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Interprofessional Collaboration

**Scope of Practice Review:
Medical Laboratory Technology**

Summary & Selected Highlights from the Literature

October 2008

Background

In June 2007, the Minister of Health and Long-Term Care requested the Health Professions Regulatory Advisory Council (HPRAC) to:

*Recommend mechanisms to facilitate and support interprofessional collaboration between health Colleges, beginning with the development of standards of practice and professional practice guidelines where regulated professions share the same or similar controlled acts, acknowledging that individual health Colleges independently govern their professions and establish the competencies for their profession.*¹

In the course of preparing an interim report to the Minister, in conjunction with its review of the scope of practice of nurse practitioners, HPRAC and the Ministry determined that it was necessary to include scope of practice reviews of six professions – dietetics, midwifery, pharmacy, physiotherapy, medical laboratory technology and medical radiation technology. Advice on the first four of these professions is complete and has been delivered to the Minister.

These reviews are being undertaken in the context of a broader review requested by the Minister of Health and Long-Term Care to explore opportunities to advance interprofessional collaboration among regulatory health Colleges. It includes a review of scopes of practice for a number of health professions that are most directly involved in interprofessional care to ensure that there are no legislative, regulatory, structural or process barriers to members of the professions working to the maximum of their scope of practice or to working in interprofessional settings or collaborative teams.

In Ontario, the legislative framework that defines health professions' scope of practice includes the *Regulated Health Professions Act, 1991 (RHPA)* and a series of profession-specific Acts. The *RHPA* contains provisions with respect to the duties and powers of the Minister, the role of HPRAC, a list of controlled acts and other statutory requirements. It also includes a procedural code governing the operation of regulatory colleges.

Each profession-specific Act includes a scope of practice statement. The scope of practice statement in the *Medical Laboratory Technology Act, 1991* states that:

*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.*²

The scope of practice statement found in each health profession act provides a generic frame of reference (or parameters) for the practice of each regulated health profession. A regulated health professional may perform his or her profession's authorized acts only in the course of practising within the profession's scope of practice. However, this statutory scope of practice statement is only one element of a profession's scope of practice. Each profession-specific Act also indicates any controlled acts the profession is authorized to perform, the title or titles restricted to members of the profession and other provisions.

¹ Letter from the Minister of Health and Long-Term Care to HPRAC. June 2007. http://www.hprac.org/en/reports/resources/HPRACletterJune28_2007.pdf

² *Medical Radiation Technology Act, 1991*. http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_91m28_e.htm

Accordingly, as part of its review of professional scope of practice HPRAC³:

- analyzes the scope of practice statement and the controlled acts authorized to the profession;
- considers the implications of the harm clause contained in the *RHPA* (which prohibits everyone except health professionals acting within their scope of practice from treating or giving advice with respect to health where serious physical harm may result);⁴
- considers regulations developed under the profession-specific Act and other legislation that may affect the profession; and
- reviews the standards of practice, guidelines, policies and by-laws developed by the regulatory college.

Collectively, these elements determine the profession's scope of practice and therefore have been considered by HPRAC in its review of the scope of practice for medical laboratory technology.

The profession of medical laboratory technology was invited to submit recommendations articulating proposed changes required to their scope of practice to enhance interprofessional collaboration and assist members in working to the maximum of their scope of practice. The College of Medical Laboratory Technologists of Ontario (CMLTO), in collaboration with the Ontario Society of Medical Technologists (OSMT) and the Canadian Society for Medical Laboratory Science (CSMLS), submitted its response to HPRAC's *Applicant Questionnaire* respecting the scope of practice review for medical radiation technology in June 2008. The submission is available on HPRAC's website.⁵

In addition to requesting access to additional controlled acts, the College of Medical Laboratory Technologists of Ontario, the Ontario Society of Medical Technologists and the Canadian Society for Medical Laboratory Science have proposed amending the profession's scope of practice statement as follows:

*“the design, performance, evaluation, reporting, interpreting and clinical correlation of clinical laboratory testing in the management of all aspects of these activities.”*⁶

HPRAC has established 10 criteria that it considers in reviewing a profession's scope of practice.⁷

³ See criteria. Review of a Professional Scope of Practice under the *Regulated Health Professions Act*. Health Professions Regulatory Advisory Council. May 2007. http://www.hprac.org/en/reports/resources/Scope_of_Practice_June_12_2007.pdf

⁴ s.30 Effective June 4, 2009, or on an earlier day to be established by proclamation, this section will be amended by striking out “physical” and substituting “bodily”. See *Health System Improvements Act, 2007*, S.O. 2007, c.10, Sched.M, ss.6 and 75 (1).

⁵ http://hprac.org/en/projects/Medical_Laboratory_Technology_Scope_of_Practice.asp

⁶ CMLTO, OSMT and CSMLS. Submission to HPRAC Regarding: Medical Laboratory Technologists' Scope of Practice. Submitted to HPRAC June 30, 2008. p.11.

<http://hprac.org/en/projects/resources/CollegeofMedicalRadiationTechnologistsOfOntarioSubmission.pdf>

⁷ See Review of a Professional Scope of Practice under the *Regulated Health Professions Act*.

http://www.hprac.org/en/reports/resources/Scope_of_Practice_June_12_2007.pdf

Purpose, Approach & Format of the Paper

This paper summarizes some of the recent literature on Medical Laboratory Technology (MLT) practice as it relates to the changes being proposed. It is not intended to represent an exhaustive review of the literature; rather, it focuses on identifying key documents that may help to inform discussions about and considerations of the scope of practice review for Medical Laboratory Technology in Ontario.

The literature reviewed in this paper should be examined in conjunction with documents highlighted in a previous literature review⁸ completed by HPRAC in January 2008. That review looked at interprofessional collaboration with respect to the legislative, regulatory, policy and structural/organizational issues that can facilitate and support health regulatory colleges and their members in advancing collaborative practice.

The literature included in the medical laboratory technology review comes from diverse sources. Initial reference documents were included in the submission to HPRAC by *The College of Medical Laboratory Technologists of Ontario* (June 30, 2008).⁹ Additional literature sources were identified through a literature search focused on the following terms:

- “scope of practice medical laboratory technology”
- “scope of practice medical laboratory technologists”
- “medical laboratory technology and scope of practice”
- “enhanced scope of practice for medical laboratory technologists”
- “medical laboratory technologists Ontario”
- “medical laboratory technolog* and interprofessional”
- “medical laboratory technolog* and collaboration”
- “medical laboratory technolog* and advanced”
- “laboratory and error” - “pre-analytical error” – “pre-analytical phase”.

Regulatory-related articles using *PubMed Search* were also reviewed. In addition, supplementary searches were undertaken to identify specific reports from government websites, health care associations, and health policy think tanks in an attempt to locate studies related to regulation and medical laboratory technology scope of practice as identified in some of the literature reviewed. Some of these searches were successful, others were not.

The literature reviewed on the issue has been organized as follows:

- Section 1 provides a high level analysis summarizing some of the key findings arising from the literature.
- Section 2 summarizes the documents reviewed organized under the following three themes: scope of practice; health system needs/improvement; and health outcomes/patient safety/ risk of harm.

⁸ See www.hprac.org for the full copy of the literature review: HPRAC. Interprofessional Regulatory Collaboration – A summary of key reference documents and selected highlights from the literature. January 2008.

⁹ CMLTO, OSMT and CSMLS. Submission to HPRAC Regarding: Medical Laboratory Technologists’ Scope of Practice. Submitted to HPRAC June 30, 2008.

Section 1: Key Findings Arising From the Literature

There is a shortage of literature related specifically to issues concerning MLT scope of practice. Included in the literature, however, is research on a number of issues related to the field of laboratory technology that can help inform discussions about scope of practice. These issues include: growth and other trends in laboratory testing; appropriateness/inappropriateness of testing; laboratory mistakes/errors; and guidelines and performance measures for error reduction.

Given the importance of laboratory tests in providing essential information to make medical decisions, there is a significant body of research examining how laboratory testing mistakes occur, whether they cause patient harm, where they are most likely to occur in the testing process and how they can be prevented.

Data from recent studies suggest that the highest incidence of laboratory-related errors occurs in the pre-analytical phase of laboratory testing. However, few studies have examined the frequency of errors in laboratory test selection and interpretation.

The literature includes a number of recent studies that have been undertaken to examine the steady increase in laboratory utilization and the perception of inappropriate use/overuse within this system. Much of this research has focused on the growing numbers of diagnostic tests being ordered by primary care physicians. Several of these studies have reported on the success of interventions aimed at improving physicians' testing practices including the incidence of 'unnecessary' testing. Many of these interventions focus on behavioural factors such as peer interaction and social influence.

There is a growing body of literature supporting the importance of good laboratory practice and compliance with accreditation standards. This literature looks at the adoption of strategies for error prevention, tracking and reduction, process redesign, the use of extra-analytical specifications and improved communication among caregivers.

Overview: Medical Laboratory Technologists

- *The laboratory is an integrated and complex system involving a wide variety of interactions among different parts and players of the health system.*¹⁰
- *Medical laboratory technology is strongly influenced by the developments of new technology and new scientific testing discoveries.*¹¹
- *Evidence-based culture underpins the practice of laboratory medicine. However, to date, evidence-based medicine appears to have had limited impact on laboratory medicine. A more evidence-based approach is needed to inform education and training of health professionals, support clinical decision making, and support decisions related to resource allocation.*¹²

¹⁰ De Capitani, C. Automation of Pre-Analytical Phase: a Performance Evaluation and Alternative Scenarios. Journal of the Association for Laboratory Automation. Vol (2) : 89– 93. 2002.

¹¹ Health Canada. An Environmental Scan of the Human Resource Issues Affecting Medical Laboratory Technologists and Medical Radiation Technologists. Section C: Findings on Medical Laboratory Technologists. Ottawa: Health Canada. 2002.

¹² Price, C. Application of the Principles of Evidence-Based Medicine to Laboratory Medicine. *Clinica Chimica Acta*. Vol 333. 147-154. 2003; Price, C. Evidence-Based Laboratory Medicine: Supporting Decision Making. *Clinical Chemistry*. Vol 46:8. 1041-1050. 2000.

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- ***The changing role and duties of MLTs are being impacted by: the availability of real-time laboratory results, more effective tests, enhanced clinical consulting roles, involvement in therapeutic decisions, efforts to prevent rather than cure disease, shift from anecdotal care to evidence-based medicine, and the assessment of outcomes for laboratory tests.***¹³
- ***The use of laboratory technicians for routine or automated testing is a current trend that is expected to continue. This also reinforces the trend of educating and training multi-skilled laboratory technologists who can respond effectively to changes in their role.***¹⁴

Health System Changes/Trends

- ***In recent decades, dramatic changes have occurred in the organization, number and type of tests, and role of medical laboratories in healthcare.*** These changes impact on the role of laboratory professionals to require greater analytical accuracy, and more stringent test selection and interpretation of results.¹⁵
- ***Trends in the practice of patient identification and specimen collection include:***¹⁶
 - Automated systems that integrate bar-coding of patient identification wristbands with proper specimen collection procedure;
 - Computerized physician order entry;
 - Standardization of specimen collection procedures within each healthcare organization;
 - Certification of phlebotomists;
 - Continued migration from glass to plastic blood tubes; and
 - Increased use of blood collection devices that have self-sheathing needles or no needles at all for patients with indwelling catheters or lines.

Patient Safety/ Risk of Harm (Laboratory Error)

- ***The quality of results provided by the laboratory is dependent on the control of pre-analytical factors such as specimen collection, specimen handling/processing, and specimen integrity.***¹⁷
- ***Improved communication between physicians and Laboratory Medicine regarding the pre-analytical phase and the implementation of educational programs for defining criteria and procedures is needed.*** Improving the education of health care professionals is seen as a critical contributor for ultimately improving patient care and outcomes.¹⁸

¹³ Plebani, M. Charting the Course of Medical Laboratories in a Changing Environment. *Clinica Chimica Acta*. Vol 319. 87-100. 2002.

¹⁴ Health Canada. An Environmental Scan of the Human Resource Issues Affecting Medical Laboratory Technologists and Medical Radiation Technologists. Section C: Findings on Medical Laboratory Technologists. Ottawa: Health Canada. 2002.

¹⁵ See, for example Plebani, M. Charting the Course of Medical Laboratories in a Changing Environment. *Clinica Chimica Acta*. Vol 319. 87-100. 2002.

¹⁶ Astion, Michael. Future Trends in Patient Identification & Specimen Collection: Automation and Standardization. *Laboratory Errors and Patient Safety*. Vol 1: 2. 2004.

¹⁷ Ajeneje, Francis. Pre-Analytical Quality Assurance: A Biomedical Perspective. *The Biomedical Scientist*. February 2007.

¹⁸ Pansini, N. et al. Total Testing Process: Appropriateness in Laboratory Medicine. *Clinica Chimica Acta*. Vol 333. 141-145. 2003.

- ***Most laboratory errors occur in the pre- or post analytical phases, whereas a minority (13–32%) occur in the analytical portion.*** Most pre-analytical errors result from system flaws and insufficient audit of the operators involved in specimen collection and handling responsibilities. Literature available on this issue, however, describes a significant heterogeneity in study designs and quality with respect to medical errors, little available data, and a lack of a shared definition of laboratory error.¹⁹
- ***Evidence suggests that quality programs developed around the analytical phase of the total testing process would only produce limited improvements, since the large majority of errors encountered in clinical laboratories still prevail within “extra-analytical” areas of testing.***²⁰
- ***Lack of standardized procedures for sample collection, including patient preparation, specimen acquisition, handling and storage, account for up to 93% of the errors currently encountered within the entire diagnostic process.*** Standardization of specimen collection procedures reduces errors by simplifying, optimizing and reducing the number of collection procedures followed in a healthcare organization. There is evidence of personnel cost savings and service quality improvement with pre-analytical phase automation.²¹
- ***Four institutional factors were significantly associated with higher overall laboratory error rates:***
 - Orders verbally communicated to the laboratory;
 - No policy requiring laboratory staff to compare a printout or display of ordered tests with the laboratory requisitions to confirm that orders had been entered correctly;
 - Failure to monitor the accuracy of outpatient order entry on a regular basis; and
 - A higher percentage of occupied beds (i.e., a busier hospital).²²
- ***Most health care organizations use some combination of centralized specimen collection services which are usually under the laboratory’s control, and decentralized services provided by nurses, physicians’ assistants and medical assistants. Institutions that favour a more centralized approach report that laboratory based control of the specimen collection process reduces errors significantly.*** Among the negative impacts of decentralization, labs repeatedly identify five factors that can directly impact errors and adverse events:²³
 - Reduced error tracking and reporting;
 - Less feedback to collection staff;
 - Difficult draws being performed by collectors who get less practice;
 - Collectors with less awareness of the impact of inadequate samples on laboratory testing;
 - Variations in collection procedures based on equipment, location, and personnel.

¹⁹ Bonini, P. et al. Errors in Laboratory Medicine. *Clinical Chemistry*. Vol 48: 5. 691-698. 2002.

²⁰ Lippi, G. et al. Recommendations for Detection and Management of Unsuitable Samples in Clinical Laboratories. *Clinical Chemistry Laboratory Medicine*. Vol 45:6. 728-736. 2007.

²¹ Lippi, G. et al. Pre-analytical Variability: the Dark Side of the Moon in Laboratory Testing. *Clinical Chemistry Laboratory Medicine*. Vol 44:4. 358-365. March 2006.

²² Valenstein, P. and Meier, F. Outpatient Order Accuracy. A College of American Pathologists Q-Probes Study of Requisition Order Entry Accuracy in 660 Institutions. *Archives of Pathology and Laboratory Medicine*. Vol 123. 1145-1150. 1999.

²³ Laboratory Errors and Patient Safety Editorial Staff. Decentralized Specimen Collection and Patient Safety. *Laboratory Errors and Patient Safety*. Vol 1: 2. 2004.

- ***Performance measures that have been identified to respond to error reduction strategies include: customer satisfaction, test turnaround times, patient identification, specimen acceptability, proficiency testing, critical value reporting, blood product wastage, and blood culture contamination.***²⁴
- ***The American Society for Clinical Pathology (ASCP) supports personnel standards for laboratory professionals with a focus on patient safety and quality laboratory testing.*** These standards include practice requirements, certification requirements, and/or licensure. The personnel standards include the following elements: appropriate academic and clinical training for laboratory professionals; passage of a competency examination offered by an approved national certification organization; appropriate continuing competency standards; and recognition of ASCP's professional terminology.²⁵

Future Priorities: Challenges & Opportunities

- ***Future challenges for sustaining changes in the role and contribution of MLTs:***²⁶
 - Guarantee the quality of laboratory tests irrespective of where they are performed;
 - Improve the quality of services;
 - Improve clinical outcomes;
 - Perform joint clinical/ laboratory research projects;
 - Awareness of the importance of the knowledge and skills required for the new role of laboratory professionals.
- ***Future research efforts to address gaps and shortcomings should focus on:***²⁷
 - Development of guidelines to support guideline-driven decision support systems to reduce the number of laboratory tests ordered by primary care practitioners.
 - A more rigorous methodology for error detection and classification and the adoption of proper technologies for error reduction.
 - Strategies to decrease computer order entry errors based on regular monitoring of the accuracy of order entry, substituting written and facsimile orders for verbal orders, and instituting a policy whereby orders entered into computer systems are routinely rechecked against orders on requisitions.

²⁴ Howantis, P. Errors in Laboratory Medicine: Practical Lessons to Improve Patient Safety. *Archives of Pathology and Laboratory Medicine*. Vol 129. 2005.

²⁵ American Society for Clinical Pathology. Personnel Standards for Laboratory Professionals. 2004.

²⁶ Plebani, M. Charting the Course of Medical Laboratories in a Changing Environment. *Clinica Chimica Acta*. Vol 319. 87-100. 2002.

²⁷ Price, C. Evidence-Based Laboratory Medicine: Supporting Decision Making. *Clinical Chemistry*. Vol 46:8. 1041-1050. 2000; Bonini, P. et al. Errors in Laboratory Medicine. *Clinical Chemistry*. Vol 48: 5. 691-698. 2002.

Section 2: Summary of the Literature

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Authors, Title and Publication	Context/Type of Document	Main Findings/Recommendations
American Society for Clinical Pathology. Personnel Standards for Laboratory Professionals. 2004.	Policy statement	<p>The American Society for Clinical Pathology (ASCP) supports personnel standards for laboratory professionals with a focus on patient safety and quality laboratory testing. These standards include practice requirements, certification requirements, and/or licensure.</p> <p>The personnel standards include the following elements: appropriate academic and clinical training for laboratory professionals; passage of a competency examination offered by an approved national certification organization; appropriate continuing competency standards; and recognition of ASCP's professional terminology.</p>
American Society for Clinical Pathology. Scope of Practice Issues Affecting Pathology and Laboratory Medicine. 2005.	Policy statement	<p>In order to protect patient health and ensure high quality laboratory testing, the ASCP opposes efforts to allow pharmacists, nurses, and other non-laboratory health care practitioners to perform and/or interpret laboratory test results. Under the guidance of pathologists, laboratory practitioners perform quality laboratory services. Only under a pathologist's supervision can the scope and competency of other members of the laboratory team be evaluated.</p> <p>Granting non-laboratory practitioners the ability to both perform and interpret laboratory test results is potentially dangerous and will impact a patient's right to have their health care provided by the most qualified medical professional. Furthermore, less qualified non-physician health care personnel (including nurses and pharmacists) with little or no experience in the laboratory cannot assess, manage or gauge the performance of laboratory staff.</p>
Grant, Moira. Guiding the Growth of Professionalism in Medical Laboratory Science: Eight Options for Positive Change. <i>Canadian Journal of Medical Laboratory Science</i> . Vol 69: 5. October 2007.	Describes eight directions for the medical laboratory science profession for constructing, maintaining and negotiating professional values and boundaries.	<p>Recommendations:</p> <ul style="list-style-type: none"> ▪ Supporting the study of the profession and its relationships with other health professions and interest groups; ▪ Redefining professionalism; ▪ Accepting personal responsibility for professionalism; ▪ Breaking down barriers and assumptions; ▪ Acting on opportunities to promote the profession; ▪ Taking advantage of the openness to change that is emerging in some health care organizations; ▪ Channelling energy effectively; ▪ Keeping an eye on the big picture (positive health care outcomes and the role of the laboratory) while remembering the potential for professional change at the level of the individual.

<p>Grant, Moira. The Challenges of Defining the Medical Laboratory Profession. <i>Canadian Journal of Medical Laboratory Science</i>. Vol 69. 2007.</p>	<p>First in a series of three articles that discusses the place of medical laboratory science in Canadian health care. The article explores common theories about medical laboratory science professions to set the stage for historical contexts and professional implications discussed in subsequent articles.</p>	<p>Theories of the profession can be classified as ‘trait theories’, which provides a static and descriptive picture, and ‘power theories’, which offer a dynamic framework.</p> <p>Commonly cited professional traits:</p> <ul style="list-style-type: none"> ▪ Educational Practices ▪ Signifiers of Expertise ▪ Collegial Activities ▪ Individual Behaviours
<p>Ontario Association of Medical Laboratories. Standards and Protocols for the Delivery of Laboratory Services in Long Term Care Facilities. November 2003.</p>	<p>In 2001, OAML member laboratories and long term care facilities established individualized, written service agreements stipulating the level of services that could be expected and the payment mechanisms for those services. (Most services are OHIP funded.)</p> <p>Factors affecting service are:</p> <ul style="list-style-type: none"> ▪ Impact of geography ▪ Role definition/ mandate of community laboratories ▪ Criticality of patients ▪ “STAT Testing” (reporting results within four hours) 	<p>Principles that inform the standards and protocols to address service provision to patients in long term care facilities:</p> <ul style="list-style-type: none"> ▪ Patients in long term care facilities are entitled to a level of service consistent with that provided to other patients in their communities; ▪ Each OAML member shall maintain a laboratory service that is administered in accordance with the highest ethical and professional standards; ▪ Each OAML member shall comply with all applicable legislation and regulations pertaining to the practice of laboratory medicine and operation of diagnostic laboratory facilities; ▪ No OAML member shall enter into any arrangement with practitioners from whom the member receives patients or specimens where the impact of such arrangements is the ordering of diagnostic procedures that are medically unnecessary; ▪ Each OAML member shall establish and follow systems of quality control that ensure the quality of laboratory services meets or exceeds the standards set by the Quality Management Program- Laboratory Services.

Health System Needs/ Improvement

Authors, Title and Publication	Context/Type of Document	Main Findings/Recommendations
<p>2005 Annual Report of the Office of the Auditor General of Ontario: 3.08 Health Laboratory Services.</p>	<p>The objective of the audit was to assess whether the Ontario Ministry of Health and Long-Term Care:</p> <ul style="list-style-type: none"> ▪ had adequate processes in place to ensure that private-sector and hospital laboratories and specimen-collection centres were complying with applicable legislation and established policies and procedures, that test results were appropriately reported, and that private-sector laboratories were funded in a cost-effective manner; and ▪ had adequate policies and procedures to ensure that public-health laboratories were reporting well-water test results on a timely basis. <p>In 2003/04 , the Ministry spent \$1.3 billion on laboratory services. Hospital laboratory expenditures accounted for \$730 million (\$541 million was paid to private-sector laboratories, with three companies receiving over 90% of these payments; and \$3.7 million paid to the OMA to operate a quality-management program for laboratory services on the Ministry's behalf).</p>	<p>Recommendations:</p> <ul style="list-style-type: none"> ▪ To help ensure that laboratories comply with the <i>Laboratory and Specimen Collection Centre Licensing Act</i> and can be relied upon to produce accurate test results, the Ministry should enhance its oversight of the OMA's quality-management activities, including obtaining sufficient information on the results of the OMA's accreditation process, as well as significant and lesser errors found in laboratory test results and evidence that corrective action has been taken on a timely basis; and until such time as it ceases its regular inspections, conduct them consistently. ▪ To help ensure that laboratory tests conducted in physicians' offices are properly performed and produce accurate results, the Ministry should assess whether the quality-assurance processes required for other medical laboratories should apply to laboratories operated by physicians. ▪ To help ensure that private laboratory services are acquired in an economical manner, the Ministry should periodically determine the actual cost of providing these services and utilize this information when negotiating payments for laboratory services. ▪ To help ensure that individuals are aware of all potential contaminants in their well water, the Ministry should indicate that the water was not tested for other contaminants, including chemical contaminants, and therefore may be unsafe to drink even when there is no significant evidence of bacterial contamination; and indicate on the test results report where individuals can obtain information on having their water tested for other contaminants. ▪ To better assist Ontarians in the timely identification of well water that is unsafe to drink, the Ministry should re-examine its policy of rejecting and not testing water samples due to missing postal codes and/or telephone numbers.
<p>Astion, Michael. Future Trends in Patient Identification & Specimen Collection: Automation and Standardization. <i>Laboratory Errors and Patient Safety</i>. Vol 1: 2. 2004.</p>	<p>Examines how the practice of patient identification and specimen collection will evolve over the next decade.</p>	<p>Trends include:</p> <ul style="list-style-type: none"> ▪ Automated systems that integrate bar-coding of patient identification wristbands with proper specimen collection procedure; ▪ Computerized physician order entry; ▪ Standardization of specimen collection procedures within each healthcare organization; ▪ Certification of phlebotomists; ▪ Continued migration from glass to plastic blood tubes; ▪ Increased use of blood collection devices that have self-sheathing needles or no needles at all

		<p>for patients with indwelling catheters or lines.</p> <p>Standardization of specimen collection procedures reduces errors by simplifying, optimizing and reducing the number of collection procedures followed in a healthcare organization.</p>
<p>Baker, G. Ross et al. The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. <i>Canadian Medical Association Journal</i>. Vol 170: 11. 1678-86. 2004.</p>	<p>This study estimates the incidence of Adverse Events (AEs) among patients in Canadian acute care hospitals.</p> <p>1 teaching, 1 large community and 2 small community hospitals in each of 5 provinces (British Columbia, Alberta, Ontario, Quebec and Nova Scotia) were randomly selected and reviewed a random sample of charts for non psychiatric, non obstetric adult patients in each hospital for the fiscal year 2000. Trained reviewers screened all eligible charts, and physicians reviewed the positively screened charts to identify AEs and determine their preventability.</p>	<p>Research into adverse events (AEs) has highlighted the need to improve patient safety. AEs are unintended injuries or complications resulting in death, disability or prolonged hospital stay that arise from health care management.</p> <p>At least 1 screening criterion was identified in 1527 (40.8%) of 3745 charts. The physician reviewers identified AEs in 255 of the charts. After adjustment for the sampling strategy, the AE rate was 7.5 per 100 hospital admissions. Among the patients with AEs, events judged to be preventable occurred in 36.9% and death in 20.8%. Physician reviewers estimated that 1521 additional hospital days were associated with AEs. Although men and women experienced equal rates of AEs, patients who had AEs were significantly older than those who did not (mean age 64.9 v. 62.0 years).</p> <p>The overall incidence rate of AEs of 7.5% in the study suggested that, of the almost 2.5 million annual hospital admissions in Canada similar to the type studied, about 185,000 are associated with an AE and close to 70,000 of these are potentially preventable.</p> <p><u>Limitations:</u> Budget constraints limited the number of hospitals in the study – generalizability of results is unknown; AE rates were not studied in small or remote hospitals; only adult patients in acute care general hospitals were included.</p>
<p>Bandali, Karim et al. Skill Integration in a Simulated and Interprofessional Environment: An Innovative Undergraduate Applied Health Curriculum. <i>Journal of Interprofessional Care</i>. Vol 22:2: 179-189. March, 2008.</p>	<p>A study proposing an innovative applied health undergraduate curriculum model that uses simulation and interprofessional education to facilitate students' integration of both technical and 'humanistic' core skills. The model incorporates assessment of student readiness for clinical education and readiness for professional practice in a collaborative, team-based, patient-centred environment. Improving the education of health care professionals is a critical contributor to ultimately improving patient care and outcomes.</p>	<p>In 2001, an estimated 24,000 preventable deaths associated with medical error were cited by the Canadian Adverse Events Study. Most are due to system errors; however, the current model of health care education may be a contributing factor.</p> <p>A review of the current models in health sciences education reveals a scarcity of clinical placements, concerns over students' preparedness for clinical education and profession-specific delivery of health care education which fundamentally lacks collaboration and communication among professions. These educational shortcomings ultimately impact the delivery and efficacy of health care. Construct validation of clinical readiness will continue through primary research at the Michener Institute for Applied Health Sciences. As the new educational model is implemented, its impact will be assessed and documented using specific outcomes measurements. Appropriate modifications to the model will be made to ensure improvement and further applicability to an undergraduate medical curriculum.</p>

<p>De Capitani, C. Automation of Pre-Analytical Phase: a Performance Evaluation and Alternative Scenarios. Journal of the Association for Laboratory Automation. Vol (2) : 89– 93. 2002.</p>	<p>Describes the automation of the pre-analytical phase in a biochemical laboratory that performs more than 3.6 million tests per year. The paper presents how an investment in the laboratory can be evaluated considering economic criteria, future performance and service quality. Alternative scenarios in terms of personnel, pre-analytical devices and management policies are also considered.</p>	<p>This paper shows how an investment in the laboratory can be evaluated from an economic point of view and also considering future performance and service quality. The laboratory is an integrated and complex system. In order to take into account complexity and integration in the study, simulation has been used. The study highlights the personnel cost saving (more than 40% of saving) and the improvement in service quality of pre-analytical phase automation, even during the period without the connection between Laboratory Information System-Hospital Information System (LIS-HIS).</p>
<p>Health Canada. An Environmental Scan of the Human Resource Issues Affecting Medical Laboratory Technologists and Medical Radiation Technologists. Section C: Findings on Medical Laboratory Technologists. Ottawa: Health Canada. 2002.</p>	<p>This report presents the combined findings of two different studies: an environmental scan performed in 1998 and an update completed in 2001.</p> <p>The environmental scan presented the Advisory Committee on Health Human Resources (ACHHR) with information as well as a number of recommendations to help it determine appropriate strategies to address human resource issues affecting medical laboratory technologists and medical radiation technologists.</p> <p>The 1998 study confirmed that serious shortages could be anticipated in both groups of technologists and that a national strategy was needed. The 2001 study confirmed a worsening of human resource shortages.</p>	<p>As of 2001, most provinces were experiencing serious shortages in medical laboratory technology. Several concurrent and sometimes conflicting forces influencing the medical laboratory workforce including:</p> <ul style="list-style-type: none"> ▪ Diminishing supply of technologists in response to a decline in employment opportunities. ▪ Anticipated retirement among the baby boom technologist workforce in the next 5 to 10 years ▪ Growth in demand for laboratory testing to diagnose the health conditions commonly associated with aging (e. g. cancer, heart disease). <p>Projecting the labour market needs of the future is difficult because of the difficulty in anticipating technological advances in this field. Medical laboratory technology is strongly influenced by the developments of new technology and new scientific testing discoveries. The future health care or laboratory restructuring initiatives that will be undertaken in response to these developments are unknown. However, the trend of using technicians for routine or automated testing is a trend that is expected to continue. Educating multi-skilled technologists who can respond effectively to changes in their roles is another emerging trend.</p> <p>Gathering complete data on the technologist workforce and incomplete databases are major limitations. The differences across Canada in the laboratory personnel used (e.g., aides, assistants) and the corresponding variations in the training requirements (e.g., on-the-job vs. certificate) make the analysis difficult.</p> <p>Ontario reports that positions are starting to open up with the risk of shortages as the workforce begins to retire in higher numbers. Ontario reports a greater shortage in the private laboratories as salaries are better in the public sector. Program officials are finding it difficult to find sufficient funding for their programs, especially with the high cost of instruments.</p>
<p>Hurst, Jerry. Are Physicians' Office Laboratory Results of Comparable Quality to Those Produced in Other Laboratory Settings?</p>	<p>In 1995, California adopted a bill that brought laboratory laws in line with the 1988 Clinical Laboratory Improvement Amendments' standards for clinical laboratories and mandated</p>	<p>The unsatisfactory failure rate for POLs was nearly 3 times (21.5% vs 8.1%) the rate for the non-POLs and about 1.5 times (21.5% vs 14.0%) for POLs that used laboratory professionals as testing or supervisory personnel. The POL unsuccessful rate was more than 4 times (4.4% vs 0.9%) the rate for non-POLs and</p>

<p><i>Journal of the American Medical Association.</i> Vol 279: 6. 1998.</p>	<p>a study comparing results in physicians' office laboratories (POLs) with other settings. This article seeks to determine whether persons conducting tests in POLs produce accurate and reliable test results comparable to those produced by non-POLs. A Survey of clinical laboratories using proficiency testing data was undertaken of all California clinical laboratories participating in the American Association of Bioanalysts proficiency testing program in 1996 (n=1110).</p> <p>Main Outcome Measures: "Unsatisfactory" (single testing event failure) and "unsuccessful" (repeated testing event failure) on proficiency testing samples.</p>	<p>more than twice (4.4% vs 1.8%) the rate for the POLs using laboratory professionals.</p> <p>Significant differences exist among POLs, POLs using licensed clinical laboratory scientists (medical technologists), and non-POLs. Testing personnel in many POLs might lack the necessary education, training, and oversight common to larger facilities. There is a need to better understand the contributing factors that result in the poorer results of POLs relative to non-POLs. In the meantime, patients should be aware that preliminary findings suggest that differences in quality of laboratory tests based on testing site may exist. Laboratory directors at all testing sites must ensure that they understand laboratory practice sufficiently to minimize errors and maximize accuracy and reliability. Directors must understand their obligation when they elect to oversee those assigned testing responsibility.</p>
<p>Neilson, E. et al. The Impact of Peer Management on Test-Ordering Behaviour. <i>The Annals of Internal Medicine.</i> Vol 141. 196-204. 2004.</p>	<p>This interrupted time-series study uses peer management through a resource utilization committee (RUC) to favorably modify test-ordering behavior in a large academic medical center with inpatient care provider order entry (CPOE) system and database of ordered tests. The participants were predominantly house staff physicians at Vanderbilt University Hospital who used CPOE systems. The RUC analyzed the ordering habits of providers during previous years and made 2 interventions by modifying software for the CPOE system.</p> <p>Measurements:</p> <ul style="list-style-type: none"> ▪ Pre- and post-intervention volumes of tests; ▪ Proportion of patients with abnormal targeted chemistry levels after 48 hours; ▪ Rates of repeated admission, transfer to intensive care units, and mortality; ▪ Adjusted coefficient of variation for test ordering; ▪ Length of stay. 	<p>Laboratory testing of hospitalized patients can be expensive and sometimes excessive.</p> <p>Voluntary reduction of testing beyond 72 hours (first intervention) decreased orders for metabolic panel component tests by 24% and electrocardiograms by 57% but not orders for portable chest radiographs. Prospective constraints on recurrent test ordering with panel unbundling (second intervention) produced an additional decrease of 51% for metabolic panel component tests and 16% for portable chest radiographs. Incidence of patients with abnormal targeted blood chemistry levels after 48 hours decreased after the intervention. Post intervention-adjusted coefficients of variation decreased for metabolic panel component tests and electrocardiography. Rates of (adjusted) monthly readmission, transfers to intensive care units, hospital length of stay, and mortality were unchanged.</p> <p>Peer management reduced provider variability by addressing the imperfect ability of clinicians to rescind testing in a timely manner. Hospitals with growing health care costs can improve their resource utilization through peer management of testing behaviors by using CPOE systems.</p> <p><u>Limitations:</u> Other activities occurring during the time period of the interventions might have influenced some test-ordering behaviors, and we assessed effects on only a limited number of commonly ordered tests.</p>
<p>Pansini, N. et al. Total Testing Process: Appropriateness in Laboratory Medicine. <i>Clinica Chimica Acta.</i> Vol 333. 141-145. 2003.</p>	<p>The need to reduce costs in Laboratory Medicine is often related to the possibility of reducing test requests without taking into account patients' outcomes. Therefore, the term "appropriateness" in Laboratory</p>	<p>The authors obtained an economic saving (119,580 euro/year) in cardiac markers request (analytical appropriateness = 60%, pre-analytical appropriateness = 40%) and also an improvement in clinical appropriateness (diagnosis and therapy). The data confirm the need to improve communications between physicians and Laboratory</p>

	<p>Medicine as referred to the specific steps (pre-analytical, analytical, post-analytical) and related to the clinical process could allow the improvement of clinical effectiveness and economic efficiency.</p> <p>Experience has shown an improvement in analytical appropriateness (reorganization and re-engineering by Laboratory automation) and pre-analytical appropriateness (critical revision of the panel for cardiac markers) by evaluating the workload and errors rate in the pre-analytical phase.</p>	<p>Medicine with respect to the pre-analytical step and to implement educational programs for defining criteria and procedures. Appropriateness in analytical and post-analytical steps contributes to achieve economic saving (Core lab, POCT) and improvement of the turn-around time (TAT).</p>
<p>Plebani, M. Charting the Course of Medical Laboratories in a Changing Environment. <i>Clinica Chimica Acta</i>. Vol 319. 87-100. 2002.</p>	<p>In recent decades, dramatic changes have occurred in the organization, number and type of tests, and role of medical laboratories in healthcare. The role of laboratory professionals has undergone a radical change, which calls for greater analytical accuracy, and more stringent test selection, and interpretation of results.</p> <p>The ancillary role of clinical laboratories in the past was analyzed in order to understand why the change has taken place, and to identify old and new areas in which laboratory information is largely used for improving upon decision making for treatment, and patient management.</p>	<p>The availability of real-time laboratory results and more effective tests, the enhanced clinical consulting role, the involvement in therapeutic decisions, the efforts to prevent rather than cure disease, the shift from anecdotal care to evidence-based medicine, and the assessment of outcome for laboratory tests have all contributed to the changing role and duties of medical laboratories.</p> <p>Crucial elements in sustaining the changes in the role and contribution of medical laboratories to a high-quality healthcare are the ability of laboratory professionals to: guarantee the quality of laboratory tests irrespective of where they are performed; improve the quality of services; improve clinical outcomes; and perform joint clinical/ laboratory research projects. A key factor in effecting the change has been the awareness of the importance of the knowledge and skills required for the new role of laboratory professionals.</p>
<p>Poutanen, S. Superbugs on the Rise: The Role of the Medical Laboratory. CMLTO Summit – April 3, 2008.</p>	<p>Presentation delivered at the College of Medical Laboratory Technologists of Ontario’s Summit in April 2008.</p>	<p>New classes of Antimicrobials have been discovered. Superbugs are rising because of 1) Antimicrobial selective pressure (inappropriate human use and animal use), and 2) transmission in the community and in hospitals (especially due to a lack of human hygiene). Solutions include measures to control selective pressure, control the transmission of superbugs and develop new treatments.</p> <p>Laboratories can contribute to all three solutions. In order to effectively do so, laboratories need appropriate staffing, expertise, materials, quality controls and collaborations.</p>
<p>Price, C. Application of the Principles of Evidence-Based Medicine to Laboratory Medicine. <i>Clinica Chimica Acta</i>. Vol 333. 147-154. 2003.</p>	<p>The principles of evidence-based medicine and the search for robust evidence on outcomes play a central role in the practice of laboratory medicine.</p>	<p>Good quality evidence lies at the foundation of all aspects of laboratory medicine. Good quality evidence is also central to being able to demonstrate the value and role played by laboratory medicine in patient care.</p>

<p>Price, C. Evidence-Based Laboratory Medicine: Supporting Decision Making. <i>Clinical Chemistry</i>. Vol 46:8. 1041-1050. 2000.</p>	<p>An evidence-based culture underpins the practice of laboratory medicine, in part because it is perceived as the scientific foundation of medicine. However, evidence-based medicine appears to have had limited impact in the sphere of laboratory medicine. Furthermore, there are some data to suggest that adherence to criteria for the use of robust evidence in scientific papers on the use of diagnostic tests is poor.</p> <p>Laboratory medicine also provides some of the more overt examples of practice lacking a good foundation of evidence—perhaps the best examples being the variations seen in testing strategies between different hospitals for the same clinical presentations. A considerable body of literature exists that is devoted to the inappropriate use of diagnostic tests. One of the greatest challenges to laboratory medicine is the suggestion that diagnostic tests are not perceived to have a major impact on patient outcomes.</p>	<p>One of the key deficiencies in the scientific literature on diagnostic tests often is the absence of an explicit statement of the clinical need (i.e., the clinical or operational question that the use of the test is seeking to answer). Several reviews of the literature on specific procedures have also demonstrated that the experimental methodology used is flawed with, in some cases, significant bias being introduced.</p> <p>Despite these limitations it is recognized that a more evidence-based approach will help in the education and training of health professionals, in the creation of a research agenda, in the production of guidelines, in the support of clinical decision making, and in resource allocation. Furthermore, as knowledge and technologies continue to be developed, an evidence-based strategy will be critical to harnessing these developments.</p>
<p>Smith, B. and McNeely, M. The Influence of an Expert System for Test Ordering and Interpretation on Laboratory Investigations. <i>Clinical Chemistry</i>. Vol 45:8. 1999.</p>	<p>The Laboratory Advisory System (LAS) is an expert system interface that works interactively with clinicians to assist with test selection and result interpretation throughout the laboratory investigation of a patient.</p> <p>To study the influence of the LAS on laboratory investigations, a repeated-measures experiment using clinical vignettes was conducted. To collect baseline data on how laboratory investigations are currently conducted, clinicians investigated one-half of the vignettes using a conventional (non-computer) approach. To determine the influence of the LAS on clinicians' behaviour, the other half of the vignettes were investigated using the LAS.</p>	<p>The LAS enhances the outcome of the investigation and improves laboratory utilization. Clinicians using the LAS (compared with conventional practice) ordered fewer laboratory tests during the diagnostic process (mean, 17.8 vs 32.7), completed the diagnostic workup with fewer sample collections (mean, 5.8 vs 7.5), generated lower laboratory costs (mean, \$194 vs \$232), shortened the time required to reach a diagnosis (mean, 1 day vs 3.2 days), showed closer adherence to established clinical practice guidelines, and exhibited a more uniform and diagnostically successful investigation.</p>

<p>Solomon, D. et al. Techniques to Improve Physicians' Use of Diagnostic Tests: A New Conceptual Framework. <i>Journal of the American Medical Association</i>. Vol 280: 23. 1998.</p>	<p>A review of the published literature on interventions aimed at improving physicians' testing practices and propose methodological standards for these studies and to review selected studies using the PRECEDE framework, a behavioural model that helps categorize interventions based on which behavioural factors are being affected. MEDLINE, EMBASE, and HEALTHStar databases were searched for the years 1966 to January 1, 1998, for English-language articles pertaining to diagnostic testing behaviour; bibliographies were scanned to identify articles of potential interest; and researchers in health services, health behaviour, and behaviour modification were contacted for proprietary and other unpublished articles. A total of 102 articles were identified that described the results of interventions aimed at changing physicians' testing practices. The review included 49 studies that compared diagnostic testing practices in intervention and control groups. Two investigators independently reviewed each article in a blinded fashion using a standard data collection form to obtain a methodologic score and to abstract the key elements of each intervention.</p>	<p>On a 38-point methodologic criteria scale, the mean \pmSD score was 13 ± 4.4. The desired behaviour change was reported in the intervention group in 37 (76%) of 49 studies. Twenty-four (86%) of 28 interventions targeted at many behavioural factors were successful, while 13 (62%) of 21 studies aimed at a single behavioural factor were successful.</p> <p>A majority of interventions to improve physicians' testing practices reported in the literature claimed success, with interventions based on multiple behavioural factors trending toward being more successful. While methodological flaws hamper drawing strong conclusions from this literature, application of a behavioural framework appears to be useful in explaining interventions that are successful and can facilitate interpretation of intervention results.</p>
<p>Stuart, P. et al. An Interventional Program for Diagnostic Testing in the Emergency Department. <i>Medical Journal of Australia</i>. Vol 177. 2002.</p>	<p>Evaluation of an intervention developed to improve test-ordering practice. The intervention comprised three integrated components: implementation of a protocol for test ordering; education program for medical staff; and audit/feedback process. Main outcome measure was test utilisation (assessed as cost per patient).</p> <p><i>Setting:</i> Public hospital emergency department with an annual census of 42 500. The study comprised a six-month pre-intervention stage (November 1998 to April 1999), which was compared with a similar post-intervention period (November 1999 to April 2000), and trends</p>	<p>The intervention appears to have produced long term modification of test ordering in the emergency department of a public teaching hospital. There was a 40% decrease in the ordering of investigations in the emergency department, with test utilisation falling from a mean of \$39.32/patient to \$23.72/patient. The decrease was similar for both laboratory and imaging tests and was sustained for the duration of the 18-month follow-up.</p>

	<p>were examined over an 18-month post-intervention period (May 1999 to October 2000).</p>	
<p>van Walraven, C. et al. Do We Know What Inappropriate Laboratory Utilization is? A Systematic Review of Laboratory Clinical Audits. <i>Journal of the American Medical Association</i>. Vol 280. 550-558. 1998.</p>	<p>Assesses studies that measure inappropriate laboratory use in light of methodological criteria.</p> <p>Systematic review of published studies was undertaken and MEDLINE, HEALTHSTAR, and EMBASE databases were searched from 1966 to September 1997 using a broad and inclusive strategy with no language restriction. In addition, the references of all retrieved studies and 3 textbooks on diagnostic testing were hand-searched. Studies were categorized based on whether the criteria were implicit (objective criteria for inappropriate utilization not provided or very broad) or explicit. Guidelines for evaluation were applied to each study by a single reviewer.</p>	<p>Laboratory utilization has steadily increased with some studies suggesting inappropriate utilization. Forty-four eligible studies were identified. Eleven studies used implicit criteria for inappropriate laboratory utilization and contained small numbers of patients or physicians. Most did not adequately assess the reliability of the implicit criteria. Thirty-three studies used explicit criteria based on the appropriateness of test choice, frequency, and timing, as well as the probability of a positive result. There were large variations in the estimates of inappropriate laboratory use (4.5%-95%). Evidence supporting the explicit criteria was frequently weak by the standards suggested for therapeutic manoeuvres, but was nonetheless compelling based on principles of physiology, pharmacology, and probability.</p> <p>Many studies identify inappropriate laboratory use based on implicit or explicit criteria that do not meet methodological standards suggested for audits of therapeutic manoeuvres. Researchers should develop alternative evidentiary standards for measuring inappropriateness of laboratory test use.</p>
<p>van Wijk, M. et al. Assessment of Decision Support for Blood Test Ordering in Primary Care: A Randomized Trial. <i>The Annals of Internal Medicine</i>. Vol 124. 274-281. 2001.</p>	<p>Randomized trial in 44 general practices that aims to compare the effect of two versions of BloodLink, a computer-based clinical decision support system, on blood test ordering among general practitioners.</p> <p>After stratification by solo practices and group practices, practices were randomly assigned to use BloodLink- Restricted, which initially displays a reduced list of tests, or Blood-Link-Guideline, which is based on the guidelines of the Dutch College of General Practitioners. Average numbers of blood tests ordered per order form per practice were measured.</p>	<p>Different methods for changing blood test-ordering behaviour in primary care have been proven effective. However, randomized trials comparing these methods are lacking.</p> <p>Results of the trial indicated that general practitioners who used BloodLink-Guideline requested 20% fewer tests on average than did practitioners who used BloodLink-Restricted.</p> <p>Decision support based on guidelines is more effective in changing blood test-ordering behaviour than is decision support based on initially displaying a limited number of tests. Guideline-driven decision support systems can be effective in reducing the number of laboratory tests ordered by primary care practitioners.</p>
<p>Verstappen, W. Effect of a Practice-Based Strategy on Test Ordering Performance of Primary Care Physicians: A Randomized Trial. <i>Journal of the American Medical Association</i>. Vol 289: 18. 2003.</p>	<p>A research study aimed at determining the effects of a multifaceted strategy to improve the performance of primary care physicians' test ordering.</p> <p>A multicentre randomized controlled trial with a balanced, incomplete block design and randomization at group level was undertaken. Thirteen groups of</p>	<p>Numbers of diagnostic tests ordered by primary care physicians are growing and many of these tests seem to be unnecessary according to established, evidence-based guidelines. An innovative strategy that focused on clinical problems and associated tests was developed.</p> <p>In this study, a practice-based, multifaceted strategy using guidelines, feedback, and social interaction resulted in modest improvements in test ordering by primary care physicians.</p>

	<p>primary care physicians underwent the strategy for 3 clinical problems (arm A; cardiovascular topics, upper and lower abdominal complaints), while 13 other groups underwent the strategy for 3 other clinical problems (arm B; chronic obstructive pulmonary disease and asthma, general complaints, degenerative joint complaints). Each arm acted as a control for the other. During the 6 months of intervention, physicians discussed 3 consecutive, personal feedback reports in 3 small group meetings, related them to 3 evidence-based clinical guidelines, and made plans for change.</p> <p>The main outcome measure: a decrease in the total numbers of tests ordered per clinical problem, and of some defined inappropriate tests, is considered a quality improvement according to existing national, evidence-based guidelines.</p>	<p>For clinical problems allocated to arm A, the mean total number of requested tests per 6 months per physician was reduced from baseline to follow-up by 12% among physicians in the arm A intervention, but was unchanged in the arm B control, with a mean reduction of 67 more tests per physician per 6 months in arm A than in arm B. For clinical problems allocated to arm B, the mean total number of requested tests per 6 months per physician was reduced from baseline to follow-up by 8% among physicians in the arm B intervention, and by 3% in the arm A control, with a mean reduction of 28 more tests per physician per 6 months in arm B than in arm A. Physicians in arm A had a significant reduction in mean total number of inappropriate tests ordered for problems allocated to arm A, whereas the reduction in inappropriate test ordered physicians in arm B for problems allocated to arm B was not statistically significant.</p>
<p>Verstappen, W. et al. Improving Test Ordering in Primary Care: The Added Value of a Small Group Quality Improvement Strategy Compared With Classic Feedback Only. <i>The Annals of Family Medicine</i>. Vol 2. 569-575. 2004.</p>	<p>The purpose of the paper is to evaluate the added value of small peer-group quality improvement meetings compared with simple feedback as a strategy to improve test-ordering behaviour.</p> <p>The study enrolled 194 primary care physicians from 27 local primary care practice groups in 5 health care regions (5 diagnostic centers). The study was a cluster randomized trial with randomization at the local physician group level. We evaluated an innovative, multifaceted strategy, combining written comparative feedback, group education on national guidelines, and social influence by peers in quality improvement sessions in small groups. The strategy was aimed at 3 specific clinical topics: cardiovascular issues, upper abdominal complaints, and lower abdominal complaints.</p> <p>The mean number of tests per physician per 6 months at baseline and the physicians' region were used as independent variables, and the mean number</p>	<p>The new strategy was executed in 13 primary care groups, whereas 14 groups received feedback only. For all 3 clinical topics, the decrease in mean total number of tests ordered by physicians in the intervention arm was far more substantial (on average 51 fewer tests per physician per half-year) than the decrease in mean number of tests ordered by physicians in the feedback arm. Five tests considered to be inappropriate for the clinical problem of upper abdominal complaints decreased in the intervention arm, with physicians in the feedback arm ordering 13 more tests per 6 months. Inter-doctor variation in test ordering decreased more in the intervention arm.</p> <p>Compared with only disseminating comparative feedback reports to primary care physicians, the new strategy of involving peer interaction and social influence improved the physicians' test-ordering behaviour. To be effective, feedback needs to be integrated in an interactive, educational environment.</p>

	of tests per physician per 6 months was the dependent variable.	
Verstappen, W. et al. Variation in Test Ordering Behaviour of GPs: Professional or Context Related Factors? <i>Family Practice</i> . Vol 21: 4. 2004.	<p>The aim of this study was to describe GPs' test ordering behaviour, and to establish professional and context-related determinants of GPs' inclination to order tests.</p> <p>A cross-sectional analysis was carried out of 229 GPs in 40 local GP groups from five regions in The Netherlands of the combined number of 19 laboratory and eight imaging tests ordered by GPs, collected from five regional diagnostic centres. In a multivariable multilevel regression analysis, these data were linked with survey data on professional characteristics such as knowledge about and attitude towards test ordering, and with data on context-related factors such as practice type or experience with feedback on test ordering data. The main outcome measure was the percentage point differences associated with professional and context-related factors.</p>	<p>The total median number of tests per GP per year was 998 with significant differences between the regions. The response to the survey was 97%. At the professional level, 'individual involvement in developing guidelines' (yes versus no), and at the context-related level 'group practice' (versus single-handed and two-person practices) and 'more than 1 year of experience working with a problem-oriented laboratory order form' (yes versus no) were associated with 27, 18 and 41% lower numbers of tests ordered, respectively.</p> <p>In addition to professional determinants, context-related factors appeared to be strongly associated with the numbers of tests ordered. Further studies on GPs' test ordering behaviour should include local and regional factors.</p>
Wensing, M. et al. Implementing guidelines and innovations in general practice: which interventions are effective? <i>British Journal of General Practice</i> . Vol 48. 991-997. 1998.	<p>It is crucial that research findings are implemented in general practice if high-quality care is to be achieved. Multifaceted interventions are usually assumed to be more effective than single interventions, but this hypothesis has yet to be tested for general practice care.</p> <p>This review evaluates the effectiveness of interventions in influencing the implementation of guidelines and adoption of innovations in general practice. A systematic literature study was carried out using MEDLINE searches for the period from January 1980 until June 1994, and 21 medical journals were searched manually. Randomized controlled trials and controlled before and after studies (with pre- and post-intervention measurements in all groups) were selected for the analysis. Clinical area, interventions used,</p>	<p>Of 143 studies found, 61 were selected for the analysis, covering 86 intervention groups that could be compared with a control group without the intervention. Information transfer alone was effective in two out of 18 groups, whereas combinations of information transfer and learning through social influence or management support were effective in four out of eight and three out of seven groups respectively. Information linked to performance was effective in 10 out of 15 groups, but the combination of information transfer and information linked to performance was effective in only three out of 20 groups.</p> <p>Some, but not all, multifaceted interventions are effective in inducing change in general practice. Social influence and management support can improve the effectiveness of information transfer, but information linked to performance does not necessarily do so. The variation in the effectiveness of interventions needs further analysis.</p>

	methodological characteristics and effects on clinical behaviour were noted independently by two researchers using a standardized scoring form.	
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Patient Safety/Risk of Harm

Authors, Title and Publication	Context/Type of Document	Main Findings/Recommendations
Ajeneye, Francis. Pre-Analytical Quality Assurance: A Biomedical Perspective. <i>The Biomedical Scientist</i> . February 2007.	Pre-analytical errors are misleading results caused by problems that occur prior to sample analysis. Controlling pre analytical factors prior to testing is a critical factor in ensuring accurate results and is essential to patient safety. The quality of results provided by the laboratory is dependent on the control of pre analytical factors such as specimen collection, specimen handling, interfering substances and patient-related factors. It has been estimated that 32–75% of errors occur in the pre-analytical phase. Guidelines for collecting samples and for evaluating submitted specimens during the analysis cycle are essential because such factors could affect patient care, and their identification and the use of continuous audit promotes quality improvements across the laboratory services.	<p>Factors of the pre analytical period that have an impact on quality of laboratory results include:</p> <ul style="list-style-type: none"> ▪ Specimen collection ▪ Sample Processing ▪ Specimen Integrity <p>With regard to analytical quality, clinicians depend on the laboratory for the detection and correction of errors; thus, the following points should be addressed:</p> <ul style="list-style-type: none"> ▪ define laboratory errors and their causes, and set up a plan for a corrective strategy; ▪ create a standard for laboratory error detection, and accurately define reporting and error risk; ▪ measure error reduction and demonstrate, via process analysis, a reduction in risk; ▪ create a culture in which the existence of error is acknowledged, as blame, shame and punishment have no part in addressing the problem; ▪ cooperation between medical and nonmedical staff outside the laboratory is essential, as is a regular update of the sample collection and transportation protocol for non-laboratory personnel.
American Society for Clinical Pathology. Quality Laboratory Practice and its Role in Patient Safety. 2006.	Policy statement.	<p>ASCP supports the development and maintenance of high quality practice standards for laboratory testing to assure patient safety and reduce medical errors associated with laboratory medicine.</p> <p>Recommendations:</p> <ul style="list-style-type: none"> ▪ Patient safety initiatives be designed to reduce errors in all clinical environments including the laboratory. ▪ Laboratory professionals recognize and identify all potential problems and vulnerabilities in laboratory settings, ▪ The establishment of electronic health records for all Americans. ▪ Laboratories closely follow the JCAHO Patient Safety Goals as they apply to pathology and laboratory medicine. ▪ The laboratory/hospital accreditation process as well as standard operating procedures be utilized to help maximize patient safety goals. ▪ The establishment of patient safety organizations as outlined in the new patient safety law, Patient Safety and Quality

		<p>Improvement Act of 2005.</p> <ul style="list-style-type: none"> ▪ Continuing medical education for physicians and allied healthcare professionals to promote patient health and safety. ▪ Certification and licensure of laboratory personnel as a means to ensure laboratory safety. ▪ Laboratory industry should hold meetings between laboratory and non-laboratory health professionals to discuss patient safety strategies. ▪ The examination of appropriate pay for performance measures as a means to improve patient safety. ▪ Collaboration within the laboratory community to optimize the value of laboratory services. ▪ States adopt direct billing requirements for pathology services. ▪ The federal government take additional steps to prevent fee splitting and other similar practices.
<p>Bonini, P. et al. Errors in Laboratory Medicine. <i>Clinical Chemistry</i>. Vol 48: 5. 691-698. 2002.</p>	<p>Reviews medical errors in the fields of laboratory medicine and blood transfusion.</p> <p>MEDLINE and literature searches were undertaken to identify results that were not biased by obsolete technology. In addition, data on the frequency and type of pre-analytical errors in a particular institution were collected.</p>	<p>The search revealed large heterogeneity in study designs and quality on this topic as well as relatively few available data and the lack of a shared definition of “laboratory error”. Nonetheless, there was considerable concordance on the distribution of errors throughout the laboratory working process: most occurred in the pre- or post- analytical phases, whereas a minority (13–32%) occurred in the analytical portion. The reported frequency of errors was related to how they were identified: when a careful process analysis was performed, substantially more errors were discovered than when studies relied on complaints or report of near accidents.</p> <p>The large heterogeneity of literature on laboratory errors together with the prevalence of evidence that most errors occur in the pre- analytical phase suggest the implementation of a more rigorous methodology for error detection and classification and the adoption of proper technologies for error reduction.</p>
<p>Boone, J. How Can We Make Laboratory Testing Safer? <i>Clinical Chemistry Laboratory Medicine</i>. Vol 45:6. 708-711. 2007.</p>	<p>Diagnostic errors occur in laboratory medicine resulting from an error or delay in diagnosis, a failure to employ indicated tests, and the use of outmoded tests. Since laboratory tests provide essential information used by physicians to make medical decisions, it is important to determine how laboratory testing mistakes occur, whether they cause patient harm, where they are most likely to occur in the testing process and how to prevent them from occurring.</p>	<p>Users of and payers for laboratory services must become partners in the laboratory’s efforts to reduce laboratory testing errors and enhance patient safety. They must be linked to a laboratory information system that provides assistance in decisions on test ordering, patient preparation, and test interpretation. Laboratory quality assessment efforts need to be expanded to encompass the detection of non-analytical mistakes. Healthcare institutions need to adopt a culture of safety that is implemented at all levels of the organization.</p>

<p>College of American Pathologists. Laboratory Test Ordering & Documentation. Undated.</p>	<p>Guidelines for laboratory testing and documentation.</p>	<p>Provides guidelines for:</p> <ul style="list-style-type: none"> ▪ Test Ordering ▪ Recording Results ▪ Resolving Problems ▪ Reporting Test Results ▪ Supplemental or Confirmatory Reporting ▪ Disease Reporting ▪ Record Keeping ▪ Confidentiality, HIPPA Regulations.
<p>Howantis, P. Errors in Laboratory Medicine: Practical Lessons to Improve Patient Safety. <i>Archives of Pathology and Laboratory Medicine</i>. Vol 129. 2005.</p>	<p>Patient safety is influenced by the frequency and seriousness of errors that occur in the health care system. Error rates in laboratory practices are collected routinely for a variety of performance measures in all clinical pathology laboratories in the United States, but a list of critical performance measures has not yet been recommended. The most extensive databases describing error rates in pathology were developed and are maintained by the College of American Pathologists (CAP). These databases include the CAP's Q-Probes and Q-Tracks programs, which provide information on error rates from more than 130 inter-laboratory studies.</p> <p>This study defines critical performance measures in laboratory medicine, describes error rates of these measures, and provides suggestions to decrease these errors. Includes a list of recommended performance measures, the frequency of errors when these performance measures were studied, and suggestions to improve patient safety by reducing these errors.</p>	<p>Error rates for pre-analytic and post-analytic performance measures were higher than for analytic measures. Eight performance measures were identified, including customer satisfaction, test turnaround times, patient identification, specimen acceptability, proficiency testing, critical value reporting, blood product wastage, and blood culture contamination. Error rate benchmarks for these performance measures were cited and recommendations for improving patient safety presented.</p> <p>Not only has each of the 8 performance measures proven practical, useful, and important for patient care, taken together, they also fulfill regulatory requirements. All laboratories should consider implementing these performance measures and standardizing their own scientific designs, data analysis, and error reduction strategies according to findings from these published studies.</p>
<p>Joint Commission on Accreditation of Healthcare Organizations. 2005 National Patient Safety Goals: Laboratory. 2005.</p>	<p>The Joint Commission establishes National Patient Safety Goals (NPSGs) each year to evaluate the safety and the quality of care provided at accredited health care organizations. These goals have specific requirements for protecting patients.</p>	<p><u>Goals:</u></p> <p>Improve the accuracy of patient identification.</p> <ul style="list-style-type: none"> ▪ Use at least two patient identifiers (neither to be the patient's location) whenever collecting laboratory samples or administering medications or blood products, and use two identifiers to label sample collection containers in the presence of the patient. Processes are established to maintain samples' identity throughout the pre-analytical, analytical and post-analytical processes. ▪ Immediately prior to the start of any invasive procedure, conduct a final verification process to confirm the correct patient, procedure, site, and availability of appropriate documents. This verification process uses active—not passive—

		<p>communication techniques. The patient's identity is re-established if the practitioner leaves the patient's location prior to initiating the procedure. Marking the site is required unless the practitioner is in continuous attendance from the time of the decision to do the procedure and patient consent to the initiation of the procedure (for example, bone marrow collection, or fine needle aspiration).</p> <p>Improve the effectiveness of communication among caregivers.</p> <ul style="list-style-type: none"> ▪ For verbal or telephone orders or for telephonic reporting of critical test results, verify the complete order or test result by having the person receiving the order or test result "readback" the complete order or test result. ▪ Standardize a list of abbreviations, acronyms and symbols that are not to be used throughout the organization. ▪ Measure, assess and, if appropriate, take action to improve the timeliness of reporting, and the timeliness of receipt by the responsible licensed caregiver, of critical test results and values. ▪ All values defined as critical by the laboratory are reported directly to a responsible licensed caregiver within time frames established by the laboratory (defined in cooperation with nursing and medical staff). When the patient's responsible licensed caregiver is not available within the time frames, there is a mechanism to report the critical information to an alternative responsible caregiver. <p>Reduce the risk of health care-associated infections.</p> <ul style="list-style-type: none"> ▪ Comply with current Centers for Disease Control and Prevention (CDC) hand hygiene guidelines. <p>Manage as sentinel events all identified cases of unanticipated death or major permanent loss of function associated with a health care-associated infection.</p>
<p>Laboratory Errors and Patient Safety Editorial Staff. Decentralized Specimen Collection and Patient Safety. <i>Laboratory Errors and Patient Safety</i>. Vol 1: 2. 2004.</p>	<p>Most health care organizations use some combination of centralized specimen collection services which are usually under the laboratory's control, and decentralized services provided by nurses, physicians' assistants and medical assistants. Institutions that favour a more centralized approach report that laboratory based control of the specimen collection process reduces errors significantly.</p>	<p>Among the negative impacts of decentralization, labs repeatedly identify five factors that can directly impact errors and adverse events:</p> <ul style="list-style-type: none"> ▪ Reduced error tracking and reporting; ▪ Less feedback to collection staff; ▪ Difficult draws being performed by collectors who get less practice; ▪ Collectors with less awareness of the impact of inadequate samples on laboratory testing; ▪ Variations in collection procedures based on equipment, location, and personnel. <p>When designing interventions in a facility, it is critical to begin with standards that have already been established as industry best practices, and then consider basic steps that are easiest to implement.</p> <p>If decentralization of phlebotomy is being considered, training and education for nurses and</p>

		other collection staff is critical.
Laposata, M. and Dighe, A. "Pre-pre" and "post-post" analytical Error: High-Incidence Patient Safety Hazards Involving the Laboratory. <i>Clinical Chemistry Laboratory Medicine</i> . Vol 45:6. 712-719. 2007.	Data from recent studies suggest that the highest incidence of laboratory-related errors occurs in the pre-analytical phase of laboratory testing. However, few studies have examined the frequency of errors in laboratory test selection and interpretation. A survey of physicians who use our clinical laboratory demonstrated that the largest number of test ordering errors appear to involve physicians simply ordering the wrong test. Diagnostic algorithms providing guidance for test selection in specific disorders are also used as the basis for the establishment of reflex protocols in the laboratory.	The provision of an expert-driven interpretation by laboratory professionals resulted in improvements both in the time to and the accuracy of diagnosis. A survey of the physician staff has shown that in the absence of such an interpretation, for patients being assessed for a coagulation disorder, approximately 75% of the cases would have involved some level of test result misinterpretation. It is clear that laboratory medicine must be learned, like any other medical specialty, by reviewing and acting upon actual clinical cases in real time. It is not possible to learn how to advise physicians about a laboratory test that should be performed or the meaning of a test result by watching a medical technologist perform a test. Current pathologists must train future pathologists regarding the meaning of clinical laboratory test results and interact with clinicians in a consultative partnership. If public policy in the US drives the government to reward pathologists who provide the value-added service of interpreting clinical laboratory test results and who improve the ability of physicians to order the correct tests as a pay-for-performance improvement measure, this could greatly spur the development of consultative laboratory medicine services to reduce medical error.
Lippi, G. et al. Pre-analytical Variability: the Dark Side of the Moon in Laboratory Testing. <i>Clinical Chemistry Laboratory Medicine</i> . Vol 44:4. 358-365. March 2006.	Remarkable advances in instrument technology, automation and computer science have greatly simplified many aspects of previously tedious tasks in laboratory diagnostics, creating a greater volume of routine work, and significantly improving the quality of results of laboratory testing. Following the development and successful implementation of high quality analytical standards, analytical errors are no longer the main factor influencing the reliability and clinical utilization of laboratory diagnostics. Therefore, additional sources of variation in the entire laboratory testing process should become the focus for further and necessary quality improvements.	Lack of standardized procedures for sample collection, including patient preparation, specimen acquisition, handling and storage, account for up to 93% of the errors currently encountered within the entire diagnostic process. Complete elimination of laboratory testing errors is unrealistic, especially those relating to extra-analytical phases that are harder to control, highlights the importance of good laboratory practice and compliance with the new accreditation standards, which encompass the adoption of suitable strategies for error prevention, tracking and reduction, including process redesign, the use of extra-analytical specifications and improved communication among caregivers.
Lippi, G. et al. Recommendations for Detection and Management of Unsuitable Samples in Clinical Laboratories. <i>Clinical Chemistry Laboratory Medicine</i> . Vol 45:6. 728-736. 2007.	A large body of evidence attests that quality programs developed around the analytical phase of the total testing process would only produce limited improvements, since the large majority of errors encountered in clinical laboratories still prevail within extra-analytical areas of testing,	Recommendations: 1) Education of and acceptance of responsibility by laboratory personnel to limit the burden of errors in the pre-analytical phase; 2) Implementation of objective and standardized; criteria for detection of unsuitable specimens A; 3) Systematic procedure for detection and monitoring of unsuitable specimens A; 4) Management of unsuitable specimens:

	<p>especially in manually intensive pre-analytical processes. Most pre-analytical errors result from system flaws and insufficient audit of the operators involved in specimen collection and handling responsibilities, leading to an unacceptable number of unsuitable specimens due to misidentification, in vitro hemolysis, clotting, inappropriate volume, wrong container or contamination from infusive routes. Detection and management of unsuitable samples are necessary to overcome this variability. This document reviews the major causes of unsuitable specimens in clinical laboratories, providing consensus recommendations for detection and management.</p>	<ul style="list-style-type: none"> a) Documentation of interference b) Prompt notification of the problem encountered in the specimen to healthcare staff in charge of the patient c) Management of unsuitable specimens for the presence of interfering substances d) Management of unsuitable specimens due to inappropriate sample volume e) Management of unsuitable specimens for clotting f) Management of unsuitable specimens for wrong or misidentification
<p>Plebani, M. and Carraro, P. Mistakes in a Stat Laboratory: Types and Frequency. <i>Clinical Chemistry</i>. Vol 43:8. 1348-1351. 1997.</p>	<p>This paper evaluated the frequency and types of mistakes found in the "stat" section of the Department of Laboratory Medicine of the University-Hospital of Padova by monitoring four different departments (internal medicine, nephrology, surgery, and intensive care unit) for 3 months.</p>	<p>Application of Total Quality Management concepts to laboratory testing requires that the total process, including pre-analytical and post-analytical phases, be managed so as to reduce or, ideally, eliminate all defects within the process itself.</p> <p>Among a total of 40,490 analyses, we identified 189 laboratory mistakes, a relative frequency of 0.47%. The distribution of mistakes was: pre-analytical 68.2%, analytical 13.3%, and post-analytical 18.5%. Most of the laboratory mistakes (74%) did not affect patients' outcome. However, in 37 patients (19%), laboratory mistakes were associated with further inappropriate investigations, thus resulting in an unjustifiable increase in costs. Moreover, in 12 patients (6.4%) laboratory mistakes were associated with inappropriate care or inappropriate modification of therapy. The promotion of quality control and continuous improvement of the total testing process, including pre- and post-analytical phases, seems to be a prerequisite for an effective laboratory service.</p>
<p>Signori, C. et al. Process and Risk Analysis to Reduce Errors in Clinical Laboratories. <i>Clinical Chemistry and Laboratory Medicine</i>. Vol 45:6. 742-748. 2007.</p>	<p>Five Italian hospital laboratories cooperated in a project in which methodologies for process and risk analysis, usually applied in fields other than health care (typically aeronautical and transport industries), were adapted and applied to laboratory medicine. The collaboration of a board of experts played a key role in underlining the limits of the proposed techniques and adapting them to the laboratory situation. A detailed process analysis performed in each center was the starting point, followed by risk analysis to evaluate risks and facilitate benchmarking among the participants.</p>	<p>Improving laboratory quality will require definition of indicators to be monitored as measures of a laboratory trend. The continuous observation of these indicators can help to reduce errors and risk of errors, thus enhancing the laboratory outcome. In addition, the standardization of risk evaluation techniques and the definition of a set of indicators can eventually contribute to a benchmarking process in clinical laboratories.</p> <p>The study involves an attempt to adapt some of the techniques of process and risk analysis, usually applied in fields different from healthcare, to the organization of clinical laboratories, with the following aims:</p> <ol style="list-style-type: none"> 1. To set up an efficient and objective procedure to quantify the risk of errors;

		<p>2. To use such a procedure for uniform detection of errors in clinical laboratories and for the definition of a benchmark strategy;</p> <p>3. To measure the impact of errors/risk of errors on the clinical laboratory outcome.</p>
<p>Silverstein, Marc. An Approach to Medical Errors and Patient Safety in Laboratory Services. Prepared for the Quality Institute Meeting 'Making the Laboratory a Partner in Patient Safety', Atlanta, April 2003.</p>	<p>Studies have documented inappropriate utilization of laboratory tests and interventions are effective in improving the utilization of laboratory tests. Laboratory practice uses many methods to reduce errors, assure patient safety, and improve quality including quality control procedures, quality assurance programs, certification of education programs, licensing of laboratory professionals, accreditation of laboratories, and federal regulation of laboratory practices.</p>	<p>Although errors still occur through all phases of the testing cycle, the proportion of errors in the analytic phase of testing is lower than the proportion of errors in the pre-analytic and post-analytic phases of testing. This suggests that collectively the methods to reduce errors in laboratory medicine practice have been effective and that further efforts to reduce errors and assure patient safety will require partnerships with providers.</p> <p>The Quality Institute, by focusing on the development of better ways to measure the effectiveness of laboratory service (quality indicators) and by holding the laboratory service industry publicly accountable (national report) for achieving these goals could lead to substantial improvements in patient safety and in the quality of laboratory services. The benefits of having a coalition that addresses major policy questions and offers solutions to issues before legal or regulatory action is required, and which acts as a clearinghouse for information could protect patient safety while dealing effectively with the important issue of access, cost, and quality of laboratory services.</p>
<p>Stahl, M. et al. Reasons for a Laboratory's Inability to Report Results for Requested Analytical Tests. <i>Clinical Chemistry</i>. Vol 44: 10. 1998.</p>	<p>There is increasing understanding of the importance of the pre-analytical circumstances on laboratory quality, including failures to report requested results. In the past, why the laboratory was unable to deliver a result was not investigated. Accordingly, when looking into the computer system for discrepancies between number of tests requested and number of tests reported, only the volume of the problem, not the reasons, could be seen.</p>	<p>The laboratory has focused on solving the major problems and has reduced the specimen- and transport-related problems. However, there are still problems:</p> <ul style="list-style-type: none"> ▪ microcoagulation in tubes; ▪ general practitioners do not always follow the instructions and rules on mailing and stability of the components; ▪ the four laboratories in the county exchange specimens for rare tests - during this procedure, specimens or results can be lost; ▪ the intensity of diagnostic work and treatment of the patients in the hospital per time unit has grossly increased, hence a new problem is that patients frequently are not available at the time for specimen sampling because of other medical procedures. In 1996, this problem accounted for 13% of all request failures. <p>The authors' goal is to detect the failures and prevent them to reduce report failures to <0.5% and to maintain this level.</p> <p>To enable inter-laboratory comparison at the national and international level, a standardized classification and definition of causes for report failures could be useful.</p>

<p>Stankovic, A. and Romeo, P. The Role of In Vitro Diagnostic Companies in Reducing Laboratory Error. <i>Clinical Chemistry and Laboratory Medicine</i>. Vol 45: 6. 781-788. 2007.</p>	<p>Laboratory errors have a significant impact on patient safety. The manufacturers of in vitro diagnostic (IVD) products play an important role in the reduction of laboratory errors by ensuring the highest possible safety and efficacy of their products. In order to achieve this, the IVD industry has implemented rigorous product development and manufacturing processes. Many IVD companies apply Six Sigma principles in order to minimize variability within the whole product life cycle, starting with customer requirements, through product design and manufacture, as well as management of the potential issues that occur after the products have been released for use. This article provides a closer look into this process using an evacuated blood collection tube as a model device.</p>	<p>By adhering and complying with regulations and guidelines that were set by legislators and standard setting bodies, IVD companies are ensuring that their products are (a) safe (i.e., do not put patients at risk of harm), and (b) effective (i.e., meet customer requirements/ needs). Furthermore, by designing IVD products for robustness or insensitivity to noise, and by controlling the manufacturing process after design transfer, <i>long term</i>, IVD companies play a critical role in reducing laboratory errors and improving patient outcomes.</p>
<p>Valenstein, P. and Meier, F. Outpatient Order Accuracy. A College of American Pathologists Q-Probes Study of Requisition Order Entry Accuracy in 660 Institutions. <i>Archives of Pathology and Laboratory Medicine</i>. Vol 123. 1145-1150. 1999.</p>	<p>The objective of this study is to evaluate the frequency and causes of computer order entry errors in outpatients.</p> <p>Methods used were a cross-sectional survey and prospective sample of errors. Participants answered questions about their test order entry policies and practices. They then examined a sample of outpatient requisitions and compared information on the requisition with information entered into the laboratory computer system. Order entry errors were divided into 4 types: tests ordered on the requisition, but not in the computer; tests performed but not ordered on the requisition; physician name discrepancies; and test priority errors. The main outcome measure was the overall order entry error rate.</p>	<p>Laboratory test order entry errors potentially delay diagnosis, consume resources, and cause patient inconvenience.</p> <p>A total of 5514 (4.8%) of 114 934 outpatient requisitions were associated with at least 1 order entry error. The median participant reported 1 or more order errors on 6.0% of requisitions; 10% of institutions reported errors with at least 18% of requisitions. Of the 4 specific error types, physician name discrepancies had the highest error rate, and test priority errors the lowest error rate.</p> <p>Four institutional factors were significantly associated with higher overall error rates:</p> <ul style="list-style-type: none"> ▪ orders verbally communicated to the laboratory; ▪ no policy requiring laboratory staff to compare a printout or display of ordered tests with the laboratory requisitions to confirm that orders had been entered correctly; ▪ failure to monitor the accuracy of outpatient order entry on a regular basis; and ▪ a higher percentage of occupied beds (i.e., a busier hospital). <p>Computer order entry errors are common, involving 5% of outpatient requisitions. Laboratories may be able to decrease error rates by regularly monitoring the accuracy of order entry, substituting written and facsimile orders for verbal orders, and instituting a policy in which orders entered into computer systems are routinely rechecked against orders on requisitions.</p>

<p>Van der Weijden, T. et al. "Understanding laboratory testing in diagnostic uncertainty: a qualitative study in general practice." <i>British Journal of General Practice</i>. Vol 52: 974-980. 2002.</p>	<p>The aim of this study is to gain insight into the general practitioner's (GP's) motives for ordering laboratory tests for patients presenting with unexplained complaints. Better knowledge of the professional's motives for ordering laboratory tests in the case of diagnostic uncertainty may lead to interventions directed at reducing unnecessary testing.</p> <p>The GP's perceptions of determinants of test-ordering behaviour in the situation of diagnostic uncertainty were investigated. Semi-structured interviews based on surgery observations in twenty-one general practices in rural and urban areas of The Netherlands took place. The interviews were structured by evaluating the consultations and test-ordering performance of that day.</p>	<p>Dutch GPs vary considerably in their motives for ordering tests. Several motives emerged from the data, and examples of important themes include: personal routines, tolerance of diagnostic uncertainty, time pressure and tactical motives for test ordering. Complying with the perceived needs of the patient for reassurance through testing is seen as an easy, cost- and time-effective strategy. A clear hierarchy in the determinants was not found.</p>
<p>van Wijk, M. et al. Compliance of General Practitioners with a Guideline-based Decision Support System for Ordering Blood Tests. <i>Clinical Chemistry</i>. Vol 48: 1. 55-60. 2002.</p>	<p>This study determined the compliance of Dutch general practitioners with the recommendations for blood test ordering as defined in the guidelines of the Dutch College of General Practitioners.</p> <p>An audit of guideline compliance over a 12-month period (March 1996 through February 1997). In an observational study, a guideline based decision support system for blood test ordering, BloodLink, was integrated with the electronic patient records of 31 general practitioners practicing in 23 practices (16 solo). BloodLink followed the guidelines of the Dutch College of General Practitioners. We determined compliance by comparing the recommendations for test ordering with the test(s) actually ordered. Compliance was expressed as the percentage of order forms that followed the recommendations for test ordering.</p>	<p>Of 12 668 orders generated, 9091 (71%) used the decision-support software rather than the paper order forms. Twelve indications accounted for >80% of the 7346 order forms that selected a testing indication in BloodLink. The most frequently used indication for test ordering was "vague complaints" (2209 order forms; 30.1%). Of the 7346 order forms, 39% were compliant. The most frequent type of noncompliance was the addition of tests. Six of the 12 tests most frequently added to the order forms were supported by revisions of guidelines that occurred within 3 years after the intervention period.</p> <p>In general practice, noncompliance with guidelines is predominantly caused by adding tests. The authors conclude that noncompliance with a guideline seems to be partly caused by practitioners applying new medical insight before it is incorporated in a revision of that guideline.</p>