CDC/IDSA Clinician Call

July 23, 2024

Welcome & Introductions

Dana Wollins, DrPH, MGC
Senior Vice President, Strategy
Infectious Diseases Society of America

- 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.
- The views and opinions expressed here are those of the presenters and do not necessarily reflect the official policy or position of the CDC or IDSA. Involvement of CDC and IDSA should not be viewed as endorsement of any entity or individual involved.
- 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

COVID-19 Real-Time Learning Network

Brought to you by CDC and IDSA

AMERICAN SOCIETY FOR MICROBIOLOGY

SHEA The Society for Healthcare Epidemiology of America

PIDS PEDIATRIC INFECTIOUS DISEASES SOCIETY

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

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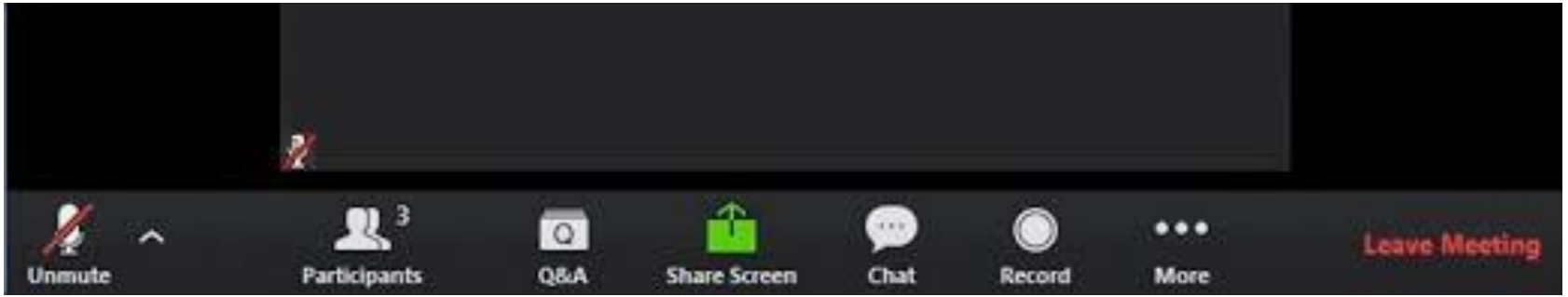
4. Q&A and Discussion – All Presenters Plus:

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

BD BACTEC™ Blood Culture Vial Supply

The latest information on the current status of BD BACTEC™ blood culture vials

July 2024

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 issues are more complex than the 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 material supplier of molded bottles to improve production line efficiency and output
- Early placement of BD BACTEC™ media on manual allocation 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 bottle shipments 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™ Lytic/10 Anaerobic/F Culture Vials, we expect to realize improvements in the September 2024 supply. In the interim, BD will continue to fill 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 warehouse, laboratory, unit, and nursing stations.
- Prioritize the use of blood culture media based on clinical need and following guidelines of local oversight committees, such as the most recent update from IDSA and/or 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 protocols with collectors to optimize recovery and minimize false positive results, respectively. (Revisit local guidelines such as CLSI)

https://bdbactec-update.com/

CDC Blood Culture Quality Tools

Jake D. Bunn, MBA, MLS (ASCP)^{CM}, LSSBB
U.S. Centers for Disease Control & Prevention

CDC Update

Blood Culture Quality Tools

Jake D. Bunn, MBA, MLS(ASCP)^{CM}, LSSBB
Clinical Laboratory Scientist
Division of Laboratory Systems
Quality and Safety Systems Branch

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

Blood Culture Contamination: An Overview for Infection Control and Antibiotic Stewardship Programs Working with the Clinical Laboratory

Blood Culture Contamination: An Overview for Infection Control and Antibiotic Stewardship Programs Working with the Clinical Laboratory

Purpose

Blood culture contamination can compromise quality of care and lead to unnecessary antibiotic exposure and prolonged length of hospitalization. Microbiology laboratories typically track blood culture contamination rates and can provide data to assist in reducing contamination rates. Infection control programs and microbiology laboratories might participate in designing and implementing interventions to decrease contamination rates, and antibiotic stewardship programs could also be engaged to optimize multidisciplinary quality improvement efforts to decrease blood culture contamination and improve the collection of blood culture specimens.

Background

Blood cultures are important diagnostic tools for identifying the pathogen(s) responsible for a patient's infection. This is especially true of patients with suspected sepsis or septic shock and for patients with suspected infective endocarditis[1, 2]. When indicated, blood cultures should be obtained prior to starting antimicrobial therapy[1–3]. A conventional blood culture set consists of an aerobic and an anaerobic bottle. For adults, 20-30 mL of blood per venipuncture (depending on the instrument manufacturer) is recommended and may require >2 bottles depending on the system[2]. At least two blood culture sets should be obtained within a few hours of each other via peripheral venipuncture when obtaining blood cultures for a total volume of 40-60 mL of blood to optimize detection of pathogens[2]. The College of American Pathologists laboratory accreditation program states that clinical laboratories have a written policy and procedure for monitoring blood cultures from adults for adequate volume and provide feedback on the results to the collectors[3]. Moreover, the monitoring and reporting of blood culture contamination rates is a laboratory quality best practice[4].

Example of a blood culture set consisting of an anaerobic and an aerobic bottle, with the latter after filling with an appropriate volume of blood.

Because blood is a normally sterile body site, positive blood cultures with a known pathogen have a generally overall high positive predictive value for infection. However, blood culture contamination is a significant problem. In the era of modern blood culturing techniques, virtually all blood culture contamination occurs during collection; the source of contaminants is usually the patient's skin or the hub or cannula of an indwelling catheter (i.e., when an existing catheter is used to obtain the specimen). Frequent causes include poor collection technique and insufficient skin disinfection. Typical organisms include coagulase-negative staphylococci, *Corynebacterium* spp., *Bacillus* spp. other than *Bacillus anthracis*, *Micrococcus* spp., and *Cutibacterium acnes* among others. Consequences include unnecessary antibiotic exposure with the potential for downstream unintended consequences (e.g., possible allergic reactions and *Clostridioides difficile* infection)[5]. Other possible consequences include the unnecessary removal of intravenous catheters or other devices, an increased length of stay, and increased costs[6]. One study found that the average length of stay was 2 days longer in patients with contaminated blood cultures compared to patients with negative cultures[6]. That same study found that direct and indirect hospital costs of a contaminated blood culture were $12,824 compared to $8,286 for a negative blood culture (savings of $4,538 for preventing a contaminated blood culture)[6].

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

CS 331454-B

Using Blood Culture Contamination Rate for Quality Improvement

Many clinical laboratories routinely calculate and report the blood culture contamination rate as a quality metric at the beginning of the month to evaluate the previous month's rate. In addition to reporting rates regularly to infection prevention and antibiotic stewardship teams, specialized reporting of rates stratified by patient care locations and collection staff (e.g., nursing or phlebotomy teams), can be undertaken to better target improvement efforts.

Prevention/Actions[5]

An in-depth discussion of the ways to address the problem of the blood culture contamination can be found in the review article by Doern *et al.*[1]. A summary of the article follows.

Full article here.

1. **Diagnostic Stewardship**
   Clinicians should strive to obtain blood cultures for the right patients, in the right settings, and at the right time. Blood cultures can be both underused and overused. An example of underuse would be not obtaining blood cultures prior to starting antibiotics for a patient with suspected sepsis. Without a blood culture collected before starting antibiotics, it can be more difficult to appropriately de-escalate antibiotic therapy given that the causative organism is more likely to remain unknown. Also, blood cultures can be underused if the appropriate volume is less than recommended (i.e., two to three 20 mL volumes of blood during initial evaluation of the patient for bacteremia) as this can decrease the sensitivity for pathogen detection. Cultures can also be overused; for example, obtaining repeat cultures in a patient with fever for whom an alternative diagnosis other than bloodstream infection is much more likely. In patients with a very low pretest probability of bloodstream infection, a positive culture is more likely to represent contamination than infection.
2. **Proper Skin Antisepsis**
   Improper skin antisepsis can lead to increases in blood culture contamination rates. It is recommended that the skin be disinfected with an alcohol containing disinfectant and allowed to dry prior to drawing blood cultures[5].
3. **Blood Culture Bottle Disinfection**
   It is standard blood culture practice to disinfect the blood culture bottle tops prior to inoculation[2].

Collection Site

Teams and Education on Proper

and Feedback

Devices

considerations for Tracking Blood Culture Events

- Review with the laboratory staff the blood culture collection procedures used in the facility and the training received by those responsible for collecting blood cultures
- Explore with laboratory staff how the site where blood cultures are collected is labeled (e.g., venipuncture or central venous catheter) and consider how to encourage collecting blood cultures from preferred sites
- Think about future tracking and facility benchmarking of blood culture utilization (e.g., blood cultures per admissions and patient days) as further data and guidance becomes available

References

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3. https://www.cap.org/laboratory-improvement/accreditation/accreditation-checklists. Accessed on 5/4/2022.
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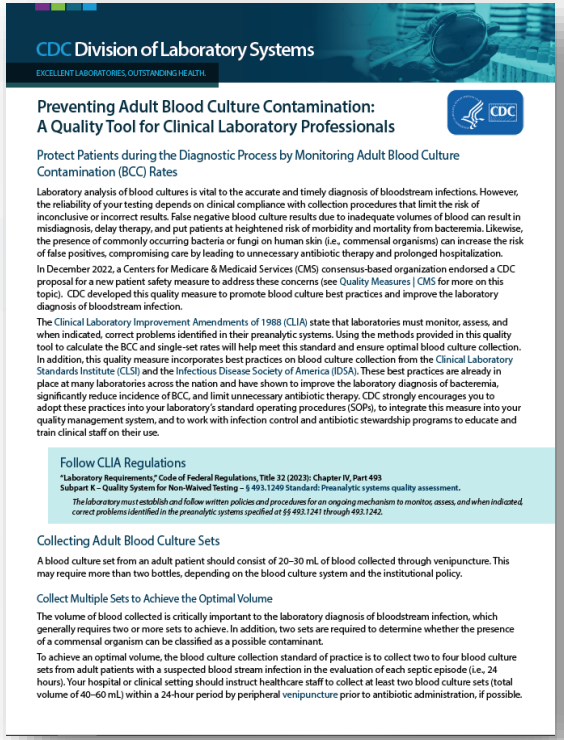
9. Zimmerman FS, Assous MV, Yinon AM, Warner-Weil T. 2018. Reducing blood culture contamination using a department report card. J Hosp Infect 99: 236–238.
10. Youssef D, Shams W, Bailey E, O'Neil TJ, Al-Abbadi MA. 2012. Effective strategy for decreasing blood culture contamination rates: the experience of a veterans affairs medical centre. J Hosp Infect 81: 288–291.

[Blood Culture Contamination: An Overview for Infection Control and Antibiotic Stewardship Programs Working with the Clinical Laboratory (cdc.gov)]

Preventing Adult Blood Culture Contamination: A Quality Tool for Clinical Laboratory Professionals

[Preventing Adult Blood Culture Contamination: A Quality Tool for Clinical Laboratory Professionals | CDC]



CDC Division of Laboratory Systems

EXCELLENT LABORATORIES. OUTSTANDING HEALTH.

Preventing Adult Blood Culture Contamination: A Quality Tool for Clinical Laboratory Professionals

Protect Patients during the Diagnostic Process by Monitoring Adult Blood Culture Contamination (BCC) Rates

Laboratory analysis of blood cultures is vital to the accurate and timely diagnosis of bloodstream infections. However, the reliability of your testing depends on clinical compliance with collection procedures that limit the risk of inconclusive or incorrect results. False negative blood culture results due to inadequate volumes of blood can result in misdiagnosis, delay therapy, and put patients at heightened risk of morbidity and mortality from bacteremia. Likewise, the presence of commonly occurring bacteria or fungi on human skin (i.e., commensal organisms) can increase the risk of false positives, compromising care by leading to unnecessary antibiotic therapy and prolonged hospitalization.

In December 2022, a Centers for Medicare & Medicaid Services (CMS) consensus-based organization endorsed a CDC proposal for a new patient safety measure to address these concerns (see Quality Measures | CMS for more on this topic). CDC developed this quality measure to promote blood culture best practices and improve the laboratory diagnosis of bloodstream infection.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) state that laboratories must monitor, assess, and when indicated, correct problems identified in their preanalytic systems. Using the methods provided in this quality tool to calculate the BCC and single-set rates will help meet this standard and ensure optimal blood culture collection. In addition, this quality measure incorporates best practices on blood culture collection from the Clinical Laboratory Standards Institute (CLSI) and the Infectious Disease Society of America (IDSA). These best practices are already in place at many laboratories across the nation and have shown to improve the laboratory diagnosis of bacteremia, significantly reduce incidence of BCC, and limit unnecessary antibiotic therapy. CDC strongly encourages you to adopt these practices into your laboratory's standard operating procedures (SOPs), to integrate this measure into your quality management system, and to work with infection control and antibiotic stewardship programs to educate and train clinical staff on their use.

Follow CLIA Regulations

"Laboratory Requirements," Code of Federal Regulations, Title 32 (2023): Chapter IV, Part 493
Subpart K – Quality System for Non-Waived Testing – § 493.1249 Standard: Preanalytic systems quality assessment.

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at §§ 493.1241 through 493.1242.

Collecting Adult Blood Culture Sets

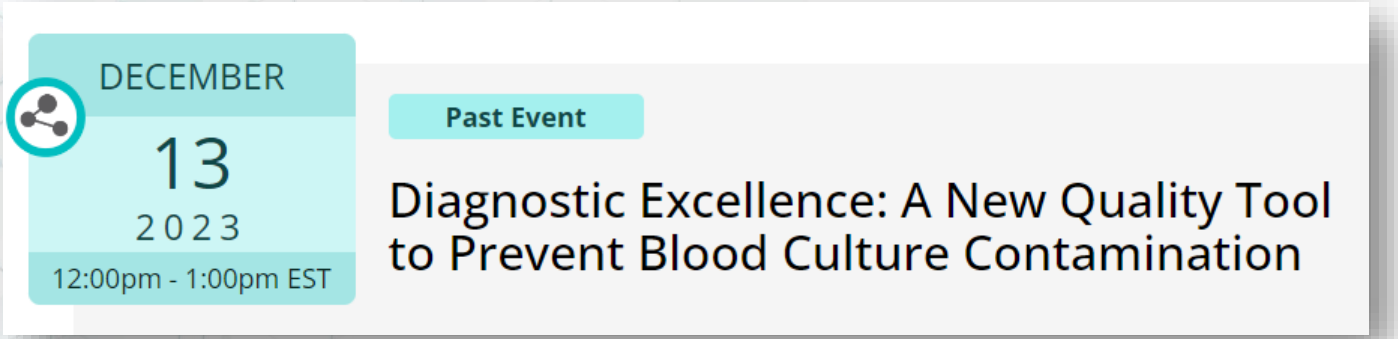
A blood culture set from an adult patient should consist of 20–30 mL of blood collected through venipuncture. This may require more than two bottles, depending on the blood culture system and the institutional policy.

Collect Multiple Sets to Achieve the Optimal Volume

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

To achieve an optimal volume, the blood culture collection standard of practice is to collect two to four blood culture sets from adult patients with a suspected blood stream infection in the evaluation of each septic episode (i.e., 24 hours). Your hospital or clinical setting should instruct healthcare staff to collect at least two blood culture sets (total volume of 40–60 mL) within a 24-hour period by peripheral venipuncture prior to antibiotic administration, if possible.

Diagnostic Excellence: A New Quality Tool to Prevent Blood Culture Contamination



[Diagnostic Excellence: A New Quality Tool to Prevent Blood Culture Contamination (cdc.gov)]

https://youtu.be/tkAl4_wmLcw

FDA Updates

U.S. FOOD & DRUG ADMINISTRATION

Disruptions in Availability of BD BACTEC Blood Culture Media Bottles - Letter to Health Care Providers

[Disruptions in Availability of BD BACTEC Blood Culture Media Bottles - Letter to Health Care Providers | FDA] – **July 10, 2024**

Medical Device Shortages List

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

Category	Product Code (Description)	Availability and Estimated Shortage Duration	Additional Information	Reason for Interruption (per 506J)	Date (YYYY/MM/DD)
Microbiology - Microbiology Devices	**MDB** (System, Blood Culturing)	• Estimated through Q4 2024	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 MDB Shortage - Letter to Health Care Providers.	• Shortage or discontinuance of a component, part or accessory of the device.	2024/07/10 Initial

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

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

Blood Culture Utilization

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Blood Culture Stewardship Opportunities

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Disclosures

- No relevant financial disclosures

- The content of this presentation represents our own views

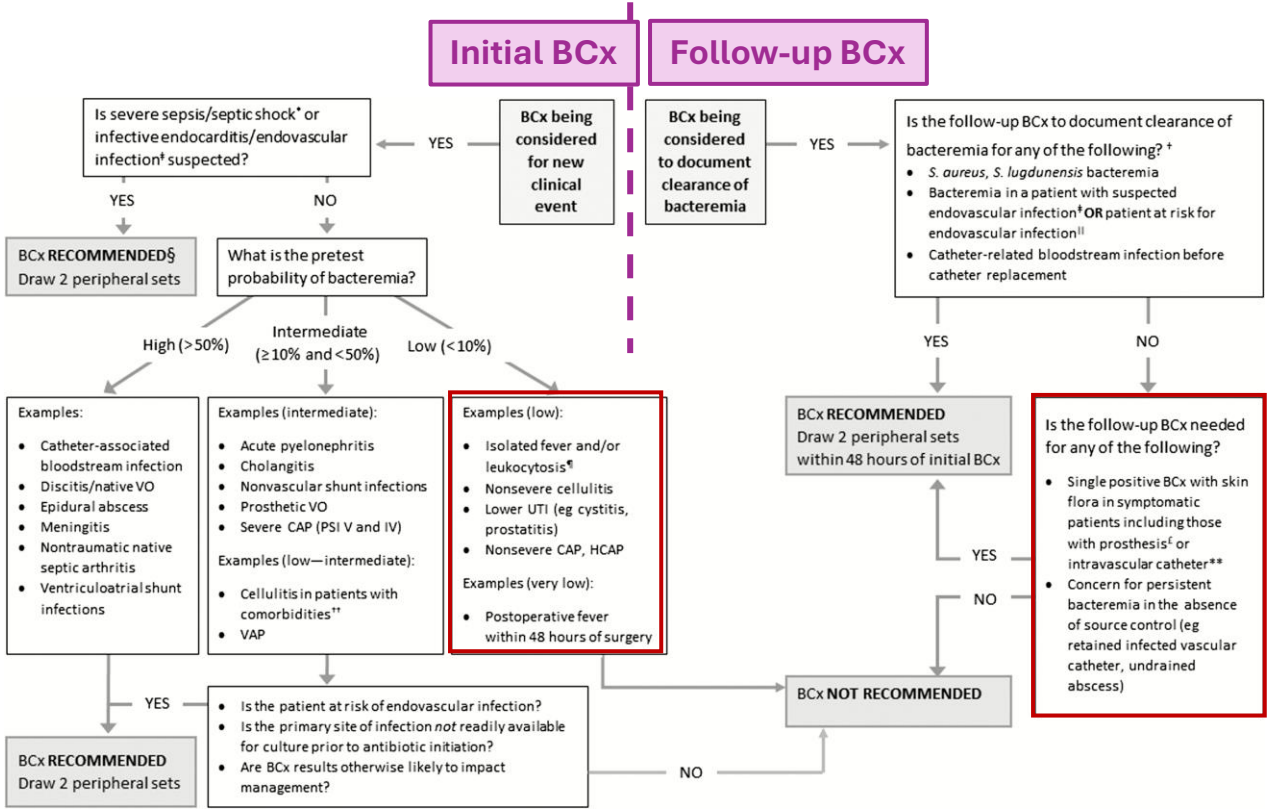
Opportunities to improve inpatient blood culture (BCx) utilization

~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

Fabre V et al . J Clin Microbiol 2022, Fabre V et al. J Clin Microbiol 2020, Siev A et al. J Crit Care 2023, Drager S et al. Eur J Intern Med 2022, Temkin E, JAMA Netw Open 2022

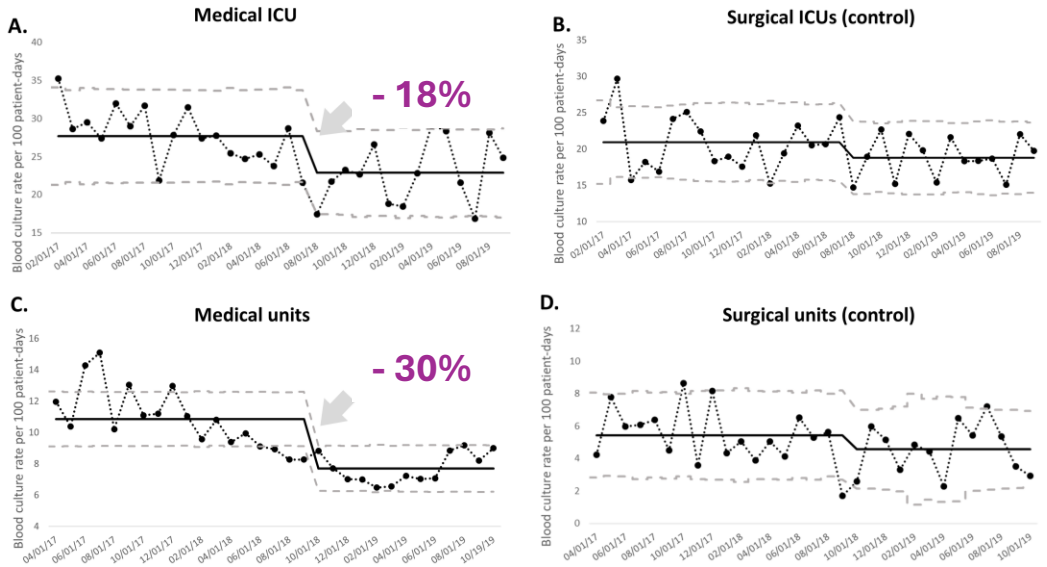
Algorithm for bacterial blood cultures recommendations in non-neutropenic (adult) patients.



Clin Infect Dis, Volume 71, Issue 5, 1 September 2020, Pages 1339–1347, https://doi.org/10.1093/cid/ciaa039

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)

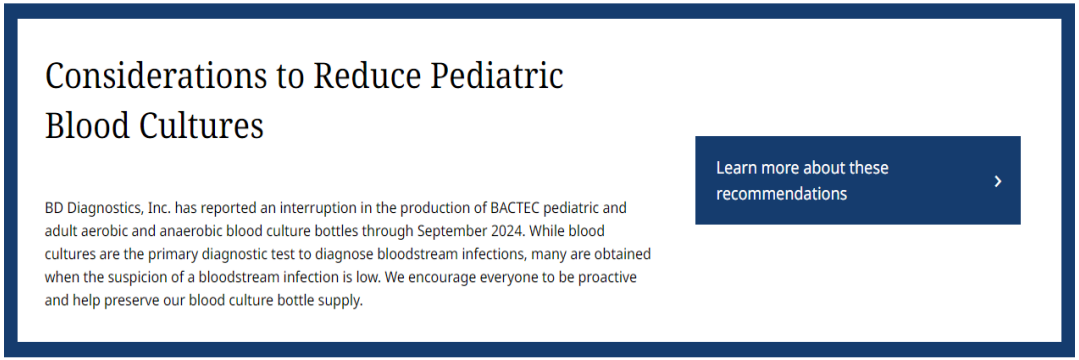
Fabre V, et al . A Diagnostic Stewardship Intervention To Improve Blood Culture Use among Adult Nonneutropenic Inpatients: the DISTRIBUTE Study. J Clin Microbiol. 2020
[1]Seidelman J, et al. Antimicrob Steward Healthc Epidemiol. 2022, [2]Wanf MC et al. Infect Control Hosp Epidemiol. 2024

Summary of low-yield BCx in non-neutropenic adults

LOW-YIELD INITIAL BLOOD CULTURES	LOW-YIELD FOLLOW-UP 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	• 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

Fabre V, Sharara SL, Salinas AB, Carroll KC, Desai S, Cosgrove SE. Does This Patient Need Blood Cultures? A Scoping Review of Indications for Blood Cultures in Adult Nonneutropenic Inpatients. Clin Infect Dis 2020

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

Woods-Hill CZ, et al. Consensus Recommendations for Blood Culture Use in Critically Ill Children Using a Modified Delphi Approach. Pediatr Crit Care Med. 2021 Apr 23.
Woods-Hill CZ, et al. Diagnostic stewardship for blood cultures in critically ill children: results of the Bright STAR Collaborative. JAMA Pediatr. 2022 May 2

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 Reserach 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 Charlc Woods-Hill

JOHNS HOPKINS
MEDICINE

Impact of number of sets in bacteremia detection

Organism	1 set	2 sets	3 sets
S. aureus	93%	97%	100%
Enterococci	67%	80%	89%
Streptococci	77%	85%	100%
E. coli	72%	91%	95%
P. aeruginosa	60%	85%	100%
C. albicans	60%	85%	95%
K. pneumoniae	78%	90%	98%

Lee A, Mirrett S, Reller LB, Weinstein MP. Detection of bloodstream infections in adults: how many blood cultures are needed? J Clin Microbiol. 2007

Mass General Brigham

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-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

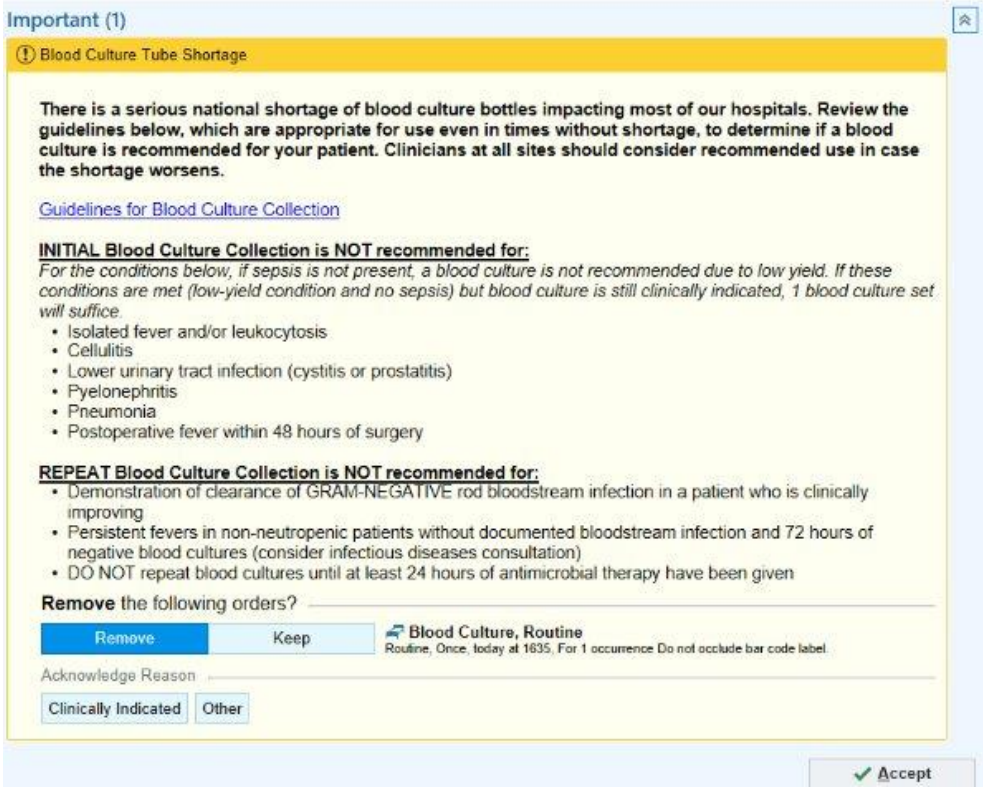
Implementation strategies for action plan development

- 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:*

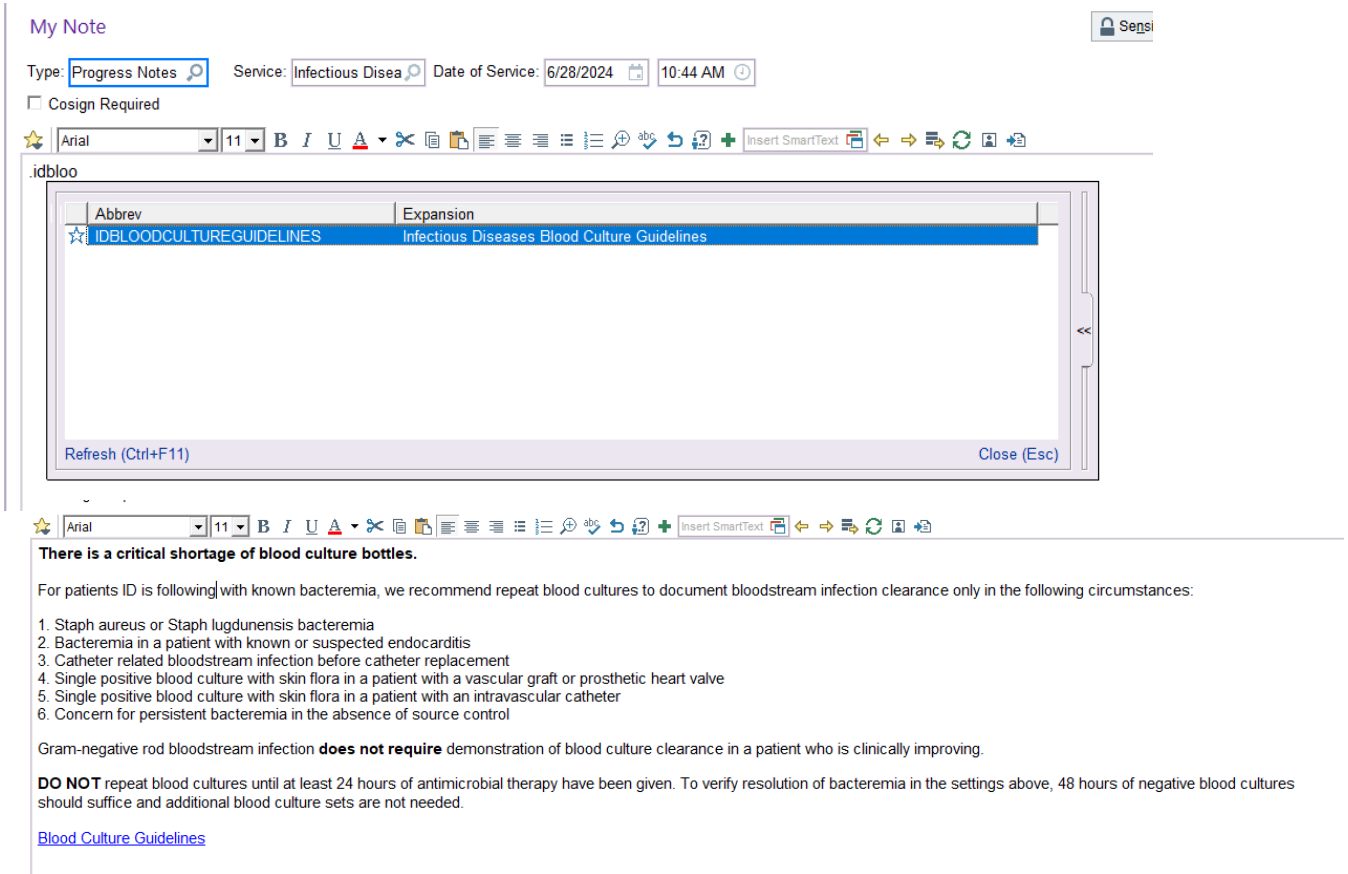
1. *Staph aureus or Staph lugdunensis bacteremia*
2. *Bacteremia in a patient with known or suspected endocarditis*
3. *Catheter related bloodstream infection before catheter replacement*
4. *Single positive blood culture with skin flora in a patient with a vascular graft or prosthetic heart valve*
5. *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



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

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. Klontz[1], Lisa A. Milien[1], David Lucier[2], Anand S. Dighe[1] John A. Branda[1], Sarah E. Turbett[1,2]

[1]Department of Pathology, Massachusetts General Hospital and Harvard Medical School, Boston, Massachusetts, USA.

[2]Department 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)

Organism	Inoculum (CFU)	Expired media time to growth (h)	Unexpired media time to growth (h)
Alcaligenes faecalis ATCC 8750	65	24.23	23.75
Candida glabrata ATCC 2950	27	20.63	20.32
Escherichia coli ATCC 25922	22	12.20	12.37
Haemophilus influenzae ATCC 10211	60 + FOS	14.62	14.62
Neisseria meningitidis ATCC 13090	11 + FOS	20.57	20.72
Pseudomonas aeruginosa ATCC 27853	53	17.43	16.27
Staphylococcus aureus ATCC 25923	31	13.20	13.37
Streptococcus pneumoniae ATCC 49619	7	12.47	13.30
Streptococcus pyogenes ATCC 19615	16	11.88	12.88
Staphylococcus lugdunensis clinical strain	22	20.27	19.62
Staphylococcus haemolyticus clinical strain	15	18.10	18.10
Streptococcus mitis/oralis clinical strain	6	14.33	13.33
Enterococcus faecalis clinical strain	24	11.83	11.83
Enterococcus faecium clinical strain	22	13.60	13.60
Corynebacterium spp. clinical strain	36	58.97	No growth 5 days
Klebsiella pneumoniae clinical strain	27	10.48	10.82
Proteus mirabilis clinical strain	40	11.70	11.68
Serratia marcescens clinical strain	60	13.97	13.63
Enterobacter cloacae complex clinical strain	36	12.03	11.87
Aeromonas hydrophila clinical strain	29	10.28	10.28
Negative control	N/A	No growth 5 days	No growth 5 days
Negative control	FOS	No growth 5 days	No growth 5 days

Klontz et al. (in press). *J. Clin. Microbiol.*

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

How do we avoid completely running out of blood culture bottles?

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

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%

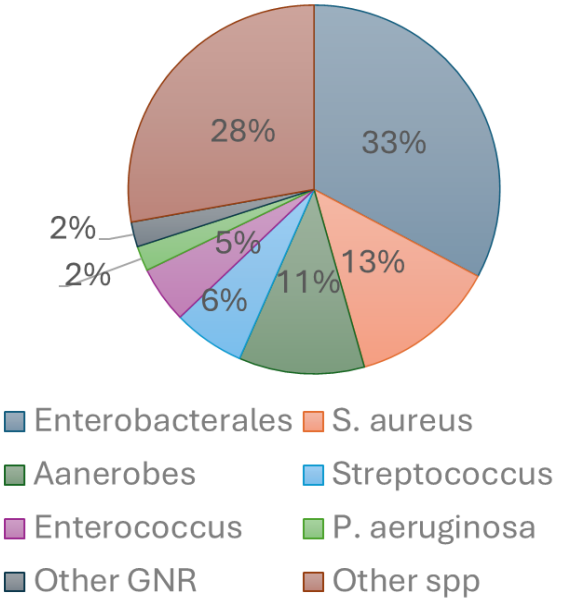
Of blood cultures repeated within 48 hour of initial set yielded useful data

What about drawing only 1 set?

93.7%

concordance between first 2-3 sets

- 319 of 15455 patients with potential pathogen in 1 bottle only
- Chart review:
  - Many also present in concomitant cultures
  - Several questionable significance (oral flora)



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 cutlures

- 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

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
- COVID-19 Real-Time Learning Network: https://www.idsociety.org/covid-19-real-time-learning-network/

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/letters-health-care-providers/disruptions-availability-bd-bactec-blood-culture-media-bottles-letter-health-care-providers
- 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

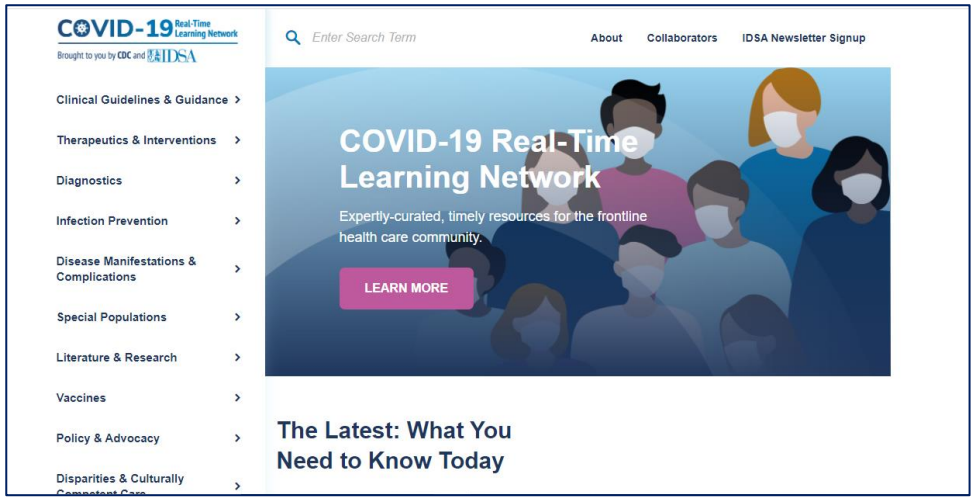
Dr. Turbett

- https://www.clinicalmicrobiologyandinfection.com/article/S1198-743X(24)00294-5/abstract

COVID-19 Real-Time Learning Network

Brought to you by CDC and IDSA

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.



Specialty Society Collaborators

American Academy of Family Physicians
American Academy of Pediatrics
American College of Emergency Physicians
American College of Obstetricians and Gynecologists
American College of Physicians
American Geriatrics Society
American Thoracic Society
Pediatric Infectious Diseases Society
Society for Critical Care Medicine
Society for Healthcare Epidemiology of America
Society of Hospital Medicine
Society of Infectious Diseases Pharmacists

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THANK YOU

We want to hear from you!

Please complete the post-call survey.

A recording of this call, slides and the answered Q&A will be posted at
www.idsociety.org/cliniciancalls

-- library of all past calls available --

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