REPORTING CRITICAL RESULTS FOR MICROBIOLOGY

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Faculty Disclosure

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“Nothing to disclose”
Objectives

- Explain the current regulations on critical results reporting
- Discuss ways to be compliant with the regulations
History

• Lundberg\(^1\) described a panic value as a laboratory test result that represents a pathophysiologic state at such variance with normal as to be life-threatening if an action is not taken quickly and for which an effective action is possible

• Critical value concept has become common practice and incorporated into accrediting agencies regulations
Definition

• Test results that are abnormal to a degree that may indicate a life-threatening situation
• Not all clinically important results are “Critical”
What are the rules?

• The Joint Commission
• College of American Pathologists
• ISO 15189
Joint Commission
NPSG.02.03.01

• Report critical results of tests and diagnostic procedures on a timely basis
  o Collaborate with organization leaders to develop written procedures for managing the critical results of tests that address the following:
    • The definition of critical results of tests
    • By whom and to whom critical results are reported
    • The acceptable length of time between the availability and reporting of critical results of tests
  o Implement procedures
  o Evaluate timeliness of reporting the critical results of tests
College of American Pathologists

• COM.30000 Critical Results Notification
  o The laboratory has procedures for immediate notification of a physician (or other clinical personnel responsible for the patient’s care) when results of designated tests exceed established “alert” or “critical” values that are important for prompt patient management decisions
College of American Pathologists

• Note: Critical results should be defined by the laboratory director in consultation with the clinicians served

• Records must be maintained showing prompt notification of the appropriate clinical individual
Summary

• Consult with clinicians to write a procedure that defines what results are critical, in what time frame the results will be communicated, and to whom they will be communicated
• Perform the procedure
• Document that you are doing the procedure
Issues

• Regulations are vague
• Most publications don’t address microbiology
• Variation between labs in:
  o What results are critical
  o What time frame the results need to be communicated in
  o Who the results are communicated to
Issues

• Balance between being too inclusive and placing too much of a burden on staff and too exclusive and risking not preventing adverse outcomes

• Many new assays being validated in labs for more rapid results, need to keep the list up to date

• Differing expectations from clinicians
Critical results lists
Clinical Microbiology Procedures Handbook

- Organisms seen in CSF
- Organisms seen in joint fluids
- + Cryptococcal antigen detection
- + CSF antigen detection
- + AFB smear
- + blood cultures (not contaminated)
- + blood films for \textit{Plasmodium} spp.

- + eye cultures growing \textit{Pseudomonas aeruginosa} or \textit{Bacillus} spp.
- Isolation of \textit{Mycobacterium tuberculosis}
- Isolation of \textit{E. coli O157:H7}
- Isolation of pathogenic \textit{neisseriae}
- Isolation of Group B strep from a pregnant woman (culture taken at 35-37 weeks gestation)
Isolation of reportable etiologic agents of any of the following:

- LGV
- Malaria
- Meningitis
- Meningococcemia
- Mumps
- Pertussis
- Plague
- Poliomyelitis
- Psittacosis
- Rabies
- Rocky Mountain spotted fever
- Rubella
- Salmonellosis
- Shigellosis
- Syphilis
- Tetanus
- Toxic shock syndrome
- Trichinosis
- Tularemia
- Typhoid
- Typhus
- Varicella
- Yellow fever
- Yersiniosis
Q-Probes data from 623 institutions

<table>
<thead>
<tr>
<th>Microbiology result</th>
<th>Participants, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive blood cultures</td>
<td>95.0</td>
</tr>
<tr>
<td>Positive CSF cultures</td>
<td>91.2</td>
</tr>
<tr>
<td>Positive AFB smear or culture</td>
<td>71.9</td>
</tr>
<tr>
<td>Positive Gram stains of sterile body fluids</td>
<td>66.8</td>
</tr>
<tr>
<td>Initial stool isolates of Salmonella, Shigella, Campylobacter, and Yersina</td>
<td>59.7</td>
</tr>
<tr>
<td>Positive latex agglutination and/or antigen detection test</td>
<td>50.7</td>
</tr>
<tr>
<td>Positive CSF VDRL</td>
<td>25.7</td>
</tr>
<tr>
<td>Other microbiology critical values</td>
<td>44.8</td>
</tr>
</tbody>
</table>
Genzen and Tormey\textsuperscript{6}

- Examples of microbiology critical values:
  - + Gram, AFB, or mycology stains or smears (CSF, blood, sterile body fluid)
  - + blood cultures
  - + CSF cultures
  - + sterile body fluid cultures
  - + stool culture for select organisms
  - + bacterial antigen tests
295 bed hospital in Northeast

- + AFB smear or culture
- + Blood culture
- + *Bordetella* smear or culture
- + Cryptococcal antigen
- + CSF smear or culture
- + *Haemophilus influenzae*, blood or CSF
- + HIV I antibody
- + *Neisseria meningitidis*, blood or CSF
- + urine culture, patients <3 years of age
- + smear or culture of any sterile body fluid
Reference lab in the Midwest

• Identification of *Acanthamoeba* spp. from CNS or ocular
• Identification of *Naegleria* spp. from CNS
• + *Babesia* PCR or smear from blood
• + bacterial antigen test from CSF
• + bacterial culture from blood, sterile body fluid, normally sterile tissue or corneal scrapings
• Identification of *B. anthracis*, *Brucella* spp., *C. botulinum*, *C. diphtheriae*, *F. tularensis*, *V. cholerae*, or *Y. pestis*
• + Cryptococcal antigen or India Ink from CSF
• Identification of a Zygomycete, dimorphic fungus, *Cryptococcus neoformans/gattii* or *Pneumocystis* spp.
• + Gram stain from a sterile body fluid or sterile site
• + Malaria/Filaria/Trypanosome PCR or smear
• *Strongyloides stercoralis* from non-intestinal sites
• *S. pneumoniae* antigen from CSF
• Toxoplasma gondii PCR from CSF, amniotic fluid or ocular
• HSV from CSF, amniotic fluid, ocular or brain tissue
• + viral culture or PCR from CSF on infant <12 months
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- + Blood cultures
- + CSF specimens
- + AFB
- *Plasmodium falciparum*
- Group A streptococci from genital sites

- Results to be communicated within 30 minutes to a licensed care giver
Time frame

- “Evaluate the timeliness of reporting critical results”
- “Records must be maintained showing prompt notification”
Q-Probes 1997

- 671 institutions
- 30 consecutive blood culture results for 60 days which ever came first
- 13,894 positive blood culture results
- Median times
  - 40 minutes to verification of results (flag + to GS)
  - 5 minutes to notification of results
  - 50 minutes total time
Q-Probes 1997

• Larger hospitals had longer notification times
• Times were longer for outpatients
• Physicians were notified more often for blood culture results vs potassium or PT results which also decreased the notification time for blood cultures
Q-Probes 1997

• Nurses were notified most commonly
• 79.8% labs in the study had all critical values communicated successfully
  o 9.7% of labs were unsuccessful 1-2%
  o 7.5% of labs were unsuccessful 2-5%
  o 3% of labs were unsuccessful >5%
Automated notification

- Closed-loop reporting systems
- Pages or messages to smartphones/tablets
- Requires person receiving message to acknowledge that they received and understood the message
- Audit trail for accountability
Systems

• Amcom$^8$
  o Commercial system marketed for lab, radiology, cardiology procedures
  o Integration with LIS and EMR, but mentions “results are entered into the Amcom system”
Systems

- **ALERTS⁹**
  - Developed and used at Vanderbilt University
  - Used for chemistry, coag, and hematology
  - Inpatients
  - Text pagers
  - If page not acknowledged, call went to telephone operators
  - Eliminated 9000 calls a year
  - Overall acknowledgement 95%
  - Decreased time of notification to <3 minutes
Data

- Liebow et al\textsuperscript{10}
- Meta-analysis of available literature as of September 2011
- Reviewed 41 studies of which 4 contained credible evidence for the timeliness and accuracy of automated notification systems and 5 contained credible evidence for call centers
- No mention if micro was included in studies
- Evidence not sufficient to make a LMBP recommendation for or against automated notification systems
Possible issues

- Requires a lot of IT support and clinician education
- Updated lists of clinicians
- Micro results can be long
- Possibly more work for the clinician
- Might still not fit the intent of more rapid intervention
- Paul Valenstein’s commentary\textsuperscript{11}
What would you do?

• No 3rd shift micro staffing
  o Residents are called in to read STAT Gram smears
  o Blood cultures sit until AM

• Was told that we can defend ourselves because we call it as soon as we see it in the morning
Options

1. Remove it from your critical value list (in consultation with clinicians)
2. Keep it on the list and defend your position that you call as soon as it is identified
3. Ask for staffing
I picked #3

• Informed Infectious Diseases know that we aren’t calling + blood cultures on 3rd shift
• Collected data for 3 months
  o 90 + blood cultures on 3rd shift
  o 34 clinically significant + blood cultures
  o Time delay from signal + to call 1-8 hours (average 4.9 hours)
• Will be training 3rd shift staff (once they are fully staffed) to read + blood cultures
What would you do?

• Receive a call from an angry clinician that missed a positive Gram smear joint fluid on a patient
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• + Blood cultures
• + CSF specimens
• + AFB
• *Plasmodium falciparum*
• Group A streptococci from genital sites

• Results to be communicated within 30 minutes to a licensed care giver
Options

- Say “Of course, anything you would like doctor” and put it on the critical value list
- Say “absolutely not, the list is made and nothing can be added”
- Put joint fluids on the “Call” list
Updated FAHC

- + Blood cultures
- + AFB smears and cultures
- + CSF specimens for any infectious agent
- + Blood parasites

- Positive Gram smears from sterile fluids added to “Call” list
• Lab wide critical value policy must match the micro procedures
What would you do?

- Blood cultures drawn in ED and patient went home
- Blood cultures +, but clinician that ordered them is no longer there
Options

• Try giving the result to the nurse (ok per your procedure) but when he refuses give up

• Call the patient at home to tell them they have bacteria in their blood and they should come to the hospital

• Call the pathology resident or pathology director for microbiology who can look in the medical record to find the patient’s clinician
What would you do?

• Receive a call from hematology asking what was seen on Gram stain of a CSF that they are looking at

• Look up the result in the LIS and it isn’t in yet

• Go to hematology to look at slides
• Specimens were received over 12 hours ago
• Collected ~6 hours apart, but sat someplace before getting to the lab
• Shunt fluid which wasn’t ordered STAT
• Asked staff and only CSF’s that are ordered STAT are read immediately
Follow-up

• *Klebsiella pneumoniae* demonstrating antibiotic effect
• All non-STAT specimens were mixed in together
• Created a new slide book for all STAT and CSF specimens
• Followed CSF Gram smear turn-around time
• Set goal of 1 hour TAT
Summary

• Goal is to improve patient outcomes by getting important information to care givers quickly
• Work with physicians to develop a procedure
• Follow your procedure
• Be able to document that you are following your procedure
3. CAP All Common Checklist
QUESTIONS