Pre and Post Analytic Laboratory Testing Processes and Diagnostic Quality

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Centers for Disease Control and Prevention

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HAS NO DISCLOSURES.

CDC's Division of Laboratory Systems

US Clinical Laboratory Community

260,000

LABORATORIES IN USA

13.8 BILLION

tests per year

That's over 42 tests per year for every person living in the United States

Lab Personnel 800,000

Laboratory Medicine Best Practices Initiative (LMBP)

The Centers for Disease Control and Prevention's (CDC) Division of Laboratory Systems (DLS) has sponsored the Laboratory Medicine Best Practices (LMBP) Initiative to address the need for an evidence based, systematic, multidisciplinary, comprehensive, and transparent approach to identifying, evaluating, and recommending best practices for the field.

LMBP Aims

- Develop and apply transparent evidence-based methods for reviewing quality improvement practices
- Conduct systematic reviews to assess the effectiveness of quality improvement practices
- Provide a central source of information on the comparative effectiveness of laboratory medicine practices
- Facilitate a network for the exchange of information on effective laboratory practices

LMBP: Total Laboratory Testing Process

- Traditionally divided into 3 phases: preanalytic, analytic and postanalytic
- Analytic phase errors account for 7 to 13% of errors
- Preanalytic phase errors 46 to 68.2%
- Postanalytic phase errors 18.5 to 47%

Why Apply Evidence-based Decision Making in Laboratory Medicine

- Existing approaches do not apply to laboratory medicine quality improvement practices;
  - Published literature is limited
  - Laboratory practices vary widely

To address these issues LMBP systematic evidence reviews include the collection of unpublished data (gray data) from quality improvement projects

Using Evidence to Evaluate Practice Effectiveness

- Determine “What Works”
- Improve patient care and outcomes
- Inform decision-making
- Promote transparency & accountability
- Demonstrates “gaps” in evidence that need to be addressed with additional studies

Laboratory Medicine Best Practices Initiative (LMBP)

- Focus on Preanalytic and Postanalytic processes
- Evidence based research methods modified for laboratory use
- 11 systematic reviews (SR) now published
- American Society for Microbiology (ASM) using LMBP method
  - Urine preanalytic practices
  - C. diff algorithms SR pending publication
  - 2 updates in progress
    - Blood Culture Contamination Practices
    - Blood Stream Infection Practices To Increase Timeliness of targeted therapy

https://www.cdc.gov/labbestpractices/our-findings.html

LMBP; EFFECTIVENESS OF PRACTICES TO SUPPORT APPROPRIATE LABORATORY TEST UTILIZATION SYSTEMATIC REVIEW AND META-ANALYSIS

https://www.cdc.gov/labbestpractices/ourfindings.html

Practices to Support Appropriate Laboratory Test Utilization SR

- To Evaluate the effectiveness of 8 practices used to support appropriate clinical laboratory test utilization, both over/under utilization
  - Computerized provider order entry (CPOE)
  - Clinical decision support systems/tools
  - Education, Feedback, Test Review, Reflex testing
  - Laboratory Test Utilization (LTU) teams
  - Combination of above practices

Practices to Support Appropriate Laboratory Test Utilization SR

- 23,231 bibliographic records; 83 studies included
- 32 could not be meta-analyzed due to absence of necessary information such as standard deviation
- 51 studies included but only addressed overutilization

Practices to Support Appropriate Laboratory Test Utilization SR

- Best practices evidence supports appropriate clinical lab test utilization tools to include *CPOE with modifications*, *Reflex testing*, Combined practices
- Due to insufficient evidence (publications) practice evaluation could not be conducted for; Clinical decision support tools, Education, Feedback, Test Review and Lab Test Utilization teams (LTU)
- Diagnostic Management Teams (DMT) not included SR, newer concept, studies not available

Practices to Support Appropriate Laboratory Test Utilization SR

- Limitations of this study
  - Lack of QA unpublished (gray) data (publication bias)
  - Limited number of good quality studies due to incomplete reporting by authors
  - Considerable variation across studies in measures used to determine the presence of inappropriate lab test utilization
  - Impact of testing utilization on patient outcomes is challenging as data linking lab to outcomes is sparse
  - Only one study examined underutilization

LTU Teams; Studies Needed

- *Laboratory Test Utilization Team*:
  - Definition: multi-displinary task force providing recommendations on systematic efforts within a healthcare organization, guidance on setting standards/expectations for lab testing, introduction of new tests and elimination of testing and/or promoting and monitoring uptake of mechanisms to support appropriate test utilization
  - **Studies needed that evaluate the inclusion of LTU teams in hospitals and healthcare systems and their effect on diagnostic quality and patient outcomes**
  - Other terms for LTU teams being used are clinical lab utilization committees, clinical lab advisory committees, lab diagnostic committee, Laboratory stewardship committee

DMTs; Studies Needed

- *Diagnostic Management Team (DMT):*
  - Definition: expert, multidisciplinary consult services and support to providers in the diagnostic pathway, guiding individual diagnostic evaluations and interpretations in real-time, through aggregation of clinical information and laboratory test information and generation of patient-specific narratives - Per Dr. Mike Laposata, University of Texas Medical Branch
  - **Studies needed that evaluate the inclusion of DMT in hospitals and healthcare systems and their effect on diagnostic quality and patient outcomes**
  - CDC DLS is collaborating with Dr. Mike Laposata to do an evaluation of DMTs related to diagnostic quality

EFFECTIVENESS OF PREANALYTIC PRACTICES ON CONTAMINATION AND DIAGNOSTIC ACCURACY OF URINE CULTURES: LMBP SYSTEMATIC REVIEW AND META-ANALYSIS

http://www.cdc.gov/labbestpractices/ourfindings.html

Urine Cultures: Preanalytic Issues

- Urine cultures are one of most common cultures ordered and performed in microbiology laboratory
- Laboratory personnel often unaware of whether patient has UTI signs/symptoms or conditions of specimen collection and transport
- Unjustified ordering/improper collection of urine for urinalysis or culture and subsequent work up/reporting of results often leads to adverse healthcare events, increased cost, overtreatment, increased Abx resistance and C. diff infection

Urine Cultures: Preanalytic Issues SR

- Jan 2016 ASM published a LMBP systematic review and meta-analysis on Effectiveness of Pre-analytic practices on Contamination and Diagnostic Accuracy of Urine Cultures
- Literature search covered years 1965-2014
- 5,088 papers, only 35 papers met inclusion criteria
- Lack of recent high quality studies

Urine Cultures: Preanalytic Issues SR

- QI review question: Are there preanalytic practices related to the collection, storage, preservation, and transport of urine for microbiological culture that improve the diagnosis and management of patients with urinary tract infections?

- Quality Problem: Misdiagnosis of UTI's from false positive/false negative culture results due to poor specimen collection and handling leads to inappropriate treatment, patient harm and wasted resources
  - Eight practices assessed

- False positive rates of 15-42% (College of American Pathology Q probe data)

Urine Cultures: Preanalytic Issues SR

- Large number of studies had small sample sizes
- Various and unclear definitions of contamination
- Missing data in many cases
- Study settings varied and results may not be generalizable; adolescent health clinic versus long term care facility

ASM Systematic Review (SR) Recommendations

- Midstream urine collection from women with cleansing
- Midstream urine collection from men with cleansing
- Midstream urine collection from children with cleansing

Systematic Review-Not Recommended

- First Void Urine in men
- Midstream urine collection in children without cleansing
- Urine collection from children with sterile urine bags and/or from diapers

SR-No Recommendations for or against due to insufficient evidence

- Delayed processing of urine stored at room temp vs refrigeration vs boric acid
- Midstream urine collection in woman or men without cleansing
- Midstream urine collection vs straight cath in women

SR-No Recommendations for or against due to insufficient evidence

- Midstream urine collection from men vs collection by straight catheterization or suprapubic aspiration

- Midstream urine collection from children vs collection by straight catheterization or suprapubic aspiration

Urgent Need for Additional Studies

- ASM has tracked the literature on preanalytic practices for urine cultures since 2014 and there are few evidence based studies being published
- To encourage additional studies, the ASM Systematic Review contains a data collection form and instructions for its use (Appendix 2) to guide future QI projects on preanalytic practices associated with urine cultures in order to make best practice recommendations in future SR

Urine Cultures: pre/post analytic issues

- Recent Systematic review focused on inappropriate Antibiotic treatment of patients without signs/symptoms of UTI with positive urine cultures (Flokas, 2017)
  - Rate of inappropriate Abx treatment ranged from 17.78 to 76.67% (pooled rate 45%)
    - Similar rates in USA, Canada and Europe
  - Population studied: Adults >18, inpatients, outpatients, ED and nursing home residents, 5 studies reported presence of urinary catheters
    - Overtreatment associated with female sex, Urine culture with higher microbial count, + nitrates, + pyuria + gram neg bacteria
  - 8 studies implemented *Urine Culture Abx Stewardship interventions* to reduce Abx treatment with up to an 80% reduction in inappropriate management.
    - Included *education* about existing clinical guidelines and natural history of asymptomatic bacteriuria (ASB) diagnostic/therapeutic pitfalls associated with differentiating ASB from UTI AND/OR organizational inventions

Urine Culture Antimicrobial Stewardship Strategies

- Introduction of requirement that physician should contact microbiology lab by phone in order to acquire the results of urine cultures worked in 2 institutions with a 37% and a 75% decrease in prescribing abx, respectively (Flokas, 2017)
- One Australian Antimicrobial Stewardship 2018 Program suggests:
  - Not performing urine cultures if no signs or symptoms of infection
  - Recommending non-antibiotic management of UTI in women with mild to moderate symptoms or when urinary catheter in place
  - Withholding antimicrobial susceptibility results on culture positive urines from non- catheterized patients with comment that most of these results represent asymptomatic bacteriuria

Urine Culture Antimicrobial Stewardship Ideas

- EHR data contains patient signs and symptoms or lack thereof, consider institutional development of a combined report (*electronic tracking tool*) which pulls together patient signs/symptoms, urinalysis, urine culture results.
  - Signs/symptoms to consider: dysuria, urgency, frequency, suprapubic pain
- LAB receives EHR tracking tool data of UTI signs/symptoms when urine culture ordered, consider no work up of urine culture if patient does not have UTI signs/symptoms
- Add interpretative comments to report to explain findings of tests such as specimen quality (epithelial cells present indicates superficial contamination….)

Other Issues-What Can We Do?

- Practice of using urinalysis/microscopic results to reflex to urine culture could be standardized and studied across institutions and populations to collect data which support practice, if effective. Insufficient data exists at present to make recommendation
  - Dipstick results reported to be insufficiently sensitive for detection of UTI
  - Detection of bacteria by flow cytometry highly variable in sensitivity and specificity
  - What levels of WBCs indicate significant pyuria?
  - What levels of epithelial cells indicate contamination?
  - Urine gram stain- requires skill in reading gram stains and is labor intensive

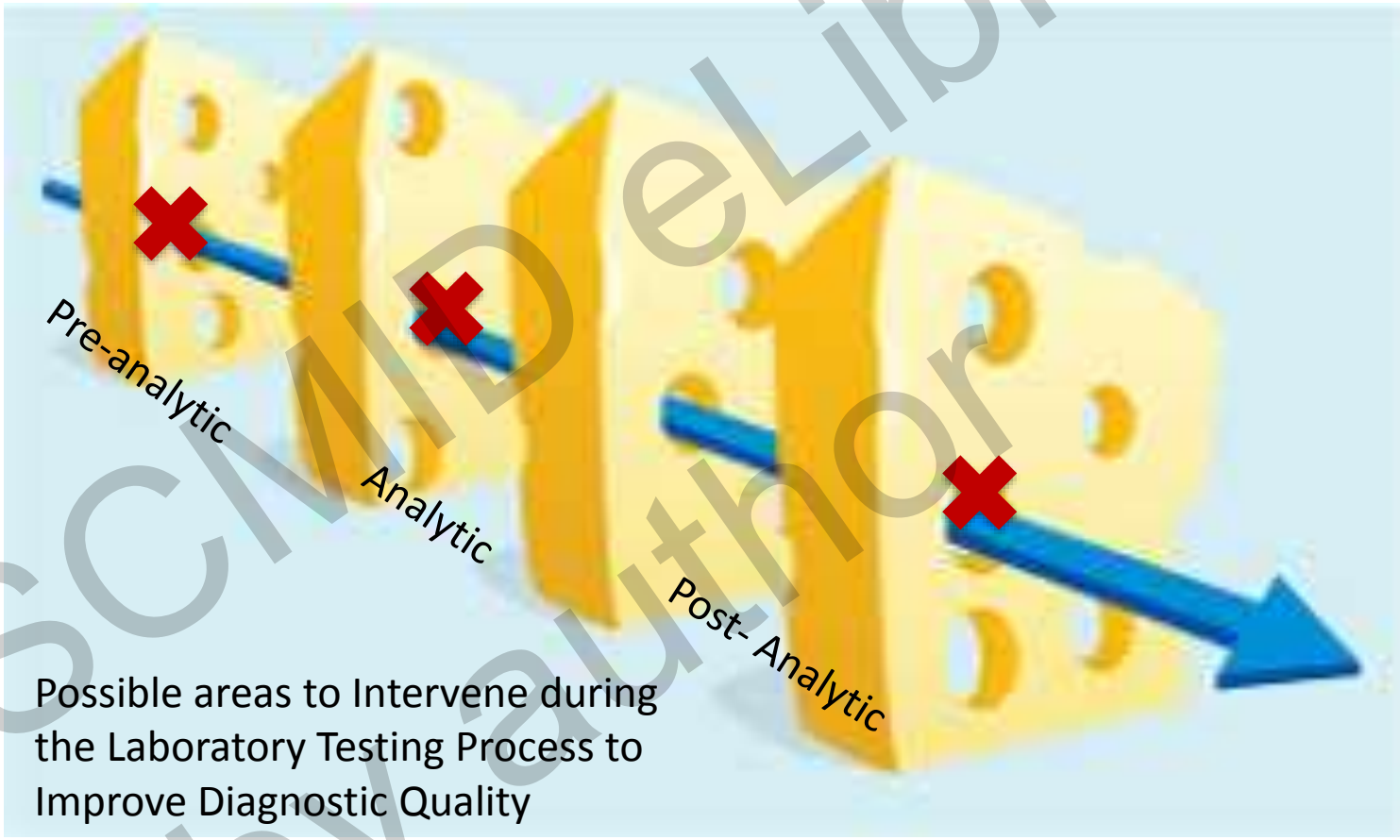
ASM C. *difficile* Systematic Review

- ASM led LMBP systematic review and meta-analysis of algorithms that include nucleic acid amplification tests (NAAT) for the diagnosis of C. *difficile;* in press
  - Significant limitation of evidence base was the failure to incorporate preanalytic parameters and clinical outcomes in the study designs
  - Lack of evidence base to assess overall impact of testing practices on population health outcomes

Real Time Electronic Tracking Lab Tool To Improve C. *diff* Test Quality

- Stanford University study (Troung et al 2017)
- Electronic tracking used by lab personnel to enforce preanalytic lab testing criteria
  - Diarrhea (>/= 3 unformed stools in 24 hrs)
  - Absence of laxative intake in prior 48 hrs
- Outcome measures:
  - C. diff test utilization, decreased
  - Hosp. Acquired C. diff incidence rate, decreased
  - Oral Vancomycin days of therapy, decreased
  - Clinical complication rates, no change between cancelled tests and negative tests

Swiss Cheese Model of Systems Errors



Adapted for Laboratory from psnet.ahrq.gov

ASM LMBP Systematic Reviews Updates In Progress

- ***Blood Culture Contamination:*** Effectiveness of practices to reduce blood culture contamination: A Laboratory Medicine Best Practices systematic review and meta-analysis
- ***Bloodstream Infection:*** Effectiveness of Practices To Increase Timeliness of Providing Targeted Therapy for Inpatients with Bloodstream Infections: a Laboratory Medicine Best Practices Systematic Review and Meta-analysis

Conclusions

- Need for additional laboratory studies which include preanalytic variables and are linked to therapy and patient outcomes in order to evaluate impact on diagnostic quality

- Encourage collaborative laboratory studies across healthcare institutions which use standardized measures and data collection so that they may be collated and compared easily

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QUESTIONS?

Thank you!!

For more information, contact CDC
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