

Using Blood Screening and Pathogen Reduction to Ensure Blood Safety and Availability



Marion LANTERI, PhD
Vice President of Scientific Affairs



Blood Safety in the U.S.

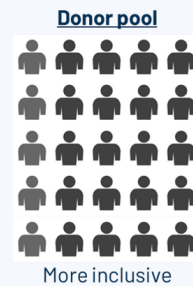
- Blood Screening at Creative Testing Solutions (CTS):
 - CTS screens ~70% of the U.S. blood and plasma supply
 - Screens blood collected by American Red Cross, Vitalant, OneBlood, and others
 - Screens source plasma collected by Grifols and others in the U.S. and Canada
- Pathogen Reduction (PR) using FDA approved technology:
 - INTERCEPT Blood Systems for Plasma and Platelets

Blood
Screening

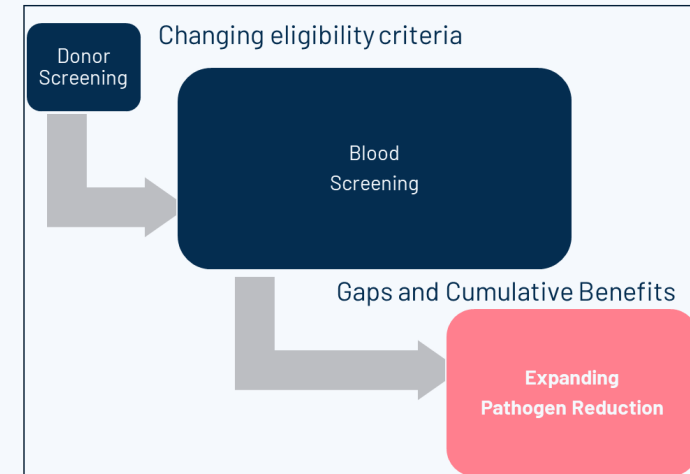
Pathogen
Reduction

Outline

- Blood safety toolbox
 - Blood screening and Pathogen Reduction (PR)
- Gaps and cumulative benefits
 - Vector-borne agents
 - Classic agents
 - Surveillance
- Now vs. in the future

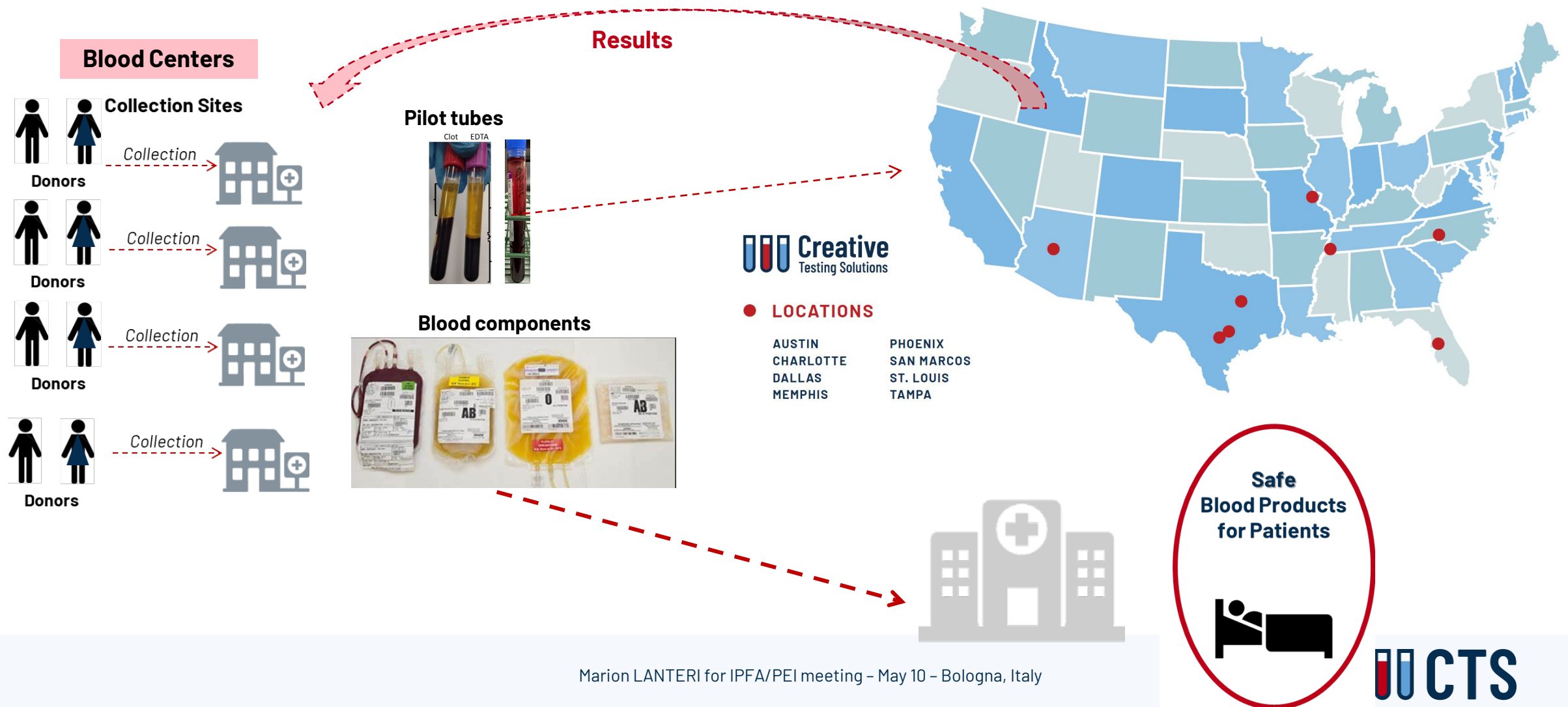


Expanding The Toolbox



Blood Screening at Creative Testing Solutions

High throughput testing



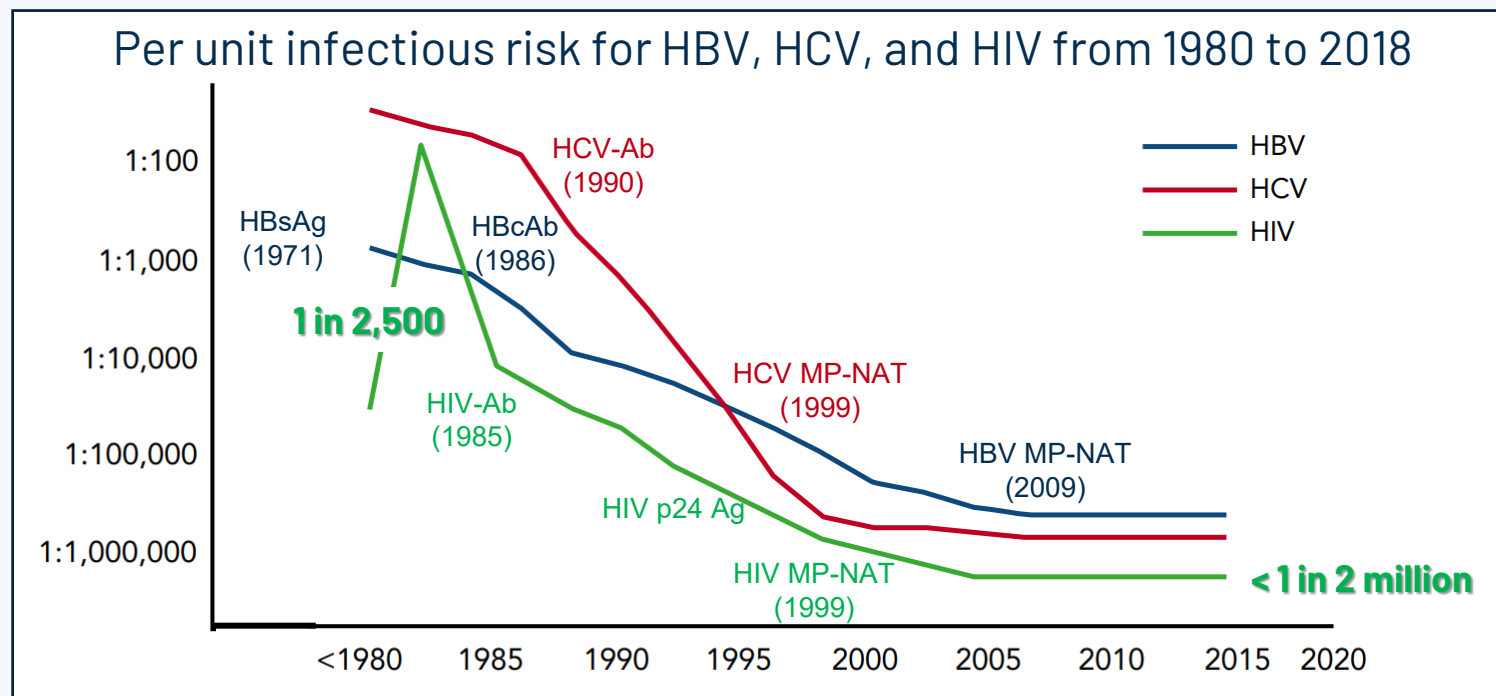
Blood and Plasma Screening Platforms/Assays used at CTS

Blood screening - routine testing for 9 pathogens using 11 screening tests and 16 confirmatory

	Test	Vendor	System
Classic agents	HIV/HCV/HBV NAT [#]	Grifols	Panther
	Anti-HIV-1/2 plus O [#]	Bio-Rad for QuidelOrtho	VIP
	Anti-HCV [#]	QuidelOrtho	VIP
	Anti-HBc	QuidelOrtho	VIP
	HBsAg [#]	Bio-Rad for QuidelOrtho	VIP
	Anti-HTLV-I/II	Avioq. Inc.	VIP
	CMV	Fujirebio for Beckman Coulter	PK7400
	Syphilis	New Market Bio. for Beckman Coulter	PK7400
	Syphilis RPR ^{**}	Arlington Scientific	ASI Evolution
	HAV/B19 NAT [#] (source plasma only)	Grifols	Panther
	HAV/B19 NAT (recovered plasma only)	Roche	c6800
Vector-borne agents	WNV NAT	Grifols	Panther
	Babesia species NAT	Grifols	Panther
	Anti- <i>T. cruzi</i>	Ortho	VIP
Donor Health & Component Quality	ABO/Rh	Diagast for Beckman Coulter	PK7400
	Triglyceride	Beckman Coulter	AU680
	Ferritin	Beckman Coulter	AU680
	Serum Protein Electro. [#] (source plasma only)	Sebia Electrophoresis	Capillarys
	HLA Class I and II	Immucor GTI Diagnostics	Gemini
	RBC Antibody Screen	Immucor	Neo Iris
	Antibody Identification	QuidelOrtho	Vision

[#] source plasma screening only; ^{**}RPR used for confirmatory blood/source plasma/tissue donation screening

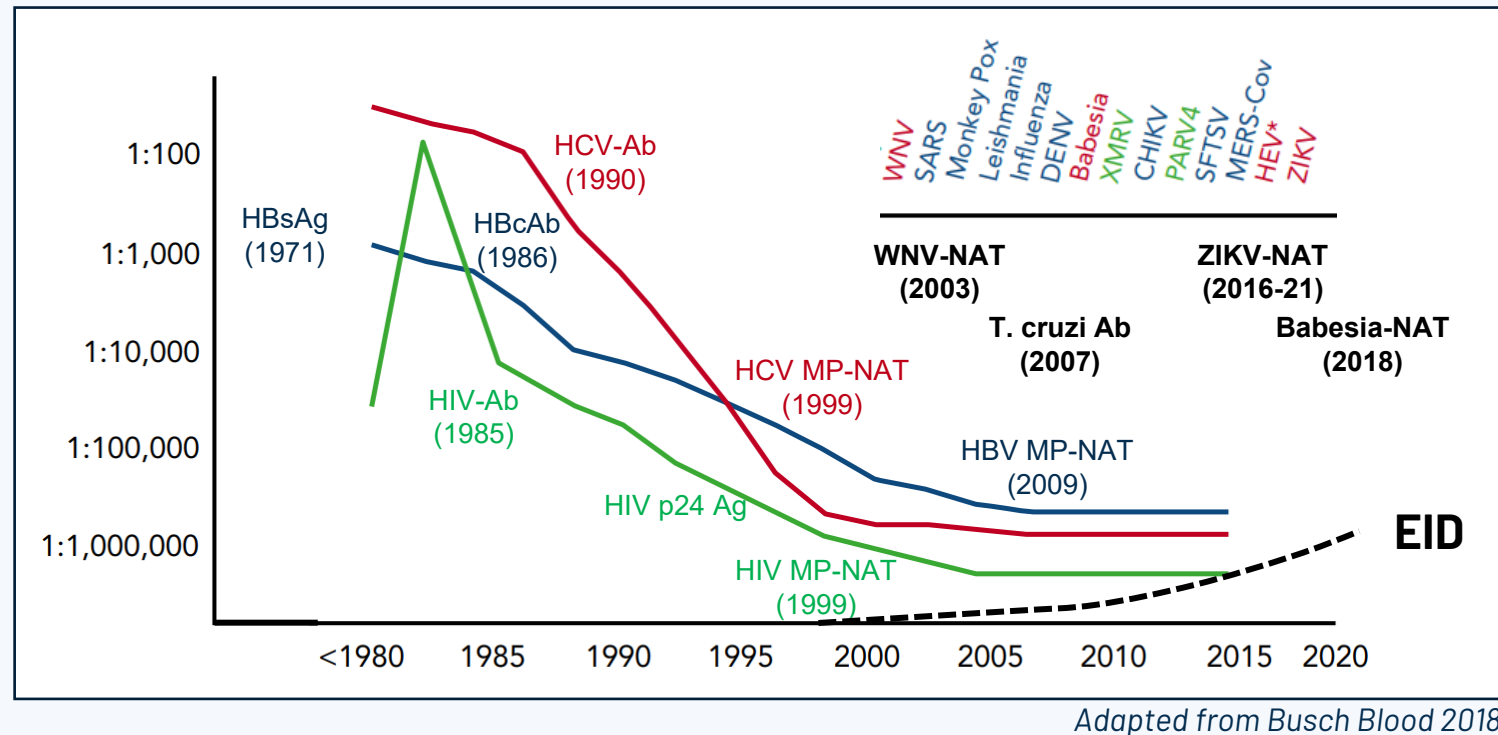
Advances in Blood Screening Tests Progressively Reduced the Risk of HIV, HBV, HCV Transfusion-Transmitted Infection



Adapted from Busch Blood 2018

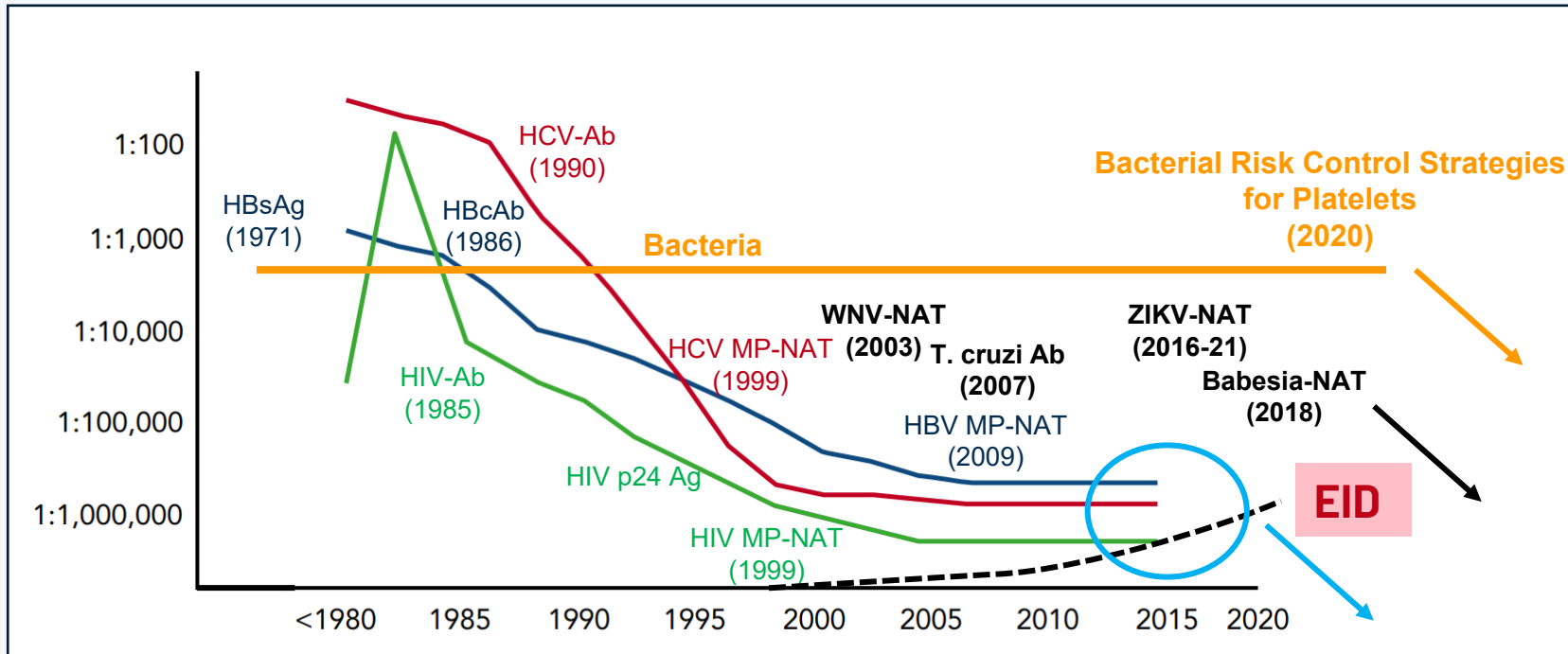
- Blood safety has heavily relied on blood screening for
 - Classic agents

Advances in Blood Screening Tests Progressively Reduced the Risk of Transfusion-Transmitted Viral and Parasitic Infections



➤ Additional assays have been implemented over the past decades

Advances in Blood Safety Have Progressively Reduced the Risk of Transfusion-Transmitted Infections



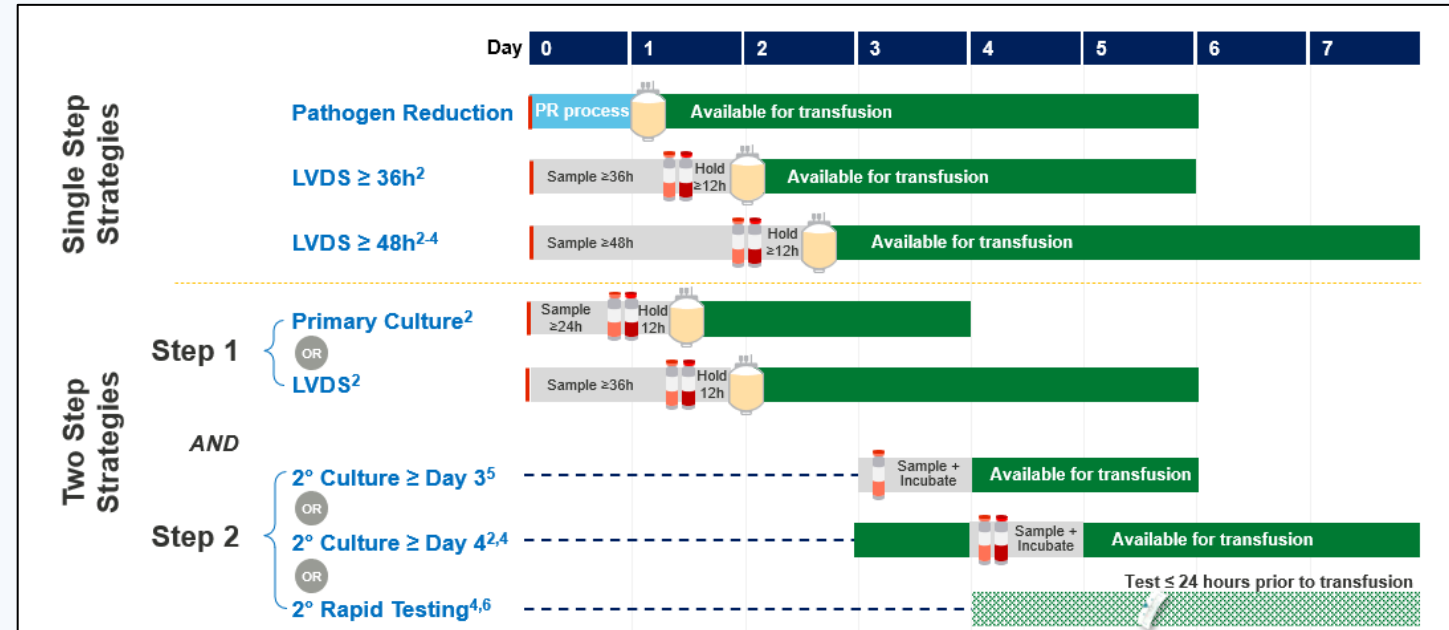
Adapted from Busch Blood 2018

- Blood safety heavily relies on blood screening
- Pathogen Reduction is now part of the tools available
- ✓ Both can be used to ensure blood safety and **availability**

The Use of Pathogen Reduction Increased Over the Past Few Years

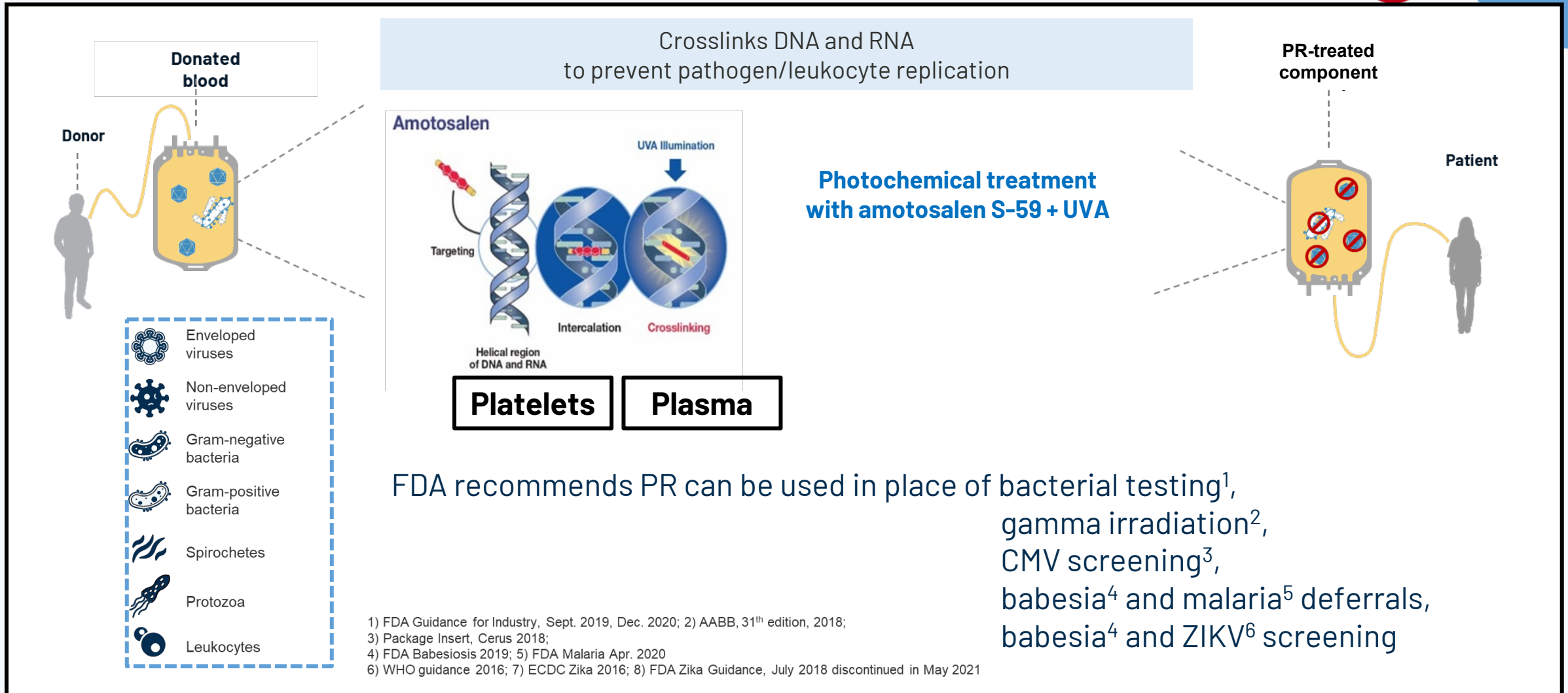
- U.S. FDA bacterial guidance (Dec. 2020):
Recommended all blood centers/hospitals adopt improved bacterial mitigation strategies by Oct. 2021

ARC: >90% PR-PLTs
OneBlood: >60% PR-PLTs
Vitalant: >20% PR-PLTs
CTS Priority testing for faster turnaround time

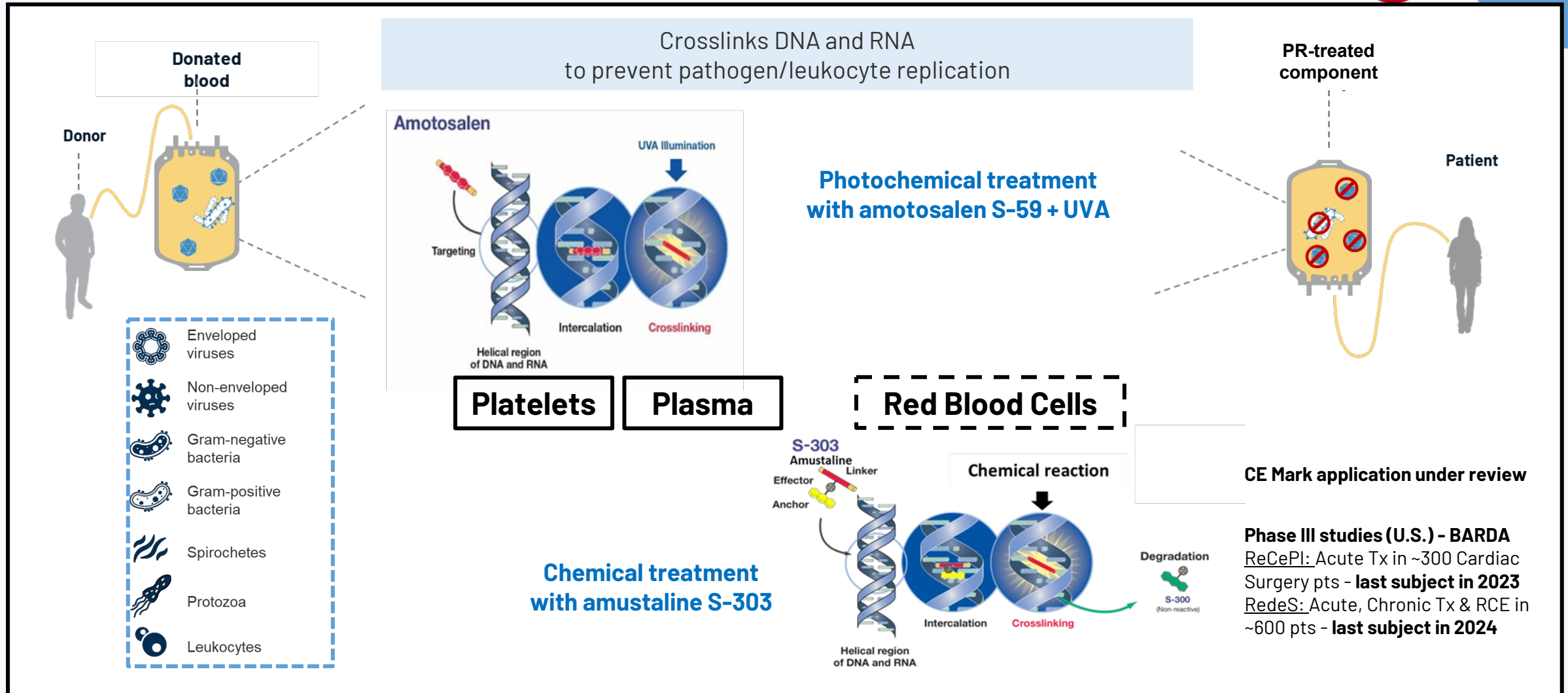


- COVID-19 – Blood shortages
- Blood safety and availability
 - Pathogen reduction increases platelet availability (day 1 release, no hold)
 - Broad spectrum inactivation increases platelet safety beyond bacteria

The Promises of Pathogen Reduction

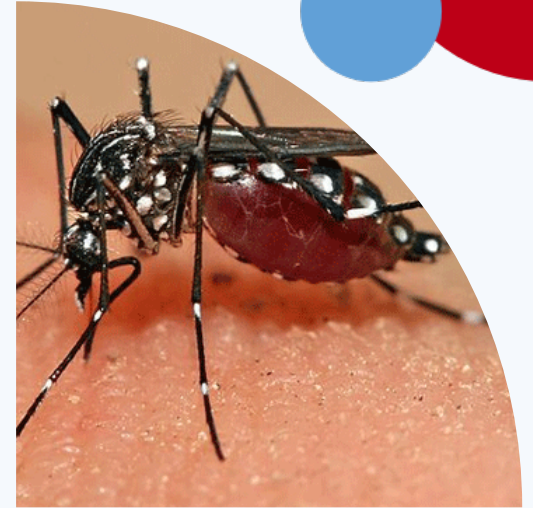


The Promises of Pathogen Reduction



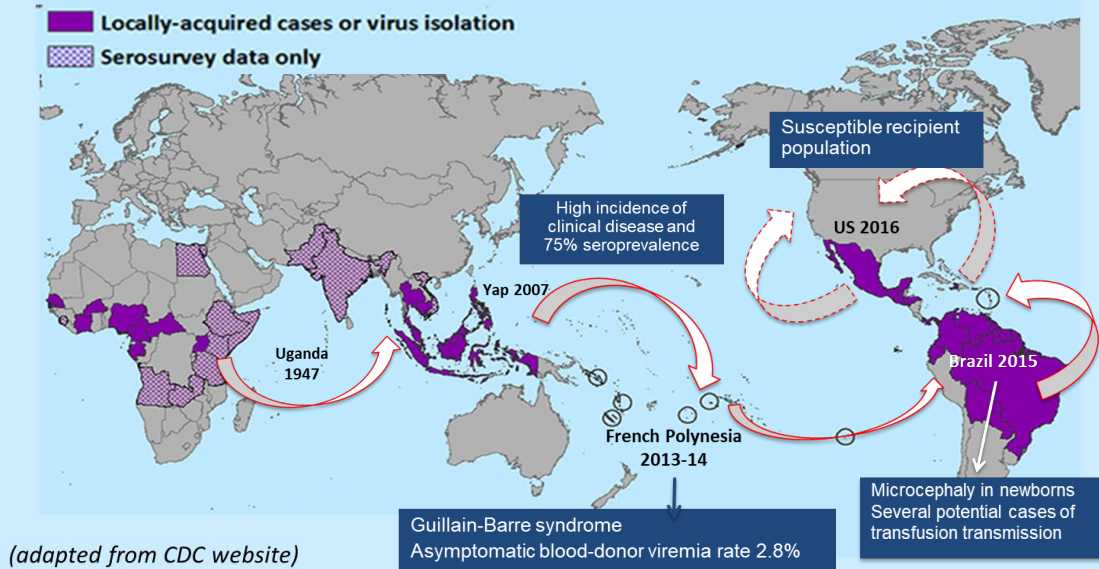
Gaps and Cumulative Benefits

Vector-Borne Agents

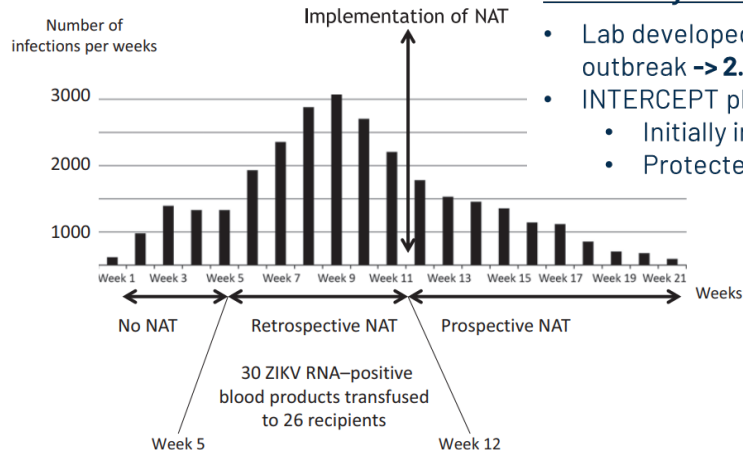


Zika Virus - Lessons Learnt

ZIKV spread, expanded clinical associations, and evidence for potential transfusion-transmissions



Musso ISBT Science Series (2016)

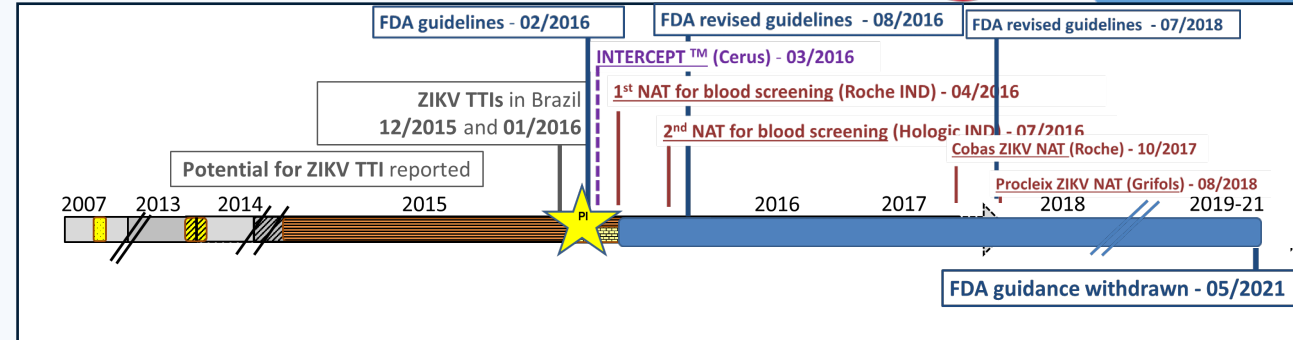


French Polynesia (2013/2014):

- Lab developed NAT assay implemented week 12 of the outbreak → **2.8 % of blood donors tested ZIKV RNA+**
- INTERCEPT platelets were in routine use since 2010
 - Initially implemented to prevent DENV/CHIKV
 - Protected platelet recipients for 12 weeks

Brazil (2015):

- GBS + Congenital syndromes
- **ZIKV TTI cases**



U.S. (2015-2021):

- Development of research assays
- Pathogen reduction in Puerto Rico
- ZIKV screening under IND then licensed
- ✓ ZIKV outbreak waned down
- ✓ Risk mitigation strategies discontinued

Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components

Guidance for Industry

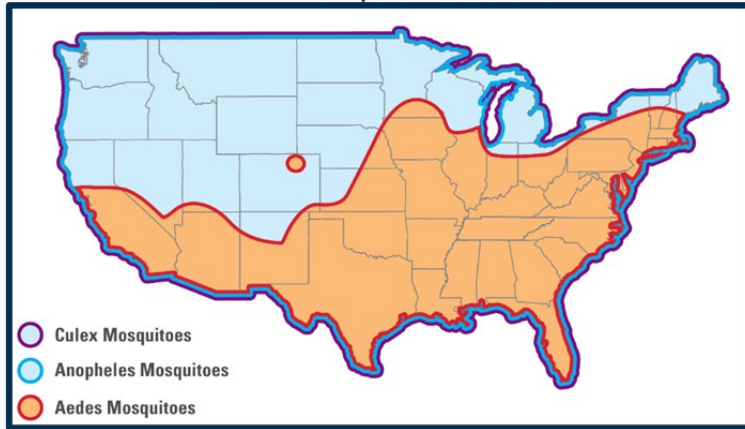
1. Test all donations collected in the US and its territories with an investigational individual donor nucleic acid test (ID-NAT) for ZIKV under an investigational new drug application (IND), or when available, a licensed test **or**
2. **Implement pathogen reduction technology for platelets and plasma using an FDA-approved pathogen reduction device** as specified in the Instructions for Use of the device. If an FDA-approved pathogen reduction device becomes available for Whole Blood or red blood cells, you may implement pathogen reduction technology for such products rather than testing the donations as described in section IV.A.1.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
July 2018

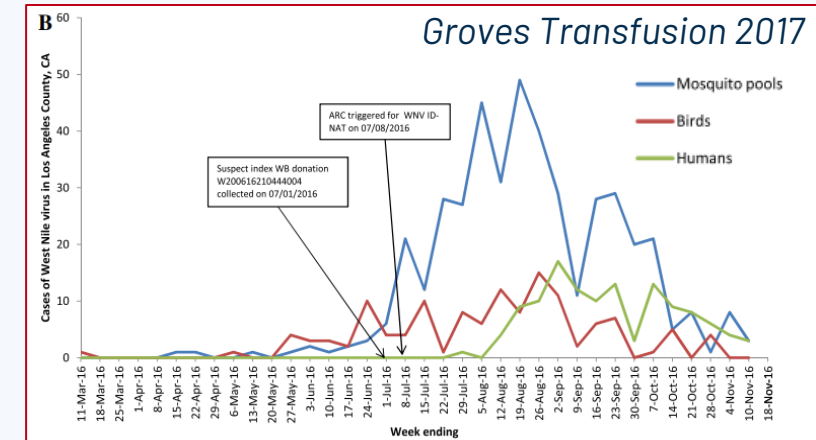
PR helped maintain blood availability
While blood screening assays were being developed
Mosquito-borne agent outbreaks are unpredictable

The Risk with Mosquito-Borne-Agents

Culex mosquitoes(WNV)



- WNV emerged in 1999
- 23 TTI cases in 2002, NAT IND 2003
- MP-NAT → seasonal ID-NAT
 - Triggering strategies
- 16 TT-WNV documented for 95,005,117 donations screened
- Residual risk: 1:5.94 million



Aedes mosquitoes(ZIKV, DENV, CHIKV, YFV)



EDITORIAL

Lanteri & Busch Transfusion 2012

**Dengue in the context of “safe blood” and global epidemiology:
to screen or not to screen?**

The Journal of Infectious Diseases

MAJOR ARTICLE

IDSa
Infectious Diseases Society of America

hivma
hiv medicine association

OXFORD

Sabino JID 2016

Transfusion-Transmitted Dengue and Associated Clinical Symptoms During the 2012 Epidemic in Brazil

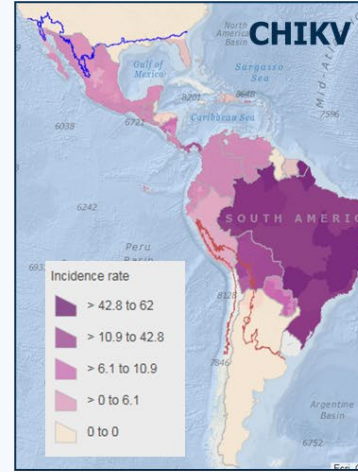
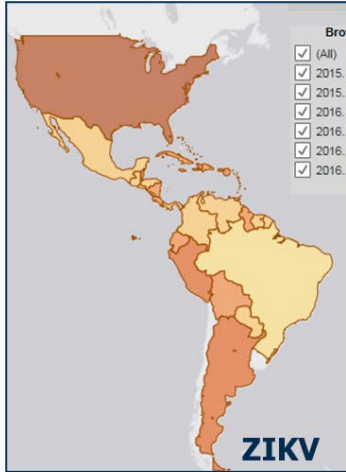
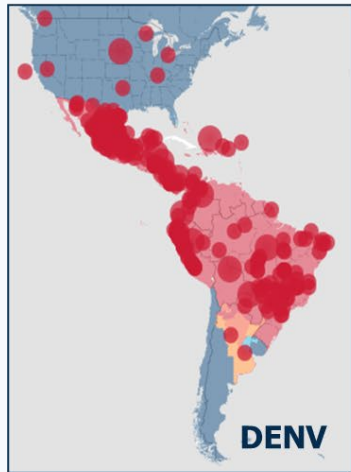
- No significant clinical difference in between DENV RNA+ and DENV RNA- recipients

OneBlood approach to locally acquired DENV:

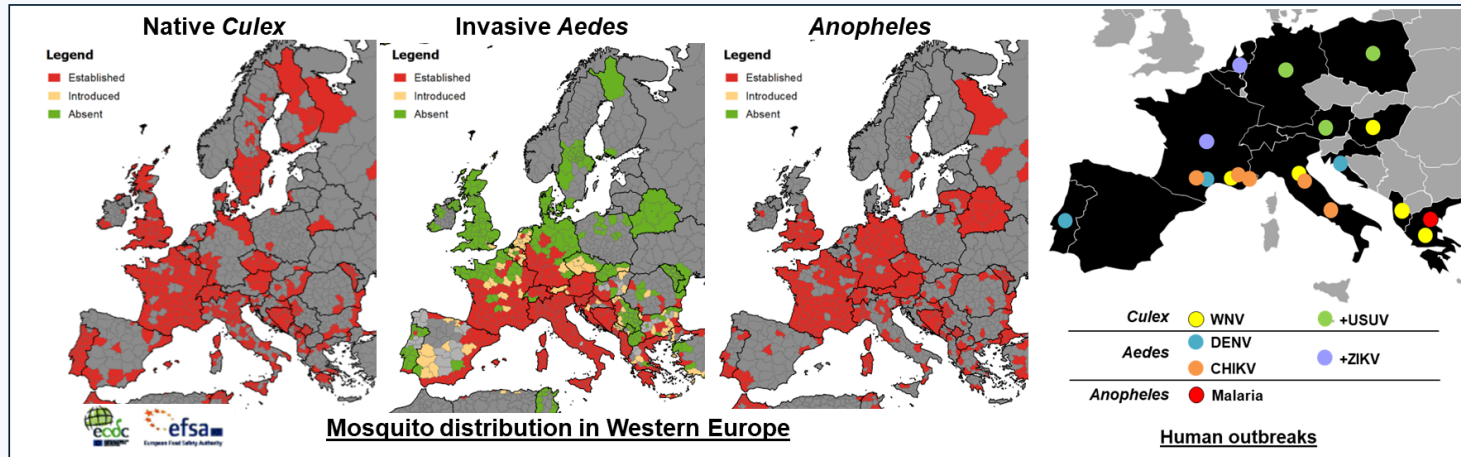
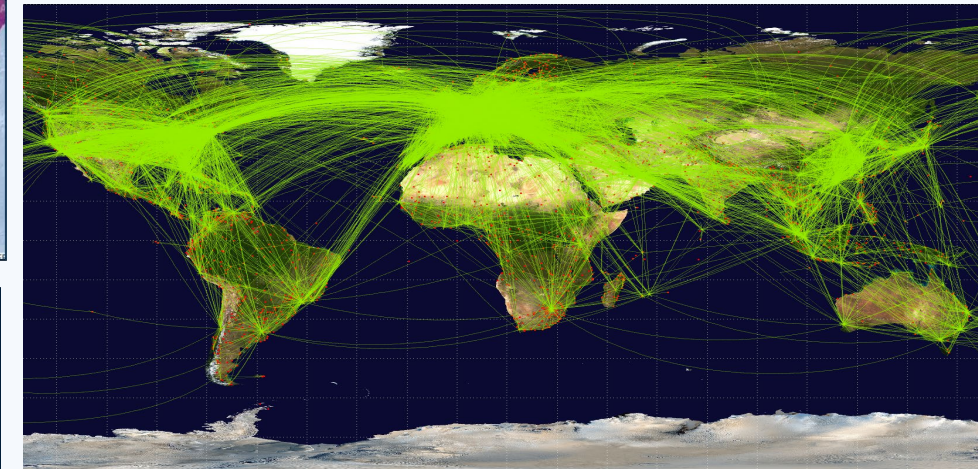
when >1 local DENV case / zip code

- Platelets are PR-treated and distributed
- RBC and plasma are quarantined
- Donors are called 7 days after donation to verify absence of symptoms
- If no symptoms or PDI after 7 days, quarantined products are released

The Risk with Mosquito-Borne-Agents



- Increasing frequency and diversity of EIDs
- Implementing blood screening one agent at a time may not be cost-efficient
- Deferrals, if feasible, impact blood availability



- Mosquito-borne EID are unpredictable
- Most probable in vector endemic areas
- ✓ Use multiplexed blood screening assays
- ✓ Use PR for preparedness

Maintaining Blood Availability with PR During Epidemics

Preparedness

Proactive

RAPID COMMUNICATIONS

Potential for Zika virus transmission through blood transfusion demonstrated during an outbreak in French Polynesia, November 2013 to February 2014

D Musso (dmusso@im-pf), T Nhan*, E Robier*, C Roche*, D Bierlaire*, K Zisour*, A Shan Yan*, V M Cao-Lormeau*, J Broult*

1. Unit of Emerging Infectious Diseases, Institut Louis Malardé, Tahiti, French Polynesia
2. Centre hospitalier du Taaoe, Tahiti, French Polynesia

Online ahead of print
Musso D, Nhan T, Robin E, Roche C, Bierlaire D, Zisour K, Shan Yan A, Cao-Lormeau VM, Broult J. Potential for Zika virus transmission through blood transfusion demonstrated during an outbreak in French Polynesia, November 2013 to February 2014. *Lancet Infect Dis*. 2014;14(4):e10. Available online: <http://www.eurosurveillance.org/ViewArticle.aspx?articleId=26276>

Article submitted on 31 March 2014 / published on 10 April 2014

Preparing for a potential outbreak of DENV/CHIKV, INTERCEPT for platelets was implemented in 2010. In 2013, ZIKV emerged. **"In areas endemic for Aedes species, a preparedness plan to respond to future outbreaks of ZIKV infection should include emergency plans to sustain blood supply."**

virus (ZIKV) serotypes 1 and 3 [3]. To the best of our knowledge, the occurrence of ZIKV infection resulting from transfusion of infected blood has not been investigated. Since other arboviruses have been reported to be transmitted by blood transfusion [4], several prevention procedures were implemented in date to prevent transfusion of ZIKAV through transmission in French Polynesia, including nucleic acid testing (NAT) of blood donors. We report here the detection of ZIKAV in 42 of 1,505 blood donors, who were asymptomatic at the time of blood donation.

Background
ZIKAV, an arthropod-borne virus (arbovirus) belonging to the family *Flaviviridae* and genus *Flavivirus* [5], was first isolated in 1947 from a monkey in the Zika forest, Uganda [6]. Sporadic human Zika fever cases have been reported since the 1960s [7]. The first documented outbreak outside Africa and Asia occurred in 2007 in the Yap State, Micronesia. In the North Pacific, where Zika fever was characterised by rash, conjunctivitis and arthralgia [8].

obtained from all blood donors and publication of data related to ZIKAV testing was approved by the Ethics Committee of French Polynesia (reference 46/CEPS).

ZIKAV nucleic acid testing (NAT) of samples of all donations was implemented routinely from 13 January 2014. In February, samples of donations collected from 21 November 2013 to 12 January 2014 were retrospectively tested. We report here the results of ZIKAV NAT for all donors who donated blood from 21 November 2013 to 17 February 2014.

Laboratory and clinical findings
On the basis of protocols implemented for WNV NAT [14], blood donor samples were tested in minipools. In order to increase the sensitivity of detection and to reduce the occurrence of false-negative results, sera from no more than three blood donors were included in each minipool.

Musso Eurosurveillance 2014

Scalable

COMMENTARY

Emergency response of four transfusion centers during the last Chikungunya outbreak in Italy

Luca Pierelli^{1,2}, Michele Vacca², Gina Zini³, Maddalena Maresca³, Giacomo Menichella⁴, Susanna Santinelli⁴, Maria Alba Stigliano⁵, Gabriele Mandarello⁶, Roberto Gasbarri⁶, and Stefania Vaglio⁷

2017 CHIKV outbreak in Rome:

- Quarantine for RBC and plasma (5 days)
- PR for platelets
 - 4 centers increased by 236% their production of PR-Platelets

"In large metropolitan areas, the chance to avoid PC quarantine for infectious outbreak by PR must be based on the presence of an adequate number of centers (at least 1 per 1,000,000 inhabitants) that have already PR in their production policy."

Regional Blood Center, Rome.
Address reprint requests to Prof. Luca Pierelli, Transfusion Medicine, San Camillo Forlanini Hospital, Cincione Giustolunge 87, 00152 Rome, Italy; e-mail: lpierelli@mc.com.
Received for publication February 6, 2018; revision received June 30, 2018; and accepted July 11, 2018.
doi:10.1111/ncf.14892
© 2018 AABB
TRANSFUSION 2018;58(3):2027–2030

Volume 58, December 2018 TRANSFUSION 3027

Pierelli Transfusion 2017

Strategic

MEETING REPORT

Pathogen reduction of blood components during outbreaks of infectious diseases in the European Union: an expert opinion from the European Centre for Disease Prevention and Control consultation meeting

Dragoslav Domanović¹, Ines Ushiro-Lumb², Veerle Compernelle³, Sergio Brusini⁴, Markus Funk⁴, Pierre Gallian⁵, Jørgen Georgsen⁶, Mart Janssen⁷, Teresa Jimenez-Marco⁸, Folke Knutson⁹, Giancarlo M. Liumbruno¹⁰, Polona Mali¹¹, Giuseppe Marano¹², Yuyun Maryuningsih¹³, Christoph Niederhauser¹⁴, Constantina Politis¹⁵, Simonetta Pupella¹⁶, Guy Rautmann¹⁷, Karim Saadat¹⁸, Inad Sandil¹⁹, Ana P. Sousa²⁰, Stefania Vaglio²¹, Claudio Velati²², Nicole Verdun²³, Miguel Vesga²⁴, Paolo Rebulla²⁵

¹European Centre for Disease Prevention and Control (ECDC), Stockholm, Sweden; ²National Transfusion Microbiology Reference Laboratory, NHS Blood and Transplant and Public Health England, London, England; ³Transfusion Research

Once PRT is in use, scale up is easier THEREFORE, a country at risk of EID may consider implementing PR technologies (at least partially in strategically selected blood centres) also to improve national capacity and capability to respond to outbreaks. The operational decision to implement PRT should, regardless of the benefits and limitations, consider above all the improvement in blood safety achieved by PR during a potential outbreak or epidemic.

most cases) laboratory screening of blood donations is not available. The meeting brought together 26 experts and representatives of national competent authorities for blood from thirteen European Union and European Economic Area (EU/EEA) Member States (45), Switzerland, the World Health Organization, the European Directorate for the Quality of Medicines and Health Care of the Council of Europe, the US Food and Drug Administration, and the ECDC. During the

applied to the blood supply, the risk of transfusion-transmitted infections (TTIs) is very low. Such strategies can largely, but not completely, prevent infectious blood from entering the blood supply. Despite the relatively rare occurrence of TTIs, the microbial safety of transfusion continues to arouse substantial medical, public and political interest. Blood safety is continuously challenged by the residual risk from existing blood-borne infections and the threat from newly emergent pathogens.

Blood Transfus 2019; 17: 433–48 DOI 10.2450/2019.0288-19
© 2019 CTS

All rights reserved – For personal use only
No other use without permission

433

Domanovic Blood Transfus. 2019

The Risk with Tick-Borne-Agents

Centers for Disease Control and Prevention

MMWR

Morbidity and Mortality Weekly Report

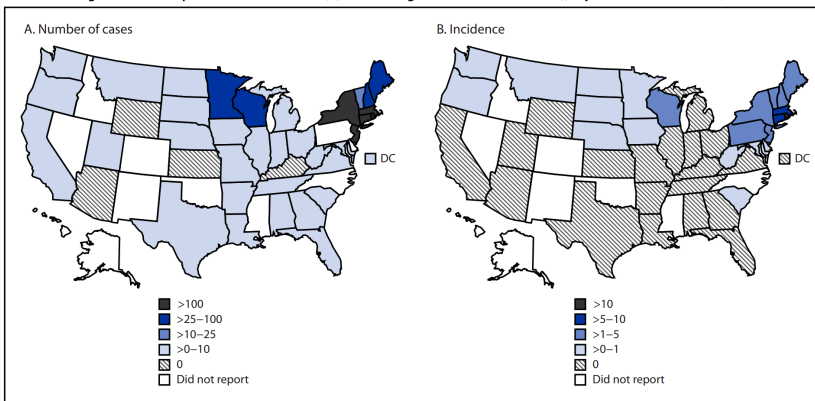
Weekly / Vol. 72 / No. 11

March 17, 2023

Trends in Reported Babesiosis Cases — United States, 2011–2019

Megan Swanson, MPH¹; Amy Pickrel, MS²; John Williamson, ScD¹; Susan Montgomery, DVM¹

FIGURE. Average number of reported babesiosis cases (A)* and average babesiosis incidence (B),* by state — United States, 2011–2019



What is added by this report?

During 2011–2019, U.S. babesiosis incidence significantly increased in northeastern states. **Three states (Maine, New Hampshire, and Vermont) that were not considered to have endemic babesiosis had significantly increasing incidences and reported case counts similar to or higher than those in the seven states with known endemic transmission.**

What are the implications for public health practice?

As case rates rise in multiple states, tick prevention messaging, provider education, and traveler risk awareness should be emphasized.

- Clinical cases
- vs. Asymptomatic cases
- FDA recommended blood donation screening in the following 15 states or jurisdictions:
 - Connecticut, Delaware, Maine, Maryland, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, Wisconsin, and D.C.

- Expanding blood screening (research) to neighboring states?
 - Multiplexed blood screening assays : *B. microti* vs. *B. duncani*
 - Public health surveillance

Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis

Guidance for Industry

Availability of Appropriate Screening Measures or Screening Tests

Licensed Screening Tests: On March 6, 2018, FDA licensed two independent assays for screening donors for *B. microti*: the Imugen *Babesia microti* Arrayed Fluorescent Immunoassay (AFIA) for the detection of *B. microti*-specific antibodies and the Imugen *Babesia microti* Nucleic Acid Test (NAT) for the detection of DNA of *B. microti*. However, the manufacturer notified FDA of the permanent discontinuance of both donor screening tests in November 2018. **On January 24, 2019, FDA licensed the Grifols Procleix Babesia Assay for the detection of RNA from *Babesia* species (*B. microti*, *B. duncani*, *B. divergens*, and *B. venatorum*) in whole blood specimens for use in screening donors of whole blood and blood components.**

Pathogen Reduction: FDA has approved **pathogen reduction** devices that report effective reduction of *B. microti* for indicated plasma or platelet components in the instructions for use, which can be used **as an alternative to testing or donor questions.**

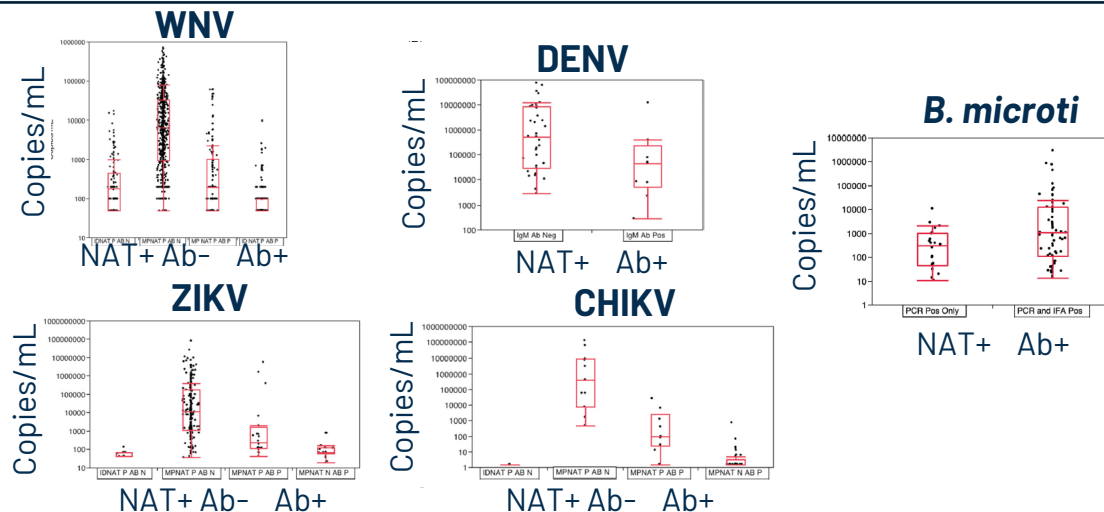
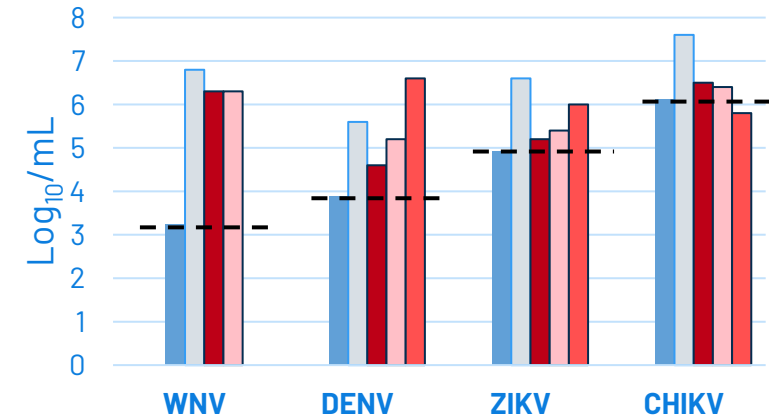
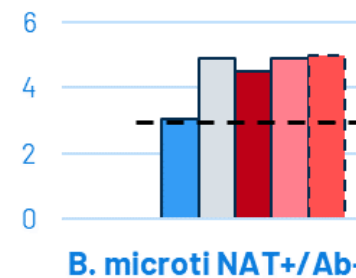
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
May 2019

Susan L. Stramer¹ | Marion C. Lanteri² | Jaye P. Brodsky³ |
 Gregory A. Foster¹ | David E. Kryzstof¹ | Jamel A. Groves¹ |
 Rebecca L. Townsend¹ | Edward Notari⁴ | Sonia Bakkour⁵ | Mars Stone⁵ |
 Graham Simmons⁵ | Bryan Spencer⁶ | Laura Tonnetti⁴ | Michael P. Busch⁵

TRANSFUSION

Mitigating the risk of transfusion-transmitted infections with vector-borne agents solely by means of pathogen reduction

Methods: Antibody (Ab) status and pathogen loads (copies/mL) were obtained for donations from US blood donors testing nucleic acid (NAT)-positive for WNV, DENV, ZIKV, CHIKV, and *B. microti*. Infectivity titers derived from pathogen loads were compared to published PRT log₁₀ reduction factors (LRF); LRFs were also reviewed for *Plasmodium* and *T. cruzi*. The potential positive impact on donor retention following removal of deferrals from required questioning and testing for WNV, *Babesia*, *Plasmodium*, and *T. cruzi* was estimated for American Red Cross (ARC) donors.



Pathogen	Highest genomic load (log ₁₀ copies/mL)	Projected ratio infectivity: GEq ^a	Projected highest infectious titers (log ₁₀ copies/mL)	Log reduction factors (log ₁₀ copies/mL)			
				Plasma	Platelets	100% plasma	65% PAS/35% plasma
WNV	7.2 × 10 ⁵ (5.85)	1:400	1800 (3.25)	≥ 6.8 ¹⁹	> 6.3 ²	≥ 6.3 ²	N/A
DENV	7.79 × 10 ⁷ (7.89)	1:10 ⁴	7790 (3.89)	> 5.6 ²⁰	> 4.6 ²¹	> 4.1 ²¹	> 6.6 ²²
ZIKV	8.3 × 10 ⁷ (7.92)	1:10 ³	83,565 (4.92)	> 6.6 ²³	> 5.2 ²⁴	> 5.4 ²⁴	> 6.0 ²⁵
CHIKV	1.3 × 10 ⁸ (8.11)	1:100	1.3 × 10 ⁶ (6.11)	≥ 7.6 ²⁶	> 6.5 ²	> 6.4 ²⁶	> 5.8 ²⁷
<i>Babesia microti</i>	11,022 (4.04)	1:100	110.2 (2.04)	≥ 4.9 ¹	> 4.5 ^{2,28}	≥ 4.9 ²	> 5.0 ²⁸
<i>B. microti</i> NAT+/Ab-	2.99 × 10 ⁶ (6.47)	1:100	29,906 (4.48)	> 6.5 ¹	> 6.5 ²	≥ 6.6 ²	> 5.2 ²⁹
<i>Trypanosoma cruzi</i>	> 6.7 ¹	> 8.4 ²	≥ 7.8 ²	N/A			

➤ PR can reduce the levels of WNV, DENV, ZIKV, CHIKV and *B. microti* characterized in blood donors

Increasing Blood Availability

- FDA allows PR as an alternative to:
 - Screening for Babesia, in addition to bacteria and CMV
 - Donor deferrals for Babesia, and most recently malaria

TABLE 4 Number of donors deferred for risk of infection with or testing reactive for vector-borne pathogens at the American Red Cross in 2019^a

Vector-borne agent	Available U.S. mitigation options	Number of deferred donors	Number of additional platelet donations with A/UVA PRT ^b	Number of additional RBC donations with S-303/GSH PRT ^b
WNV	MP-NAT/ID-NAT	45	5	40
<i>Babesia</i>	Deferral, ID-NAT, PRT	89	9	80
<i>Plasmodium</i>	Deferral due to travel, PRT	26,673	2667	24,006
<i>Trypanosoma cruzi</i>	Deferral, first time serology	951	95	856
Total		27,758 ^c	2776	24,982

^aThe number of donations from ARC blood donors deferred in 2019, as required by FDA guidance due to affirmative responses to donor questioning for risk of *Plasmodium* infection due to travel and those deferred due to reactive results following testing by NAT or antibodies to WNV, *Babesia*, or *T. cruzi* are reported.

^bBased on 10.35% of all collections during 2019 at the ARC representing platelet donors (476,752 collections involving apheresis-derived platelets/4,605,660 total collections including 4,128,908 involving whole blood or apheresis-derived red cells).

^c1.79 donations/donor based on 4,605,660 donations in 2019 from 2,574,695 donors.

➤ PR may provide an opportunity to replace deferrals associated with donor questioning for vector-borne agents allowing for significant donor retention and likely increased blood availability

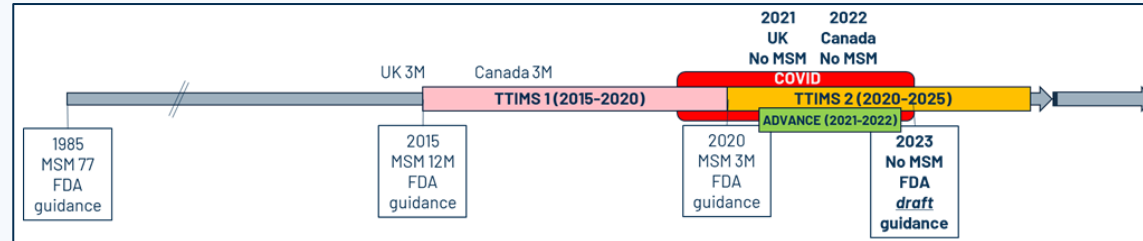
Gaps and Cumulative Benefits

Classic Agents



Progresses in HIV Prevention and Treatment - Impact on Blood Screening

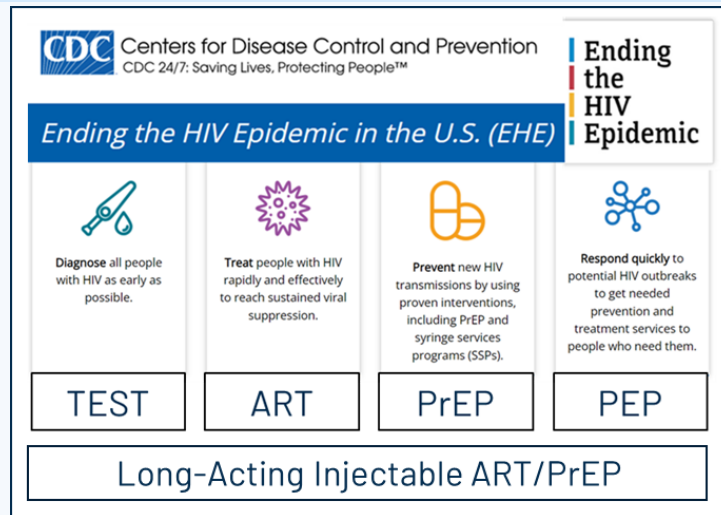
MSM deferrals have been relaxed to increase donor inclusion and blood availability



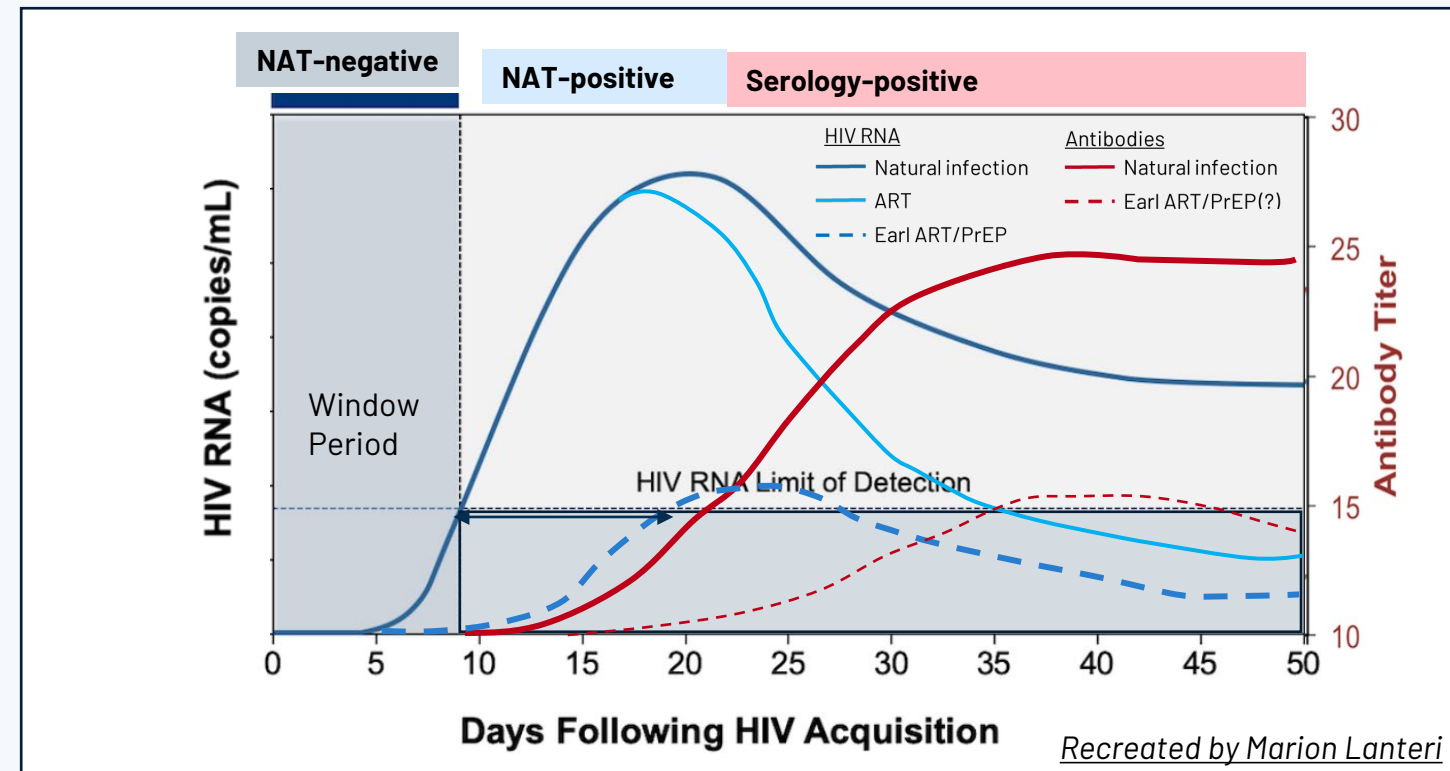
Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products

Draft Guidance for Industry

- Residual risk with window period infections
 - DHQ questions about sexual risk



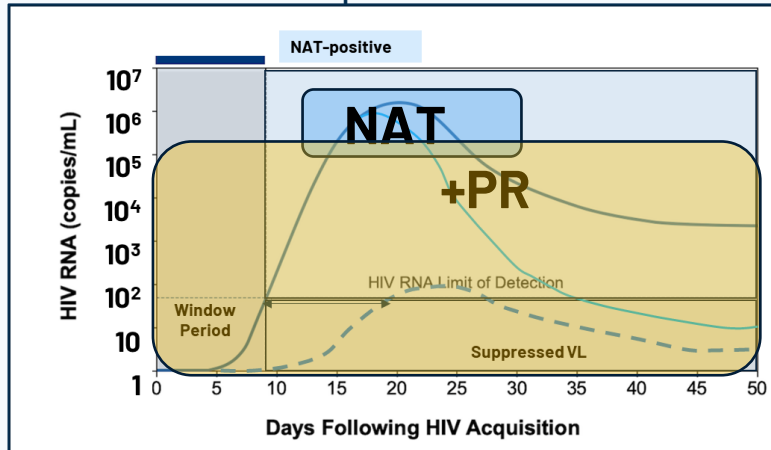
- Risk with ARV intake → suppressed viral loads
 - DHQ questions about drug intake
- Non-compliance
- U=U (sexually) vs. U≠U (transfusion)



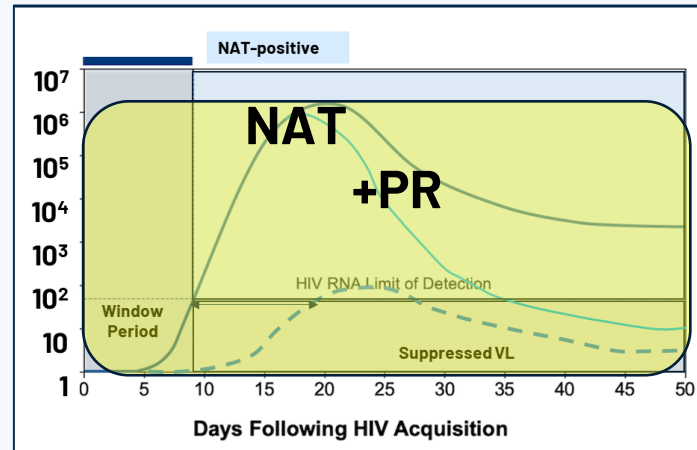
Using PR to cover current limitations

- To cover current limitations
 - Donor selection
 - Non-compliance
 - Recent risk / ARV
 - Blood screening
 - Window Period
 - ART suppressed
- Preparedness (e.g. Monkeypox) ➤ Accepting more donors

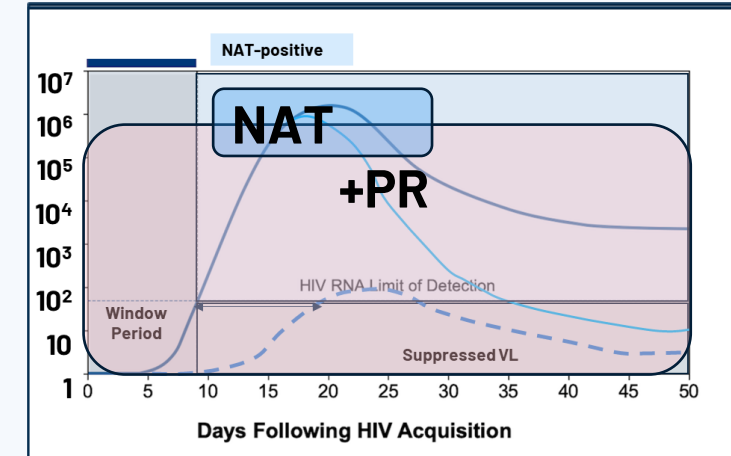
LRF ≥ 5.4 for platelets in PAS



LRF > 6.2 for plasma



RBC PR is not yet available



- With universal PR
 - Remove more deferrals for all
- 2023 ISBT abstract (Domingue et al.)
 - "Using pathogen reduction and blood screening to mitigate HIV, HBV, and HCV transfusion-transmitted infections after changing sexual behavior deferrals."

The Future of Blood Screening With Universal PR

+ HEV?

Can we simplify routine testing ? Using PR +NAT

Pathogen	Serology-Based Screen + Confirmatory	Nucleic Acid-Based Screen + Confirmatory
HIV-1/2	Possible discontinuation of serology-based screening?	NAT for agents not inactivated by PR NAT in larger pools? Multiplexing NAT?
HCV		
HBV		
HTLV-I/II		
<i>T. pallidum</i>		
WNV		
<i>Babesia</i>		
<i>T. cruzi</i> *		
CMV*		
Total		

Blood Safety and Availability

- The problem with EID
 - Unpredictable
 - Deferrals impacts blood availability, donor retention, recruitment
- EID outbreaks will continue
 - Climate change
 - Travels
- Pathogen reduction
 - Broad spectrum inactivation
 - Bacteria, viruses, parasites, leukocytes
 - Platelet sustainability during outbreaks
 - CHIKV, DENV, ZIKV
 - Plasma safety
 - CCP during COVID-19 pandemic
 - PR-Cryo
 - Preparedness
 - Scalable strategic approach
 - Deferrals can be relaxed
 - Malaria/babesia/ZIKV/WNV/HIV/Vaccines
 - To increase donor inclusion/blood availability
 - Not available for RBC
- Universal PR
 - Change of paradigm in blood safety
 - Relaxing deferrals/screening
 - Increasing blood availability
- Blood screening:
 - A pillar of blood safety
 - Viruses, parasites
 - Decreased risk of TTI
 - <1 in 2 million
 - Can be multiplexed
 - Decreased cost
 - Allows for surveillance
 - Prevalence/Incidence
 - Risk of TTI
 - Public Health surveillance

➤ PR+NAT

Acknowledgements

- Creative Testing Solutions:
 - 1,000 employees, 8 labs., R&D
 - CEO Sally Caglioti / COO Phillip Williamson
- Vitalant Research Institute (VRI)
 - Michael Busch / Brian Custer and teams
 - Cores (epidemiology, biorepository, molecular, Immunology)
- American Red Cross
 - Susan Stramer and team
- OneBlood
 - Rita Reik and team
- Funding organizations:
 - FDA/NIH
 - NHLBI
 - CDC
- Industry partners
 - Blood screening assays
 - Diagnostics
 - Pathogen Reduction
- Academic collaborators
 - US
 - Brazil / South Africa
 - IPFA
 - AABB: Association for the Advancement of Blood & Biotherapies
 - ISBT: International Society for Blood Transfusion

Italian Gelato!

We'll go for more tomorrow (come with us...)



Galleria 63

