



***Completing the Picture –
Attaining a Safe, Sustainable Blood
Supply with Pathogen Inactivation***

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Chief Scientific Officer, CERUS

IPFA PEI, May 17, 2017

Blood Safety and the Cerus Mission



Blood transfusion is a critical supportive therapy for healthcare – for all people

- >70 million transfusions per year



Blood transfusion can transmit infectious diseases

- HIV, HBV, HCV, WNV, DENV, CHIKV, ZIKV, etc.

Our Mission

Cerus will establish INTERCEPT as the standard of care for transfused blood components globally and enable our customers to do everything in their power to deliver safe and effective blood products to patients.



Blood should be:

- Available when needed
- Required to be safe for transfusion



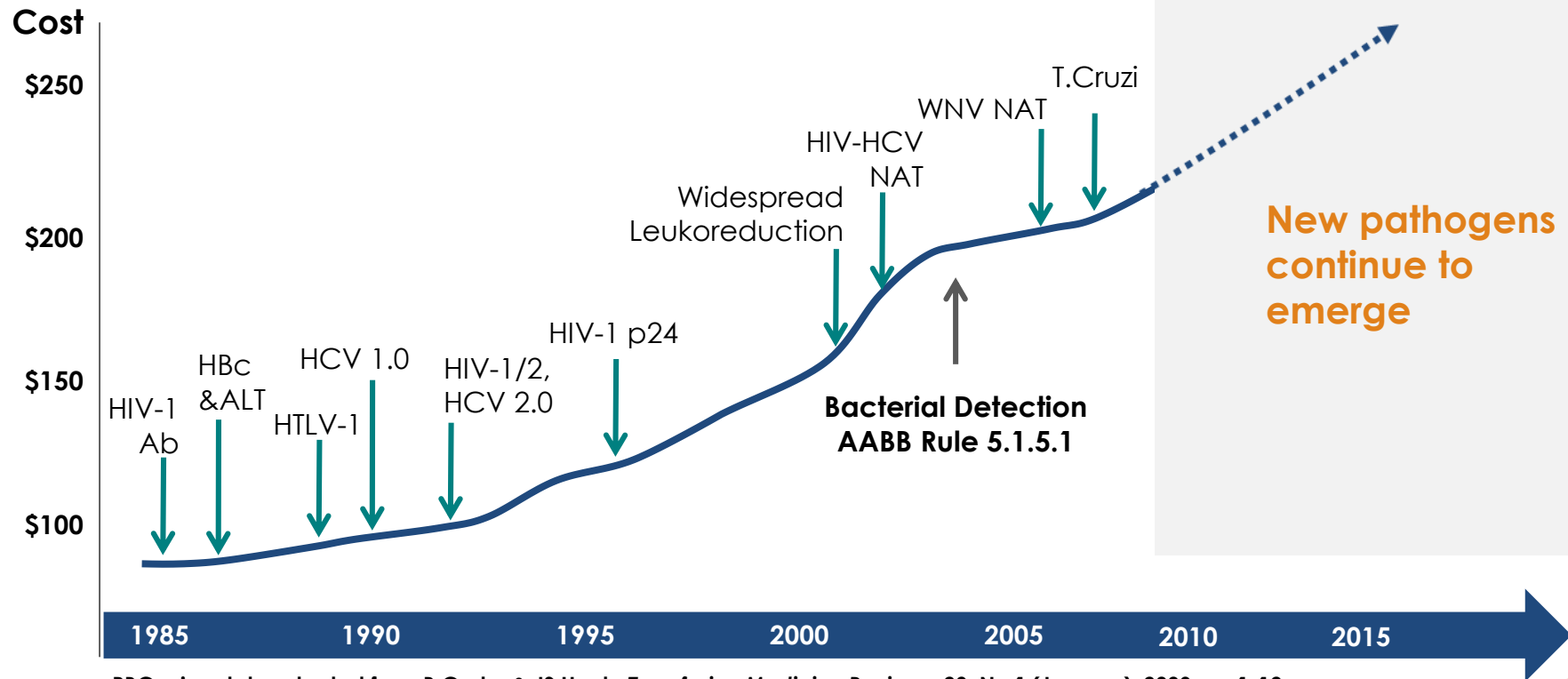
Blood safety standards are evolving based on recommendations from leading industry groups

Emerging Pathogens: Is testing a sustainable solution?

Development time, cost, continual addition of new pathogens

30 years of development = protection against 9 agents

HIV, Hepatitis B, Hepatitis C, HTLV, bacteria, West Nile virus, T. Cruzi, Syphilis, Leukocytes



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

2003

Pathogen Inactivation

Risks to Blood Safety and Supply: Emerging Pathogens

- Emergence of Pathogens is Unpredictable¹⁻³
 - Globalization, climate change (increase spread of *Aedes* spp. and arboviruses)
 - Adaptation of vectors to new areas, hosts
 - Viral mutation - small change in virus could improve mosquito transmission
- Deferrals are the primary mitigation tactic; tests take time to develop.³
- Live viral vaccines require one month deferral
- Impacts platelet availability – product importation to affected areas.^{4,5}
- Deferrals lead to difficulties in donor retention, recruitment.⁶

Recent Arboviral Outbreaks in Europe⁷⁻¹⁴

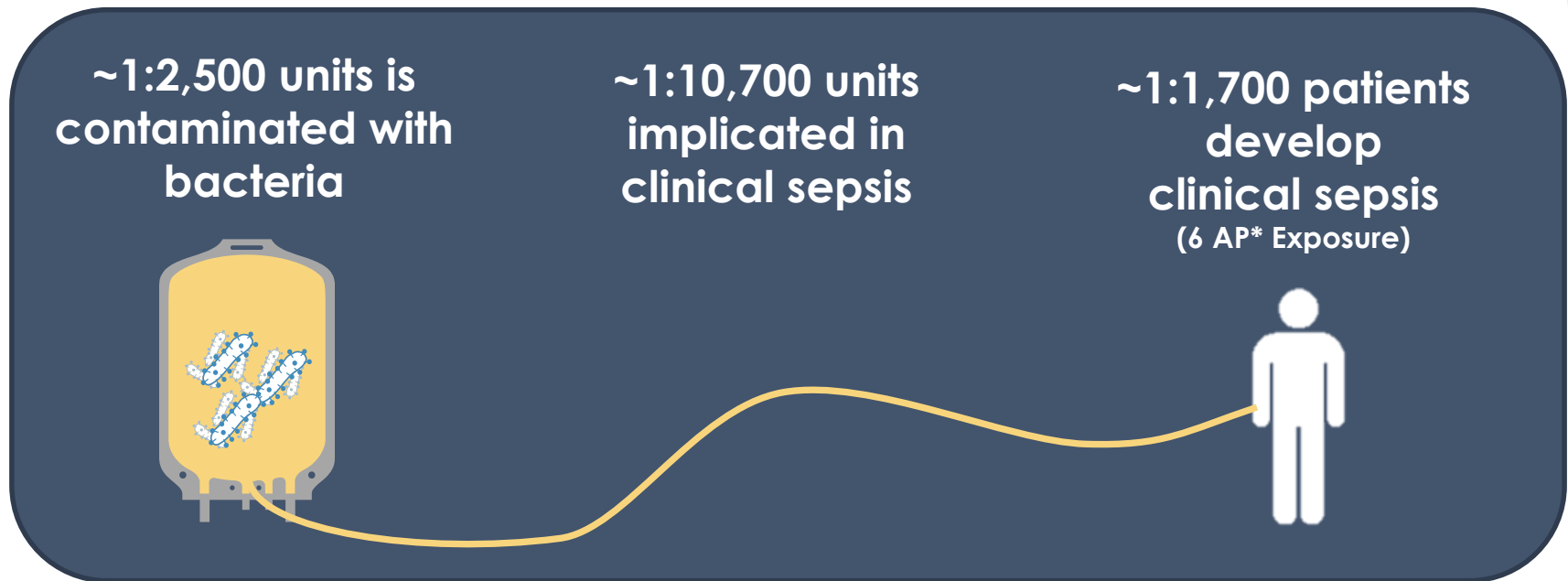
Year	Area	Arbovirus
2015	Nimes, France	Dengue
2014	Montpellier, France	Chikungunya
2012/2013	Madeira, Portugal	Dengue
2010	Croatia	Dengue
2010/2011	Greece	WNV
2008-2010	Italy	WNV
2008	Hungary	WNV
2007	Emilia-Romagna, Italy	Chikungunya

1. Lui Helmersson J et al. EBioMedicine 2016;7:267-277.
2. Tssetsarkin KA et al. PLoS Pathog 2007;3(12):e201.
3. Schmidt M et al. Transfus Med Hemother 2014;41:10-17.
4. Liumbruno GM et al. Blood Transfus. 2008 Oct; 6(4): 199–210.
5. Rasongles P, et al. Transfusion 2009;49:1083-91.
6. Custer B et al. Transfusion 2007;47:1514-1523.
7. Succo T et al. Euro Surveill. 2016 May 26;21(21).
8. Delisle E et al. Euro Surveill. 2015 Apr 30;20(17).
9. Dengue outbreak in Madeira, Portugal, Oct–Nov 2012. Stockholm: ECDC; 2013.
10. Gjenero-Margan I et al. Euro Surveill. 2010 Sep 2;15(35).
11. Danis K et al. Euro Surveill. 2011 Aug 25;16(34).
12. Barzon L et al. Euro Surveill. 2009 Aug 6;14(31).
13. Krisztalovics K et al. Euro Surveill. 2008 Nov 6;13(45).
14. Carrieri et al. J Vector Ecol. 2011 Jun;36(1):108-16.



Risks to Blood Safety and Supply: TA-Sepsis is Under Reported Due to Passive vs. Active Surveillance

- Platelets contaminated with bacteria continue to be transfused despite use of early culture.¹⁻⁵
- Transfusion-related sepsis is greatly under-reported due to passive vs. active surveillance methods. Patient risk is 10- to 40-fold higher when comparing active vs. passive surveillance.⁵



¹Dumont, LJ et al. *Transfusion*. 2010 Mar;50(3):589–99. |

²Pearce, S et al. *Transfus Med*. 2011 Feb;21(1):25–32.

³Murphy, WG et al. *Vox Sang*. 2008 Jul;95(1):13–9.

⁴Walther-Wenke, G et al. *Vox Sang*. 2011 May;100(4):359–66. |

⁵Hong H, et al. *Blood*. 2016;127(4):496–502.

*Apheresis platelet unit

Reactive Approaches Alone Have Limits

Published July 2016

EDITORIAL

Assuring blood safety and availability: Zika virus, the latest emerging infectious disease battlefield

Threats to blood safety from infectious agents, and subsequent public health action, are hardly novel. Transfusion transmission of *Treponema pallidum*, the etiologic agent of syphilis, was recognized in the early 20th century soon after the first successful transfusions, and in response, donor tests for syphilis-related antibodies were introduced.¹ Later in the 1960s, hepatitis B virus was found to cause posttransfusion jaundice, and sensitive donor screening tests for hepatitis B surface antigen (HBsAg) were added to donor testing in the early 1970s. The AIDS epidemic in the 1980s presented an entirely new kind of challenge to blood safety, with the need to respond urgently to a newly emerging blood-borne and sexually transmitted infection with catastrophic implications. A massive scientific and public health response to AIDS resulted in discovery of human immunodeficiency virus (HIV) as the etiologic agent and then licensure of blood donor screening tests a year later. Since the emergence of HIV, numerous recognized and emerging blood safety concerns (e.g., human T-lymphotropic virus, hepatitis C virus [HCV], cytomegalovirus, malaria, variant Creutzfeldt-Jakob disease, Chagas disease, and bacterial contamination) have been addressed by a multitiered approach comprising donor deferrals through education and risk factor-based screening with questionnaires; a limited physical examination; use of deferral registries to prevent future unsuitable collections; laboratory testing for markers of infection including nucleic acid tests (NATs) for some agents; and use of pathogen reduction technologies (PRTs) for certain blood components, all within a system highly regulated by the US Food and Drug Administration (FDA). Nevertheless, more recently emerging threats, including arboviruses and parasites, have presented novel challenges related to unpredictable local vector-borne spread and have exposed continued vulnerabilities to blood safety that call for urgent action.

Arboviruses, transmitted by arthropods (primarily mosquitoes), are relatively new emerging threats to

blood safety and present a particular challenge due to rapid and large-scale epidemics affecting the United States and its territories. While more than 100 pathogenic arboviruses are known to exist and some, particularly yellow fever and dengue, have been associated with outbreaks historically in the continental United States, none has caused recent outbreaks before the emergence of West Nile virus (WNV) in 2002. Unlike typical blood-borne viruses such as hepatitis viruses and HIV, which establish chronic infections, arboviruses cause predominantly acute infections, thus presenting a threat to blood safety only while a donor is transiently viremic, either during the disease incubation period or with an asymptomatic or a mild, undetected symptomatic infection. The challenge arises from rapid epidemic spread of an arbovirus in new geographic areas, resulting in immediate safety risks to the blood supply and an urgent need for intervention. Additionally, direct viral detection in donated blood, a generally costly measure, is needed since testing for antibodies, which take time to develop after infection and persist, would fail to interdict most infectious donations and result in deferral of large numbers of acceptable donors with previously resolved infections.

The US WNV epidemic was the first example of a large-scale arboviral threat to the US blood supply, requiring an urgent response across government and nongovernment agencies. Beginning with reports in August 2002 of a WNV infection acquired by organ transplantation, ultimately being traced to a WNV-infected blood transfusion received by the organ donor, awareness of a rapidly spreading vector-borne, transfusion-transmitted agent associated with morbidity (e.g., neurologic disease) and mortality led to calls for blood donor screening tests for WNV.² Collaborations among federal agencies, state public health laboratories, blood collection organizations, and test kit manufacturers led to the availability of investigational donor screening tests within 7 months of a November 2002 workshop in which consensus had been reached on the urgency and path forward. Fortunately, WNV isolates had been sequenced and were available for sharing, and technology platforms for NAT of blood donations for HIV and HCV could be readily adapted to WNV by the manufacturers. WNV has since become endemic in the United States, necessitating an indefinite program of donation testing. A decade later, there have been regional outbreaks of other arboviral diseases, namely chikungunya,

“Interventions are needed that are both precautionary and independent of the specific threat such as PRT for all blood components”

Kuehnert MJ and Epstein JS. *Transfusion*. July 2016.

■ Reactive approaches like testing are problematic:

- Delayed implementation due to development time, regulatory reviews, etc.
- Potential cost/logistics impact due to additive testing

ing Zika virus epidemic. More broadly, as increasing numbers of emerging infections threaten blood safety, progressive addition of donor screening tests targeting individual pathogens has become problematic for many reasons, including uncertainty and delay in their implementation as well as increased costs for and impacts on blood center logistics. A new paradigm is needed!

The conclusions, findings, and opinions expressed by authors contributing to this work do not necessarily reflect the official position of the U.S. Department of Health and Human Services, the Public Health Service, the Centers for Disease Control and Prevention, or the Food and Drug Administration.

doi:10.1111/trf.13673

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TRANSFUSION 2016;56:1669–1672

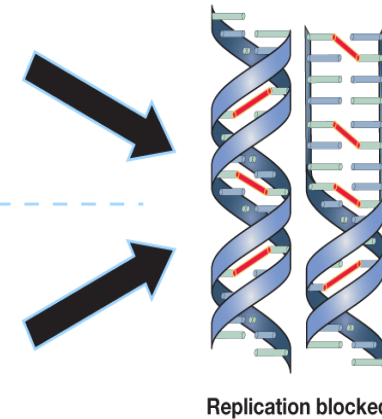
Contents

- Risks to Blood Safety and Sustainability
- **Addressing the Need:
The INTERCEPT Blood System**
- Moving Toward a Complete Solution
- Conclusion

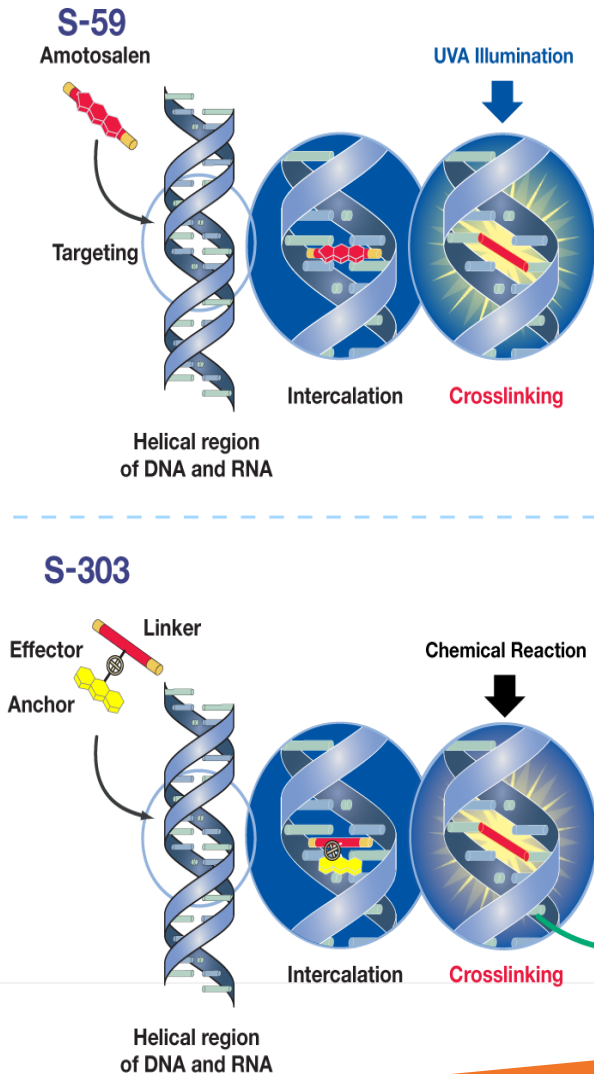
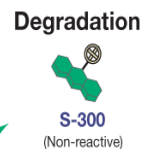
Mechanisms of Action of INTERCEPT Technologies

Platelets & Plasma

Separate technologies to **optimize pathogen inactivation** with conservation of functional activity through nucleic acid targeting without reactive oxygen species

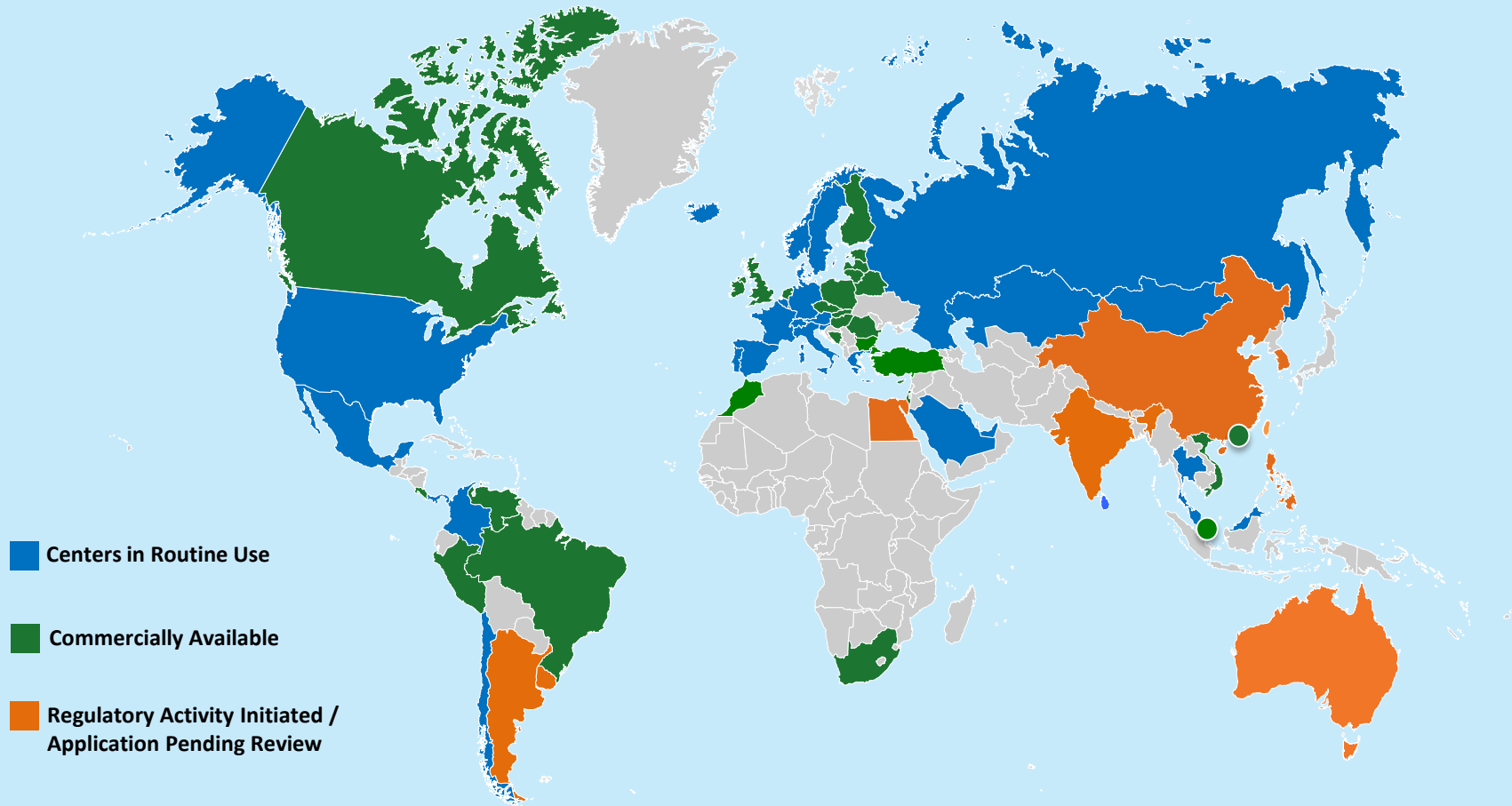


Red Cells



INTERCEPT Blood System for Platelets & Plasma : Global Status

- More than **10** years of routine use
- Kits sold to produce **> 4,000,000** INTERCEPT platelet and plasma units
- Used in **>150** Blood Centers in **25** countries

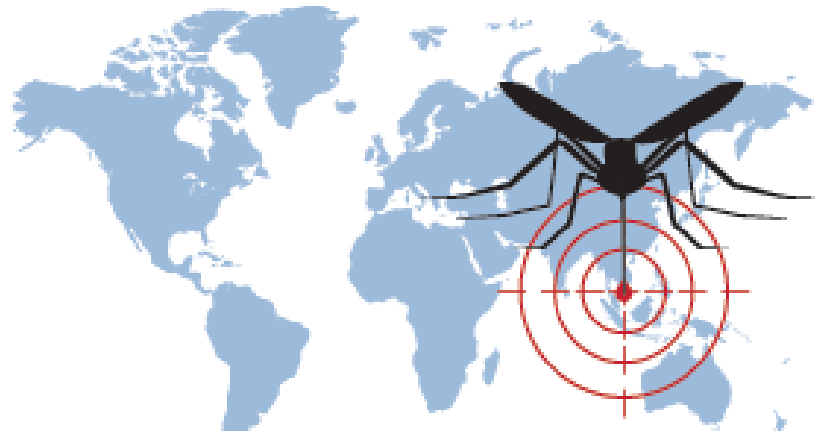


Last update: March 2017

The INTERCEPT Blood System: Maintaining Safe and Adequate Supply During Arboviral Outbreaks

INTERCEPT has been called upon to sustain platelet availability during arboviral outbreaks:

- 2005 CHIKV epidemic on Ile de La Réunion, France.¹
- 2010 DENV/CHIKV outbreaks in Guadeloupe and Martinique, French Polynesia.²
- 2013/2014 French Polynesia able to proactively address Zika outbreak with PI.²
- 2014 CHIKV and DENV outbreaks in the Caribbean region.³
- 2016 ZIKV outbreak in Puerto Rico.⁴



1. Rasongles P, et al. *Transfusion* 2009;49:1083-91. 2. Bierlaire D, et al. *Transfusion* 2017. 3. Rico S, et al. BMT Tandem Meeting; February 2016. 4. Weiner E, et al. AABB 2016, SP454. 5. WHO Interim guidance WHO/ZIKV/HS/16.1 February 2016. 5. FDA Guidance for Industry August 2016.

Demonstrated Safety in Routine Use: Hemovigilance Programs

	>400,000 INTERCEPT Platelets Evaluated in Routine Use		
	French National Hemovigilance ¹	Swiss National Hemovigilance ²	Multicenter Cerus HV ³
# INTERCEPT Platelet Transfusions	214,293 ¹	167,200 ²	19,175
# Patients Receiving INTERCEPT Platelets	~36,000	~28,000	4,067
INTERCEPT ATR Rate	~0.3% ⁴	~0.3% ²	~0.6%
Conventional ATR Rate	~0.3% ⁴	~0.4% ²	NA

1. 2006-2008 Transfusion Data: Cazenave, J. P., Isola, A., Kientz, D. (2013). Pathogen Inactivation of Platelets. Platelet Transfusion Therapy (pp. 159). Bethesda, MD: AABB Press. 2009-2015 Transfusion Data: French National Agency for Medicine and Health Product Safety/ANSM, Hemovigilance Activity Reports

2. SwissMedic Haemovigilance Annual Report 2015.

3. Knutson F et al. Vox Sanguinis 2015.

4. French National Agency for Medicine and Health Product Safety/ANSM, Hemovigilance Activity Reports, 2009-2011.

Integration of Pathogen Reduction into US Policy:

As option to replace of certain tests and/or procedures

RISK	GUIDANCE OR STANDARD	PATHOGEN REDUCTION TECHNOLOGY (PRT)
 Bacterial Contamination	FDA Draft Guidance: ¹ Recommends PRT or bacterial testing	PRT can eliminate the need for primary and secondary testing, including rapid testing.
	AABB Standard 5.1.5.2: ² Methods required to detect bacteria or use PRT in platelet components	PRT can be used as an alternative to bacterial detection.
 ZIKA Virus TTI	ECDC Guidance for Zika WHO Guidance Revised FDA Guidance for Zika ³ Recommend testing, import or PRT	PRT can be used in place of Zika testing for platelet and plasma components.**
 CMV TTI	AABB Standard 5.19.2: ² Policy required to reduce the risk of CMV	INTERCEPT PRT demonstrates inactivation of CMV in platelets in PAS-3 with ≥ 4.9 pfu/mL log reduction. ⁶
 TA-GVHD*	AABB Standard 5.19.3.1: ² Methods known to prevent TA-GVHD required; include irradiation or PRT	PRT meets AABB standard which allows for irradiation or Pathogen Reduction.

*Transfusion-Associated Graft vs. Host Disease

**Data for pathogen reduction of ZIKA by the INTERCEPT Blood System, pathogen reduction system, has not been submitted for FDA review.

1. "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion," FDA Draft Guidance for Industry, March 2016.

2. "Standards for Blood Banks and Transfusion Services," AABB, 30th edition, 2015.

3. "Zika Virus and Safety of Substances of Human Origin," ECDC, July 2016.

4. "Maintaining a safe and adequate blood supply during Zika virus outbreaks. Interim guidance. WHO, February 2016.

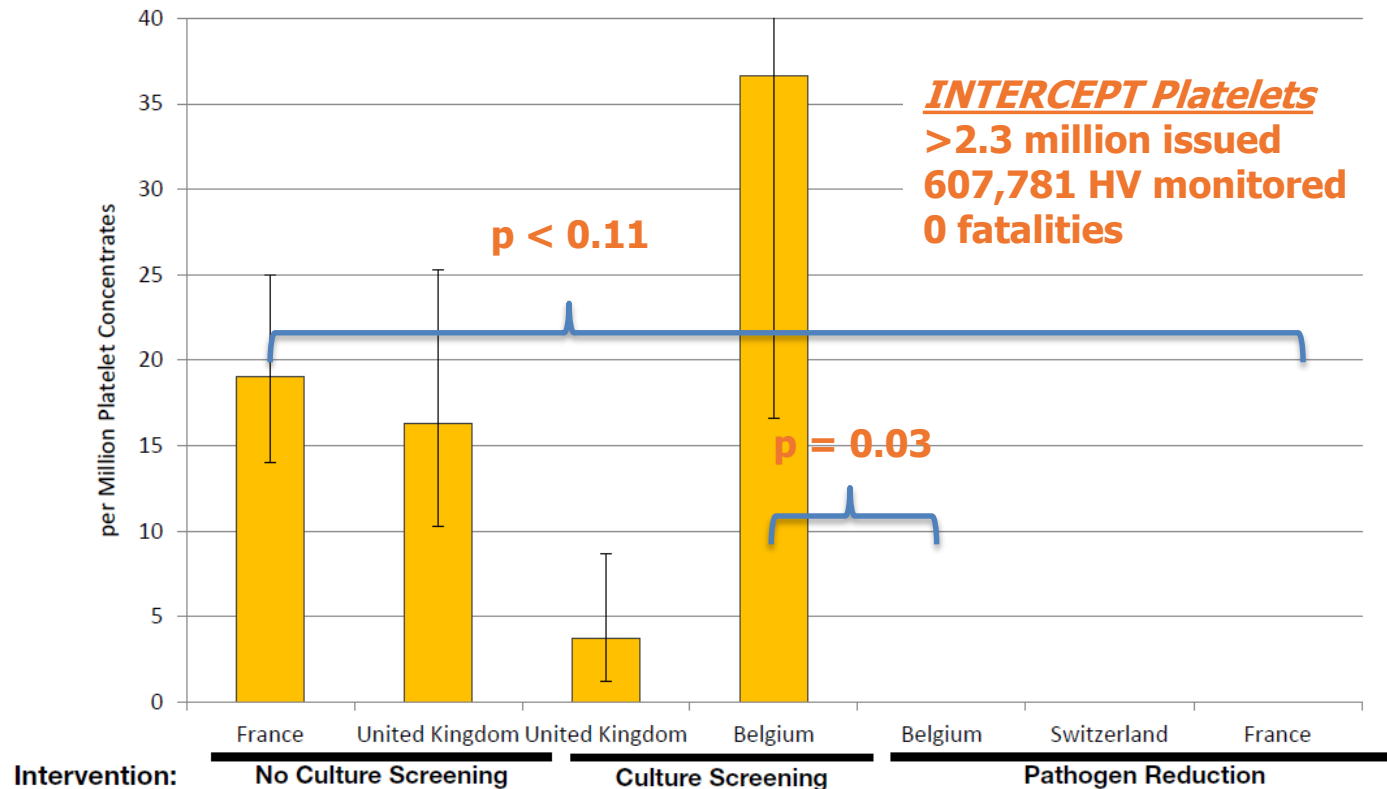
5. "Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus," FDA Guidance for Industry, August 2016.

6. The INTERCEPT Blood System for Platelets Package Insert, Cerus Corporation; Mar 15, 2016.

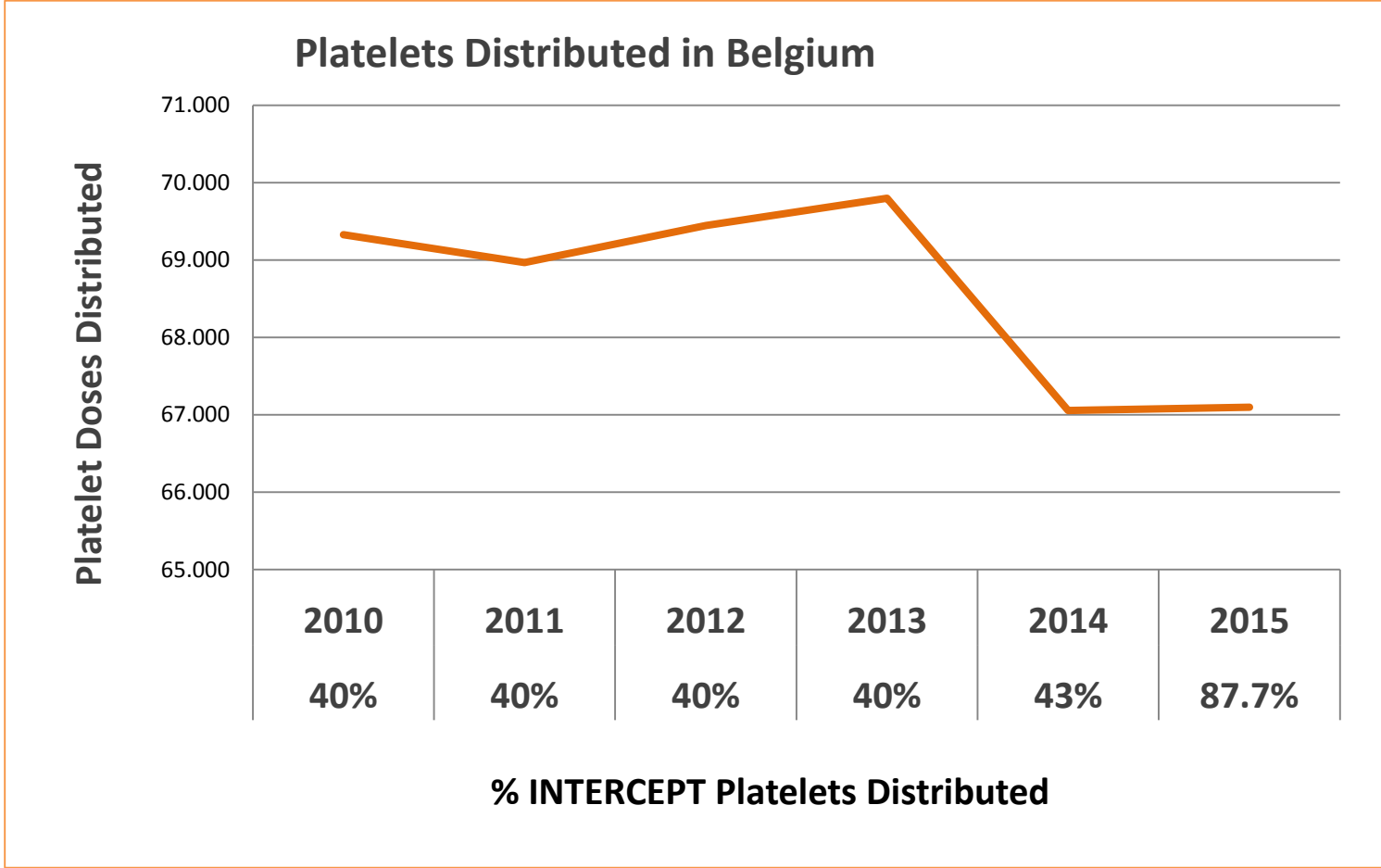
Proven Efficacy of INTERCEPT Platelets in Bacterial Sepsis Risk Reduction

French, Belgian and Swiss Hemovigilance Programs 2006 - 2015

Figure 2: Rates Per Million (95% Confidence Intervals) of Bacterial Contamination of Platelet Concentrates Detected by Septic Transfusion Reactions or Bedside Surveillance, and Reported to National Hemovigilance Programs



Platelet Usage in Belgium has not Increased Concurrent with INTERCEPT Platelet Implementation



Here, Now: INTERCEPT Platelets, Plasma are Established and Proven in Routine Use

No Increase in Platelet, RBC Utilization with INTERCEPT Routine Use Experience in Innsbruck, Austria¹

- Platelet and RBC use were comparable between INTERCEPT and control arms.
- Adverse reaction rates were similar between the INTERCEPT and control periods for the general population (C 1.3%, 1.4%), Hem-Onc (C 4.2%, T 4.4%), cardiac surgery patients (C 0, T 0.1%).

Study Summary

Arm (Time Period)	# Patients	# Transfusions
INTERCEPT-Treated Platelets (April 2013-Dec. 2014)	1694	7705
Conventional Platelets(April 2011-Dec. 2012)	1797	8611

Comparable Utilization of Platelet and RBC Components²

Patient Population	# Platelets Transfused		# RBCs transfused	
	Conventional Mean ± SD	INTERCEPT-Treated Mean ± SD	Conventional Mean ± SD	INTERCEPT-Treated Mean ± SD
Total	4.8 ± 9.7	4.5 ± 8.9	10.8 ± 15.3	10.2 ± 13.9
Hem-Onc	9.8 ± 15.7	9.0 ± 15.3	13.7 ± 18.8	13.0 ± 17.0
Cardiac Surgery	2.5 ± 4.0	2.6 ± 3.2	7.3 ± 12.5	7.1 ± 10.7
Pediatric	7.3 ± 16.0	4.1 ± 6.4	7.7 ± 9.7	6.3 ± 5.9
Neonate	2.7 ± 3.1	2.8 ± 3.1	4.1 ± 6.7	5.1 ± 5.8
Massive Transfusion³	3.0 ± 2.1	3.3 ± 2.0	16.4 ± 7.4	16.2 ± 7.3

1. Amato M et al. Vox Sanguinis 2016.

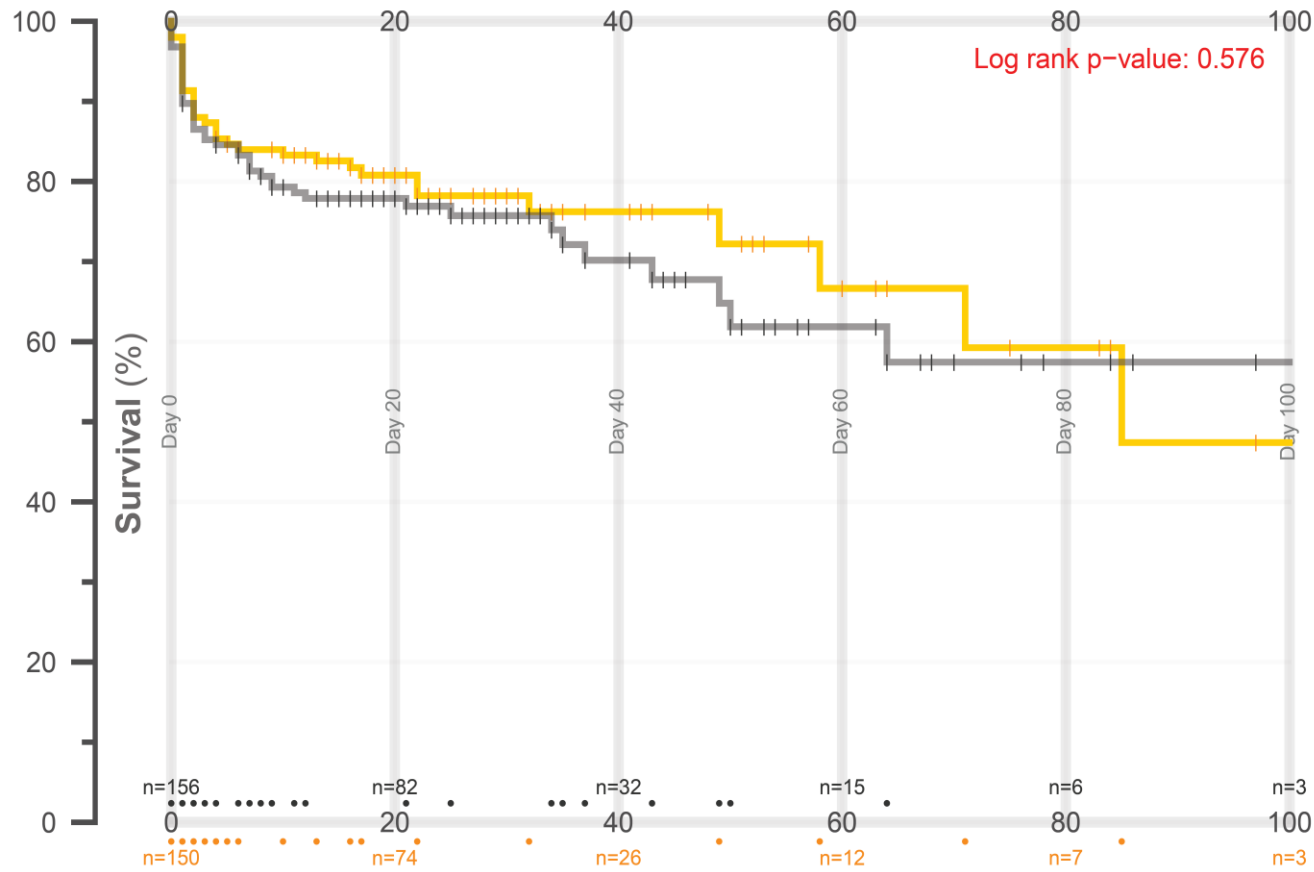
2. P value > 0.05 for all, with exception of Pediatric population for # platelets transfused (p= 0.02); decrease in # of pediatric patients undergoing HSCT during test period.

3. Nussbaumer et al. Vox sanguinis 2017.

Proven Efficacy in Bleeding Patients Massive Transfusion before and after INTERCEPT Platelet Introduction

- 150 Patients before INTERCEPT
- 156 Patients after INTERCEPT

Patient Survival

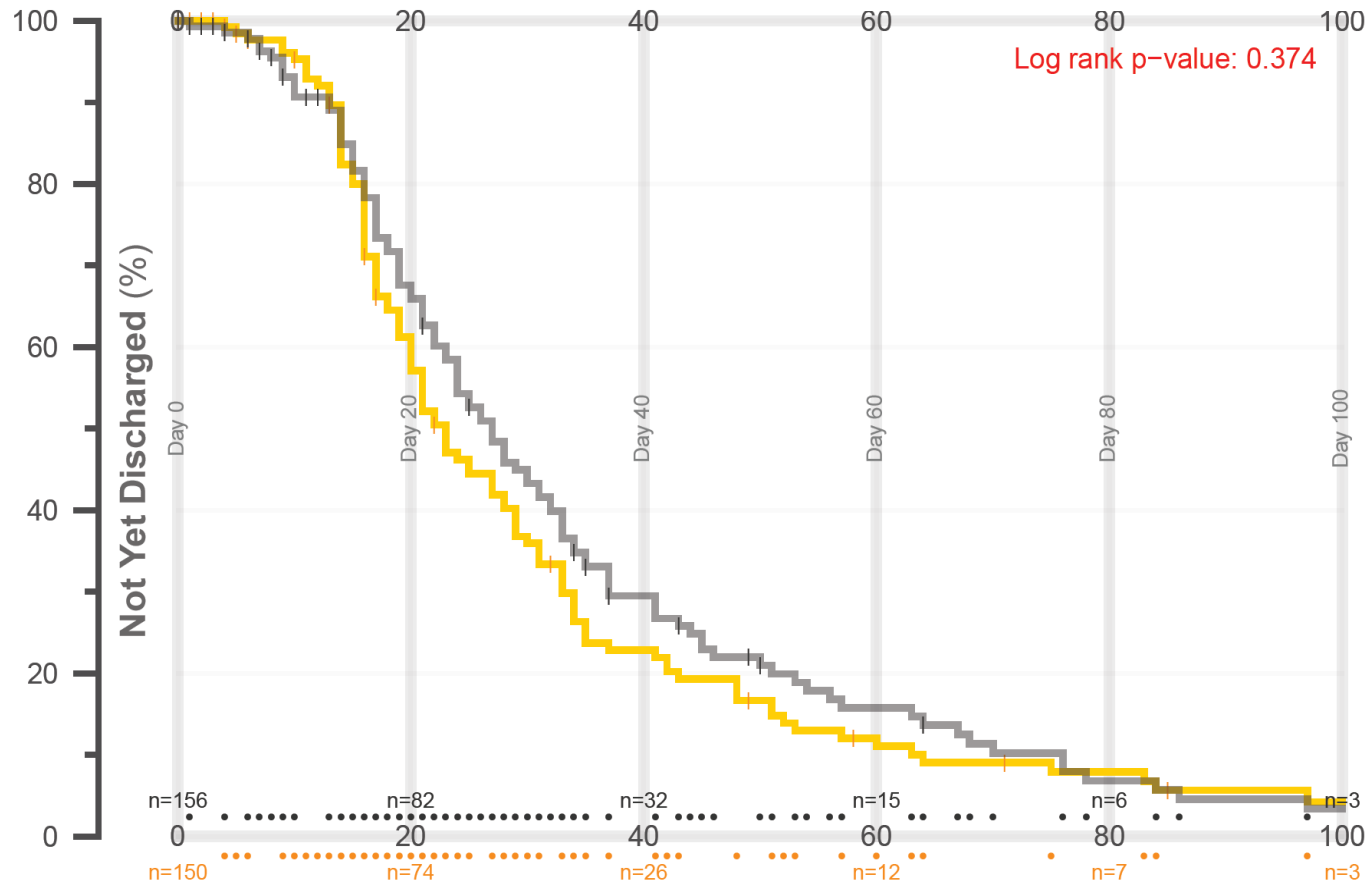


Massive Transfusions: ≥ 1 Platelets plus ≥ 10 RBC on a Calendar Day

Proven Efficacy in Bleeding Patients Massive Transfusion before and after INTERCEPT Platelet Introduction

- 150 Patients before INTERCEPT
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Patient Time to Discharge



Massive Transfusions: ≥ 1 Platelets plus ≥ 10 RBC on a Calendar Day

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Robust Pathogen Inactivation with the INTERCEPT 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
DENV	>4.4¹
ZIKV	≥5.8²
Bluetongue	≥4.4
Calicivirus	>6.8
Adenovirus	>5.9
P. falciparum	>7.9
B. microti	>4.9 ³

: ¹Santa Maria et al. *Transfusion*, 56, S4, 11A, ²Laughhunn et al. *Transfusion* epub 2017, ³Tonetti et al. *Transfusion* 56, S4, 195A.

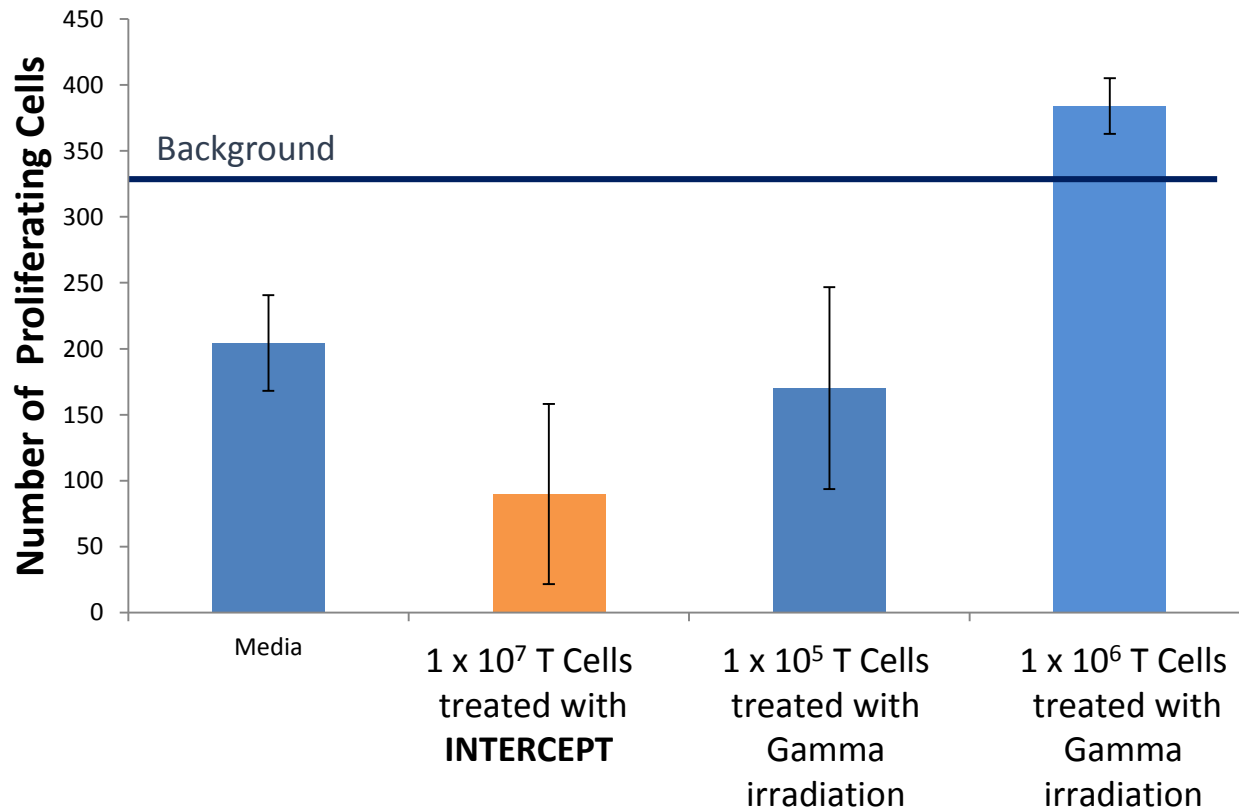
S-303 Inactivation of T-Lymphocytes in RBC with a Limited Dilution Assay¹

INTERCEPT is more effective at T cell inactivation than irradiation

Log₁₀ Inactivation

>6.2

>4.2



¹ Castro G et al. Vox Sanguinis (2016) 111 (Suppl. 1), 166

INTERCEPT RBC Clinical Trial Overview

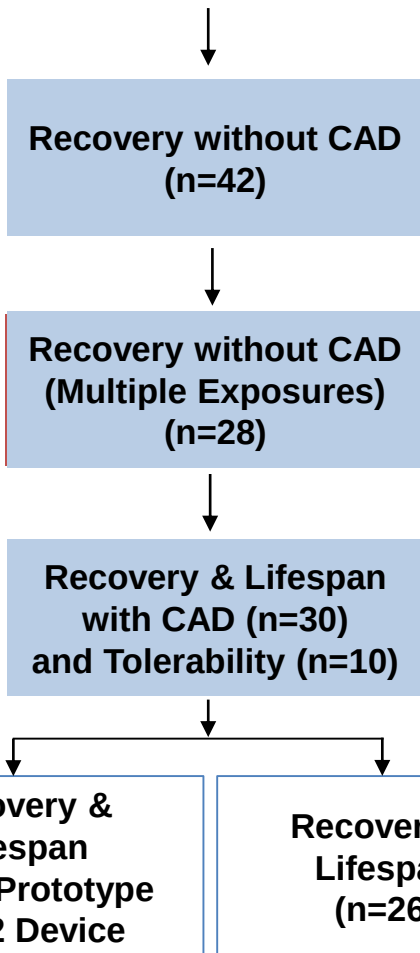


Legend

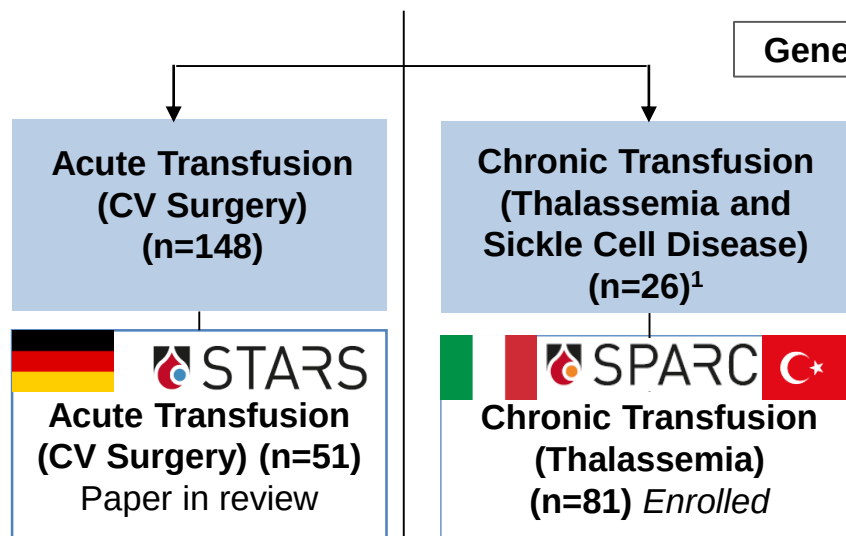
Generation 1

Generation 2

Phase 1: Healthy Blood Donors



Phase 3: Patients



- **Primary endpoints met successfully:**
 - In EU Phase III in acute anemia patients (n=51).
 - In US Phase II recovery & survival in healthy subjects.
- **Completed enrollment:**
 - EU Phase III RBC study in chronic anemia (n=81).
- **CE mark submission upon completion of CMC studies**
 - Scheduling of TUV submission date.

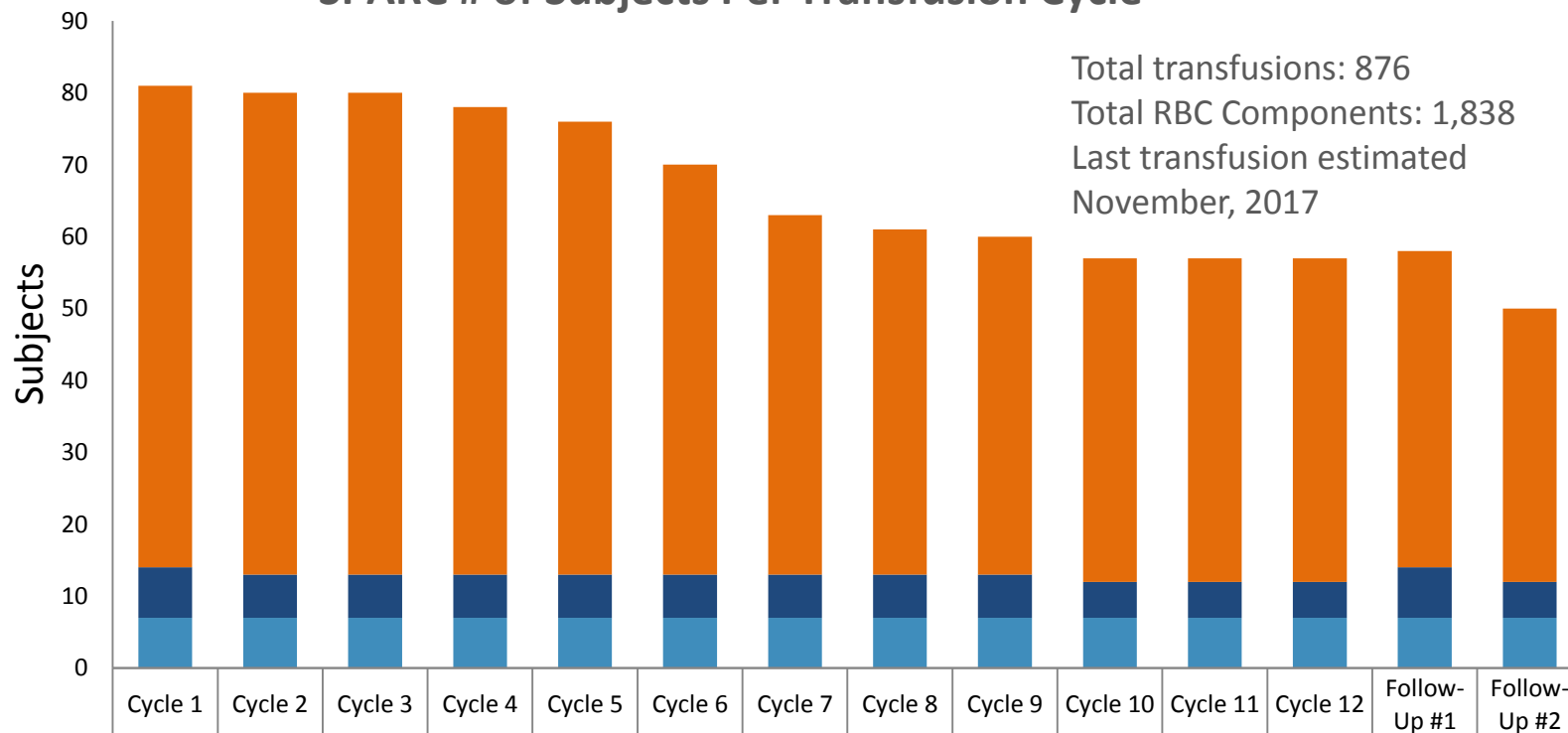
1. Low titer antibody to S-303 treated RBCs observed in two patients with chronic anemia resulting in study stop of the Phase 3 trials with the 1st Generation System and reformulation of the system.

2. Randomized, Double-Blind, Controlled, Parallel Group Study with the INTERCEPT Blood System for Red Blood Cells in Regions at Potential Risk for Zika Virus Transfusion-Transmitted Infections (RedeS)

3. Randomized, Double-Blinded, Controlled, Parallel Group, Non-inferiority, Phase III Study to Evaluate the Efficacy and Safety of the INTERCEPT Blood System for Red Blood Cells in Patients undergoing Complex Cardiac Surgery Procedures (ReCePI).

4. Randomized, Double-Blind, Controlled, Crossover Study to Evaluate the Efficacy and Safety of the INTERCEPT Blood System for Red Blood Cell Pathogen Reduction in Patients with Sickle Cell Disease in an Exchange Transfusion Program (SCient).

SPARC # of Subjects Per Transfusion Cycle



No evidence of emergent S-303 antibodies

INTERCEPT RBC Clinical Trial Overview



Legend

Generation 1

Generation 2

Phase 1: Healthy Blood Donors

Recovery without CAD
(n=42)

Recovery without CAD
(Multiple Exposures)
(n=28)

Recovery & Lifespan
with CAD (n=30)
and Tolerability (n=10)

Recovery &
Lifespan
(n=27) Prototype
Gen 2 Device

Recovery &
Lifespan
(n=26)

Phase 3: Patients

Acute Transfusion
(CV Surgery)
(n=148)

  **STARS**
Acute Transfusion
(CV Surgery) (n=50)
Paper in review

Chronic Transfusion
(Thalassemia and
Sickle Cell Disease)
(n=26)¹

   **SPARC** 
Chronic Transfusion
(Thalassemia)
(n=70) *Enrolled*

• US funding by BARDA accelerates a comprehensive RBC program

- Base Period and Additional Options (~\$180M).
- Major Phase 3 & Phase 4 clinical development effort.
- Manufacturing scale-up and disposable advances.
- PI & in-vitro studies
- PMA submission

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  STARS
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(CV Surgery) (n=50)
Paper in review

Chronic Transfusion
(Thalassemia and
Sickle Cell Disease)
(n=26)¹

  SPARC 
Chronic Transfusion
(Thalassemia)
(n=70) *Enrolled*

BARDA Funding

 RedeS 
Acute Tx
(n=600+up to 20K)²
Enrolling

 ReCePi 
Acute Tx
(CV Surgery)³
Design

 SClient 
Chronic Tx
(SCD & Thal)⁴
Design

1. Low titer antibody to S-303 treated RBCs observed in two patients with chronic anemia resulting in study stop of the Phase 3 trials with the 1st Generation System and reformulation of the system.
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Complete, Comprehensive PI/PRT Solution might Simplify Current Testing Algorithms

Current Practices

DHQs	Donor Deferrals		
HBV	HBsAg	HBc	NAT
HCV	HCV 3.0	NAT	
HIV	HIV1/2 EIA	NAT	
Zika*	NAT		
Dengue*	NS1	NAT	
CHIKV*	NAT		
Bacteria	Culture		
Leukocytes	Gamma Irradiation		

With Robust PI/PRT



Safer Blood

May enable simplification of current testing algorithms

while retaining the donor base

* no current commercialized test

** INTERCEPT for Red Cells is in Development

In Conclusion...

- Emerging pathogens and their unpredictability call for a proactive measure to effectively mitigate TTI risk, and to maintain blood supply.
- Particularly true with platelets in event of outbreak; susceptible to expiry, which can lead to logistical supply issues, loss of donors & blood shortages.
- Bacteria pose the greatest infectious transfusion risk in platelets, which is often under-reported; culture misses >50% of cases.
- ***The INTERCEPT Blood System provides a comprehensive solution, demonstrated to maintain blood safety and availability.***
 - Today, INTERCEPT Platelets and Plasma are available to help ensure blood sustainability.
 - INTERCEPT RBC System is in active development; provides an opportunity to simplify TTI mitigation strategies (i.e., testing, deferrals, travel, MSM).
 - INTERCEPT RBC will bring pathogen reduction technology to all major blood components.



Thank you.

INTERCEPT
BLOOD SYSTEM
Illuminator

INTERCEPT
BLOOD SYSTEM

INTERCEPT REGULATORY APPROVALS

United States (FDA)

2014 (platelets and plasma)

Switzerland (Swissmedic)

2009 (platelets), 2010 (plasma)

Germany (PEI)

2007* (platelets), 2011* (plasma)

France (ANSM)

2003 (platelets), 2006 (plasma)

CE mark, Class III

2002 (platelets), 2006 (plasma)

* First blood center marketing authorization approved.

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www.cerus.com

Use of INTERCEPT is contraindicated in patients with a history of allergic response to amotosalen or psoralens.
No pathogen inactivation system has been shown to inactivate all pathogens.