Detection and Prevention of Clinical Microbiology Laboratory-Associated Errors

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Effective as of January 2000, the purpose of the Cumitech series is to provide consensus recommendations regarding the judicious use of clinical microbiology and immunology laboratories and their role in patient care. Each Cumitech is written by a team of clinicians, laboratorians, and other interested stakeholders to provide a broad overview of various aspects of infectious disease testing. These aspects include a discussion of relevant clinical considerations; collection, transport, processing, and interpretive guidelines; the clinical utility of culture-based and non-culture-based methods and emerging technologies; and issues surrounding coding, medical necessity, frequency limits, and reimbursement. The recommendations in Cumitechs do not represent the official views or policies of any third-party payer.

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Detection and Prevention of Clinical Microbiology Laboratory-Associated Errors

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INTRODUCTION

• “Between the health care we have and the care we could have lies not just a gap, but a chasm” (12).
• “Error in medicine is common and may cause harm. However, isolating the factors underlying specific types of errors has proved to be a formidable task. The types of errors that occur vary widely because of the extreme complexity and heterogeneity of the tasks involved in medical care. Furthermore, many of the devastating errors happen too infrequently for observation or single-institution studies to identify the risk factors and patterns of causation. As a result, studies of errors to date have generally measured only the frequency and outcomes of specific types of errors, not the roles of particular contributing factors” (11).

In its 1999 report, *To Err is Human: Building a Safer Health Care System*, the Institute of Medicine essentially stated that health care in the United States had major problems and that preventable medical errors claim 44,000 to 98,000 American lives each year at a cost of $17 billion to $29 billion in hospital expenses nationwide (13). A 2001 report from the Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the 21st Century*, stated that the delivery of health care cannot continue as currently designed and needs fundamental changes (12). The report stated that health care should be safe, effective, patient centered, timely, efficient, and equitable. Many experts agree that the report is changing medicine as we know it. The changes involve proactive, systematic, and procedural approaches to accomplish these goals. Emphasis will shift from a culture of blame to a culture designed to create better outcomes (the specified goals).

Clinical microbiology (CM) largely remains a science of interpretive judgment. The judgmental, intricate, and demanding nature of the procedures performed in a CM laboratory (CML) and the critical results of stains, cultures, and antimicrobial susceptibility testing can lend themselves to errors and can lead to adverse outcomes. Inaccurate results can directly influence both presumptive (empiric) and long-term therapeutic regimens and can cause prolonged lengths of stay, misdiagnosis by the clinician, adverse side effects of inappropriate therapy, etc.

Laboratory personnel have the opportunity to be proactive in the reduction of errors. By being proactive participants, by establishing measurable standards of quality, and by assigning accountability, microbiology laboratory personnel can strategically position themselves to be essential and influential forces in decreasing errors that can cause harm to patients.

At present, some CMLs are in the nascent stages of developing quality assurance protocols to decrease CML-associated errors. These protocols are analogous to those used in the early stages of nonstandardized quality control years ago (e.g., hit-and-miss or sporadic quality control, which involved the use of any handy strain of *Escherichia coli* for monthly susceptibility testing). These early protocols eventually evolved into today’s standardized guidelines for acceptable quality control susceptibility procedures. Likewise, this *Cumitech* emphasizes the importance of and the need for the development of logical, practical, and standardized protocols which ensure quality by reducing the numbers of errors associated with CMLs.

The purpose of this *Cumitech* is to provide clinical microbiologists with (i) strategies to define, detect, describe, categorize, and prevent CML-associated errors and (ii) six projects which have been used to detect and reduce CML-associated errors. The magnitudes and impacts of these errors, a working definition of the ever-expanding concept of medical errors, categories of laboratory errors, and examples of errors are presented. Six projects designed to reduce CML-associated errors are described. The educational projects are designed to detect, examine, and prevent CML-associated errors. These practical and laboratory-tested projects can be performed directly and unaltered as presented in Appendix B or can serve as templates and be modified to suit the needs of particular institutions. The projects can be incorporated into interdisciplinary quality assurance programs hospital-wide. In addition, Table 1 shows examples of relevant CML-associate errors. These examples provide numerous opportunities to detect and correct errors in most CMLs.

It is anticipated that the *Cumitech* will provide the catalyst for CML personnel to formulate systematic, evidence-based approaches to address and minimize preventable CML-associated errors.
DEFINITION OF ERRORS

The Institute of Medicine defines a medical error (sometimes called an “adverse medical event”) as “the failure of a planned action to be completed as intended or the use of a wrong plan to achieve the aim” (13), e.g., adverse drug reactions, wrong-site surgery, pressure ulcers, incorrect patient identification, and laboratory errors. Medical errors include “near-miss” events, which are defined as situations in which errors are detected prior to any negative impact on patient care. An example of a near miss would be changing (before the physician received the report) an erroneous result of the recovery of *Neisseria gonorrhoeae* from a 3-year-old child from whom only a saprophytic *Neisseria* sp. was isolated. Near-miss events require a proactive system of checks and balances, such as frequent supervisory or computer reviews. They are valuable sources of information because they present opportunities to learn from mistakes and to institute preventive measures.

Medical errors can occur in any part of the health care system and can result in suboptimal care. A CML-associated error can be defined as any incident, deviation, variance, or sentinel or adverse event which is related to the laboratory and which might result in suboptimal patient care. CML-associated errors (e.g., inappropriate orders, misread handwritten orders, incorrect handling of a specimen, incorrect workup of isolates, and miscommunication of results) can occur anywhere along the preanalytical, analytical, and postanalytical paths from ordering a test to the interpretation of the test results by the caregiver. Situations that should be considered errors can become apparent when the following questions (among others) are asked. (i) What should *not* happen in the microbiology laboratory? (ii) How can problems be prevented? (iii) How should the *ideal* microbiology laboratory be designed to reduce the potential for errors? (iv) What are the common problems and physician complaints? (v) If the highest-quality patient care is a primary goal, how would current specimen management and processing protocols change to reduce the potential for errors? Addressing these issues requires an interdisciplinary approach, regardless of the responsible department or cost center and regardless of who is blamed for the error. The challenge is to maximize the delivery of accurate, timely, and clinically relevant results so that clinicians can optimize desired patient outcomes. The report of the Institute of Medicine (13) states that most errors are not caused by carelessness but instead are the result of poorly designed systems. The key to reducing errors is to shift attention away from the caregivers and toward the system itself, because finding fault at the individual level only obscures the underlying source that unwittingly allows the errors to occur (17).

### Table 1. Potential errors associated with CML

<table>
<thead>
<tr>
<th>Stages and process</th>
<th>Example(s) of Errors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preanalytical</td>
<td></td>
</tr>
<tr>
<td>Physician ordering test</td>
<td>Incorrect patient but wrong test request; correct test request but wrong patient</td>
</tr>
<tr>
<td>Drawing or collecting specimen</td>
<td>Incorrect sample, timing, specimen container, or label; incomplete label</td>
</tr>
<tr>
<td>Clerk writing or entering order into system</td>
<td>Incorrect interpretation of orders; wrong orders entered</td>
</tr>
<tr>
<td>Linking patient identification to specimen</td>
<td>Incorrect identification of patient; incorrect label on specimen</td>
</tr>
<tr>
<td>Transporting specimen to laboratory</td>
<td>Specimen lost, dropped, damaged, or spilled or not received by laboratory; delays in transport to laboratory; transport of specimen in inappropriate container or at inappropriate temperature</td>
</tr>
<tr>
<td>Accessioning specimen</td>
<td>Incorrect number assigned to specimen</td>
</tr>
<tr>
<td>Sampling and dividing specimens</td>
<td>Measurement error</td>
</tr>
<tr>
<td>Matching specimen with order</td>
<td>Incorrect matching of specimens with corresponding orders</td>
</tr>
<tr>
<td>Sorting and centrifugation</td>
<td>Mix-up of specimen during decanting or processing</td>
</tr>
<tr>
<td>Managing inventory</td>
<td>Incorrect or back-ordered inventory</td>
</tr>
<tr>
<td>Ordering supplies</td>
<td>Incorrect standing orders</td>
</tr>
<tr>
<td>Paying invoices</td>
<td>Incorrect billing</td>
</tr>
<tr>
<td>Analytical</td>
<td></td>
</tr>
<tr>
<td>Technical procedures, manipulations, interpretations, education</td>
<td>Incorrect identification of isolates; incorrect antimicrobial susceptibility testing and reporting; incorrect workup of isolates; failure to adhere to established procedures; incorrect preparation, use, and storage of quality control reagents; failure to perform quality control; use of outdated procedures; failure to train all laboratory employees at all sites in a consistent manner</td>
</tr>
<tr>
<td>Postanalytical</td>
<td></td>
</tr>
<tr>
<td>Reviewing and approving test results</td>
<td>Untimely review; review too cursory</td>
</tr>
<tr>
<td>Transmitting test result</td>
<td>Result transmitted to incorrect site or physician</td>
</tr>
<tr>
<td>Collecting and charting results</td>
<td>Results inserted into incorrect chart</td>
</tr>
<tr>
<td>Storing samples</td>
<td>Incorrect storage conditions; storing specimens in wrong location</td>
</tr>
</tbody>
</table>
A hospital or laboratory system that can be used to report CML-associated errors consistently should be in place. Such a system can include computerized forms for real-time reporting within the information system. The data to be reported, collected, summarized, examined, and monitored can include the following: the service or department involved in the event, the type of event (preanalytical, analytical, or postanalytical), the type of error (near-miss or actual error), the person(s) involved, a description of the event, how the event was discovered (e.g., quality control or supervisory review, a call from another department, or an anonymous report), the effect of the event on the patient, the immediate action taken to prevent or minimize harm, and the appropriate persons to be notified. Each event and all of the information related to the event could be assigned codes or numbers and be tracked. The laboratory information system can be used both to achieve the goals of quality assurance of clinical laboratories and to reduce errors (4).

**SCOPE AND MAGNITUDE OF LABORATORY ERRORS**

Bologna et al. (5) showed that the laboratory testing process has 255 activity steps from the time that a physician writes an order to the time that the processed specimen is stored. Sixty-three (25%) of the 255 steps were sources of potential errors. The steps can conveniently be placed into three categories (Table 1):

- preanalytical (e.g., specimen processing, writing orders, interpretation of handwriting, entering orders, collecting and transporting specimens, and accessioning specimens into the laboratory),
- analytical (e.g., diagnostic assays, including biochemical testing, subculturing, incubation, identification, antimicrobial susceptibility testing, referral testing, and interpretation of results), and
- postanalytical (e.g., interpretation of results, reviewing results, reporting results by computer, and managing and communicating critical results).

The possibility for making an error exists at each step of the laboratory diagnostic process; however, corroborative studies have shown that the probability of errors is greatest during the preanalytical phase (18). In a 3-month study involving laboratory test requests, the overall laboratory error rate was 0.47% (189 tests with errors/40,490 tests) (16). The distribution of errors was as follows: preanalytical, 68.2%; analytical, 13.3%; postanalytical, 18.5%. Overall, nearly three-fourths of the errors had a nominal effect on patient outcome, almost one-fifth of the errors resulted in unjustifiable increases in costs, and 6% of the errors were associated with inappropriate care or modification of therapy.

The College of American Pathologists surveyed 631 hospitals in 1990 and reported that serious (non-clerical) errors were made at a rate of 4.48 errors per 10,000 billable tests (7). A total of 3.97 errors per 10,000 billable tests (89%) were near-miss events which were detected and corrected before any remedial action was required. The remaining 0.51 errors per 10,000 tests (11%) were associated with adverse patient outcomes. Clerical errors were made at a rate of 4.45 errors per 10,000 billable tests. Errors with adverse patient outcomes were detected more often in laboratories with a systematic program for the reporting and monitoring of medical errors than in labs without such a program. The underlying assumption is that these errors exist everywhere, but they will not be corrected unless they are detected. Therefore, one laboratory that reports more errors than another laboratory might not be inferior but could be considered more diligent in addressing adverse events in a proactive manner and potentially even safer. The report also stated that there is a positive correlation between the detection of errors and computerization to flag errors in the laboratory, because the detection of errors by systematic computer monitoring is more efficient than detection by a manual methodology.

**SOURCES AND EXAMPLES OF CML-ASSOCIATED ERRORS**

The following are examples of errors and situations in which errors could occur. The errors are grouped into four general categories.

1. Failure to have written procedures consistent with standardized, recommended methods
   a. Use of protocols that have not been updated or reviewed at least annually by the CML director or designee
   b. Incomplete or inaccurate procedures for CML activities (e.g., quality control; specific tests, such as identification, antimicrobial susceptibility testing, antigen or antibody detection, and culturing of catheter tips; and autoclaving)
   c. Insufficient procedural detail (e.g., the incubation temperatures, culture media, and safety precautions to be used and the time intervals for incubation or reporting)
   d. Not having the procedure manuals easily accessible to employees to optimize adherence to protocols
   e. Not having (or having and not using) protocols for tests which could yield clinically relevant results (see project 3 on the relevancy of testing
for extended-spectrum beta-lactamases [ESBLs] in Appendix B)

2. Use of outdated, inaccurate, nonstandardized, or unapproved practices instead of currently approved procedures
   a. Outdated procedures
   b. Procedures that have undergone “procedural drift” due to unapproved modification
   c. Unwritten procedures (e.g., doing things “your own way,” using ill-advised shortcuts, following laboratory myths, or using outdated product inserts)
   d. Not adhering to the standardized protocol (e.g., inoculating specimens onto incorrect media; reading cultures at insufficient incubation times; or inappropriate specimen workup, such as identifying and performing antimicrobial susceptibility testing with all throat specimen isolates)

3. Inadequate training in the importance of adhering to established procedures, assay techniques, and interpretative decisions
   a. Inadequate or infrequent competency testing of laboratory employees on all shifts in all laboratory sections in assay performance (e.g., misreading of Gram-stained cerebrospinal fluid [CSF])
   b. Failure to recognize unusual results during review of results (e.g., an unusual antimicrobial susceptibility pattern or an obviously incorrect result)
   c. Failure to include an essential comment on a report (e.g., that an essential medium or nutrient was inadvertently not used in culturing of a specimen or that a specimen was transported or processed in a nonoptimal manner)
   d. Reporting conflicting results issued from different sections of the same laboratory (see project 5 in Appendix B)

4. Ineffective communication of an employee with managerial or health care personnel
   a. Failure to perform an ordered test (see project 2 in Appendix B)
   b. Failure to communicate critical results accurately and coherently (see project 4 in Appendix B).
   c. Failure to report critical results to the appropriate health care worker (see project 1 in Appendix B)

**TRACKING AND REPORTING CML-ASSOCIATED ERRORS**

Many medical adverse events, either near misses or actual errors, are readily recognized by laboratorians and clinicians and are corrected appropriately through a system of checks and balances as part of their quality assurance programs. For example, reporting a group A streptococcus as penicillin resistant becomes a near miss rather than an actual error when the event is detected through supervisory review of results and/or computerized alert systems. Such near misses are medical errors that must be documented because they might have had a negative impact on patient care.

Adverse outcomes linked to obvious errors associated with the CML are rarely documented. Inasmuch as CML data have been linked to improved patient outcomes, it seems reasonable that errors could contribute to poor patient outcomes (1, 2, 3, 6, 8, 9, 14, 15, 19). Although the correlation between actual adverse patient outcomes and medical errors associated specifically with the CML has yet to be fully appreciated, it is likely that many laboratory-associated errors do occur, especially during the preanalytical stage. Specific areas for improvement in the preanalytical stage include order entry and overall specimen management. In the analytical stage and, to a lesser extent, in the postanalytical stage, prevention of errors can occur in many ways, e.g., participation in laboratory proficiency testing programs, improvements in detection of errors, use of standardized testing methods, monitoring of the technical training and education levels of laboratorians, and reporting of accurate and clear clinically useful information. In addition, frequent, regular, and improved interactions and communications between CM personnel and other health care workers are always the foundation of error-free testing and reporting.

**EDUCATION**

A vital key to the prevention CML-associated errors (especially in the preanalytical stage of testing) is an ongoing comprehensive education program which (i) constantly stresses the fact that sound laboratory practices are major deterrents to medical errors and (ii) addresses known sources of errors at the preanalytical, analytical, and postanalytical stages. The program should be directed to both inter- and intradepartmental personnel and, quite simply, should stress the “dos and don’ts” of CMLs. Overlap and redundancy are appropriate in such a program. Therefore, both written communication (paper and electronic) and verbal communication (face-to-face discussions and interactions through grand rounds, through lectures, and by telephone) are essential components of this type of educational program. The text and tone of all types of communications should be concise and should be able to be easily read and understood in just a few moments.
Written Communication
Newsletters, bulletins, brochures, mailings, announcements, and other regularly published and easily read forms of printed communications from the CML can be extremely effective in providing important information to all hospital personnel. Topics such as how to collect specimens, new or alternative tests that are available, how to interpret results, how to order appropriate tests, and changes in laboratory information systems can be addressed in a dedicated microbiology section of each regular publication. A laboratory user’s guide, a manual of tests, or some other similar document should be readily available, at point-of-care locations, to physicians, nurses, and other health care workers who take care of patients. Ideally, these test guides should be available both in hard copies and on websites in a hospital information system (HIS). To be effective, the manuals and guides should provide the following: appropriate instructions for patient specimen site preparation; specimen selection, collection, and transport; reasons to reject specimens; test methods; test turnaround times; and interpretation of results.

Electronic Communication
Electronic communications can be effective media for educating those who use the services of a CML. Important and timely information can be programmed into an HIS so that nurses and physicians can view the updated information on the first screen displayed after logging onto the system. In addition, electronic comments directed to preventing preanalytical errors at the specimen collection level can be appended to the test results; e.g., “Insufficient volume of blood was added to the blood culture bottles. 10 ml per bottle is needed to optimize detection of pathogens.”

Oral Communication
Direct oral communication is an excellent way to underscore printed and electronic messages, to develop sound laboratory practices, and to help prevent medical errors. Often, no form of communication is more effective than speaking directly to physicians, nurses, residents, unit coordinators, medical technologists, and phlebotomists at important venues such as lectures, classes, conferences, and grand rounds. Direct oral communications reinforce written and electronic communications and allow a personal rapport to be established with hospital personnel.

Appendix A provides four examples of written communications which have been used to educate physicians and nurses. These communications are printed exactly as they were originally published and distributed to physicians.

PROJECTS DESIGNED TO DETECT AND REDUCE ERRORS ASSOCIATED WITH CMLs
The authors have conducted six projects at their respective institutions to detect, examine, and prevent CML-associated errors. Most of these practical and laboratory-tested projects can be performed directly as presented in this Cumitech. Alternatively, the projects can serve as templates, which can be modified to suit the needs of particular institutions. The projects listed below are discussed in Appendix B and are formatted as issue, action, expected results, and follow-up. Actual data regarding the progress or success of the project are presented in notes at the ends of the descriptions of some projects.

Projects
1. Determining if appropriate health care workers receive critical value reports and if the reports are clinically useful
2. Reduction of transcription, translation, and ordering errors
3. Improving the detection of ESBL-producing bacteria in a health care system with multiple CMLs
4. Effective communication of critical values by telephone
5. Correlation of surgical pathology and CM results
6. Use of data from a laboratory information system to identify persons who misread the results of group A Streptococcus antigen tests

APPENDIX A
EXAMPLES OF WRITTEN COMMUNICATIONS DESIGNED TO PREVENT CML-ASSOCIATED ERRORS

EXAMPLE 1
This example is adapted from Microbiology Clinical Brief, a publication for the medical staff of a health care system.

Tuberculosis Meningitis
Tuberculosis meningitis is an uncommon disease in the United States (fewer than 200 cases annually). Highly sensitive and specific CML screening tests for tuberculosis meningitis do not exist, and the laboratory tests that are available are relatively expensive. Direct acid-fast smears and cultures of CSF for Mycobacterium tuberculosis have low sensitivities (0 to 30% and 50%, respectively). For cultures and smears to be positive, a large amount of CSF (>7 ml) and multiple specimens are necessary. Even when these specimen requirements are met, a negative test result does not rule out disease.

In the last 6 years, the CML has performed 310 acid-fast cultures of CSF specimens. During this time, the diagnosis for only one of three patients clinically diagnosed
with tuberculosis meningitis was confirmed by culture, and confirmation was achieved only after a large amount of CSF was cultured. The diagnosis of tuberculosis meningitis, therefore, is difficult and requires a correlation of clinical and laboratory information, often with the aid of infectious disease and neurologic consultations.

Therefore, acid-fast smears and cultures of CSF will no longer be performed routinely because (i) the sensitivities of these tests are poor, (ii) the prevalence of tuberculosis in the Midwest is low, and (iii) the tests are relatively expensive. Specimens will be held for 7 days, and the ordering physician will be notified. If tuberculosis meningitis is seriously suspected, please contact the CML at [telephone number]. An infectious disease consult is strongly recommended in these cases.

References


Contact for Scientific Information [provide names and telephone numbers]:

EXAMPLE 2

This example is adapted from Microbiology Clinical Brief, a publication for the medical staff of a health care system.

Viral Encephalitis (HSV, CMV, and VZV)

In patients with confirmed herpes simplex virus (HSV) encephalitis, cultures of CSF rarely contain recoverable virus because the sensitivity of CSF culture for HSV is only 0 to 4%. With the advent of PCR assays to detect HSV, the laboratory diagnosis of HSV encephalitis has improved dramatically (sensitivities, 75 to 100%). Therefore, the PCR test (instead of culture) will be routinely performed with CSF specimens when culture for HSV is ordered. In addition, the sensitivities of CSF cultures for cytomegalovirus (CMV) and varicella-zoster virus (VZV) also are poor. Therefore, PCR tests instead of culture will be routinely performed with CSF specimens when cultures for CMV and VZV are ordered.

The exception to the very low sensitivity of CSF culture for HSV is when central nervous system (CNS) disease is due to primary, not reactivated, HSV infection. Most cases (>95%) of adult and childhood HSV encephalitis are caused by reactivation of the virus. In contrast, patients with perinatally or neonatally acquired HSV or patients of any age with meningitis associated with primary genital HSV can have more frequent (up to 24%) positive cultures.

In the neonate or infant less than 6 months old, ideally, both PCR tests and culture of CSF for HSV should be performed.

The means of detection of HSV, CMV, or VZV from CSF specimens will be converted to the PCR method, except for infants less than 6 months old. In these cases, PCR and culture will be performed. For optimum detection of HSV, CMV, or VZV, 0.5 ml of uncentrifuged CSF is needed for PCR and an additional 1.0 ml of uncentrifuged CSF is needed for culture.

In spite of the vastly increased sensitivities of the PCR tests, false-negative results can occur; therefore, a negative PCR test result does not rule out HSV infection. In a patient with HSV infection, the test can be negative because (i) inhibitors of the PCR can be present in the specimen or (ii) HSV DNA can be present at concentrations too low to be detected by the PCR. The diagnosis of HSV infection of the CNS should not rely solely on the results of a PCR assay. The result should be considered in conjunction with the clinical presentation and laboratory test results.

The approximate cost of PCR testing for HSV, CMV, or VZV is $[cost].

References


Contacts for scientific information [provide names and telephone numbers]:

EXAMPLE 3

This example is adapted from Pathologist, a newsletter to the physicians of a community hospital system.

Ordering Correct HIV Quantitation and HIV Genotyping Tests

There is a confusing array of tests for human immunodeficiency virus (HIV) available to health care providers, which can result in the ordering of the incorrect test. The fact that the commonly used (and brand) names of several HIV tests look and sound similar to each other contributes to the selection of inappropriate orders. In addition, unit coordinators and nurses occasionally (i) incorrectly transcribe physicians’ orders for HIV tests or (ii) select the incorrect test in the HIS.

The more common incorrectly ordered HIV tests are regular quantitative HIV, ultrasensitive quantitative HIV, qualitative HIV, and HIV genotyping. The information in Table A1 can be helpful in deciding which tests to order, which tests physicians often request, and which tests to select in the health information system. Table A1 includes the following information about each test: common name, the name of the test (code) in the HIS, and general features.
EXAMPLE 4

This example is adapted from Pathologist, a newsletter for the physicians of a community hospital system.

Clinical Microbiology Test Results Will Look Different

Most computer systems have major limitations in establishing codes for tests; therefore, the most logical abbreviations for tests are often unavailable. In addition, abbreviations which make sense to a microbiologist might not make sense to clerks, physicians, etc. To enable a variety of users to choose the proper code for a test, great care should be used when establishing these computer codes.

Now, nurses and unit coordinators will see new microbiology test screens and order codes. The test-ordering screens in the HIS and the test codes used to order clinical microbiology cultures and other tests have been redesigned (i) to make ordering easier, more logical, and more user friendly for those persons who enter orders for microbiology tests; (ii) to reduce the chances of entering incorrect test orders; and (iii) to make the tests easier to find and use in the HIS.

Physicians Will See New Microbiology Test Descriptions

The redesign mandated changes in the test descriptions seen by physicians when they view microbiology results. The new descriptions will have a more logical nomenclature and will be more indicative of the type of test performed and the type of specimen submitted for the test. For example:

- **WOUND CULTURE** will appear as CULT AEROBIC SWAB
- **TISSUE CULTURE** will appear as CULT AEROBIC TISSUE
- **FLUID BC BOTTLE** will appear as CULT FLUID PLEU/PERITONEAL
- **BODY FLUID CULTURE** will appear as CULT FLUID OTHER
- **ANAEROBIC CULTURE** will appear as CULT ANAEROB FLD/TIS
- **_FUNGUS CULTURE OTHER** will appear as CULT FUNGAL NON SKIN
- **HSV GENITAL CULTURE** will appear as CULT VIR HSV GENITAL

Contact [provide names and telephone numbers] if you have any questions regarding these changes.

APPENDIX B

EXAMPLES OF PROJECTS DESIGNED TO DETECT AND PREVENT CML-ASSOCIATED ERRORS

PROJECT 1: DETERMINING IF APPROPRIATE HEALTH CARE WORKERS RECEIVE CRITICAL VALUE REPORTS AND IF THE REPORTS ARE CLINICALLY USEFUL

**Issue**
The College of American Pathologists requires individual institutions to define “critical results,” “critical values,” or “panic values.” Although the importance of and process for communicating critical values to a responsible health care worker have been detailed and emphasized all too frequently, there can be a delay before any action is initiated in response to these reports. The objective of this project is to determine if the appropriate health care worker receives the reports and if any necessary action was initiated as a result of the information in the reports. The nature of the action is not to be evaluated.

**Actions**
1. Prepare a customized form similar to the sample shown in Figure B1 and submit the form to the medical director or other appropriate person for endorsement or approval. The footnotes on the sample form are for
Use in customizing your own document and should be deleted from the final form. You may choose to use paper communication or electronic communication, if the health care workers at your institution have access to electronic forms of communication. The form can be used to monitor responses to critical values such as positive blood cultures.

2. Send the approved form within 24 h to each clinician who received the result by telephone. The number of surveys distributed depends on the size of your institution, but at least 50 should be sent.

3. Make sure that the person to whom the form is to be returned is stated clearly on the form.

4. If a response is not received, send a follow-up questionnaire.

5. Arrange for the collection of the forms, analysis of the data, and follow-up for nonreturned forms.

**Expected Results**

Most health care workers will view the questionnaire as an appropriate quality assurance improvement tool, and a 50 to 70% response rate is expected. However, a few health care workers may not return the form.
care workers may be antagonistic or view the questionnaire as a challenge to their expertise.

Follow-Up
After analysis of the responses, report the results to the director, administrator, or other appropriate personnel. Also, share the information with members of the laboratory staff so that they can appreciate their role in the delivery of quality health care. As a result of this survey, the process by which critical values are communicated and to whom they are communicated might need to be revised.

PROJECT 2: REDUCTION OF TRANSCRIPTION, TRANSLATION, AND ORDERING ERRORS

Issue
CML personnel have a continuous problem with incorrect orders made by unit coordinators, nurses, and satellite laboratory personnel. Examples of such errors include the following: (i) handwritten manual test requisitions used by surgery personnel are not filled out accurately, are not complete, do not match accompanying specimens, and/or do not reflect a surgeon’s verbal orders; (ii) a routine culture order for tissue is written by a physician, but tissue is received with a computer order for a urine culture; (iii) an order for a molecular probe for Chlamydia trachomatis is written by a physician and entered into the HIS, but a cervical swab specimen is received in viral culture medium (which is inappropriate for probe testing); (iv) an order for viral culture is written by a physician and entered into the HIS, but “fungal culture” is written on the specimen label; (v) an order for a culture of lung tissue for acid-fast bacilli is written by the physician, but another health care worker selects “aerobic culture” in the HIS. In these situations, laboratory personnel do not know what the physician wants, incorrect tests could be performed, requested tests might not be performed, specimen processing is delayed, reimbursement for testing can be reduced, laboratory personnel do not make efficient use of their time, and health care funds are wasted.

Actions
1. On a daily basis, survey the printed copies of orders corrected by laboratory setup technologists to determine the numbers and types of corrected errors. Keep a record of the time necessary to correct the errors.
2. Analyze the errors, interview the ordering personnel associated with the errors, and determine the reasons for the errors.
3. Give satellite laboratory personnel “cheat sheets” to help them detect order errors before the orders and specimens are sent to the main or core CML.
4. Organize continuing education lectures or workshops for hospital unit coordinators, nurses, and other appropriate health care providers on how to order CM tests correctly in the HIS, and give them cheat sheets for their 10 more commonly ordered tests.
5. Give on-site HIS training to surgical nurses who use manual test requisitions instead of the HIS to order CM tests.
6. Examine the HIS ordering screens, and determine if the content of the HIS could be made more logical and user-friendly.
7. Redesign HIS CM test ordering screens to ensure ease of CM test selection, and educate HIS training personnel on how to train employees to order CM tests properly.
8. Analyze the project monthly to determine the number of corrected orders, the time used to correct orders, and the labor costs associated with the corrections.

Expected Results
Analysis should show the following: (i) that there is a decrease in the number of orders per month requiring correction and that there is a decrease in the number of hours per month used to correct the orders, (ii) that the labor costs associated with correcting orders are [$ amount]/month, and (iii) that CM test ordering screens within the HIS could be made more user-friendly than the current screens, which contain a list of complex and user-unfriendly CM test computer codes required to be used by the individuals entering orders for the CML.

After education of the people who order CM tests, the number of corrected orders and the amount of time used to correct them should be reduced. As a result of participation in the educational process, the satellite laboratory personnel, unit nurses, unit coordinators, and surgical nurses should feel responsible (have “ownership”) for proactively ordering CM tests correctly. The labor costs associated with these activities should be reduced.

Follow-Up
The quality and quantity of corrected orders should continue to be monitored periodically.

Note
This study was performed in a community hospital system in the Midwest, and the following results were found: setup technologists were correcting an average of 164 orders/month (range, 81 to 207 orders/month) and were using an average of 41 h/month (range, 20 to 52 h/month) troubleshooting and correcting these orders. The average labor cost associated with these corrections was $533/month (range, $260 to $676/month). This cost did not include (i) the effects of the corrected orders on patient care or (ii) the costs associated with the nurses’ or physicians’ time required to help correct the errors.

PROJECT 3: IMPROVING THE DETECTION OF ESBL-PRODUCING BACTERIA IN A HEALTH CARE SYSTEM WITH MULTIPLE CMLS

Issue
The failure to detect (by screening and confirmation) ESBL-producing bacteria is not necessarily a “mistake” per se. However, such failure can result in delayed initiation of bacterium-specific antimicrobial therapy, adverse patient outcomes, increased hospital costs, and increased lengths of hospital stay (16). Although the National Committee for Clinical Laboratory Standards (NCCLS) has published recommendations and methods for screening and confirming
ESBL production by \textit{E. coli} and \textit{Klebsiella} species, the detection of ESBLs is still not incorporated into routine use in many CMLs. Therefore, ESBL-producing bacteria in any given facility will fail to be detected if routine testing for ESBL production is not performed in the CML which serves that facility.

This study can assess (i) the prevalence of ESBL-producing bacteria in a multilaboratory hospital system or a specific geographic region with multiple CMLs and (ii) the clinical and financial impacts of increased rates of detection of this clinically relevant mechanism of antimicrobial resistance.

**Actions**

1. Determine the number of ESBL-producing isolates reported by the CML within a region or system before and after incorporation of NCCLS guidelines for detecting ESBL-producing \textit{E. coli} and \textit{Klebsiella} species into CMLs which formerly did not perform such testing.

2. Correlate the therapeutic decisions, clinical outcomes, lengths of stay, and reduction of costs associated with increased rates of detection and reporting of ESBL-producing isolates.

**Expected Results**

There should be a striking increase in the number of newly detected, clinically relevant ESBL producers. Reduced lengths of hospital stay and reduced hospital costs should be associated with the clinical actions taken in response to reports of the newly detected bacteria.

**Follow-Up**

Detection of ESBL producers can be monitored, and a review team can examine the correlating medical and cost outcomes information each month or quarter. As the process continues to improve, the team can have the ability to manage what they monitor.

**Note**

This study was performed in a large area served by nine CMLs. The rate of compliance with screening for ESBL-producing bacteria increased from 18.3 to 97% over a 16-month period. Eight of the nine CMLs improved their rates of compliance to 100%. Improved detection of ESBL-producing bacteria resulted in the more timely implementation of appropriate antimicrobial therapy, which subsequently resulted in improved medical outcomes and cost outcomes (cost savings, approximately $10,000 per patient; reduced length of stay, approximately 13 days).

**PROJECT 4: EFFECTIVE COMMUNICATION OF CRITICAL RESULTS BY TELEPHONE**

**Issue**

Reducing the rate of avoidable errors is essential. One area in which major opportunities exist for this is the clear and accurate communication of results by telephone. The airline industry has dealt with this issue of miscommunication by requiring pilots to repeat all instructions which they receive from the air traffic controller. This project involves implementation of such a protocol adapted to the clinical laboratory.

Such a study completed at a large university medical center confirmed that this straightforward approach of simply having telephoned laboratory results stated back to the caller improved the accuracy of the laboratory report (1). At another hospital, the process of having the message repeated required an average of 13 s at a nominal cost of $0.11 to $0.16 per call. While it may be difficult to determine the actual cost savings of this practice, communicating critical laboratory information in an accurate manner provides an environment that promotes optimal patient care.

**Actions**

1. At the beginning of each outgoing telephone report from the laboratory, before the results are given, read the following statement to the person receiving the report: “To make sure I have given you the right information, would you please repeat the patient’s name, the test, and result once I give it to you?”

2. Give the laboratory information and ask the person to repeat it. After the person has responded, either (i) say that the information is correct and thank him or her, or (ii) if the information repeated was incorrect, again request that the message be repeated.

3. Document when this phone call was made, to whom it was made, and whether the results were repeated accurately. Optionally, you may record the category of the recipient (e.g., clerk, nurse, physician, or other).

**Expected Outcome**

An anticipated low rate of potential errors in communicating the telephone message will be discovered and simultaneously corrected.

**Follow-Up**

Periodically, documentation from work card entries can be monitored to determine the percentage of phone calls for which the results were repeated successfully (goal, 100%).

**Note**

In the laboratory of the 500-bed community hospital where this project was performed, the rate of errors for all telephone calls made from the laboratory was 4%. CM had the highest error rate (10%), and hematology had the lowest error rate (1%). The recipients with the highest rates of errors were physicians (27.3%). The error rate for nurses was 4.8%, and the error rate for those noted only as “other” was 3.7%. No errors were recorded for clerks and unit coordinators, although some may have been included in the “other” category.

As of January 2004, the Joint Commission on Accreditation of Healthcare Organizations requires the “read back” of all laboratory test results which must be communicated by telephone (mostly critical value results) to the person who makes the call and gives the results. This new read-back process should be documented by the caller.
PROJECT 5: CORRELATION OF SURGICAL PATHOLOGY AND CM RESULTS

Issue
There is not always a correlation between the fungus observed and microscopically identified in tissue in the surgical pathology department and the organism cultured from the same specimen in the CML. Discrepancies can be a result of inadequate or discordant selection of the specimens or the lack of correlation of CM and surgical pathology results or communication between the two areas reporting results for the same specimen. A study done in 1997 reported on the correlation between microscopically observable fungi reported as *Aspergillus* in cytology specimens and whether or not growth of the same specimens from cultures corroborated this finding (10). The findings for the cytology specimens were neither specific nor sensitive for the diagnosis of infection due to *Aspergillus* when they were used without culture information (10).

Actions
1. Generate a list of lung biopsy specimens from which fungal organisms were reported by the pathology department for a particular time frame. By using the laboratory information system (LIS), determine if a similar specimen was received for culture during the same period of time by the CML and, if so, what fungal identification was reported.
2. Compare the surgical pathology results with the microbiology culture reports to determine the following:
   a. the number of specimens sent to the pathology department but not to the CML,
   b. the rate of discordance between the pathology and the microbiology results, and
   c. the quantity and types of errors (e.g., which errors were associated with discrepant reports and which ones could result in serious adverse clinical impacts).
3. Develop a prospective program between the two laboratory sections that will provide coordinated communication before a final report is submitted from either section individually. Discrepancies may be found in the initial examination of the data. However, a formal system of communication, consultations, and interactions between the two sections could prospectively allow dialogue between the sections and potential discovery of discrepancies while the specimen is being examined and processed by the two sections.
4. Develop a prospective quality assurance system to monitor the continuance of these consultations.

Expected Outcome
The correct diagnosis of fungal infections can be optimized by joint efforts of the two laboratory sections. Patient care will be favorably affected by providing information that should lead to the correct therapy and management of fungal diseases. In addition, a formal means of communication will provide more opportunities for discussion and consultation between surgical pathologists, clinical microbiologists, and clinicians and will facilitate correct specimen ordering practices and the correct diagnosis of fungal infections.

Follow-Up
An ongoing system will be devised whereby the pathology department informs the CML regularly and in a timely fashion when fungal findings are observed in sterile tissues. When fungi grow from tissues at sterile sites, the CML will correlate the findings for the tissue with the surgical pathology results in order to aid in determination of the significance of the culture findings.

Note
This study was performed at a large medical center, and the following results were found.

1. Four lung biopsy specimens with discrepant CM and surgical pathology results were detected and were considered to be clinically relevant enough to be investigated and to initiate discussions between the two laboratory sections (Table B1).
2. Detected errors
   a. An *A. fumigatus* strain isolated in the CML was inaccurately reported as *Candida* by surgical pathology. If a specimen had not been sent to the CML, the patient might have been inappropriately treated.
   b. Three biopsy specimens in which hyphal growth was observed in surgical pathology sections did not grow fungi in culture. These discrepancies could have occurred because (i) the CML received a swab specimen rather than a tissue specimen (although a comment which indicated submission of an inappropriate specimen would have been included in the final CML report), (ii) the specimen could have been sent in formalin and accidently cultured, or (iii) an inadequate amount of specimen was submitted to the CML.

When a discrepancy between the surgical pathology results and the CM results was observed, the remaining tissue (if it had been saved) was reprocessed for culture. In some cases, reculturing yielded the growth of a fungus with a morphology consistent with the fungal structures observed in surgical pathology. Therefore, the initial processing of the specimen for culture was assumed to have been inadequate.

<table>
<thead>
<tr>
<th>Pathology results</th>
<th>Microbiology results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consistent with <em>Candida</em></td>
<td><em>Aspergillus fumigatus</em></td>
</tr>
<tr>
<td>Consistent with <em>Aspergillus</em></td>
<td>No fungus isolated</td>
</tr>
<tr>
<td>Invasive <em>Aspergillus</em></td>
<td>No fungus isolated</td>
</tr>
<tr>
<td>Suggestive of <em>Aspergillus</em></td>
<td>No fungus isolated</td>
</tr>
</tbody>
</table>
PROJECT 6: USE OF DATA FROM A LABORATORY INFORMATION SYSTEM TO IDENTIFY PERSONS WHO MISREAD THE RESULTS OF GROUP A STREPTOCOCCUS ANTIGEN TESTS

Issue
Rapid tests to detect group A Streptococcus antigen incorporate methods (e.g., color development or particle agglutination) which yield subjectively read endpoints. Therefore, one or more individuals performing these tests may interpret and report results that are significantly different from those reported by other individuals.

The purpose of this project is to identify individuals whose interpretations and results are significantly different from those of their peers who perform the same test. Individuals who report significantly higher rates of positive results may be overreading test results. Similarly, individuals who report significantly higher rates of negative results may be underreading test results. Information on the test results reported by individuals is readily available in the LIS.

Factors To Be Considered before Comparing Individuals’ Results
Care must be taken to ensure that the patients being tested by each individual are demographically well characterized. Demographic factors that can skew the results of the analysis include the age of the patient, the time of year in which testing occurs, and the time of day in which specimens are collected. Several studies with children have shown a bell-shaped curve when the positivity rate is plotted against the age of the patients. The peak age for group A streptococcal pharyngitis is 5 to 7 years. The time of the year affects the analysis because the number of specimens tested from patients with viral pharyngitis is higher during the winter months than during the summer months. The percentage of tested patients who are infected with group A Streptococcus may actually be higher in the summer months. The time of specimen collection is important because ambulatory patients who are seen on the third shift (e.g., between midnight and 8 a.m.) tend to be sicker than those seen on the first and second shifts (e.g., between 8 a.m. and midnight). Thus, positivity rates should be higher for individuals who primarily test specimens collected during the third shift. Laboratories which undertake this project should determine if the demographic phenomena described above (and perhaps others) apply to the population of patients served by the laboratory.

Actions
There are several ways to accomplish this project, all of which are beyond the scope of this Cumitech. Consult an LIS manager to determine the available options.

1. Data obtained from the LIS should include all of the following: the patient’s medical record number, the patient’s age, the patient’s sex, the specimen accession number, the specimen collection date, the specimen collection time, the antigen test result, the confirmatory test result (if performed), and the code for the technologist who performed the antigen test.
2. The data should be downloaded into a personal computer as a formatted text file.
3. The data should be analyzed by someone experienced with the use of a pivot table for antigen positivity rates by patient age, season of the year, and time of specimen collection. The overall percent positivity by patient sex should also be determined.
4. Ideally, the results reported by an individual should not differ statistically from the results reported by the group of individuals who routinely interpret and report the results of the test. Individuals who are identified as "outliers" (after taking into account the demographic factors described above) should undergo competency assessment in a nonthreatening fashion and should receive remedial training if the assessment indicates that it is necessary. Follow-up analysis similar to that described above should be conducted after the remedial training intervention.

Expected Outcome
Completion of this project should result in more accurate test results and less variation in the interpretation of results.

REFERENCES


