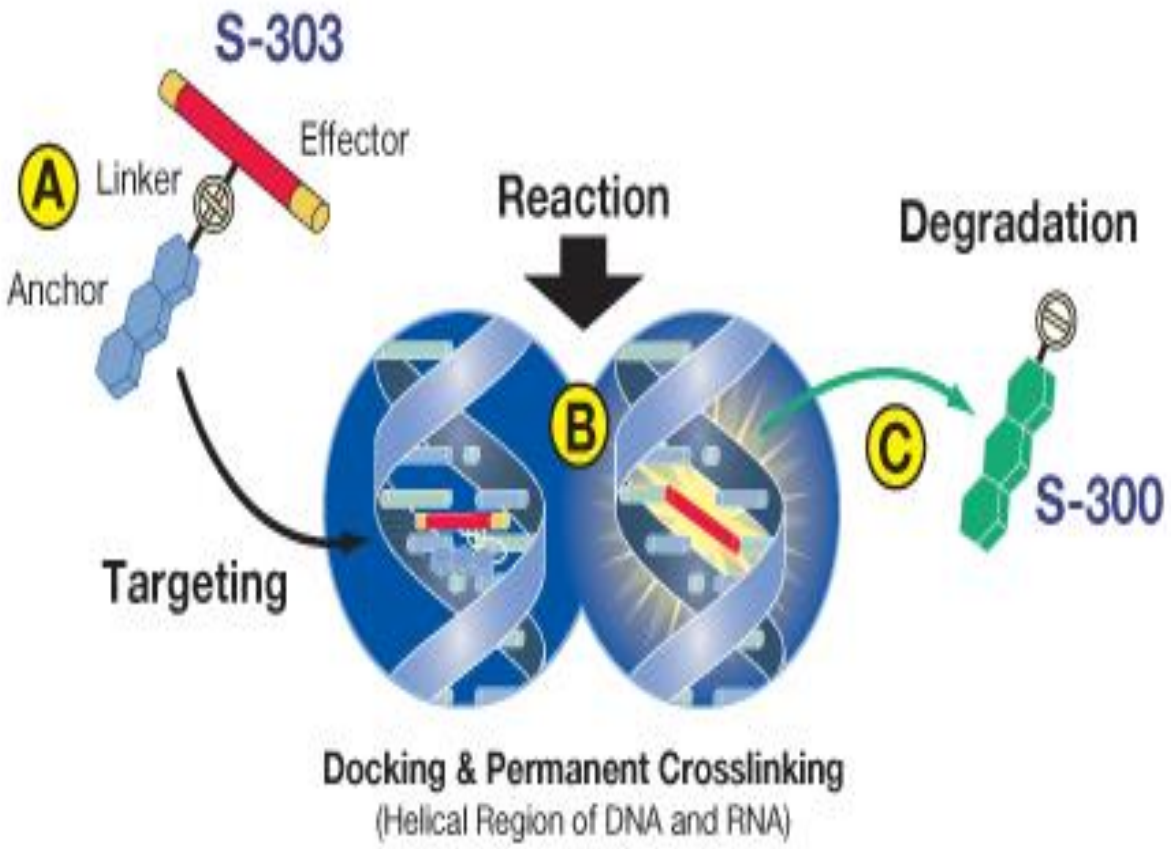
Higher cost but, decreased wastage for active trauma/OB medical centers

Clinical Need for Red Cell Pathogen Reduction

- Provide protection against emerging pathogens
- Allow general replacement of the incremental testing paradigm
- Permit replacement of gamma irradiators for GVHD and diminish ^{137}Cesium dirty bomb risk
- Relaxation of donor deferrals to enlarge donor pool and provide social equity
  - Zika, malaria travel deferrals
  - MSM deferral
- Address Babesia and other pathogen risk in the US
- Lower plasma content and possible reduced reactions

INTERCEPT Red Blood Cells

- **Mechanism of Action**
  - **S-303 (Amustaline) is a nucleic acid-targeted alkylator with rapid inactivation kinetics**
    - **3 components: Acridine anchor, effector and linker**
  - **The acridine anchor** targets nucleic acids where it (A) intercalates and reversibly binds to the helical regions of the molecule. **The effector** irreversibly cross-links (B) the nucleic acids preventing replication or transcription.
  - **S-303 hydrolyzes** to an inactive derivative S-300 (C)
  - **Glutathione (GSH) is used to quench side reactions**



Amustaline S-303

- UV-A cannot be used effectively in RBCs as Hgb absorbs UV-A
- S-303 is a quinacrine-binds and crosslinks without photoactivation
- Alkylation occurs quickly; S303 decomposes with a $T_{1/2}$ of 25 min
- S-303 ⟶ S-300 decomposition product
- A quenching agent – glutathione (GSH) reduces side effects
- S-303 crosses cell membranes but GSH does not –
- S-303 RBC suitable for 35-42 days of storage
- Phase III RCT showed S-303 vs Control were equivalent for RBC usage or patient outcome.
- ReCePI Phase III RCT – complex CV surgery underway in US

Pathogen Inactivation with the IBS RBC System

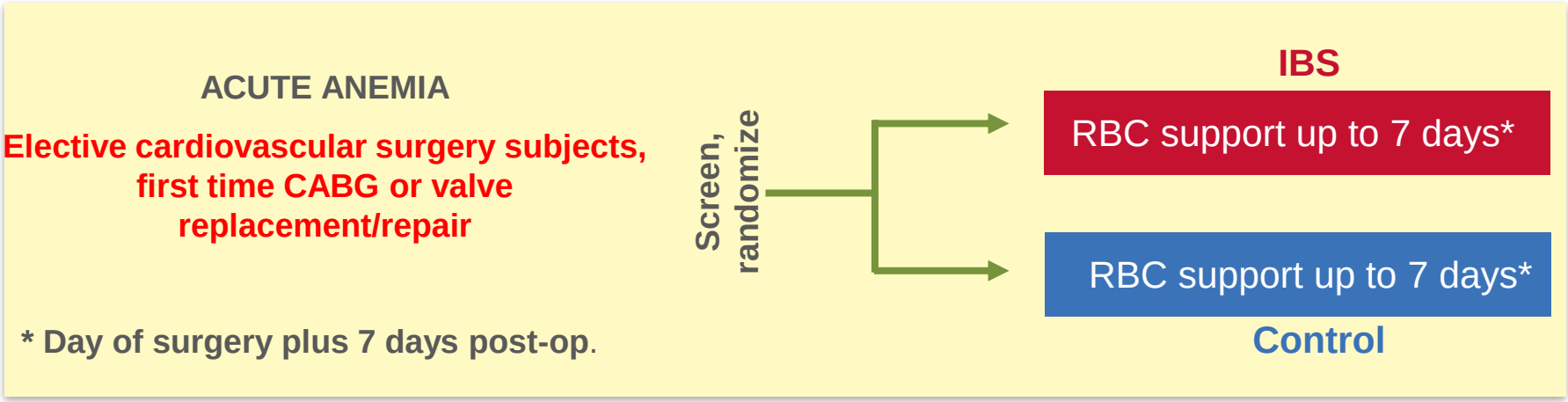
Organism	Log_{10} Reduction
Cell associated-HIV	>5.4
DHBV	>5.1
BVDV	>4.8
Cell associated-CMV	>3.9
CHIKV	>7.1
ZIKV	≥5.8[1]
Bluetongue	≥4.4
Calicivirus	>6.8
Adenovirus	>5.9
P. falciparum	>7.9
B. microti	>4.9[2]

[1]Santa Maria *et al. Oral* S16 - 010C, [2] *Tonetti et al. Poster: SP438*

ReCePI Red Cell Pathogen Inactivation Study

Objective:

- To evaluate the safety & efficacy of the IBS Red Cell System in cardiovascular surgery subjects



- **Primary Efficacy End Point: Acute Kidney Injury within 48 hrs. of surgery**
- Safety endpoints: AEs, SAEs & TRs until day 28
- S-303 antibodies at day 28±3 days; and 75 ±15 days

ReCePI Study Protocol Review

- **Primary Endpoints**
  - **<u>The primary efficacy endpoint</u> is:**
    - **the proportion of patients, who have received at least one study transfusion with a diagnosis of renal impairment defined as:**
    - **Any raised sCr level, occurring after transfusion of a study RBC, of ≥0.3 mg/dL (or 26.5 µmol/L) from the pre-surgery baseline within 48±4 hours of the end of surgery.**
  - **<u>The primary safety endpoints are</u>:**
    - **Proportion of patients with any treatment-emergent adverse events (TEAEs) possibly, probably or definitely related to study RBC transfusion through 28 days after the last study transfusion; and**
    - **Proportion of patients with treatment-emergent antibodies with confirmed specificity to IBS RBCs by end of study (i.e., 75±15 days after the last study transfusion).**

Protocol Review

Inclusion Criteria:

Qualifying "complex cardiac surgeries":

- **Single Vessel Coronary Artery Bypass Graft, repeat procedure.**
- **Multiple Coronary Artery Bypass Grafts, first or repeat procedure.**
- **Single Valve Repair or Replacement, repeat procedure.**
- **Multiple Valve Repair or Replacement, first or repeat procedure.**
- **Surgery involving both Coronary Artery Bypass Graft(s) and Valve Repair(s), first or repeat procedure.**

➢ **One or more of the following procedures, with or without Coronary Bypass Graft(s):**

- **Left ventricular aneurysm repair,**
- **Ventricular and/or atrial septal defect repairs,**
- **Batista procedure (surgical ventricular remodeling),**
- **Surgical ventricular restoration,**
- **Congenital defect repair, and aortic root procedures**

Leukocyte Nucleic Acid Damage More Efficient with IBS than with Gamma Radiation

Adducts:

Gamma irradiation — **1/37,000 base pairs (Oxidative)**

S-59 Amotosalen + UVA (Adducts) — **1/83 base pairs**

Platelets and Plasma Components

Grass JA et al. Blood 1998; 91(6):2180-2188
Slide adapted from the original provided by Dr. J Aubuchon

Red Cell Components

Unpublished data for S-303
Treatment 200 µM S-303/ 2 mM GSH @ rt. 20 hrs. incubation

Whole blood units (N=3) the adduct — **averaged to 1/53 base pairs (Adducts)**

RBC prepared ESOL (N=3) — **average of 1/38 base pairs (Adducts)**

Inhibition of APC function (MLR)
Inhibition of cytokine production

FOOD INSECURITY

PLATELET INSECURITY

Bridgeport Hospital and Milford Hospital

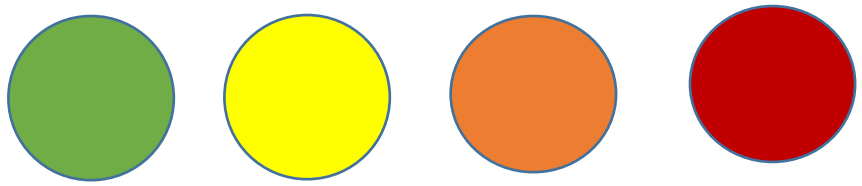
Bridgeport, CT / Milford, CT

BLOOD COMPONENT DASHBOARD

Tuesday December 27, 2022

Edward Snyder, MD, FACP Director **Lisa Krause, MT(ASCP, Manager)**

COMPONENT	STATUS	DEFICIENT COMPONENT/REMEDIATION
RED CELLS		Requests for O+ and 0- will be screened
PLATELETS		Only half units of extended platelets are available
PLASMA		
CRYOPRECIPITATE		



CURRENT STATUS

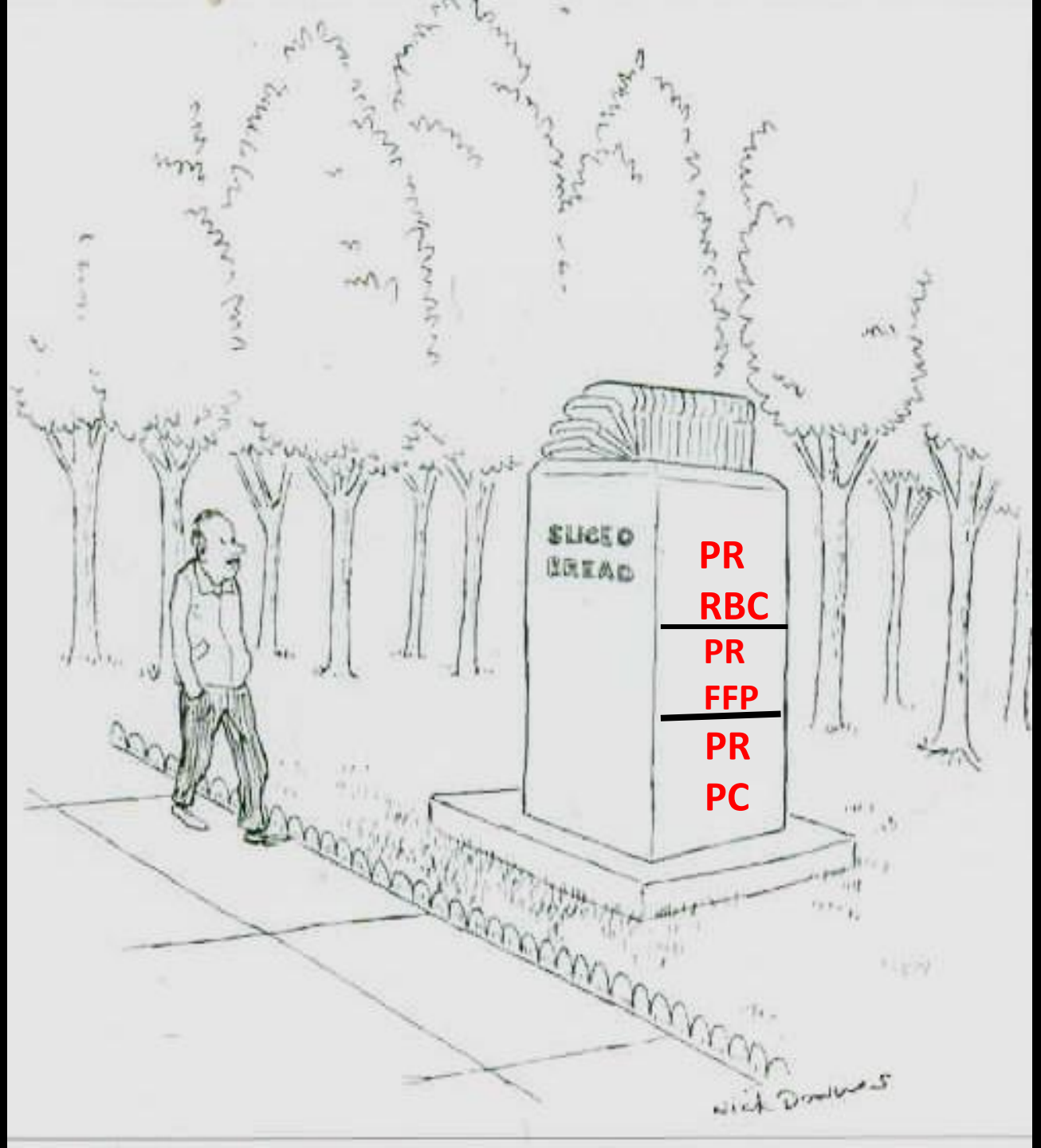
Future Infectious Threats to the Blood Supply

- 70-75% of new infectious threats are Zoonoses
- Types – Viral, Bacterial, Parasitic, Mycotic (>50 new pathogens in last 40 yrs)
- Etiology –
  - Rain and other Forests are being cleared
  - Animal Habitats are being destroyed
  - Dam building destroying habtats forcing animal migration
  - Wet (live animal) markets
  - Pathogens jumping from animal to man leading to human infections

- Examples
  - HIV
  - Ebola
  - West Nile
  - Monkey Pox
  - Zika
  - Covid19
  - SARS
  - Babesia
  - Malaria
  - Chikungunya
  - Dengue
  - Encephalomelitis
  - Rabies
  - Hantavirus
  - Plague
  - Lyme
  - Ehrlichia
  - WEE; EEE
  - Crimean-Congo Hem. Fever
  - Simian Hemorrhagic Fever
  - Bacterial
  - Toxoplasmosis
  - Leishmania
  - “Turtle Pox” next?

New Pathogen Reduced Blood Products HCPCS P

CY Year	New CY HCPCS P-Code	New HCPCS P-Code Long Descriptor	Final CY OPPS Payment Amount
2022	P9073	Platelets, pheresis-pathogen reduced, each unit	$706.22
2023	P9073	Platelets, pheresis-pathogen reduced, each unit	$707.95


SLICED
BREAD
PR
RBC
PR
FFP
PR
PC