Three Percent is for Wimps

ACHIEVING AND MAINTAINING BLOOD CULTURE CONTAMINATION RATES BELOW ONE PERCENT

Dennis Ernst, MT (ASCP), NCPT (NCCT)

2/25/2020
I. Define the impact of blood culture contamination on patients and the facility

II. List the most common human errors that contaminate blood cultures

III. Discuss a new technique that significantly, immediately, and sustainably reduces contamination rates
Diagnosing the #1 cause of death and readmission in US Hospitals

Blood cultures remain the gold standard for diagnosing sepsis, with an accepted 3% contamination rate.
The (In)accuracy of Blood Culture Results

- **All Blood Cultures**: 8% Positive
  - Typical Positive Rate

- **Positive Blood Cultures**: 40% False Positive
  - 3% Contamination
  - Are actually False Positive

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ED Blood Culture Contamination Rates by Personnel

Lab staff

Study A: 1.1%
Study B: 3.1%

ED staff

Study A: 5.0%
Study B: 7.4%
### Contamination Rates

<table>
<thead>
<tr>
<th></th>
<th>Centralized settings</th>
<th>Decentralized settings</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1.0-3.1</td>
<td>4.2-8.4</td>
</tr>
</tbody>
</table>
The Cost of Contamination

Inpatient cost to treat: $2,083 – 8,720

Increased LOS: Up to 3.3 days

Outpatient: Follow-up testing & treatment: $152/false positive

26% of pediatric outpatients unnecessarily hospitalized
What this means at a typical hospital

3% BLOOD CULTURE CONTAMINATION RATE IN AN EMERGENCY DEPARTMENT

<table>
<thead>
<tr>
<th>Patient Safety</th>
<th>Hospital Economics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cultures / month:</td>
<td>833</td>
</tr>
<tr>
<td>Contamination Rate:</td>
<td>× 3.0%</td>
</tr>
<tr>
<td>Patients impacted by false positives / month:</td>
<td>= 25</td>
</tr>
<tr>
<td>Patients / year</td>
<td>300</td>
</tr>
<tr>
<td>Avg. cost per incident(^1,2)</td>
<td>× $4,200</td>
</tr>
<tr>
<td>Avoidable costs:</td>
<td>= $1,260,000</td>
</tr>
</tbody>
</table>
What this means at a typical hospital

2% BLOOD CULTURE CONTAMINATION RATE IN AN EMERGENCY DEPARTMENT

**Patient Safety**

<table>
<thead>
<tr>
<th>Cultures / month:</th>
<th>833</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contamination Rate:</td>
<td>× 2.0%</td>
</tr>
<tr>
<td>Patients impacted by false positives / month:</td>
<td>= 17</td>
</tr>
</tbody>
</table>

**Hospital Economics**

<table>
<thead>
<tr>
<th>Patients / year</th>
<th>200</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avg. cost per incident$^1,2$</td>
<td>× $4,200</td>
</tr>
<tr>
<td>Avoidable costs:</td>
<td>= $840,000</td>
</tr>
</tbody>
</table>


Monthly cost savings by reducing contamination rate one percentage point

Blood cultures drawn per month

$0  $5,000  $10,000  $15,000  $20,000  $25,000  $30,000

50  100  150  200  250  300  350  400  450  500  550  600  650  700  750  800  850  900  950  1,000
Annual cost savings by reducing contamination rate one percentage point

Blood cultures drawn per month

- Annual cost savings increase as the number of blood cultures drawn per month increases.
Blood culture contamination can have a devastating impact...

~ 1.2 MILLION
patients impacted by false-positive blood culture results annually in the United States1, the MAJORITY of which are treated with antibiotics

$4 BILLION+
is spent by our healthcare system each year on unnecessary treatment associated with false-positive blood culture results

3 MILLION +
antibiotic-resistant and C. diff infections each year and 48,000 people die – represents a 50% increase in infections and 100% increase in deaths since the 2013 CDC report
False-positive blood cultures increase many harmful patient safety risks

- Unnecessary Antibiotics
- Acute Kidney Injury (AKI)
- Antibiotic-Resistant Infections
- Extended Length of Stay
- Exposure to HAIs & HACs
- Risk of C. Difficile
- False-Positive CLABSIs

Misdiagnosed Patient
Unnecessary False Positive CLABSI Reporting

“43% of reported CLABSIs likely represented contaminants,”
- Boyce et al, AJIC, June 2013

• If a patient with a central venous catheter (CVC) has ONE positive blood culture bottle due to any non-common commensal organism it must be reported as a CLABSI.

• Increases risk of Standardized Infection Ratio (SIR) penalties – fine up to 2% of total annual CMS reimbursement.
Laboratory Impact
of reducing blood culture contamination

1. Improves workflow
2. Reduces unnecessary tests
3. Improves processes, productivity, performance
4. Reduces overtime
5. Significantly reduces avoidable costs
Poll Question #1
WE HAVE DONE THE FOLLOWING TO TRY TO REDUCE BLOOD CULTURE CONTAMINATION
Best Practices

Proper site prep

Collection technique
Best practices: site prep
Best practices: site prep
Best Practices

Proper site prep
Best Practices

- Proper site prep
- Cleansing stoppers
- Not repalpating
Best Practices

- Proper site prep
- Cleansing stoppers
- Not repalpating
- Friction scrub
Best Practices

Cleansing stoppers

Not repalpating

Friction scrub

30-second contact

Proper site prep

CDC: Avoid line draws

Collection technique
What Should we Target?

YOUR CONTAMINATION RATE

ASM “Threshold”

3%

Target recommended by industry experts (2011)

2%
Poll Question #2
THE CURRENT BLOOD CULTURE CONTAMINATION RATE AT MY HOSPITAL IS:
It is the opinion of the authors that consideration should be given to the establishment of a **new universal threshold value of ≤1.0%**.

When contamination rates **rise above 1%**, objective, step-wise quality improvement programs designed to improve patient care and reduce unnecessary costs should be implemented.”
Training and education on “best practices” will not solve the problem.

**Human Factor(s)**
Risk of contamination during assembly, preparation of supplies and skin prep

**Skin Flora**
You can disinfect but not sterilize the skin. Up to 20% of skin flora remains viable in the keratin layer of the skin even after skin prep.

**Skin Plug and Fragments**
will enter the culture specimen bottle and commonly will contain viable microorganisms (when present)
Manual Diversion Technique

Peer-reviewed published data has shown only modest unsustainable reductions in contamination

Lowest published contamination rate achieved is 2.2%

1. Prep the site
2. Prep the discard tube
3. Withdraw 1.5-2.0 mL
4. Discard the tube
5. Apply culture bottles
Manual Diversion Technique

CHALLENGES

- Adds additional steps to an already complex procedure
- Susceptible to touch point contaminations
- Difficult, if not impossible to disinfect waste tube top
- Risk of cross-contamination of the sheathed inoculation needle
  - Can lead to contamination of both bottles = “True Positive”
- No consistency in achieving required 1.5-2.0mL diversion volume
- Requires continuous staff training, education and oversight to ensure compliance
- Not an engineered approach: **NOT** practical, reproducible or sustainable
**Manual Diversion (waste tube)**

**Innovation for Reducing Blood Culture Contamination: Initial Specimen Diversion Technique**  
n = 3,733

- 9 months
- 44% reduction in BCC
- 2.2% BCC rate with manual ISD

**Effect of Initial Specimen Diversion Technique on Blood Culture Contamination Rates**  
n = 27,145

- 11 months
- 30% reduction in BCC
- 2.4% BCC rate with manual ISD

**Modification of Blood Test Draw Order to Reduce Blood Culture Contamination**  
n = 490
- 2 months
- 60% reduction in BCC
- 2.0% BCC rate with manual ISD

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**Use of ISDD**

Reduction in Blood Culture Contamination in the ED Through the Use of Initial Specimen Diversion Device®  
n = 1,808

- 12 months
- 92% reduction in BCC
- 0.2% BCC rate
The Initial Specimen Diversion Device®

- The first 1.5 – 2.0 mL of blood contains normal skin flora even when properly prepped
- Diverting the first 1.5 – 2.0 mL removes contaminates
The Initial Specimen Diversion Device®

STERIPATH® GEN2

- Reduction in false positives up to 92%
- 12-month sustained contamination rate as low as 0.2%
- Positive predictive value as high as 97%
- Reduction in vancomycin DOT up to 37%
- Shorten length of stay by average of 2 days
- Reduce HAIs / HACs by as much as 23%
- Avg. annualized cost savings of $945,000
Human Factors Engineered Out
1.5-2.0 mL Diversion Isolation Chamber

User-Controlled Negative-Pressure Diversion

Second Blood Flow Path

Product Design Prevents Bypassing Diversion

Active Initial Specimen Diversion Mechanism

9” Luer For Peripheral IV Start Blood Culture Draws

Human Factors Engineered Out
Integrated Syringe Collection

For Pediatrics (0.6 – 0.8 mL)

Requires FDA Market Clearance
Poll Question #3

BLOOD CULTURES AT OUR FACILITY ARE DRAWN BY:
ISDD® Peer-Reviewed Published Studies

Clinical Infectious Diseases 2017 (July)
Journal for Emergency Nursing 2018 (Nov)
Journal of Clinical Microbiology 2019 (Jan)
American Journal of Infection Control 2019 (Jan)
Journal of Hospital Infection 2019 (March)

Reduction in Blood Culture Contamination Through Use of Initial Specimen Diversion Device

Clinical Practice Guidelines

Efficacy of a Novel Specimen Collection System in Reducing Blood Culture Contamination Rates

Estimated Clinical and Economic Impact through Use of a Novel Blood Collection Device To Reduce Blood Culture Contamination in the Emergency Department: A Cost-Effectiveness Analysis

Model to evaluate the impact of hospital-based interventions targeting false-positive blood cultures on economic and clinical outcomes

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Reduction in Blood Culture Contamination Through Use of Initial Specimen Diversion Device

Mark E. Rupp, MD, Matthew Sarwar, MD, et al

Division of Infectious Disease, Department of Medicine, University of Nebraska Medical Center

Objective: To determine whether the use of Steripath Initial Specimen Diversion Device (Steripath) was associated with a reduction in blood culture contamination.

Methods: This was a single-center, prospective, controlled, matched-pair, open-label trial during a 12-month period involving 904 patients with 1,808 blood cultures. Blood cultures were obtained using blinded randomization into two groups: 1) Phlebotomist collected two cultures from each patient: one using Phlebotomy best practices and one using Steripath Initial Specimen Diversion Device. Outcomes: Primary endpoints were: comparison of contamination rates, length of hospital stay, and 30-day readmission rates. The study was approved by the Institutional Review Board. The trial was registered at ClinicalTrials.gov (NCT02916005).

Results: Between January 1, 2016 and December 31, 2016, 904 patients were enrolled and 1,808 blood cultures were collected. Blood culture contamination was reduced from 7.9% to 2.7% (P = 0.006). Length of hospital stay did not differ between groups. The 30-day readmission rates were 11.9% and 11.4% in the Steripath and Phlebotomy groups, respectively (P = 0.63).

Conclusion: Use of Steripath was associated with a significant decrease in blood culture contamination in patients undergoing procedures requiring two blood cultures.

Keywords: Blood culture contamination, Reynold’s test, Steripath

© 2017 Clinical Infectious Diseases
Reduction in Blood Culture Contamination Through the Use of Initial Specimen Diversion Device®

- *Clinical Infectious Diseases* - 2017:65 (15 July)

6 Months

1,342 patients
2,684 cultures
Reduction in Blood Culture Contamination Through the Use of Initial Specimen Diversion Device®

Clinical Infectious Diseases - 2017:65 (15 July)

INTERVENTION PERIOD

6 Months
1,342 patients
2,684 cultures

12 Months
904 patients
1,808 cultures

No change in true bacteremia detection
[65/904 (7.2%) vs. 69/904 (7.6%), P=0.41]

Positive Predictive Value = 97%
Reduction in Blood Culture Contamination Through the Use of Initial Specimen Diversion Device®

Clinical Infectious Diseases - 2017:65 (15 July)

- Pre-Intervention: Phlebotomy Best Practice - 2.6%
- Phlebotomy Best Practices - 1.8%
- Steripath: Increased 12-fold without Steripath - 0.2%
- Post Intervention: Phlebotomy Best Practice - 2.8%

Researchers calculated the study institution would save $1.8M/year with Steripath.
Reduction of Blood Culture Contaminations in the Emergency Department using Steripath® ISDD®

Department of Defense Healthcare Quality and Safety Award Winner – 2016 (Submitted for Publication)

Brooke Army Medical Center

LTC Charlotte Lanteri Ph.D., et al

Department of Emergency Medicine

Single center, prospective, open label trial

Blood cultures collected in the Emergency Department. Patients randomized to either standard method or use of Steripath via venipuncture and peripheral IV starts.

92% reduction in contamination with Steripath
Steripath: 0.6% (5/784) contamination rate
Standard procedure: 7.7% (52/672) contamination rate

Saved over $235,000 during 5-month trial period
**TITLE:** Impact of Initial Specimen Diversion Device® and Molecular Pathogen Identification on Vancomycin Use

**CONFERENCE:** SHEA Conference – 2017
Submitted for Publication

**INSTITUTE:** Brooke Army Medical Center

**AUTHORS:** David Chang, MD, et al

**AFFILIATIONS:** Infectious Diseases, Microbiology, Antimicrobial Stewardship Program

**DESIGN:** Single center, retrospective, non-randomized

**METHOD:** Comparison of Vancomycin DOT before and after interventions to reduce pathogen detection time (Verigene®) and blood culture contamination (Steripath® in ED).

**RESULTS:** Vancomycin DOT per 1,000 patient days decreased 20%, 49.56 to 39.31 (P=0.001) after implementation of PCR.

Steripath resulted in an incremental decrease in vancomycin DOT by 37% (P=0.007), 39.31 to 24.87

**SUMMARY:** Greater de-escalation of Vancomycin DOT was best achieved through a combination of a molecular detection assay and Steripath.
Don’t Stick Me Again - Reducing Blood Culture Contamination in the Adult Emergency Department

CONFERENCE: ENA Conference Award Winner – 2019

INSTITUTE: Inova Fairfax Hospital

AUTHORS: Kara Bauman, MN, RN, CEN, CPEN, TCRN

AFFILIATIONS: Adult Emergency Department

DESIGN: Single center, prospective, controlled, non-randomized trial

METHOD: 12-month trial period the ISDD was used for blood culture collection via venipuncture and peripheral IV starts.

RESULTS: 82% reduction in blood culture contamination. (0.8% v 4.4%)

SUMMARY: Reduced costs. Promoted antibiotic stewardship. 69% of Steripath draws were via PIV starts.
**TITLE:** Hospital-wide Phlebotomy Elimination of Blood Culture Contamination Using Steripath Gen2 Initial Specimen Diversion Device (ISDD)

**CONFERENCE:** AHA Health Forum Educational Webinar – 2019
Pending submission for publication

**INSTITUTE:** Stanford Health Care

**AUTHORS:** Lucy Tompkins, MD, PhD et al

**DESIGN:** Single center, prospective, controlled study

**METHOD:** Blood cultures were obtained hospital-wide by Phlebotomy team using the Steripath Gen2 Initial Specimen Diversion Device compared to standard method.

**RESULTS:** 0.0% (ISDD – 0/4,462) v 1.5% (standard procedure - 35/2,456)

**SUMMARY:** Up to 88% user-compliance.
Prevent up to 103 patients from exposure to risks of false positives
ZERO false positive CLABSIs when Steripath was used.
Steripath ISDD® Clinical and Economic Impact Study

Impact of Hospital-Based Interventions [Phlebotomy & Steripath® ISDD®]
Targeting False-Positive Blood Cultures on Economic and Clinical Outcomes
Journal of Hospital Infection - 2019 (March)

Absolute Components of Cost per False Positive Blood Culture
(Hospital Perspective)

<table>
<thead>
<tr>
<th>Component</th>
<th>Cost (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Costs</td>
<td>$4,817</td>
</tr>
<tr>
<td>HAI / HAC Events</td>
<td>$373</td>
</tr>
<tr>
<td>Add'l Procedures/Tests/IV Access</td>
<td>$494</td>
</tr>
<tr>
<td>Add'l Blood Cultures &amp; Lab Workup</td>
<td>$127</td>
</tr>
<tr>
<td>ELOS</td>
<td>$3,198 (2.4-Days P=0.0076)</td>
</tr>
</tbody>
</table>

Total cost to hospital per false positive blood culture event = $4,817
(The use of ISDD) would save the typical 250- to 400-bed hospital $1.9M or $186 per blood culture, and prevent 34 HACs (including three C. difficile cases)" 

– Journal of Hospital Infection - 2019 (March)
### Major Academic Institutions: Blood Culture Contamination Cost Studies (2019)

<table>
<thead>
<tr>
<th>Study Institution/Researcher</th>
<th>Study Description</th>
<th>Incremental Hospital Costs per Blood Culture Contamination Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Houston</td>
<td>Steripath ISDD Cost-Benefit Study (J. Clin Micro - 2019)(^1)</td>
<td>$4,739</td>
</tr>
<tr>
<td>University of Nebraska Medical Center (^*)</td>
<td>Retrospective ISDD Cost Effectiveness Study (^3) (Submitted for publication)(^3)</td>
<td>$3,409</td>
</tr>
</tbody>
</table>

\(^*\)Pending publication


\(^3\)Reference on file

Average Cost Per False Positive Event: $4,321
<table>
<thead>
<tr>
<th>#</th>
<th>Institution</th>
<th>Publication/Conference</th>
<th>Study Period (months)</th>
<th>Starting BCC Rate (%)</th>
<th>ISDD BCC Rate (%)</th>
<th>BCC Reduction (%)</th>
<th>Cost Savings (Annualized)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>University of Nebraska Medical Center</td>
<td>Clinical Infectious Diseases, July 2017</td>
<td>12</td>
<td>2.6%</td>
<td>0.2% (P=0.001)</td>
<td>92%</td>
<td>$1,800,000</td>
</tr>
<tr>
<td>2</td>
<td>Lee Health System (4 sites)</td>
<td>Journal of Emergency Nursing, Nov. 2018</td>
<td>7</td>
<td>3.5%</td>
<td>0.6% (P=0.0001)</td>
<td>83%</td>
<td>$1,100,000</td>
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<tr>
<td>3</td>
<td>Brooke Army Medical Center</td>
<td>DOD Healthcare Quality Safety Award, 2016</td>
<td>5</td>
<td>7.7%</td>
<td>0.6%</td>
<td>92%</td>
<td>$564,000</td>
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<td>4</td>
<td>Brooke Army Medical Center</td>
<td>SHEA, 2017</td>
<td>14</td>
<td>2.6%</td>
<td>0.6%</td>
<td>92%</td>
<td>$1,800,000</td>
</tr>
<tr>
<td>5</td>
<td>Medical University of South Carolina</td>
<td>Institute for Healthcare Improvement, 2016</td>
<td>8</td>
<td>4.2%</td>
<td>0.6%</td>
<td>86%</td>
<td>NR</td>
</tr>
<tr>
<td>6</td>
<td>Rush University Medical Center</td>
<td>IDSA – IDWeek, 2017</td>
<td>3</td>
<td>4.3%</td>
<td>0.6%</td>
<td>86%</td>
<td>NR</td>
</tr>
<tr>
<td>7</td>
<td>Medical University of South Carolina</td>
<td>Institute for Healthcare Improvement, 2017</td>
<td>20</td>
<td>4.6%</td>
<td>0.9%</td>
<td>80%</td>
<td>$447,000</td>
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<tr>
<td>8</td>
<td>Inova Fairfax Hospital</td>
<td>ENA, 2019 (Awarded Best Evidence-Based Project)</td>
<td>12</td>
<td>4.4%</td>
<td>0.8%</td>
<td>82%</td>
<td>$932,000</td>
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<tr>
<td>9</td>
<td>Beebe Healthcare</td>
<td>ASM, 2018</td>
<td>4</td>
<td>3.0%</td>
<td>0.8%</td>
<td>75%</td>
<td>NR</td>
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<tr>
<td>10</td>
<td>VA Houston</td>
<td>ENA, 2018</td>
<td>7</td>
<td>5.5%</td>
<td>0.9% (P=0.01)</td>
<td>83%</td>
<td>NR</td>
</tr>
<tr>
<td>11</td>
<td>Shaare Zedek Medical Center</td>
<td>American Journal of Infection Control, March 2019</td>
<td>6</td>
<td>5.2%</td>
<td>1.0% (P=0.006)</td>
<td>81%</td>
<td>NR</td>
</tr>
<tr>
<td>12</td>
<td>University of Houston</td>
<td>J. Clin. Micro, January 2019</td>
<td>12</td>
<td>2.6%</td>
<td>0.2% (P=0.001)</td>
<td>92%</td>
<td>$1,800,000</td>
</tr>
<tr>
<td>13</td>
<td>Mass General / Harvard / WingTech</td>
<td>Journal of Hospital Infection, March 2019</td>
<td>12</td>
<td>2.6%</td>
<td>0.2% (P=0.001)</td>
<td>92%</td>
<td>$1,800,000</td>
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ISDD can save the hospital $4,739 per false positive blood culture event

ISDD can save the hospital $4,817 per false positive blood culture event and $1.9M annually and prevent 34 HACs including 3 C. diff
Your Contamination Rate:
What Should You Target?

ALL BLOOD CULTURES

Negative: 90%

False Positive = 3%

POSITIVE BLOOD CULTURES

True Positives: 60%

False Positives = 40%
Your Contamination Rate:
What Should You Target?

ALL BLOOD CULTURES

NEGATIVE: 90%

POSITIVE: 10%

POSITIVE BLOOD CULTURES

TRUE POSITIVES = 100%

• Personal Productivity
• Departmental Efficiency
• Effective Antibiotic Stewardship
Thank You!