About the Clinician Call: Initiated in 2020 as a forum for information sharing among frontline clinicians caring for patients with COVID-19. Now expanded to address timely topics in infectious diseases—all from a clinical perspective.

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This webinar is being recorded and can be found online at www.idsociety.org/cliniciancalls.
CDC/IDSA Clinician Call:
BD BACTEC Blood Culture Bottle Shortage

Jointly hosted with ASM, SHEA and PIDS
1. BP Update

Chris Beddard
VP, Microbiology, BD Life Sciences
VP, Global Platform Leader, Microbiology Diagnostic Solutions

2. CDC Blood Culture Quality Tools

Jake D. Bunn, MBA, MLS (ASCP)CM, LSSBB
Clinical Laboratory Scientist
Division of Laboratory Systems
U.S. Centers for Disease Control and Prevention

3. Blood Culture Utilization

Valeria Fabre, MD
Associate Professor of Medicine,
Division of Infectious Disease
Associate Hospital Epidemiologist
Johns Hopkins University School of Medicine

4. Q&A and Discussion – All Presenters Plus:

Aaron M. Milstone, MD, MHS
Professor of Pediatrics
Division of Infectious Disease
Johns Hopkins University School of Medicine

Sarah E. Turbett, MD
Associate Director, Clinical Microbiology Laboratories
Assistant Professor of Pathology and Medicine
Massachusetts General Hospital
Harvard Medical School

Romney M. Humphries, PhD, D(ABMM), M(ASCP)
Director, The Division of Laboratory Medicine
Professor of Pathology, Microbiology, & Immunology
Medical Director of the Microbiology Laboratory
Vanderbilt University Medical Center

Carl Newman, Deputy Director, Office of Supply Chain Resilience
U.S. Food and Drug Administration

Ryan Lupert, JD, Regulatory Counsel, Acting Deputy Office Director for Patient Safety and Product Quality, U.S. Food and Drug Administration
Question?
Use the “Q&A” Button

Comment?
Use the “Chat” Button
PARTICIPANT POLL
BP Update

Chris Beddard
BD Life Sciences
Why is this happening?

BD is experiencing reduced availability of blood culture vials from our supplier which we expected to be temporary in nature. After investigation and analysis, we determined the issue is more complex than our supplier originally communicated, and their manufacturing issues will limit BD’s ability to supply BD BACTEC™ blood culture vials to meet full global demand.

How is BD addressing the issue?

We understand the critical role that blood culture media play in diagnosing and treating infections, and are taking all necessary measures to address this important issue. BD is collaborating with the U.S. Food and Drug Administration to review all potential options to resolve this challenge as quickly as possible. In response to the ongoing challenges, BD has already implemented various mitigation measures. These include:

- Working directly with our raw materials supplier of molded bottles to improve production line efficiency and output.
- Early procurement of BD BACTEC™ media on manual inoculation to closely manage supply and ensure equitable distribution.
- Reducing transit times where possible with air shipment to meet regional needs and improve inventory levels.
- Modifying manufacturing schedules to rapidly respond to bottlenecks from our supplier.

When will product availability improve?

Based on actions currently deployed at our supplier and the temporary sourcing of glass bottles for BD BACTEC™ Upjohn Anaerobic Culture Vials, we expect to realize improvements in the September 2024 supply. In the interim, BD will continue to fulfill customer orders regularly and as supply is available. As this is a dynamic and evolving situation, we will provide another supply update by September 2024.

Recommended Actions:

- Assess current inventory levels of BD BACTEC™ blood culture media in your system warehouses, laboratory, unit, and nursing stations.
- Prioritize the use of blood culture media based on clinical need, following guidelines of local oversight committees, such as the most recent update from IDSA and the World Health Organization as applicable to your region.
- Partner with your internal clinical teams to align on and implement a BD BACTEC™ blood culture media utilization strategy.
- Emphasize the importance of proper blood volume collection and disinfection of skin portals with collectors to optimize recovery and minimize false positive results, respectively (Refer local guidelines such as CLSI).

https://bdm.bdbactec-update.com/
CDC Blood Culture Quality Tools

Jake D. Bunn, MBA, MLS (ASCP)CM, LSSBB
U.S. Centers for Disease Control & Prevention
National Patient Safety Measure

CMS Consensus-Based Entity (CBE)
Endorsement and Maintenance

Adult Blood Culture Contamination Rate; A national measure and standard for clinical laboratories and antibiotic stewardship programs

CBE ID: 3658  Steward: Centers for Disease Control and Prevention  Status: Endorsed  Status Last Updated: 12 December, 2022

https://p4qm.org/measures/3658
Preventing Adult Blood Culture Contamination: A Quality Tool for Clinical Laboratory Professionals

Laboratory analysis of blood cultures is critical for accurate and timely diagnosis of bloodstream infections. However, the reliability of culture testing depends on clinical compliance with collection procedures that limit the risk of incomplete or incorrect results. False negative blood cultures result due to inadequate volumes of blood, a result in nosocomial, delayed therapy, and potential mortality. To prevent such complications, laboratories must ensure optimal blood culture collection rates. In addition, the process measure incorporates best practices on blood culture collection from the Clinical Laboratory Standards Institute (CLSI) and the Infection Control Practices Advisory Committee (ACIP). These best practices are essential to identify every laboratory accessing the system, have drawn to improve the laboratory diagnosis of bloodstream infections.

Follow the guidelines to improve the laboratory's diagnostic accuracy and reduce diagnosis errors, as well as to optimize care processes identified in the proposed system (tactual and check patient flow through the system). To achieve optimal volume:

1. The volume of blood collected is critically important to the laboratory's diagnosis of bloodstream infection, which is generally required two or more sets to cultures. In addition, two sets are required to determine whether the presence of a commercial organism can be classified as a possible contaminant.
2. To achieve the optimal volume, the blood culture collection standard of practice is to collect two to four blood culture sets from adults patients with suspected bloodstream infection in the evaluation of multi-drug resistant (certain, 24 hours), Your hospital or clinical setting should consider healthcare staffs to collect at least two blood culture sets (total volume of 40-60mL) within 24 hours period prior to antibiotic administration, if possible.

Collect Multiple Sets to Achieve the Optimal Volume

The volume of blood collected is critically important to the laboratory's diagnosis of bloodstream infection, which is generally required two or more sets to cultures. In addition, two sets are required to determine whether the presence of a commercial organism can be classified as a possible contaminant.

To achieve the optimal volume, the blood culture collection standard of practice is to collect two to four blood culture sets from adult patients with suspected bloodstream infection in the evaluation of multi-drug resistant (certain, 24 hours). Your hospital or clinical setting should consider healthcare staffs to collect at least two blood culture sets (total volume of 40-60mL) within 24 hours period prior to antibiotic administration, if possible.
Diagnostic Excellence: A New Quality Tool to Prevent Blood Culture Contamination

https://youtu.be/tkAl4_wmLcw
### Disruptions in Availability of BD BACTEC Blood Culture Media Bottles - Letter to Health Care Providers

**July 10, 2024**

#### Medical Device Shortages List

**Medical Device Shortages List | FDA – July 10, 2024**

<table>
<thead>
<tr>
<th>Category</th>
<th>Product Code (Description)</th>
<th>Availability and Estimated Shortage Duration</th>
<th>Additional Information</th>
<th>Reason for Interruption (per 506.I)</th>
<th>Date (YYYY/MM/DD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microbiology - Microbiology Devices</td>
<td>MDB (System, Blood Culturing)</td>
<td>Estimated through Q4 2024</td>
<td>To provide recommendations to health care providers and laboratories that use blood culture media bottles intended for bloodstream infection testing, the FDA is providing a <strong>MDB Shortage - Letter to Health Care Providers</strong>.</td>
<td>Shortage or discontinuance of a component, part or accessory of the device.</td>
<td>2024/07/10 Initial</td>
</tr>
</tbody>
</table>
Take Home Messages

Those who collect blood cultures should be:

- Performing routine skin disinfection prior to collection to minimize the risk of contamination of the blood culture and the need to recollect additional blood cultures.

- Ensuring proper blood volume collection to avoid a need to recollect additional blood cultures.
Questions?

Contact: DLSinquiries@cdc.gov
Blood Culture Utilization

Valeria Fabre, MD
The Johns Hopkins Hospital

Aaron M. Milstone, MD
Johns Hopkins University School of Medicine

Sarah Turbett, MD
Massachusetts General Hospital

Romney M. Humphries, PhD, D(ABMM), M(ASCP)
Vanderbilt University Medical Center
Blood Culture Stewardship Opportunities

Valeria Fabre, MD
Associate Professor of Medicine
Division of Infectious Disease
Johns Hopkins University School of Medicine

Aaron Milstone, MD, MHS
Professor of Pediatrics
Division of Infectious Disease
Johns Hopkins University School of Medicine
Disclosures

• No relevant financial disclosures

• The content of this presentation represents our own views
Opportunities to improve inpatient blood culture (BCx) utilization

~90% of blood cultures obtained from adult inpatients are negative

- Based on an evidence-based algorithm (next slide), 30% of BCx in a medical ICU and 50% of BCx in medicine floors at a tertiary hospital in Baltimore were inappropriate
  - 60% of BCx in the ICU at a tertiary center in NYC
  - 40% of BCx in a Swiss hospital
  - 25% of BCx in a SICU at a tertiary hospital in North Carolina

Algorithm for bacterial blood cultures recommendations in non-neutropenic (adult) patients.

**Initial BCx**
- Is severe sepsis/septic shock* or infective endocarditis/endothelial infection† suspected?
  - **YES**
  - BCx RECOMMENDED
    - Draw 2 peripheral sets
  - **NO**
  - What is the pretest probability of bacteremia?
    - High (>50%)
    - Intermediate (≥10% and <50%)
    - Low (<10%)

**Follow-up BCx**
- Is the follow-up BCx to document clearance of bacteremia for any of the following?‡
  - *S. aureus, S. lugdunensis* bacteremia
  - Bacteremia in a patient with suspected endovascular infection§ or patient at risk for endovascular infection†
  - Catheter-related bloodstream infection before catheter replacement
- **YES**
  - BCx RECOMMENDED
    - Draw 2 peripheral sets within 48 hours of initial BCx
- **NO**
  - BCx NOT RECOMMENDED

---

*Severe sepsis/septic shock:
- Sepsis with severe organ impairment

†Infective endocarditis:
- Valve infection

‡Bacteremia:
- Presence of bacteria in the bloodstream

§Endovascular infection:
- Infection involving blood vessels

©Catheter-related bloodstream infection:
- Bacteremia caused by a catheter

---

**Examples:**
- Catheter-associated bloodstream infection
- Discitis/native VO
- Epidural abscess
- Meningitis
- Nontraumatic native septic arthritis
- Ventriculostial shunt infections

**Examples (intermediate):**
- Acute pyelonephritis
- Cholangitis
- Nonvascular shunt infections
- Prosthetic VO
- Severe CAP (PSI V and IV)

**Examples (low—intermediate):**
- Cellulitis in patients with comorbidities
- VAP

**Examples (low):**
- Isolated fever and/or leukocytosis
- Nonsevere cellulitis
- Lower UTI (eg cystitis, prostatitis)
- Nonsevere CAP, HCAP

**Examples (very low):**
- Postoperative fever within 48 hours of surgery

---

**Is the patient at risk of endovascular infection?**
- NO

**Is the primary site of infection not readily available for culture prior to antibiotic initiation?**
- NO

**Are BCx results otherwise likely to impact management?**
- NO

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The content of this slide may be subject to copyright; please see the slide notes for details.
Implementation of a BCx algorithm to reduce unnecessary BCx in adult medicine units

- Education on BCx indications & collection best practices to ordering providers
- Implementation of the evidence-based BCx algorithm to guide BCx decisions (paper-based)
- Regular feedback regarding BCx utilization rates, and examples of inappropriate BCx

- Reduction of single sets in medicine floors
- Increase in BCx positivity in ICU
- No negative impact on the CMS Sep-1 measure, readmission, or mortality

Other hospitals have implemented the BCx algorithm (adult surgical\(^1\), MICU and SICU\(^2\)) and have observed a 20-70% relative reduction in BCx utilization without safety concerns (readmission, length of stay, or 30-day mortality)

---

Summary of low-yield BCx in non-neutropenic adults

LOW-YIELD INITIAL BLOOD CULTURES

- Non-severe CAP
- Post-op fever within 48hs
- Isolated fever
- Isolated leukocytosis
- Persistent fever without clinical change and negative blood cultures in last 48-72 hours
- Persistent leukocytosis without clinical change and negative blood cultures in last 48-72 hours
- Non-severe CAP
- Non-severe cellulitis
- Post-operative fever within 48hs from surgery
- Lower UTI (cystitis, prostatitis)
- Surveillance blood cultures (e.g., before procedures, line placement, TPN initiation, etc.) in patients without suspicion for bacteremia

LOW-YIELD FOLLOW-UP BLOOD CULTURES

- Repeat blood cultures to document clearance of bacteremia caused by organisms other than *Staphylococcus aureus*, *Staphylococcus lugdunensis*, or *Candida* in patients without infective endocarditis/endovascular infection (e.g., cardiac device infection, septic thrombophlebitis) who showed clinical response and source control has been achieved

- Repeat blood cultures to rule out blood culture contamination in immunocompetent patients without prosthetic implants

BCx Stewardship in critically ill children

- Consensus Recommendations for Blood Culture
- 14-hospital study:
  - **33%** relative reduction in BCx rate
  - **36%** relative reduction in CLABSI rate
  - **13%** relative reduction in broad-spectrum antibiotic use
- Safe: No difference in mortality, PICU readmission, PICU length of stay before and after the intervention, number of sepsis, severe sepsis/septic shock cases before and after the intervention

http://HopkinsChildrens.org/brightstar
https://www.hopkinsmedicine.org/antimicrobial-stewardship

SUGGESTED STRATEGIES TO CONSERVE BCx BOTTLES

✓ Determine the magnitude of the problem
✓ Identify clinical areas/units with highest blood culture utilization (usually inpatient medicine, ICU, surgery, and Oncology units) using electronic health record data
✓ Review your data to assess drivers of unnecessary blood cultures
✓ Review the content of the algorithm with ordering providers, especially residents, hospitalists, and advanced practice practitioners
✓ Educate consultants who are more likely to recommend blood cultures such as Infectious Diseases and Nephrology
✓ Engage unit director and bedside nurses in applying the Blood Culture Algorithm
✓ Highlight common infections where blood cultures are low yield (e.g., non-severe CAP, uncomplicated cellulitis, lower UTIs, isolated fever +/- leukocytosis, post-operative fever first 48 hours)
✓ Use a graded approach to conserve blood culture bottles based on anticipated supply reduction (e.g., low yield blood cultures, non-critically ill patients first)
✓ Highlight infections in which is important to get 2 sets of blood cultures (e.g., severe sepsis, endovascular infection)
✓ Monitor appropriateness of use and feedback data to units (could be a random sample of cases)
Acknowledgements

• Society of Healthcare Epidemiology of America (2018 SHEA Research Scholar Award)

• CDC Prevention Epicenters Program (currently funding a JHU-led large collaborative project to characterize and improve blood culture utilization in hospitalized adults)

• JHU collaborators
  • Sara E. Cosgrove
  • Karen C. Carroll
  • Aaron Milstone

• BrighT STAR – funded by AHRQ, co-led by Drs. Aaron Milstone and Charlotte Woods-Hill
### Impact of number of sets in bacteremia detection

<table>
<thead>
<tr>
<th>Organism</th>
<th>1 set</th>
<th>2 sets</th>
<th>3 sets</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>S. aureus</em></td>
<td>93%</td>
<td>97%</td>
<td>100%</td>
</tr>
<tr>
<td><em>Enterococci</em></td>
<td>67%</td>
<td>80%</td>
<td>89%</td>
</tr>
<tr>
<td>Streptococci</td>
<td>77%</td>
<td>85%</td>
<td>100%</td>
</tr>
<tr>
<td><em>E. coli</em></td>
<td>72%</td>
<td>91%</td>
<td>95%</td>
</tr>
<tr>
<td><em>P. aeruginosa</em></td>
<td>60%</td>
<td>85%</td>
<td>100%</td>
</tr>
<tr>
<td><em>C. albicans</em></td>
<td>60%</td>
<td>85%</td>
<td>95%</td>
</tr>
<tr>
<td><em>K. pneumoniae</em></td>
<td>78%</td>
<td>90%</td>
<td>98%</td>
</tr>
</tbody>
</table>

BD BACTEC Blood Culture Bottle Shortage: Practical Implementation Strategies and Considerations

Sarah E. Turbett, MD
Associate Director, Clinical Microbiology Laboratories
Massachusetts General Hospital

July 2024
Action Plan Development

• Get organized:
  • Build a team with key stakeholders
    • Hospital and/or enterprise leadership
    • Information technology
    • Emergency preparedness
    • Supply chain
    • Clinical leadership (inpatient, outpatient, emergency medicine, intensive care, clinical pathology, pediatrics)
    • Nursing and phlebotomy leadership
    • Materials management
    • Subject matter experts (infectious diseases, microbiology)
Action Plan Development

• Gather your data
  • Learn the scope of the problem
    • Understand demand
      • Calculate total blood culture bottle use by location
  • Understand current supply
    • Calculate current inventory
    • Centralize supply for improved monitoring
  • Understand potential impact of shortage on anticipated inventory
• Calculate a run rate and estimate days/weeks of inventory
• Dashboard helpful
Action Plan Development

• Develop and document goals/guidance
  • Goal:
    • Maximize benefit to populations of patients at time of shortage
  • Guidance:
    • Phased approach based on projected inventory
      • Prioritizes beneficence, equity, solidarity, and efficacy
      • Rooted in transparency and two-way communication
Action Plan Guidance: Response Categories

• CONSERVATION:
  • Response to inventory reductions that is unlikely to jeopardize clinical care.
  • Example: measures to improve utilization.

• RATIONING:
  • Response to serious depletion of inventory to levels that could jeopardize clinical care without restriction.
  • Example: Reducing the number of blood cultures ordered.

• SEVERE RATIONING:
  • Response to a severe and potentially critically inadequate supply of blood culture bottles.
  • Example: case-by-case review of blood culture orders.
Action Plan Guidance: Enacting Thresholds

• For the response categories:
  • Need to determine at what threshold each response will be enacted
    • Determined by the incident management team
    • Reviewed regularly
Implementation strategies for action plan development

• CONSERVATION: Return to best practices
  • Eliminate blood culture draws before orders are placed

• Reinforce proper blood culture collection and transport
  • Sterile practice and hand hygiene to reduce contamination
  • Ensure bottles are adequately filled
  • Ensure expedited transport to laboratories

• Review blood culture contamination rates by location
  • Drill down on areas with high rates
Implementation strategies for action plan development

• CONSERVATION: Improve utilization
  • Turn off best practice alerts (BPA’s) that prompt for blood cultures when intravenous antibiotics are ordered
  • Remove daily and more often frequencies from the blood culture orderable
  • Create a BPA highlighting low-yield conditions to reduce blood culture ordering
  • Engage infectious diseases in utilization efforts
    • EPIC smart phrases indicating when to draw blood cultures in consult and follow up notes
Implementation strategies for action plan development: BPA

- Went live July 1st
- Fires in the emergency department and inpatient space at Enter Orders
- Fires for adult patients only
- Suppressed if the Sepsis BPA fired in the past 6 hours
- 34% reduction in blood culture volume within a 2 week period

Courtesy of Lindsay Germaine, MPH
Implementation strategies for action plan development: Epic dot phrase

There is a critical shortage of blood culture bottles.

**[if choose WITHOUT bacteremia]** For patients ID is following **without known bacteremia**, during the day please reach out to the ID physician prior to ordering and collecting blood cultures unless already advised to do so by the ID physician. Overnight, the decision to draw blood cultures should be based on the following guidelines. [Insert link to blood culture guidelines].

**[if choose WITH bacteremia]**
For patients ID is following **with known bacteremia**, we recommend repeat blood cultures to document bloodstream infection clearance only in the following circumstances:

1. Staph aureus or Staph lugdunensis bacteremia
2. Bacteremia in a patient with known or suspected endocarditis
3. Catheter related bloodstream infection before catheter replacement
4. Single positive blood culture with skin flora in a patient with a vascular graft or prosthetic heart valve
5. Single positive blood culture with skin flora in a patient with an intravascular catheter
6. Concern for persistent bacteremia in the absence of source control

Gram-negative rod bloodstream infection **does not require** demonstration of blood culture clearance in a patient who is clinically improving.

**DO NOT** repeat blood cultures until at least 24 hours of antimicrobial therapy have been given. To verify resolution of bacteremia in the settings above, 48 hours of negative blood cultures should suffice and additional blood culture sets are not needed.

Courtesy of Lindsay Germaine, MPH
Implementation strategies for action plan development: Epic dot phrase

There is a critical shortage of blood culture bottles.

For patients ID is following with known bacteremia, we recommend repeat blood cultures to document bloodstream infection clearance only in the following circumstances:

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Blood Culture Guidelines

Courtesy of Lindsay Germaine, MPH
Laboratory mitigation strategies for action plan development

• RATIONING
  • Use of expired blood culture bottles to increase supply?

  Spiked 5 commercial blood culture bottles (BCBs) that had been stored beyond their expiration date at room temperature and “tropical conditions”
  • 5 organisms: *S. aureus*, *E. coli*, *P. aeruginosa*, *C. albicans*, *S. pneumoniae*, concentration 105 CFU
  • BCBs were **stable 4-7 months after expiration date**

Hardy et al. (2024). *Clinical Microbiol and Infect*. [https://doi.org/10.1016/j.cmi.2024.06.014](https://doi.org/10.1016/j.cmi.2024.06.014)
Laboratory mitigation strategies for action plan development

• Use of expired BD BACTEC blood culture bottles to increase supply?

Evaluation of Expired BD BACTEC™ Blood Culture Vials

Erik H. Klontz1, Lisa A. Milien2, David Lucier2, Anand S. Dighe1 John A. Brunda1, Sarah E. Turbett2

1Department of Pathology, Massachusetts General Hospital and Harvard Medical School, Boston, Massachusetts, USA.
2Department of Medicine, Massachusetts General Hospital and Harvard Medical School, Boston, Massachusetts, USA.

• Evaluated expired BD BACTEC Aerobic/F culture vials for:
  • Sterility: passed visual inspection
  • pH: observed 7.15 ± 0.01; expected 7.2 ± 0.1
  • Vacuum draw: observed 30.5 ± 2 mL; expected > 8 mL
  • Growth of 20 organisms compared to unexpired media:
    • No difference in time to detection (p = 0.533)

<table>
<thead>
<tr>
<th>Organism</th>
<th>Inoculum (CFU)</th>
<th>Expired media time to growth (h)</th>
<th>Unexpired media time to growth (h)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcaligenes faecalis ATCC 8750</td>
<td>65</td>
<td>24.23</td>
<td>23.75</td>
</tr>
<tr>
<td>Candida glabrata ATCC 2950</td>
<td>27</td>
<td>20.63</td>
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<td>Escherichia coli ATCC 25922</td>
<td>22</td>
<td>12.20</td>
<td>12.37</td>
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<tr>
<td>Haemophilus influenzae ATCC 10211</td>
<td>60 + FOS</td>
<td>14.62</td>
<td>14.62</td>
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<tr>
<td>Neisseria meningitidis ATCC 13090</td>
<td>11 + FOS</td>
<td>20.57</td>
<td>20.72</td>
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<tr>
<td>Pseudomonas aeruginosa ATCC 27853</td>
<td>53</td>
<td>17.43</td>
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<tr>
<td>Staphylococcus aureus ATCC 25923</td>
<td>31</td>
<td>13.20</td>
<td>13.37</td>
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<td>Streptococcus pneumoniae ATCC 49619</td>
<td>7</td>
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<td>13.30</td>
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<td>Streptococcus pyogenes ATCC 19615</td>
<td>16</td>
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<tr>
<td>Staphylococcus lugdunensis clinical strain</td>
<td>22</td>
<td>20.27</td>
<td>19.62</td>
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<td>Staphylococcus haemolyticus clinical strain</td>
<td>15</td>
<td>18.10</td>
<td>18.10</td>
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<td>Streptococcus mitis/oralis clinical strain</td>
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<td>Enterococcus faecalis clinical strain</td>
<td>24</td>
<td>11.83</td>
<td>11.83</td>
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<td>Enterococcus faecium clinical strain</td>
<td>22</td>
<td>13.60</td>
<td>13.60</td>
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<tr>
<td>Corynebacterium spp. clinical strain</td>
<td>36</td>
<td>58.97</td>
<td>No growth 5 days</td>
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<tr>
<td>Klebsiella pneumoniae clinical strain</td>
<td>27</td>
<td>10.48</td>
<td>10.82</td>
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<td>Proteus mirabilis clinical strain</td>
<td>40</td>
<td>11.70</td>
<td>11.68</td>
</tr>
<tr>
<td>Serratia marcescens clinical strain</td>
<td>60</td>
<td>13.97</td>
<td>13.63</td>
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<td>Enterobacter cloacae complex clinical strain</td>
<td>36</td>
<td>12.03</td>
<td>11.87</td>
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<td>Aeromonas hydrophila clinical strain</td>
<td>29</td>
<td>10.28</td>
<td>10.28</td>
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<tr>
<td>Negative control</td>
<td>N/A</td>
<td>No growth 5 days</td>
<td>No growth 5 days</td>
</tr>
<tr>
<td>Negative control</td>
<td>FOS</td>
<td>No growth 5 days</td>
<td>No growth 5 days</td>
</tr>
</tbody>
</table>

Addressing severe blood culture bottle shortage

VUMC Response

Romney Humphries, PhD D(ABMM)

VANDERBILT UNIVERSITY MEDICAL CENTER

Vanderbilt Medical Laboratories
Supply shortages: VUMC

VUMC Enterprise:
- 1741 licensed beds, active transplant programs
- 1 free-standing pediatric hospital, 3 regional hospitals

Expectation:
80% of typical usage will be available

Reality:
<1% of AEROBIC bottle orders fulfilled by distributor
Drop shipment direct from BD (max 450 sets a week) = 30% of typical use even with stewardship efforts

How do we avoid completely running out of blood culture bottles?
What else can we do to preserve bottles?

• Stopped inoculating fluids into blood culture bottles
• Stopped “pan culturing” lumens for pediatric HSCT
• Reinforced best practices:
  • Minimize contamination
  • No drawing cultures before order

• Brainstorming:
  • No repeat orders within 48 h
  • Limiting blood culture draws to 1 set (optimal is 2-3 sets)

• Data pulled from January 1 – June 15 2024 to assess potential impact
Data on repeats within 48 h

- 16.7% of cultures
  - Only 5% yielded discordant results vs. initial set
    - 17 instances of a new positive
      - 16 were typical skin commensals
      - 1 possible true positive
    - 78 instances of repeat cultures to resolve a contaminated first set
      - 68 repeat contaminants
      - 7 potential pathogens
      - 3 negative

0.3% Of blood cultures repeated within 48 hour of initial set yielded useful data
What about drawing only 1 set?

• 319 of 15455 patients with potential pathogen in 1 bottle only

• Chart review:
  • Many also present in concomitant cultures
  • Several questionable significance (oral flora)

93.7% concordance between first 2-3 sets
ED Patients: SEP-1

- Patients meeting SEP-1 criteria (n=787)
  - 5.1% cultures positive
  - 30% present in only 1 set
  - 0.2% of patients had clinically significant cultures

- Patients coded as septic by ED attending (n=533)
  - 18% of cultures positive
  - 5.1% positive in only 1 set
  - For 48.1% of these patients, the single blood culture set was the only positive culture

Based on these data, allowed for 2 sets to be collected for ED patients coded as sepsis / septic shock by ED attending
Implementation

- No repeat cultures within 48 h
- Only 1 culture orderable per signing period

57.8% reduction

No significant change in positivity rates or contamination rates
Clinical impact: TBD
Additional considerations

- Exception process in place to bypass restrictions: microbiologist on call
  - 2-10 calls a day
    - Generally for good clinical reasons

- Repeat cultures:
  - Use 2 anaerobic bottles for clearance documentation of *S. aureus*
  - Use Myco/F Lytic bottle for candidemia clearance

- Short-expiration bottles
  - Received from BD to supplement supply (good to August 8)
  - Can we get further extensions?
What to do if the worst comes to pass and you run out of blood culture bottles?

- Investigate alternative vendors for bottles -- must be incubated manually
- Manual blood cultures
  - Procedure involves collection of blood in SPS Vacutainer (BD 364960), which is inoculated into 30 mL brain heart infusion broth and incubated 14 days*
- Extend expiration date on available bottles
- Draw anaerobic or aerobic bottles alone if supply greater for 1 bottle type
  - Caveats: strict aerobes (yeast, Pseudomonas etc) or strict anaerobes (Clostridium spp)
It takes a team to do this!

• Patty Wright
• Tom Talbot
• David Gaston
• Lili Tao
• Lab Operations:
  • David Vinson
  • Susan Sefers
  • Pat Purcell
  • Pamela Foster
  • Perceus Mody
  • The entire microbiology lab
• Health IT: Hamilton Wen
• Analytics: Caroline Taylor
• Trainee help:
  • Turner Conrad
  • Michael Pettit
  • Nicholas McKenzie
• Material Management:
  • Justin Griggs
  • Pat Fischer
• Nursing
• Communications (Madison Agee)
• BD colleagues
• Cardinal colleagues
Q&A/ Discussion
Selected Resources

Program Links:
• This webinar is being recorded and can be found with the slides online at https://www.idsociety.org/cliniciancalls

Ms. Beddard
• https://bdbactec-update.com/

Jake D. Bunn
• https://p4qm.org/measures/3658
• https://p4qm.org/measures/3658
• https://www.cdc.gov/labquality/blood-culture-contamination-prevention.html
• https://reach.cdc.gov/event/diagnostic-excellence-new-quality-tool-prevent-blood-culture-contamination
• https://www.youtube.com/watch?v=tkAl4_wmLcw
• https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/medical-device-shortages-list

Drs. Fabre and Milstone
• https://academic.oup.com/cid/article/71/5/1339/5703622
• https://www.hopkinsmedicine.org/johns-hopkins-childrens-center/what-we-treat/specialties/infectious-diseases/programs-centers/bright-star

Dr. Turbett
• https://www.clinicalmicrobiologyandinfection.com/article/S1198-743X(24)00294-5/abstract
An online community bringing together information and opportunities for discussion on latest research, guidelines, tools and resources from a variety of medical subspecialties around the world.

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Society for Healthcare Epidemiology of America
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Society of Infectious Diseases Pharmacists

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Contact Us:
Dana Wollins (dwollins@idsociety.org)
Deirdre Lewis (dlewis@idsociety.org)