

Response to

Canadian Society for Medical Laboratory Science (CSMLS)
College of Medical Laboratory Technology of Ontario (CMLTO)
Ontario Society of Medical Technologist's (OSMT)

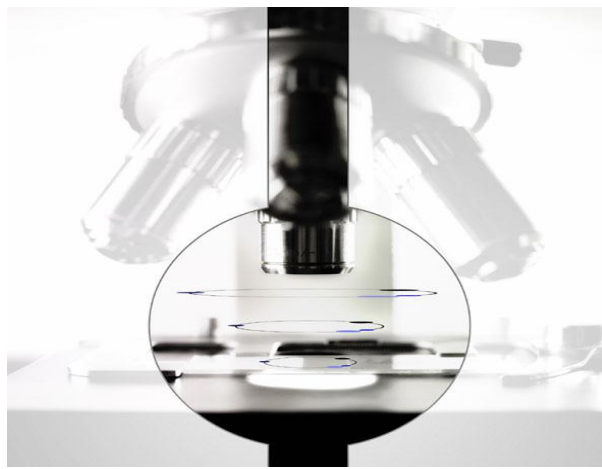
Joint submission to the

Health Professions Regulatory Advisory Council (HPRAC)

on

- Proposed changes in scope of practice of Medical Laboratory Technologists (MLT)
- Regulation of Medical Laboratory Technician/Assistants (MLT/A)

Prepared by Ontario Association of Medical laboratories



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Section 1 - Expanded scope of practice for MLTs

Ontario Association of Medical Laboratories

The Ontario Association of Medical Laboratories (OAML) is the industry association representing community laboratories in Ontario. As non-hospital laboratories, our members perform over 50% of the diagnostic testing performed in the province, providing important clinical information to over 19,000 clinicians. The laboratories collect, transport, and analyze specimens associated with over 15,000,000 patient visits each year. Other testing is performed in hospital and public health laboratories.

Patient specimens are collected in the community laboratories' 324 licensed specimen collection centres located throughout the province. In addition, community laboratories provide phlebotomy services to more than 700 long term care, nursing and retirement homes in the province. Community laboratories also provide phlebotomy services to more than 26,000 patients in their own homes each year. The professional staff of our member laboratories includes pathologists, medical microbiologists, haematologists, clinical chemists, medical laboratory technologists (MLT), MLT's with advanced registration with the CSMLS.

We thank you for the opportunity to provide feedback on the CSMLS/CMLTO/OSMT submission. We will first respond to the CSMLS/CMLTO/OSMT's recommendations for proposed changes in scope of practice of MLTs and then respond to the CSMLS/CMLTO position that there is an urgent and compelling public interest to regulate Medical Laboratory Technicians/Assistants (MLT/A).

Introduction

The OAML has the greatest respect for the contribution that MLTs make to patient care. Some reports estimate that lab test results contribute about 70% of a patient's medical record, while up to 80 % of all clinical treatment decisions are based on laboratory tests¹. MLTs study clinical chemistry, microbiology, hematology, transfusion science, histology and may specialize in cytology and clinical genetics. Upon graduating, MLTs must maintain currency in their field of practice and be able to demonstrate core competencies such as an understanding of the principals of analytical techniques, an ability to recognize the relationship among analyses, diagnosis and clinical information, and use scientific knowledge to investigate unusual findings, interpret results and analyze quality control data. All these activities must be accomplished in a quality management framework (CSMLS Competency profile). In addition, after practicing for five years and completing an additional 15 advanced courses or a technical paper, an MLT may be eligible to receive the designation of advanced registered technologist (ART).

MLTs have ample technical knowledge to make a significant contribution to patient care; however, the OAML cannot support all the recommendations for proposed changes in the scope of practice of Medical Laboratory Technologists proposed in the CSMLS/CMLTO/OSMT's submission. Our primary concern with expanding the scope of practice, as described in the submission, is that instead of supporting inter-professional collaboration, it may actually undermine the achievement of this objective. To provide optimal patient care, it is critical that all the appropriate members of the health team contribute their own unique knowledge and expertise.

Medical laboratory technologists do have extensive knowledge of medical laboratory science, however, they do not bring to the table the same extensive clinical experience with patients that is provided by other health care professionals. We feel strongly that the best patient care can be achieved when medical decisions are made having a complete clinical understanding of the patient. The *Regulated Health Professions Act* as it stands now encourages inter-professional collaboration. Some of the changes suggested in the submission will encourage independent decisions without appropriate consultation with other health professionals which may put the

patient at risk. The best patient care can be achieved by all health care practitioners availing themselves of an MLT's strong background in medical laboratory science.

We will begin by identifying the current scope of practice statement for medical laboratory technology as set out in the *Medical Laboratory Technology Act*, and follow with a summary of the CSMLS/CMLTO/OSMT's proposed enhancements to the scope of practice of MLTs. For each proposed change, our response will indicate whether the OAML supports the change and where we object, we will comment on the validity of the arguments used in support of the proposed change. Our response will also identify misleading information, unsubstantiated claims and other errors of fact or omissions in the CSMLS/CMLTO/OSMT submission. It is necessary that HPRAC has as accurate a picture as possible of the practice of medical laboratory technology in Ontario to make informed recommendations to the Minister on this matter.

The Current Scope of Practice Statement for Medical Laboratory Technology Set out In the *Medical Laboratory Technology Act* is:

Scope of Practice

The practice of medical laboratory technology is the performance of laboratory investigations on the human body or on specimens taken from the human body and the evaluation of the technical sufficiency of the investigations and their results. 1991, c. 28, s. 3.

Authorized Acts

In the course of engaging in the practice of medical laboratory technology, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to take blood samples from veins or by skin pricking. 1991, c. 28, s. 4.

Additional Requirements for Authorized Acts

A member shall not perform a procedure under the authority of Section 4 unless the procedure is ordered by a member of the College of Physicians and Surgeons of Ontario or the Royal College of Dental Surgeons of Ontario or by a prescribed person. 1991, c. 28, s. 5 (1); 1997, c. 9, s. 5.

Summary of CSMLS/CMLTO/OSMT proposed changes to the scope of practice of MLTs

The CSMLS/CMLTO/OSMT submission proposes that MLTs would be selectively authorized to perform one or more of the following additional authorized acts:

1. Initiate laboratory tests in the form of follow-up testing or not to perform procedures or tests that are unnecessary or harmful
2. Initiate laboratory tests in point of care situations
3. Perform vein and arterial punctures for diagnostic and therapeutic purposes
4. Take patient histories and engage in patient education
5. Collect throat swabs
6. Collect specimen for Pap test
7. Take microbiological and genetic samples

This would occur by prescribing classes of certificates of registration and imposing terms, conditions and limitations on certificates of registration of members of each class. The selection would be based on requisite competencies plus practice circumstances and requirements.

1. Initiate laboratory tests in the form of follow-up testing or not to perform procedures or tests that are unnecessary or harmful

The OAML cannot support this change to the scope of practice of MLTs. Currently, initiating laboratory tests is a routine part of MLT practice, but only with the express consent of a prescriber, or through the use of delegation, medical directives, or professional judgement. We do not see this restriction as an unnecessary barrier or causing an unnecessary delay of health care services, but rather as an inducement to necessary inter-professional collaboration. When an MLT recommends to the laboratory's Medical Director or a physician an additional lab test that would improve patient care, this is not a "work around". Rather, this is the MLT interacting as he should with another healthcare professional. This manner of inter-professional collaboration promotes patient safety by ensuring that the laboratory's Director's or physician's knowledge is not excluded from the decision making process.

Senior MLTs who have the required expertise and additional post MLT education do have the knowledge, skills and judgement to support primary care providers in test selection, result interpretation, and identifying the required follow-up tests. MLTs' training, however, does not include the clinical evaluation of patients. Without this skill, the MLT should not be performing this task independently. Neither is this type of clinical training included as one of the core competencies expected of an entry level medical laboratory technologist in 2010.

In addition, MLTs do not have access to the patient's complete medical history, which is also necessary to make an informed decision about the appropriate test to order. The ordering of inappropriate tests results in unnecessary cost to the system and patient inconvenience.

The submission inaccurately states that health services are delayed because MLTs cannot take advantage of results that are flagged or instruments that provide reflexive testing. Laboratories are very conscious of the need for prompt turnaround for test results. As such, the laboratories' leadership teams put in place mechanisms to allow them to take advantage of these technological advances to safely reduce unnecessary delays. MLTs in consultation with their Medical Directors develop standard operating procedures for situations in which it

would be prudent to order additional tests such as using testing algorithms or for out of range or certain atypical results.

The submission also makes a number of other arguments to support this expanded scope of practice including the anticipated human resource shortages and geographic variation in availability of health care professionals. Neither of these situations justifies excluding the input of other healthcare professionals from decisions that will impact patient safety. There are innovative technological solutions available to make this an unnecessary risk to patient safety. For example, technology exists to allow haematologists in major centres to view blood films prepared in northern locations. There isn't a need to exclude the input of other health care professionals. A collaborative effort among professionals needs to be encouraged.

Finally, this particular extension of MLTs' proposed scope of practice should be divided into two activities, as the risk of harm to the patient from initiating laboratory tests in the form of follow-up testing is substantially less than the risk of harm from MLTs cancelling other procedures or tests ordered by another healthcare professional. We have concerns about the advisability of permitting MLT's independent judgement to cancel tests that they think are unnecessary or duplicative without consulting the healthcare professional who originated the order. MLTs do not have access to all the necessary clinical information to make that decision. E.g. based on the physical appearance of the patient, a physician may suspect that a lab result is not correct and request a duplicate test. Without this clinical information, the MLT may cancel what they see as unnecessary repeat test to the detriment of the patient. As the regulation now stands, this situation would be prevented. The regulation requires consultation with the physician before any test request is cancelled which is a prudent course of action.

2. Initiate laboratory tests in point of care situations

The OAML cannot support this expansion of the MLTs' scope of practice for the same reasons identified above. We interpret this proposed change to mean essentially the same as the previous proposed expansion of the MLTs' scope of practice, except that the MLTs will initiate laboratory tests based on the dialogue with the patient and the patient's physical

appearance instead of as a result of reviewing a patient's laboratory test results or test requests.

An MLTs' training now and in the future focuses on the technical aspects of medical laboratory science and does not include clinical evaluation of patients. Without this skill set, MLTs are not qualified to initiate testing independently in point of care situations. The submission states that MLTs would initiate timely referral to other healthcare professionals when the MLT assesses that the patient's condition is beyond their scope of practice or competence. MLTs do not have clinical training in direct patient care to safely assess whether the patient's condition is beyond their scope of practice or competence. This is a situation where inter-professional collaboration is required, not independent judgement. In addition, the inappropriate ordering of tests would add unnecessary cost to the system.

The submission suggests that by permitting MLTs to initiate laboratory tests in point of care situations instead of requiring patients to obtain a test order from their primary care provider, participation rates for prevention, screening and chronic disease management programs would increase and costs to the government for these programs would be reduced. This claim was not substantiated by evidence. In fact, it appears that the government, at least in one of its programs, is taking exactly the opposite approach to increasing participation rates. During the design of the Colon Cancer Check Program, the Ministry of Health and Long Term Care and Cancer Care Ontario decided that the primary care provider is in the best position to provide counsel and direction to the program participant.

3. Perform vein and arterial punctures for diagnostic and therapeutic purposes

The OAML supports expanding the scope of practice to include performing venous and arterial punctures for diagnostic purposes, but not therapeutic purposes. While we do support the position that MLTs educational preparation and technical expertise are suited to performing punctures for diagnostic purposes, their training does not extend to injecting substances for therapeutic purposes. Patients who are injected with substances are potentially subject to anaphylactic shock, which could have very serious consequences.

MLT training does not extend to injecting substances for therapeutic purposes or, more importantly, include treatment of patients experiencing anaphylactic shock, nor will this knowledge be included as one of the core competencies expected of an entry level medical laboratory technologist in 2010. Even if the initial training for treating patients who experienced anaphylactic shock was provided, it would be extremely difficult and costly for MLTs to maintain competency in emergency resuscitation on an ongoing basis.

The submission supports this expansion of MLTs scope of practice by stating that it would free up other healthcare professionals, particularly physicians and nurses, and thus increasing their accessibility to the public and decreasing costs to the system. This may be true but of greater importance is ensuring patient safety is not put at risk.

4. Take patient histories and engage in patient education

The OAML does not support expanding the scope of practice to include taking patient histories. MLTs are not trained in this clinical aspect of patient care, nor will this knowledge be included as one of the core competencies expected of an entry level medical laboratory technologist in 2010.

The OAML supports expanding the scope of practice to include patient education. This is an excellent application of an MLT's scientific knowledge base, especially for those MLTs with advanced certification; however, additional practical and theoretical training in patient education would be required.

5. Collect throat swabs

The OAML supports expanding the scope of practice to include collecting throat swabs, but the scope would have to be restricted to only adult patients. Children are at risk of experiencing a laryngospasm during the collection process. MLT training does not include responding to this type of medical emergency situation, nor will this knowledge be included as one of the core competencies expected of an entry level medical laboratory technologist in 2010. From a practical point of view, MLTs, even if initially trained, would have difficulty in obtaining enough practical experience to maintain this competency.

6. Collect specimen for Pap test

The OAML does not support expanding the scope of practice to include the collection of specimens for Pap tests. MLTs have insufficient knowledge and training for examination by palpation. Physician training goes far beyond the basic skills required for the collection of a Pap specimen. During the specimen collection process, physicians have the opportunity to use their knowledge and experience to recognize physical signs of other disease states. Even MLTs with advanced certification do not have this knowledge base. As well, this knowledge will not be included as one of the core competencies expected of an entry level medical laboratory technologist in 2010. In addition, a review of the submission's cross jurisdiction survey of scopes of practices demonstrates that collection of specimens for Pap tests is not supported by any other jurisdiction in Canada with the exception of Quebec. This indicates a national lack of support for expanding MLTs' scope of practice to this degree.

7. Take microbiological and genetic samples

The OAML supports expanding the scope of practice to include taking microbiological and genetic samples with the proviso that it be restricted to cheek and wound swabs from adults for this task.

8. Administer a substance by injection to allow injections for therapeutic procedures, e.g. allergy testing and intra-muscular injections

The OAML does not support expanding the scope of practice to include administering a substance by injection to allow injections for therapeutic procedures, e.g. allergy testing and intra-muscular injections. Patients who are injected with substances are subject to anaphylactic shock, which could be lethal in a very short period of time. MLT training does not extend to injecting substances for therapeutic purposes, or more importantly, include treatment of patients experiencing anaphylactic shock. This knowledge will not be included as one of the core competencies expected of an entry level medical laboratory technologist in 2010. Even if the initial training were provided, it would be extremely difficult and costly for MLTs to maintain competency in emergency resuscitation.

The submission proposes that expanding MLTs' scope of practice would free up other healthcare professionals, particularly physicians and nurses, thereby increasing their accessibility to the public and decreasing costs to the system. This argument may be true but of greater importance is ensuring patient safety is not endangered. The submission does not seem to consider the risks to patient safety and consequential costs associated with this proposed expansion to the scope of practice.

Other Comments

Members of the profession support for the expanded scope of practice

HPRAC asked submitters to comment on whether members of their profession were in favour of this change. The CMLTO indicated that they had engaged 510 MLTs in 6 of their 8 electoral districts. It is not clear exactly what engaged means. CMLTO reported that participants strongly believe they should have the opportunity to work to their full competency. The interpretation of this information is unclear. Does it mean that they support all the proposed changes to the scope of practice? Even if this is the correct interpretation of this information, it means that only 7% of the 7,533 MLTs registered with the College were asked to comment on these extensive changes. This can hardly be considered an endorsement by members of the College.

Other evidence of support by its members included the results of a survey that the CMLTO conducted in May, 2008. It is not clear from the information provided whether all of its members were contacted, however, the CMLTO did report that 1,255 responses were received and that the responses supported the changes. From a statistical point of view, it seems unlikely that everyone surveyed using random sampling techniques would agree with everything that was proposed. Even if this is the case, it only represents 16% of MLTs currently registered in the province. This figure would likely be even lower if MLTs were informed of the very real possibility that the government may consider it prudent to make it compulsory for MLTs to carry liability insurance since the expanded scope of practice allowing independent decisions does carry with it an increased risk of harm to patients.

Support for the expanded scope of practice by other professions

When asked by HPRAC to describe the consultative process with other professions, the response in the submission indicated that during the Crystal Clear Summit sponsored by the CMLTO, the consensus of those present appeared to be in support of an expanded role for MLTs. A full list of attendees was supplied. As the OAML was represented at this Summit, we feel this is a misrepresentation of the facts. Attendees were not asked to vote or even provide a show of hands to support the conclusion that those present supported all the proposed changes.

Conclusions

We do support a limited expansion of the scope of practice for some of the acts requested in the submission; however, we cannot support all the changes requested. We feel strongly that the best patient care can be provided by having a complete picture of the patient when medical decisions are made. The *Regulated Health Professionals Act* as it stands now encourages inter-professional collaboration. Some of the changes suggested in the submission will encourage independent decisions without appropriate consultation with other health professionals and may put the patient at risk. Optimal patient care can be achieved by all healthcare practitioners availing themselves of an MLT's strong background in medical laboratory science. We do support the following expansion in the scope of practice for MLTs:

- Perform venous punctures for diagnostic purposes but not therapeutic purposes
- Engage in patient education but only after additional training
- Collect throat swabs but for only adults
- Take microbiological and genetic samples restricted to wound and cheek swabs from adults

Section 2 - Regulation of MLAs

The OAML does not support the position that there is an urgent and compelling public interest need to regulate Medical Laboratory Assistants and the Medical Laboratory Technicians (referred to jointly in the Submission as MLA/Ts) under the *Regulated Health Professions Act, 1991* as a separate class of members of the CMLTO. We believe the submission overstates the problem and presents a position which is based on unsubstantiated claims and anecdotal stories. We feel this is an unfair slight on both the MLAs as well as the quality assurance programs in place for laboratories and specimen collection centres across the province.

Our response to the submission will begin with a summary of our main concerns with the CMLTO/CSMLS's position. We will then provide HPRAC with an overview of the quality assurance programs in place in laboratories and specimen collection centres that ensure high quality of work throughout the path of work flow from the pre-analytical, analytical to post-analytical stages. This overview provides the necessary context in which to consider the CMLTO/CSMLS's claims. We will also identify and respond to various unsubstantiated or inaccurate claims, which leave the reader to draw incorrect conclusions.

The following is a summary of our main concerns with the submission:

1. The case has not been made that MLAs are the primary source of pre-analytical errors, so it is not reasonable to link the reduction of pre-analytical errors with regulating MLAs. Nurses, clerks, medical laboratory technologists, physicians or medical laboratory assistants all take part in pre-analytical processes of specimen collection.
2. Inadequate recognition is being given to the fact that current accepted quality management methodology focuses on system, process and design changes and not on individual employees to correct errors. Evidence supports that the application of quality management principles in laboratories, specimen collection centres and hospitals has proven successful in reducing errors¹.

3. Inadequate recognition is being given to the contribution of stringent laboratory accreditation programs to ensuring the competency of all staff and to ensuring continuous improvement processes are in place to reduce all errors throughout the path of work.
4. Inadequate recognition is being given to legislative and regulatory requirements and licensing and inspection programs, as well as to organizationally imposed mandatory quality system processes, policies and procedures. All of these contribute to helping ensure the quality of laboratory operations and specimen collection centres.
5. Inadequate recognition is being given to the role that the Colleges of Physicians and Surgeons and the College of Medical Laboratory Technologists play in ensuring that MLAs are trained, competent and supervised. MLAs perform their functions with the oversight of these regulated health professions. MLAs are not self-employed and do not work as independent practitioners. If the Medical Director does not meet his responsibilities to ensure an MLA's competence, the public have recourse through the College of Physicians and Surgeons. If an MLT or other health professional feels an MLA is incompetent or being asked to do something beyond their scope of practice, they can also lodge a complaint with the College of Physicians and Surgeons.

Quality in Laboratories

An understanding of the environment in which MLA's operate is necessary to make an informed judgement on the risk of harm to the public. As indicated above, MLAs are not self-employed and do not work as independent practitioners. Laboratories and specimen collections centres operate in a highly regulated environment. We will first review the regulated environment of laboratories, then specimen collection centres, and conclude this section with an explanation of the role that physicians play in ensuring the competency of MLAs.

Laboratories in Ontario are accredited through the Quality Management Program for Laboratory Services (QMP-LS). Accreditation is based on the requirements in ISO -15189 Medical Laboratories – Particular Requirements for Quality and Competence. Laboratory policies and procedures required under this standard are based on nationally and internationally accepted standards of laboratory practice by the Clinical Laboratory Standards Institute (CLSI), formerly NCCLS. These standards cover quality management systems, pre-analytical, analytical and post-analytical areas of testing. They also include discipline specific areas, phlebotomy, and safety practices in the laboratory and Point of Care testing. Accreditation to this standard is achieved by demonstrating conformance to all requirements during a peer assessment visit. Laboratories that satisfactorily address all identified non-conformances within 90 days of peer assessment visits are granted accreditation. To maintain accreditation, QMP-LS conducts ongoing surveillance through proficiency tests and self-assessments to ensure the requirements for accreditation are met between accreditation visits (OLA requirements).

Laboratories value highly the quality of the work they do and continually strive to ensure that errors throughout the laboratory process are minimized and patient safety is maximized. The Medical Director of the laboratory has overall responsibility and accountability for the quality of the laboratory operation, which includes all three stages of the diagnostic process (pre-analytical, analytical, and post-analytical). Regardless of the academic or professional training, certification, or prior work experience, internal orientation and training in the organizational policies and procedures is provided to employees. Policies, as well as extensive detailed standard operation

procedures which are reviewed on an ongoing basis by the professional team, provide the MLAs with the direction they must follow to ensure that quality standards are met.

MLAs may perform tasks at all three stages in the laboratory process: pre-analytical stage (entering patient information into a computer), analytical stage (loading specimens onto an analyzer), and post-analytical stage (filing reports). The procedures associated with each of these areas will be unique to each employer; as such, most MLA training is on-the-job training provided by the employer. It is the responsibility of the employer to ensure employees' competency and knowledge of organization specific policies and procedures. OLA requirement 1.B.10 states, "the facility shall evaluate staff skills to perform assigned tasks following training and periodically thereafter. The lab's policy shall include actions to be taken if an individual fails to meet the skills assessment requirement."

Next we will provide an overview of the MOHLTC's inspection program for specimen collection centres. Specimen collection centres (SCC) are licensed by the MOHLTC's Laboratories Branch and inspected to ensure compliance with the *Laboratory and Specimen Collection Centres Licensing Act* and its regulation. In addition, in 2006, the Ministry issued an extensive SCC checklist to which all SCCs must comply. Included in that list are the tasks and responsibilities defined in the regulation as acceptable for MLAs to perform.

The inspection list requires that inspectors look for evidence to support that MLAs are trained and familiar with the laboratory's documented procedures, that policies exist to ensure action is taken if an individual fails to meet skills assessment, that specimen collection and handling instructions are available to anyone responsible for specimen collection, that supervision of the facility occurs, and that each phlebotomist has a Certificate of Staff Qualification on site (MOHLTC, Laboratories Licensing and Inspection Services' checklist). Inspectors are required not only to look for written policies and procedure that meet requirements, but evidence that these procedures are followed. In addition, these inspections are unannounced. If evidence of non-conformance to regulations is found, the laboratories must identify and document their corrective action to the Ministry.

In addition to the process and procedures put in place as a result of laboratory accreditation and the Laboratories Branch inspection process to ensure that MLAs operate in a safe manner, physicians also have a role in ensuring the competency of MLAs. The *Regulated Health Professions Act* provides an exemption allowing a person to perform the controlled act of phlebotomy if the person taking the blood sample is employed by a laboratory or specimen collection centre licensed under the *Laboratory and Specimen Collection Centre Licensing Act*. The *Laboratory and Specimen Collection Centre Licensing Act* (LSCCLA) specifies that “no person shall be employed by the owner or operator of a specimen collection centre for the purpose of taking specimens from the human body unless a legally qualified medical practitioner has certified in writing that the person has competence in the technique of taking and collecting specimens from the human body.”

In the next section of our response to the CMLTO/CSMLS’s submission, we will identify and respond to various unsubstantiated or inaccurate claims, which unfairly slight both the MLAs as well as the quality assurance programs in place for laboratories and specimen collection centres across the province.

Unsubstantiated or Inaccurate Claims

1. Majority of errors are due to MLA/Ts

“Research evidence (supported by anecdotal evidence and by information from stakeholders in the medical laboratory sector) indicates that the majority of errors committed in laboratory testing are committed during the pre and post-analytical phases where MLA/Ts predominate. Accordingly, we believe the same public interest considerations that led to the regulation of MLTs under the RHPA support the regulation of MLA/Ts under the same regime.”

If not explicit, then certainly implicit in the submission is the identification of the MLA as a significant contributor to pre-analytical errors. In Ontario, about 50% of the testing is performed by community laboratories. Thirty per cent of these specimens are collected in physician offices and may be collected by the physician himself/herself, a nurse or other staff person in the office. Very few MLAs work in physicians’ offices.

The other 50% of the testing volume in the province is performed in hospitals. There is a variety of persons who collect and label specimens in hospitals including nurses, residents, phlebotomists, MLTs and MLAs. No evidence has been provided that points to the medical laboratory assistant as a significant source of pre-analytical errors. Therefore, it cannot be assumed that regulating MLAs is the answer to pre-analytical errors. In fact, evidence supports that the application of quality management principles in laboratories, specimen collection centres and hospitals rather than regulation has proven successful in reducing errors. The Institute of Medicine's report "To Err is Human: Building a Safer Health System" (2000), suggests that the majority of medical errors do not occur as a result of individual incompetence; rather, they are caused due to a failure in systems, processes and conditions which cause people to make mistakes. To err is human but given adequate leadership, better alternatives and improved processes and systems, errors can be reduced (CLMA Trillium submission to CMA Accreditation Committee).

2. No established levels of competence for MLA/Ts to perform their duties, no quality assurance or other regulatory mechanisms

“The CMLTO's concern is that MLA/Ts often practice beyond their professional competencies and individual knowledge, skills and judgment. There are no established levels of competence for MLA/Ts to perform their duties, no quality assurance or other regulatory mechanisms to ensure requisite competencies and safe and effective performance of their duties, and no public complaints process for the public or other healthcare providers to access.”

We have two issues with this statement. First is the unsubstantiated claim that MLA/T often practice beyond their professional competencies and individual knowledge, skills and judgment. No evidence has been provided to support this claim. As indicated above, the public and MLTs can make complaints to the Laboratories Branch of the MOHLTC and the College of Physicians and Surgeons if they believe this to be the case.

Our second issue is with the inaccuracy of the statement that there are no established levels of competence for MLA/Ts to perform their duties, no quality assurance or other regulatory mechanisms to ensure requisite competencies and safe and effective performance of their duties. The provincial quality assurance program described above clearly demonstrates that MLAs work in a highly regulated environment where competency must be established and

documented. Competencies are based on demonstrated ability to follow standard operating procedures that meet accreditation and regulatory requirements. MLAs are not self-employed and do not work as independent practitioners. MLAs are under the supervision of two groups of regulated health professionals, MLT and physicians who must answer to their Colleges for any unprofessional behaviour. MLAs must follow approved standard operating procedures and policies of the organization that employs them.

3. Operating beyond level of competency

“It is apparent that as MLA/Ts assume more functions in locations that are more remote and where the existence of requisite supervisory personnel are scarce, the need to have MLA/Ts operating under a regulatory scheme that sets consistent and comprehensive standards for the conduct of their work are particularly important. In areas where there are insufficient MLTs, MLA/Ts are more likely to be asked or required to fill the gap through various forms of delegations and assignments. Once again, the CMLTO is convinced that the public interest and the effectiveness and integrity of the healthcare system are best served if these individuals are subject to an effective, consistent and pan-Ontario regulatory framework.”

We have two issues with this statement. The first issue is that this statement implies that there does not already exist an effective, consistent and pan-Ontario regulatory framework that sets consistent and comprehensive standards for the conduct of MLAs' work. As already explained above, there exists a pan-Ontario regulatory framework which governs the work environment of MLAs -- the Ontario Laboratory Accreditation system which specifies over 400 requirements to which all laboratories in Ontario must comply and the Laboratories Branch's extensive SCC checklist to which all SCC must comply.

Our second issue deals with the unsubstantiated claim that in areas where there are insufficient MLTs, MLA/Ts are more likely to be asked or required to fill the gap through various forms of delegations and assignments. As MLAs do not work as independent practitioners, CSMLS/CMLTO are claiming that they have knowledge that either MLTs or physicians are requesting MLAs to act beyond their scope or making the assumption that they will act in this unprofessional manner. It would appear that if this were indeed happening, it would reflect poorly on either the College of Physician and Surgeons or the CMLTO. If that is the situation, the solution lies in addressing the issue with the regulated health professionals involved. The solution does not lie in increasing the number of persons

to be regulated, but rather insuring those that are regulated perform up to their professional standard.

4. Risk of harm to patients

“The CMLTO asserts - and most stakeholders agree - that what MLA/Ts do carries with it a substantial risk of harm to individual patients. Those who support regulation of MLA/Ts believe doing so will lower the risk of harm to patients. Yet, in matters of public protection (e.g. professional conduct, sexual abuse), MLA/Ts are held to a lower standard than Medical Laboratory Technologists (MLTs) and other RHPA regulated practitioners, or to no standard at all. Furthermore, given the extent of MLA/Ts' exposure to the public, the CMLTO believes regulation is necessary to achieve the RHPA objective of ensuring individuals are treated with sensitivity and respect in dealings with health professionals.”

We have two issues with this statement. The first issue being that the submission makes statements that are not grounded in fact. The OSMT is a stakeholder, yet the OSMT did not support this submission which includes inaccurate statements of this nature.

The second issue is the statement that MLA/Ts are held to a lower standard than Medical Laboratory Technologists (MLTs) and other RHPA regulated practitioners or to no standard at all. As described above, MLAs work in a highly regulated environment with extensive quality assurance programs. The Medical Director has overall responsibility and accountability for the quality of the laboratory operation including the behavior of employees. This statement implies that the Medical Director and/or the employer who is liable for employees' actions would take no action if a complaint of misconduct or sexual abuse were raised against an MLA. No evidence is provided for this assertion which we do not believe to be true.

5. Training program

“We believe that these trends increasingly demand that anyone involved in laboratory testing must be adequately trained to function effectively and safely within their scope of practice, must be subject to comprehensive quality assurance processes, including continuing education.”

The community laboratory sector is satisfied with the quality of students graduating from the approved training programs in the province. Laboratories expect students to graduate with basic English and math skills, and a basic understanding of the laboratory work environment.

MLAs graduate understanding the scope of their role and that of the health professionals working in the laboratory.

In Ontario, private schools must be approved by the Ontario Society of Medical Technologists as a precondition for the Ministry of Colleges Training and Universities to approve their Medical Laboratory Assistant/Technician program. The approval process includes a detailed review of all aspects of the program including curriculum, faculty, equipment and clinical placements as well as an onsite visit. Our member laboratories which provide clinical placements as part of the schools' program provide feedback to the schools on an ongoing basis. This feedback includes the laboratory's recommendations for curriculum changes to help the students be more prepared for employment in a laboratory or specimen collection centre.

Regarding training at the facility, OLA requirement 1.B.10 specifies that "the facility shall evaluate staff skills to perform assigned tasks following training and periodically thereafter. The lab's policy shall include actions to be taken if an individual fails to meet the skills assessment requirement." In addition, OLA requirement I.B.12 specifies that the laboratory shall have a policy for continuing education. OLA assessor guidance documents specify that assessors are to look for evidence of continuing education of all staff.

6. Absence of consumer choice

"In most cases, neither the public nor the referring practitioner has any choice about who collects, prepares or analyzes samples and prepares reports, or has any idea of the person's competencies and whether that person is regulated or unregulated. Due to the absence of consumer choice and system transparency, the CMLTO and CSMLS believe there is a special duty to ensure the public is protected and has concluded that public protection is best achieved through effective, joint regulation of MLA/Ts and MLTs under the RHPA."

This comment is inaccurate. Both the public and the practitioner have a choice about who collects, prepares or analyzes samples and prepares reports. There are 10 community laboratory providers with multiple laboratory locations and over 300 specimen collection centres in the province. Specimen collection centres are required to post their MOHLTC license and laboratories post their accreditation status. If a patient does not see a license or has a question regarding an employee's competency or regulatory status, they can seek

clarification from the staff present. If the response is not satisfactory they can avail themselves of another facility.

7. Lack of Supervision

“Increasing evidence shows that the legislative requirement for MLA/Ts to be supervised by other RHPA practitioners is not being effectively observed or enforced outside the laboratories, for example in specimen collection centres and other venues such as long-term care facilities. A significant number of MLA/Ts do not have the quality of their performance monitored effectively either by supervisors in licensed facilities, by supervisors who are themselves regulated professionals, or by regulated professions who delegate or assign to MLA/Ts.”

Once again these are unsubstantiated claims that RHPA practitioners are not effectively supervising MLA/Ts. No actual evidence is provided. The MOHLTC’s Laboratories Branch, which inspects SCCs to ensure compliance with *the Laboratory and Specimen Collection Centres Licensing Act* and its regulations, requires that inspectors check the frequency of supervisors’ visits to the facility. The CSMLS/CMLTO submission does not provide data from the Laboratories Branch to support their claim of a lack of supervision at these facilities. The CSLMS/College could have also sought out evidence to support this claim from the College of Physicians and Surgeons as MLAs are under the direction of the Medical Director. Community laboratories provide phlebotomy services to many LTC facilities and nursing homes, but no evidence of complaints to the College of Physicians and Surgeons indicating that Medical Directors are not fulfilling their responsibility to ensure adequate supervision of the MLAs was provided. The words “increasing evidence” imply that someone has been tracking this problem over time. Yet evidence from the appropriate organizations to track complaints of this nature, Laboratories Branch and the College of Physicians and Surgeons, was not supplied to support the claim.

8. Shortage of human resources issues

“One of the objectives of regulation is to identify and address any human resources issues in the MLA/T profession and to help ensure that labs have the human resources they require at levels of competency they can rely on.”

Our member laboratories work closely with the private schools to provide feedback on the number of MLTs their organization will need in the future. Member laboratories are not experiencing or anticipating experiencing a shortage of MLAs/Ts.

Conclusions

The OAML firmly believes that the current pan-Ontario regulatory structure (the *Laboratory and Specimen Collection Centre Licensing Act, 1990*, laboratory accreditation through QMP-LS, physician responsibility for competency and supervision of MLAs), more than adequately protects public safety and the public interest.

1. The OAML does not support the regulation of MLAs/MLTs.
2. The OAML believes the submission overstates the problem in a dramatic fashion and presents a position which is not valid based on the evidence submitted. There is insufficient evidence that MLAs are the primary source of pre or post analytical errors, so basing the need to regulate MLAs is an inappropriate conclusion.
3. Inadequate recognition has been given to the evidence that reduction in analytical errors in the laboratory and medical errors in hospitals has been achieved by changes in systems and processes, not by focusing on changing the individual.
4. Inadequate recognition has been given to laboratory accreditation programs, regulatory requirements and licensing and inspection programs, all of which contribute to helping ensure the quality of laboratory operations.
5. Inadequate recognition has been given to the importance of employee training in laboratory specific systems, processes and standard operating procedures as mechanisms for ensuring quality laboratory operations.
6. Inadequate recognition has been given to the role of two other regulated health professionals providing oversight in laboratory operations: physicians and medical laboratory technologists.

Laboratories operate in a highly regulated environment. Unless there is a well identified need with clear benefits to be gained, imposing further requirements places unnecessary demand on government resources. The CMLTO/CSMLS submission has not adequately demonstrated that a need exists for regulation of MLA or that benefits will be achieved through regulation.

Reference

1. Landro, L. Hospitals Move to Cut Dangerous Lab Errors. The Wall Street Journal June 14, 2006