Competency Assessment of Microbiology Medical Laboratory Technologists in Ontario, Canada

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Accreditation in Ontario, Canada, requires that licensed clinical laboratories participate in external quality assessment (also known as proficiency testing) and perform competency evaluation of their staff. To assess the extent of ongoing competency assessment practices, the Quality Management Program—Laboratory Services (QMP-LS) Microbiology Committee surveyed all 112 licensed Ontario microbiology laboratories. The questionnaire consisted of a total of 21 questions that included yes/no, multiple-choice, and short-answer formats. Participants were asked to provide information about existing programs, the frequency of testing, what areas are evaluated, and how results are communicated to the staff. Of the 111 responding laboratories, 6 indicated that they did not have a formal evaluation program since they perform only limited bacteriology testing. Of the remaining 105 respondents, 87% perform evaluations at least annually or every 2 years, and 61% include any test or task performed, whereas 16% and 10% focus only on problem areas and high-volume complex tasks, respectively. The most common methods of evaluation were review of external quality assessment (EQA) challenges, direct observation, and worksheet review. With the exception of one participant, all communicate results to staff, and most take remedial action to correct the deficiencies. Although most accredited laboratories have a program to assess the ongoing competency of their staff, the methods used are not standardized or consistently applied, indicating that there is room for improvement. The survey successfully highlighted potential areas for improvement and allowed the QMP-LS Microbiology Committee to provide guidance to Ontario laboratories for establishing or improving existing microbiology-specific competency assessment programs.

In Ontario, legislation requires the licensure, external quality assessment (EQA) (also known as proficiency testing), and accreditation of all clinical laboratories. The Ontario Medical Association (OMA) is the agency designated by the Ministry of Health and Long-Term Care (MOHLTC) to monitor proficiency of laboratory test performance and to accredit laboratories. The Quality Management Program—Laboratory Services (QMP-LS) is a department of the OMA and is a mandatory EQA and accreditation program for licensed medical laboratories in Ontario, Canada.

All QMP-LS EQA programs are accredited with respect to ISO/IEC 17043:2010 (Conformity assessment—General requirements for proficiency testing) (1), and the QMP-LS accreditation division is a signatory to the Mutual Recognition Arrangement (MRA) of the International Laboratory Accreditation Cooperation (ILAC) and the regional Asia Pacific Laboratory Accreditation Cooperation (APLAC). The accreditation requirements are based on ISO 15189 (2) and are augmented with international standards for safety and point-of-care testing, national standards for blood safety, government regulation, and generally accepted principles of good practice (3).

The accreditation division of QMP-LS requires clinical laboratories (hospital, private, and public health) to establish skill evaluation testing or competency evaluation of their staff as part of a comprehensive quality management program. During accreditation visits, laboratories are required to demonstrate that a competency program is in place and that evaluation results are kept, and, while there are suggested assessment methods, there are no explicit accreditation requirements for the content of the program or the frequency of testing. In the United States, the Clinical Laboratory Improvement Act (4) mandates that competency assessment be completed for all technical, supervisory, and testing personnel for each test that an individual is approved to perform and must include the following elements for each test evaluated: (i) direct observation of routine test performance; (ii) monitoring the recording and reporting of test results; (iii) review of intermediate test results, quality control (QC) records, proficiency testing results, and preventative maintenance records; (iv) direct observation of performance of instrument maintenance and function checks; (v) assessment of test performance through testing of previously analyzed specimens, blind samples, or external proficiency samples; and (vi) assessment of problem-solving skills (4, 5, 6, 7).

An initial assessment is required within the first 6 months following the initial training period and annually thereafter.

For more in-depth guidance on performing competency assessments, laboratories are more likely to rely on published recommendations such as those from the Clinical and Laboratory Standards Institute (CLSI) (8) or other peer-reviewed publications (9, 10, 11, 12, 13, 14, 15). Many publications are not specific to microbiology and address staff competency evaluation from the perspective of laboratory medicine in general. The most comprehensive document providing guidance to microbiology laboratories for how they may achieve compliance with CLIA in establishing a comprehensive competency evaluation program is Cumitech 39, which was updated in the reviews by Sharp and Elder (6, 7).
Competency Assessments in Microbiology Laboratories

For each EQA discipline, QMP-LS has a volunteer, scientific committee of laboratory physicians, scientists, and medical laboratory technologists (MLTs) who provide technical and clinical advice for the program. The members of the QMP-LS Microbiology Committee have noted problems related to competency in laboratories with performance issues and were concerned that Ontario microbiology laboratories may not have had a comprehensive competency evaluation program beyond determining the competency of staff following initial training and, if they had, that it may not be sustained over time. Although Cumitech and CLSI documents are useful resources, the lack of specific guidance for microbiology laboratories was identified by the committee as an opportunity to help laboratories formulate a microbiology-specific competency evaluation program by gaining insights from their peers. A pattern-of-practice survey designed to gather information on current practices in Ontario for ongoing competency assessment of MLTs was provided to licensed bacteriology laboratories across Ontario in July 2011, with the goal of assessing these practices and providing feedback and guidance to laboratories.

MATERIALS AND METHODS

A mandatory Web-based pattern-of-practice survey was provided on a password-protected website to 112 Ontario laboratories that are licensed to perform bacteriology testing. These included laboratories holding single-test licenses such as for Gram stain only, group A streptococcus throat screens, or Clostridium difficile antigen or toxin detection. The survey consisted of a total of 21 questions covering areas of ongoing competency assessment and did not apply to posttraining assessment of new staff members. The questionnaire consisted of 4 yes/no questions, 3 yes/no questions with a follow-up explanation, 5 multiple-choice questions, and 9 short-answer questions. Participants were also requested to submit blank copies of their competency assessment forms and were asked for permission to share the forms in the committee comments for the benefit of other laboratories. The survey was designed to obtain information on basic operations of a competency program and provide laboratories with the opportunity to share their approach to competency assessment.

The who, what, when, where, and how of competency assessment programs. Laboratories were asked if they have policies in place to assess staff competency on an ongoing basis. If policies are in place, laboratories were asked to provide information on who is tested, who performs the testing, the components of the assessment are selected, and how competency assessment is performed. When the evaluation is performed, how the staff members are evaluated, and how competency assessment is documented. Laboratories were also asked to review their competency assessment records for randomly selected technologists (25% up to a maximum of 25) and to determine how many were evaluated on an annual basis from 2007 to 2011.

Impact of competency assessment on laboratory operations. To determine what impact competency assessment programs have on laboratory operations and staffing resources, laboratories were asked how many full-time equivalents (FTE) are assigned to administer, review, and document competency evaluations. To adjust for the size of the sample and the level of testing, laboratories were requested to include only the numbers of MLT FTEs in the bacteriology section as opposed to those for the entire department, which may consist of other sections such as virology, parasitology, etc. The impact on staffing resources was defined as the ratio of FTEs required to perform the competency evaluations to the total number of MLT FTEs performing testing in the bacteriology laboratory.

Feedback and remedial action. Laboratories were asked if they had established criteria to define successful completion of the assessment and, if they had, what criteria were used. If the results of the assessment of a staff member were unsatisfactory, laboratories were asked whether remedial action had been taken and, if so, what type of action was taken and to provide two examples of the most common issues requiring remediation.

Laboratories were also requested to provide information and examples of what arrangement, if any, was in place to provide feedback to the staff. Laboratories were asked to perform a self-assessment on the quality of competency assessment in their facility by rating the quality of their program as well as whether they felt it had a positive impact on the quality of service provided on a scale of 1 (not well developed) to 5 (extremely well developed).

RESULTS

Responding laboratories. Of the 112 licensed Ontario laboratories that received the survey, 111 responded. One laboratory closed during the survey period and did not submit a response. Of the 111 respondents, 7 indicated they did not have a formal policy or process for ongoing competency assessment. Of these, 6 performed minimal bacteriology testing (rapid testing and loading and unloading of blood culture bottles [Gram stain only]), and 1 indicated they had an informal process for ongoing competency evaluation and were in the process of developing policies and procedures. Analysis of the responses was performed for the 105 laboratories that submitted a response, performed informal or formal evaluations, and provided a comprehensive bacteriology service.

The who, what, when, and where of competency assessments. Of the 105 respondents, 99 (94%) responded that they regularly assess the ongoing competency of their MLTs in bacteriology (Table 1). The six laboratories that did not perform regular assessments indicated they would do so as required or as problems arise. Eighty-seven percent (91/105) of participants indicated they performed ongoing assessment annually or at least once every 2 years (Table 1). In addition to annual testing, most laboratories have established criteria for when an individual’s competency must be reassessed such as after extended leave (85%), when duties (71%) or test methodologies (84%) change, or when internal indicators suggest problems (90%). The majority (64/105 [61%]) of laboratories include any test or task performed in their competency assessment program, while 17 (16%) focus on problem tests/tasks and 11 (10%) focus only on high-volume or highly complex tests/tasks (Table 1). The most common tasks assessed include microscopy (83%), specimen processing (75%), culture interpretation (73%), and organism identification (72%). Laboratory information system (LIS)/data management was the least frequently assessed ongoing competency (54%). Only 4% of participants indicated performing ongoing assessment for nucleic acid amplification tests (NAAT) or other molecular methods (Table 1).

How is ongoing competency monitored? Assessment of performance with respect to EQA challenges was the most common approach for the ongoing evaluation of specific core competencies. Direct observation of routine test performance and review of worksheets and patient reports were other major assessment tools. Approaches such as introduction of a blind/unknown sample or a written or oral quiz were not as commonly used. Some laboratories used Web-based competency assessment programs such as the College of American Pathologists (CAP) competency assessment program (http://www.cap.org/apps/cap.portal?_nfpb WindowLabel=cntvwrPlt&cntvwr) and Medical Training Solutions (MTS) competency assessment program (http://www.medtraining.org/labcontent.aspx).

Of the 105 participants who responded, the majority indicated...
that managers, senior technologists, and/or supervisors are responsible for performing competency evaluations. However, one-third (35/105) of laboratories also indicated that assessments by peer technologists are used. Evaluations by laboratory directors and/or medical/clinical microbiologists are uncommon (9 laboratories of 105 respondents).

Laboratories were asked to provide two examples of how competencies are assessed for specific laboratory core areas such as specimen processing, microscopy, culture interpretation, organism identification, and antimicrobial susceptibility testing, and the responses are summarized in Table 2.

**Do laboratories establish criteria for successful completion of competency assessment and communicate results and do they take remedial action?** Most (75%) of the laboratories evaluated have established thresholds, benchmarks, or criteria for passing or failing an assessment. Many establish a passing grade for objective evaluations such as quizzes or unknown panels. Of the 31 laboratories that provided information on their protocols, 12 indicated that they use a threshold of 100%, 14 that they use 80%, 2 that they use 85% or 90%, and 3 that they use 70% or 75%. For more-subjective evaluations such as worksheet assessments or result reporting, performance is based on a simple pass or fail.

Almost all laboratories stated that they communicate and document competency assessments (Table 3). Of the 105 laboratories, 74 (70%) have sign-off competency assessment documents, 56 (53%) have individual competency assessment folders for each staff member, and 31 (30%) use a commercial electronic documentation system.

All but 7 of the 105 respondents (93%) indicated that remedial action is taken if the individual fails the evaluation. Most laboratories indicated that retraining, reviews, continuing education
programs, and reevaluation would be part of any follow-up for any staff member who does not perform well on competency assessments. However, only four laboratories indicated that restricting the individual’s rotations to areas of demonstrated competency until competency has been established or other actions would be considered.

Common competency issues. The most common competency issue requiring remediation was associated with Gram staining and interpretation. Additional common areas of concern included failure to understand or lack of familiarity with laboratory protocols, difficulties in performing antimicrobial susceptibility testing, including technical issues (e.g., inconsistent length of incubation for disk diffusion testing or of measurement of zone diameters), lack of familiarity with appropriate methods, inconsistent interpretations of antibiograms, failure to recognize unusual phenotypes, and reporting inconsistencies (Table 4). Other areas which often required remedial action included LIS/data entry and biosafety.

Self-assessment of ongoing competency assessment programs. Approximately half (47%) of the respondents indicated that they would rate their laboratory’s competency assessment program as moderately well-developed, whereas 30% and 23% rated their programs as less than moderately well-developed and better than moderately well-developed, respectively. The majority (88%) felt that their competency assessment program had a positive impact compared to 12% who indicated there was no impact on the quality of service provided.

The cost of ongoing competency assessment. Of the 105 laboratories, 79 (75%) had 10 or fewer full-time equivalent (FTE) technologists performing bacteriology tests and 10 (10%) had 20 or more FTEs. To determine the impact on staffing resources, laboratories were asked to estimate the proportion of FTEs to the total number of MLT FTEs required to review competency assessments. Many respondents either misinterpreted the question or overestimated the time required to perform their competency assessments. However, among the 45 laboratories that appear to have correctly interpreted the question, the proportion of FTEs to MLT FTEs required to perform competency assessments was 2% to 6% or one FTE for 17 to 50 MLTs depending on the comprehensiveness of the program. The proportion of MLTs assessed for competency increased over the survey period (Fig. 1). The number of laboratories assessing at least 80% of MLTs in a year more than doubled from 35 (33%) in 2007 to 78 (74%) in 2010.

DISCUSSION

The goal of competency assessment is to improve the laboratory’s performance by identifying areas requiring education and/or training of the staff and thus ensuring patient safety. Ongoing competency assessment outside initial training is not as universally implemented and, in some cases where it exists, may be limited in scope and intensity. Performing competency assessment as the need arises is a reactive rather than a proactive approach. The goal should be to detect problems before they happen. Ongoing assessment needs to be incorporated into a laboratory’s quality management system. In Ontario, competency assessment is mandated by Ontario Laboratory Accreditation (OLA). However, there is little explicit direction as to what components or which areas should be included in a competency program or the frequency with which staff member should be evaluated.

The first step in developing a competency program is to determine which staff members should be assessed, which areas of the laboratory should be included, the frequency with which staff member should be evaluated, and how to measure competency. Although technologists, technicians, and clerks should all be as-

### Table 4: Common competency issues requiring remedial action

<table>
<thead>
<tr>
<th>Competency</th>
<th>% reporting laboratories (n = 105)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gram stain misinterpretation</td>
<td>27</td>
</tr>
<tr>
<td>Failure to follow or understand or lack of familiarity with protocols</td>
<td>23</td>
</tr>
<tr>
<td>Antimicrobial susceptibility testing problems: method, interpretation, reporting</td>
<td>20</td>
</tr>
<tr>
<td>Preanalytical problems: labeling, setup, accessioning</td>
<td>6</td>
</tr>
<tr>
<td>Postanalytical problems: incorrect reporting, inappropriate turnaround time, communication</td>
<td>7</td>
</tr>
<tr>
<td>Problems with LIS/data entry</td>
<td>7</td>
</tr>
<tr>
<td>Lack of familiarity with biosafety</td>
<td>7</td>
</tr>
</tbody>
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![Fig 1](http://jcm.asm.org/ on August 15, 2017 by guest)
sessed, the scope and frequency of assessment may be tailored to the individual’s responsibilities. In smaller laboratories with fewer resources, it may be preferable to focus on key areas in the laboratory. This can be based on the importance or impact of the procedure or the competency of the individual being evaluated. Ongoing assessment of proficiency with LIS/data management systems, such as use of proper codes and specimen workup data entry and accessioning, was the least frequently monitored core competency. This is a key area to include in evaluation programs since most laboratories are now paperless and entirely dependent on information technology. Only a few laboratories indicated performing competency evaluation for NAAT or other molecular tests. Although this is likely a reflection of the number of laboratories performing these assays in routine testing or the level of services, the rate at which NAAT are being implemented in bacteriology highlights the need to include these methods as part of a competency assessment program. The absence of proper EQA programs for many of these assays, particularly in Canada, makes it difficult for laboratories to design effective evaluation strategies. Finally, only two laboratories indicated that they include biosecurity as part of the assessment. With the pending implementation of the Human Pathogens and Toxins Act (17), which is similar in intent to the Select Agents rule (18) and is to become law in December 2015, laboratories must be aware that this legislation mandates that all laboratories develop biosecurity plans and that assessment of biosecurity knowledge has become an important component of competency evaluation.

The extent of assessment in each area will largely be defined by the laboratory’s resources which will also determine what type of measures are to be included in the evaluation. The frequency with which staff members should be evaluated is also limited by available resources, but laboratories should assess each individual annually in at least one area of responsibility.

Competency evaluation of staff members should include measures that allow determination of what the individual knows, what the individual can do, and if the individual actually follows policies and procedures or uses the “know-can-do” approach (10, 16). Determining what individuals know and can do is usually straightforward and assesses what they have learned and whether or not they can apply that knowledge. Measures can include assessment of problem-solving skills through quizzes and observation of testing of patient or EQA samples or testing of simulated samples (5, 7). However, all of these measures are performed with the individual being aware of the assessment, which may encourage some to be more diligent in adhering to policies and procedures (10). By far the most common method used for ongoing assessment for all core competencies is review of performance on EQA samples. Despite best intentions, the individuals testing samples are aware that they are being used to monitor their performance, which limits the utility of EQA challenges as an evaluation tool, so they should not be used alone. Other approaches such as blind samples and quizzes are not commonly used. Quizzes test theoretical knowledge and, to a certain extent, problem-solving skills and are intended to test whether individuals can perform the test but not whether they perform the test correctly (10, 11). Nonobservational evaluations such as random worksheet audits, review of QC records, instrument printouts, and second reviews can identify situations where, despite the knowledge and ability to perform the task, an individual under pressure may take the liberty of modifying protocols. Another tactic to be covertly introduced is a simulated specimen or previously tested specimen into the workflow. However, there are substantial logistical issues in implementing such a program. LIS limitations may make it difficult to assign a hospital or laboratory identification number to a nonexistent patient with a staff physician in order not to raise the suspicion of the staff member being assessed. Despite these limitations and time and resource requirements, blind samples are more likely to provide valuable insight into how the staff members perform their duties in real time.

The final components of a competency assessment program are communication and remedial action. Without proper communication of results to the individual, opportunities to correct deficiencies will be lost and the program will lose its value. Most participants verbally communicated results to the technologist, but one-third did so as part of the individual’s annual performance appraisal. Most laboratories indicated that remedial action would be taken in the event that an individual failed the evaluation. Unless the issue arises because of deliberate negligence, remediation should not be punitive but should rather be educational (7). Corrective actions should include but not be limited to discussion of the concerns with the individual, determining the root cause(s) for the issue, continuing education opportunities, mentoring, and training. Careful consideration should be given to restricting the individual’s responsibilities before the individual is allowed to return to the area of concern. Finally, corrective actions and, more importantly, reevaluation must be successful before the individual is allowed to test patient samples.

Most laboratories in Ontario do have a process for ongoing competency evaluation of their staff. However, there is room for improvement. Laboratories need to define competency evaluation programs as part of their QA/QC requirements. Such programs need to be defined in terms of goals and scope. Clearly, this approach may not be appropriate for all, depending on the availability of staff and resources, but programs to be considered should include some basic elements in their programs as follows. (i) Evaluate knowledge and the skills to perform specific tasks and determine whether staff members are applying policies. We recommend that nonobservational evaluations such as worksheet evaluations, random reviews of cultures, and/or anonymous samples integrated into the routine workflow be used as a means of evaluating staff. (ii) Determine what core competencies need to be evaluated.
which best reflect the laboratory’s level of service. Gram stain and interpretation of cultures were cited as the most common areas evaluated. However, other areas that require evaluation include, but are not limited to, performance of specialized testing such as typing, agglutination reactions, specialized microscopy, biosecurity, and LIS management. (iii) Perform competency evaluations soon after training and on an annual basis thereafter. (iv) Design the program to allow communication of results to individuals with respect to their performance. A yearly performance appraisal is not sufficient. Results of competency evaluations, whether satisfactory or not, should be communicated in real time and allow feedback. (v) Design the program to provide opportunities for nonpunitive remediation. Reevaluation, retraining, or reassignment can be considered in situations when the staff member does not meet expectations. Performance improvement programs must establish expectations and be clearly communicated to the individuals.

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REFERENCES