

Interim Guidance in Response to the Blood Culture Bottle Shortage for CMS Region VIII

Mountain Plains Regional Disaster Health Response System (MPRDHRS)

Medical Advisory Panel (MAP)



Panelists



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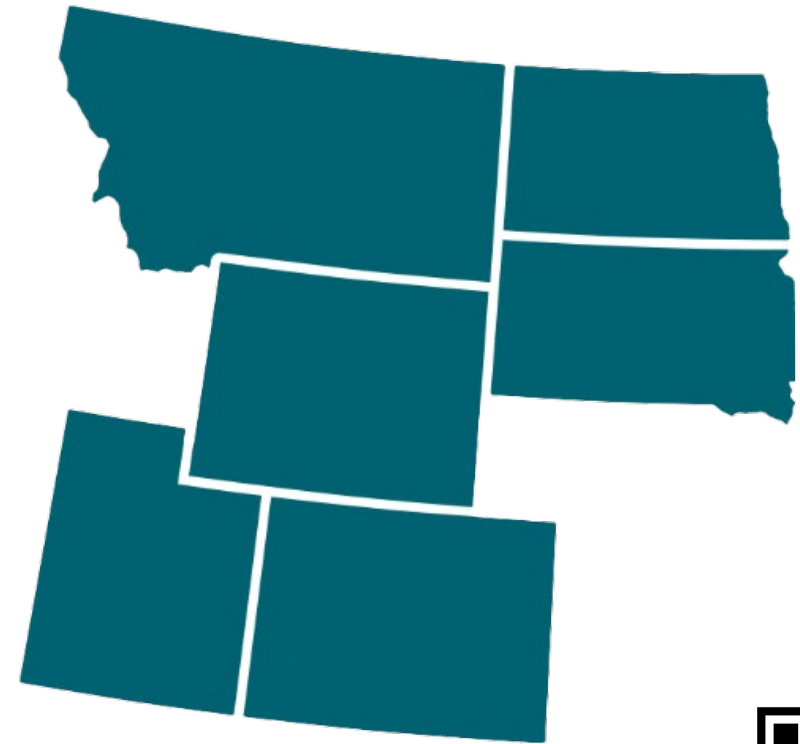
MAP Executive Committee
Director of Emergency Management
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Clinical Advisor for Utah/Wasatch
County Healthcare

Regional Disaster Response

Awarded through HHS Administration for Strategic Preparedness and Response, MPRDHRS operates out of Denver Health and **serves Region VIII (Colorado, Utah, Wyoming, Montana, South Dakota, North Dakota)** in improving medical surge and clinical specialty capabilities for disasters affecting more than one state.

MPRDHRS builds on existing medical surge and disaster preparedness foundations across industries and government, fostering and maturing multi-state partnerships as well as industry assets to create an integrated, tiered system of disaster health care.

<https://mountainplainsrdhrs.org/>



What is the Medical Advisory Panel (MAP)

- A subgroup within the MPRDHRS
- Group of medical and public health subject matter experts
- Designed to be rapidly pulled together to offer clinical or technical assistance or guidance on health-related or public health “incidents”



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MAP Resources



Interim Guidance on Becton Dickinson (BD) Bactec™
Blood Culture Bottle Shortage for Region VIII
<https://mountainplainsrdhrs.org/wp-content/uploads/2024/08/MPRDHRS-MAP-Blood-Culture-Bottle-Shortage-Interim-Guidance.pdf>



Interim Guidance One-Page Placard
<https://mountainplainsrdhrs.org/wp-content/uploads/2024/08/MPRDHRS-MAP-Blood-Culture-Bottle-Shortage-Guidance-Placard.pdf>

Situation

- July 10 – FDA announces shortage in BD Bactec™ blood culture bottles
- Problem stems from plastic bottle manufacturing
- Unclear timeline for resolution, may begin to improve in late September
- Possible use of glass bottles



Background

3 major companies

- **BD Bactec™ System (AFFECTED)**
- BioMerieux BacT/Alert® System (NOT AFFECTED)
- Thermo Fisher SIGNAL System (NOT AFFECTED)

Impact is heterogeneous and uneven

Some health systems seeing very significant decreases in orders

Potential patient harm

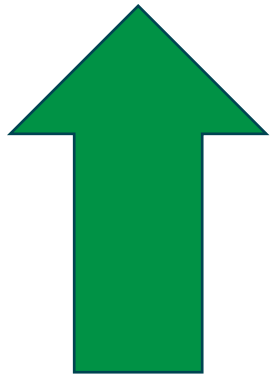
- Missing bacteremia
- Prolonged exposure to broad spectrum antibiotics
- Inability to tailor antibiotic duration
- Source control

Addressing Shortages in Health Care

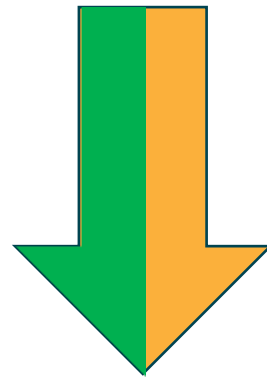
Crisis Conceptualization (IOM/NAM 2009) – 3 levels of strategies



Core Principles



INCREASE
YIELD



DECREASE
WASTE



RESTRICT &
RATION

Conventional Strategies

Increase Yield

- Ensure adequate volume
- Ensure proper aseptic technique

Facility-Level Tracking

- Situational awareness
- Communication with leadership
- Consider implementing clinical decision support tools



Conventional Strategies: Reduce Waste

Reducing Blood Culture Use in Clinically Stable Patients DO NOT COLLECT

- ≥ 2 sets at once
- “Hold” cultures
- Cultures for low risk infections (e.g., CAP or UTI) not requiring hospitalization
- Cultures for isolated leukocytosis or fever
- Cultures to document clearance when pts improving and no concern for endovascular infections, *S. aureus*, or *Candida spp*
- Cultures for isolated fevers within 48 hours of surgery
- Daily cultures in patients with neutropenia in the absence of clinical indication
- Repeat cultures for 1 out of 2 cultures with normal skin flora for patients without clinical suspicion of ongoing infection
- Wait at least 48 hours prior to collecting surveillance cultures when needed



Contingency Strategies

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

- Use only 1 set of culture bottles for BSI where documentation of clearance is necessary
- Do not collect blood cultures in patients requiring hospitalization for infection but without sepsis and low risk of bloodstream infection, including:
 - Uncomplicated community acquired pneumonia
 - Uncomplicated non-purulent cellulitis
 - Uncomplicated lower urinary tract infections
 - Uncomplicated cholecystitis
 - Uncomplicated diverticulitis.



Deeper Contingency Strategies

Clinical strategies to reduce blood culture bottle use (continued):

- Consider not collecting blood cultures for patients with intermediate risk for BSI including:
 - Septic arthritis
 - Cholangitis
 - Pyelonephritis
 - Moderate community acquired pneumonia



Crisis Strategies

Clinical strategies to reduce blood culture bottle use

- Collect a single set of blood cultures for patients with suspicion for sepsis.
- 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. Do not delay giving appropriate antibiotics.



Triggers

- No clear data to guide triggers to move between levels
- Must consider equity and regional coordination
- Consider that everyone should employ Conventional strategies
- Moving to Contingency or Crisis must be based on:
 - Accurate estimates of use (e.g., burn rate)
 - Anticipated resupply rate
 - Options for outsourcing
- Consider Contingency when anticipated supply <4 weeks

Regional Coordination

- Local coordination for moving between levels
- Resource sharing between hospitals with BD Bactec™ system
- “Out sourcing” most critical blood cultures
 - Consider coordinating with commercial labs
 - Consider coordinating with hospitals that do not use BD Bactec™ system

CMS Considerations

- SEP-1 – Severe Sepsis and Septic Shock Value Based Program



Hospital Inpatient Quality Reporting (IQR) Program

Support Contractor

**SEP-1 Early Management Bundle, Severe Sepsis/Septic Shock:
v5.5a Measure Updates and v5.0b Through v5.2b Analysis Results**

**December 11, 2018
2 p.m. ET**

Question 19:

Would having only one set of blood cultures drawn prior to the antibiotic still be considered as a fallout, or does it meet the blood culture requirement?

As long as one blood culture was collected within the specified time frame, Value "1" (Yes) would be selected for the *Blood Culture Collection* data element.



CMS Considerations

Blood Culture Media Bottles Disruptions in Availability

2024-8-16



The Department of Health and Human Services (HHS), including CMS, CDC, and FDA, are monitoring this supply situation. CMS is committed to carefully analyzing the quality measure data as they become available to assess for potential reliability or validity issues or other data discrepancies. CDC will also continue to monitor data through the National Healthcare Safety Network. Based on this ongoing data analysis and with appreciation for the conservation strategies which may be in use, CMS will consider whether there is a need for future action with respect to the use of certain quality measures in the value-based programs for the relevant performance period(s). CMS will continue to coordinate with partner agencies and the hospital industry to monitor the disruption. HHS is exploring additional opportunities to better understand which providers are affected by this disruption and to what extent they are impacted, which will also inform future actions.

Legal Considerations

- Guidance within this document summarize recommendations from major medical societies and institutions
- Recommendations are consistent with modifying standard of care
- As of now, no public health orders or emergency declarations in Region VIII
- Work with your legal group and public health leaders for specific rules within your state



Region 8

MOUNTAIN PLAINS

Regional Disaster

Health Response System