Approaches to Accountability: The Role of Ontario Laboratory Accreditation

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CIHR FUNDING: PHE-101967

Research Objective

The goal of the overall study was to identify the approaches to accountability in the Ontario Medical Laboratory Sector (MLS) and to determine the views on challenges and benefits of the approaches currently in place. For this presentation we focus on Ontario Laboratory Accreditation (OLA).

Background

The Medical Laboratory Sector (MLS) in Ontario provides approximately 80%[1] of the objective data for diagnosis, monitoring and treatment of patients, as well as playing an important role in disease control and surveillance.

The Ontario MLS can be categorized into four sub-sectors, based on their public-private ownership status: hospital-based laboratories (private not-for-profit), community-based laboratories (private for-profit investor-owned); laboratories found in physician offices (private for-profit small businesses) and public health laboratories (public)

Laboratory testing is a highly complex process involving three stages, pre-analytical (test ordering, specimen collection and transportation), analytical (conducting the test) and post-analytical phases (interpretation of results). The majority of errors in the laboratory sector occur in the pre-analytical phase (between 46-68.2% of total errors in this sector).[2] As a result, quality cannot be measured in a single metric but rather includes a variety of assessments and approaches that require a systems approach. Quality assurance in this sector is shifting to a focus on transparency and accountability.

Research Methodology

A case study design based on a mix methods approach incorporating quantitative (i.e., scoping review of peer review and gray literature) and qualitative data (i.e., 20 semi-structured interviews with open-ended questions). Key stakeholders in the Ontario MLS including physicians, medical technologists, laboratory managers, laboratory owners and representatives from professional organizations were interviewed to determine their views on the approaches to accountability in this sector. The interview data was analyzed using qualitative analysis supported by NVivo9™ software.

The overall study focused on four major accountability approaches used in Canada and internationally, financial incentives, regulations, information directed towards potential users, and reliance on professionalism and stewardship. Included in the analysis is an examination of the affect of goals, governance/ownership structures, and the production characteristics (i.e., contestability, measurability and complexity)of the goods and services being delivered on the success of accountability approaches used.

Results

Accountability Approaches: The approaches to accountability are mixed and all four approaches are used to a varying extent in the MLS. The complexity of the relationship between the different approaches are articulated in this statement from a manager of a regional hospital-based laboratory:

"We are accountable fiscally first to our executive vice president for maintaining a balanced budget…accountability for performance to meet the anticipated customer demands and align ourselves with the strategic plan….we are accountable through performance indicators which are chosen and monitored to ensure that we are meeting the performance of expectations of our customers and includes things like turnaround time and accuracy…… so from a patient safety point of view we have direct accountability to the medical director and from the operational piece around fiscal management and performance to the VP , we have a dual accountability."

Regulation: However regulation is the main approach to accountability as stated by an Educator from a medical laboratory program:

"Regulation is what really drives our business. You know we have the Ontario Laboratory Accreditation process and then there are also other regulations just for best practice, people are following and when you are a leading academic institution, you need to follow those, you need to be aligned with your peers."

The Ministry of Health and Long-Term Care (MOHLTC), under the *Ontario Laboratory and Specimen and Collection Centre Licensing Act*, licenses and regulates Ontario's medical laboratories. The *Act* sets out the guidelines that are used to own, operate and license a specimen collection center or a laboratory in Ontario. All public health laboratories, hospital-based laboratories, community-based laboratories and specimen collecting centers must be licensed and renewed annually. Laboratories found in physician offices are not required to follow the guidelines set out by the *ACT*.

Ontario Laboratory Accreditation: Regulation 682 in the *Act* specifies that the Ontario Medical Association is the agency responsible to carry out a quality management program for the Ontario MLS. The Quality Management Program—Laboratory Services (QMP-LS) is funded by the MOHLTC. QMP-LS is responsible for Ontario Laboratory Accreditation (OLA) and for External Quality Assessment (EQA) programs. OLA examines the quality of laboratory services using a management process that includes all three analytical phases.

Acknowledgements

1. Research participants
2. Ontario Quality Laboratory Management Program: Laboratory Services
3. Professor Raisa Deber, PhD. University of Toronto

Views on Ontario Laboratory Accreditation

Benefits: As articulated by laboratory managers:

"I think what it has done it has raised a different level of awareness for our profession and on some level has put on the map in terms of a more cutting edge approach to regulatory standards."

"I believe that we are better off in Ontario I believe we are producing a better outcome for our patients as a result of a program like OLA."

Challenges: While OLA provides guidelines for all phases of the laboratory process, challenges exist when collaborating with other providers in the pre-analytical phase of test ordering, specimen collection and transportation:

"OLA only controls the lab. But, the accountability of lab tests, part of it depends on the physicians. So, I don't think there was enough physician education to tell them when a test needs more work or what tests need more time, which tests cost more."

Take Away Messages

Laboratory tests are highly measurable in the analytical phase, but gain much of their value by being embedded within a system of care, in which providers order tests appropriately, (pre-analytical phase) and are aided in interpreting and acting upon the results (post-analytical phase).

The laboratory is not a stand-alone entity but is an integral part of a healthcare continuum. Further investigation is needed to better understand the interface between the laboratory and healthcare providers outside of the laboratory working in different healthcare sectors (e.g., primary care versus institutional care) to improve the quality of care in the pre-analytical phase.

This insight will become increasing important in light of the growing reliance on point of care testing performed by non laboratory providers outside of the laboratory.

References Cited

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2. Plebani, M. (2006). Errors in clinical laboratories or errors in laboratory medicine. *Clinical Chemistry and Laboratory Medicine* 44(6), 750-759.