Systematic Assessment of Culture Review as a Tool to Assess Errors in the Clinical Microbiology Laboratory

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Context.—Daily supervisory review is a common practice in microbiology laboratories; however, there are no publications describing errors corrected by this practice.

Objective.—To determine (1) the correction rates for routinely reviewed positive cultures, (2) the correction rates for negative cultures, and (3) the types of corrections that are found, including the number with potential clinical significance.

Design.—We prospectively assessed errors identified during culture report review for all positive (10-month period) and negative (1-month period) cultures at a single, university-based clinical microbiology laboratory in the United States. Errors were classified using predefined categories, and total and per category error rates were determined. A $\chi^2$ test was used to assess significant differences between error rates.

Results.—A total of 112,108 culture reports were examined; 914 reports required a total of 1043 corrections. Of 101,703 positive culture reports, 786 (0.8%) required 900 corrections, 302 (0.3%) of which were potentially clinically significant. Of 10,405 negative culture reports, 128 (1.2%) required 143 corrections, 5 (0.05%) of which were potentially clinically significant. The rate of potentially clinically significant errors was significantly higher among positive versus negative culture reports ($P < .001$). Errors from positive culture reports most commonly involved susceptibility (374 [42%]), reporting (275 [31%]), and identification workup (217 [24%]). Most potentially significant errors from positive culture reports involved susceptibility testing ($n = 253$) and specimens from wound or lower respiratory tract ($P < .001$).

Conclusions.—Review of culture reports from positive cultures from nonsterile sites with special attention to antimicrobial susceptibility testing and reporting would be most likely to detect potentially significant errors within the clinical microbiology laboratory.

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The detection of clinically significant errors is central to hospital quality improvement efforts. Identification of errors, analysis of their causes, and interventions to prevent recurrence are fundamental principles of improving patient safety. The Joint Commission’s National Patient Safety Goals and Sentinel Event Policy are examples of national efforts designed to improve the quality of patient care.1 Accurate and timely clinical laboratory test results are essential factors in providing quality patient care.

The Joint Commission requires daily supervisory review of patient results (Laboratory Standard QC.1.90); however, review of every result is not required.2 Laboratories may design their own algorithms to determine which results to review. Although supervisory review of all laboratory results is not required by the College of American Pathologists Laboratory Accreditation Program, it can be used to address the College of American Pathologists phase II question (Microbiology Checklist Question Micro.11100): “Is there a documented system in operation to detect and correct significant clerical and analytical errors, and unusual laboratory results, in a timely manner?”2'2 Automated laboratory instruments may have computerized systems for result review; however, human review is required in many circumstances. In the microbiology laboratory, this frequently takes the form of daily review of reported and/or intermediate culture or other test results for completeness and accuracy. The reviewer is often a supervisor or experienced microbiologist.

In our laboratory, review of positive cultures and other microbiology testing has been carried out for more than 30 years. Workup and report sections of bacterial and fungal cultures, serology, parasitology, and molecular testing are reviewed daily within 24 hours of reporting. Negative culture reports (CRs), cultures, or direct examinations with no reported organisms or only normal resident organisms are not routinely reviewed. In recent years, review of CRs has been rotated within 5 clinical technologist leads, all of whom are experienced clinical microbiologists.

This study is a logical extension of our previous work in detecting errors in microbiology identified through cor-
were classified into 5 predefined technical categories (Table 1), for example, in the category of identification workup, failure to uncorrect, could have led to inappropriate treatment decisions. Potentially clinically significant corrections were those that, if left reported, and on the basis of potential clinical significance. Po-

### MATERIALS AND METHODS

#### Culture Report Corrections

In our laboratory, daily culture review is rotated among 5 clinical technologist leads, all of whom are certified as either Medical Technologists (American Society for Clinical Pathology) or Registered Microbiologists (National Registry of Microbiologists) and have at least 15 years of experience in clinical microbiology. Once finalized, CRs are reviewed for completeness of report and workup, adherence to laboratory protocols, correlation between reported organism identification and identification test results, review of antimicrobial susceptibility testing for unusual patterns, and agreement between reported organism identifications, antimicrobial susceptibility, workup tests, and direct Gram stain. Corrections identified by the leads during routine positive CR review in our laboratory were prospectively assessed for 10 months (October 2004 through July 2005). Negative CRs were reviewed for 1 month (October 2005) by one of the leads. Types of reports reviewed included bacterial culture, fungal culture, direct ex Kennedy et al. 2008. Curr Opin Hematol. 15:272-277.

#### RESULTS

#### Correction Rates

The number and percentage of corrections found are presented in Table 2 (all corrections) and Table 3 (potentially clinically significant corrections). For all cultures, 914 of 112 108 CRs required a total of 1043 corrections (0.9%). For positive cultures, 786 (0.8%) of 101 703 CRs required a total of 900 corrections. For negative cultures, 128 (1.2%) of 10 405 CRs required a total of 143 corrections. The difference between the number of potentially clinically significant corrections made to positive and negative CRs is statistically significant (P < .001). Only 3.5% of the corrections from negative CRs are potentially significant, one tenth the rate for positive CRs (34%). Most corrections to negative CRs (138/143) were minor corrections not likely to impact patient care. Almost half (42%) of all corrections from the positive CRs and most (84%) of the potentially clinically significant corrections fell into the susceptibility category. The largest subcategory of susceptibility testing corrections was D-zone testing for inducible clindamycin resistance in *S. aureus* isolates, a total of 164 (44%) of 374 corrections. Furthermore, 40% of potentially clinically significant corrections involved D-zone testing. More specifically, the most frequent D-zone-related errors included incorrect or no D-zone comment reported (n = 98) and D-zone results not entered (n = 46). In the identification (ID) workup category, 205 (94%) of 217 corrections related to missing ID workup results; however, only 28 (9%) were potentially clinically significant. In the report category, 70 (25%) of 275 corrections related to reported β-strep comments (eg, “no beta-hemolytic streptococci isolated”), and 42 (15%) related to reported

#### Table 1. Technical Correction Categories With Examples

<table>
<thead>
<tr>
<th>Category</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Setup</td>
<td>Specimen was set up on incorrect plates.</td>
</tr>
<tr>
<td>Direct exam</td>
<td>Discrepancy between direct Gram stain and culture growth not addressed.</td>
</tr>
<tr>
<td>Identification workup</td>
<td>Identification tests performed were inadequate to support identification, or identification tests were performed, but results were not entered in workup.</td>
</tr>
<tr>
<td>Report</td>
<td>Workup correct but incorrect quantity, identification, or comment reported.</td>
</tr>
<tr>
<td>Susceptibility</td>
<td>Appropriate susceptibility testing not performed or results not entered correctly, including comments.</td>
</tr>
</tbody>
</table>

#### Table 2. Classification of All Corrections

<table>
<thead>
<tr>
<th>Category</th>
<th>No. (%) of Positive CR Corrections (n = 900)</th>
<th>No. (%) of Negative CR Corrections (n = 143)</th>
<th>Significance (P)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Setup</td>
<td>3 (0.003)</td>
<td>0</td>
<td>.49</td>
</tr>
<tr>
<td>Direct exam</td>
<td>31 (0.028)</td>
<td>0</td>
<td>.02</td>
</tr>
<tr>
<td>Identification workup</td>
<td>217 (0.194)</td>
<td>98 (0.087)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Report</td>
<td>275 (0.245)</td>
<td>45 (0.040)</td>
<td>.83</td>
</tr>
<tr>
<td>Susceptibility</td>
<td>374 (0.334)</td>
<td>0</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Potentially clinically significant</td>
<td>302 (0.269)</td>
<td>5 (0.004)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

* CR indicates culture report.

#### Table 3. Classification of Potentially Clinically Significant Corrections

<table>
<thead>
<tr>
<th>Category</th>
<th>No. (%) of Positive CR Corrections (n = 302)</th>
<th>No. (%) of Negative CR Corrections (n = 5)</th>
<th>Significance (P)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identification workup</td>
<td>28 (9)</td>
<td>5 (100)</td>
<td>.03</td>
</tr>
<tr>
<td>Report</td>
<td>21 (7)</td>
<td>0</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Susceptibility</td>
<td>253 (84)</td>
<td>0</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Percent total CR</td>
<td>0.29</td>
<td>0.05</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

* CR indicates culture report.

The University of Washington (Seattle) Human Subjects Division does not require approval for this type of study.

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rected reports. Another study looked at using laboratory incident reports as a means of identifying errors. Despite the fact that review of CRs is a standard, longstanding practice in many microbiology laboratories, there are no published data analyzing the ability of this process to detect potentially clinically significant errors. We undertook this study to determine (1) the correction rate for routinely reviewed positive cultures, (2) the correction rate for negative cultures, and (3) the types of corrections that are found, including the number with potential clinical significance.

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that the process of culture review can be used to detect from a throat culture, a potential *Staphylococcus aureus* we report, the organisms insufficiently identified were an category. In each case, a potential pathogen was not ade-

By reviewing negative CRs were all in the ID workup cat-

common correction was missing workup data, such as fail-

serologic rather than biochemical testing. The second most

cultures (Figure). A total of 22% of urine cultures received
corrections and 14% of potentially clinically significant corrections, followed by LRT cultures (22% of LRT cultures).

### Classification of corrections by culture site

- **LRT** indicates lower respiratory tract; **NS** other nonsterile sites, including environmental, genital tract, stool, and upper respiratory tract cultures; and **Misc** miscellaneous requests, including direct examinations, rule out cultures, and reference identifications.

- **No. of potentially clinically significant corrections, shown on the left axis**
- **No. of nonsignificant corrections, shown on the left axis**
- **% of all cultures received, shown on the right axis**

**COMMENT**

This study makes a number of significant contributions to the patient safety literature in microbiology. To our knowledge, it is the first published report demonstrating that the process of culture review can be used to detect clinically significant errors in the microbiology laboratory. This is the first published report quantifying that the actual error rate in a microbiology laboratory is less than 1%. In addition, the study data strongly suggest that laboratories with limited resources can focus their efforts to maximize the identification of clinical significant errors.

Review of positive CRs yielded an average of 79 corrections per month, 49 of which (62%) were unlikely to be significant. The remaining 30 were potentially clinically significant, an average of 1 per day. Of these 30, 25 (83%) were related to antimicrobial susceptibility testing. Over the course of 1 month, only 5 potentially significant errors were found in the negative CRs, an average of 1 every 6 days. Cultures from sterile sites had a lower rate of correction than urine, LRT, and wound cultures. Wound and LRT cultures together accounted for more than half (54%) of the potentially significant corrections. Other cultures with a low rate of correction include direct microscopic exams, “rule out” cultures where 1 specific organism is of concern (eg, *Legionella, Nocardia*), and reference isolates sent to the laboratory for identification and/or susceptibility testing.

By reviewing only positive CRs, 86% of all corrections and 98% of potentially clinically significant corrections would have been identified. Reviewing negative CRs, those with no organisms, or only normal resident organisms reported would require review of approximately 300 to 350 reports every day, essentially doubling the number of daily reviews. With an average yield of only approximately 1 potentially clinically significant error per week in a large, full-service, university microbiology laboratory, routine review of negative cultures may not be warranted, particularly if resources are limited.

Uncorrected errors relating to antimicrobial susceptibility testing have the potential for clinical impact through inappropriate antimicrobial selection or delay in treatment. Antimicrobial susceptibility is a complex and ever-evolving aspect of microbiology and could be a focus for review. In particular, the large number of D-zone–related corrections required suggest that the need for additional training and/or changes to the process in our laboratory.

Sterile sites are more likely to yield pure cultures and, due to the likelihood of significance, there are fewer work-up decisions; most isolates from sterile sites are identified fully and tested for susceptibility. Urine, LRT, or wound cultures may be pure or mixed; however, they are more likely to grow organisms with different degrees of identity or susceptibility requirements, depending on relative or absolute quantity, specimen type, or patient clinical history. These cultures are more complex to work up, and therefore they are more likely to have errors. If culture review were limited to only positive cultures from nonsterile sites (environmental, genital, upper and lower respiratory, stool, urine, and wound cultures), 246 (81%) of potentially clinically significant and 671 (75%) of all errors would have been identified.

Strengths of this study include the large number of CRs included, the prospective study design, and the use of standardized definitions. In particular, corrections were classified as potentially clinically significant with input from an infectious disease specialist. The culture review process used in this study cannot be used to identify some types of errors, such as delays in reporting, or errors due to preanalytical variables. Another limitation of this study is that interreviewer reliability was not assessed.
CONCLUSION

Neither The Joint Commission nor the College of American Pathologists requires daily supervisory review of every single patient result. Laboratories with limited resources may want to review only selected reports. In clinical microbiology, delta checks and critical results are less useful as criteria for review than they are in other areas of the clinical laboratory. We present an analysis of the errors identified through the process of culture review, which may help laboratories target the types of reports to review. Specific areas where potentially clinically significant errors are most likely include susceptibility testing, wound and LRT cultures, and changes in protocol. Conversely, areas with a very low likelihood for detecting potentially clinically significant errors include negative cultures, cultures to rule out specific organisms, and cultures likely to be pure.

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References