PATH2QUALITY

"Clarifying Roles, Responsibilities and Critical Elements in Quality Management Systems as Applied to the Professional Work of Ontario's Laboratory Physicians"

November 27, 2009

Symposium Synopsis

Executive Summary

Path2Quality is a collaborative initiative of the Ontario Medical Association (OMA) Section on Laboratory Medicine and the Ontario Association of Pathologists. Path2Quality advocates for Ontario's laboratory physicians, particularly in matters related to quality management as it affects laboratory physicians' professional work.

On November 27, 2009, Path2Quality, in conjunction with the Health Policy Department of the OMA, hosted a symposium of key stakeholders involved or interested in quality assurance as it applies to the professional work of Ontario's laboratory physicians. The purpose of the Symposium was essentially three-fold: i) to help clarify for front-line practitioners their responsibilities to these organizations; ii) to provide an opportunity for the profession, via Path2Quality, to present to those organizations front-line practitioners' issues, concerns and needs related to quality assurance; and iii) to refine the role of Path2Quality in this arena moving forward.

The organizations participating in this Symposium included: the Royal College of Physicians and Surgeons of Canada (RCPSC); the Canadian Medical Protective Association (CMPA); the Canadian Association of Pathologists (CAP); the College of Physicians and Surgeons of Ontario (CPSO); Cancer Care Ontario (CCO); the Quality Management Program for Laboratory Services (QMP-LS) and the Institute for Quality Management in Healthcare (IQMH); the Ontario Forensic Pathology Service (OFPS); the Ontario Association of Medical Laboratories (OAML); and the Ontario Medical Association (OMA). Additionally, all five Ontario University Chairs of Pathology and Laboratory Medicine along with some front-line laboratory physicians were represented.

The symposium enabled Path2Quality and the participating organizations to articulate their roles, responsibilities and commitment to assuring quality in the professional work of laboratory physicians. The discussions highlighted overlaps in responsibilities that sometimes cause confusion for the profession, as well as opportunities for collaboration among the various stakeholders.

Most importantly, the process revealed the need for a comprehensive framework for quality management that embraces all of the stakeholders and promotes synergy in their collective efforts. (e.g., guidelines development, continued professional development, accreditation, etc.).

Specifically, there is interest in the development of practice guidelines, as well as an interest in advocacy for improved resources in order that organizations and practitioners are able to subscribe to such guidelines.

It was suggested that Path2Quality take the lead in developing this framework. In doing so, Path2Quality could help: develop the overall program framework; define the role organizations might play in designing the program and implementing it; as well, as develop associated timelines for the plan.

As a first step, Path2Quality was encouraged to take the lead in establishing a steering committee that includes the key partners and relevant stakeholders to address the needs and issues identified by the Symposium.

The Symposium Proceedings provided here are intended to serve as a record of the discussions that took place November 27, 2009, and to give the front-line practitioners represented by Path2Quality more background with respect to the work Path2Quality is undertaking on their behalf.

Symposium participants and support staff: Dr. D. Bach (moderator, in foreground), and (left to right) Mr. Jeff Sumner (OAML), Dr. J. Sproule (CMPA), Dr. B. Mullen (Path2Quality), Dr. J. Srigley (Path2Quality), Ms. J. McNeil (OMA), and Ms. K. Bugeja (Path2Quality)

Preamble

Path2Quality is a collaborative initiative of the Ontario Medical Association (OMA) Section on Laboratory Medicine (OMA Section) and the Ontario Association of Pathologists (OAP). It advocates for laboratory physicians. In particular, Path2Quality is committed to addressing quality management issues as they relate to the professional work of laboratory physicians.

On November 27, 2009, Path2Quality, in conjunction with the Health Policy Department of the OMA, hosted a symposium of key stakeholders involved in, or interested in, quality assurance as it applies to the professional work of Ontario's laboratory physicians. This Symposium marked a milestone in the discussions between the OMA Section and the OAP. The organizations have sought to define and clarify for their joint memberships various issues related to quality management as it impacts laboratory physicians – and the Symposium was a major step in beginning to do so.

Appendix 1 provides a complete listing of all participants and observers and Appendix 2 a description of the participating organizations. With the exception of the Ontario Hospital Association, virtually all invited organizations participated in the Symposium. Key participating organizations included: the Royal College of Physicians and Surgeons of Canada (RCPSC); the Canadian Medical Protective Association (CMPA); the Canadian Association of Pathologists (CAP); the College of Physicians and Surgeons of Ontario (CPSO);Cancer Care Ontario (CCO); the Quality Management Program for Laboratory Services (QMP-LS) and the Institute for Quality Management in Healthcare (IQMH); the Ontario Forensic Pathology Service (OFPS); the Ontario Association of Medical Laboratory (OAML); and the Ontario Medical Association (OMA). Additionally, all five Ontario University Chairs of Pathology and Laboratory Medicine along with some front-line laboratory physicians were represented. Moderating the Symposium was OMA Past-President, Dr. David Bach, a practicing radiologist who works in an academic setting and a Past-President of the OMA.

Specific Goals of the Symposium

By bringing together and soliciting the input and recommendations of the key organizations involved or interested in the various aspects of quality management that affect the professional work of laboratory physicians (e.g., RCPSC, CMPA, CAP, CPSO, CCO, QMP-LS/ IQMH, OFPS, OAML, and OMA), the Symposium offered participants the opportunity to:

- Share their understanding of their respective roles, responsibilities and interests in quality management as they affect or guide the professional work of laboratory physicians;
- Explore the potential overlaps that may exist in the above, and in so doing, determine when those overlaps are desirable and advantageous, and alternatively, when they are undesirable and inefficient; this was with a view to identifying potential remedies to address the latter;
- Explore the gaps that may exist in the above, and identify potential solutions, including resource implications where possible, to address them; and,
- Refine the role of Path2Quality in this arena moving forward.

It was Path2Quality's intention to communicate the outcomes of the day to the OMA Section and OAP members, and in so doing, begin to clarify for them:

- The roles and responsibilities of the various organizations with an interest in quality management related to the professional work of laboratory physicians in Ontario;
- How they as individual practitioners, and as a profession, should respond to multiple, and sometimes conflicting, requests to participate in various aspects of quality management programs;

- How the resource implications of increasing quality management demands on them will be dealt with; and

- The role of Path2Quality.

Structure of this Synopsis

This report is structured to capture the day's outcomes and as such, is organized with discussion of the following elements:

A) Summary of the practice environment and professional work of today's laboratory physician;
B) An overview of contributors to the quality of the professional work of today's laboratory physician;
C) Description by the participating organizations of their roles and responsibilities;
D) Mapping the roles and responsibilities of organizations within the domains which contribute to quality, and the associated gaps and overlaps;
E) Discussion of overlaps and gaps;
F) Potential role of Path2Quality;
G) Next Steps.

A) Summary of the Practice Environment and Professional Work of Today's Laboratory Physician

Several presenters from Path2Quality synthesized for the group the key factors defining the practice environment and professional work of today's laboratory physician, and the many challenges the profession currently faces. These factors include:

- Concerns regarding inadequate human resources. The laboratory physician population is on average older than the overall physician population in Ontario. In addition, the rate of growth in laboratory physician numbers lags far behind workload increases, particularly of cancer cases.
- Current workload pressures that reflect:
  - Increasing demand overall - attributable to, among other pressures, an aging population and greater emphasis on chronic disease management;
  - Technological and scientific advances in medicine and pathology that increase case volumes and intensify complexity (e.g., increased biopsy volumes, predictive testing [Her2], explosion of point of care testing, etc.); and,
  - System demands such as the current, and increasing, quality reporting requirements;
- Insufficient laboratory infrastructure resources to meet the many demands.
- The legal responsibilities of laboratory physicians for quality of care as in relation to patients, the CPSO, the RCPSC, QMP-LS, laboratories, and hospitals are multiple. A summary with respect to these was provided by the OMA General Counsel and may be found in Appendix 3.

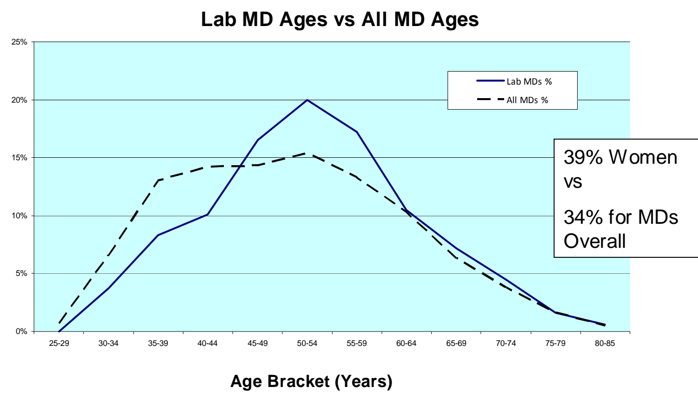
Other potentially important influences on the profession and discussed by participants included the following:

- Impact of new technologies, such as digital imaging, that will affect how and where laboratory medicine is / can be practiced;
- Changing external environment, particularly increased public awareness of quality issues and increased patient expectations related to access to test results;
- Changing legislation, e.g., Bill 171 that will require facility operators to report on capacity and competence, as well as quality assurance regulation that will make CPD mandatory;
- The disconnect in the current structure whereby laboratory directors have all the responsibilities and duties but no control over the operating environment. Laboratory directors are placed at undue risk with the CPSO, CMPA, and QMP-LS (OLA) if they are unable to perform their fiduciary duties due to lack of appropriate resources;
- Different pressures put on laboratory physicians working within hospitals, with their respective fiscal constraints, versus owner-operator laboratories;
- Potential regionalization of laboratory services;
- Absence of system-wide planning for laboratory and laboratory physicians that results in a mismatch between residency training positions and actual jobs available; and,

- ‘Commodification’ of the professional work of laboratory physicians whereby it is becoming increasingly difficult to differentiate when a pathologist is providing a medical diagnosis versus a laboratory providing a result.

Some of the pressures described were depicted in a slide presentation made as an introduction to the Symposium, a few slides from which are reproduced below:

Lab MD - Demographics



Source: Ontario Physician Human Resources Data Centre

Path2Quality Symposium - November 27, 2009 9

Lab MD – Geographic Distribution

		Population per Lab MD
Ontario		**25,038**
	range	
	Toronto Central	**8,354**
	Central East	**52,162**
comparators		
Australia		**15,500**
New Zealand		**20,250**

Sources: Ontario Physician Human Resources Data Centre; Royal College of Pathologists of Australasia

Path2Quality Symposium - November 27, 2009 10

Lab MDs – Current Pressures

	1998	2008	Absolute Increase	% Increase
All MDs	20,265	23,767	3,502	17.3%
Radiation Oncologists	115	164	49	42.6%
Medical Oncologists	128	173	45	35.2%
Diagnostic Radiologists	677	887	210	31.0%
Pathologists	402	463	61	15.2%

Source: Ontario Physician Human Resources Data Centre

22% are Part-time

Path2Quality Symposium - November 27, 2009 17

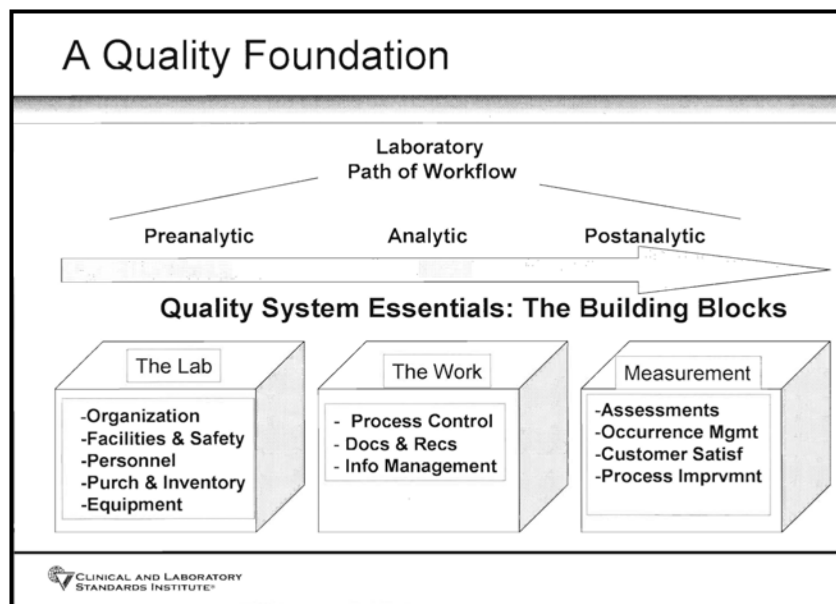
B) Overview of Contributors to the Quality of the Professional Work of Today's Laboratory Physician

With respect to quality management, laboratory physicians oversee laboratories and, thus, are responsible for the quality management systems employed by those laboratories. For this reason, laboratory physicians must have extensive background in the operation of quality management systems, and a detailed understanding of quality system essentials.

Laboratory testing is a complex series of work processes that begin at the patient (pre-analytic) and that end at report receipt by the ordering practitioner (post-analytic). Only some of these work processes take place in the laboratory, and only some of them involve the professional decision-making/ interpretive skills of an individual laboratory physician.

Despite this, as depicted in Figure 1 below, the quality systems' responsibilities of laboratory directors encompass the continuum of work processes, extending from pre-analytic to post-analytic, and include oversight for all of the quality system essentials that form a quality management system for a laboratory.

Figure 1



Lucia M. Berte, CLSI Subcommittee on Quality Management Systems

With respect to the professional work performed by laboratory physicians, there are multiple contributors to ensuring its high quality. Chief amongst these are:

- Training
- Credentialing
- Quality assurance programs
- Continuous professional development
- User feedback
- Peer assessment and accreditation
- Standards of best practice - internal quality assessment
- External quality assessment

As illustrated further in this report, key stakeholders at the national and provincial levels contribute to the quality of laboratory physician work through these key influences on the professional practice of laboratory physicians.

Path2Quality is aware that focused work in the area of standards of best practice is of particular interest to laboratory physicians in the province. This was a focus at the Symposium.

With respect to standards of best practice, laboratory physicians already have access to a variety of offerings that include recommendations / clinical guidelines from various groups such as: regulatory bodies; advisory groups; professional societies; local institutional programs etc.

With respect to this, a pattern-of-practice survey regarding pathology quality assurance practices in Ontario conducted by QMP-LS in September 2008, demonstrated that actual quality assurance practices are variable and may not be well documented. It would appear that laboratory professionals may require guidance on which quality assurance practices are essential, especially in the area of quality assurance practices which should be employed at a local level (internal quality assurance – IQA).

C) Description By The Participating Organizations Of Their Roles And Responsibilities

The invited organizations (RCPSC, CMPA, CAP, CPSO, CCO, QMP-LS/ IQMH, OFPS, OAML, and OMA) shared their understanding of their respective roles, responsibilities and interests in quality management as they affect or guide the professional work of laboratory physicians. While Appendix 3 includes the detailed report provided by each organization, a brief summary for each is provided below.

Royal College of Physicians and Surgeons of Canada

The Royal College of Physicians and Surgeons of Canada (RCPSC) is responsible for setting the standards for specific training requirements and for the certification of all specialists, including laboratory physicians. It regularly examines those standards and uses them to form the basis of their accreditation survey programs offered in Canadian universities.

This year, the RCPSC, together with the Canadian Medical Association and other national medical associations, formed the Ad-Hoc Working Group on Pathology and Laboratory Medicine to study quality practices in pathology and laboratory medicine in Canada. The outcome of a recent survey by that group is due shortly.

Canadian Medical Protective Association

With respect to quality assurance, the Canadian Medical Protective Association (CMPA) has three major roles: it assists physicians in medical legal matters including legal actions and investigations by the regulatory bodies and institutions; it is one of the largest providers of CME and CPD with respect to education and risk management; and it contributes to policy development.

Currently the CMPA has concerns regarding the distinction between quality improvement and accountability reviews and is advocating for clarification in this area.

Canadian Association of Pathologists

The Canadian Association of Pathologists (CAP) is a voluntary professional organization for laboratory physicians and scientists. It promotes quality assurance in the following ways: it provides CPD through its Annual Meeting and new online initiatives, and supports participation in the RCPSC's Maintenance of Competence Program; it supplements resident education and training; it develops new and / or endorses existing standards of best practice; and it advocates for adequate resources for practitioners.

College of Physicians and Surgeons of Ontario

The College of Physicians and Surgeons of Ontario (CPSO) is ultimately accountable for a physician's practice from three perspectives: registration – entry to practice; quality assurance, including peer assessment; and discipline with respect to professional misconduct. The CPSO is putting together strategies and programs to provide a more structured quality assessment process that views the individual and system together. Peer assessment, in all areas for which the College has assessment protocols, takes place through its Quality Assurance Program.

Cancer Care Ontario

Consistent with its objectives to improve quality, accountability and innovation in all aspects of cancer control, Cancer Care Ontario (CCO) develops quality assurance processes, best practice guidelines and standards, and utilizes a performance management system that together drive quality improvement at the hospital / regional centre levels. The Pathology and Laboratory Medicine Program at CCO has developed the Pathology Checklist Reporting Project and Molecular Oncology Report. CCO is building more electronic data stores which give it the potential to report quality metrics at the level of the individual practitioner.

Ontario Hospital Association

The Ontario Hospital Association (OHA) was invited to participate in the Symposium. Its member hospitals have a significant interest in quality assurance issues as they relate to laboratory physicians, because most laboratory physicians work in hospitals, and because the responsibility for quality in hospitals is defined in the Public Hospital's Act and rests with hospital boards. Unfortunately, the OHA did not attend the Symposium.

Quality Management Program – Laboratory Services

The Quality Management Program – Laboratory Services (QMP-LS)' responsibility is to ensure the appropriate standards for laboratory testing are met in the province, and in doing so to protect patient care. QMP-LS fulfills this responsibility through its mandatory Ontario Laboratory Accreditation (OLA) program and through external quality assessment achieved through inter laboratory comparisons of analytic work. At present, QMP-LS' External Quality Assurance (EQA) program has some surveys that contain a medical interpretive component considered to be voluntary and educational for laboratory physicians.

QMP-LS with the sponsorship of the Ministry of Health and Long Term Care recently undertook a substantive review of various aspects of quality assurance systems as they apply to laboratory physician work - the Professional Interpretation and its Quality Management (PIQM) Task Force. The PIQM draft report focused on some suggestions for EQA for laboratory physicians; that report is currently under revision.

Ontario Forensic Pathology Service

The Ontario Forensic Pathology Service (OFPS) is a statutory body that was created in July, 2009. It maintains a register of pathologists to provide services under the Coroners Act. One of the features of the Register includes a reciprocal reporting relationship with the CPSO regarding pathologists on the Register in instances of incapacitation, restriction of performance, professional misconduct and incompetence.

OFPS' main quality assurance program is comprised of quality indicators and educational opportunities. The OFPS also provides a toolkit comprised of practice guidelines, structured reports, etc. that is modeled after the CCO approach. Currently the OFPS is developing a Performance Information Management System that is intended to track key performance indicators. The OFPS has partnered with the University of Toronto to establish a residency training program in forensic pathology as well as with the University's Centre for Forensic Science and Medicine to offer a number of CME programs to support CPD.

Ontario Association of Medical Laboratories

The Ontario Association of Medical Laboratories (OAML) represents nine independently-owned laboratory companies. Its quality assurance program consists of consensus guidelines developed for community physicians that focus on appropriate testing and interpretation of results as well as communiqués for important industry communications (e.g., expedited results, communication of critical results). Quality assurance related to the professional work of laboratory physicians, however, tends to be the mandate of member laboratories.

Ontario Medical Association

The Ontario Medical Association (OMA) is an advocacy group for the medical profession overall, therefore, its work in quality assurance tends to be at a high level. Examples include: improving the legislative framework within which physicians practice; and developing and/or influencing policy at the provincial level (e.g., interprofessional care) or with key stakeholders (e.g., CPSO and revalidation). Of interest, the 2008 Physician Services Agreement negotiated between the OMA and the MOHLTC established precedent by allocating funding to physicians who adhere to clinical practice guidelines for diabetes management.

QMPLS is a partnership between the MOHLTC and the OMA which operates at arms-length from each.

The Institute for Quality Management in Health Care (IQMH), a subsidiary of the OMA, was recently created, in order that QMP-LS may market itself and its products in non-traditional jurisdictions.

The OMA also provides support to OMA Sections and individual members dealing with practice (including quality assurance related) issues. The OMA has been particularly helpful to the Section on Laboratory Medicine as it has explored the issues discussed in this Symposium.

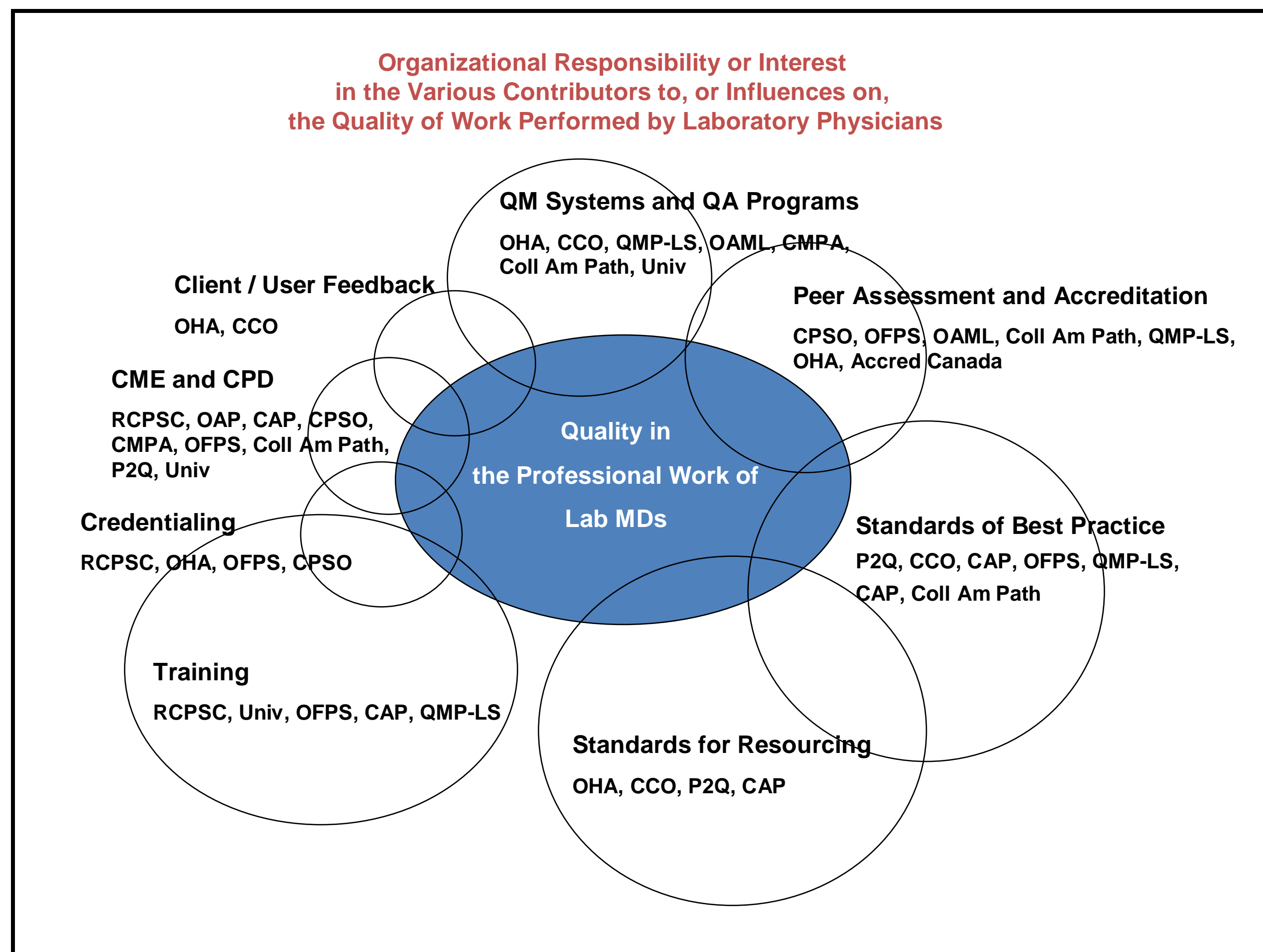
Symposium participants and observers (front to back): Dr. M. McLachlin (Path2Quality), Dr. D. MacDonald (Path2Quality), Dr. S. Joshi (Path2Quality), Ms. B. LeBlanc (OMA), Dr. G. Flynn (QMP-LS), Dr. C. Sawka (CCO), Dr. D. Divaris (CCO), Dr. V. Alexopoulou (CAP), Dr. F. Smaill (McMaster Univ.), Dr. G. Jansen (Univ. of Ottawa), Dr. S. Chakrabarti (Univ. of Western Ontario), Dr. J. Ramsay (OMA Section), Dr. C. Chorneyko (OAP), and Dr. B. Sawka; and (at the door) Dr. R. Hegele (Univ. of Toronto)

D) Mapping the Roles and Responsibilities of Organizations Within the Domains Which Contribute to Quality, and the Associated Gaps and Overlaps

At the conclusion of the organizational reports, a Venn diagram was presented that attempted to depict the various influences on the quality of the professional work of laboratory physicians. Participants were asked to situate their organization within the domains in Figure 2 - below. Included in the schematic are three organizations identified by Symposium attendees but not present that day: the Ontario Hospital Association (OHA), Accreditation Canada (Accred Canada), and the College of American Pathologists (Coll Am Path).

While Figure 2 may not be entirely comprehensive or fully representative of all the current organizational interests in these spheres, it is illustrative of the complexity of the current situation.

Figure 2



E) <u>Discussion of Overlaps and Gaps</u>

As can be seen, there is considerable overlap in all the domains. ***In some instances, these overlaps are felt to be desirable and / or complementary, providing opportunities for stakeholder collaboration.*** For example, it was suggested that:

- Path2Quality could provide expertise and practical experience in the development of best practice guidelines and standards of best practice, and QMP-LS could provide the infrastructure support for communication;
- The university departments could link with the RCPSC to develop a fellowship or diploma programs in quality management thereby filling a void in formal quality management training. Queen's University expressed an interest in hosting a fellowship while QMP-LS would like to attract fellows to work in its organization'
- The five Universities could work together to ensure the number of residency training positions corresponds to the vacant positions available in the system;

- A CAP workshop on laboratory management held for residents and practitioners would supplement the residency training in quality management;

In other instances, participants saw synergies among stakeholders even though they may not necessarily operate within the same domain at present. For example, it was suggested that:

- Residency programs could more fully incorporate the community experience given that a significant proportion of laboratory physicians practice in that environment;

- New laboratory directors, and perhaps hospital administrators to whom they report, might profit from an orientation and training program offered by QMP-LS in order that they fully understand the Ontario laboratory structure and fiduciary duties of all players and institutions;

- Path2Quality might work with the OHA to facilitate a better understanding among hospital board trustees of quality of care as it involves hospital laboratories;

- The CPSO and RCPSC could jointly address licensure requirements for foreign graduates.

Symposium attendees discuss organizational roles and responsibilities (left to right): Dr. C. Sawka (CCO), Dr. R. Hegele (Univ. of Toronto), Dr. D. Divaris (CCO), and Dr. G. Jansen (Univ. of Ottawa)

Alternatively, a review of the overlaps prompted discussion among attendees of redundancies, and highlighted the confusion this creates for the front-line practitioner trying to prioritize the various demands made of them. For example:

- There is a perceived overlap between the CPSO's peer assessment program and other quality management programs. Specifically, candidates' submission of laboratory data to the CPSO was felt to be redundant to other program submissions. (It was explained by the College representatives that although information about the physician and the laboratory is collected, this information is used strictly to provide context and is not used to evaluate the physician per se.);

- CCO's synoptic reporting requirements are felt to conflict with other demands put on pathologists. (It was explained by CCO representatives that the evolution from narrative to synoptic reports came from the laboratory medicine profession and that synoptic reporting is viewed as being critical for quality management purposes consistent with CCO's mandate to report quality to the public. As such, these reporting requirements also extend to surgery, medical oncology and radiation oncology.);

- Different accreditation standards are employed by Accreditation Canada vs. QMP-LS. The latter assesses against ISO 15189 which is endorsed by the Canadian Standards Association and the

Standards Council of Canada. Accreditation Canada does not use these same standards resulting in different assessment methodologies (e.g., checklist versus on-site visits);

- There is an un-necessary overlap between QMP-LS and other EQA providers with respect to quality assurance for HER-2 testing. This sort of system inefficiency would be even less desirable it if was replicated for quality assurance for other forms of laboratory testing.

In general, the discussion about overlaps served to underscore sources of stress and confusion for practicing laboratory physicians. Multiple organizations are involved in quality management, but they all employ different standards and processes for defining quality improvement.

Chief amongst the gaps identified was a comprehensive framework for quality management that encompasses all of its various domains, embraces all of the stakeholders, and helps promote synergy among their collective efforts thereby minimizing the development of ad hoc quality management approaches to specific tests, guidelines development, accreditation, etc.

Also missing are sufficient resources to:
- ***address increasing direct patient care-related work***
- ***the pressures associated with the current quality management requirements of those organizations who are already 'players' in the field***
- ***the anticipated increase in quality management requirements, from current, and new parties with an responsibility or interest in the area***

Symposium attendees began to identify elements comprising / the attributes of a quality management framework / program. These included the following:

- Incorporates all of the key stakeholders, building upon the momentum created by the Symposium;
- Guided by an overarching vision, goals and objectives;
- Goes beyond EQA and IQA to embrace all the domains outlined in the diagram;
- Includes a broader definition of "professional work" to reflect all the professional competencies of laboratory physicians, e.g., health advocate, communicator, health manager, educator, in addition to those competencies listed by the Royal College;
- Robust enough to create the value proposition that secures interest / buy-in at the institutional level;
- Strives for a clear definition of standards (be they licensure requirements, laboratory accreditation, peer assessment, or best practices); and,
- Best practice guidelines, in turn, would address key practice environment issues such as appropriate resources, workload, etc.

A suggestion made was that the quality management system envisaged might ideally be captured within an alternate funding model thereby allowing government to legitimately respond to funding and other issues, e.g., human resources, outside hospital global budgets.

The benefits of developing a quality management framework / program from a stakeholder organizational perspective were described:

- Facilitates a clear understanding of responsibilities among the key stakeholders;
- Promotes collaboration and minimizes confusion among the stakeholders;
- Can serve as primary source for development of quality indicators and standardized quality management processes; and,
- Can serve as a single source for the development / consolidation of standards of best practice (similar to CPD Ontario).

From a laboratory physician perspective, development of a quality management framework / program will enable the profession to:

- Understand expectations with respect to quality standards;
- Be able to measure performance against a defined standard; and,
- Allocate appropriate personal and group resources / time.

F) Role of Path2Quality

There was general agreement that Path2Quality should take the lead in developing a framework that would describe the various elements of a comprehensive quality management plan for the professional work of laboratory physicians.

There was general agreement that, with a framework in hand, a project plan could be developed, including:

- Delineation of the various project components and associated deliverables;
- Priorizaton of the various components;
- Exploration of partnerships, where necessary, to address components of the plan; and,
- Description of resource implications for the project and application to various agencies for project support.

G) Next Steps

Since the Symposium the Path2Quality Executive has met on a number of occasions – including a half-day priority setting meeting on January 13, 2010. At that time a number of actions and initiatives were decided upon:

- The Path2Quality secretariat will provide Symposium Proceedings to:
  - Symposium participants and observers;
  - Groups and organizations invited to the Symposium, but which were not able to attend; and
  - Members of the OMA Section and OAP (and post the Proceedings on those member web-sites).

- Path2Quality will strike a Steering Committee that will:
  - In the first instance be constituted of the Executive of Path2Quality, and supported by the Path2Quality secretariat;
  - Determine how best to ensure representation of the interests of the breadth of the laboratory medicine community, and of key stakeholders - an early deliverable in the anticipated detailed project plan (below)

- The Steering Committee will approach a number of organizations with the intent of exploring the possibility of future partnerships/ joint initiatives, including in the first instance CCO, the OHA, the OMA and QMP-LS.

- The Steering Committee will approach other organizations (including the other participants at the Symposium), with the intent of creating enhanced channels of communication, and seeking synergies that might be explored in the future.

- The Steering Committee will develop a high level project plan – to provide definition of goals and deliverables for the next 3 years.

- The Steering Committee will seek the input of the membership at the:
  - OMA Section Annual General Meeting (May, 2010);
  - OMA Section Laboratory Director Symposium (May, 2010); and
    OAP AGM (Fall, 2010).

Appendix 1

Symposium Participants

Dr. David Bach (Symposium Moderator), Past-President, Ontario Medical Association

Mr. Dan Faulkner, Director, Quality Management/Research, College of Physicians and Surgeons of Ontario

Dr. Gregory Flynn, Managing Director, Quality Management Program – Laboratory Services, and Chief Executive Officer, Institute for Quality Management in Health Care

Dr. Laurette Geldenhuys, President, Canadian Association of Pathologists *(by teleconference)*

Dr. Suhas Joshi, Executive Member, Path2Quality, and Past-President, Ontario Association of Pathologists

Ms. Barb LeBlanc, Executive Director, Health Policy, Ontario Medical Association

Dr. Denis MacDonald, Executive Member, Path2Quality, and Treasurer, Ontario Medical Association Section on Laboratory Medicine

Dr. Bill McCauley, Medical Officer, Quality Management, College of Physicians and Surgeons of Ontario

Dr. Meg McLachlin, Executive Member, Path2Quality and Vice-Chair, Ontario Medical Association Section on Laboratory Medicine

Dr. Brendan Mullen, Co-Chair, Path2Quality, and
Chair, Ontario Medical Association Section on Laboratory Medicine

Dr. Andrew Padmos, Chief Executive Officer, Royal College of Physicians and Surgeons of Canada

Dr. Michael Pollanen, Chief Forensic Pathologist, Ontario Forensic Pathology Service

Dr. Carol Sawka, Vice-President, Clinical Programs and Quality Initiatives, Cancer Care Ontario

Mr. Jim Simpson, Legal Counsel, Ontario Medical Association

Dr. James Sproule, Managing Director, Physician Services, Canadian Medical Protective Association

Dr. John Srigley, Co-Chair, Path2Quality, and President, Ontario Association of Pathologists

Mr. Jeff Sumner, Vice-President and Chief Scientific Officer, Gamma-Dynacare Laboratories, representing Ontario Association of Medical Laboratory

Dr. Virginia Walley, Executive Member, Path2Quality, and Past-Chair of Ontario Medical Association Section on Laboratory Medicine

Symposium Observers

Dr. Vina Alexopoulou, Vice-President, Canadian Association of Pathologists

Ms. Kathy Bugeja, Ontario Medical Association Section on Laboratory Medicine and Path2Quality

Dr. Subrata Chakrabarti, Deputy Academic Chair, Dept. of Pathology, University of Western Ontario

Dr. Kathy Chorneyko, Board Member, Ontario Association of Pathologists

Dr. Terence Colgan, Chair, Pathology Interpretive Quality Management Task Force, Quality Management Program – Laboratory Services

Mrs. Linda Crawford, Director, Ontario Laboratory Accreditation, Quality Management Program – Laboratory Services

Dr. Dimitrios Divaris, Clinical Advisor, Pathology Project, Cancer Care Ontario

Ms. Jane Gun-Munro, Director, External Quality Assessment, Quality Management Program – Laboratory Services

Dr. Richard G. Hegele, Professor and Chair, Dept. of Laboratory Medicine and Pathology, University of Toronto

Dr. Gerard Jansen, Division Head of Anatomical Pathology, Dept. of Pathology and Laboratory Medicine, The Ottawa Hospital

Dr. Christina MacMillan, Board Member, Ontario Association of Pathologists

Ms. Jean McNeil, Senior Administrative Assistant, Health Policy, Ontario Medical Association

Dr. Jennifer Ramsay, Council Member, Ontario Medical Association Section on Laboratory Medicine

Dr. Barry Sawka, Pathologist, Grand River Hospital

Dr. Fiona Smaill, Professor and Chair, Dept. of Pathology and Molecular Medicine, McMaster University

Dr. Victor Tron, Head, Dept. of Pathology and Molecular Medicine, Queen's University

Appendix 2

Participating Organizations' Descriptions of Their Roles and Responsibilities

During the Symposium, spokespeople for each of the participating organizations were asked to provide a brief summary of their organization's role, responsibilities and interests in quality management as they affect or guide the professional work of laboratory physicians. The summaries, supplied by each organization, are provided below.

The Royal College of Physicians and Surgeons of Canada

The Royal College of Physicians and Surgeons of Canada (RCPSC) is responsible for setting the standards for specific training requirements and certification of all specialists, including laboratory physicians. It regularly examines those standards and uses them to form the basis of the over 700 accreditation survey programs offered in Canada through its 17 universities. These university programs are reviewed every 6 years.

To accomplish these tasks, the RCPSC has established 65 committees: 29 specialty and 34 sub-specialty committees. In an effort to ensure that the standards are comprehensive both nationally and provincially, the RCPSC is seeking input / feedback from the national specialty societies as well as from the Chairs, Professors, and Department Heads within Canada's Academic Health Sciences Centres on how the Royal College can strengthen the membership of its specialty committees.

In order to be more responsive, the accreditation process itself is also under review and the examination and assessment processes that are applied to residents, specifically:

1. STACERS – Structured Assessment of Clinical Encounters Reports; and
2. Residency membership and assessment – the preference of the College is towards milestone assessments during training in addition to comprehensive exit assessments.

This year, the RCPSC, together with the Canadian Medical Association and other national medical associations formed the Ad-Hoc Working Group on Pathology and Laboratory Medicine to study quality practices in pathology and laboratory medicine in Canada. The Working Group conducted a survey evaluation process that reached out to all laboratory and pathologists across Canada. Respondent observations and concerns elucidated during the survey centered on 4 principal issues:

1. Workload
2. Education
3. Emerging Technologies
4. Quality Assurance and Quality Management

The results and potential opportunities are currently being reviewed and considered by the Working Group.

Canadian Medical Protective Association

The Canadian Medical Protective Association (CMPA) has three major roles in assisting laboratory physicians:

1. assistance in medical legal matters;
2. education and risk management; and
3. contribution to policy development.

Medical legal assistance to members includes: legal actions, investigations by the regulatory college, as well as hospital investigations. The CMPA also assists in billing matters, privacy matters, human rights and criminal matters associated with medical professional work.

With respect to education and risk management, the CMPA is one of the largest providers of CME and CPD in Canada. The Association helps members improve their risk management, support patient safety and also helps them respond better to adverse events when they occur. Recent educational symposia conducted by the Association in Hamilton and Collingwood this year were directed specifically at laboratory physicians.

The CMPA is very concerned about reviews and investigations of adverse events that occur at the CPSO and within hospitals and institutions. In particular, the Association strongly advises that Quality Improvement reviews must be separate from Accountability Reviews.

CMPA strives to promote a just culture of safety where the interests of patients and health care workers are protected when adverse events are investigated. CMPA's perspective is outlined in two very important CMPA documents which can be obtained from its web site: 1) Learning from adverse events: fostering a just culture of safety in Canadian hospitals and health care institutions, and 2) Reporting and responding to adverse events: a medical liability perspective.

It is the view of the CMPA that Quality Improvement (QI) reviews must be set up by properly constituted Quality Improvement committees. This is necessary to protect information that is obtained and documented in the QI process from being produced in other forums or investigations, such as Accountability Reviews including hospital investigations, College investigations, legal actions or other forums.

If information from a QI review is not protected from being produced in an Accountability Review or an investigation, the participants in QI reviews will be reluctant to attend to provide their point of view. QI reviews are meant to focus on system issues with the intention of improving patient safety.

Accountability Reviews have a different purpose from the outset: to look at the performance of the individual(s) involved. Accountability Reviews should obtain information independently through their own process and not from the QI process.

Canadian Association of Pathologists

As articulated in its Mission Statement, “The Canadian Association of Pathologists (CAP-ACP) is a voluntary professional organization of laboratory physicians and scientists whose mission is to provide national leadership in Pathology and Laboratory Medicine through the promotion of excellence in practice, education and research, and through the fostering of integrity and high standards of ethical behaviour. The CAP- ACP aims to provide continuing professional development to all subgroups within its membership. The CAP-ACP will also advocate for high quality and standards for patient care, promote collegiality, and advocate for the professional interests of laboratory physicians and scientists.”

The CAP-ACP thus currently sees its major roles in quality assurance in the following areas:

1. Continuing Professional Development: Through the Annual Meeting and new online initiatives, and supporting participation in the Royal College's Maintenance of Competence Program

2. Training: Supplementing resident education

3. Standards for Best Practice: Developing standards collaboratively with other organizations and endorsing existing guidelines (e.g., the College of American Pathologists’ Cancer Checklist). Recent partnerships include interaction with Accreditation Canada and the Canadian Standards Association to examine the various quality assurance systems that are in place across Canada with the view to raising QA standards nationally.

4. Standards for Resourcing: Advocating for adequate resources for pathologists to practice.

The College of Physicians and Surgeons of Ontario

The College of Physicians and Surgeons of Ontario (CPSO) is ultimately accountable for a physician's practice from 3 perspectives:

1. Registration – entry to practice;
2. Quality assurance; and
3. Professional misconduct.

The College's quality improvement programs are both general and specialty-specific. In an effort to dispel the myths surrounding its activities vis-a-vis laboratory medicine:

- Pathology is neither a particular focus nor target of the College, it has come up through a random process;
- There is a legislative firewall that prevents public disclosure of any information coming out of the quality assurance process; and
- The CPSO facilitates quality assurance reviews for the laboratory medicine community, i.e., helps it develop a program for the specialty.

With respect to continuing competence, the College believes individuals and the system cannot be examined separately as they are interrelated in a quality context. That is why the College is putting together strategies and programs to provide a more structured assessment process where the system and the individual are viewed together.

The CPSO is not willing to transfer out its role in peer assessment to credible replacements. Peer assessment, in all areas for which the College has assessment protocols, will continue to take place through its Quality Assurance Program. The CPSO has indicated a number of components of an assessment program that need to be in place for an assessment to be deemed acceptable. If an external organization developed a program that contained all of the components of assessment and the program was reviewed by the Quality Assurance Committee and deemed an acceptable alternative to random peer assessment, the College has indicated a willingness to exempt physicians from random peer assessment should they be participating in such a program.

Cancer Care Ontario

Cancer Care Ontario (CCO) is a provincial agency with a mandate to oversee the full spectrum of cancer control. Its focus is on working with its partners to improve quality, accountability and innovation in all aspects of cancer control. It has an explicit clinical accountability framework that uses a model of joint clinical and administrative leadership accountability for quality of services provided. CCO works with clinical leaders (provincial leads and regional counterparts in each of the 14 regional cancer programs, mapped to LHIN boundaries) to review evidence to generate best practice documents such as guidelines and standards. It uses performance data to drive improvements and has the capacity to implement system improvements. It funds cancer services and uses a performance management system where it links funding to quality and holds the regional leads accountable for improvements against an agreed upon list of priorities.

CCO has a mandate to report on quality to the public and does this through its annual Cancer System Quality Index. It reports at both the provincial and LHIN levels. CCO has a robust internal reporting system at the regional cancer program and individual hospital level. This information is used to guide improvements and for its performance management system.

CCO is building more electronic data stores which give it the potential to report quality metrics at the level of the individual practitioner. Many internal groups want access to hospital and individual level data for quality management purposes. Surgeons and pathologists have indicated their desire to access their own data shown against an aggregate of their peers. Surgical, pathology and regional cancer program leads

also would like access to individual provider data. The providers have expressed concern about the possible misuse of this data by their supervisors and perceive the potential for this information to be used, not in a constructive manner for quality improvement purposes, but in a punitive way to document deficiencies in provider performance. CCO is committed to sharing data for the purposes of quality improvement, and will do so only in the presence of a well-articulated and transparent quality management process and policy that is understood and endorsed by the majority of providers, and assurance that this data will not, on its own, be used in a punitive manner.

CCO is very enthusiastic to participate in the Path2Quality process. It offers experience in developing quality indicators and reporting those indicators to enable quality management. Through its Pathology and Laboratory Medicine Program and the Program in Evidence Based Care, it has the potential to assist Path2Quality in the development of a standardized quality management process that builds on existing best practice.

CCO looks forward to working with Path2Quality on the development of an action plan that will result in a standardized quality management framework for interpretive diagnostics and clinical care. This should be useful for all cancer care, not just for pathology diagnosis. CCO also recognizes the importance of such a framework outside the cancer domain.

Quality Management Program – Laboratory Services

Quality Management Program – Laboratory Services (QMP–LS)' responsibility is to ensure appropriate standards for laboratory testing and to protect patient care. QMP–LS primarily fulfills this responsibility through Ontario laboratory accreditation (OLA) and through external quality assessment (EQA) achieved through inter laboratory comparisons at every phase of laboratory testing.

QMP–LS has operated a cytology EQA program since 1978 and a bone marrow program since 1990. Since 2004 these surveys have not been subjected to performance evaluation, and have been considered "voluntary and educational".

OLA is mandatory for all licensed laboratories in Ontario. The primary purpose of accreditation is to determine if appropriate laboratory processes are in place, and to ensure those processes are effective through ongoing surveillance activities. Accreditation requirements are based on the international standard ISO 15189-2007.

The link between accreditation and EQA within QMP-LS centers on a condition of accreditation that the laboratory must demonstrate competence in EQA surveys conducted by QMP–LS and meet the generally-accepted standards of proficiency in such tests. QMP–LS' OLA Division requires the laboratory to participate in inter laboratory comparisons, where available and appropriate, for all classes of tests included in accreditation. However, there is a gap at present in that currently, QMP–LS' EQA surveys that contain an interpretive component are considered to be voluntary and educational. Because performance is not evaluated, they do not meet the criteria that OLA has adopted for formal inter laboratory comparison schemes.

This gap could be addressed by a new, not-for-profit, subsidiary corporation that partners with QMP–LS' EQA, OLA and KT (Knowledge Transfer) divisions. The Institute for Quality Management in Healthcare (IQMH) offers accreditation, proficiency testing and educational services (interactive training series, webcasts, workshops and publications) to health care organizations and individuals in jurisdictions, other than Ontario, to develop their knowledge of quality management systems and stay up-to-date on the latest developments in the field. IQMH is wholly owned by the OMA, has an independent Board of Directors and does not have a reporting relationship with the MOHLTC.

Ontario Forensic Pathology Service

The Ontario Forensic Pathology Service (OFPS) is a statutory body that was created in July, 2009 in the aftermath of the Goudge enquiry. Forensic pathology is the smallest and newest sub-specialty recognized by the Royal College of Physicians and Surgeons of Canada with a residency training program established at the University of Toronto. The OFPS also partners with the Centre for Forensic Science and Medicine of the University of Toronto to offer a number of CME programs as part of its commitment to supporting the CPD needs of its practitioners.

The Amendment of the Coroners Act, which is the statute governing the OFPS, requires the Chief Forensic Pathologist to:

1. Supervise and direct forensic pathology services in Ontario;
2. Maintain a Register of pathologists to provide services under the Act;
3. Establish Rules for the Register;
4. Report to CPSO regarding pathologists on the Register; and
5. Respond to complaints made against pathologists on the Register

To-date, 161 pathologists are on the Register grouped within 3 main categories:

1. Those physicians who are accredited to perform the full spectrum of autopsies, including homicide cases;
2. Those pathologists within community-based hospitals and AHSCs who perform routine coroners' autopsies; and
3. Pediatric pathologists who perform autopsies on unexpected infant and child deaths.

OFPS' main quality assurance program is focused on peer review with respect to autopsy reports in homicides. This program is comprised of quality indicators and educational opportunities. The OFPS also provides a toolkit comprised of practice guidelines, structured reports, synoptic templates and professional report templates that are modeled after the CCO approach to quality assurance.

Currently, the OFPS is developing a Pathology Information Management System that is intended to track key performance indicators.

The relationship with the CPSO is described as a positive reporting relationship. Specifically, the Chief Forensic Pathologist is required to report registered pathologists to the CPSO, in the following circumstances: incapacitation (illness, intoxication); restriction (based on performance); professional misconduct; and incompetence.

Similarly, the CPSO is required to report to the Chief Forensic Pathologist any concerns it may have with respect to a registered pathologist.

Even within this context, the emphasis is on remediation education, i.e., identify the problem, identify the knowledge gap, collaboratively prepare and administer a program of CPD, (targeted retro- and prospective review of cases as required), and assess performance after CPD.

Ontario Association of Medical Laboratories

Representing nine independently-owned laboratory companies, which perform over 95% of all diagnostic testing for patients outside of hospital, the mission of the Ontario Association of Medical Laboratories (OAML) is to promote professionalism, accountability and excellence in the delivery of laboratory services in Ontario and to work with other health-care providers and their associations to effect positive change in health-care delivery in Ontario. OAML members agree to abide by a common code of ethics and conduct their laboratory businesses in accordance with agreed-upon principles and guidelines.

In existence over 14 years, the quality assurance program consists of consensus guidelines developed by expert panels for community physicians that focus on appropriate testing and interpretation of results as

well as communiqués for important industry communications (e.g. expedited results, communication of critical results).

While historically, quality assurance related to the professional work of laboratory physicians has not been part of the mandate of the OAML, some community laboratories are rapidly becoming national reference laboratories and have introduced very sophisticated programs for monitoring performance. For example, Gamma-Dynacare's pathologist program is a mandatory peer review program that includes: both random and targeted reviews; secondary case triaging; assessments of externally referred work; mandatory secondary reviews of all new cancers; as well as an educational component.

Ontario Medical Association

The Ontario Medical Association (OMA) is an advocacy group for the profession overall.

The OMA's quality assurance focus is on improving the legislative framework within which physicians practice as well as improving their practice environment (e.g., advocating for adequate information technology). Until recently, the OMA collaborated with the Ontario Hospital Association (OHA) in drafting the Joint OMA-OHA Hospital Bylaws which provided a quality framework. Other quality foci of the OMA include its evolving policy on Interprofessional Care teams and quality, as well as exploration of the link between quality, continuous professional development and continuing competence as evidenced by the Association's active engagement in the CPSO's revalidation proposal.

The 2008 Physician Services Agreement negotiated between the OMA and the MOHLTC established precedent by allocating funding to physicians who adhere to clinical practice guidelines for diabetes management.

QMPLS is a partnership between the MOHLTC and the OMA which operates at arms-length from each. The Institute for Quality Management in Health Care (IQMH), a subsidiary of the OMA, was recently created, in order that QMP-LS may market itself and its products in non-traditional jurisdictions.

The OMA also provides support to Sections and individual members dealing with practice (including quality assurance related) issues. The OMA has been particularly helpful to the Section on Laboratory Medicine as it has explored the issues discussed in this Symposium. Resources available through the OMA include those directed to economic analysis, health policy development, legal counsel, communications and public affairs advice, and other support as required.

Appendix 3

Laboratory Medicine - Legal Duties Regarding Quality of Care
(a summary prepared by Mr. Jim Simpson, General Counsel, OMA)

Laboratory physicians are subject to the following legal requirements regarding the quality of care they provide:

1. Patients

At common law, physicians owe a duty of care to their patients to practice within the requisite standard of care. A breach of that standard which causes damages to a patient is negligence. Physicians are civilly liable for any such damages so caused.

2. CPSO

The regulatory scheme of the College is set out in the *Regulated Health Professions Act* (RHPA) and the *Medicine Act* and the regulations thereunder. There are two aspects to the statutory scheme relating to quality of care.

a) failure to maintain the standard of practice of the profession

It is professional misconduct to "fail to maintain the standard of practice of the profession".[i] If a panel of the Discipline Committee finds a member has failed to maintain the standard of practice of the profession, it may make one or more of the following orders:

1. Directing the Registrar to revoke the member's certificate of registration.
2. Directing the Registrar to suspend the member's certificate of registration for a specified period of time.
3. Directing the Registrar to impose specified terms, conditions and limitations on the member's certificate of registration for a specified or indefinite period of time.
4. Requiring the member to appear before the panel to be reprimanded.
5. Requiring the member to pay a fine of not more than $35,000 to the Minister of Finance.[ii]

b) Quality Assurance

The RHPA establishes a Quality Assurance Committee at the College and requires the CPSO Council to make regulations prescribing a quality assurance program.[iii] The RHPA requires,

> **82.** (1) Every member shall co-operate with the Quality Assurance Committee and with any assessor it appoints and in particular every member shall,
> (a) permit the assessor to enter and inspect the premises where the member practises;
> (b) permit the assessor to inspect the member's records of the care of patients;
> (c) give the Committee or the assessor the information in respect of the care of patients or in respect of the member's records of the care of patients the Committee or assessor requests in the form the Committee or assessor specifies;
> (d) confer with the Committee or the assessor if requested to do so by either of them; and
> (e) participate in a program designed to evaluate the knowledge, skill and judgment of the member, if requested to do so by the Committee.
>
> **Inspection of premises**
> (2) Every person who controls premises where a member practises, other than a private dwelling, shall allow an assessor to enter and inspect the premises.
>
> **Inspection of records**
> (3) Every person who controls records relating to a member's care of patients shall allow an assessor to inspect the records.

Bill 171 (Health System Improvement Act) made extensive amendments to the RHPA (effective June 4, 2009) to create mandatory minimum requirements for the College's quality assurance programs and to grant new powers to the College's Quality Assurance Committee. Specifically,

Minimum requirements for quality assurance program

80.1 A quality assurance program prescribed under section 80 shall include,

(a) continuing education or professional development designed to,
(i) promote continuing competence and continuing quality improvement among the members,
(ii) address changes in practice environments, and
(iii) incorporate standards of practice, advances in technology, changes made to entry to practice competencies and other relevant issues in the discretion of the Council;
(b) self, peer and practice assessments; and
(c) a mechanism for the College to monitor members' participation in, and compliance with, the quality assurance program.

Powers of the Committee

80.2 (1) The Quality Assurance Committee may do only one or more of the following:

1. Require individual members whose knowledge, skill and judgment have been assessed under section 82 and found to be unsatisfactory to participate in specified continuing education or remediation programs.
2. Direct the Registrar to impose terms, conditions or limitations for a specified period to be determined by the Committee on the certificate of registration of a member,
i. whose knowledge, skill and judgment have been assessed or reassessed under section 82 and have been found to be unsatisfactory, or
ii. who has been directed to participate in specified continuing education or remediation programs as required by the Committee under paragraph 1 and has not completed those programs successfully.
3. Direct the Registrar to remove terms, conditions or limitations before the end of the specified period, if the Committee is satisfied that the member's knowledge, skill and judgment are now satisfactory.
4. Disclose the name of the member and allegations against the member to the Inquiries, Complaints and Reports Committee if the Quality Assurance Committee is of the opinion that the member may have committed an act of professional misconduct, or may be incompetent or incapacitated.

The current Quality Assurance program of the College is set out in Part VII of O.Reg. 114/94 under the *Medicine Act*. A new draft quality assurance regulation is currently posted on the CPSO's website in its document; "Consultation on Proposed Amendments to the QA Regulations". This document includes its Peer or Practice Assessment and its Continuing Professional Development proposals.[iv] The College requests comments upon the draft quality assurance regulation by December 22, 2009.

3. Royal College of Physicians and Surgeons of Canada

Specialists have required a certificate of examination issued by the Royal College of Physicians and Surgeons of Canada as a qualification for the issuance of a certificate of registration by the CPSO since 1993.

The proposed amended Quality Assurance regulation (see above) will require specialists to complete their Continuing Professional Development in accordance with the requirements of the Royal College of

Physicians and Surgeons of Canada or a CPSO-approved Continuing Professional Development organization.[v]

4. Hospitals

The OHA-OMA Prototype Hospital By-Laws set out the criteria for appointment and re-appointment to the medical staff of a hospital which include,

> "a demonstrated ability to provide patient care at an appropriate level of quality and efficiency", and "adequate training and experience for the privileges requested".[vi]

The Medical Advisory Committee is responsible for,

> supervising the practice of medicine, dentistry, midwifery and extended class nursing in the hospital,[vii] and
> making recommendations to the board concerning the quality of care provided in the hospital by the medical staff, dental staff, midwifery staff and by the extended class nursing staff.[viii]

The Public Hospitals Act provides that a hospital's by-laws may make the head of each department responsible to advise the medical advisory committee with respect to the quality of medical diagnosis, care and treatment provided to the patients of his or her department.[ix] The Act further requires,

> **Duty where serious problem exists**
> 34(3) If [Chief of Staff or the head of a department] becomes aware that, in his or her opinion a serious problem exists in the diagnosis, care or treatment of a patient, the officer shall forthwith discuss the condition, diagnosis, care and treatment of the patient with the attending physician.
>
> **Relieving attending physician**
> (3.1) If changes in diagnosis, care or treatment satisfactory to the officer are not made promptly, he or she shall,
> (a) assume forthwith the duty of investigating, diagnosing, prescribing for and treating the patient; and
> (b) notify the attending physician, the administrator and, if possible, the patient that the member of the medical staff who was in attendance will cease forthwith to have any hospital privileges as the attending physician for the patient.

The Prototype Hospital By-laws require the chief of each department to,

> supervise the professional care provided by all members of the medical, dental and midwifery staff, and extended class nursing staff with respect to diagnosing, prescribing for or treating out-patients in the Hospital;
>
> be responsible for the organization and implementation of a quality assurance program in the department, and cooperate with the Program Medical Director to ensure that it is integrated with program-wide quality assurance measures;
>
> advise the Medical Advisory Committee … with respect to the quality of medical, and where appropriate, dental, diagnosis, care and treatment provided to the patients and out-patients of the department;
>
> advise the Chief of Staff, and the Program Medical Director, and the Chief Executive Officer of any patient who is not receiving appropriate treatment and care;
>
> report to the Medical Advisory Committee, and the Program Medical Director, and to the department on activities of the department including utilization of resources and quality assurance;

review or cause to be reviewed, in communication with the Program Medical Director, the privileges granted members of the department including members of the dental staff, members of the midwifery staff and extended class nursing staff for the purpose of making recommendations for changes in the kind and degree of such privileges;

be a member of the Medical Advisory Committee; and

establish a process for continuing education related to the department through and with the Program Medical Director.[x]

5. Cancer Care Ontario

The Hospital Management Regulation requires hospitals, when requested to do so by the Minister, to provide information, from records of personal health information including x-ray films, to Cancer Care Ontario.[xi]

Duty to Report

Section 85.5 of the Health Professions Procedure Code requires,

Reporting by employers, etc.

85.5 (1) A person who terminates the employment or revokes, suspends or imposes restrictions on the privileges of a member … for reasons of professional misconduct, incompetence or incapacity shall file with the [College] Registrar within thirty days after the termination, revocation, suspension, imposition or dissolution a written report setting out the reasons.

Same

(2) If a person intended to terminate the employment of a member or to revoke the member's privileges for reasons of professional misconduct, incompetence or incapacity but the person did not do so because the member resigned or voluntarily relinquished his or her privileges, the person shall file with the [College] Registrar within thirty days after the resignation or relinquishment a written report setting out the reasons upon which the person had intended to act.

Application

(3) This section applies to every person, other than a patient, who employs or offers privileges to a member … for the purpose of offering health services.

6. Laboratories

Laboratories in Ontario must be licensed by the Director of Laboratory and Specimen Collection Centre Licensing appointed under the *Laboratory and Specimen Collection Centre Licensing Act.*[xii] The License specifies the tests or classes of tests that the laboratory may perform and the conditions under which the laboratory may perform the tests.[xiii] All licenses are subject to the following conditions,

1. the operation of the laboratory meet the requirements of a quality management program;
2. the owner and the operator of the laboratory permit [QMPLS] to carry out a quality management program,[xiv]
3. the operator and owner engage the services of a laboratory director who meets the prescribed qualifications,[xv]
4. the laboratory shall,
    (a) have adequate laboratory staff who are qualified to perform the classes of tests for which the licence is sought; and
    (b) have equipment and premises that are suitable for the performance of the tests for which the licence is sought.[xvi]
5. the owner and the operator of a laboratory shall ensure that the staff of the laboratory establish a quality control program that is acceptable to the Director,[xvii]

The prescribed qualifications for the laboratory director are that the person,

(a) is a legally qualified medical practitioner who has been certified by the Royal College of Physicians and Surgeons of Canada in a branch of laboratory medicine; or
(b) is a legally qualified medical practitioner who has two years of post-graduate training in a clinical laboratory or laboratories approved by the Director; or
(c) has obtained from a university approved by the Director an academic doctorate degree with a relevant chemical, physical or biological science as a major subject and has two post-graduate years of laboratory training and experience in a laboratory or laboratories approved by the Director; or
(d) has obtained from a university approved by the Director a master's degree with a relevant chemical, physical or biological science as a major subject and has five post-graduate years of laboratory training and experience in a laboratory or laboratories approved by the Director.[xviii]

The Director may revoke or refuse to renew a licence where any test "is incompetently performed" by the laboratory.[xix] If [QMPLS] reports to the Director that the operation of a laboratory do not meet the requirements of the program, the Director may impose any conditions upon the laboratory's licence that the Director considers necessary or advisable in order that the health of the public be protected.[xx]

The Act allows the Minister to enter into an agreement with [QMPLS] to provide for the carrying out of a quality management program acceptable to the Director.[xxi]

Inspectors
The Minister may appoint inspectors for the purposes of enforcing the Act.[xxii] Inspectors may at all reasonable times inspect the premises, operations, all records and test samples of all laboratories and specimen collection centres to ensure that the provisions of the Act are complied with.[xxiii]

Colorectal Cancer Screening Registry
The regulation requires laboratories that participate in the provincial colorectal cancer screening program to report the results of tests performed to Cancer Care Ontario for the purposes of the Colorectal Cancer Screening Registry.[xxiv]

7. QMP-LS

QMP-LS has entered into an agreement with the Minister. The agreement requires,

(1) QMP-LS, as agent for the Minister, will develop and carry out a program of quality management that includes:
 (a) examining and evaluating the proficiency of testing in laboratories;
 (b) an accreditation program;
 (c) developing quality criteria for the performance of tests in laboratories, within timeframes acceptable to the Minister; and
 (d) developing and disseminating guidelines for the performance of tests.
(2) QMP-LS will prepare written materials describing the purpose, procedures and standards of the QMP-LS program and ensure that all laboratories are fully informed as to the purpose of the program.
(3) QMP-LS will establish an internal process to provide quality criteria for use by laboratories,
(4) QMP-LS will establish *ad hoc* committees as required, based on the priorities set by the Minister, to develop and disseminate guidelines for the performance of laboratory tests.

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i Section 1(1), ¶2, O.Reg. 856/93 under the *Medicine Act*.
ii Section 51(2) of the *Health Professions Procedural Code*, Schedule 2 to the *Regulated Health Professions Act*.
iii HPPC, section 80.
iv http://www.cpso.on.ca/uploadedFiles/policies/consultations/QAamendments_Sept09.pdf

[v] Section 29(2)(a).
[vi] Section 7.4.2 (2)(c) and (g).
[vii] Section 7(2)(b), O.Reg. 965.
[viii] Section 7(2)(a)(v), O.Reg. 965.
[ix] Section 34(2).
[x] Section 7.10.3.
[xi] Section 23(a), O.Reg. 965.
[xii] Section 9(1).
[xiii] Section 9(2).
[xiv] Section 9(14)(a), (b).
[xv] Section 4(1)¶1, 2 O.Reg. 682.
[xvi] Section 5(a), (b) O.Reg. 682.
[xvii] Section 9(1)(d).
[xviii] Section 6(1) O.Reg. 682.
[xix] Section 9(17) (b).
[xx] Section 9(15).
[xxi] Section 19.
[xxii] Section 16(1).
[xxiii] Section 16(3).
[xxiv] Section 9(1)(a.1), O.Reg. 682.