BEST PRACTICES FOR BLOOD CULTURE:
MANAGING THE SHORTAGE OF BLOOD CULTURE BOTTLES

David J. Weber, MD, MPH, FIDSA, FSHEA, FRSM (London)
Sanders Distinguished Professor of Medicine, Pediatrics and Epidemiology
Associate Chief Medical Officer, UNC Medical Center
Medical Director, Hospital Epidemiology, UNC Medical Center
University of North Carolina at Chapel Hill

UNC
SCHOOL OF MEDICINE

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

- **10 July 2024**: The U.S. Food and Drug Administration (FDA) is aware that the U.S. is experiencing interruptions in the supply of BD BACTEC blood culture media bottles because of recent supplier issues. The disruption in supply of this device is expected to impact patient diagnosis, follow up patient management, and antimicrobial stewardship efforts. The FDA recommends laboratories and health care providers consider conservation strategies to prioritize the use of blood culture media bottles, preserving the supply for patients at highest risk.
- In developing strategies to preserve the supply for patients at highest risk, please consider the following:
  - Performing blood culture collections when medically necessary, following clinical guidelines, such as those provided below.
  - Prioritizing use for patients with clinical signs and symptoms of a bloodstream infection.
  - Performing routine disinfection of skin protocols prior to collection to minimize the risk of contamination of the blood culture.
  - Ensuring proper blood volume collection to avoid a need to recollect additional samples.
  - Utilizing safe blood collection and transfer devices to minimize the risk of damage to blood culture media bottles.
  - Referring to the following guidelines for best practices for blood collection and potential considerations for prioritization for use of blood culture media bottles:

https://www.fda.gov/medical-devices/letters-health-care-providers/disruptions-availability-bd-bactec-blood-culture-media-bottles-letter-health-care-providers

Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases: 2024 Update by IDSA & ASM

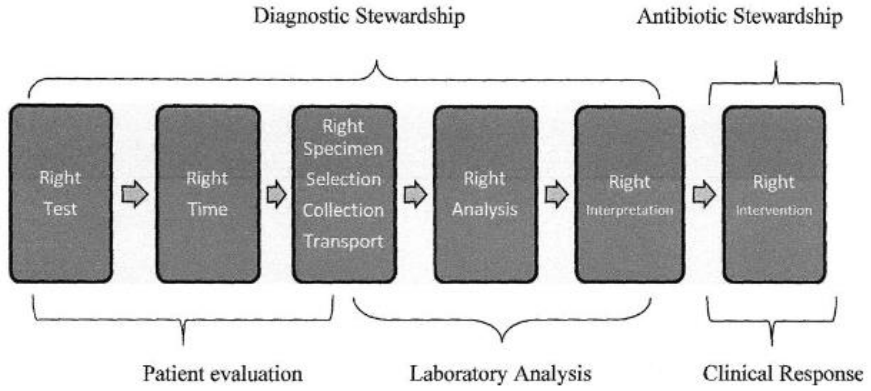

Figure 1. Interaction of diagnostic stewardship and antibiotic stewardship resulting in positive patient outcomes.

Table 3. Recommended Volumes of Blood for Culture in Pediatric Patients [3, 8]

Weight of Patient (kg)	Total Patient Blood Volume (mL)	Recommended Volume of Blood for Culture (mL)		Total Volume for Culture (mL)	% of Total Blood Volume
		Culture No. 1	Culture No. 2		
≤ 1	50–99	2	—	2	4
1.1–2	100–200	2	2	4	4
2.1–12.7	>200	4	2	6	3
12.8–36.3	>800	10	10	20	2.5
>36.3	>2200	20–30	20–30	40–60	1.8–2.7 or less

Key points for the laboratory diagnosis of bloodstream infections:

- Volume of blood collected, not timing, is most critical.
- Disinfect the venipuncture site with chlorhexidine or 2% iodine tincture in adults and children >2 months old (chlorhexidine NOT recommended for children <2 months old.
- Draw blood for culture before initiating antimicrobial therapy.
- Catheter-drawn blood cultures have a higher risk of contamination (false positives).
- Do not submit catheter tips for culture.
- Never refrigerate blood prior to incubation.
- Use a 2–3 bottle blood culture set for adults, at least one aerobic and one anaerobic; use 1–2 aerobic bottles for children.
- *Streptococcus pneumoniae* and some other gram-positive organisms may grow better in anaerobic than aerobic bottles.

Miller JM, et al Clin Infect Dis 2024;5 March

Disruptions in Availability of Becton Dickinson (BD) BACTEC™ Blood Culture Bottles

Print

Distributed via the CDC Health Alert Network
July 23, 2024, 2:45 PM ET
CDCHAN-00512

Summary

The Centers for Disease Control and Prevention (CDC) is issuing this Health Alert Network (HAN) Health Advisory to inform healthcare providers, laboratory professionals, healthcare facility administrators, and state, tribal, local, and territorial health departments of a critical shortage of Becton Dickinson (BD) BACTEC™ blood culture media bottles. This shortage has the potential to disrupt patient care by leading to delays in diagnosis, misdiagnosis, or other challenges in the clinical management of patients with certain infectious diseases. Healthcare providers, laboratory professionals, healthcare facility administrators, and state, tribal, local, and territorial health departments affected by this shortage should immediately begin to assess their situations and develop plans and options to mitigate the potential impact of the shortage on patient care.

https://emergency.cdc.gov/han/2024/han00512.asp

CDC: Disruptions in Availability of BD BACTEC Blood Culture Bottles: Current Situation

- Update 1 August, 2024: CDC is alerting healthcare providers, laboratory professionals, healthcare facility administrators, and state, tribal, local, and territorial health departments of a critical shortage of Becton Dickinson (BD) BACTECTM blood culture media bottles. This shortage has the potential to disrupt patient care by leading to delays in diagnosis, misdiagnosis, or other challenges in the clinical management of patients with certain infectious diseases.
  - Users may experience delays in supply of BD BACTECTM blood culture media bottles over the coming months.
  - Assess your situation and develop plans and options to mitigate the impact of the shortage on patient care.
  - This page will be updated when new information or resources become available. Check back often for updates.
- Recommendations for Healthcare Providers and Phlebotomists
  - Implement practices to optimize the use of blood cultures at your facility.
  - Take steps to prevent blood culture contamination.
  - Ensure that the appropriate volume is collected when collecting blood for culture.
- Laboratory Professionals and Healthcare Facility Administrators
  - If your laboratory or facility will be impacted by the bottle shortage, determine whether you have alternative options for blood cultures (e.g., working with a nearby facility or sending samples out to a laboratory not affected by the shortage).
  - Monitor current and future supplies of blood culture bottles at your laboratory or facility and report any potential shortages or interruptions to the Food and Drug Administration (FDA).

https://www.cdc.gov/healthcare-associated-infections/bd-bactec-availability/index.html

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BLOOD CULTURE BOTTLE INVENTORY MANAGEMENT AND CLINICAL CONSERVATION DURING SUPPLY SHORTAGES

Endorsed by the Society for Healthcare Epidemiology of America (SHEA)

Authors: Geehan Suleyman,[1] Nicholas M. Moore,[2] Elizabeth Palavecino,[3] Amanda Harrington,[4] Romney Humphries,[5] Paige M.K. Larkin,[6] Rosemary She*,[7] Laura Filkins*[8]

*Co-senior authors

Affiliations:

1. Henry Ford Health, Detroit, MI
2. Rush University Medical Center, Chicago, IL
3. Wake Forest University School of Medicine, Winston Salem, NC
4. Loyola University Medical Center, Maywood, IL
5. Vanderbilt University Medical Center, Nashville, TN
6. American Society for Microbiology, Washington, DC
7. City of Hope, Duarte, CA
8. University of Texas Southwestern Medical Center, Dallas, TX

ile:///U:/home/UNCMC%20Files/CASP-SHEA-ASM-Blood-Culture-shortage-FAQ_FINAL-5%20August.pdf

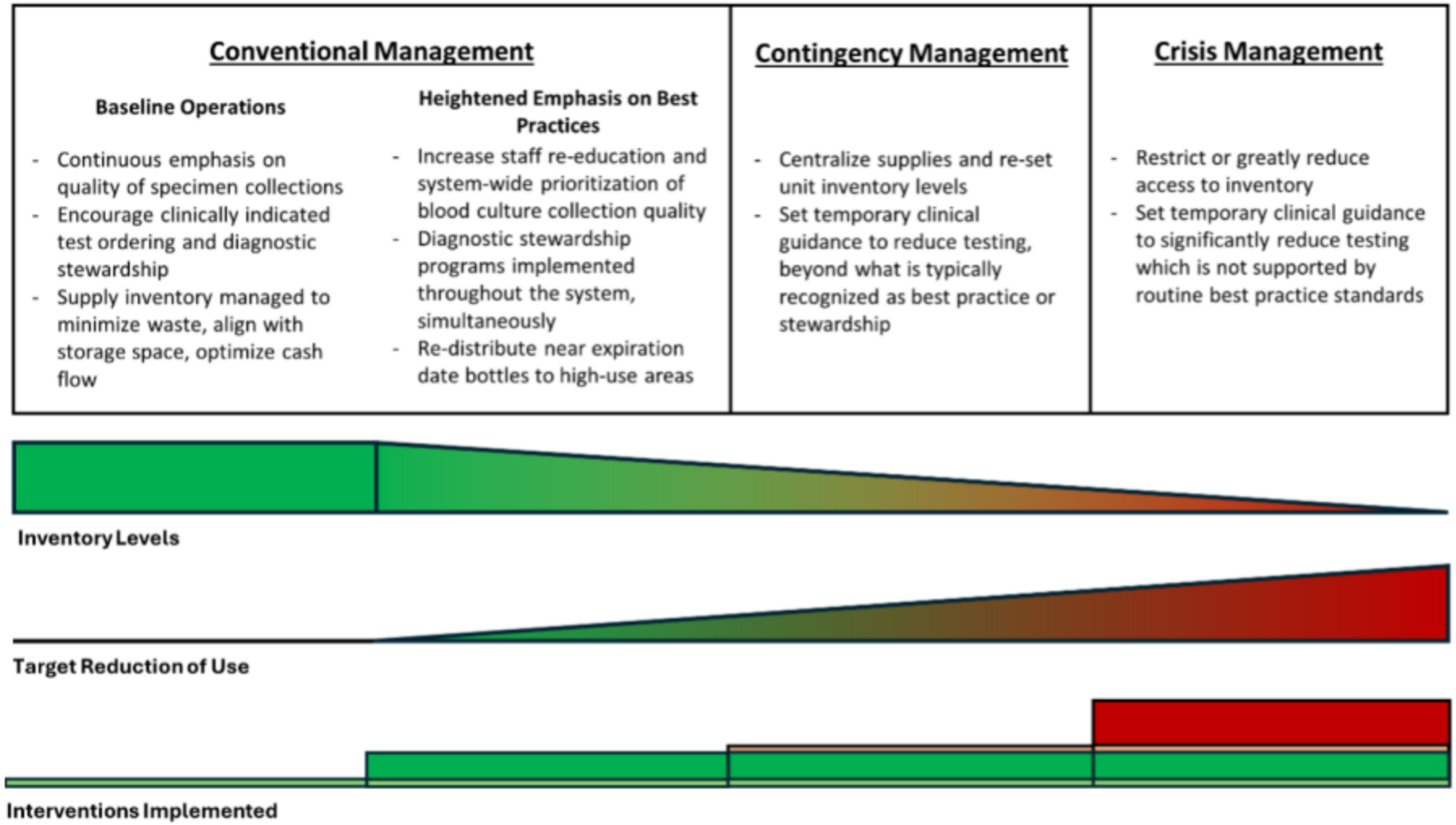


Figure 1. Tiered response categories that may be implemented based on the severity of BC bottle shortages. During BC bottle shortages, healthcare systems should first determine baseline inventory management and clinical utilization practices. Depending on the severity of the BC bottle shortage and target reduction of use required for an individual institution, different interventions may be required. We recommend that first interventions include emphasizing best practices to improve patient care and conserve supplies (conventional management of BC bottle inventory). During severe shortages, best practice interventions may not be sufficient. In those cases, in addition to best practice interventions, systems must identify additional conservation methods that reduce use beyond what is typically recognized as best practice (contingency management) or what is not supported by best practices standards (crisis management).

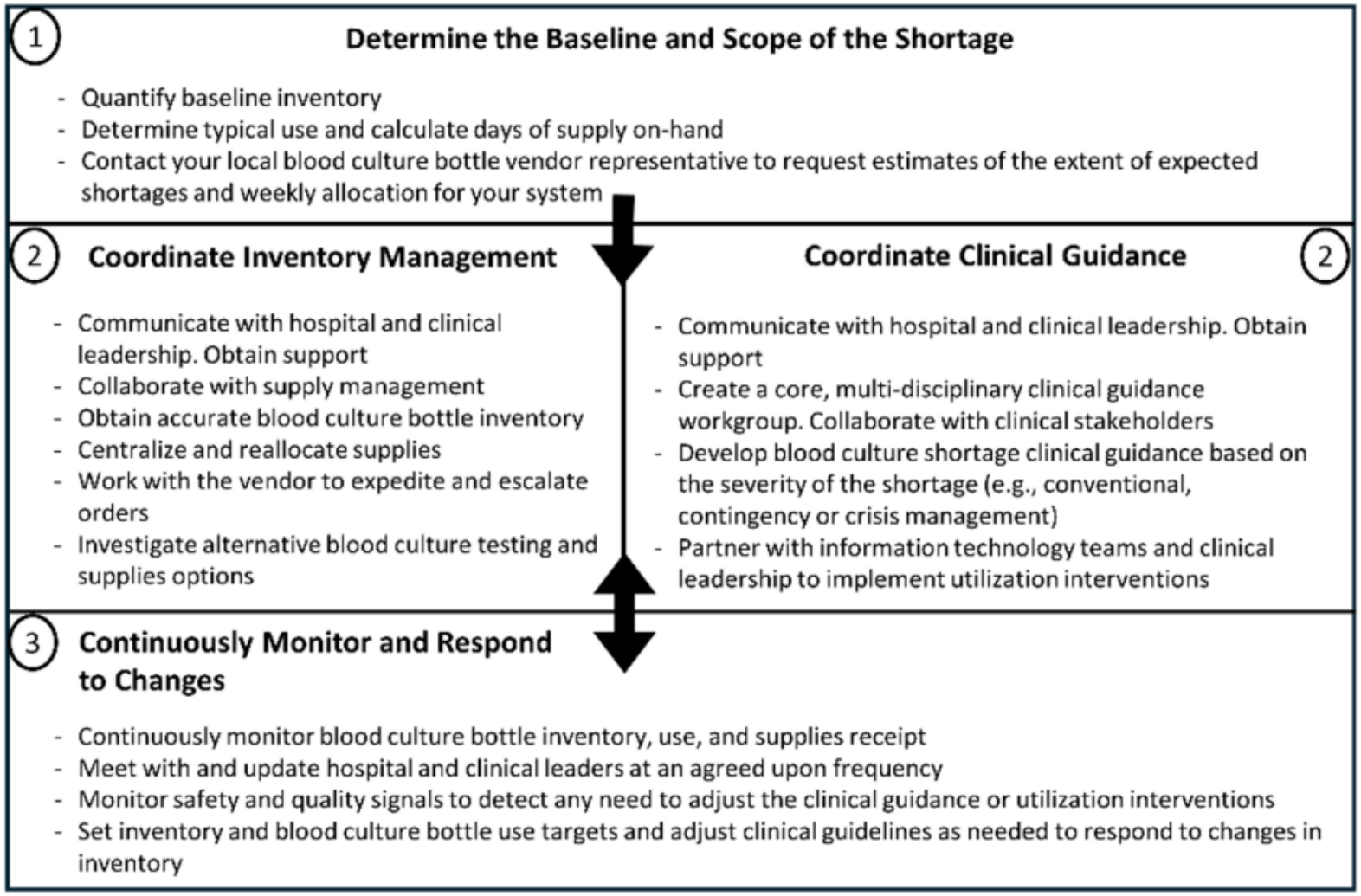


Figure 2. Recommended steps and tasks for laboratories to take to help organize their system's response to a BC bottle shortage. When coordinating a response to BC bottle shortages, we recommend that laboratory leaders first determine the baseline bottle inventory for their system and estimate the extent and scope of the shortage. Next, both inventory management strategies and clinical guidance to reduce use must be coordinated. These activities generally require collaboration with different groups and experts but should be managed at the same time. Depending on the system, laboratory leaders may or may not be delegated to coordinate these responses. Therefore, it is imperative to first communicate with hospital and clinical leadership, determine the status of the system's response, and identify areas in which laboratory expertise is needed. After initial coordination and strategies are developed, an iterative process of monitoring and responding to changes should proceed until the shortage is resolved.

Summary Box 1. Strategies to optimize diagnostic yield of blood cultures and reduce need for recollection

Optimize volume of blood collected

- Blood culture bottle fill volume is the single most critical factor to recover and isolate microorganisms *in vitro*
- Blood culture bottles should be filled with the optimal blood volumes recommended by the manufacturer
- A typical blood culture set comprises of one aerobic bottle and one anaerobic bottle for adult patients

Timing of blood culture sampling

- Blood cultures should be collected **before** initiation of antimicrobial therapy
- Multiple blood cultures may be drawn consecutively without an intervening timeframe between draws
- Draw timing considerations in relation to fever do not increase yield of blood cultures

Minimizing blood culture contamination

- Skin antisepsis should be performed using chlorhexidine gluconate or iodine tincture to minimize the risk of contamination of blood cultures with skin microbiota
- Blood culture contamination is minimized by carefully observing antisepsis of collection sites, collector training, and monitoring of contamination rates coupled with collector education and feedback
- Use of specimen diversion strategies may help reduce blood culture contamination rates

Minimizing sample rejection

- Ensure collectors understand the importance of proper specimen labeling, specimen stability requirements, and transport instructions to minimize sample rejection

Attention to quality metrics related to blood cultures

- The microbiology laboratory is responsible for monitoring the quality metrics tracking blood culture contamination rate and blood culture bottle fill volumes
- A rigorous program to provide feedback to collectors and improve performance on quality metrics improves diagnostic yield of blood cultures

Summary Box 2. Stewardship approaches to optimize indications for blood cultures according to specific settings.

General Principles

- Pre-test probability of bacteremia and the likelihood of detecting a clinically significant organism should be carefully considered before ordering any test for infectious diseases and is especially important during times of critical supplies shortages
- Repeat blood cultures within 48 h of initial blood cultures are of low yield (-5%) in providing new or significant results compared to initial cultures

Immunocompetent Adult Patients in Inpatient Setting

- Avoid routine use of blood cultures in immunocompetent patients with isolated fever or leukocytosis, uncomplicated cellulitis, uncomplicated cystitis or prostatitis, and non-severe pneumonia
- Avoid routine collection of blood cultures in response to fever within the first 48 h after surgery
- A published algorithm may be considered to steward blood culture collection (1)
- Optimize initial specimen collection when evaluating suspected sepsis or endocarditis
- Avoid blood culture collections for persistent fever after initial blood cultures are negative in patients with stable or improving clinical status

Emergency Department Setting

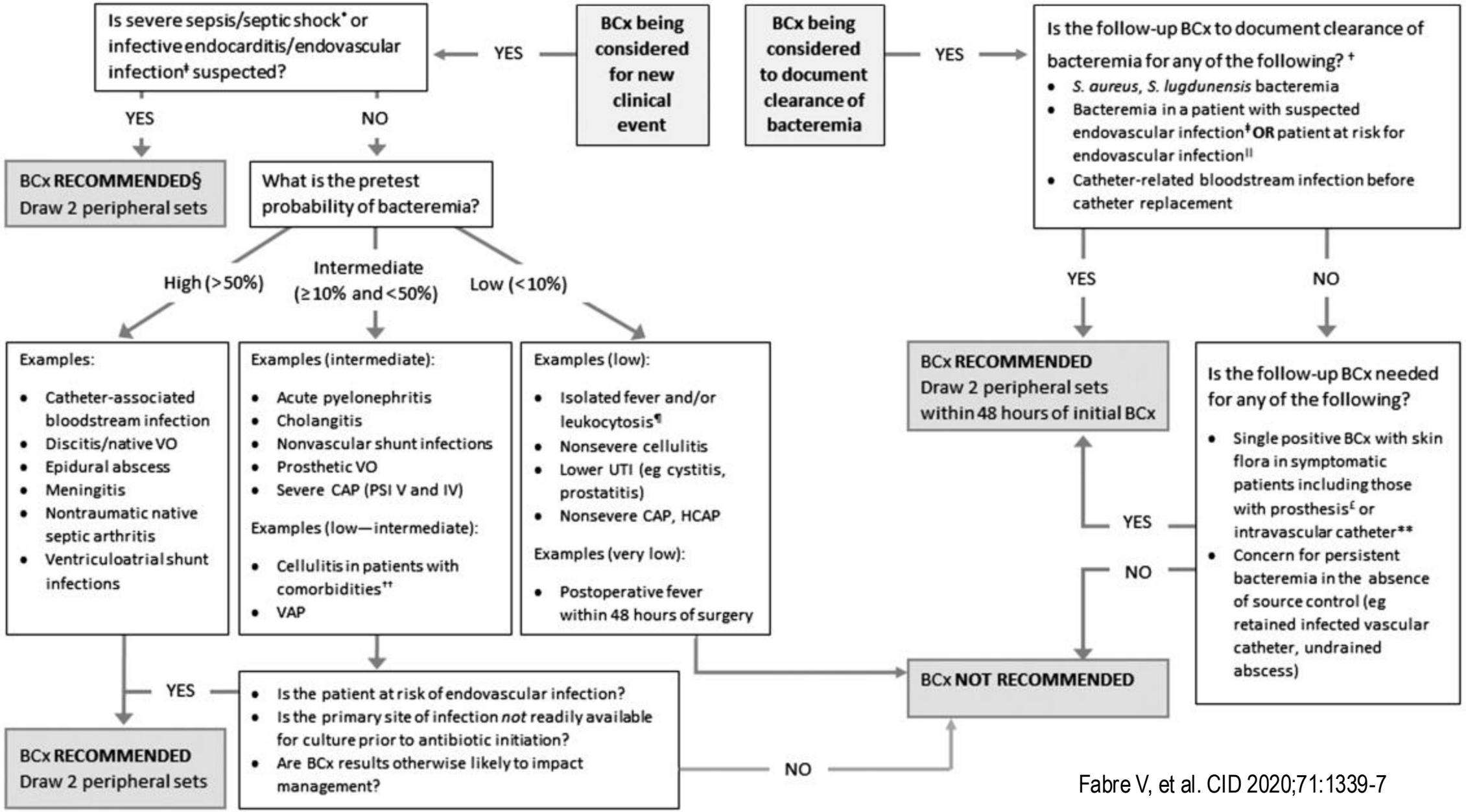
- The Shapiro decision rule and other clinical prediction rules may aid in reducing unnecessary blood cultures in the ED
- Attention to proper specimen site disinfection protocols can reduce blood culture contamination if ED does not have dedicated phlebotomists

Pediatric Patients

- A published study with 19 recommendations may be considered to steward blood culture collection (2)
- Avoid routine collection of blood cultures in non-critically ill patients with cellulitis, but without signs of a serious infection or specific risk factors
- Avoid blood cultures in patients with mild community acquired pneumonia and non-toxic, immunized patients able to be managed in the outpatient setting (including the ED)
- Blood cultures to document clearance are not necessary for Streptococcus pneumoniae in a patient with clinical improvement of community acquired pneumonia
- Blood cultures are not recommended for the evaluation and diagnosis of bronchiolitis
- Avoid blood cultures in patients presenting with acute gastroenteritis, unless septicemia is suspected

Patients with Neutropenia

- Initial work-up of fever in neutropenic patients should include at least two blood cultures, e.g., one peripheral and one catheter drawn culture
- Avoid daily blood cultures in clinically stable patients with persistent fever and neutropenia after initial work-up is performed.
- Response to empiric therapy can be evaluated 3-5 days after therapy initiation
- Avoid collecting multiple blood culture sets from each port of a single line



Fabre V, et al. CID 2020;71:1339-7

Algorithm for bacterial blood cultures recommendations in nonneutropenic patients. The algorithm is not a substitute for clinical judgment

Table 1. Pretest Probability of Bacteremia in Common Clinical Scenarios (Percentages as Reported in the Studies)

< 5% (Very Low)	< 10% (Low)	Between 10% and < 20% (Low-moderate)	Between 20% and < 50% (Moderate)	≥ 50% (High)
Fever within first 48 h of surgery [12–14, 42, 55]	Uncomplicated cellulitis [6, 15–17, 43, 44], including periorbital cellulitis [45, 46]	Cellulitis in patients with severe comorbidities [18, 27, 28]	Severer sepsis	Discitis and VO [39, 40, 47] Epidural abscesses [40, 41] Acute nontraumatic native septic joints [48]
Isolated fever [5, 6]	Lower urinary tract infection [19, 20]	…	Acute pyelonephritis [29, 30, 49, 50]	Meningitis [6]
…	…	…	Cholangitis [32, 33] Pyogenic liver abscess [34]	…
…	CAP [6, 22, 23, 51–53] HCAP [21, 22, 52, 56]	VAP [25, 26]	Severe CAP [31]	…
…	…	…	Nonvascular shunt infections [35]	Ventriculoatrial shunt infections [35]
…	…	…	Severe sepsis [54, 57] Shaking chills in febrile patient [6]	Septic shock [6] Catheter-related bloodstream infections

Abbreviations: CAP, community-acquired pneumonia; HCAP, healthcare-associated pneumonia; VAP, ventilator-associated pneumonia; VO, vertebral osteomyelitis.

Fabre V, et al. CID 2020;71:1339-7

A Diagnostic Stewardship Intervention To Improve Blood Culture Use among Adult Nonneutropenic Inpatients: the DISTRIBUTE Study

ABSTRACT: Interventions to optimize blood culture (BCx) practices in adult inpatients are limited. We conducted a before-after study evaluating the impact of a diagnostic stewardship program that aimed to optimize BCx use in a medical intensive care unit (MICU) and five medicine units at a large academic center. The program included implementation of an evidence-based algorithm detailing indications for BCx use and education and feedback to providers about BCx rates and indication inappropriateness. Neutropenic patients were excluded. BCx rates from contemporary control units were obtained for comparison. The primary outcome was the change in BCxs ordered with the intervention. Secondary outcomes included proportion of inappropriate BCx, solitary BCx, and positive BCx. Balancing metrics included compliance with the Centers for Medicare and Medicaid Services (CMS) SEP-1 BCx component, 30-day readmission, and all-cause in-hospital and 30-day mortality. After the intervention, BCx rates decreased from 27.7 to 22.8 BCx/100 patient-days (PDs) in the MICU (P <0.001) and from 10.9 to 7.7 BCx/100 PD for the 5 medicine units combined (P <0.001). BCx rates in the control units did not decrease significantly (surgical intensive care unit [ICU], P=0.06; surgical units, P=0.15). The proportion of inappropriate BCxs did not significantly change with the intervention (30% in the MICU and 50% in medicine units). BCx positivity increased in the MICU (from 8% to 11%, P<0.001). Solitary BCxs decreased by 21% in the medicine units (P<0.001). Balancing metrics were similar before and after the intervention. BCx use can be optimized with clinician education and practice guidance without affecting sepsis quality metrics or mortality.

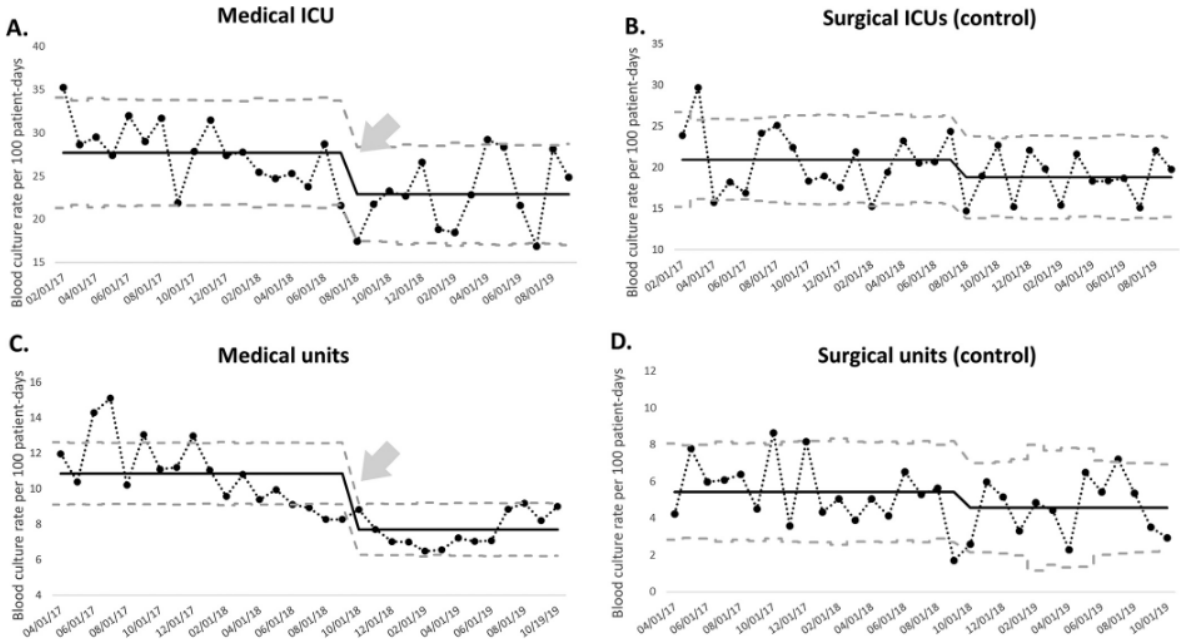


FIG 1 Trends of blood cultures in the intervention and control units during the study period. Arrows indicate the intervention. Black solid lines indicate average blood culture rate, and each black circle indicates average blood culture rate for each month. Upper and lower dashed gray lines indicate "control" limits (average rate + [3 × SD]).

Fabre V, et al. J Clin Microbiol 2020;10:e01053-20

WHO NEEDS A BLOOD CULTURE? A PROSPECTIVELY DERIVED AND VALIDATED PREDICTION RULE

Abstract: The study objective was to derive and validate a clinical decision rule for obtaining blood cultures in **Emergency Department (ED)** patients with suspected infection. This was a prospective, observational cohort study of consecutive adult ED patients with blood cultures obtained. The study ran from February 1, 2000 through February 1, 2001.

Table 3. Decision Rule

Major Criteria	Minor Criteria (1 point each)
Suspect endocarditis (3 points)	Temperature 38.3–39.3°C (101.0–102.9°F)
Temperature > 39.4°C (103.0°F) (3 points)	Age > 65 years
Indwelling vascular catheter (2 points)	Chills
	Vomiting
	Hypotension (systolic blood pressure < 90 mm Hg
	White blood cell count > 18,000 cells/mm^3
	Bands > 5%
	Platelets < 150,000 cells/mm^3
	Creatinine > 2.0 mg/dL

Either 1 major criterion or 2 or more minor criteria is an indication to obtain a blood culture. If these are not present, a blood culture is not indicated by the rule.

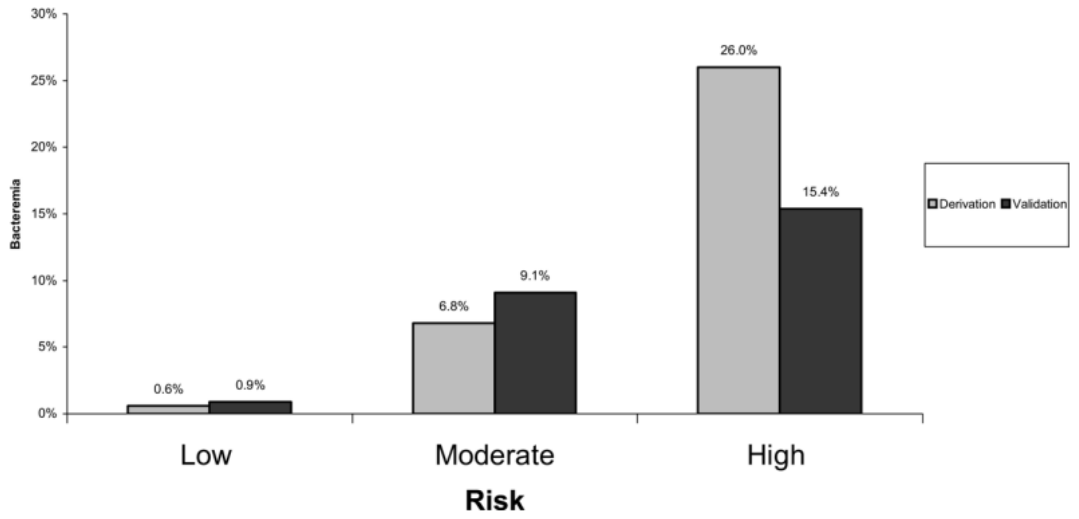


Figure 2. Bacteremia by risk group. Figure demonstrates risk of bacteremia stratified by risk group: low (0–1 points), moderate (2–4 points), and high (> 4 points).

Shapiro NI, et al. J Emerg Med 2008;35:255-64.

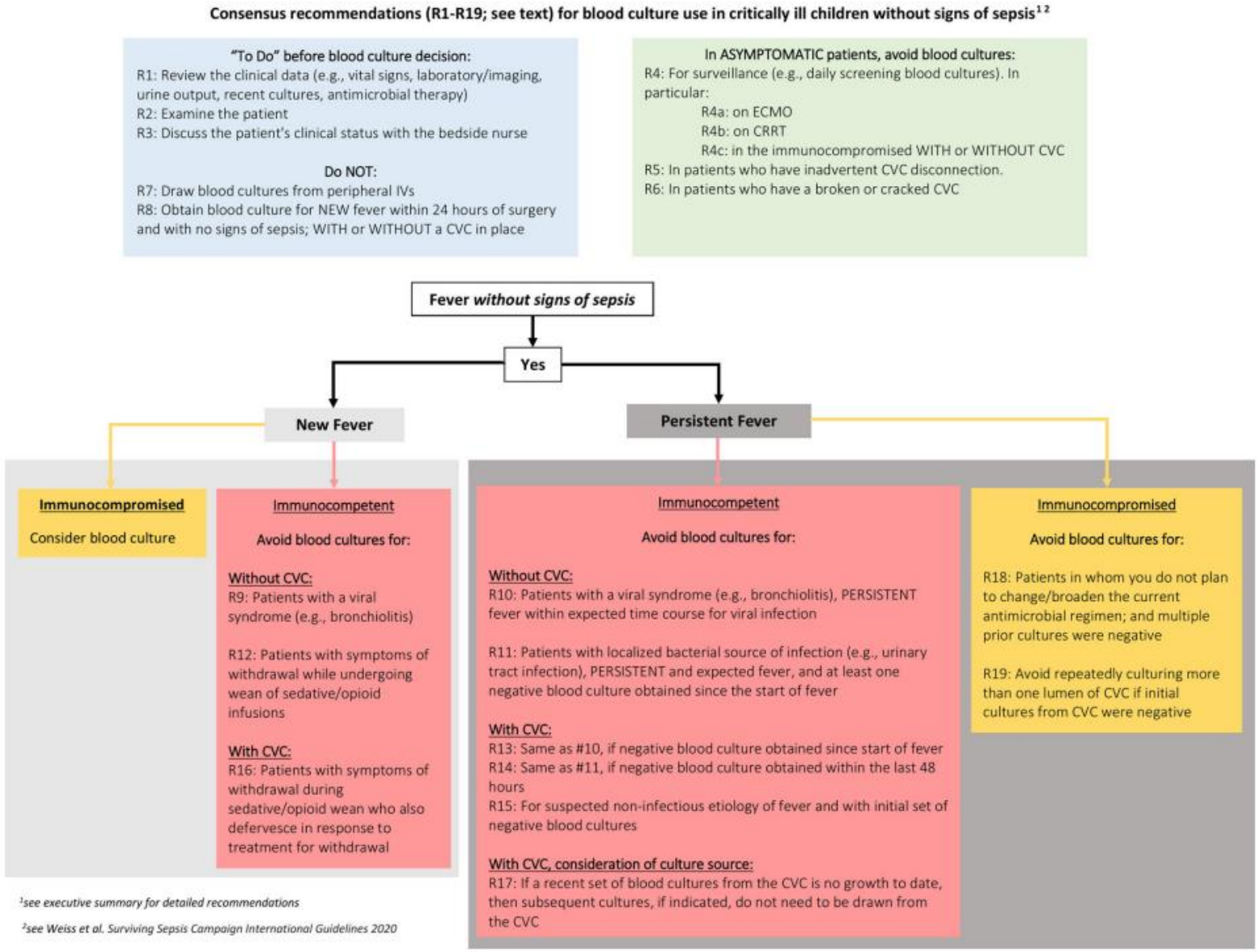


Figure 1.
Delphi consensus recommendations for blood culture use in critically ill children without signs of sepsis

Research in Context

- Blood culture practices in critically ill children vary widely, and overuse of cultures can lead to false positive results, unnecessary antibiotics, and patient harm.
- Diagnostic stewardship efforts can safely reduce blood culture overuse, but no standards or guidelines currently exist to guide clinicians in specific scenarios.
- To meet this need, a multi-center collaborative called Bright STAR used a modified Delphi method to develop the first-ever consensus recommendations for reducing blood culture overuse in the pediatric intensive care unit.

At the bedside

- We recommend that every PICU consider implementing diagnostic stewardship for blood cultures to avoid unnecessary testing and excess antibiotics in critically ill children.
- A multidisciplinary expert panel developed 19 recommendations for blood cultures that can be avoided in critically ill children.
- Additional study is needed to determine optimal implementation strategies.

Woods-Hill, CZ et al.
Pediatr Crit Care Med 2021;22:774-84