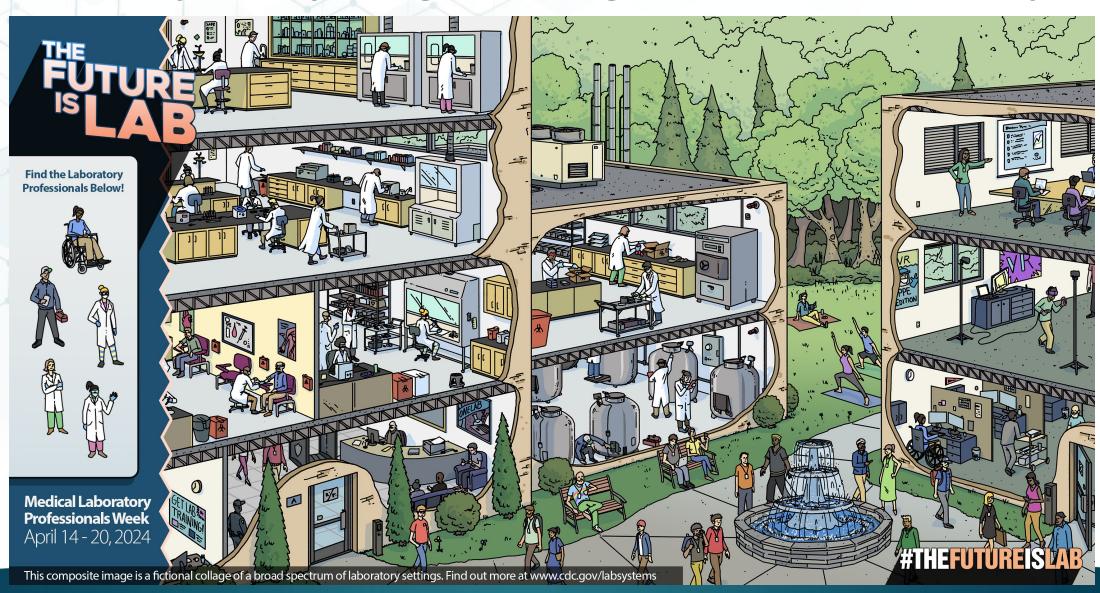
Thank you for joining, we'll begin the call momentarily.



Laboratory Outreach Communication System (LOCS) Call

Monday, July 15, 2024, at 3:00 P.M. ET

- Welcome
 - Sean Courtney, CDC Division of Laboratory Systems
- Situational Update and Response to the Highly Pathogenic Avian Influenza A(H5N1)
 Outbreak in U.S. Dairy Cattle
 - Todd Davis, CDC Influenza Division
- CDC Efforts to Expand Testing Capacity and Enhance Surveillance
 - Sean Courtney, CDC Division of Laboratory Systems
- BD Update
 - Chris Beddard, BD Life Sciences
- CDC Culture Quality Tools
 - Jake D. Bunn, CDC Division of Laboratory Systems
- Blood Culture Utilization
 - Valeria Fabre, Johns Hopkins University

About DLS



Four Goal Areas



Quality Laboratory Science

 Improve the quality and value of laboratory medicine for better health outcomes and public health surveillance



Highly Competent Laboratory Workforce

 Strengthen the laboratory workforce to support clinical and public health laboratory practice



Safe and Prepared Laboratories

 Enhance the safety and response capabilities of clinical and public health laboratories



Accessible and Usable Laboratory Data

 Increase access and use of laboratory data to support response, surveillance, and patient care

We Want to Hear From You!

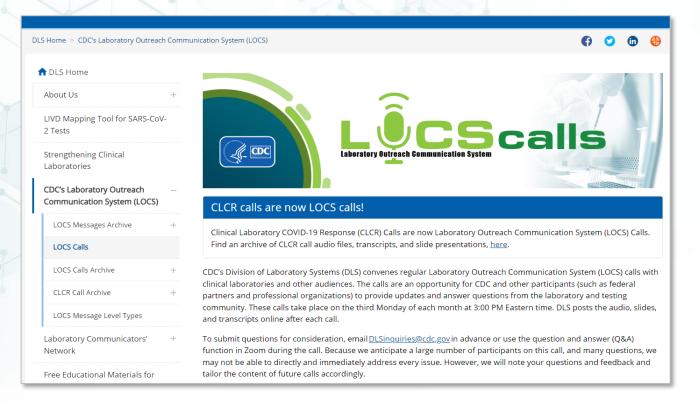
Training and Workforce Development

Questions about education and training?

Contact LabTrainingNeeds@cdc.gov



LOCS Calls



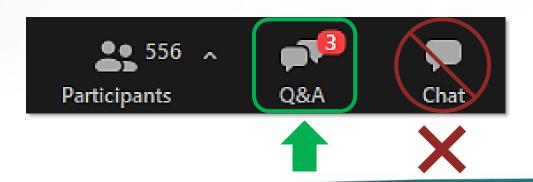
On this page, you can find:

- LOCS Call information
- Transcripts
- Slides
- Audio Recordings

https://www.cdc.gov/locs/calls

How to Ask a Question

- Using the Zoom Webinar System
 - Click the Q&A button in the Zoom webinar system
 - Type your question in the Q&A box and submit it
 - Please do not submit a question using the chat button



- For media questions, please contact
 CDC Media Relations at media@cdc.gov
- If you are a patient, please direct any questions to your healthcare provider

Division of Laboratory Systems

Slide decks may contain presentation material from panelists who are not affiliated with CDC. Presentation content from external panelists may not necessarily reflect CDC's official position on the topic(s) covered.



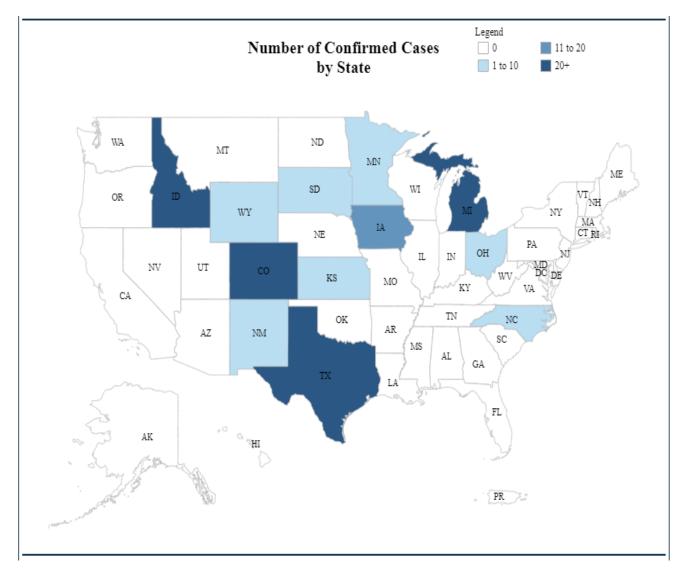
Situational Update and Response to the Highly Pathogenic Avian Influenza A(H5N1) Outbreak in U.S. Dairy Cattle

Todd Davis
Branch Chief (acting)
Virology, Surveillance and Diagnosis Branch
Influenza Division
National Center for Immunization and
Respiratory Diseases
Centers for Disease Control and Prevention



Cattle Outbreak Update

- As of July 11, 2024, USDA has confirmed HPAI in dairy herds in **145** farms across 12 states:
 - **CO (30)**, **IA (13)**, ID (27), KS (4), **MI (26)**, **MN (7)**, NC (1), NM (8), OH (1), SD (5), **TX (22)**, WY (1)
- Other animal species reported on dairy premises:
 - 5 wild birds (2 TX farms)
 - 14 cats (3 MI, 3 NM, 1 OH, 2 TX, 1 CO, 2 MN farms)
 - 2 racoons (1 NM, 1 MI)
 - 2 opossums (MI)



https://www.aphis.usda.gov/livestock-poultry-disease/avian/avian-influenza/hpai-detections

https://www.aphis.usda.gov/livestock-poultry-disease/avian/avian-influenza/hpaidetections/hpai-confirmed-cases-livestock



Monitoring of Exposed Persons

Monitoring Strategies

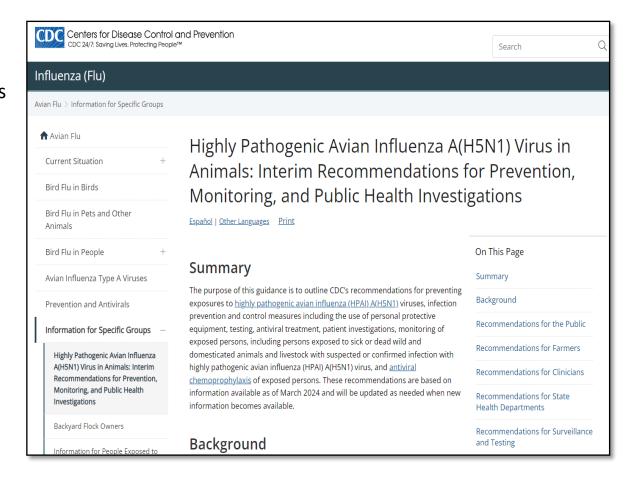
- Active outreach to states with positive cattle herds
- State public health labs perform monitoring of exposed individuals for symptoms and testing of symptomatic individuals
- Enhanced influenza surveillance
- Planned epidemiologic studies
- Since March 2024 >32,000 specimens have been tested at PHLs that would have detected A(H5) or other novel viruses.

Since Feb 2022 (bird exposure)

- CDC and state and local health departments actively monitor people exposed to infected birds, poultry or other animals for 10 days after exposure
 - At least 9,500 people monitored and
 - At least 350 people tested for novel influenza A

Current outbreak (cattle exposure)

- >1,390 people actively monitored
- Additional persons passively monitored
- States and CDC have tested >61 persons



How CDC is monitoring influenza data to better understand the current avian influenza A (H5N1) situation in people | Avian Influenza (Flu)



A(H5N1) Human Cases Associated with Dairy Cattle exposure

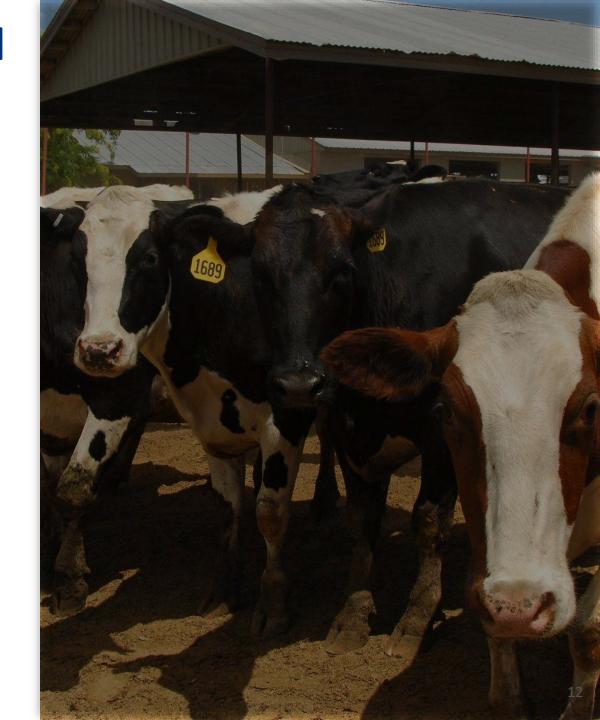
- April 1 Texas announced 1st human infection *
- May 22 Michigan announced 2nd human infection[†]
- May 30 Michigan announced 3rd human infection †
- July 3 Colorado announced 4th human infection#
 - Adults working at dairy farms and in contact with cows
 - 1st, 2nd and 4th cases reported conjunctivitis only, 3rd reported minor respiratory symptoms
 - All offered oseltamivir, mild illness and recovered without hospitalization
 - No human-to-human transmission



[†] Influenza A (H5N1) (michigan.gov)

[#] Colorado state health officials identify a human case of avian flu





Additional A(H5) cases confirmed following exposure on poultry farm in Colorado



Home > Health officials confirm human cases of avian flu in Colorado poultry workers

Health officials confirm human cases of avian flu in Colorado poultry workers

- Colorado Department of Public Health and Environment reporting a total of five human cases of avian influenza in workers responding to an avian influenza outbreak at a commercial egg layer operation on July 14th.
- CDC has confirmed four of the cases; one additional case is presumptive positive and pending confirmation at CDC.



A(H5N1) Human Case in Texas, 2024

Genetic sequencing of the viruses found in infected cattle and human sequence, indicate:

- B3.13 genotype:
 - PA, HA, NA and M gene segments from Eurasian wild bird lineages
 - PB2, PB1, NP and NS gene segments from American wild bird lineages.
- No known markers of resistance to approved antiviral drugs (PA, NA, M2)
- No impact of mutations to current CDC influenza diagnostic assays at U.S. and global public health laboratories' ability to detect H5N1 viruses
- Human virus sequenced (from the conjunctival sample and NP) had PB2 E627K mutation

Uyeki TM,... Davis CT. N Engl J Med. 2024 Jun 6;390(21):2028-2029.



<u>Technical Update: Summary Analysis of Genetic Sequences of Highly</u> Pathogenic Avian Influenza A(H5N1) Viruses in Texas (cdc.gov)

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24-009491-005-original
      A/feline/USA/24-009116-002-original/2024
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      A/trumpeter swan/Kansas/W23-928/2023
      A/peregrine falcon/California/24-005915-001-original/2024
```

1st human case of A(H5N1) from Michigan

- No amino acid changes were identified in the HA gene sequence from the Michigan patient specimen compared to the HA sequence from the case in Texas
- The genome of the human virus from Michigan did not have the PB2 E627K change detected in the virus from the Texas case
 - Notable change (PB2 M631L) compared to the Texas case that is known to be associated with viral adaptation to mammalian hosts
 - Detected in 99% of dairy cow sequences but only sporadically in birds
- Genome of A/Michigan/90/2024 was closely related to sequences detected in infected dairy cows
- Virus isolation successful.
- No markers known to be associated with influenza antiviral resistance found
- Virus is closely related to two existing HPAI A(H5N1) candidate vaccine viruses that are already available to manufacturers, and which could be used to make vaccine if needed.



A/Texas/37/2024 Technical Update: Summary Analysis of the Genetic Sequence of a Highly Pathogenic Avian Influenza A(H5N1) Virus Identified in a Human in Michigan | Avian Influenza (Flu) (cdc.gov) A/trumpeter swan/Kansas/W23-928/2023

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24-009491-005-original S19 L001
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                   24-013789-002-original S5
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     A/turkey/South Dakota/23-036898-001-original/2023
          A/skunk/New Mexico/24-006483-001-original/2024
               A/peregrine falcon/California/24-005915-001-original/2024
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2nd human case of A(H5N1) from Michigan

- Partial HA and full-length NA of the viral RNA from the 2nd case from Michigan
- Virus isolation unsuccessful
- No changes in the receptor binding domain that would impact infectivity or transmissibility between humans (i.e., no changes associated with receptor binding specificity; virus remains fully avian).
 - No HA changes identified in antigenic sites that would impact CVV cross-protection.
 - NA sequence confirms no changes associated with reduced antiviral susceptibility.

A(H5N1) case detected in Colorado

- Genetic sequencing was not possible due to low viral load in sample
- Virus isolation unsuccessful



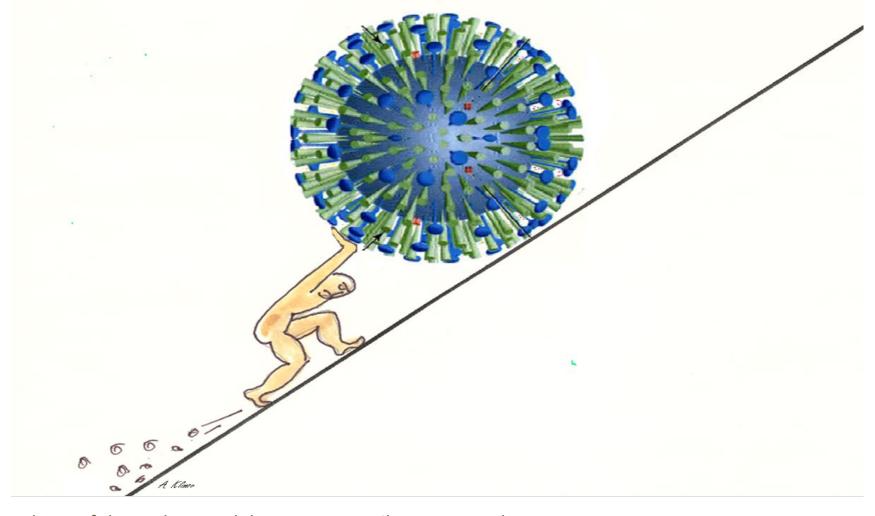
Diagnostic testing

- FDA granted enforcement discretion for the use of conjunctival swabs with the CDC Human Influenza Virus Real-Time RT-PCR
 Diagnostic Panel, Influenza A/H5 Subtyping Kit
 - <u>05/31/2024</u>: Lab Advisory: Enforcement Discretion Granted for the Use of Conjunctival Swabs with the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel, Influenza A/H5 Subtyping Kit
 - Extended to November 1st
- Completed recommendations/protocol for conjunctival sample collection methods for healthcare providers
 - Produced a Desk Reference Graphic (i.e., Job-Aid) describing the procedure for collecting and transporting conjunctival specimens for H5N1 testing in a patient with conjunctivitis and suspected H5N1 infection.
 - Conjunctival Swab Specimen Collection for Detection of Avian Influenza A(H5) Viruses (cdc.gov)
 - Detailed protocol distributed to partners via CDC and APHL
- Universal Transport Media being added to the Instructions for Use of CDC's A/H5
 - Allow samples in this collection media to be tested using the CDC A/H5 assay



Thank you!

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



The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



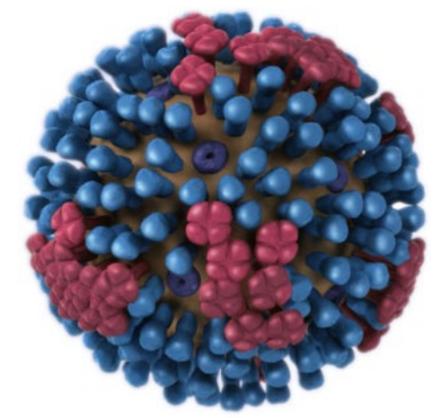
U.S. Centers for Disease Control and Prevention



CDC Efforts to Expand Influenza Testing Capacity and Enhance Surveillance

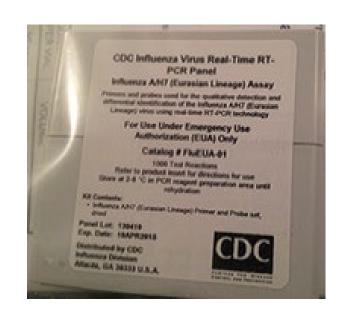
Sean Courtney, PhD
CDC Division of Laboratory Systems

July 15, 2024 LOCS Call



Strategies to Improve Readiness and Testing Capacity

- Engagement with laboratories and industry partners to gauge interest in test development and validation studies
- CDC offers royalty free access to influenza A(H5) diagnostic test assay
 - Available since 2023
- CDC working with the Association of Public Health Laboratories (APHL) and the American Clinical Laboratory Association (ACLA) to disseminate information to laboratories



Royalty Free Licensing Agreements

- CDC Influenza A(H5) diagnostic assay design
- 15 agreements in progress with industry partners and commercial laboratories

Status	Number of Laboratories
Signed and executed agreements	8
Pending	3
In progress	4

Development of an Influenza A(H5) Test Utilizing CDC Assay Design

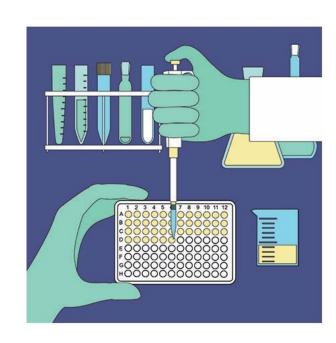
- Manufacturing companies can design, validate, submit, or pre-position for submission to FDA
- Engagement with companies to discuss assay designs
 - Molecular, multiplex, and rapid testing





Manufacturing Non-Virulent Control Material

- Test development requires validation studies
 - Control material needed for studies
- Wild type virus and Candidate Vaccine Viruses (CVVs)
 used as control material require USDA permits to
 receive material and BSL-3+ (wt) or BSL-2+ (CVV)
 biosafety labs to handle infectious virus
- CDC developing alternative positive control material (BPL or gamma irradiated) inactivated influenza viruses to distribute
 - Would **not** require USDA permit or enhanced biocontainment to handle



CDC Call to Industry

- Primary Challenge: Influenza A(H5) subtyping tests only available at CDC and within state/local PHL networks
 - Lack of access to testing in clinics/hospital networks may lead to delayed diagnosis of influenza A(H5)
 - Testing demand may exceed capacity/slow PH response if H5 epidemiology were to change in the future
- Open call for innovative solutions to meet the CDC's diagnostic test development needs
- Competitive process for test developers to potentially obtain funding from CDC
 - Develop, validate, manufacture test
 - Apply to FDA for regulatory approval and if approval is obtained to distribute test for influenza A(H5)
- Concept papers under review
 - Anticipate award contract(s) by the end of August 2024

Enhanced Summer Influenza Surveillance Strategy

- Enhance surveillance in summer months
 - Encourage ongoing influenza testing
 - Novel influenza A detection by subtyping Flu A specimens
 - Maintain flow of influenza positive specimens
 - Monitor data for any unexpected patterns
- Updated guidance for submission criteria published on May 31, 2024
- Commercial laboratories submit Flu A and B positive samples to public

health laboratories

Flu A positive, subtype negative	Yes
Flu A positive, subtype A(H1)	Yes
Flu A positive, subtype A(H1)pdm09	No

Thank you!



Disclaimer

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the U. S. Centers for Disease Control and Prevention.



Division of Laboratory Systems

BD Update

Chris Beddard
BD Life Sciences



Division of Laboratory Systems

CDC Update Blood Culture Quality Tools

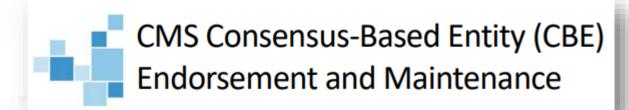
Jake D. Bunn, MBA, MLS(ASCP)^{CM}, LSSBB Clinical Laboratory Scientist

Division of Laboratory Scientist

Quality and Safety Systems Branch



National Patient Safety Measure



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

CBE ID: 3658 Steward: Centers for Disease Control and Prevention Status: Endorsed Status Last Updated: 12 December, 2022

https://p4qm.org/measures/3658

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

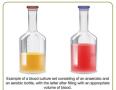


Blood Culture Contamination: An Overview for Infection Control and Antibiotic Stewardship Programs Working with the Clinical Laboratory (cdc.gov)

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

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

Blood cultures are important diagnostic tools for identifying the pathogen(s) responsible for a patient's infection. This is especially true of patients with suspected sepsis or septic shock and for patients with suspected infective endocarditis1,2. When indicated blood cultures should be obtained prior to starting antimicrobial therapy1.2. A conventional blood culture set consists of an aerobic and an anaerobic bottle. For adults, 20-30 mL of blood per venipuncture (depending on the instrument manufacturer) is recommended and may require >2 bottles depending on the system2. At least two blood culture sets should be obtained within a few hours of each other via peripheral venipuncture when obtaining blood cultures for a total volume of 40-60 mL of blood to optimize detection of pathogens2, The College of American Pathologists laboratory accreditation program states that clinical laboratories have a written policy and procedure for monitoring



blood cultures from adults for adequate volume and provide feedback on the results to the collectors3. Moreover the monitoring and reporting of blood culture contamination rates is a laboratory quality best practice4

Because blood is a normally sterile body site, positive blood cultures with a known pathogen have a generally overall high positive predictive value for infection. However, blood culture contamination is a significant problem In the era of modern blood culturing techniques, virtually all blood culture contamination occurs during collection the source of contaminants is usually the patient's skin or the hub or cannula of an indwelling catheter (i.e., when an existing catheter is used to obtain the specimen). Frequent causes include poor collection technique and insufficient skin disinfection. Typical organisms include coagulase-negative staphylococci, Corynebacterium spp., Bacillus spp. other than Bacillus anthracis, Micrococcus spp., and Cutibacterium acres among others Consequences include unnecessary antibiotic exposure with the potential for downstream unintended consequences (e.g., possible allergic reactions and Clostridioides difficile infection)⁵. Other possible consequences include the unnecessary removal of intravenous catheters or other devices, an increased length of stay, and increased costs⁵. One study found that the average length of stay was 2 days longer in patients with contaminated blood cultures compared to patients with negative cultures. That same study found that direct and indirect hospital costs of a contaminated blood culture were \$12,824 compared to \$8,286 for a negative blood culture (savings of



drawn within 24 hours of the positive one is negative

Using Blood Culture Contamination Rate for Quality Improvement

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

An in-depth discussion of the ways to address the problem of the blood culture contamination can be ound in the review article by Doern et al.5. A summary

Full article here.

Clinicians should strive to obtain blood cultures for the right patients, in the right settings, and at the right time. Blood cultures can be both underused and overused. An example of underuse would antibiotics for a patient with suspected sepsis. antibiotics, it can be more difficult to appropriate de-escalate antibiotic therapy given that the causative organism is more likely to remain unknown. Also, blood cultures can be underused it the appropriate volume is less than recommended (i.e., two to three 20 mL volumes of blood during initial evaluation of the patient for bacteremia as this can decrease the sensitivity for pathoger detection. Cultures can also be overused: for example, obtaining repeat cultures in a patient with fever for whom an alternative diagnosis other than bloodstream infection is much more likely. In patients with a very low pretest probability of likely to represent contamination than infection.

2 Proper Skin Antisensis

Improper skin antisepsis can lead to increases in blood culture contamination rates. It is alcohol containing disinfectant and allowed to dry prior to drawing blood cultures

Blood Culture Bottle Disinfection the blood culture bottle tops prior to inoculatio

ith lower rates of blood culture tral venous catheters7. Thus, wn blood cultures are preferred drawn cultures except when the theter-associated bloodstrea pected². In these cases, both atheter draws are indicated

ith patients and donning gloves prior lood cultures.

drawn by phlebotomy teams are

nonstrated that providing contamination rates can decrease amination rates^{9, 10} Antibiotic ograms can also consider tracking the impact of contamination rates

n promise in further reducing nination rates. These devices small amount of potentially lood and then collect blood for

nsiderations for Tracking ing Blood Culture ion Events

ardship and infection prevention ald meet with laboratory personnel tracking and reporting of blood

· Understand locations in the facility where commonly, the type of staff who collect blood

Review with the laboratory staff the blood culture collection procedures used in the facility and the training received by those responsible for collecting blood cultures

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

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- Miller JM, Binnicker MJ, Campbell S, Carroll KC, Chapin KC
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- Skoglund E, Dempsey CJ, Chen H, Garey KW. 2020. Estimated Clinical and Economic Impact through Use of a Novel Blood Collection Device To Reduce Blood Culture
- . Snyder SR, Favoretto AM, Baetz RA, Derzon JH, Madison BN veternatic review and meta-analysis Clin Riochem 45: 999-101:
- 8. Boyce JM, Pittet D, Healthcare Infection Control Practices Force. 2002. Guideline for Hand Hygiene in Health-Care Setting endations of the Healthcare Infection Control Practices Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygier
- 7immerman FS Accrus MV Vinnon AM Wiener, Well V 2018
- 10. Youssef D. Shams W. Bailey B. O'Neil TJ. Al-Abbadi MA 2012. Effective strategy for decreasing blood culture

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



<u>Preventing Adult Blood Culture Contamination: A</u>

<u>Quality Tool for Clinical Laboratory Professionals | CDC</u>

CDC Division of Laboratory Systems

EXCELLENT LABORATORIES, OUTSTANDING HEALTH

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



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

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

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

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

Follow CLIA Regulations

"Laboratory Requirements," Code of Federal Regulations, Title 32 (2023): Chapter IV, Part 493

Subpart K - Quality System for Non-Waived Testing – 5 493.1249 Standard: Preanalytic systems quality assessment.

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated,

correct problems identified in the preanalytic systems specified at §§ 493.1241 through 493.1242.

Collecting Adult Blood Culture Sets

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

Collect Multiple Sets to Achieve the Optimal Volume

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

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

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



https://www.cdc.gov/nhsn/xls/master -organism-com-commensals-lists.xlsx Overview of BCC Measure

Applicable CLIA Regulations

CLIA Law & Regulations (cdc.gov)

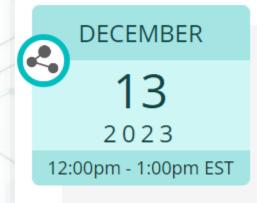
Critical Steps to include in SOPs

Calculations for BCC and Single-Sets

Info on how to classify microorganisms using the NHSN Common Commensals List Suggested nudges to inform clinicians of low blood volume and BCC



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



Past Event

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

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



https://youtu.be/tkAl4_wmLcw

FDA Updates



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

<u>Disruptions in Availability of BD BACTEC Blood Culture Media Bottles -</u> <u>Letter to Health Care Providers | FDA - July 10, 2024</u>

Medical Device Shortages List

Medical Device Shortages List | FDA – July 10, 2024

Category \$	Product Code (Description) \$	Availability and Estimated Shortage Duration	Additional Information \$	Reason for Interruption (per 506J)	Date (YYYY/MM/DD) 🕶
Microbiology - Microbiology Devices	MDB (System, Blood Culturing)	Estimated through Q4 2024	To provide recommendations to health care providers and laboratories that use blood culture media bottles intended for bloodstream infection testing, the FDA is providing a MDB Shortage - Letter to Health Care Providers.	Shortage or discontinuance of a component, part or accessory of the device.	2024/07/10 Initial

Take Home Messages

Those who collect blood cultures should be:

- Performing routine disinfection prior to collection to minimize the risk of contamination of the blood culture and the need to recollect additional blood cultures.
- Ensuring proper blood volume collection to avoid a need to recollect additional blood cultures.

Questions?





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

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Blood Culture Stewardship Opportunities

Valeria Fabre, MD
Associate Professor of Medicine
Division of Infectious Disease
Johns Hopkins University School
of Medicine

Aaron Milstone, MD MHS
Professor of Pediatrics
Division of Infectious Disease
Johns Hopkins University
School of Medicine

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- The content of this presentation is solely the responsibility of the speakers and does not represent the official view of any funding agency

Opportunities to improve inpatient blood culture (BCx) utilization

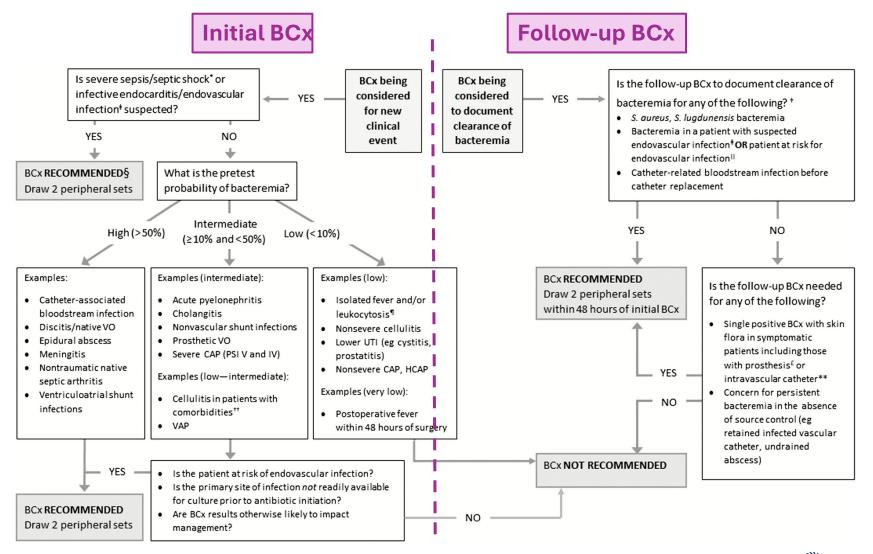
• >90% of BCx obtained from inpatients are negative



ng

- Based on an evidence-based algorithm (next slide), 30% of BCx in a medical ICU and 50% of BCx in medicine floors at a tertiary hospital in Baltimore were inappropriate
 - 60% of BCx in the ICU at a tertiary center in NYC
 - 40% of BCx in a Swiss hospital
 - 25% of BCx in a SICU at a tertiary hospital in North Carolina
- In 40-80% of BCx the appropriate volume is not collected
- ~20% of bacteremia cases were missed due to lack of anaerobic BCx, single sets, or inappropriate patient selection in a national study of BCx practices in Israel

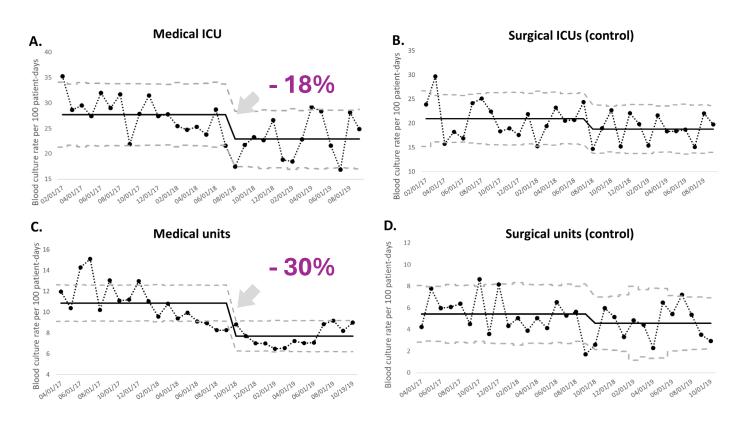
Algorithm for bacterial blood cultures recommendations in non-neutropenic (adult) patients.





Implementation of a BCx algorithm to reduce unnecessary BCx in adult medicine units

- Education on BCx indications & collection best practices to ordering providers
- Implementation of the evidence-based BCx algorithm to guide BCx decisions (paper-based)
- Regular feedback regarding BCx utilization rates, and examples of inappropriate BCx



- Reduction of single sets in medicine floors
- Increase in BCx positivity in ICU
- No impact on Sep-1 measure, readmission, or mortality

Other hospitals have implemented the BCx algorithm (adult surgical ICUs at Duke¹, MICU and SICU at Baylor²) and have observed a 20-70% relative reduction in BCx utilization without safety concerns (readmission, length of stay, or 30-day mortality)

Opportunities to improve inpatient BCx utilization: Units with high BCx utilization

Hospital University of Pennsylavania (2015) –excluded BCx drawn in the ED for patients not admitted to the hospital-

- General medicine 51.1%
- Oncology 25.9%
- Intensive care unit 19.0%
- Surgery 18.4%
- Transplant 2.8%
- Emergency 1.8%

Delphi consensus recommendations for BCx in critically ill children

Consensus recommendations (R1-R19; see text) for blood culture use in critically ill children without signs of sepsis¹²

"To Do" before blood culture decision:

- R1: Review the clinical data (e.g., vital signs, laboratory/imaging, urine output, recent cultures, antimicrobial therapy)
- R2: Examine the patient
- R3: Discuss the patient's clinical status with the bedside nurse

Do NOT:

- R7: Draw blood cultures from peripheral IVs
- R8: Obtain blood culture for NEW fever within 24 hours of surgery and with no signs of sepsis; WITH or WITHOUT a CVC in place

In ASYMPTOMATIC patients, avoid blood cultures:

- R4: For surveillance (e.g., daily screening blood cultures). In particular:
 - R4a: on ECMO
 - R4h: on CRRT
- R4c: in the immunocompromised WITH or WITHOUT CVC R5: In patients who have inadvertent CVC disconnection.
- R6: In patients who have a broken or cracked CVC



http://HopkinsChildrens.org/brightstar

Fever without signs of sepsis **New Fever Immunocompromised** Immunocompetent Consider blood culture Avoid blood cultures for: Without CVC: R9: Patients with a viral syndrome (e.g., bronchiolitis) R12: Patients with symptoms of withdrawal while undergoing wean of sedative/opioid infusions With CVC: R16: Patients with symptoms of withdrawal during sedative/opioid wean who also defervesce in response to treatment for withdrawal

negative blood cultures

With CVC, consideration of culture source:

R17: If a recent set of blood cultures from the CVC is no growth to date, then subsequent cultures, if indicated, do not need to be drawn from the CVC

R15: For suspected non-infectious etiology of fever and with initial set of

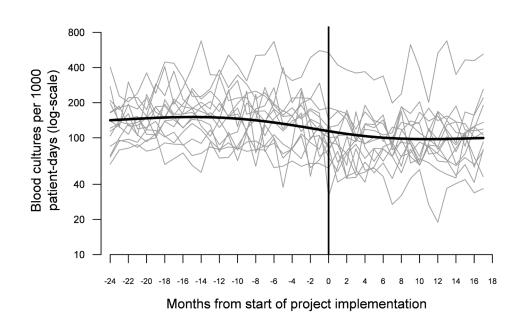
Yes **Persistent Fever** Immunocompetent Immunocompromised Avoid blood cultures for: Avoid blood cultures for: R18: Patients in whom you do not plan R10: Patients with a viral syndrome (e.g., bronchiolitis), PERSISTENT to change/broaden the current fever within expected time course for viral infection antimicrobial regimen; and multiple prior cultures were negative R11: Patients with localized bacterial source of infection (e.g., urinary tract infection), PERSISTENT and expected fever, and at least one R19: Avoid repeatedly culturing more negative blood culture obtained since the start of fever than one lumen of CVC if initial cultures from CVC were negative R13: Same as #10, if negative blood culture obtained since start of fever R14: Same as #11, if negative blood culture obtained within the last 48

Woods-Hill CZ, et al. Consensus Recommendations for Blood Culture Use in Critically Ill Children Using a Modified Delphi Approach. Pediatr Crit Care Med. 2021 Apr 23.

²see Weiss et al. Surviving Sepsis Campaign International Guidelines 2020

1see executive summary for detailed recommendations

BrighT STAR results: blood cultures



33% relative reduction in BCx rate (95% CI: 26-39%)

- 36% relative reduction in CLABSI rate (95% CI: 20-49%)
- <u>13%</u> relative reduction in broad-spectrum antibiotic use*
- No difference in mortality, PICU readmission, PICU length of stay before and after the intervention
- No difference in the number of sepsis, severe sepsis/septic shock cases before and after the intervention

^{*}Days of broad-spectrum antibiotics for PICU days ≥ 3

Summary

 BCx stewardship interventions have shown to safely reduce overall BCx use, while improving its utilization. This is a great opportunity to introduce BCx stewardship in your institutions and sustain it once the BCx bottle shortage subsides

- Microbiologists and Antibiotic stewardship/HEIC teams must work together to develop an appropriate BCx stewardship plan adapted to their current and anticipated BCx bottle supply
 - Implement guidance on appropriate indications with focus on reducing low yield BCx (include in local guidelines, educate ordering providers)
 - Implement EHR modifications
 - Implement prior-authorization

Summary: Low-yield BCx in adult inpatients

LOW-YIELD INITIAL BLOOD CULTURES

- Non-severe CAP
- Post-op fever within 48hs
- Isolated fever
- Isolated leukocytosis
- Persistent fever without clinical change and negative blood cultures in last 48-72 hours
- Persistent leukocytosis without clinical change and negative blood cultures in last 48-72 hours
- Non-severe CAP
- Non-severe cellulitis
- Post-operative fever within 48hs from surgery
- Lower UTI (cystitis, prostatitis)
- Surveillance blood cultures (e.g., before procedures, line placement, TPN initiation, etc.) in patients without suspicion for bacteremia

LOW-YIELD FOLLOW-UP BLOOD CULTURES

- Repeat blood cultures to document clearance of bacteremia caused by organisms other than Staphylococcus aureus, Staphylococcus lugdunensis, or Candida in patients without infective endocarditis/endovascular infection (e.g., cardiac device infection, septic thrombophlebitis) who showed clinical response and source control has been achieved
- Repeat blood cultures to rule out blood culture contamination in immunocompetent patients without prosthetic implants

SUGGESTED STRATEGIES TO CONSERVE BCx BOTTLES

- ✓ Meet with the Clinical Microbiology Laboratory to discuss current and expected BCx bottle supplies
- ✓ Identify clinical areas/units with highest BCx utilization.
- ✓ Target high-use areas for education first
- ✓ Consider a stepwise approach to conserve BCx bottles based on anticipated supply reduction.
- ✓ Prioritize reducing low-yield BCx first (expected reduction ~40% -70% depending on local practices)
- ✓ Meet with EHR to discuss implementation of electronic decision support tools to optimize BCx orders.
 - Make most recent BCx results available upon clicking on a new BCx order
 - Hard-stops for repeat BCx
 - Include a link to the BCx algorithm or list low-yield indications to deter clinicians from ordering unnecessary BCx
 - Critically review order sets that contain blood cultures and remove blood cultures from order sets for conditions with low risk of bacteremia

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Monday, August 19 3 PM - 4 PM ET



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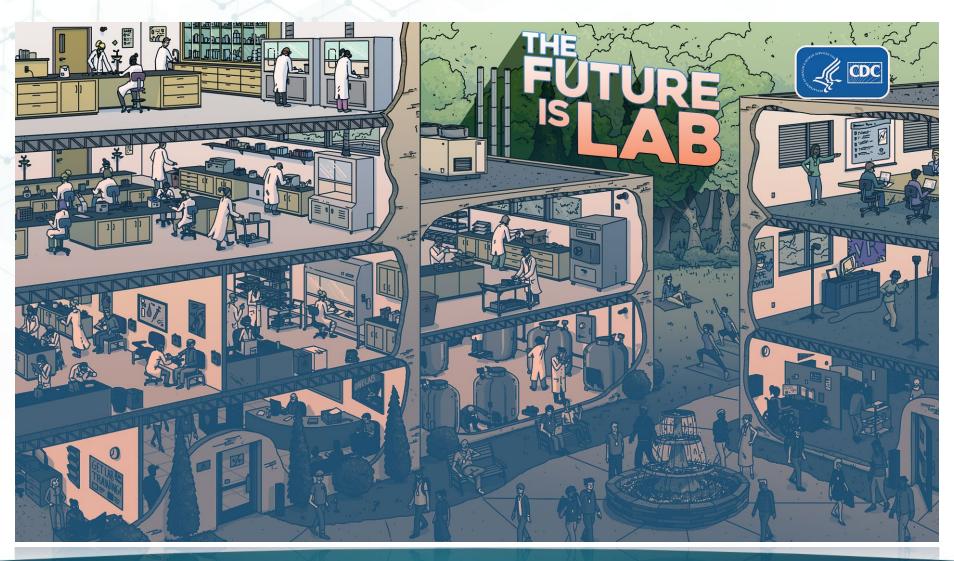
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Thank You For Your Time!





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