

MEASURE WORKSHEET

This document summarizes the evaluation of the measure as it progresses through NQF's Consensus Development Process (CDP). The information submitted by measure developers/stewards is included after the Brief Measure Information, Preliminary Analysis, and Pre-meeting Public and Member Comments sections.

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Brief Measure Information

NQF #: 3658

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

Measure Steward: Centers for Disease Control and Prevention

Brief Description of Measure: The Blood culture contamination (BCC) rate is a process measure designed to follow healthcare providers' adherence to pre-analytic blood culture collection instructions established by the hospital clinical laboratory in patients 18 years or older. Blood culture contamination is defined as having certain commensal organisms (bacteria or fungus that normally colonizes human skin, without causing disease) isolated from only one blood culture set out of two or more sets collected within a 24-hour period (this is considered a false positive test result).

A secondary related measure is the single set blood culture rate in patients 18 years or older. A single set blood culture in a 24-hour period is not an adequate volume of blood to make an accurate diagnosis of bacteremia (which can lead to false negatives) and a single set blood culture positive predefined commensal organisms cannot be evaluated using the definition for possible contamination without the second set blood culture. The purpose of the measure is to ensure that all hospitals that collect blood cultures follow best practices for how blood culture collection is performed by healthcare providers and monitor the performance of the healthcare providers by calculating and reporting the blood culture contamination and single set rate back to collecting personnel and hospital units. This will allow process improvements to be implemented to reduce BCC contamination to be measured and evaluated on a monthly basis.

Developer Rationale: Blood culture contamination (BCC) is defined as having a commensal organism (which is a bacteria or fungus that normally colonizes human skin, without causing disease) isolated from only one blood culture set out of two or more sets collected within a 24-hour period (this is considered false positive test result). The purpose of the measure is to ensure that all hospitals that collect blood cultures follow a standard operating procedure (SOP) for how blood culture collection is performed by healthcare providers and monitor performance of the healthcare providers using this SOP by following a standard for determining the blood culture contamination rate.

The blood culture contamination rate is used as a monitor of healthcare providers' ability to follow the SOP correctly. If they are following the SOP correctly, the contamination rate will be 3% percent or less. Low contamination rates result in appropriate and optimal use of antibiotics, which reduces adverse patient events such as overuse of antibiotics, increased exposure to hospital acquired infections like *Clostridium difficile* colitis, development of antibiotic resistant bacteria, and extended length of hospital stay. This national quality measure will bring all healthcare institutions up to the same recommended standards of quality and safety guidelines.

The overall BCC contamination rate should be evaluated on a monthly basis or more in the institutions who currently analyze and report the rate. It is calculated by dividing the total number of contaminated blood culture sets by the total number of blood culture sets collected during the monthly evaluation period.

Generally, in adults with a suspicion of a blood stream infection, two - four blood culture sets should be obtained in the evaluation of each septic episode (defined as a 24-hour period). An adequate amount of blood culture volume is needed to detect the presence of true bacteremia or septicemia. When only one blood culture set is collected out of the two - four recommended sets this is called a single set blood culture. One method to determine if the appropriate amount of blood volume is being collected is to evaluate the single set blood culture rate. This overall single set blood culture rate should be evaluated on a monthly basis or more in the institutions who currently analyze and report the rate. It is calculated by dividing the total number of single set blood cultures without another set collected within 24 hours by the total number of blood culture sets collected during the monthly evaluation period.

This measure supports the Hospital Onset Bacteremia & Fungemia measure currently in development by the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) Division of Healthcare Quality Promotion (DHQP) and the National Healthcare Safety Network (NHSN) Hospital Onset Bacteremia & Fungemia module slated to be implemented late 2022 – early 2023.

It does this in 2 ways:

- A. The BCC measure monitors blood culture contamination rate, which will rise, resulting in false positive blood cultures, when blood cultures are not collected correctly. False positive blood culture results may result in an artificial rise in the Hospital Onset Bacteremia (HOB) rate.
- B. Accurate diagnosis of bacteremia/fungemia requires 40 to 60 mL of blood be drawn per septic episode. False negative results may occur when too little blood is drawn. The secondary measure addresses single set blood cultures (20 mL or less) which do not provide the blood volume needed to accurately diagnose bacteremia/fungemia. False negative results could cause an artificial lowering of the HOB rate. In addition, 2 blood culture sets are required to determine if the growth of commensal bacteria (skin flora) in the blood culture is more likely to be due to contamination (single set positive) or a true infection (both sets positive). A single set blood culture does not allow the laboratory or the clinician to determine if the presence of commensal bacteria meets the criteria for reporting.

Numerator Statement:

Primary Measure – Blood Culture Contamination Rate:

Total number of blood culture sets with growth of a commensal organism in only one blood culture set out of two or three blood culture sets collected within a 24-hour period.

Sub Measure – Single Set Blood Culture Rate:

Total number of single set blood cultures collected either one bottle or one set (1 aerobic and 1 anaerobic bottle) in one blood draw within 24-hour period.

Denominator Statement:

Primary Measure – Blood Culture Contamination Rate:

Total number of all blood culture sets collected which are eligible to be considered for contamination per eligibility criteria

Primary Measure Eligibility Criteria:

Patient ≥ 18 years old

Patient may be present in any department of the hospital such as ICU, ED, inpatient floors, step down units. (No outpatients)

At least two blood culture sets drawn in a 24-hour period

Sub Measure – Single Set Blood Culture Rate:

Total number of two or three sets and single sets, either one bottle or one blood culture set (1 aerobic and 1 anaerobic bottle), collected in a 24-hour period

Sub Measure Eligibility Criteria:

Patient ≥ 18 years old

Patient may be present in any department of the hospital such as ICU, ED, inpatient floors, step down units. (No outpatients)

Denominator Exclusions: Primary Measure: Only a single set collected (must have two sets or more collected) within a 24-hour period; Patient ≤ 18 years in age

Measure Type: Process

Data Source: Other (specify): Laboratory Information Systems (LIS) data; Blood Culture Analyzer Software

Preliminary Analysis: New Measure

Criteria 1: Importance to Measure and Report

1a. [Evidence](#)

1a. Evidence. The evidence requirements for a ***structure, process or intermediate outcome*** measure are that it is based on a systematic review (SR) and grading of the body of empirical evidence where the specific focus of the evidence matches what is being measured. For measures derived from patient report, evidence also should demonstrate that the target population values the measured process or structure and finds it meaningful.

The developer provides the following description for this measure:

- This is a new process measure at the facility level designed to follow healthcare providers' adherence to pre-analytic blood culture collection instructions established by the hospital clinical laboratory. A secondary related measure is the single set blood culture rate, collected to ensure that all hospitals collecting blood cultures follow best practices for how blood culture collection is performed.
- The developer provides a logic model that depicts the preanalytical flow of when a blood culture should be ordered, standard operating procedures for correct culture collection, and when there is increased likelihood of a contamination event.

The developer provides the following evidence for this measure:

- | | | |
|---|---|--|
| • Systematic Review of the evidence specific to this measure? | ☒ Yes | ☐ No |
| • Quality, Quantity and Consistency of evidence provided? | ☐ Yes | ☒ No |
| • Evidence graded? | ☐ Yes | ☒ No |

Summary:

- The evidence to support the need for a national quality measure on blood culture contamination is drawn from a systematic review, other publications, laboratory accreditation standards, and laboratory guidelines. The systematic review does not discuss the quality, quantity, and consistency of the studies nor provide graded evidence. The developer also uses a CDC library literature review and review of the College of American Pathology (CAP) quality measures and American Society of Microbiology (ASM) Cumitechs.
- The evidence provided details best practices and procedures for blood culture collection, the impacts of poor collection practices, and methods to improve collection practices and reduce contamination rates, specifically:
 - The systematic review from 2012 discusses the effectiveness of practices to reduce blood culture contamination but the developer summary focuses on the problems related to contaminated blood cultures and does not summarize best practices identified in the review.
 - A 2021 Congressional directive to reduce blood culture contamination, citing the “enormous clinical implications, laboratory ramifications, and economic costs”;
 - A microbiology inspection checklist from CAP requiring laboratories requiring a) a written procedure for monitoring blood culture contamination rates and a contamination threshold set, and records of corrective action if the threshold is exceeded; and b) monitoring of blood

culture volumes drawn and records of feedback to clinical staff, as larger volumes of blood increase the likelihood of true positive cultures (whereas too little volume increases the likelihood of false negatives)

- Publications on antibiotic stewardship and risks from overuse.
- A 2020 publication that uses several studies and meta-analyses to provide updates on the problem of blood culture contamination and methods for addressing it. These proposed methods for improvement include: patient selection; skin antisepsis; blood culture bottle disinfection; blood culture collection site; single vs. double needle; sterile gloves and hand hygiene; blood culture kits and standard procedures; blood sampling and volume; use of phlebotomy teams and education; multidisciplinary/multimodal performance improvement; surveillance and feedback; and initial specimen diversion.

Exception to evidence

- N/A

Questions for the Committee:

- *What is the relationship of this measure to patient outcomes?*
- *Is the evidence directly applicable to the process of care being measured?*
- *Are there, or could there be, performance measures of a related health outcome, OR evidence-based intermediate clinical outcomes, intervention/treatment?*
- *Is there evidence of a systematic assessment of expert opinion beyond those involved in developing the measure?*

Guidance from the Evidence Algorithm

Process measure (Box 1) -> Evidence is based on a systematic review (Box 3) -> Summary of the quality, quantity, and consistency of the evidence is not provided (Box 4) -> The evidence provided is not graded but is high quality and accompanied by additional empirical evidence (Box 6) -> Rate as MODERATE

Preliminary rating for evidence: ☐ High ☒ Moderate ☐ Low ☐ Insufficient

1b. [Gap in Care/Opportunity for Improvement](#) and [Disparities](#)

1b. Performance Gap. The performance gap requirements include demonstrating quality problems and opportunity for improvement.

- The developer provides blood culture contamination and single set rates from their Premier Healthcare Database testing dataset for the years 2012-2017. Overall, there were 6,688,221 blood culture sets in this dataset, with 1,067,876 identified as single sets.
- Annual percent contaminated blood cultures range from 3.25% to 2.73% within this timespan.
 - The developer states that although the overall contamination rate in this timespan is just under the 3% benchmark at 2.99%, this rate represents 168,250 events, which potentially led to unnecessary patient care actions by providers due to the false positive result.
 - Annual percent single set blood culture rates range from 14.2% to 22.0% within this timespan.
- Among 259 facilities, the contamination culture rates by quartile among complete collected cultures (n=5,620,345 complete cultures) were as follows:
 - First quartile: 1.97 percent
 - Median: 2.67 percent

- Third quartile: 3.5 percent
- The single culture rate by quartile among all cultures (n= 6,688,221 total units):
 - First quartile: 4.25 percent
 - Median: 6.45 percent
 - Third quartile: 10.43 percent

Disparities

- Using data from one of the testing datasets (Premier Healthcare Database 2012-2017, n=5,212,521), blood culture contamination was more likely to occur with patients who were Black (Odds Ratio (OR)=1.21, p=<0.0001), non-Hispanic (OR=1.04, p=0.0156), unmarried (OR=0.9, p=<0.0001), or male (OR=0.94, p=<0.0001).
- Patients age 80 years or older were also more likely to have a contaminated blood culture than those ages 18-39 (OR=0.71, p=<0.001) or 40-59 (OR=0.87, p=<0.001).

Questions for the Committee:

- *Is there a gap in care that warrants a national performance measure?*

Preliminary rating for opportunity for improvement: ☐ High ☒ Moderate ☐ Low ☐ Insufficient

Committee Pre-evaluation Comments:

1a. Evidence

- Conceptually, this metric makes sense and would be valuable clinically. As far as evidence, there is good evidence that contaminated blood cultures lead to increased antibiotic use. I see minimal evidence presented that contamination rates can be reduced using and by how much. There are some single-study weak observational papers suggesting reductions in blood culture contamination using different approaches, and certainly no evidence of causal reduction of blood culture contamination because of reporting (particularly noted at JHHS as the overall contamination rate seems to have been decreasing over time, year over year. There is good evidence that high enough volume of blood is needed for adequate sensitivity of blood cultures. There is no evidence presented that multiple sets (defined by me and most other ID docs as one aerobic and one anaerobic bottle from one site) of blood cultures is superior to multiple sets, particularly in the setting of poor access or obtaining blood cultures from central lines. Multiple sets answer the question of whether a blood culture is a contaminant or whether the bacteremia is persistent, which is a different question than is this patient bacteremic. I am also unclear about the evidence of under 3% to be optimal. While I generally support the goals and specifications of this metric, it should be noted that causality, the evidence behind benchmarks, the ability to reduce contamination rates and the specific evidence tying reduction in blood contamination to reduces LOS or reduced antibiotic use is overstated based on consensus statements and before/after studies in the setting of declining baseline contamination rates.
- Agree with moderate rating, as evidence provided, while indirect, is compelling.
- process measure
- The evidence is not clearly presented - instead these are consensus guidelines. Specifically, there is not evidence presented which links a measure like this to decrease in the issue.
- Agree
- Moderate evidence for a process measure

- Preliminary rating of moderate.
- Adequate evidence supports the need for this measure.
- The purpose of the measure is to ensure that blood culture collections follow a standard operating procedure to reduce contamination. This is a new process measure at the facility level. The developer submitted a systematic review from 2012 that discusses the effectiveness of practices to reduce blood culture contamination, a 2021 Congressional directive to reduce blood culture contamination, a microbiology checklist with requirement for labs, publications on antibiotic stewardship and risk of overuse and a 2020 publication that uses several studies and meta-analyses to provide updated on the problem of blood culture contamination.
- There is a systematic review, other publications, laboratory accreditation standards, and laboratory guidelines. The systematic review does not discuss the quality, quantity, and consistency of the studies nor provide graded evidence. Evidence provided details best practices and procedures for blood culture collection, the impacts of poor collection practices, and methods to improve collection practices and reduce contamination rates.

1b. Gap in Care/Opportunity for Improvement and Disparities

- Data on variability of blood culture contamination rates from Premier and Cerner data base were presented
- Seems moderate, with strong evidence for disparities. Gap, while narrow, appears to point towards preventable adverse consequences and given volume of cultures could be meaningful.
- moderate evidence political directive yes for PG
- Insufficient
- no concerns
- I'm not sure there's sufficient performance gap if the overall contamination rate is already below the benchmark, it may be that an argument can be made from a disparities perspective but really seems like the absolute rates are already low. The secondary outcome seems to have more of a performance gap but I'm not sure the evidence for that is as strong.
- Approximately 3% contamination rate.
- Performance data suggest the need for a measure, especially in the single draw for culture (sub measure). There were disparity data noted.
- There were disparities noted in the over 80 age group having increased likelihood of a contaminated blood culture, blood culture contamination was more likely to occur with patients who were Black, non-Hispanic, unmarried or male.
- Although the overall contamination rate in this timespan is just under the 3% benchmark at 2.99%, this rate represents 168,250 events, which potentially led to unnecessary patient care actions by providers due to the false positive result. This is a concern. Further, there were disparities noted by race, age and ethnicity that warrant analysis.

Criteria 2: Scientific Acceptability of Measure Properties

Complex measure evaluated by Scientific Methods Panel? ☐ Yes ☒ No

Evaluators: Staff

2a. Reliability: [Specifications](#) and [Testing](#)

2a1. Specifications requires the measure, as specified, to produce consistent (reliable) and credible (valid) results about the quality of care when implemented.

2a2. Reliability testing demonstrates if the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise enough to distinguish differences in performance across providers.

Specifications:

- The developers considers the sub-measure to be part of the overall measure, but it is calculated separately from the primary measure, with a different numerator and denominator that are not subsets of the primary measure.
- It is not clear from the submission how the sub-measure should be reported with relation to the primary measure.

Reliability Testing:

Reliability testing conducted at the Accountable Entity Level:

- Reliability testing was conducted using the Premier Healthcare Database and Cerner Health Facts, two large electronic healthcare databases that contain data from both private and academic U.S. hospitals. The Premier Healthcare Database and Cerner Health Facts house laboratory information systems (LIS) data.
- The developer cites a study from the Division of Healthcare Quality and Promotion (DHQP) using the above datasets to establish reliability: Trends and Variability in Blood Culture Utilization and Positivity among U.S. Hospitals: 01-01-2012 – 12-31-2017.
 - The developer confirms that the data evaluated from this time period all meet the eligibility criteria outlined in the current measure's specifications.
 - To test reliability of both the primary measure, Blood Culture Contamination Rate, and the sub-measure, Single Set Blood Culture Rate, the developers used a Split Sample Reliability test-retest approach in which the total contamination rate is measured once using a random subset of patients, and then measured again using a second random subset exclusive of the first.
- For the primary measure, Blood Culture Contamination Rate, 5,620,345 blood culture episodes were used and 168,250 contaminated episodes were included in the analysis, with an overall contamination rate of 2.994%. Using a split-sample analysis, the developer calculated the Intraclass Correlation Coefficient (ICC) using the Spearman-Brown prediction formula. The agreement between the two groups was 0.81253.
 - The developer states that according to a standard interpretation, an ICC between 0.8 – 0.99 represents "Almost perfect agreement."
- For the sub-measure, Single Set Blood Culture Rate, 6,688,221 blood culture sets were examined with 541,613 single sets identified, for a single culture rate of 8.10%. Using a split-sample analysis, the ICC for the two groups was 0.78635.
 - The developer states that according to a standard interpretation, an ICC between 0.6 – 0.79 represents "Substantial agreement."

Questions for the Committee regarding reliability:

- *Do you have any concerns that the measure cannot be consistently implemented (i.e., are measure specifications adequate)?*

Preliminary rating for reliability: ☒ **High** ☐ **Moderate** ☐ **Low** ☐ **Insufficient**

2b. Validity: [Validity testing](#); [Exclusions](#); [Risk-Adjustment](#); [Meaningful Differences](#); [Comparability](#); [Missing Data](#)

2b2. Validity testing should demonstrate the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality.

2b2-2b6. Potential threats to validity should be assessed/addressed.

Validity Testing

- Validity testing conducted at the Accountable Entity Level:
 - The developer hosted a panel presentation with Q&A for eight subject matter experts (SMEs) who are part of or associated with the laboratory community, and who have extensive knowledge of laboratory best practice standards for blood culture collection and contamination rate reporting. After the meeting all participants were sent a survey about the proposed measure.
 - The developer states that all eight SMEs agreed or strongly agreed that the measure would be a good indicator to discern between good and poor quality of care.
 - The actual question asked of the SMEs was “Do you feel that this proposed NQF measure for hospitals and healthcare institutions to calculate the blood culture contamination rate would be an effective measure to monitor blood culture collection to reduce the contamination rate.”

Exclusions

- The measure uses exclusions (patients less than 18 years of age and single sets). The developer did not test for exclusions since excluded data was not collected in the dataset.

Risk-Adjustment

- The measure is not risk adjusted or stratified.

Meaningful Differences

- The developer provides blood culture contamination and single set rates from their Premier Healthcare Database testing dataset for the years 2012-2017.
 - Among 259 facilities, the contamination culture rates by quartile among complete collected cultures (n=5,620,345 complete cultures) were 1.97 percent at the first quartile, 2.67 percent at the median, and 3.5 percent at the third quartile.
 - The single culture rate by quartile among all cultures (n= 6,688,221 total units) was 4.25 percent at the first quartile, 6.45 percent at the median, and 10.43 percent at the third quartile.

Missing Data

- The developer states that test accountability practices ensure there is no missing data. A record is created in the LIS for every blood culture collected which provides a mechanism to ensure every culture is tested and resulted.

Comparability

- The measure only uses one set of specifications for this measure.

Questions for the Committee regarding validity:

- *Do you have any concerns regarding the validity of the measure (e.g., exclusions, risk-adjustment approach, etc.)?*

Preliminary rating for validity: ☐ High ☒ Moderate ☐ Low ☐ Insufficient

Committee Pre-evaluation Comments:

2a. Reliability

- 2a1. Reliability-Specifications
 - this should be highly reliable and the developers have shown this.
 - No concerns about reliability
 - high
 - All are clearly defined
 - no concerns
 - reasonable, no concerns
 - none
 - No concerns about implementation.
 - The developer provided data indicated that from 2012-2017 the annual percent of contaminated blood cultures was slightly below the benchmark of 3% (at 2.99%) but that this represented 168,250 events.
 - No concerns
- 2a2. Reliability – Testing
 - No
 - No concerns about reliability
 - no
 - No concerns
 - no concerns
 - reasonable, no concerns
 - no
 - No.
 - The primary measure is blood culture contamination rate and the sub measure is dingle set blood culture rate. Preliminary rating for reliability testing was graded as high on the measure worksheet.
 - None

2b. Validity

- The clinical (vs statistical) validity (does the metric validly measure contamination) could be influenced by timing of antibiotic administration compared to timing of obtaining blood cultures and whether a second set is obtained. Also some commensal organisms described in NHSN can also be pathogenic. Some cultures could be misclassified as contaminants when they are truly pathogens and vice versa. As far as measurement validity, true positives and true negatives should be easy to determine.
- Agree with moderate rating
- moderate - no
- It is not clear to me that the measure data elements reflect the quality of care provided and adequately identifies differences in quality
- no concerns

- there is face validity to the measure but the validity testing is just to survey 8 experts seem insufficient.
- no
- No.
- The developer queried a panel of 8 SMEs who felt that the measure was an effective measure to reduce contamination rate. Exclusions include patients less than 18 years of age. My concern is that how do we know that having contaminated blood cultures results in adverse events (treating physicians are aware when blood culture results return as "probably contaminant") and is this considered?
- No concerns

2b2-2b6. Potential threats to validity

- 2b2-3. Other Threats to Validity (Exclusions, Risk Adjustment)
 - I don't believe risk adjustment, exclusions or missing data are an issue here. It may be valuable to include pediatric cases.
 - Does not need to be risk adjusted and agree with this determination.
 - not risk adjusted or stratified - NA?
 - Not risk adjusted
 - not risk adjusted
 - N/A
 - N/a not risk adjusted or stratified.
 - Given the disparities noted previously, there may need to be risk adjustment at the facility level.
 - not risk adjusted
 - There is no risk-adjustment
- 2b4-7. Threats to Validity (Statistically Significant Differences, Multiple Data Sources, Missing Data)
 - There is a conceptual framework to suggest that this metric would be important as a meaningful difference. I don't see good evidence presented (yet) showing this metric impacts outcomes. If we are using before/after at least have a control hospital.
 - No
 - no
 - No missing data (surprising)
 - no concerns
 - Again given the small performance gap not sure what to make of the meaningful differences.
 - No missing data reported.
 - No.
 - the developer states that there is no missing data due to records created in the LIS for every blood culture collected.
 - No

Criterion 3. [Feasibility](#)

3. Feasibility is the extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

- Blood culture contamination data is generated by a lab professional who uses LIS software to analyze the data.
- The developer states that all data elements are in defined fields in a combination of electronic sources, but that in some cases, depending on the facility, the evaluation could be done manually as well using SOP criteria. As such, this measure should pose no collection burden and there would be no additional investments in infrastructure or software to obtain the needed data elements.
- The developer is currently evaluating United States Core Data for Interoperability (USCDI) and Fast Healthcare Interoperability Resources (FHIR) standards and plan to work with data interoperability experts to streamline reporting.

Questions for the Committee:

- *Are the required data elements routinely generated and used during care delivery?*
- *Are the required data elements available in electronic form, e.g., EHR or other electronic sources?*
- *Is the data collection strategy ready to be put into operational use?*

Preliminary rating for feasibility: ☐ High ☒ Moderate ☐ Low ☐ Insufficient

Committee Pre-evaluation Comments:

3. Feasibility

- These data are readily available in the EMR and do not seem to require chart or other human abstraction, thus likely to not be overly burdensome if the electronic infrastructure is in place.
- Currently has some barriers but seems like EMR updates may help make this more universally reported and standardized
- moderate - none
- Moderate
- all data fields in EMR but use a combination of electronic and manual data collection
- no concerns
- The developer states that all data elements are in defined fields in a combination of electronic sources, but that in some cases, depending on the facility, the evaluation could be done manually as well using SOP criteria.
- None.
- Not clear - uses electronic and in some cases manual evaluation. The developer is currently evaluating US Core Data for Interoperability and Fast Healthcare Interoperability Resources to streamline reporting. This seems a potential difficulty for some facilities at this time.
- No concerns since the data is mostly generated through laboratory databases.

Criterion 4: Use and Usability

4a. Use (4a1. [Accountability and Transparency](#); 4a2. [Feedback on measure](#))

4a. Use evaluates the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4a.1. Accountability and Transparency. Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

Current uses of the measure

Publicly reported? ☐ Yes ☒ No

Current use in an accountability program? ☐ Yes ☒ No ☐ UNCLEAR

Planned use in an accountability program? ☒ Yes ☐ No ☐ NA

Accountability program details

- The measure is currently used for quality improvement internally at facilities. Rates are to be reported to individual patient care units for tracking and follow-up.
- The developer intends the measure to be used for public reporting and in a regulatory or accreditation program as well.

4a.2. Feedback on the measure by those being measured or others. Three criteria demonstrate feedback: 1) those being measured have been given performance results or data, as well as assistance with interpreting the measure results and data; 2) those being measured and other users have been given an opportunity to provide feedback on the measure performance or implementation; 3) this feedback has been considered when changes are incorporated into the measure

Feedback on the measure by those being measured or others

- The developer interviewed the Director of the Division of Medical Microbiology at Johns Hopkins University School of Medicine in order to obtain the feedback of a large hospital system currently implementing the blood culture contamination rate evaluation and reporting in a variety of hospital settings (community-level, suburban, and university). They have successfully implemented blood culture contamination rate evaluation and reporting and have experienced a decrease in the rate and increased collaboration between units as a result.
 - The Director states that contamination results are reported monthly to the hospitals, and individual department results specifically to key stakeholders in those particular units such as emergency departments, intensive care units, oncology units, phlebotomy, and infection prevention and control/CLBASI groups.
 - The overall hospital rate is also shared so that units can compare their rates with the overall hospital rates.
 - Raw data including the names of individuals who collected contaminated cultures is also provided so that they can be retrained.
 - A CLABSI reduction committee also receives the monthly rates so they can provide detailed education back to units.
- Challenges reported include:
 - The requirement to obtain specimens via lines for certain patient populations.
 - High turnover of phlebotomists.
 - Lack of leadership support to hire more phlebotomists.

Questions for the Committee:

- *How have (or can) the performance results be used to further the goal of high-quality, efficient healthcare?*
- *How has the measure been vetted in real-world settings by those being measured or others?*

Preliminary rating for Use: ☒ Pass ☐ No Pass

4b. Usability (4a1. [Improvement](#); 4a2. [Benefits of measure](#))

4b. Usability evaluates the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4b.1 Improvement. Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated.

Improvement results

- By implementing blood culture contamination rate evaluation and reporting, Johns Hopkins University Teaching Hospital's contamination rates dropped from 3-4% to 1%.

4b2. Benefits vs. harms. Benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

Unexpected findings (positive or negative) during implementation

- No unexpected negative findings.
- The developer notes that positive findings include recognition of the value of trained phlebotomists and nursing champions, and that focusing on this initiative led to other quality metrics such as improving blood culture utilization and reduction in blood cultures obtained via lines.

Potential harms

- No harms experienced.

Additional Feedback:

- [Summary of feedback from MAP]

Questions for the Committee:

- *How can the performance results be used to further the goal of high-quality, efficient healthcare?*
- *Does the timeframe for determining contamination events pose a burden for reporting (2 or more samples collected within a 24 hr period)?*
- *Do the benefits of the measure outweigh any potential unintended consequences?*

Preliminary rating for Usability and use: ☐ High ☒ Moderate ☐ Low ☐ Insufficient

Committee Pre-evaluation Comments:

4a. Use

- This measure is not yet part of public reporting

- Planned use in accountability programs
- yes
- Feedback has been limited at this point
- no concerns
- no concerns
- Internally right now. The developer intends the measure to be used for public reporting and in a regulatory or accreditation program as well.
- Results may be used to decrease contamination of samples, thereby, improving patient safety when a systemic infection is suspected.
- New measure. Not currently publicly reported or used in an accountability program but developer states there are plans to do so.
- Not being publicly reported yet, but CDC plans to do so. Feedback is being considered.

4b. Usability

- I believe there is minimal harm and the potential for significant benefit if reporting this metric drives improvement.
- No concerns
- planned - unknown
- Harm of additional measure without clear signal that this will lead to improvement
- no concerns
- no concerns
- benefits > harms
- There are no apparent harms.
- By implementing blood culture contamination rate evaluation and reporting, Johns Hopkins Univ Hosp rate dropped from 3-4% to 1%. Unintentional positive findings include recognition of the value of trained phlebotomists and nursing champions and that focusing on this initiative led to other improved quality metrics such as reduction in blood cultures obtained via lines. No harms reported.
- No concerns about usability

Criterion 5: [Related and Competing Measures](#)

- No related or competing measure identified.

Committee Pre-evaluation Comments:

5: Related and Competing Measures

- n/a
- None
- none
- none
- No related or competing measure identified.
- None given.
- none
- no concerns

Public and NQF Member Comments (Submitted as of June 10, 2022)

Member Expression of Support

- No public comments received.

Scientific Acceptability Evaluation

RELIABILITY: SPECIFICATIONS

1. **Are submitted specifications precise, unambiguous, and complete so that they can be consistently implemented?** ☐ Yes ☒ No
2. **Briefly summarize any changes to the measure specifications and/or concerns about the measure specifications.**
 - The developers considers the sub-measure to be part of the overall measure, but it is calculated separately from the primary measure, with a different numerator and denominator that are not subsets of the primary measure.
 - It is not clear from the submission how the sub-measure should be reported with relation to the primary measure.
 - Expert panel reports that their facilities use a variety of laboratory information systems and/or laboratory analyzer software systems to obtain the data elements, including EPIC beaker, Cerner Millenium custom report, Sunquest, BACTEC with Epicenter.
 - It is not clear from the submission whether all these systems report data in the same way.

RELIABILITY: TESTING

3. **Reliability testing level:** ☒ **Accountable-Entity Level** ☐ **Patient/Encounter Level** ☐ **Neither**
4. **Reliability testing was conducted with the data source and level of analysis indicated for this measure:**
☒ **Yes** ☐ **No**
5. If accountable-entity level and/or patient/encounter level reliability testing was NOT conducted or if the methods used were NOT appropriate, was **empirical VALIDITY testing** of patient-level data conducted?
☐ **Yes** ☐ **No**
6. **Assess the method(s) used for reliability testing:**
 - Reliability testing was conducted using the Premier Healthcare Database and Cerner Health Facts, two large electronic healthcare databases that contain data from both private and academic U.S. hospitals. The Premier Healthcare Database and Cerner Health Facts house laboratory information systems (LIS) data.
 - The developer cites a study from the Division of Healthcare Quality and Promotion (DHQP) using the above datasets to establish reliability: Trends and Variability in Blood Culture Utilization and Positivity among U.S. Hospitals: 01-01-2012 – 12-31-2017.
 - The developer confirms that the data evaluated from this time period all meet the eligibility criteria outlined in the current measure's specifications.
 - To test reliability of both the primary measure, Blood Culture Contamination Rate, and the sub-measure, Single Set Blood Culture Rate, DHQP used a Split Sample Reliability test-retest approach in which the total contamination rate is measured once using a random subset of patients, and then measured again using a second random subset exclusive of the first.
7. **Assess the results of reliability testing**

- For the primary measure, Blood Culture Contamination Rate, 5,620,345 blood culture episodes were used and 168,250 contaminated episodes were included in the analysis, with an overall contamination rate of 2.994%. Using a split-sample analysis, the developer calculated the Intraclass Correlation Coefficient (ICC) using the Spearman-Brown prediction formula. The agreement between the two groups was 0.81253.
 - According to standard interpretation, an ICC between 0.8 – 0.99 represents “Almost perfect agreement.”
 - For the sub-measure, Single Set Blood Culture Rate, 6,688,221 blood culture sets were examined with 541,613 single sets identified, for a single culture rate of 8.10%. Using a split-sample analysis, the ICC for the two groups was 0.78635.
 - According to standard interpretation, an ICC between 0.6 – 0.79 represents “Substantial agreement.”
8. Was the method described and appropriate for assessing the proportion of variability due to real differences among measured entities? **NOTE:** If multiple methods used, at least one must be appropriate.
- ☒ **Yes** ☐ **No** ☐ **Not applicable**
9. Was the method described and appropriate for assessing the reliability of ALL critical data elements?
- ☐ **Yes** ☐ **No** ☒ **Not applicable** (patient/encounter level testing was not performed)
10. **OVERALL RATING OF RELIABILITY** (taking into account precision of specifications and all testing results):
- ☒ **High** (NOTE: Can be HIGH only if accountable-entity level testing has been conducted)
- ☐ **Moderate** (NOTE: Moderate is the highest eligible rating if accountable-entity level testing has not been conducted)
- ☐ **Low** (NOTE: Should rate LOW if you believe specifications are NOT precise, unambiguous, and complete or if testing methods/results are not adequate)
- ☐ **Insufficient** (NOTE: Should rate INSUFFICIENT if you believe you do not have the information you need to make a rating decision)
11. **Briefly explain rationale for the rating of OVERALL RATING OF RELIABILITY and any concerns you may have with the approach to demonstrating reliability.**
- Specifications are precise and can be consistently implemented (Box 1) -> Empirical testing conducted using the measure as specified (Box 2) -> Empirical testing conducted at the accountable entity level (Box 4) -> Split-sample reliability testing used (Box 5) -> Based on the reliability statistic, there is high certainty that results are reliable (Box 6a) -> Rate as HIGH

VALIDITY: TESTING

12. **Validity testing level (check all that apply):**
- ☒ **Accountable-Entity Level** ☐ **Patient or Encounter-Level** ☐ **Both**
13. **If patient/encounter level validity testing was provided, was the method described and appropriate for assessing the accuracy of ALL critical data elements? NOTE:** Data element validation from the literature is acceptable.
- ☐ **Yes**
- ☐ **No**
- ☒ **Not applicable** (patient/encounter level testing was not performed)
14. **Method of establishing validity at the accountable-entity level:**
- ☒ **Face validity**
- ☐ **Empirical validity testing at the accountable-entity level**

☐ N/A (accountable-entity level testing not conducted)

15. **Was the method described and appropriate for assessing conceptually and theoretically sound hypothesized relationships?**

☒ Yes

☐ No

☐ Not applicable (accountable-entity level testing was not performed)

16. **Assess the method(s) for establishing validity**

- The developer hosted a panel presentation with Q&A for eight subject matter experts (SMEs) who are part of or associated with the laboratory community, and who have extensive knowledge of laboratory best practice standards for blood culture collection and contamination rate reporting. After the meeting all participants were sent a survey about the proposed measure.

17. **Assess the results(s) for establishing validity**

- The developer states that all eight SMEs agreed or strongly agreed that the measure would be a good indicator to discern between good and poor quality of care.
 - The actual question asked of the SMEs was “Do you feel that this proposed NQF measure for hospitals and healthcare institutions to calculate the blood culture contamination rate would be an effective measure to monitor blood culture collection to reduce the contamination rate.”

VALIDITY: ASSESSMENT OF THREATS TO VALIDITY

18. **Please describe any concerns you have with measure exclusions.**

- The measure uses exclusions (patients less than 18 years of age and single sets). The developer did not test for exclusions since excluded data was not collected in of the dataset.

19. **Risk Adjustment**

19a. **Risk-adjustment method**

☒ None (only answer Question 19b and 19e) ☐ Statistical model ☐ Stratification

☐ Other method assessing risk factors (please specify)

19b. **If not risk-adjusted, is this supported by either a conceptual rationale or empirical analyses?**

☐ Yes ☐ No ☐ Not applicable

19c. **Social risk adjustment:**

19c.1 Are social risk factors included in risk model? ☐ Yes ☐ No ☐ Not applicable

19c.2 Conceptual rationale for social risk factors included? ☐ Yes ☐ No

19c.3 Is there a conceptual relationship between potential social risk factor variables and the measure focus? ☐ Yes ☐ No

19d. **Risk adjustment summary:**

19d.1 All of the risk-adjustment variables present at the start of care? ☐ Yes ☐ No

19d.2 If factors not present at the start of care, do you agree with the rationale provided for inclusion?
☐ Yes ☐ No

19d.3 Is the risk adjustment approach appropriately developed and assessed? ☐ Yes ☐ No

19d.4 Do analyses indicate acceptable results (e.g., acceptable discrimination and calibration)
☐ Yes ☐ No

19d.5. Appropriate risk-adjustment strategy included in the measure? ☐ Yes ☐ No

19e. **Assess the risk-adjustment approach**

- Not applicable.

20. **Please describe any concerns you have regarding the ability to identify meaningful differences in performance.**
- The developer provides blood culture contamination and single set rates from their Premier Healthcare Database testing dataset for the years 2012-2017.
 - Among 259 facilities, the contamination culture rates by quartile among complete collected cultures (n=5,620,345 complete cultures) were 1.97 percent at the first quartile, 2.67 percent at the median, and 3.5 percent at the third quartile.
 - The single culture rate by quartile among all cultures (n= 6,688,221 total units) was 4.25 percent at the first quartile, 6.45 percent at the median, and 10.43 percent at the third quartile.
21. **Please describe any concerns you have regarding comparability of results if multiple data sources or methods are specified.**
- Not applicable. This measure only uses one set of specifications.]
22. **Please describe any concerns you have regarding missing data.**
- The developer states that test accountability practices ensure there is no missing data. A record is created in the LIS for every blood culture collected which provides a mechanism to ensure every culture is tested and resulted.

For cost/resource use measures ONLY:

If not cost/resource use measure, please skip to question 25.

23. **Are the specifications in alignment with the stated measure intent?**
- ☐ Yes ☐ Somewhat ☐ No (If “Somewhat” or “No”, please explain)
24. **Describe any concerns of threats to validity related to attribution, the costing approach, carve outs, or truncation (approach to outliers):**
25. **OVERALL RATING OF VALIDITY taking into account the results and scope of all testing and analysis of potential threats.**
- ☐ **High** (NOTE: Can be HIGH only if accountable-entity level testing has been conducted)
- ☒ **Moderate** (NOTE: Moderate is the highest eligible rating if accountable-entity level testing has NOT been conducted)
- ☐ **Low** (NOTE: Should rate LOW if you believe that there are threats to validity and/or relevant threats to validity were not assessed OR if testing methods/results are not adequate)
- ☐ **Insufficient** (NOTE: For instrument-based measures and some composite measures, testing at both the accountable-entity level and the patient/encounter level is required; if not conducted, should rate as INSUFFICIENT.)
26. **Briefly explain rationale for rating of OVERALL RATING OF VALIDITY and any concerns you may have with the developers’ approach to demonstrating validity.**
- Threats to validity assessed (Box 1) -> Empirical validity testing not conducted (Box 2) -> Face validity assessed by experts at the accountable entity level (Box 3) -> The results indicate agreement that the measure can be used to distinguish quality (Box 4) -> Rate as MODERATE

FOR COMPOSITE MEASURES ONLY: Empirical analyses to support composite construction

27. **What is the level of certainty or confidence that the empirical analysis demonstrates that the component measures add value to the composite and that the aggregation and weighting rules are consistent with the quality construct?**
- ☐ High

- ☐ Moderate
- ☐ Low
- ☐ Insufficient

28. Briefly explain rationale for rating of EMPIRICAL ANALYSES TO SUPPORT COMPOSITE CONSTRUCTION

- [Summary]

ADDITIONAL RECOMMENDATIONS

29. If you have listed any concerns in this form, do you believe these concerns warrant further discussion by the multi-stakeholder Standing Committee? If so, please list those concerns below.

- [Summary]

Criteria 1: Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. Measures must be judged to meet all sub criteria to pass this criterion and be evaluated against the remaining criteria

Please separate added or updated information from the most recent measure evaluation within each question response in the Importance to Measure and Report: Evidence section. For example:

2021 Submission:

Updated evidence information here.

2018 Submission:

Evidence from the previous submission here.

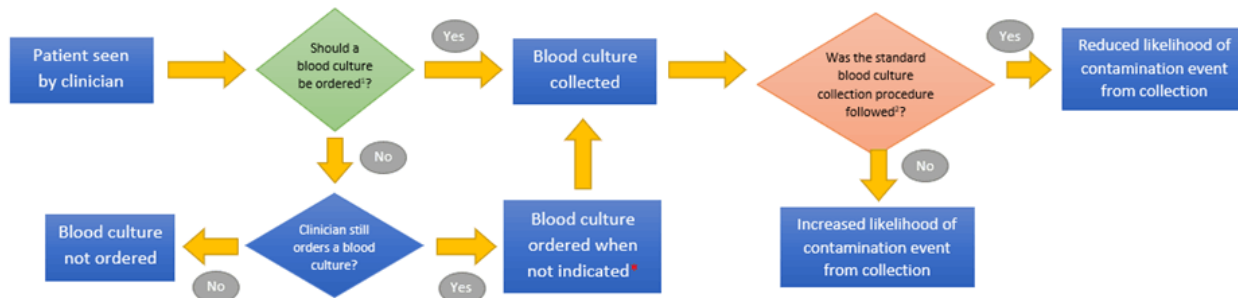
1a.01. Provide a logic model.

Briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

[Response Begins]

Blood Culture: Preanalytical Flow

Blood Culture: Preanalytical Flow



*See Box #4 (Postanalytical Flow)

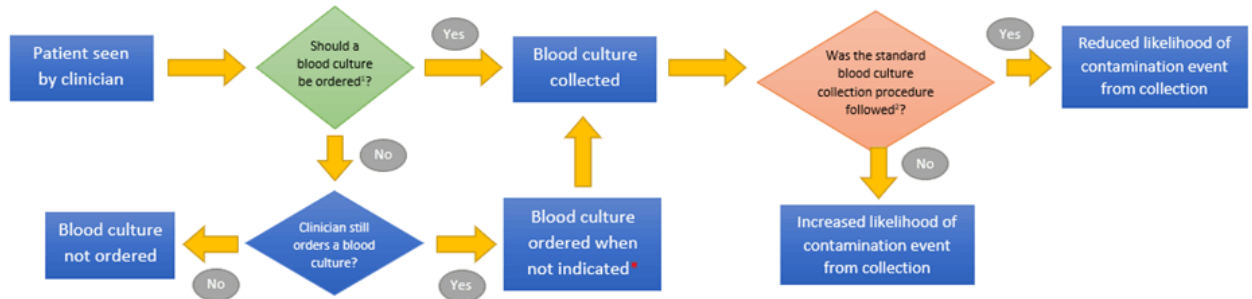
1. Indications for ordering a blood culture:

- Cholangitis
- Complicated pneumonia
- Complicated skin and soft tissue infections (SSTIs)
- Febrile neutropenia
- Fever without a source
- Meningitis
- Osteomyelitis
- Pyelonephritis
- Septic arthritis
- Suspected endovascular infections including Central Line-Associated Blood Site Infections (CLABSIs)
- Suspected infective endocarditis
- Suspected sepsis
- Unexplained leukocytosis

2. Standard Operating procedures for blood culture collection should outline steps to reduce the risk for a contamination event such as:

- Performing hand hygiene prior to specimen collection.
- Using the appropriate skin disinfectant product such as chlorhexidine gluconate (CHG) or 2% iodine tincture to cleanse the specimen collection site prior to collection.
- Disinfecting the top of the blood culture bottle with isopropyl alcohol prior to collection.
- Selecting the appropriate anatomical site for collection.
- Collecting adequate volume
 - Collection of at least two blood culture sets within a septic episode (24-hour window).
 - Consisting of one aerobic and one anaerobic bottle in each set.
 - 10 mL of blood collected in each bottle for a total of 40 mL.

Blood Culture: Preanalytical Flow



*See Box #4 (Postanalytical Flow)

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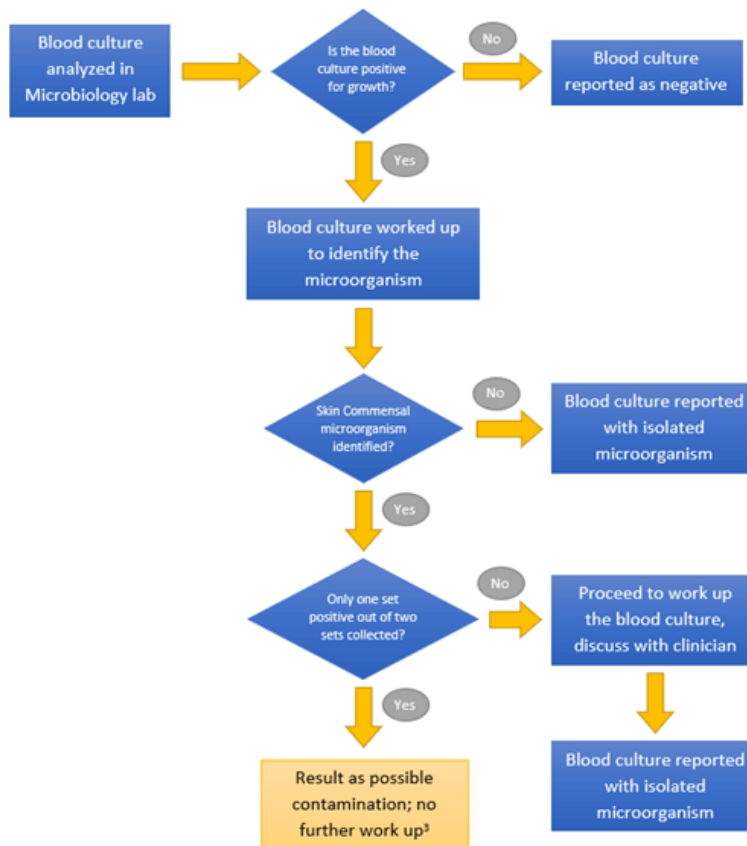
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Blood Culture: Analytical Flow

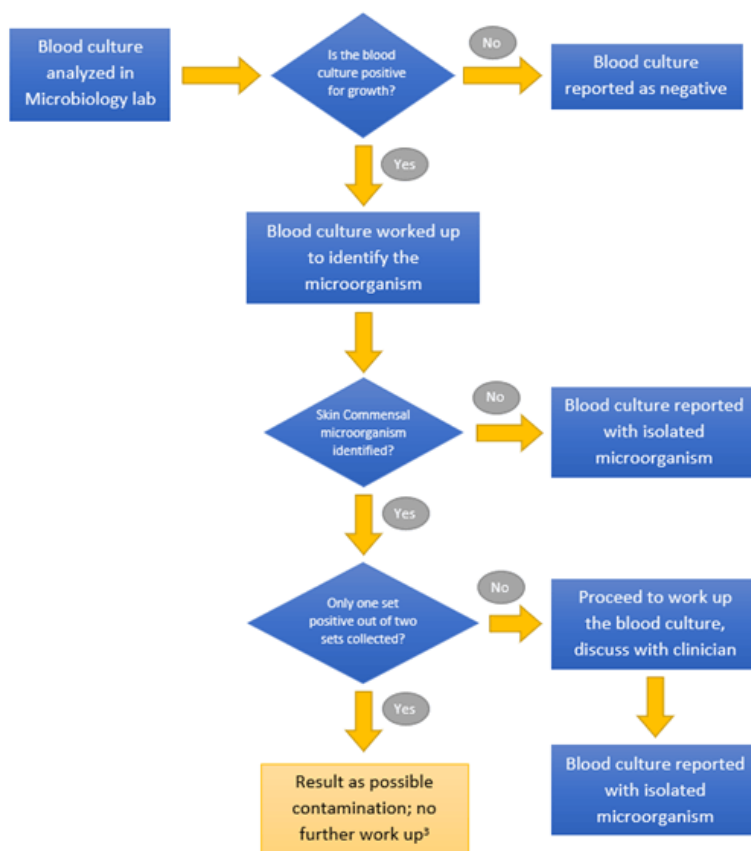
Blood Culture: Analytical Flow



3. If the clinician takes action based off of the contaminated blood culture result adverse patient events may occur such as:

- Misuse or inappropriate use of antibiotics causing:
 - Hospital-acquired *C. difficile* colitis
 - Allergic reactions
 - Drug-drug interactions
 - Antibiotic resistance emergence
 - Disruption of the host microbiome
- Prolonged hospital stays leading to:
 - Potential increased exposure to hospital-acquired infections such as MRSA and *C. difficile* colitis
 - Increased patient costs, and overall hospital costs (labor and resources).
- Exposure to additional needlesticks causing:
 - Hematomas
 - Loss of venous access
 - Blood loss resulting in iatrogenic anemia
 - Low patient and caregiver satisfaction

Blood Culture: Analytical Flow



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 - Hematomas
 - Loss of venous access
 - Blood loss resulting in iatrogenic anemia
 - Low patient and caregiver satisfaction

Blood Culture: Post Analytical Flow

Blood Culture: Post Analytical Flow



4. Potential areas of improvements / interventions:

- Implementing the use of a dedicated phlebotomy team for blood culture collection.
- Implementing the use of diversion devices to divert the initial portion of blood drawn.
- Evaluating current standard operating procedures to ensure they reflect best practice guidelines and provide a clear process for personnel to follow.
- Providing additional training and routine competency assessments for personnel who collect blood culture specimens.
- Providing additional training and guidance to ordering clinicians to ensure blood cultures are only ordered when indicated.

Blood Culture: Post Analytical Flow



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[Response Ends]

1a.02. Select the type of source for the systematic review of the body of evidence that supports the performance measure.

A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data.

[Response Begins]

Other (specify)

[Other (specify) Please Explain]

CDC Library literature review

Assessment of College of American Pathology (CAP) quality measures.

Assessment of American Society of Microbiology (ASM) Cumitechs

[Response Ends]

If the evidence is not based on a systematic review, skip to the end of the section and do not complete the repeatable question group below. If you wish to include more than one systematic review, add additional tables by clicking "Add" after the final question in the group.

Evidence - Systematic Reviews Table (Repeatable)

Group 1 - Evidence - Systematic Reviews Table

1a.03. Provide the title, author, date, citation (including page number) and URL for the systematic review.

[Response Begins]

N/A

[Response Ends]

1a.04. Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the systematic review.

[Response Begins]

N/A

[Response Ends]

1a.05. Provide the grade assigned to the evidence associated with the recommendation, and include the definition of the grade.

[Response Begins]

N/A

[Response Ends]

1a.06. Provide all other grades and definitions from the evidence grading system.

[Response Begins]

N/A

[Response Ends]

1a.07. Provide the grade assigned to the recommendation, with definition of the grade.

[Response Begins]

N/A

[Response Ends]

1a.08. Provide all other grades and definitions from the recommendation grading system.

[Response Begins]

N/A

[Response Ends]

1a.09. Detail the quantity (how many studies) and quality (the type of studies) of the evidence.

[Response Begins]

N/A

[Response Ends]

1a.10. Provide the estimates of benefit, and consistency across studies.

[Response Begins]

N/A

[Response Ends]

1a.11. Indicate what, if any, harms were identified in the study.

[Response Begins]

N/A

[Response Ends]

1a.12. Identify any new studies conducted since the systematic review, and indicate whether the new studies change the conclusions from the systematic review.

[Response Begins]

N/A

[Response Ends]

1a.13. If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, describe the evidence on which you are basing the performance measure.

[Response Begins]

The evidence to support the need for a national quality measure for blood culture contamination and to ensure the appropriate amount of blood culture volume is evaluated for septicemia and bacteremia is available in many different forms of publications and, laboratory accreditation standards, and laboratory guidelines. The evidence from many sources provided in 1a.14 includes research on the patient impacts of poor blood culturing processes, and interventions to improve blood culture collection.

[Response Ends]

1a.14. Briefly synthesize the evidence that supports the measure.

[Response Begins]

The problem with blood culture contamination and its impact on patient care has been researched for decades. The 3% benchmark for blood culture contamination was adopted as a performance benchmark in 2007 when the Clinical and Laboratory Standards Institute (CLSI) included the “3% maximum blood culture contamination rate” in their guidelines.

Although there is no current benchmark for single set blood cultures laboratories must ensure optimal blood culture collection and collecting only one blood culture set to evaluate a patient for septicemia and bacteremia could lead to false positives.

Below is a summary of a number of these best practice guidelines and publications which are widely distributed and available for use and review.

House of Representatives passage of H.R. 4355, Military Construction, Veterans Affairs, and Related Agencies Appropriations Act, 2022 (“MILCON-VA”) July 2021

- <https://www.congress.gov/bill/117th-congress/house-bill/4355/text>
- Congressional Directive “Reducing Blood Culture Contamination – The Committee is aware that blood culture contamination leads to enormous clinical implications, laboratory ramifications, and economic costs.”
- The legislation’s committee report directs the Department of Veterans Affairs (VA) to prioritize the development of a quality measure for blood culture contamination of under 1% to prevent unnecessary, avoidable health risks and harm to veterans undergoing blood testing for the diagnosis of sepsis.
- https://bilirakis.house.gov/sites/bilirakis.house.gov/files/wysiwyg_uploaded/2021.11.30%20False%20Positive%20Sepsis%20Tests%20Letter%20to%20CMS.pdf

The following references show current laboratory accreditation standards and laboratory best practice guidelines demonstrating the methods used to track and report blood culture contamination and blood culture volume (single sets). Each bullet point contains statements from each reference.

College of American Pathologists, Microbiology Inspection Checklist 06/04/2020

- <http://appsuite.cap.org/appsuite/learning/LAP/TLTM/resources/checklists/2020/cl-mic.pdf>
- MIC.22635 Blood Culture Contamination Phase II
- The laboratory monitors blood culture contamination rates and has established an acceptable threshold
- NOTE: The laboratory must determine and regularly review the number of contaminated cultures. Tracking the contamination rate and providing feedback to units and persons drawing cultures is one method that has been shown to reduce contamination rates. Other measures for consideration in monitoring blood culture contamination include the types of skin disinfection used and line draws. The threshold may be established in collaboration with other relevant institutional groups (eg, infection prevention). The laboratory must perform and record corrective action if the threshold is exceeded.
- Evidence of Compliance:
- ✓ Written procedure for monitoring blood culture contamination rates and threshold determination AND
- ✓ Records of contamination rates and corrective action if threshold is exceeded
- AND
- ✓ Records of feedback to responsible parties

College of American Pathologists, Microbiology Inspection Checklist 06/04/2020

- <http://appsuite.cap.org/appsuite/learning/LAP/TLTM/resources/checklists/2020/cl-mic.pdf>

- MIC.22640 Blood Culture Volume
- The laboratory has a written policy and procedure for monitoring blood cultures from adults for adequate volume and providing feedback on the results to blood collectors.
- NOTE: Larger volumes of blood increase the yield of true positive cultures. The volume collected must be in accordance with manufacturer instructions (in most systems it is 20 mL). The laboratory should periodically monitor collected blood volumes and provide feedback to clinical staff. Automated blood culture systems approved or cleared by the FDA may use smaller volumes per culture set and are acceptable.
- Evidence of Compliance:
 - ✓ Records of monitoring of volume at a defined frequency
 - AND
 - ✓ Records of feedback to the clinical staff

CLSI M47 ED2-2021 Principles and Procedures for Blood Cultures (Proposed Draft) Published for public comment on May 11, 2021

- <https://www.clsi.org/standards/products/microbiology/documents/m47/>
- "It should be possible to achieve blood culture contamination rates substantially lower than 3% even if 0% is not reached; when best practices are followed, a target contamination rate of 1% is achievable."
- Example QA Indicators for Assessing Blood Culture Preexamination, Examination, and Post-examination Activities (Specimen Collection):
 - Blood culture contamination rate (which may be additionally stratified by location, phlebotomist, etc.)
 - The benchmark for blood culture contamination rates is < 3%, with a goal of 1% when best practices are followed.
 - Proportion of blood culture bottles inoculated with more or less than the recommended blood volume
 - Proportion of blood culture sets submitted include only a single inoculated bottle.
 - Proportion of blood culture specimens collected from indwelling vascular access devices
 - Proportion of blood culture specimens rejected because of collection errors (eg, no patient ID on the blood culture bottle)
 - The optimal number of blood culture sets varies. However, a single set is clearly inadequate. In the case of positive blood cultures due to skin contamination, when multiple sets are obtained, usually only one set is positive. Thus, multiple sets can help distinguish a false-positive blood culture from positive cultures. Additionally, obtaining multiple blood culture sets increases the blood volume cultured, which is the most important factor in microbial recovery from blood. A single blood culture set contains insufficient blood volume. Moreover, with only a single blood culture set, it is impossible to detect continuous bacteremia or distinguish between contamination and true bacteremia.

J Michael Miller et al, A Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases: 2018 Update by the Infectious Diseases Society of America and the American Society for Microbiology, Clinical Infectious

- <https://www.idsociety.org/practice-guideline/laboratory-diagnosis-of-infectious-diseases/>
- Blood cultures contaminated with skin flora during collection are common, but contamination rates should not exceed 3%. Laboratories should have policies and procedures for abbreviating the workup and reporting of common blood culture contaminants (eg, coagulase-negative staphylococci, viridans group streptococci, diphtheroids, Bacillus spp other than B. anthracis). These procedures may include abbreviated identification of the organism, absence of susceptibility testing, and a comment that instructs the clinician to contact the laboratory if the culture result is thought to be clinically significant and requires additional workup and susceptibility results.

The following publications provide research showing the impacts of poor blood culture collection practices and methods to improve blood culture collection to reduce the blood culture contamination rate and ensure patients are being appropriately evaluated for septicemia and bacteremia by collecting an adequate volume of blood. Each bullet point contains statements from each reference.

Snyder SR, et al. Effectiveness of practices to reduce blood culture contamination: A Laboratory Medicine Best Practices systematic review and meta-analysis. Clin Biochem. 2012 Sep;45(13-14):999-1011. doi:

10.1016/j.clinbiochem.2012.06.007. Epub 2012 Jun 16. PMID: 22709932; PMCID: PMC4518453

- <https://pubmed.ncbi.nlm.nih.gov/22709932/>
- Up to 40% of patients with contaminated (false positive) blood cultures are started on unnecessary antibiotics and blood culture contamination results in an 80% increase in total microbiology charges and from 1-5 extra days in the hospital. On a national scale, blood culture contamination results in nearly 1 million extra hospital days, 200,000 courses of unneeded antibiotics and over 1 billion dollars of excess cost.

- False positive results can lead to inappropriate patient diagnosis, follow-up, and unnecessary treatment, creating substantial adverse consequences for patients and cost burdens for the healthcare system. This includes re-collection of blood cultures, other laboratory tests for reevaluation, incorrect or delayed diagnosis due to errors in clinical interpretation, inappropriate antibiotic treatment as well as unnecessary and longer hospital stays and costs associated with these outcomes.

Doern GV, et al. A comprehensive update on the problem of blood culture contamination and a discussion of methods for addressing the problem. *Clinical Microbiology Reviews*. January 2020

- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6822992/>
Blood cultures have long been recognized as one of the most important tests performed in clinical microbiology laboratories. Unfortunately, blood cultures are frequently contaminated. There is a substantial cost associated with contaminated blood cultures, a defined impact on clinical microbiology laboratory practice, and, perhaps most importantly, the potential for negative outcomes among patients from whom blood cultures have been obtained
- There are several untoward clinical consequences of contaminated blood cultures, the most obvious of which is increased antibiotic exposure. Bates et al. found that intravenous antibiotic charges were 39% higher for contaminant blood culture episodes than among culture-negative patients.
- Souvenir et al. demonstrated that 41% of blood culture contaminant episodes due to CoNS were treated with antibiotics (with 34% receiving vancomycin unnecessarily).
- Lee et al. showed that 41% of 178 patients with contaminants received unneeded intravenous antibiotics.
- Many patients who are started on antibiotics for contamination events receive prolonged therapy. van der Heijden and colleagues found that the median antibiotic course among patients receiving antibiotics after contamination events was 7 days, while Souvenir et al. found a mean duration of 6.5 days of vancomycin for CoNS contamination episodes.
- Among hospitalized patients, contaminated blood cultures were associated with a 5.4-day increase in hospital stay compared with that of hospitalized controls matched for age, comorbidity score, and admission month.
- While the risks for these adverse events vary substantially by patient-level and facility-level variables, Hauck and Zhao estimated that each additional night in a hospital increases a patient's risk for an adverse drug reaction by 0.5%, for hospital-acquired infections by 1.6%, and for pressure ulcers by 0.5%
- Table 2 in this publication describes interventions that can be implemented by clinical care teams to improve blood culture collection practices.
 - Such as:
 - Patient Selection - Performing blood cultures on patients with a very low likelihood of bacteremia results in positive cultures more frequently representing false positives.
 - Skin Antisepsis - blood culture contamination rate among adult inpatients was significantly lower in hospitals using tincture of iodine (2.1%) than in those institutions using an povidone iodine (2.9%) for blood culture skin disinfection
 - Blood Culture Bottle Disinfection - Although they are covered with a lid, the rubber septa of blood culture vials are not sterile, and it is standard practice to disinfect the tops of culture bottles prior to inoculation
 - Blood Culture Collection Site - It is preferable to obtain blood for culture via venipuncture rather than from intravascular catheters. A meta-analysis of nine studies that met carefully chosen quality metrics demonstrated that blood collected through an intravascular catheter had, on average, a 2.69-fold greater likelihood of being contaminated than blood collected by venipuncture (95% CI, 2.03 to 3.57)
 - Single Needle versus Double Needle - a meta-analysis of 8 studies demonstrated a decrease in contamination rate from 3.7% to 2.0% associated with the double-needle technique
 - Sterile Gloves and Hand Hygiene - The use of sterile gloves was associated with a significant decrease in blood culture contamination in a single-center crossover trial.
 - Blood Culture Kits and Standard Procedures - In some studies, the use of blood culture collection kits (with or without sterile gloves) and standardized operating procedures has been associated with a significant decrease in blood culture contamination
 - Blood Sampling and Volume - Sampling an appropriate amount of blood is essential in optimizing the performance characteristics of blood cultures. The detrimental effect on pathogen detection by culturing an inadequate amount of blood is well known. In this regard, whenever possible, two or three 20-ml volumes of blood should be obtained in the initial evaluation of adult patients suspected of having bacteremia
 - Phlebotomy Teams/Education - A meta-analysis of five large studies conducted in several U.S. hospitals, four of which were designated good quality, showed excellent strength of evidence supporting reduced

contamination rates by trained phlebotomists compared to non-phlebotomists. The mean odds ratio of all five studies of 2.58 (95% CI, 2.07 to 3.20) favors phlebotomy teams for decreasing blood culture contamination. Several authors have detailed educational programs associated with successful reduction in blood culture contamination.

- Multidisciplinary/Multimodal Performance Improvement - In many instances, interventions to minimize blood culture contamination have not been studied individually, and instead, multiple measures are introduced in multimodal performance improvement projects that often include education and training, kits, sterile gloves, phlebotomy teams, etc.
- Surveillance and Feedback - Surveillance and feedback systems have been shown in multiple studies to result in improved blood culture contamination rates, particularly when contamination rates are reported in a timely manner and directed individually to those who perform phlebotomy. In one study, education combined with feedback to individual phlebotomists proved more effective than education alone.
- Initial Specimen Diversion - Commercially available device shows promise as a cost-effective means to decrease contamination.

Redefining the antibiotic stewardship team: recommendations from the American Nurses Association/Centers for Disease Control and Prevention Workgroup on the role of registered nurses in hospital antibiotic stewardship practices. JAC Antimicrob Resist. 2019 Jul 26;1(2):dlz037. doi: 10.1093/jacamr/dlz037. PMID: 34222911; PMCID: PMC8210263.

- <https://www.cdc.gov/antibiotic-use/healthcare/pdfs/ANA-CDC-whitepaper.pdf>
- Patients exposed to antibiotics can develop a variety of adverse drug reactions specific to individual agents, such as nephrotoxicity. However, patients exposed to antibiotics are also at risk for a variety of unique adverse reactions due to the antibacterial effects of the drugs, which can indiscriminately alter a patient's bacterial population (known as the microbiome). This disruption is known to increase risks for diarrhea, including a diarrheal super-infection caused by *Clostridioides difficile* bacteria which can cause colitis which can be serious and even fatal. Moreover, there is growing evidence that disruption of the microbiome can lead to other serious adverse outcomes, such as sepsis.

Bekeris LG, Tworek JA, Walsh MK, Valenstein PN. Trends in blood culture contamination: a College of American Pathologists Q-Tracks study of 356 institutions. Arch Pathol Lab Med. 2005 Oct;129(10):1222-5. doi: 10.5858/2005-129-1222-TIBCCA. PMID: 16196507.18

- <https://pubmed.ncbi.nlm.nih.gov/16196507/>
- A blood culture was considered to be contaminated if 1 or more of the following organisms were identified in only 1 of a series of blood culture specimens: coagulase-negative *Staphylococcus* species, *Propionibacterium acnes*, *Micrococcus* species, "viridans"-group streptococci, *Corynebacterium* species, or *Bacillus* species. A blood culture series was defined as 1 or more specimens collected serially within a 24-hour period to detect a bacteremic episode. Blood cultures were processed by a variety of automated and manual methods, and isolates were identified by procedures routinely used by the participant. The definition of contamination used in this study is appropriate for calculating institutional blood culture contamination rates, but is not appropriate for clinical decision making, as rare isolates classified as contaminants using the study definition may be associated with clinical infection. Institutional contamination rates were defined as the number of contaminated cultures processed during a quarter divided by the total number of cultures performed during the quarter.

Raquel M. Martinez, Blood Culture Metrics Are Human Metrics: The Missed Opportunity for Clinical Laboratory Quality Measures to Improve the Overall Blood Culture Process, Clinical Microbiology Newsletter, Volume 43, Issue 23, 2021, Pages 205-212, ISSN 0196-4399

- <https://www.sciencedirect.com/science/article/pii/S019643992100074X>
- Monitoring blood culture contamination (BCC) rates is critical for microbiology laboratories, as inadequate blood culture (BC) volume or blood contamination can lead to adverse patient outcomes.
- Calculate the contamination rate by dividing the number of cultures containing skin contaminants by the total number of cultures collected by venipuncture, e.g., percent BCC = (number of contaminants/total number of BC sets) × 100).

McDermott KW (IBM Watson Health), Roemer M (AHRQ). Most Frequent Principal Diagnoses for Inpatient Stays in U.S. Hospitals, 2018. HCUP Statistical Brief #277. July, 2021. Agency for Healthcare Research and Quality, Rockville, MD.

- <https://hcup-us.ahrq.gov/reports/statbriefs/sb277-Top-Reasons-Hospital-Stays-2018.pdf>
- Of the 10 most common principal diagnoses in 2018, septicemia was both the most frequent (2,218,800 stays) and the costliest (\$41.5 billion in aggregate).
- Septicemia ranked as the first or second most common diagnosis among adults, both male and female.
- For each of the five most common principal diagnoses discussed (with septicemia being #1), the rate of inpatient stays per 100,000 population was highest in rural areas.

- For four of the five top diagnoses discussed (with septicemia being #1), mean length of inpatient stay and mean cost per inpatient stay were highest in large central metropolitan areas and generally decreased with rurality.
 - *Measure Developer's Note: Blood cultures are the gold standard laboratory based diagnostic tool for evaluating septicemia.*
 - *Higher rates of diagnosis = higher rates of blood culture collection = higher rates of potential blood culture contamination*

[Response Ends]

1a.15. Detail the process used to identify the evidence.

[Response Begins]

CDC Library literature review

Assessment of College of American Pathology (CAP) quality measures.

Assessment of American Society of Microbiology (ASM) Cumitechs

[Response Ends]

1a.16. Provide the citation(s) for the evidence.

[Response Begins]

Citations provided for each bullet point in section 1a.14

[Response Ends]

1b.01. Briefly explain the rationale for this measure.

Explain how the measure will improve the quality of care, and list the benefits or improvements in quality envisioned by use of this measure.

[Response Begins]

Blood culture contamination (BCC) is defined as having a commensal organism (which is a bacteria or fungus that normally colonizes human skin, without causing disease) isolated from only one blood culture set out of two or more sets collected within a 24-hour period (this is considered false positive test result). The purpose of the measure is to ensure that all hospitals that collect blood cultures follow a standard operating procedure (SOP) for how blood culture collection is performed by healthcare providers and monitor performance of the healthcare providers using this SOP by following a standard for determining the blood culture contamination rate.

The blood culture contamination rate is used as a monitor of healthcare providers' ability to follow the SOP correctly. If they are following the SOP correctly, the contamination rate will be 3% percent or less. Low contamination rates result in appropriate and optimal use of antibiotics, which reduces adverse patient events such as overuse of antibiotics, increased exposure to hospital acquired infections like *Clostridium difficile* colitis, development of antibiotic resistant bacteria, and extended length of hospital stay. This national quality measure will bring all healthcare institutions up to the same recommended standards of quality and safety guidelines.

The overall BCC contamination rate should be evaluated on a monthly basis or more in the institutions who currently analyze and report the rate. It is calculated by dividing the total number of contaminated blood culture sets by the total number of blood culture sets collected during the monthly evaluation period.

Generally, in adults with a suspicion of a blood stream infection, two - four blood culture sets should be obtained in the evaluation of each septic episode (defined as a 24-hour period). An adequate amount of blood culture volume is needed to detect the presence of true bacteremia or septicemia. When only one blood culture set is collected out of the two - four recommended sets this is called a single set blood culture.

One method to determine if the appropriate amount of blood volume is being collected is to evaluate the single set blood culture rate. This overall single set blood culture rate should be evaluated on a monthly basis or more in the institutions who currently analyze and report the rate. It is calculated by dividing the total number of single set blood cultures without another set collected within 24 hours by the total number of blood culture sets collected during the monthly evaluation period.

This measure supports the Hospital Onset Bacteremia & Fungemia measure currently in development by the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) Division of Healthcare Quality Promotion (DHQP) and the National Healthcare Safety Network (NHSN) Hospital Onset Bacteremia & Fungemia module slated to be implemented late 2022 – early 2023.

It does this in 2 ways:

- A. The BCC measure monitors blood culture contamination rate, which will rise, resulting in false positive blood cultures, when blood cultures are not collected correctly. False positive blood culture results may result in an artificial rise in the Hospital Onset Bacteremia (HOB) rate.
- B. Accurate diagnosis of bacteremia/fungemia requires 40 to 60 mL of blood be drawn per septic episode. False negative results may occur when too little blood is drawn. The secondary measure addresses single set blood cultures (20 mL or less) which do not provide the blood volume needed to accurately diagnose bacteremia/fungemia. False negative results could cause an artificial lowering of the HOB rate. In addition, 2 blood culture sets are required to determine if the growth of commensal bacteria (skin flora) in the blood culture is more likely to be due to contamination (single set positive) or a true infection (both sets positive). A single set blood culture does not allow the laboratory or the clinician to determine if the presence of commensal bacteria meets the criteria for reporting.

Problem:

Per the American Society for Microbiology (ASM) and the Clinical Laboratory Standards Institute (CLSI) the overall blood culture contamination rate should not exceed 3%, however reported contamination rates in hospitals vary widely ranging from 0.6% to 12.5% and higher contamination rates have been reported. with the highest rates associated with emergency department settings. One study reported a 26% contamination rate in pediatric outpatients. [1]

- Usually evaluated on a monthly basis to ensure timely reporting and follow up for any contamination events.
- Although 3% has been a benchmark for many years, some healthcare systems are able to maintain rates well below 3% and the goal would be to have the rate driven down to as close to 0% as possible.
- Currently, health care institutions in the United States are held to a performance standard of 3% rates of blood culture contamination. Clearly, as will be shown in this review, recent advances in practice can lead to much lower rates of contamination. If this is true, in view of the substantial negative consequences of contaminated blood cultures, the question arises, should this arbitrary 3% contamination rate threshold be reconsidered? [2]

Research estimates of all positive blood cultures, 20% to 56% are likely false positives [2]

- In a series of large clinical studies examining blood cultures and bacteremia over 4 recent decades, Weinstein and colleagues found that one-third to one-half of all positive blood cultures were judged by infectious disease physicians to represent contamination. Other studies have reported lower rates. Story-Roller and Weinstein found that 26% of all positive blood cultures were judged to contain contaminants. The overall contamination rate at the university hospital where this study was done was 3.9%. Washer et al. found that 13% of all positive blood cultures represented contamination and that overall contamination rates were 0.8% when blood for culture was obtained peripherally by phlebotomists who performed venipuncture. Rupp et al. reported that 23% of all positive blood cultures represented contamination and that overall contamination rates were 1.8% during a defined study period. Interestingly, the institutional contamination rate in this study increased to 2.8% 6 months following conclusion of the study and reversion to standard practice. Other studies have noted that 20 to 56% of all positive blood cultures are found to be contaminated.
- Up to 40% of patients with contaminated (false positive) blood cultures are started on unnecessary antibiotics and blood culture contamination results in an 80% increase in total microbiology charges and from 1-5 extra days in the hospital. On a national scale, blood culture contamination results in nearly 1 million extra hospital days, 200,000 courses of unneeded antibiotics and over 1 billion dollars of excess cost.
- Patients exposed to antibiotics can develop a variety of adverse drug reactions specific to individual agents, such as nephrotoxicity. However, patients exposed to antibiotics are also at risk for a variety of unique adverse reactions due to the antibacterial effects of the drugs, which can indiscriminately alter a patient's bacterial population (known as the microbiome). This disruption is known to increase risks for diarrhea, including a diarrheal super-infection caused by the bacteria *Clostridioides difficile* which causes colitis and can be serious and even fatal. Moreover, there is growing evidence that disruption of the microbiome can lead to other serious adverse outcomes, such as sepsis. [3]
- Skin contaminants in blood culture bottles are common, very costly to the healthcare system, and frequently confusing to clinicians." Clinicians are treating very ill patients and when a blood culture bottle grows a bacteria it is always concerning and will trigger an investigation of the source of the bacteria. The presence of bacteria, even bacteria from the skin may cause the clinician to treat initially with antibiotics to treat the bacteria and order more blood cultures to evaluate the initial blood culture results. [4]

Patient Impact (Outcomes):

When possible skin bacterial contaminants occur in blood cultures, healthcare clinicians may attempt to resolve the issue by drawing extra blood culture sets which may lead to the following adverse effects: [2] reference, section labeled clinical Impact

Exposure to additional needlesticks causing:

- Hematomas
- Loss of venous access
- Blood loss resulting in iatrogenic anemia
- Low patient and caregiver satisfaction
- Increased cost and length of hospitalization

Misinterpretation of skin contaminant as a true case of bacteremia may lead to misuse or inappropriate use of antibiotics causing: [2] reference, section labeled clinical Impact

- Hospital-acquired C. difficile colitis
- Allergic reactions
- Drug-drug interactions
- Antibiotic resistance emergence
- Disruption of the host microbiome

Misinterpretation of a skin contaminant as a true case of bacteremia has been identified to prolong hospital stays leading to: [2] reference, section labeled clinical Impact

- Potential increased exposure to hospital-acquired infections such as MRSA and C. difficile colitis
- Increased patient costs, and overall hospital costs (labor and resources)

To provide a further introduction to the proposed measure the following sections provide an overview of the clinical laboratory, describes the standard of practice for blood culture collection, and walks through the general process to order a blood culture, laboratory processing, testing, and reporting.

The Laboratory

The laboratory team is highly skilled, educated, and maintains certifications per The Clinical Laboratory Improvement Amendments of 1988 (CLIA) [5]

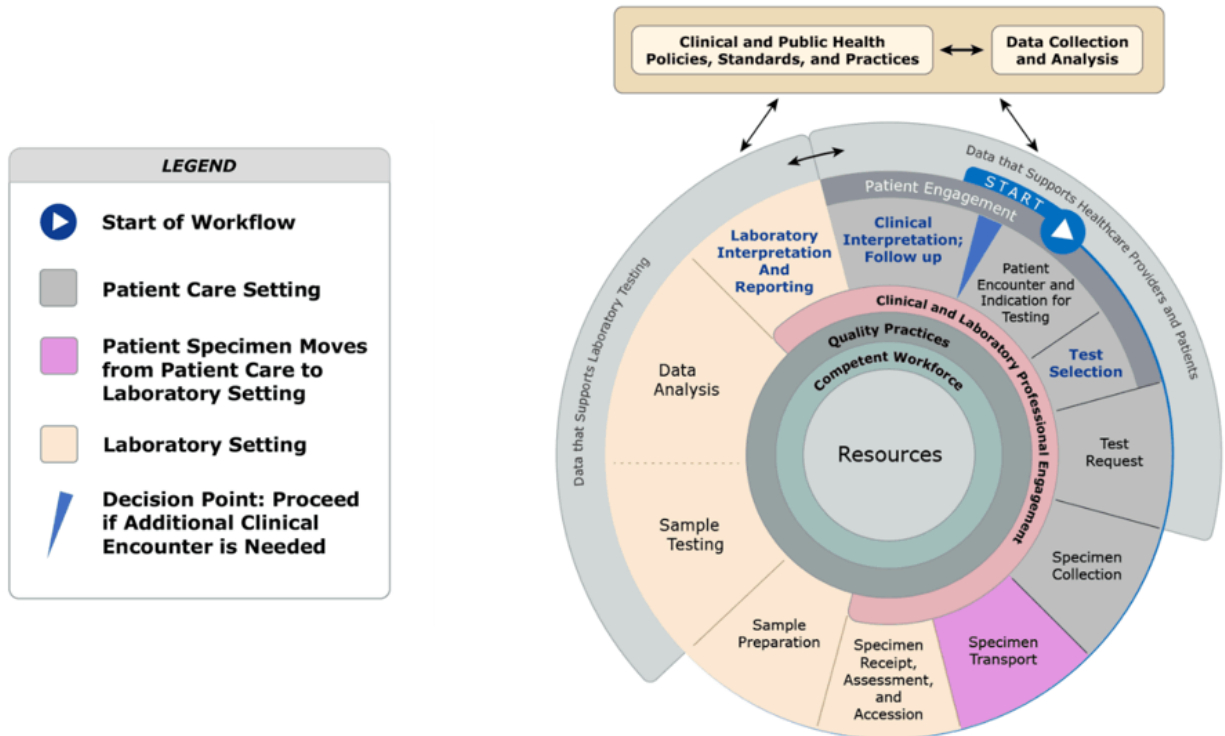
- The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations include federal standards applicable to all U.S. facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease. <https://www.cdc.gov/clia/about.html>
- Laboratory Directors
 - Licensed MD, DO, DPM or DMD and Certified in anatomic, clinical, or oral pathology
 - Board Certified by a national accreditation board related to a laboratory specialty.
- Technical Supervisors
 - Doctorate, master's, or bachelor's in laboratory science
 - At a minimum bachelor's degree in lab science and 4 years' experience in high complexity laboratory with minimum 6 months in the appropriate subspecialty
 - Board certified by a national accreditation board related to a laboratory specialty.
- Testing Personnel
 - Doctorate, master's, or bachelor's in laboratory science
 - Board certified by a national accreditation board related to a laboratory specialty.
- The laboratories are highly focused on quality assurance and continuous improvement.
 - Laboratories are required to have standard operating practices (SOPs) in place to share with and educate clinicians who are obtaining specimens to send to the laboratory for testing on how to collect the specimens correctly. They also monitor optimal specimen collection, transport, and handling. This is called the pre-analytic phase of testing.
 - Laboratories are also responsible for maintaining SOPs for test result reporting and providing result interpretations to guide the clinician care team when and as needed. This is called the post-analytic phase of testing.
 - Laboratories are CLIA certified and routinely inspected by CMS deemed accreditation agencies such as the College of American Pathologists (CAP) Accreditation | College of American Pathologists (cap.org), The Joint Commission <http://www.jointcommission.org/> and others.
 - Inspection standards are comprehensive, and any deficiencies in the pre-analytic, analytic or post-analytic phases of testing are reported back to CMS for further evaluation.

Blood Culture Collection Standard of Practice for collecting blood culture specimen

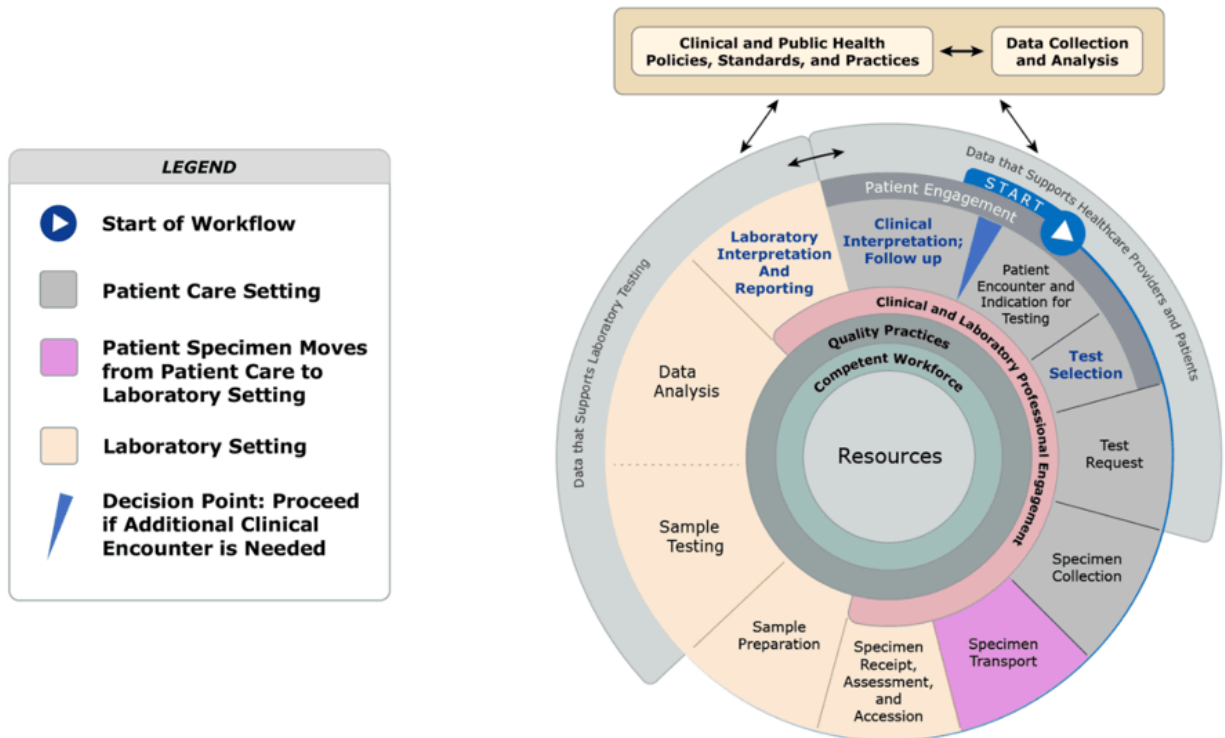
- Per The Clinical Laboratory Improvement Amendments of 1988 (CLIA) all laboratories are required to have standard operating procedures for all pre-analytical, analytical, and post-analytical laboratory processes (the total testing process).[5] (§ 493.1251 Standard: Procedure manual)

The Total Testing Process (TTP)

The Total Testing Process (TTP): An Expanded Representation



The Total Testing Process (TTP): An Expanded Representation



- CLIA regulations specify that laboratories are responsible for providing instructions for optimal specimen collection. According to the Clinical and Laboratory Improvements Act (CLIA), the clinical microbiology laboratory is responsible for the preanalytical phase of testing related to the diagnosis of infectious diseases. This includes the selection, collection, and transport of specimens. Therefore, the clinical laboratory plays a central role in providing instructions for preventing contamination during blood culture procurement. Monitoring the contamination rate serves as a proxy measurement of how well blood culture collectors are following the blood culture collection instructions.
- The TTP shown demonstrates the connection between laboratory activities and clinical interpretation and follow-up. "An exploration of the beginning and end of the loop reveals that the pre-preanalytical steps (initial procedures not performed in the clinical laboratory and not under the control of laboratory personnel) and the post-post analytic steps (final procedures performed outside the laboratory, consisting of receiving, interpreting, and using laboratory information for patient management) are more error prone. These activities are poorly evaluated and monitored, often because the process owner is unidentified, and the responsibility falls in the boundaries between laboratory and clinical departments. System failures and cognitive errors coexist to allow the generation of errors in laboratory testing; they result from multiple causes and are associated with analytic and nonanalytic reasoning. [6]

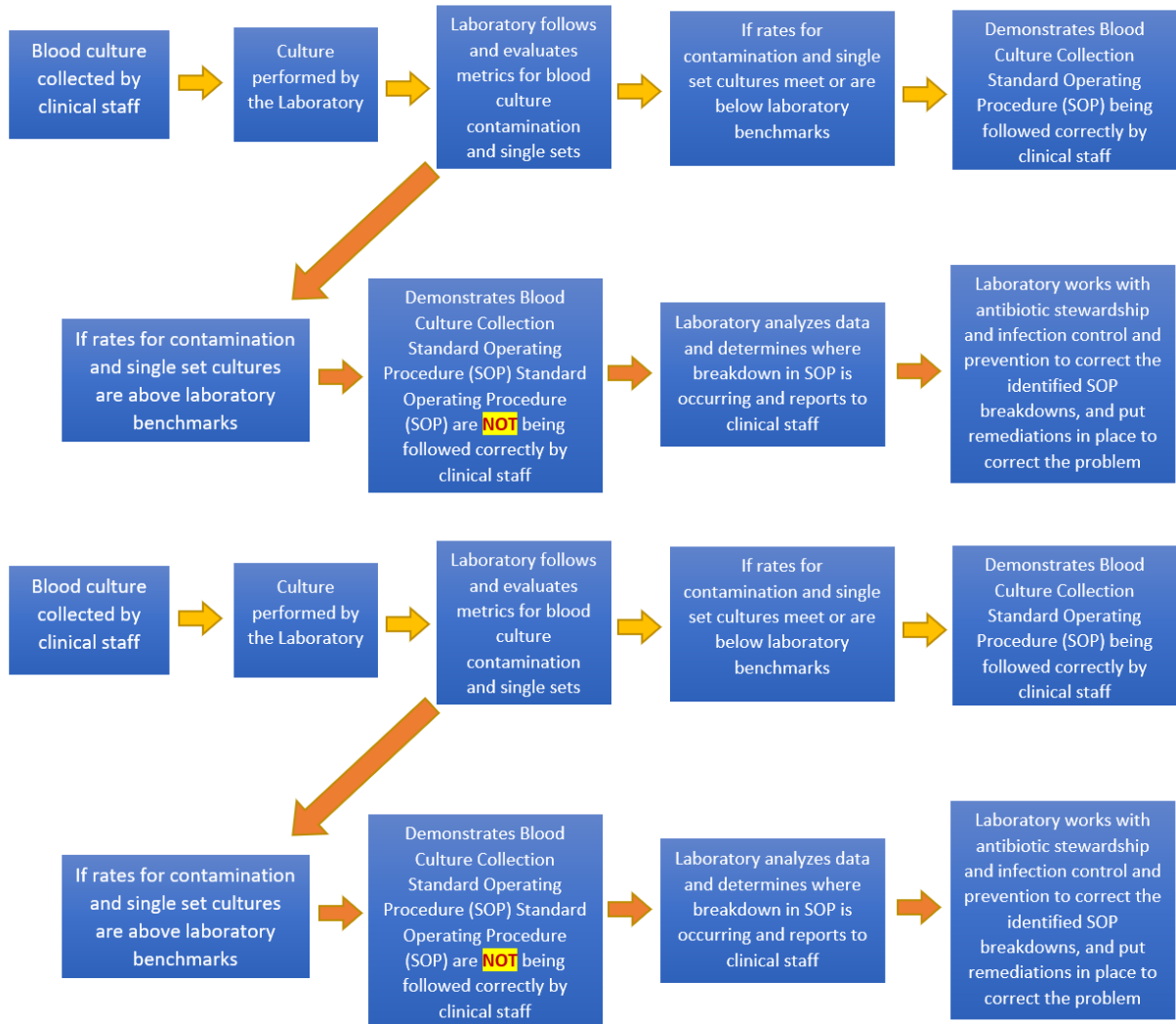
For Blood Culture Collection the standard of practice is defined as [4]:

- Collection of at least two blood culture sets within a 24-hour window
 - Consisting of one aerobic and one anaerobic bottle in each set
- Volume of blood collected, not timing, is most critical.
 - 10 mL of blood collected in each bottle for a total of 40 mL
- A second important determinant is the number of blood culture sets performed during a given septic episode. Generally, in adults with a suspicion of blood stream infection, 2–4 blood culture sets should be obtained in the evaluation of each septic episode. (Defined as a 24-hour period)
- Collection of two separate venipunctures from separate arms, if possible
- If possible, blood should be drawn for blood culture before initiating antimicrobial therapy.
- Catheter-drawn blood cultures have a higher risk of contamination (false positives).

- Do not submit catheter tips for culture without an accompanying blood culture obtained by venipuncture.

The following section is provided to demonstrate the interdisciplinary function of the Laboratory Information system (LIS) Laboratory Standard operating procedures (SOPs) and the Electronic Health Record (EHR) and how the LIS can be utilized to manage and report both pre and post analytic blood culture results as well as collect data for the BCC and single rate measure.

Flowchart showing the connection between adherence to blood culture collection standard operating procedures and the blood culture contamination and single set rates.



General processing for Blood Culture Ordering, Accessioning, Testing, and Reporting

- Blood culture is ordered in the Electronic Health Record (EHR) by clinical care team
 - This order optimally includes both aerobic and anaerobic bottles (one set)
 - Each lab test order has its own unique order code which can be pulled out of the LIS for data evaluation. For example, Blood Culture – order code: (CUBLD)
 - The order is transmitted to the Laboratory Information System (LIS) where a unique laboratory specimen accession number is created for the order.
 - The Laboratory Information System (LIS) is the platform used by laboratories to track laboratory test orders and to enter results for laboratory testing. The LIS interfaces with the patient's Electronic Health record providing results in the patient's chart.
 - The collector annotates the date and time of collection on the label
 - CLIA Requirement to have data and time annotated on all specimens collected.
 - The collector also labels the site / source of the blood draw location such as "venipuncture right arm."
 - CLIA Requirement to label site / source on all specimens collected.
 - Example of site would be "Left Antecubital Fossa."
 - Example of source would be "Blood"

- Once a blood culture is received by the laboratory the date and time of receipt is entered in the LIS
 - If blood culture not received by the laboratory, the laboratory finds this fact out when reviewing the pending order list. The laboratory follows up with the clinical team and either blood collected and sent to laboratory or order is cancelled.
- The lab order and patient data (name, date of birth, medical record number, patient location, gender, and race if available) will then display in the LIS.
- The lab verifies the patient data is identical to what is listed on label affixed to the blood culture bottle and to what is displayed in the LIS.
- If the information in the LIS does not match the information on the blood culture bottles, the floor is called, and an investigation is done to resolve the error.
- Example of comment: Single Set Blood culture collected. False negative results may occur. Please collect additional set to improve the accuracy of blood culture results.
- The blood culture set is collected by the clinical care team or phlebotomy team.
- A label is then placed on each blood culture bottle which includes the order code, and patient data (name, date of birth, medical record number, patient location, and gender).
- The blood culture set is then sent to the laboratory for processing.

Accessioning

- The lab staff will then receive the blood culture set and enter information into the Laboratory Information System (LIS) by scanning the bar code on the label or entering the accession number from the label on the blood culture bottles.
- The collection time should be entered into the LIS based off of the collection date and time labeled by the collector on the label affixed on the blood culture bottles.
- The site / source of the blood draw annotated on the bottles is entered into the LIS.
- The volume collected in each blood culture bottle is also entered into the LIS.
- If only one blood culture set was collected within a 24-hour period, a comment can be entered to provide the need to collect an additional blood culture for appropriate evaluation of septicemia and bacteremia.
- The initials or tech codes of the collecting personnel are also entered into the LIS. These may be hard coded and available in the LIS in some institutions. This allows the laboratory to track blood culture drawing personnel and identify potential issues associated with specific personnel and following the SOP for blood culture collection.
- Entering the set under a unique accession number into the LIS provides a time stamp of receipt and a time stamp of collection.

Testing and Reporting

- The microbiology laboratory staff then loads the blood culture bottle onto a blood culture analyzer for a routine incubation of 5 days
- Bottles may also be loaded into an incubator for manual reading of 5 days if an automated system is not available
- Remove the positive bottle from the incubator
- Set up slides for Gram stain; a microscopy technique performed to determine whether microorganisms are present in the sample
- Set up media to culture suspected microorganisms and then place the media into an incubator
- If the Gram stain is positive a call is made immediately by the lab to the patient's clinical care team, the time of the call and who was called is documented in the LIS.
- A positive Gram stain is considered a critical value and laboratories must have policies in place to ensure the result is immediately verbally notified to the patient's clinical care team.
- Requesting the collection of additional blood cultures
- Prescribing antimicrobials based on the Gram stain result
- Extend the hospitalization of the patient
- Wait for additional results from previously collected blood cultures before taking action
- If the action taken by the clinical care team is based on a false positive result this may lead to adverse patient events as mentioned under the problem section.
- Each microorganism has its own unique result code which can be pulled out of the LIS for data evaluation. For example, *S. aureus* – result code: (STAU)
- For microorganisms that are considered to be skin contaminants (commensal organisms), it is incumbent upon the laboratory to communicate this to the clinician and this can be done by adding an additional result code to be entered to specify the organism as a skin contaminant.

- Lab Result Code Comment: One set positive out of two sets. Possible skin contaminant no further workup performed. Please call lab if further workup needed. [2]
- How to determine if a blood culture is contaminated?
 - Contaminated blood culture defined as:
 - one blood culture set positive out of two to three sets collected with a possible skin contaminant
 - There are 2 ways to report bacteria identified as skin contaminants
 - By genus: Most species of CoNS, most species of *Corynebacterium* (diphtheroids) and related genera, Alpha-hemolytic viridans group strep, *Bacillus* spp. other than *Bacillus anthracis*, *Micrococcus* spp., viridans group streptococcus, *Cutibacterium acnes* and related species, saprophytic *Neisseria* sp. and *Moraxella* sp.
 - By genus and species: The National Healthcare Safety Network maintains a list of bacteria identified as skin contaminants by both genus and species.
<https://www.cdc.gov/nhsn/xls/master-organism-com-commensals-lists.xlsx>
 - The CDC NHSN list contains the name of the organism and corresponding SNOMED code.
- There are certain skin organisms that are considered pathogens when found in blood cultures (such as *Staphylococcus aureus* or Methicillin resistant *Staphylococcus aureus* even if only isolated in one blood culture set. These will be treated as pathogens per laboratory protocol for blood culture workup and in these cases, communication may occur between the laboratory and the clinician to discuss the patient's condition, whether the organism is a true pathogen or a contaminant, and how to proceed with working up the blood culture.
- If growth is detected, the analyzer sounds an alarm and the laboratory personnel pulls the blood culture bottle out of the instrument and:
- The instrument provides a time stamp of detection of growth of bacteria or yeast.
- Lab will then:
- Depending on the result of the Gram stain the clinical care team may then take action based on the clinical status of the patient:
- The microbiology lab will continue to work up the positive culture and report the results of the identification of the microorganism.

References

1. Snyder SR, et al. Effectiveness of practices to reduce blood culture contamination: A Laboratory Medicine Best Practices systematic review and meta-analysis. *Clin Biochem*. 2012 Sep;45(13-14):999-1011. doi: 10.1016/j.clinbiochem.2012.06.007. Epub 2012 Jun 16. PMID: 22709932; PMCID: PMC4518453.
<https://pubmed.ncbi.nlm.nih.gov/22709932/>
2. Doern GV, et al. A comprehensive update on the problem of blood culture contamination and a discussion of methods for addressing the problem. *Clinical Microbiology Reviews*. January 2020.
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6822992/>
3. Redefining the antibiotic stewardship team: recommendations from the American Nurses Association/Centers for Disease Control and Prevention Workgroup on the role of registered nurses in hospital antibiotic stewardship practices. *JAC Antimicrob Resist*. 2019 Jul 26;1(2):dlz037. doi: 10.1093/jacamr/dlz037. PMID: 34222911; PMCID: PMC8210263. <https://pubmed.ncbi.nlm.nih.gov/34222911/>
4. J Michael Miller et al, A Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases: 2018 Update by the Infectious Diseases Society of America and the American Society for Microbiology, *Clinical Infectious* <https://pubmed.ncbi.nlm.nih.gov/29955859/>
5. "LABORATORY REQUIREMENTS," Code of Federal Regulations, Title 32 (2022): ChapterIV, Subchapter G, Part 493 (Up to date as of 01/01/2022) <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493>
6. Plebani M, Laposata M. *Am J Clin Pathol*. The brain-to-brain loop concept for laboratory testing 40 years after its introduction. 2011;136:829-833

[Response Ends]

1b.02. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis.

Include mean, std dev, min, max, interquartile range, and scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include. This information also will be used to address the sub-criterion on improvement (4b) under Usability and Use.

[Response Begins]**Trends and Variability in Blood Culture Utilization and Positivity among U.S. Hospitals, 2012-2017**

Retrospective cohort study using data collected from Premier Healthcare Database and Cerner Health Facts, two large electronic healthcare databases including data from both private and academic U.S. hospitals. Premier and Cerner databases contain a comprehensive clinical record on each encounter, including sociodemographic data, comorbidities, procedures, medications, patient charges and costs, and diagnoses. Additionally, these databases contain microbiology laboratory data from approximately 500 hospitals, including specimen identification, test name, test day and time of service, and result and sensitivity data.

We evaluated the microbiology laboratory information systems data from the databases described above to identify contamination rates among complete blood cultures, and single set rates among all blood cultures by year when assessing 259 healthcare facilities. The dataset includes blood culture episodes from 5,212,521 patients.

- This analysis uses the eligibility criteria specifications defined in sp.02 Primary and Sub measure eligibility criteria.
 - Patient ≥ 18 years old
 - Patient may be present in any department of the hospital such as ICU, ED, inpatient floors, step down units. (No outpatients)
 - At least two blood culture sets drawn in a 24-hour period
 - Commensal organisms identified by using the National Healthcare Safety Network list of bacteria identified as skin contaminants. <https://www.cdc.gov/nhsn/xls/master-organism-com-commensals-lists.xlsx>
- Per the definition at least two blood culture sets (complete blood cultures) must be collected to be able to identify a probable contaminated blood culture.

Table 1. Blood Culture Contamination and Single Set Rates among blood cultures by year, Premier 2012-2017

Year	All Blood Culture episodes Complete blood culture sets (2-3 blood culture sets ≤ 24 hours) & Single Set Blood Cultures (1 blood culture set ≤ 24 hours)	Complete blood culture episodes (2-3 blood culture sets ≤ 24 hours)	# Contaminated blood cultures	% Contaminated blood cultures	# Single Set Blood Cultures	% Single Set Blood Cultures
2012	1,166,935	986,955	32,125	3.25%	179,980	15.4%
2013	1,241,033	1,061,877	32,522	3.06%	179,156	14.4%
2014	1,074,639	922,196	28,613	3.10%	152,443	14.2%
2015	1,011,969	867,144	25,879	2.98%	144,825	14.3%
2016	1,073,973	909,143	25,287	2.78%	164,830	15.3%
2017	1,119,672	873,030	23,824	2.73%	246,642	22.0%
Total	6,688,221	5,620,345	168,250	2.99%	1,067,876	16.0%

Overall, there was a total of 5,620,345 complete blood cultures (2-3 blood culture sets ≤ 24 hours) collected from 2012-2017 with 168,250 reported as false positives (overall 2.99% contamination rate).

- Although, the overall contamination rate is just below the current benchmark of 3% there were 168,250 events potentially leading to unnecessary patient care actions by healthcare providers due to the false positive result.
- Contamination events should not occur and these facilities should implement interventions to further reduce the blood culture contamination rate down to as low as possible.

Overall, there was a total of 6,688,221 blood culture sets collected from 2012-2017 with 1,067,876 identified as single set blood cultures (1 blood culture set ≤ 24 hours) (overall 16.0% single set rate).

- There is no current recommended current benchmark for single set culture rate, but the data demonstrates 1,067,876 cases where only one blood culture set out of the two to three recommended sets was evaluated for septicemia and bacteremia.
- Blood culture standard of practice guidelines recommend in adults with a suspicion of a blood stream infection, 2–4 blood culture sets should be obtained in the evaluation of each septic episode. (Defined as a 24-hour period).
- Only collecting a single set may lead false negative blood culture results since the adequate amount of blood was not evaluated for septicemia and bacteremia.

[Response Ends]

1b.03. If no or limited performance data on the measure as specified is reported above, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement. Include citations.

[Response Begins]

N/A – Performance Data included in 1b.02

[Response Ends]

1b.04. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability.

Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included. Include mean, std dev, min, max, interquartile range, and scores by decile. For measures that show high levels of performance, i.e., “topped out”, disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b) under Usability and Use.

[Response Begins]

- Currently, only College of American Pathologists (CAP) accredited laboratories have quality measures in place for blood culture contamination and blood culture volume.
- Only 30% of all CLIA accredited bacteriology labs evaluate and report blood culture contamination rates and evaluate blood culture volume. (Table 2)

Total number of CLIA certified laboratories	286,249	*
Total laboratories CLIA certified to perform bacteriology	11,930	4.2% of all CLIA labs
Total number of CAP accredited laboratories	6,744	2.4% of all CLIA labs
Total number of CAP accredited laboratories performing bacteriology	3,547	1.2% of all CLIA labs 30% of all Micro labs

**Indicates cell intentionally left blank*

Table 2: Quality Improvement and Evaluation System (QIES) Data: Accessed 5/21/2021

Note: The Quality Improvement and Evaluation System (QIES, pronounced “Keys”) is used by the Centers for Medicare and Medicaid Services to manage many aspects of administrative data that relate to several categories of healthcare providers in the U.S. CMS regularly shares with CDC data the subset of QIES data that corresponds to laboratories regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The CLIA law established CDC as the technical lead for CLIA regulations. Thus, CDC accepts, retains, and uses QIES data, as well as related proficiency testing scores and other data sources, to track changes in laboratory types, practices, and

performance. QIES data, and the related proficiency testing data, allow CDC to identify the subset of laboratories likely to be performing specific categories of laboratory tests, for example microbiology testing

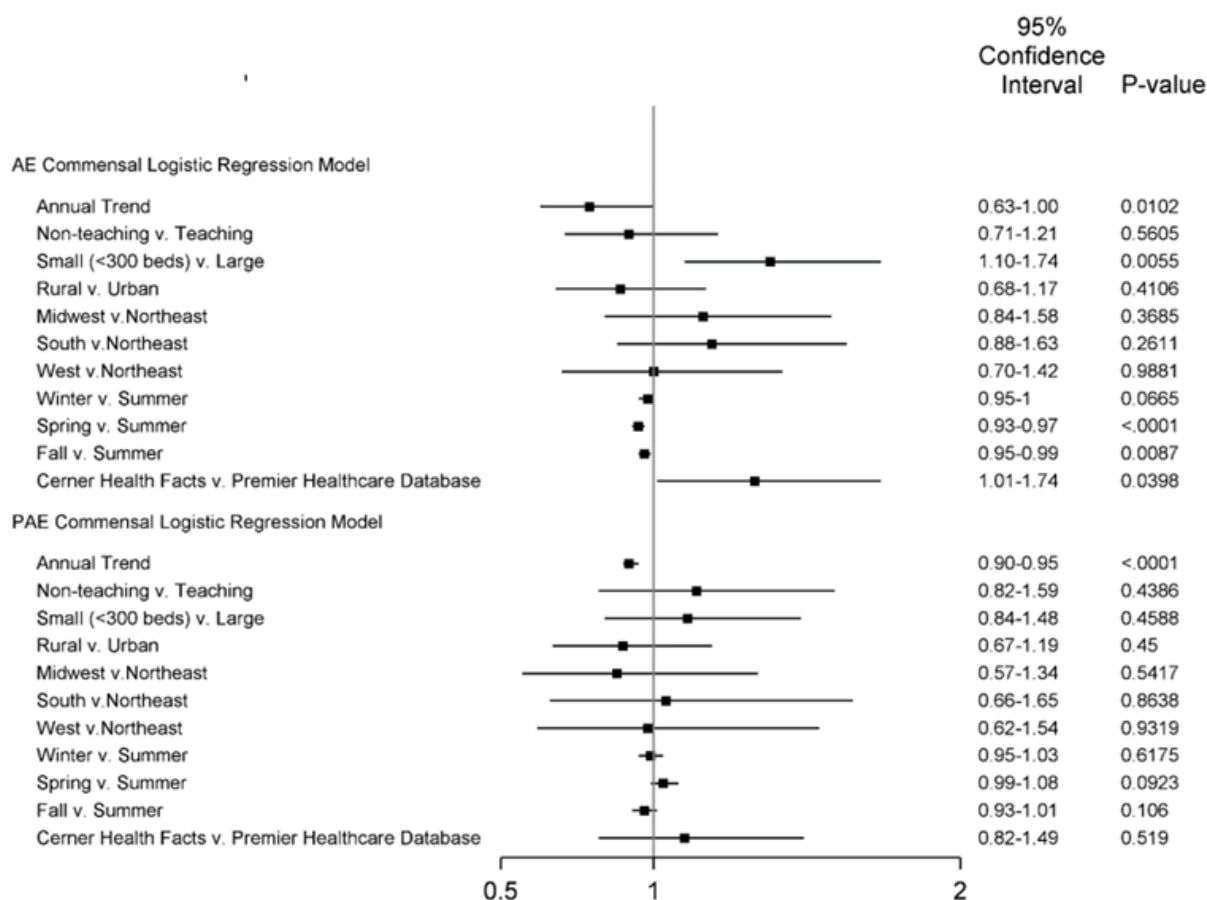
Trends and Variability in Blood Culture Utilization and Positivity among U.S. Hospitals, 2012-2017

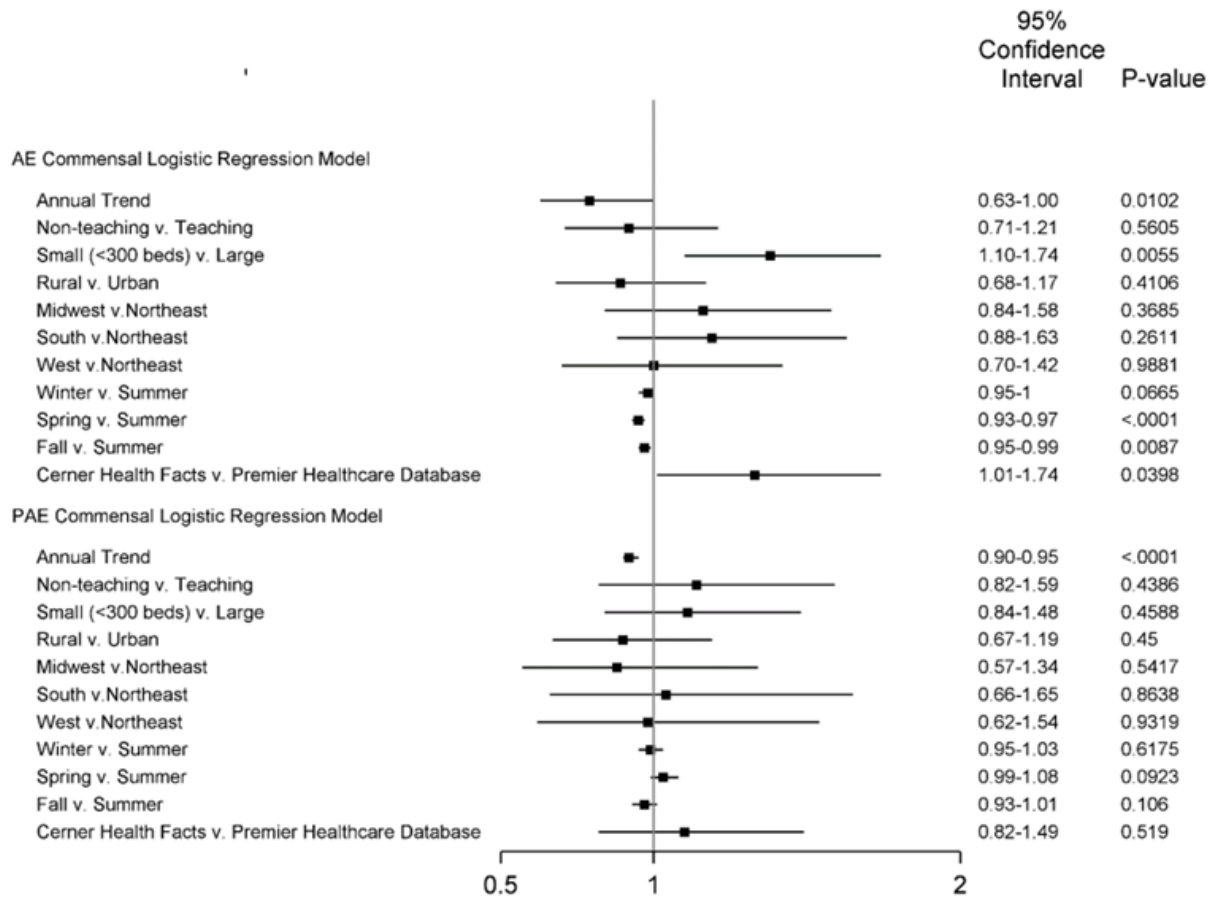
Retrospective cohort study using data collected from Premier Healthcare Database and Cerner Health Facts, two large electronic healthcare databases including data from both private and academic U.S. hospitals. Premier and Cerner databases contain a comprehensive clinical record on each encounter, including sociodemographic data, comorbidities, procedures, medications, patient charges and costs, and diagnoses. Additionally, these databases contain microbiology laboratory data from approximately 500 hospitals, including specimen identification, test name, test day and time of service, and result and sensitivity data.

- We evaluated the microbiology data from the database described above to identify if there were differences in the rates of blood culture contamination comparing facility and patient characteristics.

Figure 1. Adjusted odds ratio annual trends and characteristics of commensal positivity among admission episode (AE) and post-admission episodes, Premier Healthcare Database and Cerner Health Facts, 2012-2017

Facilities N = 259

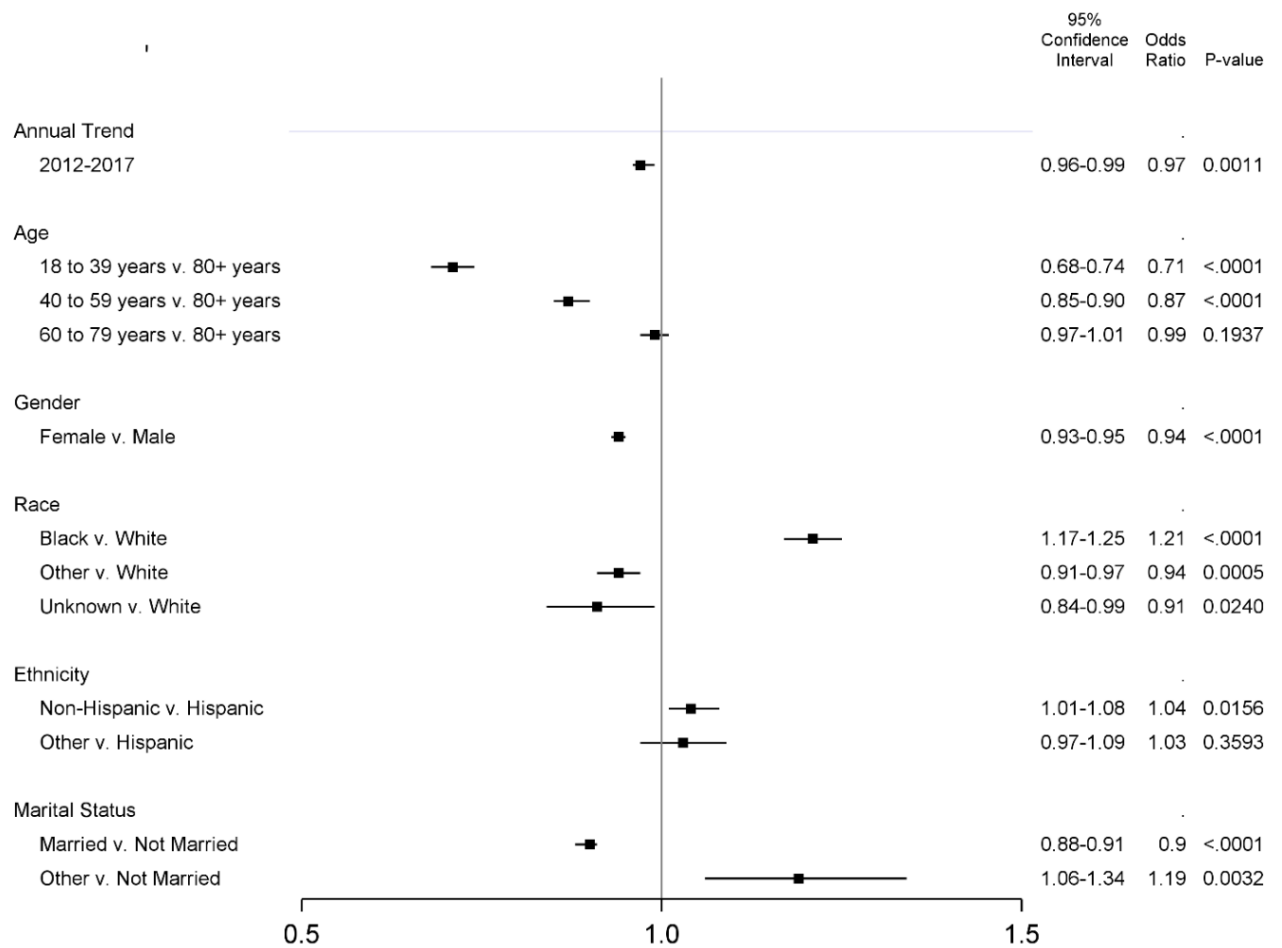


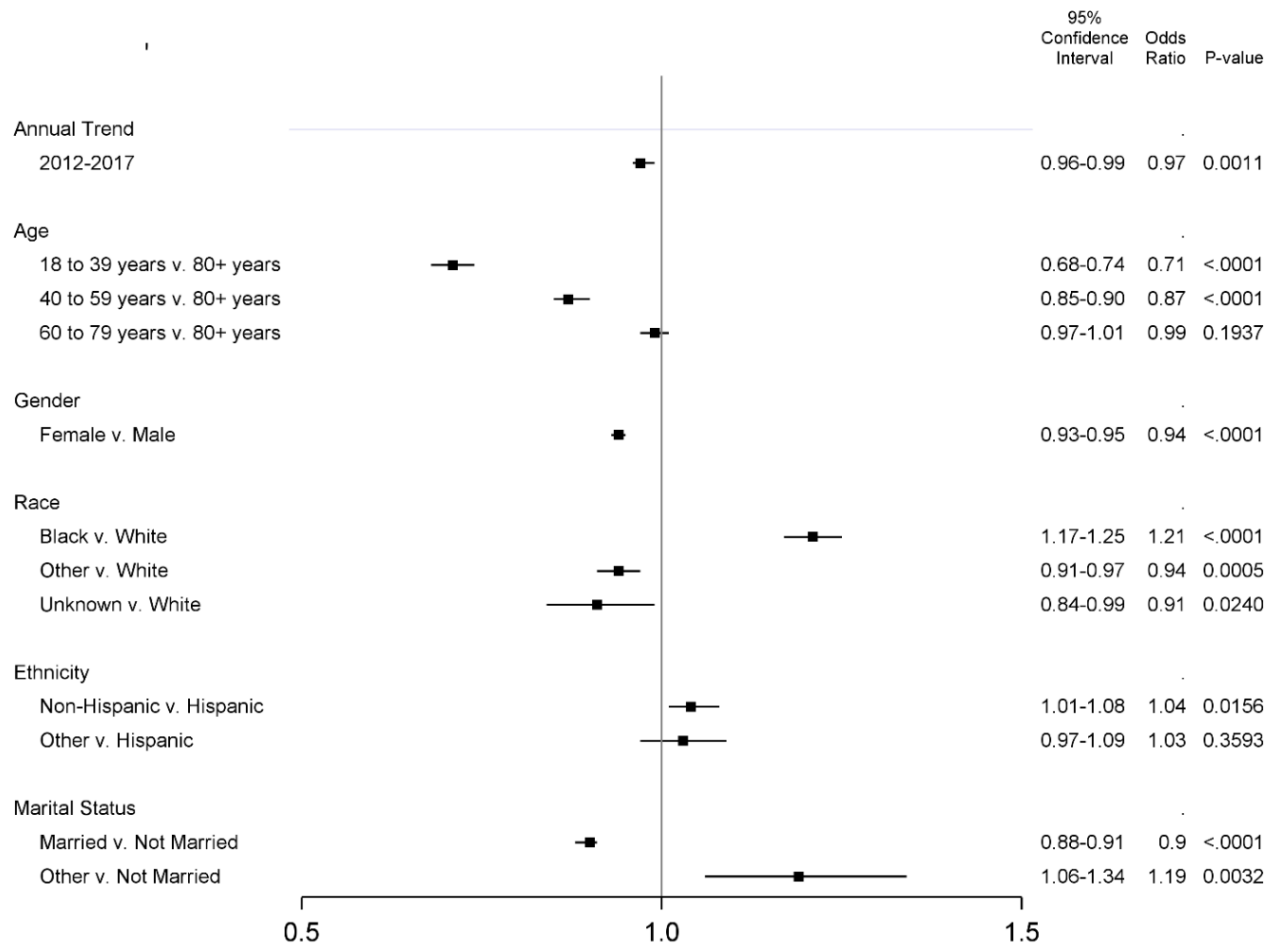


- This data demonstrates facilities with less than 300 beds were associated with significantly higher bacterial contamination (commensal positivity) (OR=1.38, p=.0055) compared to larger facilities.
- As well as the spring (OR=0.95, p<.0001) and fall (OR=0.97, p=.0087) seasons were associated with lower bacterial contamination (commensal positivity) compared to summer.

Figure 2. Adjusted odds ratio annual trend results of patient demographics and annual trends of adult inpatient admissions with ≥ 1 commensal specimen compared to admissions with 0 commensal specimens, among complete blood cultures ^a, Premier Healthcare Database 2012-2017.

Patients N=5,212,521





^a Complete blood culture defined as 2-3 blood cultures taken ≤ 24 hours of initial culture

- This data demonstrates of all patients from whom blood cultures were obtained black (OR=1.21, $p = <.0001$), non-Hispanic (OR=1.04, $p = 0.0156$), unmarried (OR=0.9, $p = <.0001$), males (OR=0.94, $p = <.0001$) were significantly more likely to have a contaminated blood culture.
- When compared to patients ages 18-39 (OR=0.71, $p = <.0001$) and 40-59 years (OR=0.87, $p = <.0001$), patients 80 years or older were more likely to have a contaminated blood culture. Odds of a contaminated culture in patients 60-79 years (OR=0.99, $p = 0.1937$) were not significantly different from patients 80 years and older.

Note: Measure Developer Key

- The OR represents the odds that an outcome will occur given a particular exposure, compared to the odds of the outcome occurring in the absence of that exposure.
 - OR=1 Exposure does not affect odds of outcome
 - OR>1 Exposure associated with higher odds of outcome
 - OR<1 Exposure associated with lower odds of outcome
 - Szumilas, Magdalena. "Explaining odds ratios." Journal of the Canadian Academy of Child and Adolescent Psychiatry = Journal de l'Academie canadienne de psychiatrie de l'enfant et de l'adolescent vol. 19,3 (2010): 227
 - <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2938757/>
- The p – value is a measure of the strength of evidence against a null hypothesis (H0)
 - The p value is calculated based on an assumption that H0 is true.
 - Small p-value (typically ≤ 0.05) indicates strong evidence against a H0, so you reject the null hypothesis.
 - A large p-value (> 0.05) indicates weak evidence against a H0, so you fail to reject the null hypothesis.
 - Dorey, Frederick. "The p value: what is it and what does it tell you?." Clinical orthopaedics and related research vol. 468,8 (2010): 2297-8. doi:10.1007/s11999-010-1402-9
 - <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2895822/>

[Response Ends]

1b.05. If no or limited data on disparities from the measure as specified is reported above, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in above.

[Response Begins]

N/A – Performance Data included in 1b.02

[Response Ends]

Criteria 2: Scientific Acceptability of Measure Properties

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. Measures must be judged to meet the sub criteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.

sp.01. Provide the measure title.

Measure titles should be concise yet convey who and what is being measured (see [What Good Looks Like](#)).

[Response Begins]

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

[Response Ends]

sp.02. Provide a brief description of the measure.

Including type of score, measure focus, target population, timeframe, (e.g., Percentage of adult patients aged 18-75 years receiving one or more HbA1c tests per year).

[Response Begins]

The Blood culture contamination (BCC) rate is a process measure designed to follow healthcare providers' adherence to pre-analytic blood culture collection instructions established by the hospital clinical laboratory in patients 18 years or older. Blood culture contamination is defined as having certain commensal organisms (bacteria or fungus that normally colonizes human skin, without causing disease) isolated from only one blood culture set out of two or more sets collected within a 24-hour period (this is considered a false positive test result).

A secondary related measure is the single set blood culture rate in patients 18 years or older. A single set blood culture in a 24-hour period is not an adequate volume of blood to make an accurate diagnosis of bacteremia (which can lead to false negatives) and a single set blood culture positive predefined commensal organisms cannot be evaluated using the definition for possible contamination without the second set blood culture. The purpose of the measure is to ensure that all hospitals that collect blood cultures follow best practices for how blood culture collection is performed by healthcare providers and monitor the performance of the healthcare providers by calculating and reporting the blood culture contamination and single set rate back to collecting personnel and hospital units. This will allow process improvements to be implemented to reduce BCC contamination to be measured and evaluated on a monthly basis.

[Response Ends]

sp.04. Check all the clinical condition/topic areas that apply to your measure, below.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- Surgery: General

[Response Begins]

Infectious Diseases (ID): Sepsis

[Response Ends]

sp.05. Check all the non-condition specific measure domain areas that apply to your measure, below.

[Response Begins]

Care Coordination: Readmissions
Disparities Sensitive
Health and Functional Status

[Response Ends]

sp.06. Select one or more target population categories.

Select only those target populations which can be stratified in the reporting of the measure's result.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Populations at Risk: Populations at Risk*

[Response Begins]

Adults (Age >= 18)

[Response Ends]

sp.07. Select the levels of analysis that apply to your measure.

Check ONLY the levels of analysis for which the measure is SPECIFIED and TESTED.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Clinician: Clinician*
- *Population: Population*

[Response Begins]

Facility

[Response Ends]

sp.08. Indicate the care settings that apply to your measure.

Check ONLY the settings for which the measure is SPECIFIED and TESTED.

[Response Begins]

Inpatient/Hospital

[Response Ends]

sp.09. Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials.

Do not enter a URL linking to a home page or to general information. If no URL is available, indicate "none available".

[Response Begins]

NA

[Response Ends]

sp.11. Attach the data dictionary, code table, or value sets (and risk model codes and coefficients when applicable). Excel formats (.xlsx or .csv) are preferred.

Attach an excel or csv file; if this poses an issue, [contact staff](#). Provide descriptors for any codes. Use one file with multiple worksheets, if needed.

[Response Begins]

No data dictionary/code table – all information provided in the submission form

[Response Ends]

sp.12. State the numerator.

Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome).

DO NOT include the rationale for the measure.

[Response Begins]

Primary Measure – Blood Culture Contamination Rate:

Total number of blood culture sets with growth of a commensal organism in only one blood culture set out of two or three blood culture sets collected within a 24-hour period.

Sub Measure – Single Set Blood Culture Rate:

Total number of single set blood cultures collected either one bottle or one set (1 aerobic and 1 anaerobic bottle) in one blood draw within 24-hour period.

The need for single set blood culture rate

Blood culture contamination cannot be evaluated unless at least two blood culture sets have been collected, as the definition of blood contamination is a single blood culture set positive out of two sets of blood cultures for a possible skin contaminant. The test result would be reported from the laboratory as follows “Single set positive out of 2 sets (or 3 sets, if this is the laboratory policy) for possible skin contaminant, please call laboratory if further work up is needed” This comment alerts the clinician that a probable contaminant event has occurred, and they may order an additional 1 or 2 blood culture sets for further evaluation.

In addition, in order to accurately diagnosis septicemia and bacteremia it is important to assess the percent of blood cultures with only one set out of the recommended two or more sets collected within a 24-hour period. Two blood culture sets are necessary to obtain at least 40 mL of blood which is the amount of blood recommended to accurately evaluate an adult patient for bacteremia and sepsis.

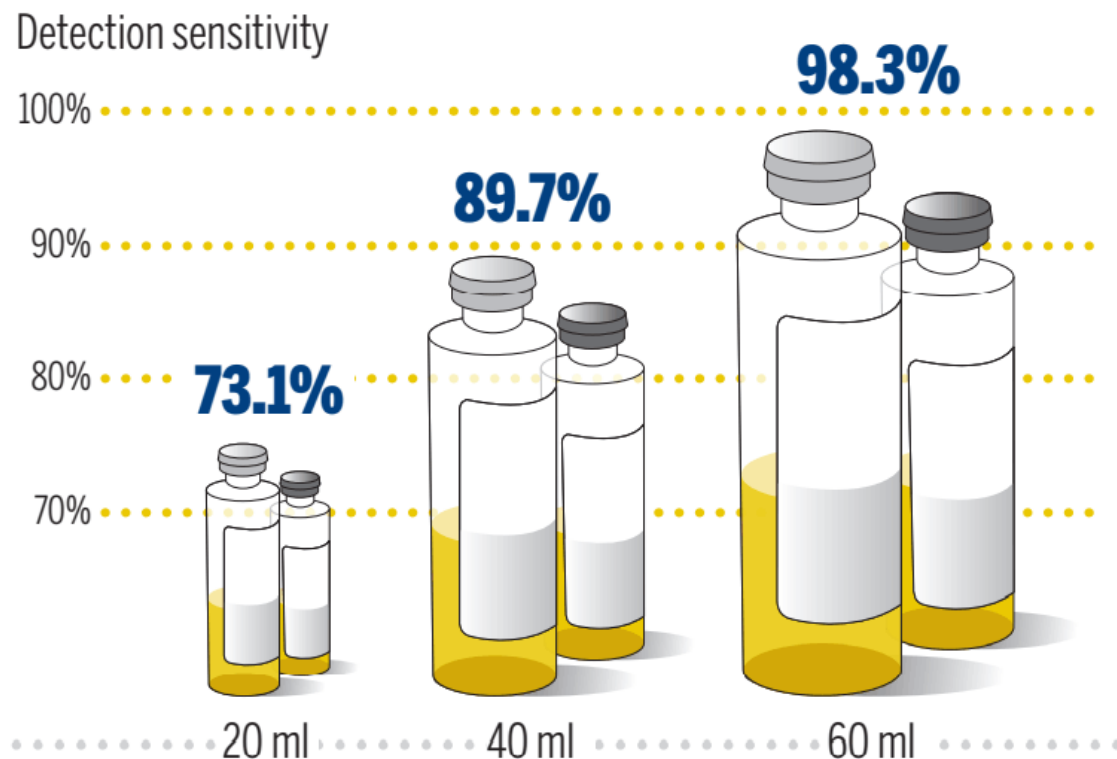
According to a publication by Lee, Andrew et al. “Detection of bloodstream infections in adults: how many blood cultures are needed?” Journal of clinical microbiology vol. 45,11 (2007): 3546-8. doi:10.1128/JCM.01555-07

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2168497/>

Data were analyzed to determine the cumulative sensitivity of blood cultures obtained sequentially during the 24-h time period. Of 629 unimicrobial episodes with ≥3 blood cultures obtained during the 24-h period, 460 (73.1%) were detected with the first blood culture, 564 (89.7%) were detected with the first two blood cultures, 618 (98.3%) were detected with the first three blood cultures, and 628 (99.8%) were detected with the first four blood cultures.

This study highlights the increase in blood culture testing sensitivity in relation to the amount of blood volume and the number of blood culture sets collected.

Adapted from Lee A, Mirrett S, Reller LB, Weinstein MP. **Detection of Bloodstream Infections in Adults: How Many Blood Cultures Are Needed?** *J Clin Microbiol* 2007;45:3546-3548.



[Response Ends]

sp.13. Provide details needed to calculate the numerator.

All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets.

Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

[Response Begins]

Calculating the Blood Culture Contamination rate

- Denominator = Using data from the Laboratory Information System (LIS) identify all blood cultures collected by identifying all blood culture order codes within a specified timeframe (usually on a monthly basis)
- **Numerator = Using data from the LIS Identify all probable contaminants by identifying all probable skin contaminants result codes within a specified timeframe (usually on a monthly basis)**
- Calculate the contamination rate by dividing the number of blood cultures containing skin contaminants by the total number of blood culture sets collected
- $BCC = (\text{Number of blood culture sets with growth of skin commensals without the same organism in other sets collected within 24 hours} / \text{Total number of BC sets}) \times 100$

Primary Measure Eligibility Criteria:

- Patient ≥ 18 years old

- Patient may be present in any department of the hospital such as ICU, ED, inpatient floors, step down units. (No outpatients)
- At least two blood culture sets drawn in a 24-hour period

Calculating the Single Set Blood Culture Rate

- Denominator = Using data from the LIS identify all blood cultures collected by identifying all blood culture order codes within a specified timeframe (usually on a monthly basis)
- **Numerator = Using data from the LIS identify all single set blood cultures by identifying all events when only one blood culture set was collected in a specified timeframe (usually on a monthly basis)**
- Calculate the single set rate by dividing the number of single sets of blood cultures by the total number of blood culture sets collected
- Single Set Blood Culture Rate = (Number of single sets without another set collected within 24 hours / Total number of BC sets) × 100

Sub Measure Eligibility Criteria:

- Patient ≥ 18 years old
- Patient may be present in any department of the hospital such as ICU, ED, inpatient floors, step down units. (No outpatients)

[Response Ends]

sp.14. State the denominator.

Brief, narrative description of the target population being measured.

[Response Begins]

Primary Measure – Blood Culture Contamination Rate:

Total number of all blood culture sets collected which are eligible to be considered for contamination per eligibility criteria

Primary Measure Eligibility Criteria:

Patient ≥ 18 years old

Patient may be present in any department of the hospital such as ICU, ED, inpatient floors, step down units. (No outpatients)

At least two blood culture sets drawn in a 24-hour period

Sub Measure – Single Set Blood Culture Rate:

Total number of two or three sets and single sets, either one bottle or one blood culture set (1 aerobic and 1 anaerobic bottle), collected in a 24-hour period

Sub Measure Eligibility Criteria:

Patient ≥ 18 years old

Patient may be present in any department of the hospital such as ICU, ED, inpatient floors, step down units. (No outpatients)

The need for single set blood culture rate

Blood culture contamination cannot be evaluated unless at least two blood culture sets have been collected, as the definition of blood contamination is a single blood culture set positive out of two sets of blood cultures for a possible skin contaminant. The test result would be reported by the laboratory as follows: “Single set positive out of 2 sets (or 3 sets, if this is the laboratory policy) for possible skin contaminant, please call laboratory if further work up is needed” This comment alerts the clinician that a probable contaminant event has occurred, and they may order an additional 1 or 2 blood culture sets for further evaluation.

In addition, in order to accurately diagnose septicemia and bacteremia, it is important to assess the percent of blood cultures with only one set out of the recommended two or more sets collected within a 24-hour period. Two blood culture sets are necessary to obtain at least 40 mL of blood, which is the amount of blood recommended to accurately evaluate an adult patient for bacteremia and sepsis.

According to a publication by Lee, Andrew et al. “Detection of bloodstream infections in adults: how many blood cultures are needed?” Journal of clinical microbiology vol. 45,11 (2007): 3546-8. doi:10.1128/JCM.01555-07

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2168497/> _

Data were analyzed to determine the cumulative sensitivity of blood cultures obtained sequentially during the 24-h time period. Of 629 unimicrobial episodes with ≥3 blood cultures obtained during the 24-h period, 460 (73.1%) were detected

with the first blood culture, 564 (89.7%) were detected with the first two blood cultures, 618 (98.3%) were detected with the first three blood cultures, and 628 (99.8%) were detected with the first four blood cultures.

This study highlights the increase in blood culture testing sensitivity in relation to the amount of blood volume and the number of blood culture sets collected.

The primary and sub-measures must be reported together to ensure patients are being appropriately evaluated for bacteremia and septicemia, and to ensure adverse patient events are avoided.

[Response Ends]

sp.15. Provide details needed to calculate the denominator.

All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets.

Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

[Response Begins]

- The denominator will include all blood culture sets that have been collected by a healthcare professional and resulted in the Laboratory Information System (LIS) by a laboratory team member.
- Manufacturers have designed blood culture bottles to hold a certain amount of blood culture volume. Each blood culture bottle can be filled with 10 mL of blood. One set of blood culture bottles would provide 20 mL of blood, and two sets would provide 40 mL of blood which is the recommended amount of blood culture volume to evaluate an adult patient for septicemia and bacteremia.

The image below is a representative of one complete set of blood culture bottles



- One of the manufacturers, Biorad has provided a booklet describing the blood culture essentials in Chapter 1.
 - https://www.biorad-usa.com/sites/subsidiary_us/files/blood_culture_booklet_-_prn_16_0097a_00_mk_approved13jul161.pdf

Blood Culture set and order definitions:

- 1 Set = 1 blood draw (venipuncture) = 1 aerobic (10 mL) and 1 anaerobic (10 mL) blood culture bottle per blood draw = 2 total bottles
- 1 Order = 2 sets = 2 blood draws (venipunctures) = 1 aerobic and 1 anaerobic blood culture bottle per blood draws = 4 total bottles
- 2 Orders = 4 sets = 4 blood draws (venipunctures) = 1 aerobic and 1 anaerobic blood culture bottle per blood draws = 8 total bottles

Note: Blood culture order could be 3 sets in some institutions depending on patient status / diagnoses

Calculating the Blood Culture Contamination rate

- **Denominator** = Using data from the LIS identify all blood cultures collected by identifying all blood culture order codes within a specified timeframe (usually on a monthly basis)
- **Numerator** = Using data from the LIS Identify all probable contaminants by identifying all probable skin contaminants result codes within a specified timeframe (usually on a monthly basis)

- Calculate the contamination rate by dividing the number of blood cultures containing skin contaminants by the total number of blood culture sets collected
- $BCC = (\text{Number of blood culture sets with growth of skin commensals without the same organism in other sets collected within 24 hours} / \text{Total number of BC sets}) \times 100$
- $\text{Single Set Blood Culture Rate} = (\text{Number of single sets without another set collected within 24 hours} / \text{Total number of BC sets}) \times 100$

Calculating the Single Set Blood Culture Rate

- **Denominator = Using data from the LIS identify all blood cultures collected by identifying all blood culture order codes within a specified timeframe (usually on a monthly basis)**
- Numerator = Using data from the LIS Identify all single set blood cultures by identifying all events when only one blood culture set was collected in a specified timeframe (usually on a monthly basis)
- Calculate the single set rate by dividing the number of single sets of blood cultures by the total number of blood culture sets collected
- $\text{Single Set Blood Culture Rate} = (\text{Number of single sets without another set collected within 24 hours} / \text{Total number of BC sets}) \times 100$

[Response Ends]

sp.16. Describe the denominator exclusions.

Brief narrative description of exclusions from the target population.

[Response Begins]

Primary Measure:

Only a single set collected (must have two sets or more collected) within a 24-hour period

Patient ≤ 18 years in age

[Response Ends]

sp.17. Provide details needed to calculate the denominator exclusions.

All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

[Response Begins]

Primary Measure:

Only a single set collected (must have two sets or more collected) within a 24-hour period

Patient ≤ 18 years in age

[Response Ends]

sp.18. Provide all information required to stratify the measure results, if necessary.

Include the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate. Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format in the Data Dictionary field.

[Response Begins]

N/A

[Response Ends]

sp.19. Select the risk adjustment type.

Select type. Provide specifications for risk stratification and/or risk models in the Scientific Acceptability section.

[Response Begins]

No risk adjustment or risk stratification

[Response Ends]

sp.20. Select the most relevant type of score.

Attachment: If available, please provide a sample report.

[Response Begins]

Rate/proportion

[Response Ends]

sp.21. Select the appropriate interpretation of the measure score.

Classifies interpretation of score according to whether better quality or resource use is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score

[Response Begins]

Better quality = Lower score

[Response Ends]

sp.22. Diagram or describe the calculation of the measure score as an ordered sequence of steps.

Identify the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period of data, aggregating data; risk adjustment; etc.

[Response Begins]

Contaminated blood culture is defined as:

- One blood culture set positive for a commensal organisms out of two to three sets collected
- Examples of bacteria identified as skin contaminants
 - Can be evaluated by genus. “Most species of Coagulase negative Staphylococcus, most species of Corynebacterium (diphtheroids) and related genera, Alpha-hemolytic viridans group strep, Bacillus spp. other than Bacillus anthracis, Micrococcus spp., viridans group streptococcus, Cutibacterium acnes and related species, saprophytic Neisseria sp. and Moraxella sp.”
 - Doern GV, et al. A comprehensive update on the problem of blood culture contamination and a discussion of methods for addressing the problem. Clinical Microbiology Reviews. January 2020. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6822992/>
 - Can be evaluated by genus and species referencing the Centers for Disease Control and Prevention National Healthcare Safety Network’s list of bacteria identified as skin contaminants. <https://www.cdc.gov/nhsn/xls/master-organism-com-commensals-lists.xlsx>
 - The skin commensal list does not include pathogens that could be possible contaminants such as Methicillin-resistant Staphylococcus aureus (MRSA)
 - There are certain organisms that may be considered pathogens even if only isolated in one blood culture set. A clinical decision would be made by the patient’s clinical care team to determine whether the identified organism is a true pathogen based off on the patient’s clinical presentation.

Calculating the Blood Culture Contamination rate

- Using data from the LIS identify all blood cultures collected by identifying all blood culture order codes within a specified timeframe (usually on a monthly basis)
- Using data from the LIS Identify all probable contaminants by identifying all probable skin contaminants result codes within a specified timeframe
 - The National Healthcare Safety Network maintains a list of bacteria identified as skin contaminants. <https://www.cdc.gov/nhsn/xls/master-organism-com-commensals-lists.xlsx>
- Calculate the contamination rate by dividing the number of blood cultures containing skin contaminants by the total number of blood culture sets collected

- $BCC = (\text{Number of blood culture sets with growth of skin commensals without the same organism in other sets collected within 24 hours} / \text{Total number of BC sets}) \times 100$

Calculating the Single Set Blood Culture Rate

- Using data from the LIS identify all blood cultures collected by identifying all blood culture order codes within a specified timeframe (usually on a monthly basis)
- Using data from the LIS Identify all single set blood cultures by identifying all events when only one blood culture set was collected in a specified timeframe (usually on a monthly basis)
- Calculate the single set rate by dividing the number of single sets of blood cultures by the total number of blood culture sets collected
- $\text{Single Set Blood Culture Rate} = (\text{Number of single sets without another set collected within 24 hours} / \text{Total number of BC sets}) \times 100$

[Response Ends]

sp.23. Attach a copy of the instrument (e.g. survey, tool, questionnaire, scale) used as a data source for your measure, if available.

[Response Begins]

Copy of instrument is NOT attached (please explain).

[Copy of instrument is NOT attached (please explain). Please Explain]

The Laboratory Information System (LIS) is the platform used by laboratories to track laboratory test orders and to enter results for laboratory testing. The LIS interfaces with the patient's Electronic Health record, providing results in the patient's chart. Data can be generated from LIS systems for many functions such as tracking turnaround times, test order counts, and in the case of the measure, the number of blood cultures reported with commensal organisms. There are many manufacturers of laboratory information systems, but they all have the same common functions and use. Laboratories have Standard Operating Procedures (SOP) in place to guide laboratory professionals on these functions and using the LIS to be better able to perform blood culture contamination and single set rate calculations in a standardized way.

An example of a laboratory standard operating procedure (SOP) is included in the attachment

NQF.NCC.Additonal.Documents uploaded in the Additional section. The laboratory SOP includes guidance for implementation of blood culture contamination rate calculation which demonstrates the use of laboratory best practice guidelines such as those available for use from the Clinical Laboratory Standards Institute.

A contaminated blood culture is defined as a blood culture set with growth of a commensal organism in only one blood culture set out of two or three blood culture sets collected.

The laboratory definition of an organism is considered to be a commensal if it is listed on the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) master list and is present in only one blood culture set out of two or three blood culture sets collected. It can be genus or genus and species. The CDC NHSN master list is updated as new commensal organisms are identified.

A single set blood culture is defined as only one set out of the recommended two – three sets of blood cultures collected within a 24-hour period. Reports can be generated from the LIS to provide data on the number of single set blood cultures collected versus two – three sets within a 24-hour period.

[Response Ends]

sp.24. Indicate the responder for your instrument.

[Response Begins]

Other (specify)

[Other (specify) Please Explain]

Lab professionals collecting and analyzing data via Laboratory Information systems (LIS) software.

Laboratories have Standard Operating Procedures (SOP) in place to guide laboratory professionals to use the LIS to be better able to perform blood culture contamination and single set rate calculations in a standardized way. In the event that an LIS is not available due to emergency situations such as power outages and cyber-attacks, all laboratories have a "downtime" SOP in place to guide them on blood culture contamination and single set rate calculations based off of the resources still available for use.

[Response Ends]

sp.25. If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.

[Response Begins]

N/A. This measure is not based on a sample of data or survey.

[Response Ends]

sp.26. Identify whether and how proxy responses are allowed.

[Response Begins]

N/A

[Response Ends]

sp.27. Survey/Patient-reported data.

Provide instructions for data collection and guidance on minimum response rate. Specify calculation of response rates to be reported with performance measure results.

[Response Begins]

N/A - Data is not patient reported

[Response Ends]

sp.28. Select only the data sources for which the measure is specified.

[Response Begins]

Other (specify)

[Other (specify) Please Explain]

Laboratory Information Systems (LIS) data

Blood Culture Analyzer Software

[Response Ends]

sp.29. Identify the specific data source or data collection instrument.

For example, provide the name of the database, clinical registry, collection instrument, etc., and describe how data are collected.

[Response Begins]

Premier Healthcare Database and Cerner Health Facts, two large electronic healthcare databases including data from both private and academic U.S. hospitals. Premier and Cerner databases contain a comprehensive clinical record on each encounter, including sociodemographic data, comorbidities, procedures, medications, patient charges and costs, and diagnoses. Additionally, these databases contain microbiology laboratory data from approximately 500 hospitals, including specimen identification, test name, test day and time of service, and result and sensitivity data.

The databases house Laboratory Information Systems (LIS) data.

The data was analyzed using the same measure specifications of the proposed primary and sub-measures.

- This analysis uses the eligibility criteria specifications defined in sp.02 Primary and Sub measure eligibility criteria.
 - Patient ≥ 18 years old

- Patient may be present in any department of the hospital such as ICU, ED, inpatient floors, step down units. (No outpatients)
- At least two blood culture sets drawn in a 24-hour period
- Commensal organisms are identified by using the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) list of bacteria identified as skin contaminants. <https://www.cdc.gov/nhsn/xls/master-organism-com-commensals-lists.xlsx>

[Response Ends]

sp.30. Provide the data collection instrument.

[Response Begins]

No data collection instrument provided

[Response Ends]

Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate fields in the Scientific Acceptability sections of the Measure Submission Form.

- Measures must be tested for all the data sources and levels of analyses that are specified. If there is more than one set of data specifications or more than one level of analysis, contact NQF staff about how to present all the testing information in one form.
- All required sections must be completed.
- For composites with outcome and resource use measures, Questions 2b.23-2b.37 (Risk Adjustment) also must be completed.
- If specified for multiple data sources/sets of specifications (e.g., claims and EHRs), Questions 2b.11-2b.13 also must be completed.
- An appendix for supplemental materials may be submitted (see Question 1 in the Additional section), but there is no guarantee it will be reviewed.
- Contact NQF staff with any questions. Check for resources at the [Submitting Standards webpage](#).
- For information on the most updated guidance on how to address social risk factors variables and testing in this form refer to the release notes for the [2021 Measure Evaluation Criteria and Guidance](#).

Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the testing results for this measure meet NQF's evaluation criteria for testing.

2a. Reliability testing demonstrates the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise. For instrument-based measures (including PRO-PMs) and composite performance measures, reliability should be demonstrated for the computed performance score.

2b1. Validity testing demonstrates that the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For instrument based measures (including PRO-PMs) and composite performance measures, validity should be demonstrated for the computed performance score.

2b2. Exclusions are supported by the clinical evidence and are of sufficient frequency to warrant inclusion in the specifications of the measure;

AND

If patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that the exclusion impacts performance on the measure; in such cases, the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).

2b3. For outcome measures and other measures when indicated (e.g., resource use):

- an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified; is based on patient factors (including clinical and social risk factors) that influence the measured outcome and are present at start of care; 14,15 and has demonstrated adequate discrimination and calibration

OR

- rationale/data support no risk adjustment/ stratification.

2b4. Data analysis of computed measure scores demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful 16 differences in performance;

OR

there is evidence of overall less-than-optimal performance.

2b5. If multiple data sources/methods are specified, there is demonstration they produce comparable results.

2b6. Analyses identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and non-responders) and how the specified handling of missing data minimizes bias.

2c. For composite performance measures, empirical analyses support the composite construction approach and demonstrate that:

2c1. the component measures fit the quality construct and add value to the overall composite while achieving the related objective of parsimony to the extent possible; and

2c2. the aggregation and weighting rules are consistent with the quality construct and rationale while achieving the related objective of simplicity to the extent possible.

(if not conducted or results not adequate, justification must be submitted and accepted)

Definitions

Reliability testing applies to both the data elements and computed measure score. Examples of reliability testing for data elements include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing of the measure score addresses precision of measurement (e.g., signal-to-noise).

Validity testing applies to both the data elements and computed measure score. Validity testing of data elements typically analyzes agreement with another authoritative source of the same information. Examples of validity testing of the measure score include, but are not limited to: testing hypotheses that the measures scores indicate quality of care, e.g., measure scores are different for groups known to have differences in quality assessed by another valid quality measure or method; correlation of measure scores with another valid indicator of quality for the specific topic; or relationship to conceptually related measures (e.g., scores on process measures to scores on outcome measures). Face validity of the measure score as a quality indicator may be adequate if accomplished through a systematic and transparent process, by identified experts, and explicitly addresses whether performance scores resulting from the measure as specified can be used to distinguish good from poor quality. The degree of consensus and any areas of disagreement must be provided/discussed.

Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, variability of exclusions across providers, and sensitivity analyses with and without the exclusion.

Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

Risk factors that influence outcomes should not be specified as exclusions.

With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74 percent v. 75 percent) is clinically meaningful; or whether a statistically significant difference of \$25 in cost for an episode of care (e.g., \$5,000 v. \$5,025) is practically meaningful. Measures with overall less-than-optimal performance may not demonstrate much variability across providers.

Please separate added or updated information from the most recent measure evaluation within each question response in the Importance to Scientific Acceptability sections. For example:

2021 Submission:

Updated testing information here.

2018 Submission:

Testing from the previous submission here.

2a.01. Select only the data sources for which the measure is tested.

[Response Begins]

Other (specify)

[Other (specify) Please Explain]

[Response Ends]

2a.02. If an existing dataset was used, identify the specific dataset.

The dataset used for testing must be consistent with the measure specifications for target population and healthcare entities being measured; e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home MDS, home health OASIS, clinical registry).

[Response Begins]

Premier Healthcare Database and Cerner Health Facts, two large electronic healthcare databases including data from both private and academic U.S. hospitals. Premier and Cerner databases contain a comprehensive clinical record on each encounter, including sociodemographic data, comorbidities, procedures, medications, patient charges and costs, and diagnoses. Additionally, these databases contain microbiology laboratory data from approximately 500 hospitals, including specimen identification, test name, test day and time of service, and result and sensitivity data. The Premier Healthcare Database and Cerner Health Facts houses laboratory information systems (LIS) data.

[Response Ends]

2a.03. Provide the dates of the data used in testing.

Use the following format: "MM-DD-YYYY - MM-DD-YYYY"

[Response Begins]

Division of Healthcare Quality and Promotion (DHQP): Trends and Variability in Blood Culture Utilization and Positivity among U.S. Hospitals:

01-01-2012 – 12-31-2017. This study used data generated from the Premier Healthcare Database and Cerner Health Facts described in 2a.02.

The data evaluated only contained blood cultures that met the eligibility criteria outlined in the measure specifications. When generating the data the search was limited to the measure specifications only. For example, limiting to complete adult blood cultures that occur in episodes with 2-3 cultures < 24 hours. Commensals were identified using the CDC NHSN master list.

Primary Measure Eligibility Criteria:

Patient ≥ 18 years old

Patient may be present in any department of the hospital such as ICU, ED, inpatient floors, step down units. (No outpatients)

At least two blood culture sets drawn in a 24-hour period

Sub Measure Eligibility Criteria:

Patient ≥ 18 years old

Patient may be present in any department of the hospital such as ICU, ED, inpatient floors, step down units. (No outpatients)

[Response Ends]

2a.04. Select the levels of analysis for which the measure is tested.

Testing must be provided for all the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Clinician: Clinician*
- *Population: Population*

[Response Begins]

Facility

[Response Ends]

2a.05. List the measured entities included in the testing and analysis (by level of analysis and data source).

Identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if a sample was used, describe how entities were selected for inclusion in the sample.

[Response Begins]

Table 3. Facility Characteristics Blood culture episodes, Premier Healthcare Database and Cerner Health Facts, 2012-2017.	Facilities 2012-2017 N=259
Census Region (%)	*
Midwest	22.7
Northeast	16.8
South	41.4
West	19.1
Geography (%)	*
Urban	76.1
Teaching (%)	*
Yes	30.6
Size (%)	*
<300 Beds	72.6

*Indicates cell intentionally left blank

[Response Ends]

2a.06. Identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis), separated by level of analysis and data source; if a sample was used, describe how patients were selected for inclusion in the sample.

If there is a minimum case count used for testing, that minimum must be reflected in the specifications.

[Response Begins]

Table 4. Patient Characteristics Blood culture episodes, Premier Healthcare Database and Cerner Health Facts, 2012- 2017.	Patients 2012-2017 N=5,212,521
Age Groups (%)	*
Less than 18 years	9.6
18 to 39 years	14.6
40 to 59 years	22.3
60 to 79 years	34.2
80 years and older	19.3
Gender (%)	*
Male	46.6
Race (%)	*
Black	16.6
Other	11.1
Unknown	0.9

Table 4. Patient Characteristics Blood culture episodes, Premier Healthcare Database and Cerner Health Facts, 2012- 2017.	Patients 2012-2017 N=5,212,521
White	71.4

*Indicates cell intentionally left blank

[Response Ends]

2a.07. If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), identify how the data or sample are different for each aspect of testing.

[Response Begins]

N/A - One dataset used for all aspects of testing

[Response Ends]

2a.08. List the social risk factors that were available and analyzed.

For example, patient-reported data (e.g., income, education, language), proxy variables when social risk data are not collected from each patient (e.g. census tract), or patient community characteristics (e.g. percent vacant housing, crime rate) which do not have to be a proxy for patient-level data.

[Response Begins]

Social risk factors evaluated for this measure were based on where a patient was evaluated for bacteremia and septicemia, and patient related characteristics. The risk factors include whether the facility was a small or large hospital, urban or rural, teaching, or non-teaching, and the geographical region. The patient-related characteristics such as age, race, marriage status, and gender were also evaluated.

Social risk factors such as income, language, education, crime rates are not fields available in the databases used for measure testing.

[Response Ends]

Note: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a.07 check patient or encounter-level data; in 2a.08 enter “see validity testing section of data elements”; and enter “N/A” for 2a.09 and 2a.10.

2a.09. Select the level of reliability testing conducted.

Choose one or both levels.

[Response Begins]

Accountable Entity Level (e.g., signal-to-noise analysis)

[Response Ends]

2a.10. For each level of reliability testing checked above, describe the method of reliability testing and what it tests.

Describe the steps—do not just name a method; what type of error does it test; what statistical analysis was used.

[Response Begins]

Blood Culture Contamination Rate

DHQP Split Sample Reliability test-retest approach in which the total contamination rate is measured once using a random subset of patients, and then measured again using a second random subset exclusive of the first.

Single Set Blood Culture Rate

DHQP Split Sample Reliability test-retest approach in which the total single set rate is measured once using a random subset of patients, and then measured again using a second random subset exclusive of the first.

[Response Ends]

2a.11. For each level of reliability testing checked above, what were the statistical results from reliability testing?

For example, provide the percent agreement and kappa for the critical data elements, or distribution of reliability statistics from a signal-to-noise analysis. For score-level reliability testing, when using a signal-to-noise analysis, more than just one overall statistic should be reported (i.e., to demonstrate variation in reliability across providers). If a particular method yields only one statistic, this should be explained. In addition, reporting of results stratified by sample size is preferred (pg. 18, [NQF Measure Evaluation Criteria](#)).

[Response Begins]

Blood Culture Contamination Rate

Split-Sample Reliability: In total, 5,620,345 complete blood culture episodes (2-3 blood culture sets $\leq$ 24 hours) and 168,250 Contaminated blood cultures were included in the analysis with an overall contamination rate of 2.994%, using 6 years of data (2012-2017). After randomly splitting the sample into two halves, there were 2,809,908 complete blood culture episodes (2-3 blood culture sets $\leq$ 24 hours) and 84,154 Contaminated blood cultures from 257 hospitals in one half with an overall contamination rate of 2.995% and 2,810,437 complete blood culture episodes and 84,096 Contaminated blood cultures from 258 hospitals in the other half with an overall contamination rate of 2.992%. As a metric of agreement, we calculated the ICC using the Spearman-Brown prediction formula, the agreement between the two independent assessments of the BCC rate for each hospital was **0.81253**.

Single Set Blood Culture Rate

Split-Sample Reliability: In total, 6,688,221 blood culture sets and 541,613 single blood culture sets (1 blood culture set in $\leq$ 24 hours) were included in the analysis with an overall single culture rate of 8.10%, using 6 years of data (2012-2017). After randomly splitting the sample into two halves, there were 3,344,757 blood culture sets and 270,449 single blood culture sets from 257 hospitals in one half with an overall single culture rate of 8.086% and 3,343,464 complete blood culture episodes and 271,164 single blood culture sets from 259 hospitals in the other half with an overall single culture rate of 8.110%. As a metric of agreement, we calculated the ICC using the Spearman-Brown prediction formula, the agreement between the two independent assessments of the single blood culture rate for each hospital was **0.78635**.

[Response Ends]

2a.12. Interpret the results, in terms of how they demonstrate reliability.

(In other words, what do the results mean and what are the norms for the test conducted?)

[Response Begins]

Blood Culture Contamination Rate

The split-sample reliability score of **0.81253** discussed in the previous section, represents almost perfect agreement of the measure reliability.

Single Set Blood Culture Rate

The split-sample reliability score of **0.78635** discussed in the previous section, represents substantial agreement of the measure reliability.

The interpretation of the results is based on the standards established by Landis and Koch (1977): Landis J, Koch G, The measurement of observer agreement for categorical data, Biometrics, 1977;33:159-174.

Interpretation Criteria for the split-sample reliability testing	Established by Landis and Koch (1977): Landis J, Koch G, The measurement of observer agreement for categorical data, Biometrics, 1977;33:159-174.
Score	Interpretation
< 0	Less than chance agreement
$0 - 0.2$	Slight agreement
$0.21 - 0.39$	Fair agreement
$0.4 - 0.59$	Moderate agreement
$0.6 - 0.79$	Substantial agreement
$0.8 - 0.99$	Almost Perfect agreement

Interpretation Criteria for the split-sample reliability testing	Established by Landis and Koch (1977): Landis J, Koch G, The measurement of observer agreement for categorical data, Biometrics, 1977;33:159-174.
1	Perfect agreement

[Response Ends]

2b.01. Select the level of validity testing that was conducted.

[Response Begins]

Systematic assessment of face validity of performance measure score as an indicator of quality or resource use (i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance)

[Response Ends]

2b.02. For each level of testing checked above, describe the method of validity testing and what it tests.

Describe the steps—do not just name a method; what was tested, e.g., accuracy of data elements compared to authoritative source, relationship to another measure as expected; what statistical analysis was used.

[Response Begins]

Systematic assessment of face validity

- On 11/12/2021 @ 300PM EST we hosted a panel presentation and Q&A discussion with 8 subject matter experts in or associated with the laboratory community. These SMEs have extensive knowledge of laboratory best practice standards for blood culture collection, such as the need for at least two sets to adequately evaluate a patient for septicemia or bacteremia. Additionally, the SMEs have extensive knowledge of blood culture contamination rate evaluation and reporting. Representatives were present from the American Society of Microbiology (ASM) and the College of American Pathology (CAP). The participant's names and titles are listed in the table below.

Names and Titles of the Subject Matter Expert Panel Participants	*
Participant	Title
Karen C Carroll MD	Professor of Pathology Director, Division of Medical Microbiology The Johns Hopkins University School of Medicine
Dan Diekema, MD, MS	Director, Division of Infectious Diseases Clinical Professor of Internal Medicine-Infectious Diseases Clinical Professor of Pathology University of Iowa Hospitals and Clinics
Mark Rupp MD	Professor and Chief, Division of Infectious Diseases Medical Director, Dept of Infection Control & Epidemiology University of Nebraska Medical Center
Melvin Weinstein, MD	Co-Director, Microbiology Laboratory Robert Wood Johnson University Hospital Emeritus Professor of Medicine (Infectious Diseases) Emeritus Professor of Pathology & Laboratory Medicine Rutgers Robert Wood Johnson Medical School
Kevin Garey, PharmD, MS	Professor and Chair University of Houston College of Pharmacy
Mike Miller, Ph.D., D(ABMM)	Director, Microbiology Technical Services, LLC
Ella Martin, MD, D(ABMM) College of American Pathology Representative	Medical Director of Microbiology Department of Pathology and Laboratory Medicine Dartmouth-Hitchcock Medical Center
Robert L Sautter, PhD, HCLD/CC(ABB), MS, MT (ASCP)SM American Society of Microbiology Representative	Owner of Sautter Consulting LLC

* Indicates cell intentionally left blank

After the meeting we sent out a survey to each participant to obtain their individual anonymous consults on the project. The intent of the survey questions is to prove face validity of the measure as it relates to the measure having a positive impact on patient care if adopted

[Response Ends]

2b.03. Provide the statistical results from validity testing.

Examples may include correlations or t-test results.

[Response Begins]

See attached survey results uploaded in the additional section

[Response Ends]

2b.04. Provide your interpretation of the results in terms of demonstrating validity. (i.e., what do the results mean and what are the norms for the test conducted?)

[Response Begins]

Systematic assessment of face validity

- Question #1 of the survey was specifically asked to identify if the measure would be a good indicator to discern between good and poor quality of care.
 - All six SME responders either agreed or strongly agreed that this would be an effective measure to improve patient care as did the two representatives from the ASM and CAP laboratory professional organizations.
- The remaining questions were developed to obtain a sense of the current state of blood culture contamination rate and reporting.
 - The responses show there is consistency amongst the responders in their standard operating processes, but there are also opportunities to further standardize.
 - In general, all responders are approaching the evaluation and reporting of blood culture contamination using a similar method, and the same types of laboratory information systems.

[Response Ends]

2b.05. Describe the method for determining if statistically significant and clinically/practically meaningful differences in performance measure scores among the measured entities can be identified.

Describe the steps—do not just name a method; what statistical analysis was used? Do not just repeat the information provided in Importance to Measure and Report: Gap in Care/Disparities.

[Response Begins]

To assess meaningful differences / clinical significance we examined the Q1 : 25 and Q3: 75 percentiles and the interquartile range (IQR) by examining facility-level blood culture contamination rate and single set blood culture rate.

[Response Ends]

2b.06. Describe the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities.

Examples may include number and percentage of entities with scores that were statistically significantly different from mean or some benchmark, different from expected; how was meaningful difference defined.

[Response Begins]

Table 5. Facility-level variation among 259 facilities, Premier Healthcare Database, 2012-2017	*	Quartile 1	Median	Quartile 3	Interquartile range (IQR)
*	n	%	%	%	%
Contaminated culture rate among complete cultures (2-3 cultures ≤ 24 hours)	5,620,345 complete blood cultures	1.97	2.67	3.5	1.53
Single culture rate among all cultures	6,688,221 total blood cultures	4.25	6.45	10.43	6.18

*Indicates cell intentionally left blank

[Response Ends]

2b.07. Provide your interpretation of the results in terms of demonstrating the ability to identify statistically significant and/or clinically/practically meaningful differences in performance across measured entities.

In other words, what do the results mean in terms of statistical and meaningful differences?

[Response Begins]

Quartile 1 is the 25th percentile (25% of facilities have rates below the level)

Median is 50th percentile (50% of facilities have rates below the level)

Quartile 3 is the 75th percentile (75% of facilities have rates below the level)

Interquartile range (IQR) is the difference between the 75th and 25th percentiles.

Koenker, R. (2005). Quantile Regression (Econometric Society Monographs). Cambridge: Cambridge University Press.
doi:10.1017/CBO9780511754098

Table 5. Facility-level variation among 259 facilities, Premier Healthcare Database, 2012-2017

Blood Culture Contamination Rate

- The current benchmark for blood culture contamination rate is ≤3%
- Quartile 1: 25% of facilities have rates below the benchmark at 1.97%
- Quartile 3: 75% of facilities have rates below the benchmark at 3.5%
- Considering blood culture contamination should not occur, an IQR of 1.53% would be considered a clinically significant difference amongst the facilities tested.
- Blood culture contamination should not occur, and ultimately the rate should be driven down to as low as possible.

Single Set Blood Culture Rate

- There is no current recommended current benchmark for single set culture rate, but each event demonstrates a case where only one blood culture set out of the two to three recommended sets was evaluated for septicemia and bacteremia.
- Quartile 1: 25% of facilities have rates below 4.25%
- Quartile 3: 75% of facilities have rates below 10.43%
- Considering collecting only a single set does not follow best practice guidelines (collection of at least two blood culture sets within a 24-hour window), an IQR of 6.18% would be considered a clinically significant difference amongst the facilities tested.
- Single set blood cultures should not occur, and ultimately the rate should be driven down to as low as possible.

[Response Ends]

2b.08. Describe the method of testing conducted to identify the extent and distribution of missing data (or non-response) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and non-responders). Include how the specified handling of missing data minimizes bias.

Describe the steps—do not just name a method; what statistical analysis was used.

[Response Begins]

When blood cultures are collected there is a record created for each culture in the laboratory information system (LIS). This record provides a mechanism to ensure the blood culture is tested and resultated. Laboratories have methods in place to ensure all cultures are resultated. Since these test accountability practices exist there would not be any missing data when evaluating blood culture contamination or the single set blood culture rate.

With the Premier datasets used for testing a record would not be available to evaluate if a blood culture was not collected and resultated.

All blood culture received in the Laboratory have a test result reported. There are no blood cultures that are received in the laboratory that do not have a result reported.

[Response Ends]

2b.09. Provide the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data.

For example, provide results of sensitivity analysis of the effect of various rules for missing data/non-response. If no empirical sensitivity analysis was conducted, identify the approaches for handling missing data that were considered and benefits and drawbacks of each).

[Response Begins]

NA - test accountability practices ensure there will not be any missing data when evaluating blood culture contamination or the single set blood culture rate.

[Response Ends]

2b.10. Provide your interpretation of the results, in terms of demonstrating that performance results are not biased due to systematic missing data (or differences between responders and non-responders), and how the specified handling of missing data minimizes bias.

In other words, what do the results mean in terms of supporting the selected approach for missing data and what are the norms for the test conducted; if no empirical analysis was conducted, justify the selected approach for missing data.

[Response Begins]

NA - test accountability practices ensure there will not be any missing data when evaluating blood culture contamination or the single set blood culture rate.

[Response Ends]

Note: This item is directed to measures that are risk-adjusted (with or without social risk factors) OR to measures with more than one set of specifications/instructions (e.g., one set of specifications for how to identify and compute the measure from medical record abstraction and a different set of specifications for claims or eQMs). It does not apply to measures that use more than one source of data in one set of specifications/instructions (e.g., claims data to identify the denominator and medical record abstraction for the numerator). Comparability is not required when comparing performance scores with and without social risk factors in the risk adjustment model. However, if comparability is not demonstrated for measures with more than one set of specifications/instructions, the different specifications (e.g., for medical records vs. claims) should be submitted as separate measures.

2b.11. Indicate whether there is more than one set of specifications for this measure.

[Response Begins]

No, there is only one set of specifications for this measure

[Response Ends]

2b.12. Describe the method of testing conducted to compare performance scores for the same entities across the different data sources/specifications.

Describe the steps—do not just name a method. Indicate what statistical analysis was used.

[Response Begins]

[Response Ends]

2b.13. Provide the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications.

Examples may include correlation, and/or rank order.

[Response Begins]

[Response Ends]

2b.14. Provide your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications.

In other words, what do the results mean and what are the norms for the test conducted.

[Response Begins]

[Response Ends]

2b.15. Indicate whether the measure uses exclusions.

[Response Begins]

Yes, the measure uses exclusions.

[Response Ends]

2b.16. Describe the method of testing exclusions and what was tested.

Describe the steps—do not just name a method; what was tested, e.g., whether exclusions affect overall performance scores; what statistical analysis was used?

[Response Begins]

The data evaluated only contained blood cultures that met the eligibility criteria outlined in the measure specifications. When generating the data the search was limited to the measure specifications only. For example, limiting to complete adult blood cultures that occur in episodes with 2-3 cultures < 24 hours. Commensals were identified using the CDC NHSN master list.

Primary Measure Eligibility Criteria:

Patient ≥ 18 years old

Patient may be present in any department of the hospital such as ICU, ED, inpatient floors, step down units. (No outpatients)

At least two blood culture sets drawn in a 24-hour period

Sub Measure Eligibility Criteria:

Patient ≥ 18 years old

Patient may be present in any department of the hospital such as ICU, ED, inpatient floors, step down units. (No outpatients)

Since the only data evaluated were only those as specified, there will not be any changes to the measure scores overall.

[Response Ends]

2b.17. Provide the statistical results from testing exclusions.

Include overall number and percentage of individuals excluded, frequency distribution of exclusions across measured entities, and impact on performance measure scores.

[Response Begins]

N/A - there were no statistical results for testing exclusions since the data evaluated did not include any exclusions.

[Response Ends]

2b.18. Provide your interpretation of the results, in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results.

In other words, the value outweighs the burden of increased data collection and analysis. Note: If patient preference is an exclusion, the measure must be specified so that the effect on the performance score is transparent, e.g., scores with and without exclusion.

[Response Begins]

N/A there were no statistical results for testing exclusions since the data evaluated did not include any exclusions.

Since the only data evaluated were only those as specified there will not be any changes to the measure scores overall.

[Response Ends]

2b.19. Check all methods used to address risk factors.

[Response Begins]

No risk adjustment or stratification

[Response Ends]

2b.20. If using statistical risk models, provide detailed risk model specifications, including the risk model method, risk factors, risk factor data sources, coefficients, equations, codes with descriptors, and definitions.

[Response Begins]

N/A

[Response Ends]

2b.21. If an outcome or resource use measure is not risk-adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (i.e., case mix) is not needed to achieve fair comparisons across measured entities.

[Response Begins]

N/A - As indicated in 2b.19, there was no risk adjustment for this measure.

[Response Ends]

2b.22. Select all applicable resources and methods used to develop the conceptual model of how social risk impacts this outcome.

[Response Begins]

Published literature

[Response Ends]

2b.23. Describe the conceptual and statistical methods and criteria used to test and select patient-level risk factors (e.g., clinical factors, social risk factors) used in the statistical risk model or for stratification by risk.

Please be sure to address the following: potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of $p < 0.10$ or other statistical tests; correlation of x or higher. Patient factors should be present at the start of care, if applicable. Also discuss any "ordering" of risk factor inclusion; note whether social risk factors are added after all clinical factors. Discuss any considerations regarding data sources (e.g., availability, specificity).

[Response Begins]

[Response Ends]

2b.24. Detail the statistical results of the analyses used to test and select risk factors for inclusion in or exclusion from the risk model/stratification.

[Response Begins]

[Response Ends]

2b.25. Describe the analyses and interpretation resulting in the decision to select or not select social risk factors.

Examples may include prevalence of the factor across measured entities, availability of the data source, empirical association with the outcome, contribution of unique variation in the outcome, or assessment of between-unit effects and within-unit effects. Also describe the impact of adjusting for risk (or making no adjustment) on providers at high or low extremes of risk.

[Response Begins]

As indicated in 2b.19, there was no risk adjustment for this measure.

[Response Ends]

2b.26. Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model or stratification approach (describe the steps—do not just name a method; what statistical analysis was used). Provide the statistical results from testing the approach to control for differences in patient characteristics (i.e., case mix) below. If stratified ONLY, enter “N/A” for questions about the statistical risk model discrimination and calibration statistics.

Validation testing should be conducted in a data set that is separate from the one used to develop the model.

[Response Begins]

N/A

[Response Ends]

2b.27. Provide risk model discrimination statistics.

For example, provide c-statistics or R-squared values.

[Response Begins]

N/A

[Response Ends]

2b.28. Provide the statistical risk model calibration statistics (e.g., Hosmer-Lemeshow statistic).

[Response Begins]

N/A

[Response Ends]

2b.29. Provide the risk decile plots or calibration curves used in calibrating the statistical risk model.

The preferred file format is .png, but most image formats are acceptable.

[Response Begins]

N/A

[Response Ends]

2b.30. Provide the results of the risk stratification analysis.

[Response Begins]

As indicated in 2b.19, there was no risk adjustment for this measure.

[Response Ends]

2b.31. Provide your interpretation of the results, in terms of demonstrating adequacy of controlling for differences in patient characteristics (i.e., case mix).

In other words, what do the results mean and what are the norms for the test conducted?

[Response Begins]

As indicated in 2b.19, there was no risk adjustment for this measure.

[Response Ends]

2b.32. Describe any additional testing conducted to justify the risk adjustment approach used in specifying the measure.

Not required but would provide additional support of adequacy of the risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed.

[Response Begins]

N/A

[Response Ends]

2a. Reliability

2b. Validity

2c. Composite – Empirical Analysis

Criteria 3: Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

3.01. Check all methods below that are used to generate the data elements needed to compute the measure score.

[Response Begins]

Other (Please describe)

[Other (Please describe) Please Explain]

Lab Professional. analyzes and analyzing data via laboratory analyzer software and / or laboratory information systems

[Response Ends]

3.02. Detail to what extent the specified data elements are available electronically in defined fields.

In other words, indicate whether data elements that are needed to compute the performance measure score are in defined, computer-readable fields.

[Response Begins]

ALL data elements are in defined fields in a combination of electronic sources

[Response Ends]

3.03. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using data elements not from electronic sources.

[Response Begins]

NA - ALL the data elements needed to compute the performance measure score are from electronic sources via laboratory analyzer software and / or laboratory information systems.

In some cases depending on the facility level the evaluation could be done manually as well using SOP criteria for when blood cultures are considered to be a contaminant, and when only a single set blood culture is collected.

[Response Ends]

3.04. Describe any efforts to develop an eQIM.

[Response Begins]

Plan to work with data interoperability experts and platforms to streamline reporting.

Currently evaluating USCDI and FHIR (Fast Healthcare Interoperability Resources) Standards

[Response Ends]

3.06. Describe difficulties (as a result of testing and/or operational use of the measure) regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.

[Response Begins]

This measure uses data generated from laboratory analyzer software and / or laboratory information systems data and as such, offers no data collection burden to laboratories, hospitals, or providers.

There would be no additional investments in infrastructure or software to obtain the data elements need for generating and evaluating these rates since the laboratory analyzer software and / or laboratory information systems already exist in laboratories.

[Response Ends]

Consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

3.07. Detail any fees, licensing, or other requirements to use any aspect of the measure as specified (e.g., value/code set, risk model, programming code, algorithm),

Attach the fee schedule here, if applicable.

[Response Begins]

N/A

[Response Ends]

Criteria 4: Use and Usability

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making.

NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement, in addition to demonstrating performance improvement.

4a.01. Check all current uses. For each current use checked, please provide:

Name of program and sponsor

URL

Purpose

Geographic area and number and percentage of accountable entities and patients included

Level of measurement and setting

[Response Begins]

Quality Improvement (Internal to the specific organization)

[Quality Improvement (Internal to the specific organization) Please Explain]

Rates should be reported to individual patient care units for tracking and follow-up.

[Response Ends]

4a.02. Check all planned uses.

[Response Begins]

Public reporting

Regulatory and Accreditation Program

Quality Improvement (internal to the specific organization)

[Response Ends]

4a.03. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing), explain why the measure is not in use.

For example, do policies or actions of the developer/steward or accountable entities restrict access to performance results or block implementation?

[Response Begins]

Further determinations to be made

[Response Ends]

4a.04. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes: used in any accountability application within 3 years, and publicly reported within 6 years of initial endorsement.

A credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.

[Response Begins]

Further determinations to be made

[Response Ends]

4a.05. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

Detail how many and which types of measured entities and/or others were included. If only a sample of measured entities were included, describe the full population and how the sample was selected.

[Response Begins]

For the Use and Usability sections we interviewed The Johns Hopkins University School of Medicine's Director of the Division of Medical Microbiology and her team.

The purpose of this interview was to obtain feedback from a large hospital system who implemented blood culture contamination rate evaluation and reporting in community level, suburban based, and university hospital settings.

The document containing all of the questions is attached in the Additional section of the application below and we added answers to the questions for each question in these sections.

What is the number of blood culture sets that your laboratories handle per year? and broken down between the number of hospitals in your system, if appropriate

Total: 51,199 processed at the main Microbiology Laboratory. Breakdown by numbers collected at various sites.

1. Tertiary Level Community Hospital with Burn Unit (Teaching Hosp)—11,723
2. Suburban based Community Hospital—12,631
3. Quaternary Care University Hospital with embedded cancer hospital (University Teaching Hosp)—26,845

[Response Ends]

4a.06. Describe the process for providing measure results, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

[Response Begins]

Describe the process for providing contamination rate results, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made? How do you calculate the contamination rate?

Contamination rates are reported monthly to all of the hospitals and groups mentioned in question 1. We provide key stakeholders of particular units like the EDs, ICUs, Oncology units, phlebotomy, Infection prevention and Control/CLABSI prevention groups, etc. with the number of blood cultures obtained, the positivity rate, and the blood culture contamination rates. We also show the overall institutional rates so a particular unit can compare its rates with that of the overall hospital rates. Raw data with the names of the individuals who collected the contaminated cultures is also provided. At the unit level, individuals with high rates of contamination are retrained. Periodically, Microbiology Laboratory personnel and on some units, Nursing personnel will provide in-services for units that have sustained high rates over time.

We have a CLABSI reduction committee that formed in 2018. This committee receives the blood culture contamination rates monthly and provides detailed education to the CLABSI unit champions. We have a one-hour didactic program on blood culture contamination prevention. In addition, we have blood culture contamination kits (peripheral and central) along with skill validation checklists to promote standardization of procedures. The unit contamination rates with details are provided to the CLABSI champions monthly and re-training is performed as needed.

Contamination rates are calculated as follows: A blood culture is "flagged" by the Laboratory Information System as a contaminant if the culture grows a typical skin colonizer such as *Bacillus* sp., *Corynebacterium* sp., *Cutibacterium* sp., coagulase negative staphylococci, viridans group streptococci, *Aerococcus* sp., *Micrococcus* sp. **AND** there are no other positive cultures within +/- 24 h of that positive result. Blood culture contamination

rates are calculated by dividing the total number of “flagged” cultures by the total number of blood cultures ordered from a particular location.

[Response Ends]

4a.07. Summarize the feedback on measure performance and implementation from the measured entities and others. Describe how feedback was obtained.

[Response Begins]

What was the feedback received from the individual units, good or bad?

Many years ago when we first rolled out this program, the response from some units with high rates initially was disappointment and frustration. However, with the data provided by the laboratory, steps were taken by some units to “own” the problem by using the data to advocate for resources. The ED at the University Teaching Hospital requested funds to expand the clinical technicians group who perform a variety of duties such as blood draws and point of care tasks. This group of individuals was highly trained and used the standardized blood culture collection kits.

[Response Ends]

4a.08. Summarize the feedback obtained from those being measured.

[Response Begins]

The Johns Hopkins University School of Medicine successfully implemented blood culture contamination rate evaluation and reporting. They have experienced a decrease in the rate, increased collaboration among laboratories, pharmacists, infectious disease, and infection prevention departments, and emergency rooms, and patient care units to ensure high quality patient care relating to the evaluation of septicemia and bacteremia.

[Response Ends]

4a.09. Summarize the feedback obtained from other users.

[Response Begins]

N/A

[Response Ends]

4a.10. Describe how the feedback described has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

[Response Begins]

The interview aligned with the proposed measure and there were not any modifications as a result of the answers provided by Johns Hopkins.

[Response Ends]

4b.01. You may refer to data provided in Importance to Measure and Report: Gap in Care/Disparities, but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included). If no improvement was demonstrated, provide an explanation. If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

[Response Begins]

For the Use and Usability sections we interviewed The Johns Hopkins University School of Medicine’s Director of the Division of Medical Microbiology and her team.

The purpose of this interview was to obtain feedback from a large hospital system who implemented blood culture contamination rate evaluation and reporting in community level, suburban based, and university hospital settings.

The document containing all of the questions is attached in the Additional section of the application below and we added answers to the questions for each question in these sections.

Were there any improvements to the rate after implementation?

Yes, the overall rates at the University Teaching Hospital dropped from 3-4% to now 1%.

Do you interface with the Antibiotic Stewardship Committee on quality improvement initiatives?

Yes, and others as well such as Infection Prevention

The decrease in blood culture contamination rate provides proof of improvement of blood culture collection and a decrease in potential adverse patient events due to a clinician's response to the contaminated blood culture.

Collaboration between laboratories, pharmacists, infectious disease, and infection prevention departments establishes a unified front to ensure each patient is appropriately evaluated for septicemia and bacteremia, gaps in care are tracked and reported, and provides assurance of high-quality patient care.

[Response Ends]

4b.02. Explain any unexpected findings (positive or negative) during implementation of this measure, including unintended impacts on patients.

[Response Begins]

Were there any unexpected findings, positive or negative during implementation including unintended impacts on patients?

We hope that here was positive impact as a result of the reduction in blood culture contamination rates.

What were the challenges associated with implementing the contamination rate evaluation and reporting that your institution found as you participated in this Quality Improvement?

- Diverse group of individuals responsible for collecting samples.
 - Difficult to educate everyone.
 - Many misconceptions about how to draw blood cultures
 - Variety of antiseptics used for skin cleansing—no standardized approach to blood culture procurement
- Requirement to obtain specimens via lines for certain patient populations.
- High turnover of phlebotomists.
- Lack of leadership support to hire more phlebotomists.

[Response Ends]

4b.03. Explain any unexpected benefits realized from implementation of this measure.

[Response Begins]

Were there any unexpected benefits realized from implementation?

Heightened awareness of the problem.

Standardization of blood culture collection in an interdisciplinary practice manual.

Recognition of the value of trained phlebotomists and nursing champions.

Focus on this initiative led to other quality metrics such as improving blood culture utilization, focusing on units that have high rates of single draws, reduction in blood cultures obtained via lines.

[Response Ends]

Criteria 5: Related and Competing Measures

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

If you are updating a maintenance measure submission for the first time in MIMS, please note that the previous related and competing data appearing in question 5.03 may need to be entered in to 5.01 and 5.02, if the measures are NQF endorsed. Please review and update questions 5.01, 5.02, and 5.03 accordingly.

5.01. Search and select all NQF-endorsed related measures (conceptually, either same measure focus or target population).

(Can search and select measures.)

[Response Begins]

[Response Ends]

5.02. Search and select all NQF-endorsed competing measures (conceptually, the measures have both the same measure focus or target population).

(Can search and select measures.)

[Response Begins]

[Response Ends]

5.03. If there are related or competing measures to this measure, but they are not NQF-endorsed, please indicate the measure title and steward.

[Response Begins]

N/A

[Response Ends]

5.04. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s), indicate whether the measure specifications are harmonized to the extent possible.

[Response Begins]

No

[Response Ends]

5.05. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

[Response Begins]

N/A

[Response Ends]

5.06. Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality). Alternatively, justify endorsing an additional measure.

Provide analyses when possible.

[Response Begins]

N/A

[Response Ends]