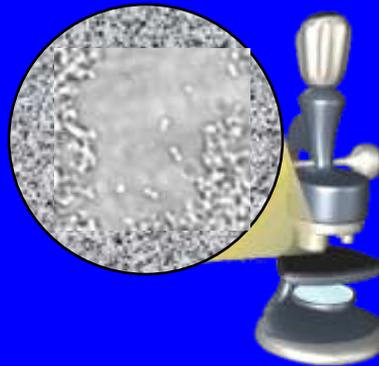




Bacterial Contamination of Platelets

A retrospective and update



Brecher –

possible conflicts:

Research grants

Advisory boards

Consultant

Honoraarium

Abbott

Amgen

Baxter/Fenwal

Biometric Imaging/Becton Dickinson

Blood Cell Storage Inc

Cerus

Circe

COBE/Gambro BCT /Claridian BCT

Cutter/Bayer/Miles/MedSep/Pall

Fresenius

Gen-Probe

Haemonetics

Hemosystems

Immunetics

Mosaic

Navigant Biotechnologies

Organon Teknika/Biomerieux

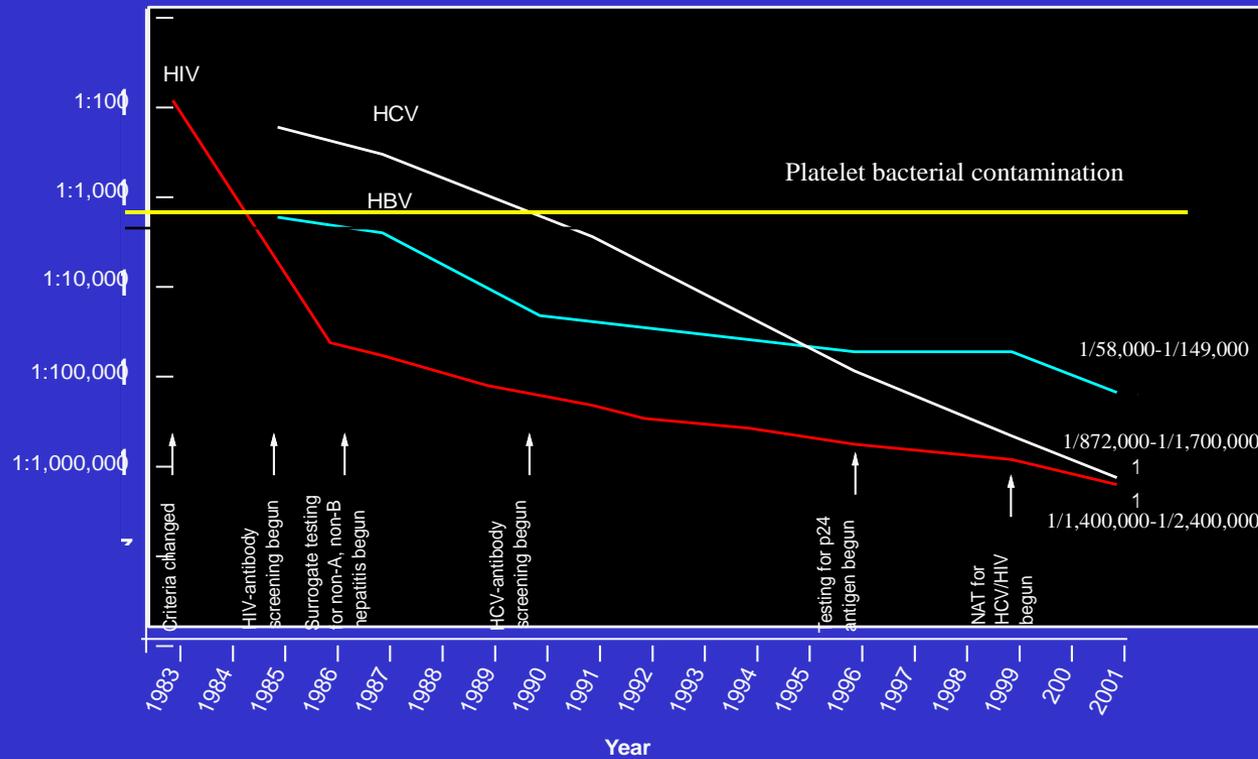
Ortho/Johnson and Johnson/Cilag Jensen

Terumo

Verax



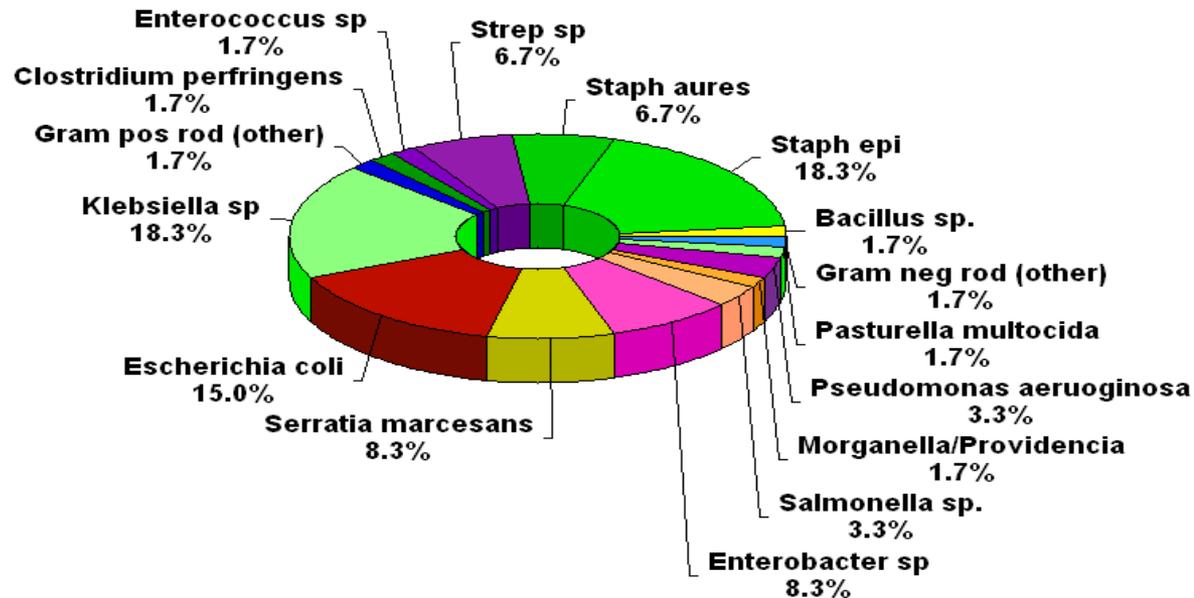
Risk of Infection per Unit Transfused



Modified from Goodnough, Shander, Brecher. Lancet 2003;363:161-69



Transfusion Fatalities Reported to FDA (1995 - 2004, 10 yrs, 60 cases) Bacterial Contamination of Platelets



Niu MT, Knippen M, Simmons L et al. Transfusion-transmitted *Klebsiella pneumoniae* fatalities, 1995 to 2004. *Transfus Med Rev* 2006;20(2):149-157.





“Thank you for puncturing your skin with your fingernail....”





Platelet transfusions in the United States

4 million platelet bags transfused/year

1:1000 - 1:2000 bacterially contaminated
(N = 2000 - 4000 bags)

1/10 to 2/5 result in clinical sepsis
(N = 200 - 1600 cases)

Perhaps 1/5 to 1/3 result in fatalities
(N = 40 - 533 deaths)

or

(1:7,500 to 1:100,000 fatalities/unit)



“Transfusion reactions occurred in
13 of 32 recipients (41%),
with 9 severe reactions (28%)
and 3 deaths (9%).”

Yomtovian RA, Palavecino EL, Dysktra AH, Downes KA, Morrissey AM, Bajaksouzian S, Pokorny MA, Lazarus HM, Jacobs MR. Evolution of surveillance methods for detection of bacterial contamination of platelets in a university hospital, 1991 through 2004. *Transfusion*. 2006 May;46(5):719-30.

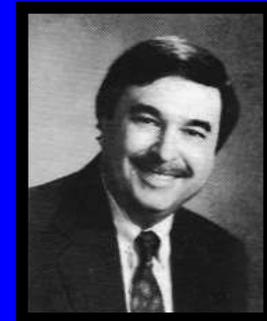


The imperative is to act so you can explain on Night Line.

Regulation is necessary to achieve the goal.

"Nothing says I care like a page of 483s"

**When all else fails do something,
give us a mandate and we will do the rest.**



Summary comments - Dr. E. Snyder

Bacterial contamination of platelets workshop September 24, 1999

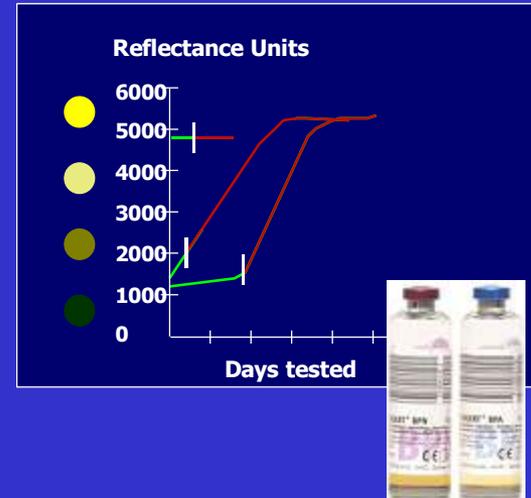
U.S. Dept of Health and Human Services, CBER

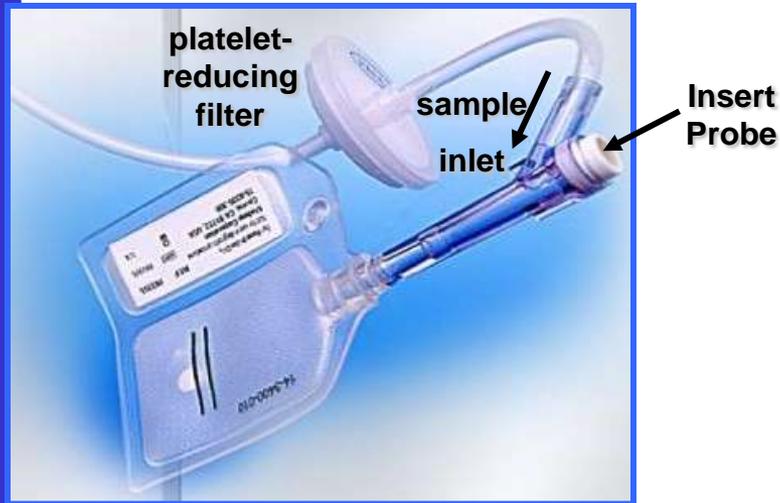


organon *teknika*

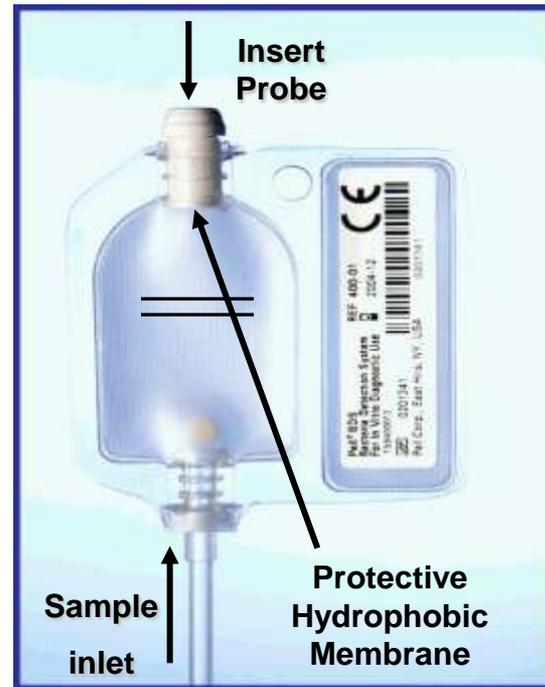


BacT/ALERT Microbial Detection System





Original (Pall BDS)
 Platelet reducing filter
 Sample inlet and probe port on
 same side



New (Pall eBDS)





The University of North Carolina at Chapel Hill

Phone: 919/966-2000 Fax: 919/966-2111
Email: trans@med.unc.edu

August 31, 2007

Open letter to the Blood Collection Community

A stress FDA meeting in Bethesda, Maryland held on August 7 and 8, 2007 addressed the safety and efficacy of methods for reducing pathogen in cellular blood products used as transfusion. At this meeting, the consensus of speakers was that bacterial contamination of platelets represents the largest transfusion transmitted disease risk.

The focus of this meeting was a discussion of surveillance strategies that targeted surveillance as a means of reducing pathogen reduction. If correct, it is unclear when such surveillance technologies will be available. Bacterial Detection Technology, however, is already available and increasing the bacterial culture has been shown to be practical and effective.

In the interim, given the current risk of bacterial contamination of platelets of approximately 1:100,000 per unit, we call for the blood collection community to immediately evaluate a program for detecting the presence of bacteria in units of platelets.

Respectfully,

Mark E. Buckler, M.D.
Director, Transfusion and Transfusion Services
Professor, Department of Pathology and Laboratory Medicine
University of North Carolina

Isaac A. Ibrahim, M.D.
E. Wanda French Professor and Chair of Pathology
and Professor of Medicine
Duke University Medical Center

Elyse Trachten, M.D.
Director, Blood Bank, Transfusion Medicine Service
Associate Professor, Department of Pathology
University Hospital of Cleveland

Paul M. Hens, M.D.
Professor, Pathology, Medicine & Oncology
Director, Transfusion Medicine
Johns Hopkins Medical Institution

Marvin A. Rappaport, M.D., F.R.C.P.(C)
Director, Transfusion Medicine
Professor, Departments of Pathology and Medicine
McMaster University

TRANSFUSION Volume 44, March 2008



Accreditation

5.1.5.1 The blood bank or transfusion service shall have methods to limit and detect bacterial contamination in all platelet components. Standard 5.6.2 applies. [Arm Prep]

TRM.44955 **Phase I**

Does the laboratory have a system to detect the presence of bacteria in Platelet components?



AABB Interorganizational Task Force on Bacterial Contamination of Platelets



Silva MA, Gregory KR, Carr-Greer MA, Holmberg JA, Kuehnert MJ, Brecher ME; Task Force. Summary of the AABB Interorganizational Task Force on Bacterial Contamination of Platelets: Fall 2004 impact survey. *Transfusion*. 2006 Apr;46(4):636-41.



Has your ability to provide platelets been affected since 30 days after implementation?

91 % of Blood Centers state there has been no change in their ability to provide platelets to hospitals

64 % of Hospital Blood Banks who both manufacture and receive platelets state there has been no change in their ability to provide platelets to patients

68 % of Transfusion Services state there has been no change in their ability to provide platelets to patients

Survey conducted 9/17/04 – 10/1/04

Silva MA, Gregory KR, Carr-Greer MA, Holmberg JA, Kuehnert MJ, Brecher ME; Summary of the AABB Interorganizational Task Force on Bacterial Contamination of Platelets: Fall 2004 impact survey. *Transfusion*. 2006;46:636-41



“Are You Currently Experiencing Increased Platelet Outdating?”

<u>Facility Type</u>	<u>No Increase</u>	<u>1-5% Inc</u>	<u>Subtotal</u>	<u>Unk</u>	<u>Total</u>
Blood Center	66 %	17 %	83 %	11 %	94 %
Hospital BB	68 %	11 %	79 %	11 %	90 %
Transfusion Serv*	66 %	11 %	77 %	9 %	84 %

* 6% of Transfusion Services do not maintain a platelet inventory; platelet components requested from supplier only when there is an order to transfuse.

Silva MA, Gregory KR, Carr-Greer MA, Holmberg JA, Kuehnert MJ, Brecher ME; Summary of the AABB Interorganizational Task Force on Bacterial Contamination of Platelets: Fall 2004 impact survey. Transfusion. 2006;46:636-41



$$18,535/4028 = 4.6 X$$

Facility	Culture Method			Non-Culture Method		
	# Cultures	Initial Positive	True Positive	# Tests	Initial Abnormal	True Positive
Blood Center	429,827	1:930	1:4723	51,025	1:158	1:5,672
Hospital Blood Bank	45,531	1:328	1:1686	118,567	1:184	0
Transfusion Service				89,903	1:244	1:17,986
Total	475,358	1:791	1:4028	259,495	1:193	1:18,535

Silva MA, Gregory KR, Carr-Greer MA, Holmberg JA, Kuehnert MJ, Brecher ME; Summary of the AABB Interorganizational Task Force on Bacterial Contamination of Platelets: Fall 2004 impact survey. *Transfusion*. 2006;46:636-41



Accreditation

TRM.44955 Phase II

Does the laboratory have a validated system to detect the presence of bacteria in platelet components?

NOTE: The sensitivity of the method must be at least 10 CFU/ml 24h after collection or at least 10⁵ CFU/ml 72h after collection. Specifically, insensitive methods, such as swirling or measuring pH or glucose concentration, do not satisfy this requirement.

DRAFT for 2009



4/11/2009 10:00:00 AM



Single donor apheresis versus pooled platelets

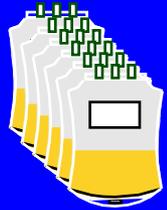


Percent utilization

1986 - 51.7% 1998 - 99.4%

Reaction rate

1986 - 1:4,818 transfusions

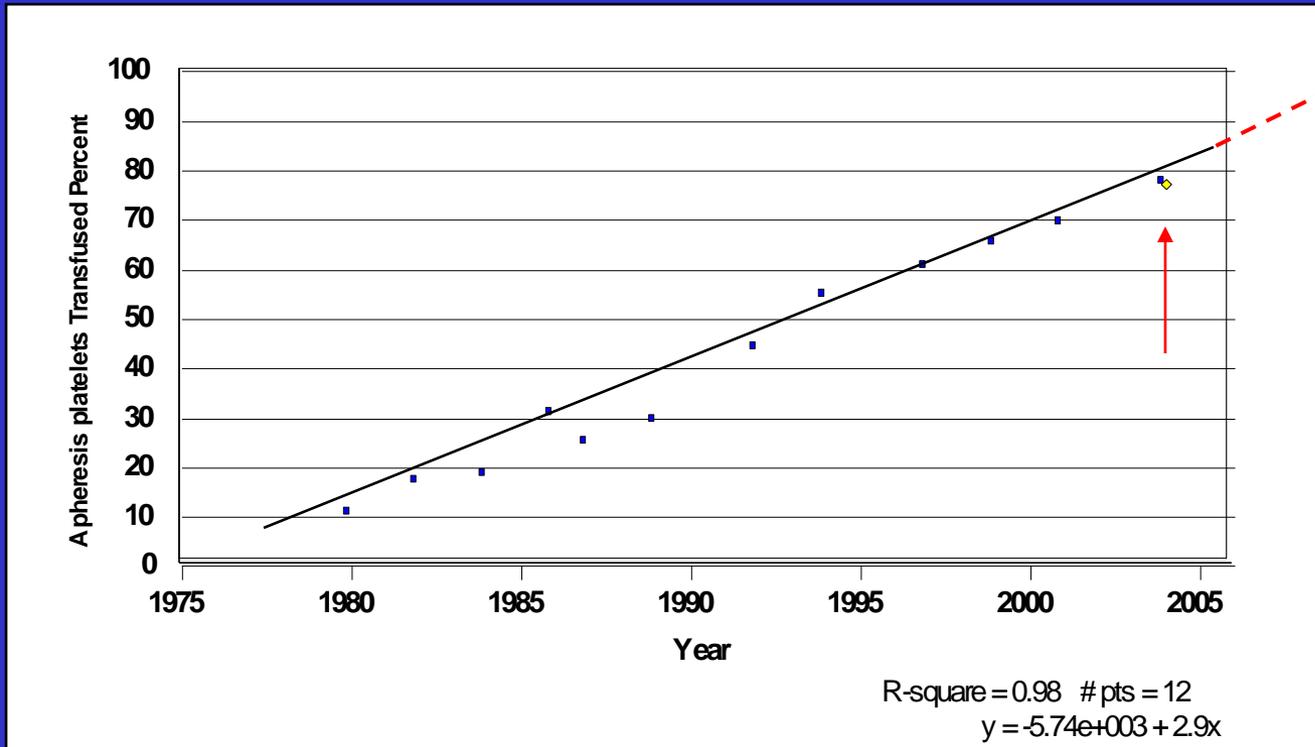


1986 - 48.3% 1998 - 0.6%

1998 - 1:15,098 transfusions

Paul Ness, Hayden Braine, Karen King, Christine Barrasso, Thomas Kickler, Alice Fuller, and Natalie Blades. Single-donor platelets reduce the risk of septic platelet transfusion reactions. Transfusion 2001 41: 857-861.





Silva MA, Gregory KR, Carr-Greer MA, Holmberg JA, Kuehnert MJ, Brecher ME; Task Force. Summary of the AABB Interorganizational Task Force on Bacterial Contamination of Platelets: Fall 2004 impact survey. *Transfusion*. 2006 Apr;46(4):636-41.



Diversion of the initial collection

3,385 collections -

First 15 mLs - 76 (2.2%) contaminated

Second 15 mLs 21 of the 76 contaminated

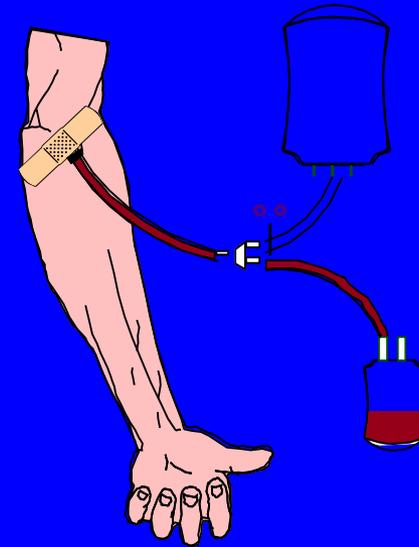
Bruneau et al., *Transfusion* 2001;41:74-81

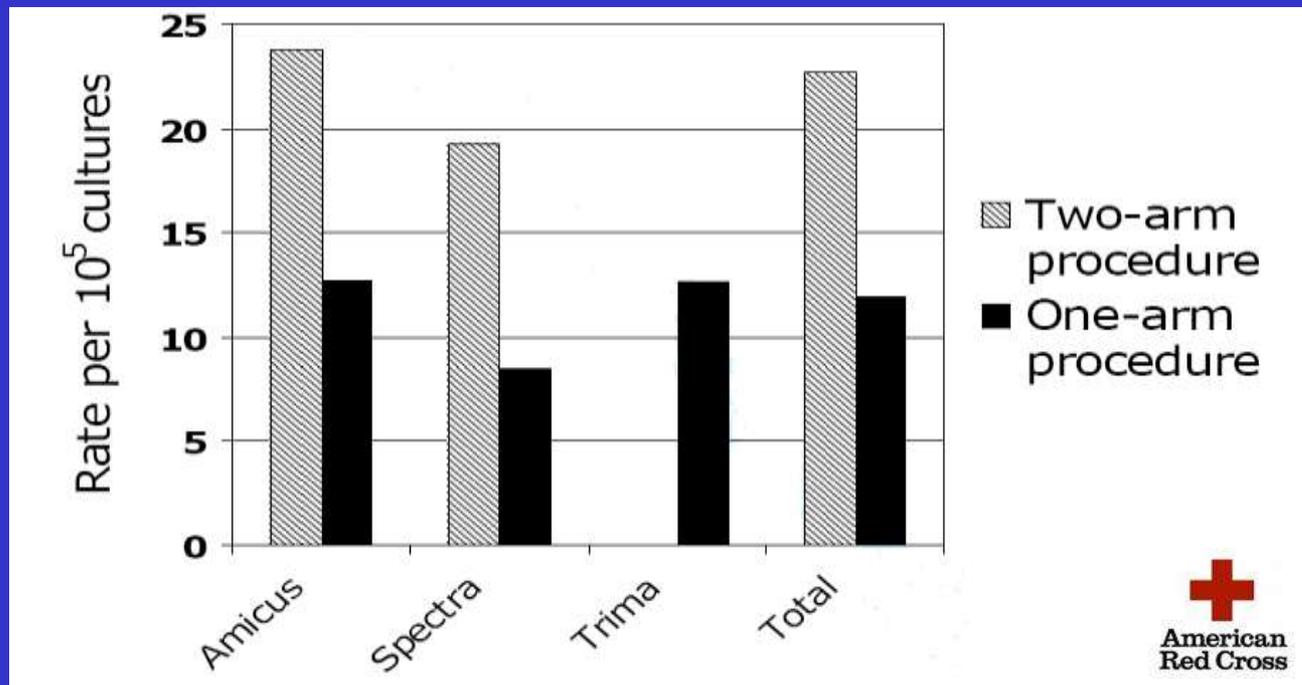
18,257 collections - 0.35% contaminated
diversion of the first 10 mLs

7,087 collections - 0.21% contaminated

p<0.05

de Korte et al., *Vox Sang* 2002;82:13-16.





Eder A. et al. Bacterial Screening of Apheresis Platelets and the Residual Risk of Septic Transfusion Reactions: The American Red Cross Experience (2004-6).

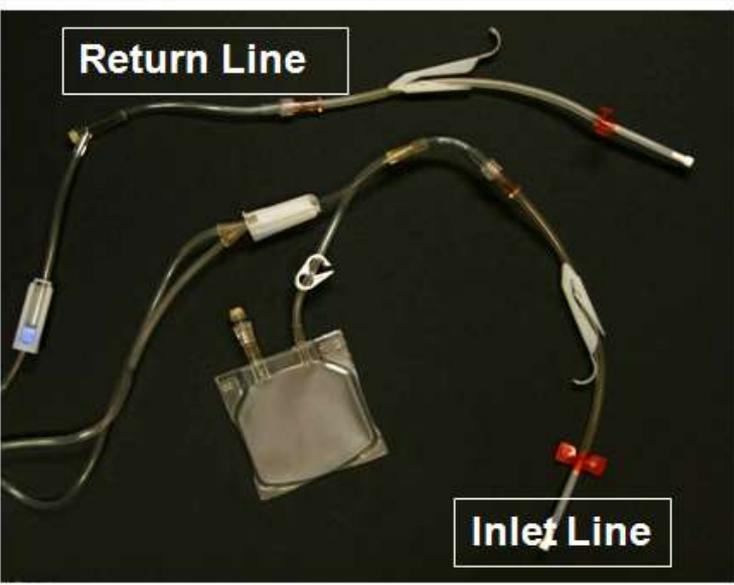
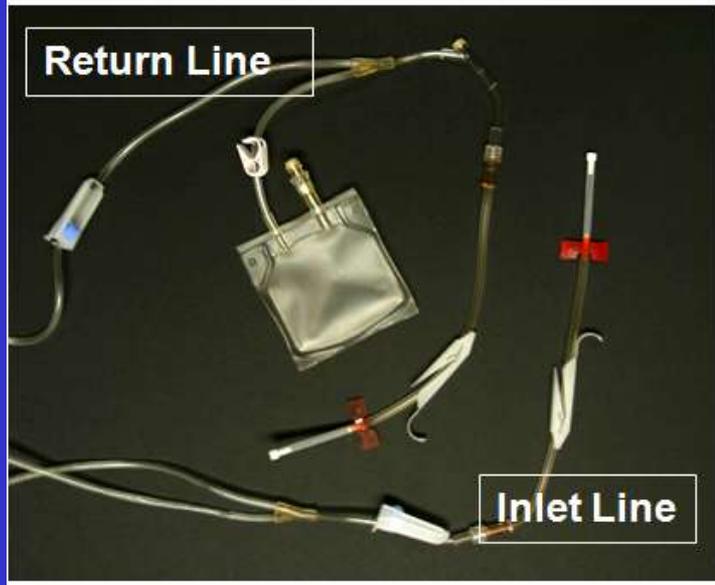
Eder AF, et al. American Red Cross Regional Blood Centers. Bacterial screening of apheresis platelets and the residual risk of septic transfusion reactions: the American Red Cross experience (2004-2006). *Transfusion*. 2007 Jul;47(7):1134-42.



Diversion Strategies:

Old Baxter kit

New Baxter kit



From Richard Benjamin, MD, PhD



A contaminated collection detection rate of 1 in 5157.

....this new procedure has been effective in identifying and preventing the transfusion of many, although not all, bacterially contaminated PLT units.

Fang CT, Chambers LA, Kennedy J, et al. Detection of bacterial contamination in apheresis platelet products: American Red Cross experience, 2004. *Transfusion*. 2005 Dec;45(12):1845-52.



Septic reaction case reports

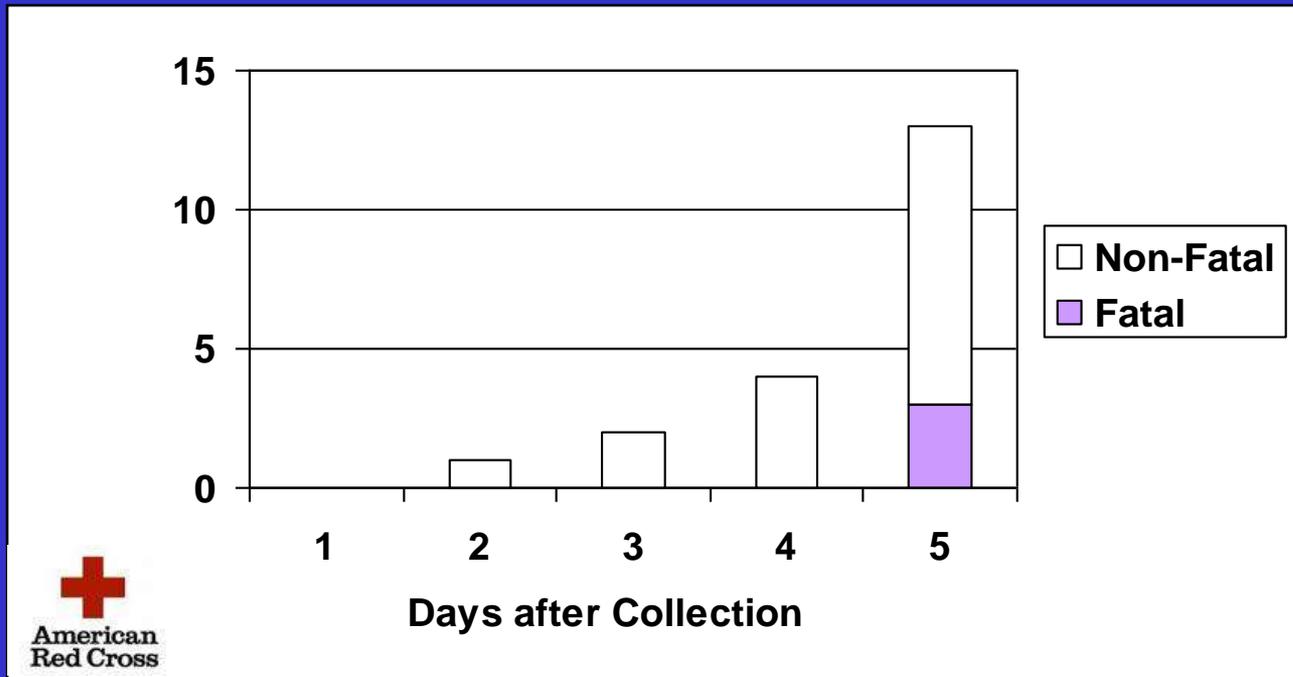
From March 2003 through December 2003, before screening, 15 septic reactions involving apheresis PLTs were reported. Twelve were assessed as high probability, 2 of which were fatal. In the same period following screening, 8 septic reactions involving apheresis PLTs were investigated and 3 were assessed as high probability.

75%

Fang CT, Chambers LA, Kennedy J, et al. Detection of bacterial contamination in apheresis platelet products: American Red Cross experience, 2004. *Transfusion*. 2005 Dec;45(12):1845-52.



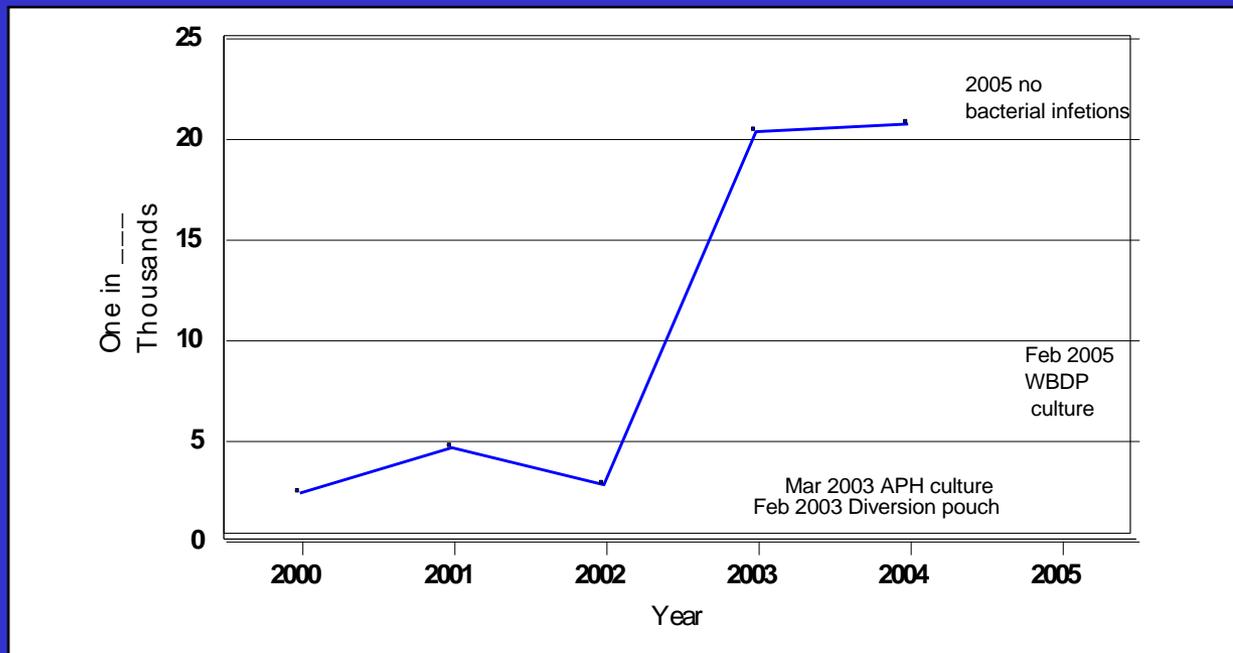
ARC Septic Transfusion Reaction Experience (03/01/04-05/31/06)



Modified from Richard Benjamin, MD, PhD

Eder AF, et al. American Red Cross Regional Blood Centers. Bacterial screening of apheresis platelets and the residual risk of septic transfusion reactions: the American Red Cross experience (2004-2006). *Transfusion*. 2007 Jul;47(7):1134-42.





Delage G, Saint-Laurent V, Itax NK, Robillard P. Cumulative Effects of Preventive Measures on Incidence of bacterial Infections in Platelet recipients. Transfusion 2006 vol 46 Supplement abstract 33A



Reports from hospitals during this 24-month time interval did not reveal any infections transmitted by BacT/ALERT screened PLTs. This contrasts with three known instances of transfusion of bacterially infected PLT apheresis components documented by BSI in the 24 months before implementation of bacterial detection testing.

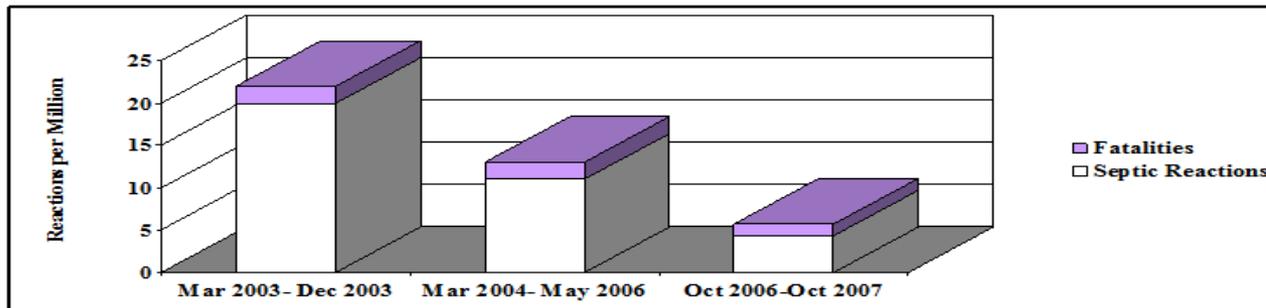
results for culturing 122,971 apheresis PLTs

Kleinman SH, Kamel HT, Harpool DR, Vanderpool SK, Custer B, Wiltbank TB, Nguyen KA, Tomasulo PA. Two-year experience with aerobic culturing of apheresis and whole blood-derived platelets. *Transfusion*. 2006 Oct;46(10):1787-94.



Hemovigilance Monitoring of Bacterial Culture Effectiveness:

	Before Culture	After Culture	After Diversion
	March 2003- Dec 2003	March 2004- May 2006	Oct 2006 – Oct 2007
Septic Reactions	12 reactions	20 reactions	4 reactions
Deaths	2 fatalities	3 fatalities	1 fatalities
Transfusions (rate)	~500,000 ~1:40,000	1,496,134 ~1:75,000	~700,000 ~1:175,000



From Richard Benjamin, MD, PhD



eBDS

118,067 apheresis and WBPCs
from 23 US Blood Centers

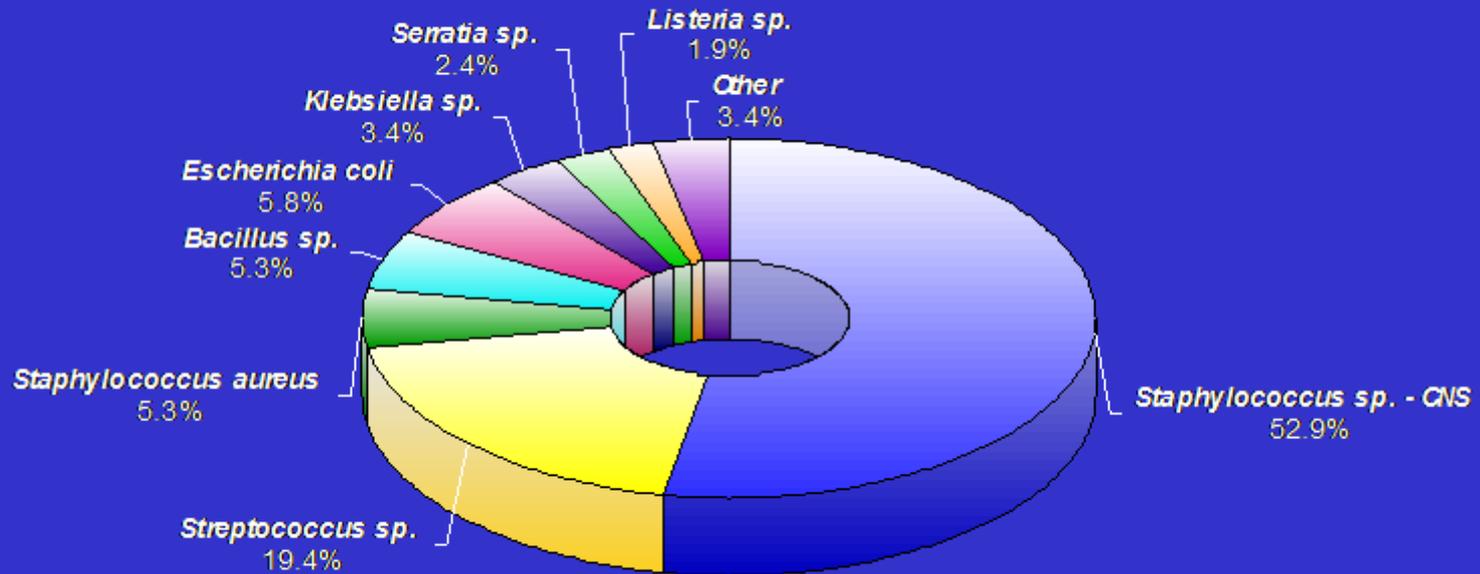
TP = 1/5,133 FP = 1/1,243
One report of a missed *S. epi*



Holme S, Bunch C, Selman G. Vox Sang 2005;89 Suppl 1 P194



True positive organisms N = 207 isolates



True positive organisms, isolated from 1,237,177 apheresis cultures (tested with 4 mL in an aerobic BacT/ALERT bottle). Examples of organisms isolated only once or twice were grouped in the "other" category. These included example(s) of *Micrococcus sp.*, *Citrobacter sp.*, *Diphtheroids/Corynebacterium*, *Enterococcus avium* (N=2), *Granulicatella adiacens*, *Lactobacillus sp.* and *Enterobacter aerogenes*. CNS = Coagulase Negative Staphylococcus. Vox Sang 2007;93:260-277. Total = 1/5977



Table 2 The time, in days, between inoculation of the sample into the culture bottle and the positive signal from the BacTAlert device for bacteria isolated from platelet concentrates

Bacteria	Number of isolates (n = 57)	Detected on day 1 screening (n = 35) (time, in days, in culture bottle before detection)	Detected at day 4 retest (n = 4) (time, in days, in culture bottle before detection)	Detected at outdate (n = 18) (time, in days, in culture bottle before detection)
Coagulase-negative <i>Staphylococci</i>	20	13 (range: 0-66 to 5-8)	1 (0-75)	6 (range: 0-13 to 1-11)
<i>Propionibacterium acnes</i>	18	10 (range: 4-39 to 5-94)	2 (3-68, 3-51)	6 (range 4-3 to 6-57)
Anaerobic <i>Streptococcal</i> spp.	3	2 (2-05, 2-93)		1 (2-1)
<i>Bacillus</i> spp.	3	2 (0-88, 2-33)		1 (0-6)
<i>Corynebacterium</i> spp.	3	1 (1-43)		2 (4-0, 4-2)
<i>Micrococcus</i> spp.	2	2 (2-89, 3/03)		
<i>Streptococcus</i> spp.	2	2 (0-39, 0-44)		
<i>Staphylococcus aureus</i>	1	(3-78)		
<i>Leuconostoc</i> spec.	1			(0-25)
<i>Bacteroides thetaiotamicron</i>	1	(2-16)		
<i>Acinetobacter baumannii</i>	1			(0-24)
<i>Proteus mirabilis</i>	1	(0-85)		
<i>Brevibacterium spec.</i>	1		(4-8)	

Early: 35/42,230 = 0.08%

Day 4: 4/3310 = 0.12%

Outdate: 18/8282 = 0.22%

a sensitivity of
less than 40%

Murphy WG, Foley M, Doherty C, Tierney G, Kinsella A, Salami A, Cadden E, Coakley P. Screening platelet concentrates for bacterial contamination: low numbers of bacteria and slow growth in contaminated units mandate an alternative approach to product safety. *Vox Sang.* 2008 Apr 2. [Epub ahead of print]



Literature reports of anaerobic bacteria in blood products

Year	Product	Organism	Outcome
1998*	Platelets	Clostridium p.	fatal
2001**	RBCs	Clostridium p.	sepsis

* McDonald et al. Transfusion Medicine 8:19-22

** Blajchman, M.A. et al. Transfusion 41: 427



Current estimate of risk from anaerobic bacteria contaminating platelet products

- True risk has not been defined
- Published studies and reporting to the FDA indicate that the risk exists although it is small
- Three mortalities from transfusion transmitted anaerobic bacteria reported to the FDA
- 2000- Clostridium p. red cells
- 2001- Clostridium p. platelets
- 2005- Eubacterium limosum platelets

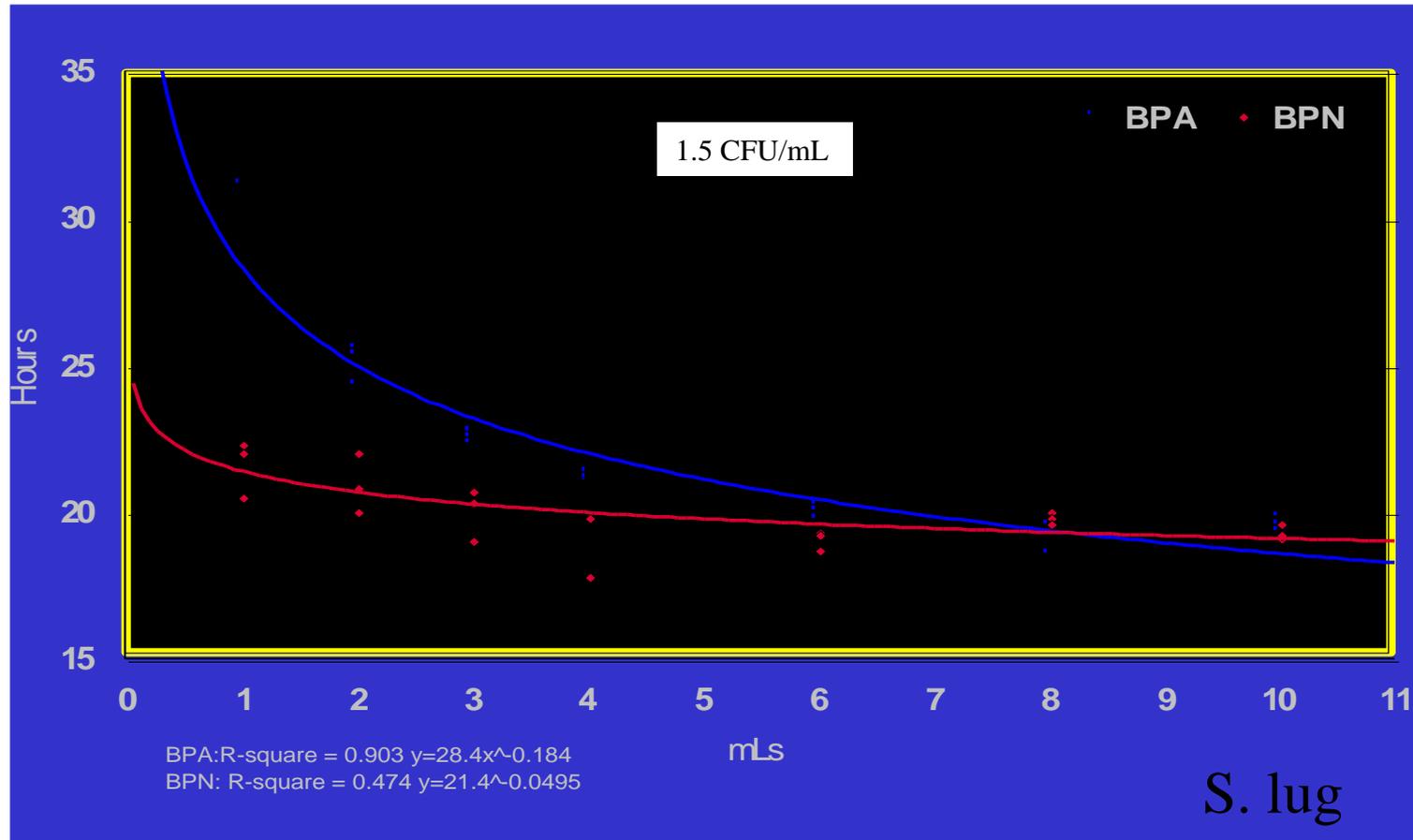
From Jaro Vostal - CBER



Streptococcal species

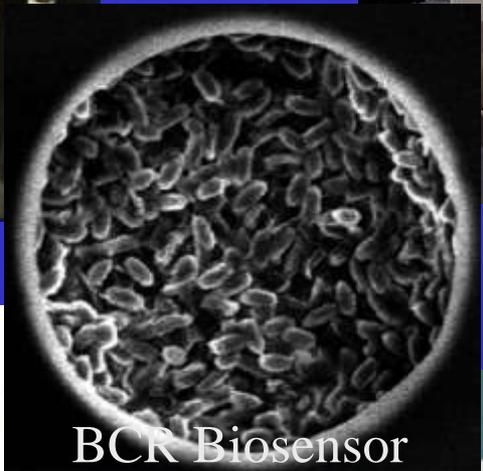
Organisms	CFU/mL	Reps	Aerobic Hours	Anaerobic Hours
<i>Strep pyogenes</i>	<3	10	19.0	13.8
<i>Strep viridans</i>	2	5	43.0	21.4





Brecher ME Hay SN. Transfusion 2007;47:1390-1394





BCR Biosensor

BacSTAT Detects Bacteria with Objective Results

Antibody Strips

Rapid Lateral-Flow Scanner

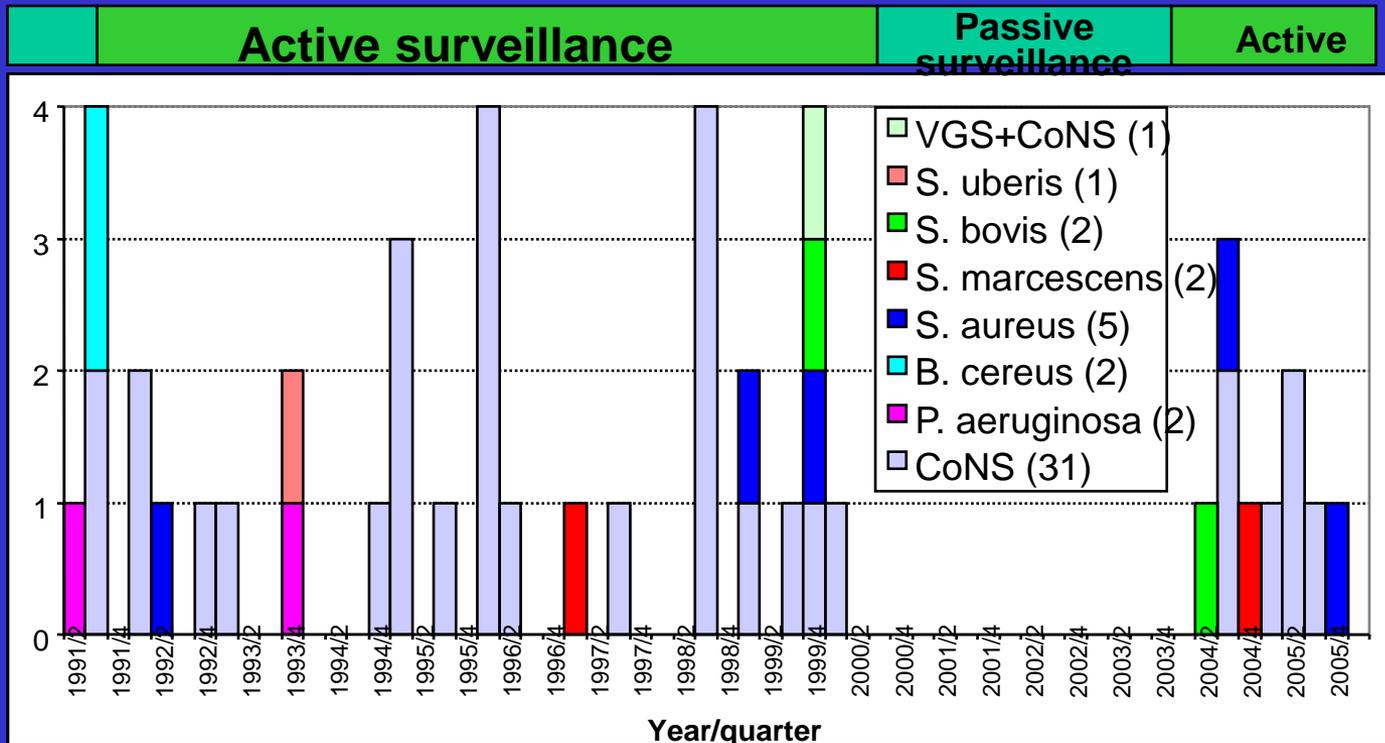
The BacSTAT employs pass/fail threshold software to determine if platelets are contaminated.

A diagram showing the BacSTAT workflow. On the left, two antibody strips are shown. A hand is shown using a rapid lateral-flow scanner to read the strips. The scanner is connected to a computer monitor displaying a software interface with green and red bars. The text explains that the software uses pass/fail thresholds to determine if platelets are contaminated.

BPAC – March 2006



Bacterial species 1991-2005, N=46

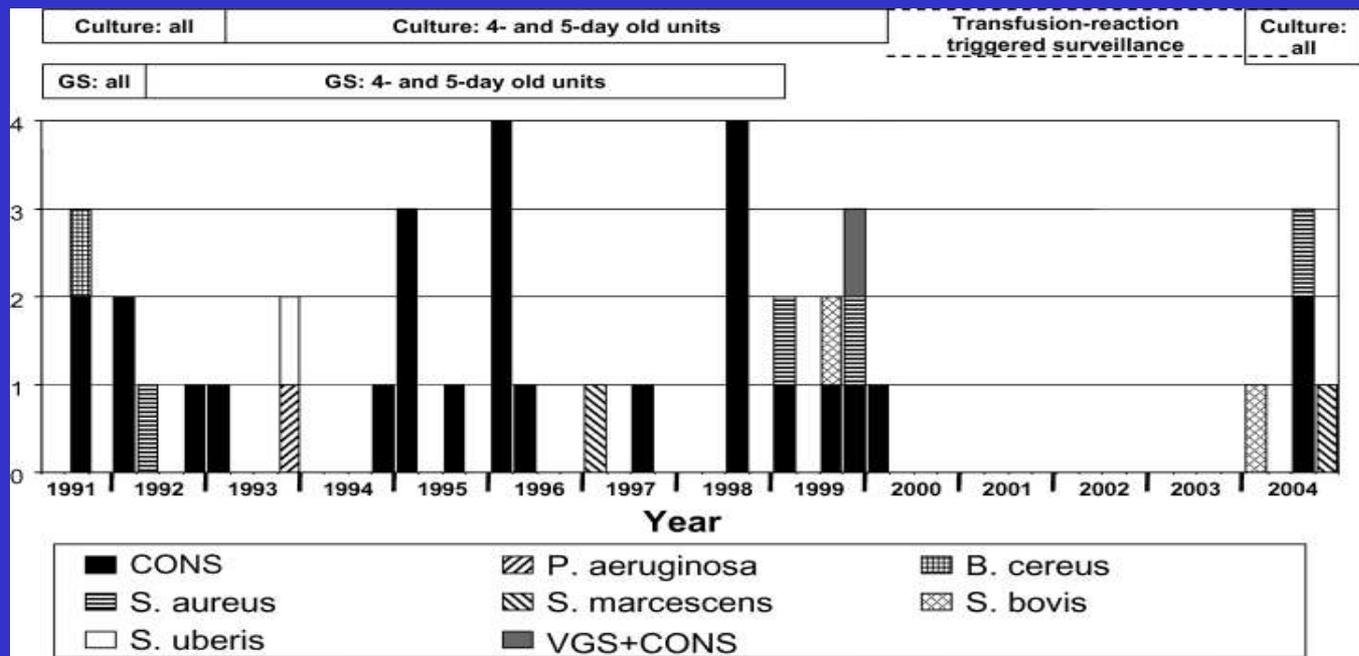


From Ros Yomtovian

Data from:

- CDC. 1992. Morb Mortal Wkly Rep 41:36-37.
- Yomtovian, R, et al.. Transfusion 2006, in press.
- Zaza S, et al. Infect Control Hosp Epidemiol 1994;15(2):82-7.
- Yomtovian, R, Jacobs, M. 2006. Unpublished data
- Sapatnekar S, et al.. Transfusion 2001;41(11):1426-30.





Yomtovian RA, Palavecino EL, Dysktra AH, Downes KA, Morrissey AM, Bajaksouzian S, Pokorny MA, Lazarus HM, Jacobs MR. Evolution of surveillance methods for detection of bacterial contamination of platelets in a university hospital, 1991 through 2004. *Transfusion*. 2006 May;46(5):719-30.

Jacobs MR, Good CE, Lazarus HM, Yomtovian RA. Relationship between bacterial load, species virulence, and transfusion reaction with transfusion of bacterially contaminated platelets. *Clin Infect Dis*. 2008 Apr 15;46(8):1214-20.



An at issue detection system with
a sensitivity of:

- 10^5 CFU/ml would have prevented all fatal reactions, 91% of serious reactions, and 79% of all reactions
- 10^3 CFU/ml would have prevented all serious reactions, 79% of all cases and 95% of all reactions



October 5, 2005- - Pall Corporation
FDA clearance for the new
Pall Acrodose™ PL System.



“Bacterial contamination of PSPs was assessed at 5.8-fold our current rate for apheresis PLTs utilizing comparable culture protocols.”

Benjamin RJ, et al. Bacterial contamination of whole blood-derived platelets: the introduction of sample diversion and prestorage pooling with culture testing in the American Red Cross. *Transfusion*. 2008 Jul 22. [Epub ahead of print]





Fatal Bacterial Infections Associated with Platelet Transfusions --- United States, 2004

In addition, deviation from culture methods that meet manufacturer's recommendations (e.g., decreased blood volume) can result in reduced sensitivity and produce false negatives. For patient B, the volume of the platelet sample was less than the manufacturer's recommended volume for platelet screening.



Blood Platelets Tainted With E.Coli Bacteria

KANSAS CITY, Mo. — A hospital patient died after receiving a unit of blood platelets tainted with E.coli bacteria, the Food and Drug Administration determined the transfusion, which took place Dec. 21, was a "manufacturing error" as it was not sterile.

"It was a major incident, and a very rare error of our site," David Graham, director of donor recruitment for the blood center, said. "We had multiple failures of that system."

Clayton Heston, executive director, said he could not blame the hospital or the patient, other than to say the person only was sent off the limited volume they were allowed, he said.

Eight hours before the error, several donors and patients undergoing surgery in various treatment rooms at the center were notified of the error, but the center did not want to release information about the Donor's health until the FDA contacted to make it public," he said.

The unit — about two to three liters of a pint — was collected from one donor, according to Dr. Jay Menitove, executive director of the center, who said the donor was developed symptoms, health officials believe the donor was carrying the bacteria at least had symptoms.

"The donor is perfectly healthy, and when contacted afterward, the donor was not healthy," Menitove said Thursday.

"The definitive source is we just don't know," Menitove said.

Rich Fiedler, the director of compliance for the Kansas City FDA, said he had an excuse to doubt the center's account of the error.

The hospital patient became sick three days after the platelets because they are stored at room temperature, Menitove said.

"In general, it's going to be caught and caught," Menitove said. "The thing is, if it's not caught, it gives the center a bad name."

Graham said the center tests all of its blood products for various contaminants but accidentally allowed the platelets in a unit to be contaminated with E.coli bacteria, he said.

The center immediately notified the FDA, which already was on site conducting contact inquiries, Graham said.

In a warning letter dated March 1, the FDA advised the blood center, saying its procedures are "not always maintained" and that the blood center had failed to conduct an adequate number of donor who experienced reactions such as fever.

Graham said the problems had been resolved.

"We made changes to our process, our policy, and we made personnel changes," he said, while declining to say whether the center had potential donors and the 40,000 people who receive blood and blood products from the Community Blood Center.

"The blood supply is safer than it has ever been," he said.

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Posted on Mon, Jul 31, 2006

email this print this

Strict scrutiny is needed to renew credibility: An appalling breakdown at the blood center

Blood center explains genesis of lethal error

By Elaine Barner, Staff Writer

August 03, 2006

Small to a friend Voice your opinion

The public demands a zero-risk blood supply, but errors happen sometimes, said Dr. Jay Menitove, executive and medical director, Community Blood Center.

"We would like to live up to that and close every gap but that is very difficult to achieve. There will always be risks associated with the transfer of blood," Menitove said.

Find Your Graduating Class



I graduated in:

1955
1956
1976
1986
1955

classmates.com

A patient in November received contaminated blood that circumvented the center's safety net. The University of Kansas Hospital received platelets from the Community Blood Center to treat a leukemia patient undergoing chemotherapy.

Food and Drug Administration protocols call for testing before blood products are received at the hospital, according to a statement issued July 26 by the hospital.

Shortly after beginning the transfusion, the patient developed symptoms that might have been associated with a transfusion reaction, the statement said.

"Because of the patient's reaction, the hospital took the unrequired step of performing its own test of the blood product given to the patient, which found a significant presence of bacteria in what should be a sterile product. This bacteria was subsequently identified as E.coli," Menitove said.

About the same time, the Community Blood Center contacted the hospital about the contamination. The center had performed the customary bacterial test of all platelets 24 hours after the draw and the test came up positive, Menitove said. There are 14 different tests, including HIV.

"The Blood Center immediately assumed responsibility for the problem, and the center and the hospital interacted with the patient's family. However, despite all possible medical interventions, the patient passed away approximately 48 hours after the transfusion," he said.

ansas City blood, plasma shop around immunity applies nearly directly used by

JILL TOYOSHIBA | THE KANSAS CITY STAR
At the Community Blood Center, a distribution technician stocks blood just released from testing labs into the inventory and rotates the stock in the refrigerated storage.

people's lives and the local health-care system makes a breakdown in is all the more appalling.

used last week that a patient died at the University of Kansas Hospital blood platelets contaminated with E. coli, a deadly bacteria. Errors at the center led to her death.

It is a three-way warning system to alert the staff to blood contamination, but the center placed too much confidence in one aspect of the system — a computer system.

It shows computer systems can malfunction. When the blood center's did not work, the center had no backup. A warning alarm had been switched off, and the center had a control screen that would have indicated the presence of contamination.

by the Food and Drug Administration after the death found problems with the center's procedures, staff training and record keeping. Jay Menitove, the center's executive director, said problems have been fixed.

The center's death has dealt a blow to the credibility of the center. The FDA and the center's directors must hold the center and its operations up to intensive scrutiny. A understandably nervous public will expect nothing less.

ansasCity.com
THE KANSAS CITY STAR.



CATEGORY

Fatal group C streptococcal infection due to transfusion of a bacterially contaminated pooled platelet unit despite routine bacterial culture screening

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BACKGROUND: An elderly man with chronic emphysematous bullae developed respiratory distress and died less than 48 hours after transfusion of a pool of eight white blood-stored platelet (PLT) blood subsets from the recipient and cultures of remnants from the pooled PLT bag grew group C streptococci (GCS). An investigation was conducted to identify both the infection's source and the reasons for the false-negative screening result.

STUDY DESIGN AND METHODS: Two blood cell (BCC) units (concentrates from the eight donations) were tested, separated, and cultured. Specimens from the implicated donor were obtained; bacteria were identified and typed by 16S rRNA and pulsed-field gel electrophoresis (PFGE). The blood center screening method was reviewed.

RESULTS: A hemolytic GCS, cultured from 1 of 8 BCC units, linked the fatal case to a single donor. The donor's throat swab collected 20 days after donation was positive for the presence of GCS, identified as *Streptococcus dysgalactiae* subsp. *equisimilis* isolated from the recipient, BCC unit, residual PLT, and donor's throat swab were indistinguishable by PFGE. The donor showed any symptoms of infection before or after donation. PLT bacterial screening at the blood center was performed using a commercially available bacterial detection system (Bio-Rad BLOT, Indianapolis) with a threshold of 11 colony-forming units per bag.

CONCLUSION: An asymptomatic donor was implicated as the source of GCS-contaminated PLTs. Current screening methods for PLTs are not sufficient to detect all bacterial contamination. Pooled PLTs are a particular challenge because the small volume of individual units places limits on culturing strategies. Improved detection of bacterial contamination of PLTs is needed.

Bacterial infection due to transfusion of contaminated platelet (PLT) concentrates is an important patient safety concern.^{1,2} Before the adoption of a standard requiring blood collection and transfusion airtight assemblies to limit and detect bacterial contamination in all PLT concentrates by AABB in 2006,³ the estimated rate of bacterial contamination of PLT products ranged from 1 in 2000 to 1 in 3000 PLT units,⁴ although the frequency of recognized reports from these products is much lower. Not all bacterially contaminated PLT units will result in a clinically recognized sepsis reaction; thus, the estimated rate of transfusion-related sepsis (1 in 100,000 units) for pooled PLTs before 2004 is likely to represent a substantial underestimation of the

ABBREVIATIONS: GCS—group C streptococci; PFGE—pulsed-field gel electrophoresis; WBC—white blood cells. From the Epidemic Intelligence Service, Office of Standards and Control Development, the Division of Healthcare Quality Promotion, and the Division of Blood Diseases, Coordinating Center for Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, Georgia; the Florida Department of Health, Tallahassee, Florida; the St. Joe Health Center, Center and Research Institute, Tampa, Florida; and Florida Blood Services, Jacksonville, Florida.

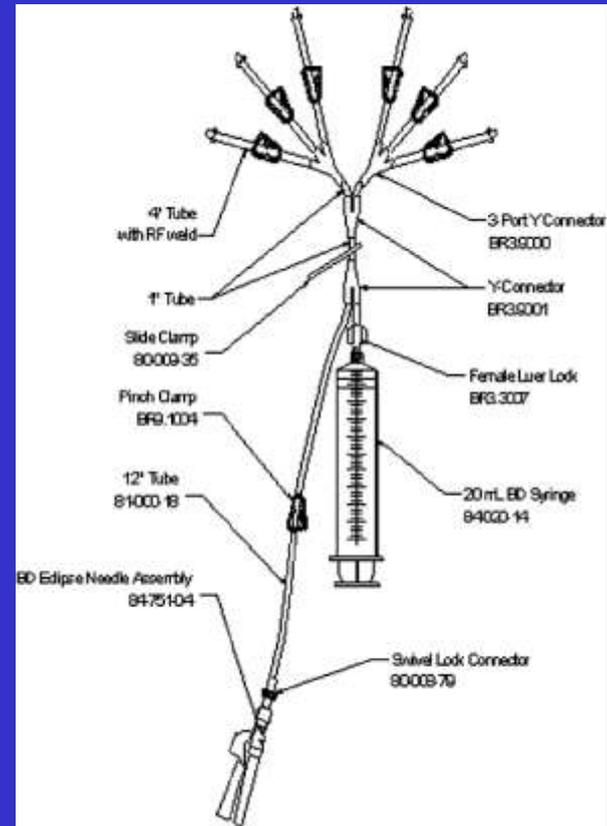
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Disclaimer: The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the Department of Health and Human Services.

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Salmonella cholerae-suis Septicemia

Patient	Diagnosis	Incubation	Outcome
JB	CML	6 days	1 recurrence, died of gi bleeding
GV	AML	12 days	died of pseudomonas sepsis
AM	ALL	7 days	1 recurrence, recovered
RD	ALL	10 days	died from chemo toxicity
SH	Hodgkins	10 days	<i>S. cholerae-suis</i> death
GL	Lymphosarcoma	10 days	death from renal failure
AD	Wiskott-Aldrich	5 days	responded, 2 recurrences

Salmonella Septicemia from Platelet Transfusions: Study of an outbreak traced to a hematogenous carrier of *salmonella cholerae-suis*.

Ann Int Med 1973;78:633-641



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From the Centers for Disease Control and Prevention: Morbidity and Mortality Weekly Report

Update: Delayed Onset *Pseudomonas fluorescens* Bloodstream Infections After Exposure to Contaminated Heparin Flush—Michigan and South Dakota, 2005-2006

JAMA. 2006;296:1831-1833.

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As of April 2006, a total of 15 patients in Michigan and 13 in South Dakota had been identified with delayed onset *P. fluorescens* bloodstream infections, with occurrences ranging from 84 to 421 days after their last potential exposure to the contaminated flush



“Canadian Consensus Conference Recommends Development and Adoption of Pathogen Inactivation Processes for Blood Components “

“In fact, the panel suggested implementation should not wait for the availability of processes for all blood components but should be applied to single components when available. Panel members agreed that there is no way to identify the populations that would benefit from PI, and that pathogen inactivated products should be available universally.”



ABC Newsletter 2007#13 April 6, 2007



Canadian Consensus Conference on Pathogen Inactivation Processes for Blood Components

FDA Finds Intercept Problematic. Following these presentations, Jaro Vostal, MD, from Food and Drug Administration, described the expectations that the agency has for safety and efficacy of PI platelets and stated clearly that the Intercept process did not meet these criteria. Peter Ganz, PhD, from Health Canada, agreed with the FDA positions and set forth the conditions that need to be met in Canada for licensure of PI components, and emphasized that “in order to be acceptable, a pathogen reducing process must further reduce the risk and must be shown not to create other potentially more serious risks.”



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Worldwide Bacterial Screening

Country/region	Percentage	Outdate	Method
Denmark	100	day 7	BacT/ALERT
Ireland	100	day 7 (retest day 4)	BacT/ALERT
Netherland	100	day 7	BacT/ALERT
Norway	100	day 6.5	BacT/ALERT
United Kingdom	100 – Scotland, Wales, N. Ireland QC - England	5-7 days	BacT/ALERT/ Pall BDS





Worldwide Bacterial Screening

Country/region	Percentage	Outdate	Method
Austria	5% (only apheresis)QC	day 5	BacT/ALERT
Germany	QC	day 5	BacT/ALERT
France	-	day 5	Gradual implementation of Pathogen reduction
Japan	-	72 hours	-



~~So, have we missed the boat?~~



Do we know where we are going?





