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### An American Perspective: Current Trends in Laboratory Management

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In the United States, laboratory medicine has become integral to the diagnosis, treatment, and management of patients. Its rather meagre start began around the 1900s, slowly evolving over the twentieth century. Advances in understanding human biochemistry and physiology have spurred the development of the technology needed to evaluate patient specimens creating the foundation for laboratory medicine.

The first clinical laboratories were no more than a corner of a physician's office with the physician performing the laboratory work. It is only in the last 50 to 60 years that the need for skilled laboratory staff with special training became evident, evolving into today's clinical laboratory scientists (CLS). It also has become clear that good managers are needed to lead these individuals.

#### Education

In the last few years, staffing concerns have reached a high point. The number of NAACLS' accredited medical technology/clinical laboratory science programmes dedicated to training CLS have decreased from almost 800 in the 1970s to the current 551 programmes. Because of fewer programmes, there are fewer students graduating resulting in a smaller selection pool. In addition, many baby boomers are looking at early retirement, thus creating even more vacancies. The US Bureau of Labor Statistics has estimated a 14 percent growth rate for laboratory professionals in the next eight to ten years, yet the ability to fill those positions with qualified individuals raises concern.

The need to support education programmes and entice potential students is critical to meeting these deficiencies. Many laboratory managers have actively worked with their local universities, high schools, and even grade schools to encourage an interest in laboratory medicine. Managers have had to become creative in developing ways to attract individuals into this profession to meet future staffing needs. In light of the current economic downturn with many unemployed, resurgence in the number of applicants to these programmes has been encouraging and offers cautious optimism about securing future laboratory professionals.

#### Technology

Over the past 20 years, clinical laboratory in vitro diagnostics (IVD) has seen significant advances due in part to enhanced computer technology. The days of manually completing laboratory tests has fortunately been replaced with compact, highly precise instrumentation that offers fast throughput. Most instruments interface with a robust laboratory information system (LIS) that provides a platform to record data, preserve it, and report it in a timely and accurate manner. Integration with an electronic medical record (EMR) system has further enhanced the laboratory's ability to provide results in a dynamic manner. Laboratory test results that used to take days or weeks to get to the patient's physician can now be provided promptly.

Growing interest in establishing totally automated laboratories grew in the last decade. Yet today, only a few laboratories utilise totally automated systems due to cost, concerns with the inflexibility of adjusting to specific work flow activities, and the high test volume needed to sustain such a system. Most laboratories have focused more on less expensive modalities by implementing a combination of timesaving systems: Pneumatic tubes, bar coding, automated tube de-cappers, automated centrifuging and aliquotting stations, and work cells. While not considered fully automated, these laboratories enjoy improved test processing accuracy, smoother workflow, and better staff utilisation.

To further assist tying equipment technology with information technology is the emergence of middleware, or software that bridges operational systems with computer applications. This rapidly growing area is providing the needed connectivity between laboratory instruments and the LIS.

#### Quality Management Systems

Quality control, testing validations, and other time-consuming activities to collect and analyse can now be done quickly and efficiently using the analyser's interfaced computer system. Since the publication of the now famous Institute of Medicine's (IOM's) report (To Err is Human) that

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declared 44,000 to 98,000 Americans die each year from medical errors, a reinvigorated commitment to improving quality management has been undertaken. The report identified laboratory errors such as ordering the wrong test (50 percent), failure to act on test results (32 percent), and delays in timely reporting (55 percent). In addition, concerted efforts by the various regulatory agencies focus on establishing stringent guidelines modeled after ISO 15189 standards and in part creating what is now termed quality management systems.

### **Laboratory Design**

Consolidation of laboratory services has become the norm. Traditionally, laboratories were broken into specific sections based on the type of testing conducted, i.e., chemistry, haematology, microbiology, virology, urinalysis, etc. Most modern laboratories now use 'open' laboratory design by removing walls that would have separated these various disciplines. Where segregation of certain laboratory services are still needed in areas such as microbiology, blood bank, or PCR clean/dirty rooms, other sections have melded into a core laboratory.

Automation and multi-platform instrumentation has allowed the laboratory to unify certain sections based on common test modalities. Haematology, chemistry, and urinalysis are often placed in one section, as are immunology and serology. Many of these tests can be performed in the core laboratory because of common instrumentation platforms. These efforts offer better use of staff, decrease need for redundant equipment, and improve overall efficiency.

As new laboratories are built or old ones renovated, the open laboratory concept is generally adopted. In addition, environmental and ergonomic concerns are also addressed. Appropriate ventilation, temperature/humidity control, and environmentally friendly venues also are considered. It not only provides a safe and environmentally responsible work place, but also improves staff morale, efficiency, and overall productivity.

### **Point-of-Care Testing**

An area that has seen significant growth and improvement over the last decade is point-of-care testing (POCT). POCT brings certain laboratory tests to the patient's bedside or treatment area. It has served as a powerful tool in dealing with immediate care situations as seen in the emergency department, during surgeries, certain outpatient settings, home testing, screening at health fairs and emergency disaster scenes. These handheld devices are designed for ease of use with minimal training required and strict quality control protocols using a wireless interface with the LIS, thus ensuring a high level of accuracy and timely test results.

### **Telepathology**

A number of disciplines, including pathology, have taken advantage of telemedicine technology. While slow to be integrated into standard practice, telepathology has gained some momentum with the improved computer capacity, greater Internet bandwidth, and the use of high colour resolution digital imaging. This has been particularly helpful for those healthcare providers who have limited access to pathologic consultations especially when time is of the essence. Intra-operative consultations during surgery utilising frozen tissue section evaluations are often requested by the surgeon. Access to an expert pathologist utilising telepathology is quick and cost effective, in addition to best utilising the pathologist's time. Use of telepathology in the immediate assessment of fine needle aspirations (FNAs) has also proven useful by providing preliminary diagnosis and/or specimen adequacy.

### **Molecular Diagnostics**

Molecular diagnostics has become a multi-billion dollar market growing at a rate of 35 to 40 percent annually. Molecular testing has become standard practice when testing for various genetic diseases (cystic fibrosis, hereditary haemochromatosis), sexually transmitted diseases (HPV & chlamydia), hepatitis and HIV viral loads, coagulation tests (Factor V Leiden & Prothrombin G20210A), and in the diagnosis of leukemias/lymphomas (B&T cell rearrangements, JAK). These highly accurate tests have proven invaluable in diagnosis and treatment of patients.

A new procedure added to the molecular testing toolbox is the microarray assay used to measure gene expression. Target DNA samples are embedded on a matrix (silicon chip, nylon membrane, or glass slide) containing from a few to hundreds of thousands of genes or gene sequences. Known probes are hybridised with the target samples to eventually reveal the complementary gene nucleotides. The inclusion of this tool in clinical practice has yet to be fully established but holds great potential for the future.

While there are numerous advantages in utilising molecular testing, there are also some limitations due to availability of specific test probes, cost of equipment and materials, access to trained personnel, and certain legal restrictions (in test ordering and result follow up). However, it is clear that molecular testing will continue to grow as clinical applications become more accessible and applicable to the diagnosis and management of patients.

### **Business**

The effort to push patient treatment and follow up to an outpatient setting has continued forcing laboratories to look at outreach laboratory testing as part of their business plan. Historically such testing was a function of large national reference laboratories. Yet as technology became more accessible, compact and affordable, more hospitalbased laboratories accepted this as an opportunity to grow their laboratory. Today, many laboratories have included outreach testing into their customer base. Laboratory tests that were once too complex to routinely perform have now been automated and/or simplified so they might be incorporated into standard test menus. Hospital laboratories that relied solely on in-patient work found that it was very limited as a revenue source. As reimbursement payments for these tests continue to decrease, it has become clear that increasing test volume can improve the bottom line.

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## Conclusion

While there are many challenges facing today's clinical laboratory, there are also many rewards. The importance of the laboratory has gained recognition in its ability to contribute significantly to patient management. It is now well established that 70 to 80 percent of all medical decisions can be attributed to laboratory data.

It is with this optimistic approach that laboratorians look forward to playing an even bigger part in healthcare and to be recognised for the skills we bring to the table. Advances in technology will continue to influence laboratory practices and how we educate our future laboratory scientists. By embracing these advances, we will be able to implement this technology into everyday practice, thus providing a higher level of patient care.



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