Mountain Plains Regional Disaster Health Response System Medical Advisory Panel

Interim Guidance on Becton Dickinson (BD) Bactec™ Blood Culture Bottle Shortage for Region VIII

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Situation: On July 10, 2024, the Food and Drug Administration announced a critical global shortage in BD Bactec™ blood culture bottles that was anticipated to last several months. The shortage is related to supply chain issues around the manufacturing of the bottles specific to the BD Bactec™ system. Supplies from Thermo Fisher and bioMérierux have not been affected but their bottles are not compatible with BD analyzers. As of early August 2024, several health centers around the nation have already identified significant decreases in availability of the BD Bactec™ bottles resulting in severely reduced supplies and the temporary inability to reorder BD Bactec™ blood culture bottles. It remains unclear when the shortage will completely resolve. Several organizations have issued guidance on addressing the current shortage and this document provides a summary of these approaches with guidance on implementation. It is intended for hospitals, health systems, and public health authorities in CMS Region VIII, but might also be useful to inform national strategies.

Background: Blood cultures are a critical part of managing patients with suspected blood stream infections (BSIs) and sepsis. Blood culture bottle shortages have the potential to harm patients and health systems on multiple levels. Blood cultures are necessary to:

- Prevent delays in initiating appropriate antibiotics
- Narrow antibiotics based on identified organisms and resistance patterns
- Determine duration of antibiotics for severe infections
- Identify potential endovascular infections that might require additional testing or treatments (e.g., echocardiograms when *S. aureus* BSI is identified)
- Inform decision-making for removal of indwelling catheters
- Determine appropriate treatment plans for patients with implanted hardware

Additionally, collecting blood cultures prior to initiation of antibiotics is a key component of the CMS sepsis bundle (CMS SEP-1), and performance on this measure can impact hospital quality scores and reimbursement.

Region 8
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Assessment: The framework for Crisis Standards of Care, created by the National Academy of Medicine (formerly the Institute of Medicine) in 2009 describes a continuum consisting of three levels of increasingly stringent resource allocation strategies when dealing with shortages in health care: conventional, contingency and crisis. These are described in more detail below, but a key aspect of crisis management is attempting to ensure equity in care is maintained and to avoid situations in which one hospital is using conventional strategies for resource preservation and allocation while a nearby hospital is employing crisis strategies. Therefore, regional planning is essential when developing approaches to dealing with critical health care shortages.

"Conventional" strategies are used when an increase in demand or decrease in supply is identified but, by using these strategies, adverse impacts on quality of care can be avoided. "Contingency" strategies are used when demand exceeds supply and substantial changes to standard workflows and protocols will be required to mitigate potential harms to patients. "Crisis" strategies are used when demand exceeds supply and care processes and protocols must be altered in ways that are expected to unavoidably impact patient outcomes. Use of these strategies means that surge capacity has been (or soon will be) exceeded and rationing of the resource in shortage is necessary.

Using these definitions, approaches to managing the current blood culture bottle shortage can conceptually be divided into conventional, contingency, and crisis approaches, recognizing that these categories have fuzzy borders. As circumstances evolve, more or less stringent conservation and allocation strategies should be adopted.

Strategies – Please note, this is general guidance only. It does not provide specific recommendations on how to care for any individual patient. Additionally, guidance must always be weighed against clinical risk and a patient's specific circumstances.

Conventional Strategies – Conventional strategies emphasize careful tracking of supplies and implementation of best practices for stewardship to reduce baseline use of blood culture supplies.

- *Facility-level tracking, monitoring, and policy considerations*
  - Consider facility-wide implementation of a clinical decision support tool (e.g., mShapiro tool – see resources below) to identify patients at the highest risk of BSI in Emergency Department settings to reduce total blood culture bottle use.
  - Ensure adequate measures to identify and track the supply of blood culture bottles as well as hospital/system blood culture utilization. An adequate real-time monitoring system will be critical to knowing when to implement more stringent guidelines vs relaxing already implemented restrictions.

- Active supplies and anticipated resupply rates should be communicated to hospital leadership to enhance regional coordination efforts.

- *Strategies to maximize sensitivity of blood cultures for individuals responsible for collecting blood cultures.*
  - Ensure adequate specimen volume (10-20ml/bottle) as inadequate collection volume reduces the sensitivity of blood cultures leading to the need for additional cultures.
  - Ensure adequate aseptic technique. Blood culture contamination, often by skin flora (e.g. *S. epidermis*), is common ranging from 0.5-12.5% of samples. Contamination often results in extra blood cultures needing to be drawn (i.e., waste of a scarce resource). There are numerous resources that describe appropriate blood culture collection techniques to avoid waste (see below).
- Clinical strategies to reduce blood culture bottle use
  - Do not collect more than 2 sets of blood cultures at any given time.
  - Do not collect "hold" blood cultures. In some cases, such as initial blood draws in the Emergency Department, blood culture bottles are collected during initial blood collection and held just in case they are needed. Only draw cultures with appropriate indications and orders.
  - Do not collect blood cultures for patients in Emergency Departments or Urgent Care settings with infections not requiring hospitalization, such as uncomplicated community acquired pneumonia, lower urinary tract infections, non-purulent skin and soft tissue infections, etc.
  - Wait for at least 48 hours after starting antibiotics to check surveillance cultures for patients with suspected or diagnosed *S. aureus* BSI, *Candida spp* BSI, or endovascular infections.
  - Avoid routine blood culture collections for immunocompetent patients with isolated fevers or leukocytosis due to extremely low yield and positivity rates.
  - Avoid routine surveillance cultures to document clearance of BSI in adult patients who are clinically improving, have adequate source control, for whom no endovascular infection is suspected, and do not have BSI with a microorganism that requires documentation of clearance (e.g., *S aureus* and *Candida spp*).
  - Avoid surveillance cultures in patients without suspicion for BSI (e.g., prior to starting TPN, daily cultures in patients receiving CRRT or ECMO, etc.).
  - Avoid blood culture collection for isolated uncomplicated fevers within 48 hours of surgery.
  - After initial cultures, avoid daily blood cultures in patients with neutropenia and persistent fevers if the patient is stable and/or improving.
  - In the absence of ongoing concern for infection or other clinical risk factors, do not repeat blood cultures for patients with 1 of 2 blood cultures positive for typical skin flora (almost always a contaminant):

- Coagulase-negative *staphylococci* species
- *C. acnes*
- *Corneybactermium* species
- *Bacillus* species
- *Micrococcus* species

Contingency Strategies – Contingency strategies are modifications to the pre-shortage standard of care that attempt to reduce blood culture utilization by reducing lower yield blood cultures.

- *Facility-level tracking, monitoring, and policy considerations*
  - Consider sequestration of blood culture bottles which could include eliminating blood culture bottles in outpatient settings and/or restricting access to blood culture bottles to phlebotomy staff or other authorized staff only.
- *Clinical strategies to reduce blood culture bottle use*
  - For patients with documented BSI where documentation of clearance is necessary (e.g., *S. aureus* or *Candida spp*), use only 1 set of blood cultures for surveillance.
  - Do not collect blood cultures in patients requiring hospitalization for infection but without sepsis with low risk of BSI such as:
    - Uncomplicated community acquired pneumonia
    - Uncomplicated non-purulent cellulitis
    - Uncomplicated lower urinary tract infections
    - Uncomplicated cholecystitis
    - Uncomplicated diverticulitis.
  - Consider not collecting blood cultures for patients with intermediate risk for BSI including:
    - Septic arthritis
    - Cholangitis
    - Pyelonephritis
    - Moderate community acquired pneumonia

Crisis Strategies – Crisis strategies are used in the most severe shortages. These are significant deviations from pre-shortage standards of care, with greater potential to impact patient outcomes. However, these strategies may be required if the threat of exhausting the blood culture supply becomes increasingly likely.

- *Clinical strategies to reduce blood culture bottle use*
  - Collect a single set of blood cultures for patients with suspicion for sepsis. Collecting just one set of blood cultures reduces the sensitivity for the detection of BSI and may lead to difficulty distinguishing true infection from contamination for certain pathogens.

- Restrict blood cultures to use for only critically ill patients or patients with severe immunocompromised states (e.g., neutropenia).
- If a facility runs out of blood culture bottles, consider transferring patients with critical illness or severe immunocompromised states who require hospitalization to other facilities. EMS systems should attempt to "divert" these patients to hospitals with blood culture capacity enroute if possible. If such patients present to a hospital with no blood culture capacity, consider transferring them to other institutions with blood culture capacity early in their care process. Do not delay giving appropriate antibiotics.

Special Considerations for Pediatric Populations

All medical providers should follow evidence-based best practices for pediatric patients. Most pediatric patients require only one set of blood cultures unless otherwise specified.

This table can provide some guidance for obtaining blood cultures on patients during initial evaluation:

Low Risk/Low Yield: Blood Cultures NOT recommended in most cases	High Risk and/or High Yield: Blood Cultures Recommended
Isolated fever and/or leukocytosis*	Severe sepsis/septic shock
Cellulitis without signs of sepsis	Suspected central line associated blood stream infection (CLABSI)-obtain 2 sets
UTI in children>3 months without signs of sepsis	Suspected osteomyelitis (fever and limp, elevated inflammatory markers)
Non-severe community acquired pneumonia	Febrile patients with central line, prosthetic heart valve, cardiac devices, other implanted hardware, concern for endocarditis-obtain 2 sets
Post operative fever in first 48 hours after surgery	Febrile infants <60 days, those 60-90 days ill appearing not meeting low risk criteria, or if antibiotics are planned (follow best practice protocols)
Periorbital cellulitis	Febrile neutropenia
Deep space neck infections, including lateral neck and or para/retropharyngeal infections	Suspected CNS infections (meningitis, intracranial infections)
Bronchiolitis with or without hypoxia/fever	Orbital cellulitis/abscess
	Suspected necrotizing skin soft tissue infections

*Does not apply to patients with neutropenia or transplant patients

Additional Considerations

Culture-driven techniques remain the standard for identifying BSI, and no true alternative exists. However, alternative techniques may reduce the need for or number of days of exposure to broad spectrum antibiotics. These approaches are available even outside of blood culture bottle shortages and could include:

- Currently, only BD Bactec™ blood culture bottles are impacted by the shortage. Institution can explore developing temporary relationships with neighboring systems that do not use the BD Bactec™ system to accommodate their most critical blood cultures. Such "outsourcing" would only work if the hospital with a severe shortage ordered blood cultures bottles for an appropriate alternative system and a neighboring system had sufficient capacity to manage the increased load. Healthcare Coalitions and State Hospital Associations should work with constituent hospitals to assess the extent of the regional shortage, provide guidance, and facilitate local resource response strategies including inter-institutional resource sharing.
- Checking a respiratory virus panel, urine legionella antigen, and urine streptococcus antigen in hospitalized patients with pneumonia.
- Consider earlier imaging to identify infection source.

Triggers

A critical question is when to implement different strategies to address ongoing shortages. There is no empirical evidence by which to develop strict triggers. However, there are several core principles that should be considered.

- Equity is a key aspect to crisis management meaning patients presenting to different hospitals should ideally encounter similar resource limitations if proactive regional coordination is being achieved. In ideal situations, hospitals using the BD Bactec™ system in a given area should proactively transition from Conventional to Contingency at similar times based on anticipated deliveries and utilization. This requires regional coordination that could be facilitated by pre-existing multi-hospital emergency management groups, hospital associations, or new multi-hospital working groups that are formed for the express purpose of coordinating response to the current shortage.
- Given the global nature of the shortage, all health facilities should be utilizing all Conventional strategies to track use and avoid waste at this time. This should include hospitals that do not use the BD Bactec™ system as reducing unnecessary blood culture use at hospitals not impacted by the shortage can increase capacity that care be shared with nearby institutions.
- There are no empirical data by which to set hard triggers to move from using conventional strategies to implementing some or all of contingency strategies or when to implement crisis strategies. Transitions between strategies must be based

on current supply (i.e., bottles on hand), current and anticipated utilization rate, and anticipated resupply rates.
    - Facilities and systems should consider implementing contingency strategies when an institution's supply is reduced to 2-4 weeks without anticipation of improvement in the supply chain.
    - Transitioning to crisis strategies could be considered when an institution's utilization rate with Contingency guidance exceeds the anticipated resupply rate with only 1-2 weeks of in stock supply.
    - While moving from conventional to contingency and to crisis, all efforts for resource sharing between institutions should be explored.

Outstanding Questions to be Followed Up by the MAP

- As blood culture supply becomes even more limited, there is growing concern about the need for blood cultures prior to antibiotics to meet CMS SEP-1 quality metric. Failure to meet this metric can result in financial penalties and damage to the institution's reputation. The MAP has already engaged CMS to obtain clarification on this point. However, in 2019 CMS conducted a webinar Q&A in which CMS representatives did state that 1 blood culture should be sufficient to meet the criteria. Additional information will be provided once CMS clarifies the requirements.
- Legal protections – Crisis strategies, and even contingency strategies, could represent significant deviation from pre-shortage care standards. This could create some legal liabilities. It remains unclear how best to address these issues. The MAP is currently engaged with Region VIII public health leaders exploring this issue.

Additional Resources

- Disruptions in Availability of BD BACTEC Blood Culture Media Bottles - Letter to Health Care Providers from FDA
- CDC HAN - Disruptions in Availability of Becton Dickinson (BD) BACTEC™ Blood Culture Bottles
- IDSA Blood Culture Bottle Shortage Homepage
- IDSA/CDC Webinar on BD Bactec™ Blood Culture Bottle Shortage
- American Society for Microbiology – Blood Culture Bottle Inventory Management and Clinical Conservation During Supply Shortages
- Johns Hopkins Medicine Blood Culture Stewardship
- Blood Culture Guidance in Non-Severely Immunocompromised Adult Inpatients – University of Nebraska
- Blood Culture Utilization in the Hospital Setting: a Call for Diagnostic Stewardship – Fabre et al.
- Does This Patient Need Blood Cultures? A Scoping Review of Indications for Blood Cultures in Adult Nonneutropenic Inpatients – Fabre et al.

- Best Clinical Practice: Blood Culture Utility in the Emergency Department – Long et al.
- Prediction of bacteremia in the emergency department: an external validation of a clinical decision rule – Jessen et al.
- Evaluating Clinical Prediction Rules for Bacteremia Detection in the Emergency Department: A Retrospective Review – McNab et al.
- AAP Clinical Practice Guideline: Evaluation and Management of Well-Appearing Febrile Infants 8 to 60 Days Old

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