Bacterial Contamination of Platelets
A retrospective and update
Brecher –
possible conflicts:

Research grants
Advisory boards
Consultant
Honorarium

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
1983-1999

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

“Thank you for puncturing your skin with your fingernail....”
Platelet transfusions in the United States

4 million platelet bags transfused/year

1:1000 to 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)
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(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%).”

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
BacT/ALERT Microbial Detection System
Original (Pall BDS)

Platelet reducing filter
Sample inlet and probe port on same side

New (Pall eBDS)

Sample inlet
Protective Hydrophobic Membrane
August 16, 2002

Open letter to the Blood Collection Community

A recent FDA workshop held in Bethesda, Maryland on August 7 and 8, 2002 addressed the safety and efficacy of methods for excluding pathogens at cellular blood products and apheresis. At the meeting, the consensus of experts was that bacterial contamination of platelets represents the largest transfusion transmitted disease risk.

The focus of this meeting was a discussion of automation strategies that targeted reductions in the risk of excluding pathogens reliably. However, it is certainly clear that automated technologies will not be complete. Technologic detection, surveillance, and testing, while currently feasible, cannot replace the need for technologic validation and testing in the practical and effective.

In the interim, given the current risk of bacterial contamination of platelets of approximately $100,000 per week, we call for the blood collection community to immediately institute a program for detecting the presence of bacterial transmission among patients.

Sincerely,

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

Sandra Triandos, M.D.
Director, Transfusion Medicine Service
Associate Professor, Department of Pathology
Duke University Hospital

M. A. Blajchman, M.D.
Professor and Chair of Pathology
University of Toronto

Paul W. Hess, M.D.
Professor, Pathology, Medicine & Surgery
Duke University Medical Center

M.D. Transfusion Medicine
Professor, Department of Pathology and Medicine.
University of North Carolina
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?
“…implementation…may cause effects on the availability of platelets…I request the AABB carefully consider delay in implementation”  C. Beato

“…after consideration of the issue, the AABB believes that further delaying the implementation of this standard will compromise both patient safety and the public health.”  K. Sazama
AABB Interorganizational Task Force on Bacterial Contamination of Platelets

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

“Are You Currently Experiencing Increased Platelet Outdating?”

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

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

<table>
<thead>
<tr>
<th>Facility</th>
<th># Cultures</th>
<th>Initial Positive</th>
<th>True Positive</th>
<th># Tests</th>
<th>Initial Abnormal</th>
<th>True Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Center</td>
<td>429,827</td>
<td>1:930</td>
<td>1:4723</td>
<td>51,025</td>
<td>1:158</td>
<td>1:5,672</td>
</tr>
<tr>
<td>Hospital Blood Bank</td>
<td>45,531</td>
<td>1:328</td>
<td>1:1686</td>
<td>118,567</td>
<td>1:184</td>
<td>0</td>
</tr>
<tr>
<td>Transfusion Service</td>
<td></td>
<td></td>
<td></td>
<td>89,903</td>
<td>1:244</td>
<td>1:17,986</td>
</tr>
<tr>
<td>Total</td>
<td>475,358</td>
<td>1:791</td>
<td>1:4028</td>
<td>259,495</td>
<td>1:193</td>
<td>1:18,535</td>
</tr>
</tbody>
</table>

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 $10^5$ 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
Single donor apheresis versus pooled platelets

<table>
<thead>
<tr>
<th>Percent utilization</th>
<th>Reaction rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>1986 - 51.7%</td>
<td>1986 - 1:4,818 transfusions</td>
</tr>
<tr>
<td>1998 - 99.4%</td>
<td></td>
</tr>
<tr>
<td>1986 - 48.3%</td>
<td>1998 - 1:15,098 transfusions</td>
</tr>
<tr>
<td>1998 - 0.6%</td>
<td></td>
</tr>
</tbody>
</table>

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 collectons - 0.21% contaminated
p<0.05
de Korte et al., Vox Sang 2002;82:13-16.

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.

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.

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

Modified from Richard Benjamin, MD, PhD

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**

Hemovigilance Monitoring of Bacterial Culture Effectiveness:

<table>
<thead>
<tr>
<th></th>
<th>Before Culture</th>
<th>After Culture</th>
<th>After Diversion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Septic Reactions</strong></td>
<td>12 reactions</td>
<td>20 reactions</td>
<td>4 reactions</td>
</tr>
<tr>
<td><strong>Deaths</strong></td>
<td>2 fatalities</td>
<td>3 fatalities</td>
<td>1 fatalities</td>
</tr>
<tr>
<td><strong>Transfusions (rate)</strong></td>
<td>~500,000</td>
<td>~1,496,134</td>
<td>~700,000</td>
</tr>
<tr>
<td></td>
<td>~1:40,000</td>
<td>~1:75,000</td>
<td>~1:175,000</td>
</tr>
</tbody>
</table>

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, isolated from 1,237,177 apheresis cultures (tested with 4 mLs 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., Diptheroids/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
Hospitals


<table>
<thead>
<tr>
<th>Bacteria</th>
<th>Number of isolates (n = 57)</th>
<th>Detected on day 1 screening (n = 35) (time, in days, in culture bottle before detection)</th>
<th>Detected at day 1 retest (n = 4) (time, in days, in culture bottle before detection)</th>
<th>Detected at outdate (n = 18) (time, in days, in culture bottle before detection)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coagulase-negative Staphylococci</td>
<td>20</td>
<td>13 (range: 0-86 to 5-8)</td>
<td>1 (0-75)</td>
<td>6 (range: 0-13 to 1-11)</td>
</tr>
<tr>
<td><em>Proteus mirabilis</em></td>
<td></td>
<td>10 (range: 4-39 to 5-94)</td>
<td>2 (3-68, 3-51)</td>
<td>6 (range: 4-3 to 6-57)</td>
</tr>
<tr>
<td><em>Bacillus spp</em></td>
<td>3</td>
<td>2 (2-05, 2-93)</td>
<td>1 (0-38, 2-33)</td>
<td>1 (0-6)</td>
</tr>
<tr>
<td><em>Staphylococcus aureus</em></td>
<td>1</td>
<td>2 (2-89, 3-93)</td>
<td>1 (0-39, 0-44)</td>
<td>2 (4-0, 4-2)</td>
</tr>
<tr>
<td>Leucobacter spec.</td>
<td>1</td>
<td>2 (1-16)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Acinetobacter baumanii</em></td>
<td>1</td>
<td></td>
<td></td>
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<tr>
<td><em>Proteus mirabilis</em></td>
<td>1</td>
<td></td>
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</tr>
<tr>
<td><em>Brevibacterium spec.</em></td>
<td>1</td>
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</tbody>
</table>

Early: 35/42,230 = 0.08%
Day 4:    4/3310 = 0.12%
Outdate: 18/8282 = 0.22%

A sensitivity of less than 40%
# Literature reports of anaerobic bacteria in blood products

<table>
<thead>
<tr>
<th>Year</th>
<th>Product</th>
<th>Organism</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>1998*</td>
<td>Platelets</td>
<td>Clostridium p.</td>
<td>fatal</td>
</tr>
<tr>
<td>2001**</td>
<td>RBCs</td>
<td>Clostridium p.</td>
<td>sepsis</td>
</tr>
</tbody>
</table>

* McDonald et al. Transfusion Medicine 8:19-22  
** Blajchman, M.A. et al. Transfusion 41: 427

From Jaro Vostal - CBER
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

<table>
<thead>
<tr>
<th>Organisms</th>
<th>CFU/mL</th>
<th>Reps</th>
<th>Aerobic Hours</th>
<th>Anaerobic Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Strep pyogenes</em></td>
<td>&lt;3</td>
<td>10</td>
<td>19.0</td>
<td>13.8</td>
</tr>
<tr>
<td><em>Strep viridans</em></td>
<td>2</td>
<td>5</td>
<td>43.0</td>
<td>21.4</td>
</tr>
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</table>
S. lug

Brecher ME Hay SN. Transfusion 2007;47:1390-1394
BacSTAT Detects Bacteria with Objective Results

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

BPAC – March 2006
Bacterial species 1991-2005, N=46

<table>
<thead>
<tr>
<th>Year/quarter</th>
<th>VGS+CoNS (1)</th>
<th>S. uberis (1)</th>
<th>S. bovis (2)</th>
<th>S. marcescens (2)</th>
<th>S. aureus (5)</th>
<th>B. cereus (2)</th>
<th>P. aeruginosa (2)</th>
<th>CoNS (31)</th>
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<tr>
<td>1991/1</td>
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Data from:

From Ros Yomtovian

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.”

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 third such incident at a hospital in Kansas City where two hospital employees have been arrested on charges of tampering with blood.

"It's never a good deal, and it's never a good day," said Dr. David Hunt, director of the hospital's blood bank. "We're trying to do our best with what we have, and we're trying to do it safely.""}

"We're doing everything we can to prevent another occurrence," Hunt said. "But it's a very difficult thing to do. We're always trying to improve our processes.""}

"I don't know if it's going to happen again," Hunt said. "But we're doing everything we can to prevent it.""}

The hospital, which has been under state scrutiny since the E. coli outbreak, said it has taken steps to improve its blood screening processes. "We're doing everything we can to prevent another occurrence," Hunt said. "But it's a very difficult thing to do. We're always trying to improve our processes.""}

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

Fernanda Luna, German E. Lapera, Laurence Benvenuto, Roger Sundaram, Chris A. Van Breda, Patricia L. Shea-Mader, Beno Jenson, Matthew J. Steneke, and Matthew J. Kaufman

Background: An identifyxxx with severe hematological disease developed sepsis secondary to the transfusion of a pooled unit, which became contaminated with group C Streptococcus (GCS). A subsequent review of the patient’s medical history revealed that he had previously undergone transfusion with a similar unit in 1994, which had been transfused 2 weeks prior. The initial culture revealed GCS, which was later confirmed by susceptibility testing.

Methods: Blood cultures were obtained from the patient and his blood donor. The donor’s blood samples were sent for special culturing and testing. A retrospective review of his medical records was also conducted.

Results: The patient’s initial blood culture grew GCS, which was later confirmed by susceptibility testing. The donor’s blood samples were negative. A retrospective review of the patient’s medical records revealed that he had previously undergone transfusion with a similar unit in 1994, which had been transfused 2 weeks prior. The initial culture revealed GCS, which was later confirmed by susceptibility testing.

Conclusions: This case highlights the importance of proper screening and testing of blood products to prevent transfusion-related infections. It also underscores the need for careful review of patient medical histories to identify potential sources of infection.

Keywords: Group C Streptococcus, Transfusion, Infection, Sepsis
### Salmonella cholerae-suis Septicemia

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

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

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.
without blood fear

Cerus

Defining Pathways for Safer Blood Products

Sixers seal NBA Finals berth

Revolutionary process kills HIV, other diseases
“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.”
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.”
## Worldwide Bacterial Screening

<table>
<thead>
<tr>
<th>Country/region</th>
<th>Percentage</th>
<th>Outdate</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Denmark</td>
<td>100</td>
<td>day 7</td>
<td>BacT/ALERT</td>
</tr>
<tr>
<td>Ireland</td>
<td>100</td>
<td>day 7 (retest day 4)</td>
<td>BacT/ALERT</td>
</tr>
<tr>
<td>Netherland</td>
<td>100</td>
<td>day 7</td>
<td>BacT/ALERT</td>
</tr>
<tr>
<td>Norway</td>
<td>100</td>
<td>day 6.5</td>
<td>BacT/ALERT</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>100 – Scotland, Wales, N. Ireland QC - England</td>
<td>5-7 days</td>
<td>BacT/ALERT/Pall BDS</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Country/region</th>
<th>Percentage</th>
<th>Outdate</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>5% (only apheresis) QC</td>
<td>day 5</td>
<td>BacT/ALERT</td>
</tr>
<tr>
<td>Germany</td>
<td>QC</td>
<td>day 5</td>
<td>BacT/ALERT</td>
</tr>
<tr>
<td>France</td>
<td>-</td>
<td>day 5</td>
<td>Gradual implementation of Pathogen reduction</td>
</tr>
<tr>
<td>Japan</td>
<td>-</td>
<td>72 hours</td>
<td>-</td>
</tr>
</tbody>
</table>
So, have we missed the boat?
Do we know where we are going?