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# The Vital Role of Medical Laboratories in Modern Healthcare: From Diagnosis to Treatment

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***ABSTRACT***
The latest innovations in clinical biochemistry, immunology, hematology, and microbiology are reviewed. Recent breakthroughs in laboratory medicine have improved the precision and accuracy of disease controls, added analytical methods or alternatives to older methods, and upgraded auto-analyzer technology. Despite there being too many examples to heap praise on each one separately, the findings of their analysis should be shared for the appearance of a new generation of transformative laboratory medicine, the professionals working behind them, and rationale that might compel others to pursue better ways to deliver analogous health care in their communities (Avivar, 2012). A new breed of clinical biochemistry, immunochemistry, and immunoassay auto-analyzers with increased throughput and random access capabilities is emphasized. The proof of their cost-effectiveness and their financial advantages over less capable analyzers are highlighted. The argument is made that this has led to a more confident profession through a significant increase in quality, output, and assurance. The improvements of an equally high standard in the Hematology laboratory are highlighted (Strain & H. Ravalico, 2021). Recent innovation initiatives in clinical microbiology that transcend instruments, equipment, and methodologies are presented. For all its past glory and by any meaningful measure, the clinical microbiology laboratory arguably is and has now been the Cinderella of laboratory medicine. The rate of growth or sophistication of clinical microbiology laboratory systems and methods falls far short of that observed in the larger fields of chemistry or cytopathology. Nonetheless, there are now signs of things starting to improve in the world of clinical microbiology. Throughout, the main objective is to provide insight into and encouragement for the pursuit of newer laboratory approaches for the growing and studious populations of laboratory medicine professionals.

1.2 **Keywords (8 keywords only)**
* Clinical laboratory * Hematology * Immunochemistry * Real-time PCR * Sample management * Microbiology * Laboratory automation

## 1.3 1. Introduction

As healthcare organizations increasingly embrace value-based care, the laboratory often finds itself at a crossroads. On one hand, strategic engagement in team-based clinical care is essential to realizing the value of laboratory medicine. On the other hand, the significant technical, regulatory

and organizational constraints that affect laboratory operations are frequently less compatible with the rapidly changing environment of healthcare restructuring. Partnerships that are built to last often require continuous effort, mutual appreciation, creativity and commitment to making things better. The best partnerships lead to growth. The marriage between laboratory medicine and healthcare excellence is no exception. All over the world, like-minded pathologists and clinical laboratory leaders have urged healthcare professionals to strategically engage laboratory medicine for value-based health care, with "value" defined in terms of the outcomes achieved for patients relative to the money spent. Over the past few years, excellent best practices for improving healthcare outcomes have emerged, each highlighting a success story of a laboratory-led healthcare project. These initiatives have re-engineered healthcare delivery pathways, re-shaped the practice of medicine and extended the role of clinical laboratories within integrated multidisciplinary teams ("laboratory-led" rather than "laboratory-centric"). The insights from the UNIVANTS of Healthcare Excellence award program link improved key performance indicators (KPIs) through strategic engagement of laboratory medicine within integrated clinical care teams to achieve better outcomes. This paper reviews the common themes, disease areas and outcomes associated with the top-performing teams with recognized best practices from the UNIVANTS award program (Strain & H. Ravalico, 2021). Innovative healthcare professionals transformed traditional standards of care to achieve exceptional outcomes, better health and/or patient safety that wouldn't have been possible without the clinical laboratory. The positive impacts of their projects were quantified and translated into monetary terms to demonstrate compelling returns on investments. Thus, the connectedness of laboratory medicine to healthcare excellence is bi-directional; laboratory leaders can drive healthcare excellence. Conversely, the need for further healthcare excellence also stimulates innovations in laboratory medicine (Avivar, 2012). The trends and findings identified through this analysis offer multiple benefits. First, they increase awareness of existing best practices for better health care and demonstrate the valuable contributions of laboratory medicine. The outcomes can serve as an inspiring call to action for others to emulate these best practices through integration of clinical care teams across their health system(s). Second, the findings also identify areas of unmet needs in the successful integration of laboratory medicine. Lastly, the findings underscore the importance of healthcare excellence and the need for healthcare professionals to unify across disciplines for the betterment of value-based health care.

## 1.4 2. Historical Perspective of Medical Laboratories

Historically, medical laboratories predated clinical medicine due to the need for assays to advance a theory or understanding of physiology. Histology and parasitology findings heavily informed therapy, with stained sections being entered into pharmacy books. Medical education developed alongside laboratory medicine to supplement scientific preparation for clinical practice. By the late 1930s, physicians felt certain laboratory techniques were essential to good medical care and made demands on clinical Labs as a result. Regional Hospitals and their Labs became major suppliers of laboratory services (Strain & H. Ravalico, 2021).

Clinical laboratories have always been intimately tied to the development of professional societies and publications related to laboratory medicine. All members take a keen interest in their historical journals. The same can be said for the journals of various organizations associated with these larger ones. Interest in historical issues and concerns has prompted mini-histories to be published in these journals. Working with colleagues in nursing and other health fields, clinical laboratories have engaged in the public wrongs of long-standing practices, developing position papers and guidelines agreed upon by them. Medical laboratory technologists and technicians celebrated their first national day and associated achievements on health-care teams with the Canadian Society for Medical Laboratory Science in the 1990s. This recognition has been building around the world in recent years to coincide with anniversaries.

The United Nations and its agencies are major purveyors of policies and directives from the Second International to the United Nations role in global governing currently in thought. Nowhere is this more important than in the health field, given the global pandemic and rise of health instability. Diagnostic Labs and laboratory services feature prominently because without them, either new vaccines would not have been validated or services created to monitor spread and compliance with health measures. Real-time polymer daughter chain reaction and other molecular lab technologies came into the public consciousness for their role in detection.

Another major trend relevant to the profession has the rise of electronic health records (EHR), which develop with substantial public investment. In Canada, local, provincial, and national undertakings provide services, with a perennial worry of small-provider, diagnostic income evolutionary systems. Increased control by smaller, competitive corporate concerns presents a serious challenge for ISO 15189-accredited medical laboratories, both economically and service-wise. EHR and health applications outside the Clinical Labs were initially non-relevant to the profession.

## 1.5 3. Types of Medical Laboratories

Medical laboratories perform a wide range of laboratory tests on clinical specimens collected on patients which may include blood, urine, tissues, cell scrapings and many more. These are performed based on biochemical, microbiological, hematological, immunological and genetic techniques and technologies. It is estimated that about 75% of clinical decision is taken based on laboratory results generated by medical laboratory professionals. Access to timely and accurate laboratory results has a huge impact on quality healthcare and patient safety (Strain & H. Ravalico, 2021). Medical laboratories are focused on improving their laboratory service provisions through effective and continuous quality improvement programs to strengthen their best practices.

(Tomo et al., 2020). Medical laboratories can generally be categorized in to (a) Diagnostic laboratories where scientific investigation takes place to arrive at test results, and (b) Non-diagnostic laboratories dealing only with preparation and transport of specimens to diagnostic laboratories. Diagnostic laboratories can also be categorized based on the type and orientation of the tests performed and the range of services provide. Clinical laboratories set up in hospitals, clinics and health centers are concerned with the diagnosis (where the need arises for treatment) of organic systemic diseases using biochemical and hematological tests. They may also provide

screening services. Forensic laboratories which may be set up at police precincts, municipalities and court complexes are responsible for performing post-mortem tests and investigation of crimes. Environmental laboratories may be set up for monitoring of air and food quality.

### 3.1. Clinical Laboratories

Clinical laboratories in general, and the clinical laboratory in particular, are health care institutions devoted to providing services in medicine based on analytical procedures. They carry out quantitative and qualitative analyses of biological fluids and tissues, physical measurements, preparation of study specimens as well as monitoring and control of these procedures. They are composed of human resources, instrumentation, information systems, and a variety of working environments. A clinical laboratory whose personnel and instruments reside in the same premises is considered integral, while a laboratory whose personnel and instruments reside in different premises is considered de-centralized (Avivar, 2012).

In clinical laboratories it is essential to guarantee the quality of the results. If the results are sub-standard, the medical intervention and decisions taken based on them will also be so. Internally, every laboratory must guarantee the quality of its equipment, instrumentation, reagents, personnel, results and methods. Regarding the analyzer, performance verification and control procedures must be programmed, carried out during operation, and periodically archived. Similarly, equipment maintenance must be on the agenda not to let failures lead to a reduction in safety or quality. External quality assurance systems are standard procedures through which the laboratories mail blind samples consistently, such as different controls with different concentration levels to keep any drift in the quality of the results from occurring.

Health care informed consent must be obtained for all laboratory services provided to the patient. This is a medical intervention covered by the patient's right to privacy and confidentiality. Demography and epidemiology studies rely on the integrity and accuracy of clinical chemistry data stored in laboratory information systems. Laboratory results stimulate further discovery of disease, and considerably influence public health decisions. Where and how samples must be collected from the patient and how they should be prepared before reaching the laboratory is an entirely automated process extending to video-phoning on the patients with a simple query for new preparing and collecting criteria.

### 3.2. Research Laboratories

At most hospitals, research laboratories are little more than idle rooms with drip pans under various pieces of equipment. In academic institutions, research laboratories are state-of-the-art, with automated pipettors, spectral lofts and such, but are generally of little assistance in performing stuffy, routine determinations or troubleshooting laboratory problems. This much is accepted and expected. However, as automation and applicability of advanced testing techniques increase, the need to both perform and add on to the knowledge of these advanced techniques, and to have on-site automated trouble shooters, will push this situation to shift dramatically (Avivar, 2012). In general, the focus of the research laboratory is to filter through tons of data to find that one precious nugget of actionable knowledge, and generate an even bigger pile of data. Obviously, the approach should be the exact opposite: The approach of research laboratories should be to eliminate all

unnecessary data and spit out the singular result that is interpretable and actionable. Efforts in this regard must include potent data filtration and reduction algorithms combined with high throughput spitting out of minimal result sets, to match the wish of the lab director. To further facilitate quality control efforts and feedback, research laboratories should maintain a direct liaison with the robots and data collectors (Strain & H. Ravalico, 2021). They should be privy to their inner workings to better facilitate control, thus preventing time loss in the event of an (internal) breakdown.

Research laboratories can provide crucial input on reagents and chips, effective troubleshooting paths, extensions of platforms, and ways of optimizing their operation. As routine laboratory operations are of extremely high throughput, the relationship may need to be somewhat of an outside contact to avoid being overwhelmed with day-to-day banalities. Research laboratories can help establish assay viability with scent tests and help with troubleshooting, most likely by working on a level of query deeper than what can be covered by routine laboratory personnel. Also, high throughput preanalytical and analytical protocols can easily be designed for Luminex and similar platforms. As the high throughput portion of these platforms is being sifted through and optimized, a visual inspection of the output is no doubt indispensable.

### 3.3. Public Health Laboratories

State Public Health Laboratories (PHLs) were established and operate in accordance with the Public Health Service Act of 1970. PHLs offer diagnostic testing for humans and animals as well as testing of environmental samples and products (Merrick et al., 2013). PHLs are often involved directly or indirectly in all activities carried out by Public Health Departments for their respective state, including but not limited to disease control, surveillance, and prevention. PHLs are public health's implementers of the communicable disease surveillance enterprise. Some PHLs send out mass mailings for general or targeted disease-surveillance efforts via the postal service to hospitals and other providers of care. PHLs confer accuracy and timeliness of identification of infectious organism and/or toxin when outbreaks of infectious disease occur within a community or state. Analyzing infectious agents during outbreaks is a prime role of PHLs, and they possess training, equipment, and expertise to carry out this critical task. PHLs are often the only state labs that process tests for these bioterrorism agents. There are tests that are not commonly available anywhere in testing for evaluation for food or environmental samples. A number of Public Health Labs also operate molecular-based tests for the detection of food-borne pathogens and which are generally unregulated. Based on the extent of operations, Public Health laboratories can be multi-branch operations, university-affiliated laboratories, or functionally be an integrated part of a Public Health Department and epidemiological services. Multi-branch operations comprise center or service operations, umbrella laboratories, and off-shore operations.

Besides the above services, some proposed functions originally perceived as unfeasible and left unexecuted decades ago may be steadily included as expanded roles of future PHL services. If a disease is infectious, there will inevitably be a demand for rapid confirmatory testing, particularly for unusual and/or virulent organisms. For some emerging infectious diseases and newly recognized illness, tests capable of direct detection in clinical specimens are yet to be developed. Core functions that Public Health Laboratories have mandated to accomplish include enabling

disease prevention, control, and surveillance; providing integrated data management; delivering reference and specialized testing; supporting environmental health and protection; delivering testing for food safety assurance; promoting laboratory improvement and regulation; assisting in policy development; and ensuring emergency preparedness and response.

## 1.6 4. The Diagnostic Process

Laboratory medicine is the single highest volume medical activity in healthcare, with an estimated 14.5 billion laboratory tests performed in the U.S. per year, or 41.1 million per day (B. Freedman, 2015). On average, physicians order nine clinical laboratory tests per patient visit and 20% of primary care physician visits include at least one laboratory test. Laboratory tests are performed in a range of settings from hospital laboratories to community laboratories to physician's office laboratories. Demand for laboratory testing is increasing disproportionately to medical activity. A number of areas in medicine and academic health centers are "high user" settings for laboratory testing, with rates of total laboratory tests performed per 1,000 outpatient visits at least double the average for similar clinics and account for very little of the total outpatient visits.

However, despite the importance of laboratory tests in the diagnostic process and providing optimal care, laboratory tests are commonly overutilized, misutilized, and underutilized. 67% of benchmarked laboratory tests are results not fulfilling laboratory test appropriateness criteria; 38% of all orders are reported to practice patterns with no supporting evidence; 1% of patients account for 31% of overall testing costs, while 4% of tests account for 44% of routine laboratory costs. It is estimated that $33 billion is wasted on laboratory tests in the U.S. healthcare system and even more in high cost academic health centers. The system for operating laboratory testing services from research laboratory bench to patient care settings and back to interpretation at the bedside is fragmented at many levels, creating a variety of opportunities for unnecessary test orders, sampling errors, delays and improper interpretation.

### 4.1. Sample Collection

Medical laboratories play a critical role in guiding the diagnosis and treatment of health conditions, in addition to researching the underlying mechanisms of disease and treatment outcome. Patient test samples are taken and examined at outpatient clinics, in bed posts, and at policlinic consultations and treatment locations, formed by continuous, automatic, electromechanical, or computer assistance. Samples taken in the sample source units are collected in accordance with protocol and transported to central laboratories or analysed at smaller laboratory units. Samples are sent in pipes, automated tracks, pneumatic tubes, or possibly transported by defined methods with a special focus on temperature, time, infection safety and security of the equipment used. Central laboratories perform a significant number of automated analyses. Rather extensive analyses can be performed the same day, but a large number of samples are also sent to other hospitals, laboratories or private laboratories. Transferred samples are generally limited to analyses with the quickest turn-around times. The sample's source will comment and describe the analysis requested to help facilitate this work.

The requisition of samples and their analysis is a focus of the management function. Methods for identifying patients and sample tubes are described and little tolerant error checks of both patient

identification and sample analyses are established. All automatic analyzers must be in use, and results that can be directly used must be printed out in the bacteriological laboratory. The minimal turnaround time need to be routinely monitored. The times must be documented and reasons for exceeding a cut-off time logged. It is essential to know whether the approach of referral and transference is optimal (Marit Andersen, 2018). Each result printed must be read by laboratory personnel, and each result must have a database for practice for all serious and potentially dangerous cases of all departments: both outpatient for general practitioners, and inpatient for bed-post and policlinics. It is crucial that proper handling of sample materials be managed. The hospital's management provides written procedures and resources for handling the sample material. Procedures and resources for reporting and following up on defective sample materials must be established and maintained.

### 4.2. Testing Methods

The most important goal of all departments in the modern laboratory is to try for the accuracy, precision, timely reporting of results and cost-effectiveness of testing. The performance of each technology depends chiefly upon the instrument set up, maintenance and the chemistry used. The non-instrumental techniques are also essential in diagnostics. These methods are classified under different chemical tests that target blood, urine, sputum, and stool to name a few sample types. Some examples of rapid, simple, cheap and effective tests are as follows (A. Pence & Liesman, 2020).

The chromatographic tests or lateral flow tests are easy to interpret, due to which they are widely used in laboratories. These tests mostly use a combination of two hyper immune serum and multiple-antigen conjugated colloidal gold reagent. The result is interpreted by the color change of the filter paper. Most companies provide control tests with their kits. Other chromatographic tests are due to compete with ELISA, so simple and cheap is on demand. The major area used for development of RDT is enteric microbes. Rotavirus and cholera tests are commercially very successful. These tests can be used in field studies as well (B. Freedman, 2015).

Serological tests, IFAT, RIFAT, CFT and IHA are costly techniques which are however very specific, confirmatory and suited for less complex sample processing protocols especially in developing countries.

Co-precipitating antigens from a virulent strain of A. precipitans were found to be species specific antigens were found to be species specific, which while being insensitive for diagnosis of acute infections, formed the basis for latex agglutination tests which are specific and sensitive as diagnostic tools for acute infections. A few test for opportunistic pathogens in AIDS have been developed.

### 4.3. Interpreting Results

Since laboratory medicine began, reports of the results of laboratory tests have been produced in various formats based on the interpretation of the pathologist, information available, advances in technology, and government policies. For example, for the tests of H. pylori in gastric, gastric and corpus cancer pathology laboratory reports, H. pylori positive status and H. pylori negative status are reported in textual form (e.g. “Positive for H. pylori”).

With the advancement of technology, some reports include annotating the histological findings of H. pylori to increase the notification of H. pylori status and diagnosis of gastric disease. Due to advertising and promotional policies to demand fresh tissues in order to improve the sensitivity and speed of detection of undifferentiated nasopharyngeal carcinoma and reduce the importation of the biopsy and cytology specimens because of biosecurity concerns, text-based pathology laboratory reports of undifferentiated nasopharyngeal carcinoma are also prepared (B. Freedman, 2015). The major problem of text-based pathology laboratory reports is that textual data or images cannot be well processed by information systems or decision support systems. As well, the advent of artificial intelligence in reading X-ray images, computer tomography images and histology images will not lead to a broader application in reading microscope slides if the reports of pathology laboratory tests remain full of text or images.

Until now, some reports of laboratory test results have been produced in semi-structured text form, such as reporting clinically significant alterations in blood test results or reporting the images of metastases in a laparoscopy-assisted liver resection. As well, currently produced reports of some laboratory tests already conform to logical report templates (e.g. producing imaging series parameters of positions and contrast agents in imaging laboratory test report). With the new inclusion of the disease concept and clinical history in the pathology laboratory report of gastric cancer, the resulting pathology laboratory report can be well processed in the end-to-end interpretation of the Esophagus, Gastric and Gastro-Esophageal junction Carcinoma.

### 1.7 5. Laboratory Technologies

Laboratory automation encompasses laboratory instruments connected to an information system that coordinate disparate analyst steps (Avivar, 2012). The laboratory automation market currently appears to be tailored to the needs of companies working with high throughput samples. This involves the supply of higher throughput machines and robotics. Extending such a conception to those labs characterized by traditional work methods would, however, prevent a large proportion of labs from complying with access conditions to possible suppliers. Lower throughput automation solutions for laboratory workflows involved in order balancing, sample sortation, and reagent and consumable management are needed.

Laboratory technology varies with the type of laboratory and in both cases with the use of those laboratories. Medical laboratories may be divided into clinical pathology and anatomical pathology. Clinical pathology involves serum, urine, faeces, and swabs being submitted for haematology or biochemistry investigations. Some samples are screened before submission for rapid tests on urine or blood. Post-tests polling and specimen archiving are rarely done off site. Biochemistry laboratories are usually heavily automated, heavily relying on robotics to minimize turn around times. The final product is usually a report with buffered, tagged and certified results, ready for sorting which is usually done off site.

Automation, however, needs extras and therefore lab technology also includes software to be interfaced with instrumentation, often taking care of patient relation management and the inputing of results in the laboratory information management system. In some labs, large patients' sample pools turned into ones with individual samples. Grouping mechanism may return to smaller pools

that have different assays run on them. Carousels are effective, combining a receptacle system and grouping mechanism but many capillaries or vials may be missed. Hence a more sophisticated approach, like depending on barcoding or radio frequency identification system, may be implemented; but with a cost in versatility. An overall answer for the low throughput sample inspection process may be designed, with lower cost and faster and more accurate.

### 5.1. Automated Systems

Contemporary clinical laboratories are creature of the last century (the 20's). The first machines appeared during the 1950's and like in any other field of knowledge, pioneering laboratories and technologist, were the ones to advance in competitive processes of the clinical laboratory. In order to start operations, modern laboratories must contend with a set of planning phases of automation, taking into account the own technical evolutions, but something even more important: the laboratory engineers must assess what to install prior to considering what the laboratory is going to work on. This is not trivial. Consider 1,000 m2 of clinical laboratory operating at 265 t/h (metric ton). With continual turnover of at least 500 hundred workers at that labor facility and dozens of firms or even commercial brands of instrumentation acquired over the fifteen or so years prior to the onset of the present work, it would be the ultimate mix between heaven for laboratory engineers and hell for laboratory technologists. This situation, however, has only been identified in literatures regarding manpower management and general sceneries of laboratory automation development, but very little compared with instrumentation automation criteria (Avivar, 2012). Additional considerations must be done prior to laboratory technicians and engineers starting to work with the very first design slide. A few critical questions must be answered at this time. Is it necessary to buy every available commercial piece of equipment? Is it necessary to buy everything a ticket provides? Is it reasonable that the criteria engineers choose differ from those of the technologist? An extensive sale and marketing experience has shown that a designed ticket (which usually is a kind of menu of needs) allows for carefully selecting manufacturers for tended laboratory machines or devices. However, it has also been shown that a single piece of equipment can be responsible for distinct sorts of aspirations, needs or wishes. Even in the same laboratory department, equipment is often acquired with a different operating philosophy.

### 5.2. Point-of-Care Testing

Point-of-care testing (POCT) is a laboratory-medicine discipline that is evolving rapidly in analytical scope and clinical application (B. Luppa et al., 2011). Testing at or near the site of sample acquisition promises to overcome the time constraints of conventional laboratory testing, and therefore accelerate the provision of treatment. A recent definition recognized POCT as medical diagnostics which are performed close to patients/subjects (to a greater extent than a few minutes transport time) (I. Khan et al., 2021). POCT is a sophisticated and rapidly evolving technology. POCT is a separate segment of the diagnostics market with highly diverse products ranging from simple blood-glucose assays to sophisticated microfluidic devices for rapid multiplexed immunoassays.

POCT ranges from blood-glucose testing to testing of whole blood for triaging heart attack and disclosing pregnancy. POCT instruments are miniaturized variants of conventional analyzers

which do not require individual reagents to prepare the sample. Rapid tests and cartridges are commercially available to reduce the complexity of sampling and testing to simply applying droplets of blood to the testing chamber. POCT shortens the time to clinical decision-making about additional testing or therapy. Crucially, this applies to clinical areas where the degree of actionability determines the overall clinical prognosis. During the early stages of an acute disease, addressing restricted-time scenarios requires rapid tests (tests must be performed on whole blood with the time-to-result of no more than one hour).

In the future, POCT will become an indispensable tool in situations where patients are more difficult to access. Tests that are able to detect emerging diseases should have the potential for portability in hospitals, airports, demonstrations and at home. Just as smartphones have transformed digital communication, POCT and mobile health will radically alter medical diagnosis, treatment monitoring and surveillance. The convergence of POCT and technology will have profound implications, including new business models, prediction and diagnosis of diseases, proactive healthcare, remote monitoring, and improved compliance.

### 5.3. Molecular Diagnostics

After successfully accomplishing the Human genome project, development of personalized medicine and advancing molecular diagnostics has been the prime agenda of scientists. Molecular diagnostics has made possible the diagnosis of previously undetected viral nucleic acids, early access of data to doctors, a deeper understanding of the disease cause, and treatment success depending upon the case. The gene based testing in all fields has flourished after the prediction of >5% in 2005. Here we discuss the current scenario, scope and limitations of Molecular diagnostics in public health care. In the last three decades, there has been a significant shift in clinical practice and healthcare delivery marked by the completion of the Human Genome Project. The successful completion has laid a challenge to extract information from the encoded human genome sequences which can be utilized to create medicines, vaccines, and diagnostic tests. Molecular biological methods for the detection and characterisation of microorganisms have revolutionised diagnostic microbiology. However, research focus has been shifting to understanding complex organization in cells, tissues, and organs to achieve integration of different functions for homeostatic coordination of body physiology. This biological organization is being compared for normal and pathological states to create a new approach for disease detection and modulation (Tandon et al., 2015). In the setting of infectious disease emergencies, rapid and accurate identification of the causative agent is critical to optimizing antimicrobial therapy. It is evident that molecular diagnostics is now upon us, with real-time PCR becoming the standard of diagnosis for many infectious disease emergencies in either monoplex or multiplex format. Other molecular techniques such as whole or partial genome sequencing, microarrays, broad-range PCR, restriction fragment length polymorphisms, and molecular typing are also being used. For most small clinical laboratories, implementation of these advanced molecular techniques is not feasible owing to the high cost of instrumentation and reagents. If these tests are not available in-house, samples can be sent to national reference laboratories for real-time PCR assays that can be completed in 1 day. Over time, commercial real-time PCR tests and instrumentation will become more standardized

and affordable, allowing individual laboratories to conduct tests locally, thus further reducing turnaround time. Although real-time PCR has expanded our diagnostic capability, it must be stressed that such molecular methodology is only an additional tool in the diagnosis of infectious diseases in emergency situations. Phenotypic methodologies still play a critical role in identifying, confirming, and providing antibiotic susceptibility testing for many microbial pathogens. As multiplex assays become increasingly available, there will be greater temptation for taking a "shotgun" approach to diagnostic testing. These new technologies will not substitute for a proper history and physical examination leading to a thoughtful differential diagnosis. These new molecular tests increase the capability of the diagnostician to rapidly identify the microbiological etiology of an infection. An added advantage of rapid diagnostic tests is the capability to rule out certain diagnoses for which unnecessary antimicrobial therapy may otherwise be instituted and/or continued (K. Krishna & M. Cunnion, 2012).

## 1.8 6. Quality Assurance in Laboratories

Diagnostic, therapeutic, preventive, rehabilitation, and palliative procedures have nowadays to be combined with appropriate laboratory and imaging diagnostic tests within the network of the best evidence-based medicine, that are interpreted and respected. These procedures should be performed by suitably trained medical doctors or other health professionals, with a licence or registration, who are granted a proper recognition equivalent to the complexity and potential risk category of the procedures. In addition, the results of these procedures should have a proper format in accordance with available rules and guidelines for a given type of test and modality, including sufficient main information, and references to the accreditation standard, information about the examiner and the institution issuing the report. The diagnostic tests should be performed at medical laboratories or imaging departments accredited in compliance with the relevant accreditation standard. There should also be adequate quality assurance of all laboratory and imaging diagnostic tests, ensuring patient safety. The quality assurance system have to be implemented, documented, and maintained in accordance with the relevant standard. The quality assurance system and its documentation is a set of policies, procedures, and responsibilities necessary for planning, execution, and assessment of targets (product qualities) in compliance with laws, and improving its processes and products continually. Quality assurance is a means of regularly checking that personal and management practices in producing procedures are being correctly applied, appropriate, and effective for desired outputs. Quality assurance is also an evaluation of a diagnostic test's attributes and predictive values and is aimed to identify failure, weaknesses, best practice, or standards. Quality assurance ensures that expected grades of quality, and safety by standard third-party testing and certification are, as a minimum, required in the production of medical laboratories and imaging departments (Zima, 2017).

### 6.1. Standards and Protocols

Qualitative standards, specifications, protocols, reference systems, and methods express the qualities that must be met by a product or service. They form a systematic approach to the definition and assurance of quality, consistent with customers' needs. Quality management can consider such issues as product and service design, manufacturing, procurement, testing,

distribution, installation, and maintenance. It essentially defines the framework of a quality management system. A prerequisite for proper assessment of quality is an assurance that its specifications are known. The establishment of national standards allows routine laboratories to make valid measurements. In order to apply this measurement capability and assure measurement quality, clinical laboratories must individually develop a quality management system and implement it in their laboratory activities (Avivar, 2012). The scope of operation and user access of a medical diagnostic laboratory is determined by regulations or standards of accreditation organizations. The laboratory should state its location as well as such operating characters as fields of examination or service, measurement processes, and relevant standards or procedures. The nature of laboratory facilities and systems including instrumentation and computing equipment should also be indicated together with contingency and disaster response plans to assure continuous operation. Access guidelines should include, where applicable, contact points in addition to operating hours, methods of receipt, and the identification of up-front specimen screening procedures. Reference ranges with associated imprecision, uncertainty, and interpretive comments should be established and routinely updated for each measurement result. Any circumstances leading to value modification should be communicated to society whenever possible. The laboratory should provide adequate patient or client data management in compliance with applicable regulations. Archiving of patient or client data and data retention periods should be stated and adhered to. Storage of measured samples for possible future redetermination should also be ensured. The laboratory has to assure the confidentiality of patient or client data as far as possible.

### 6.2. Accreditation Processes

Accreditation is a procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks. It is a good way to demonstrate competence of the laboratory. Accreditation is a tool to recognize laboratories worldwide. In some countries accreditation is mandatory or will be mandatory in some years. Accreditation and the linked periodical audits are a stimulant for keeping the quality system alive. Accreditation, and not the end-of-year inspectors, ensures that we'll improve quality of our services. Permanent documenting of on-going processes guarantees high standard of services for our clients – patients, physicians. Quality is consciously taken care of. Better documentation of processes and responsibilities. In order to achieve and maintain accreditation, fulfilling the standard ISO 15189:2012, Medical laboratories – Requirements for quality and competence, is necessary (Zima, 2017). To avoid ambiguities and misinterpretations, terms and definitions are explained. Principal resources include: international legal regulations; European legal regulations; and national legal regulations, rules, standards, rules of ministries etc. A constituent document is an official paper describing the essential characteristics of a body, such as the statute or an administrative order. A constituent document entails an organisation advertises its name, registered address, as well as the date of issue, publication, or entry into the trade register codes and registration numbers.

A laboratory uses equipment and resources needed for its work. A workplace is a specific place in which planned tasks, jobs, and activities are executed. A laboratory information system is a full

system installed in the connected equipment for acquiring, processing, interpreting, and archiving data and for performing other activities related to the management of laboratory technical and economic activities. A reasonable expert is a laboratory staff member with acquired relevant education and work experience in laboratory practice. Quality quantitative indicator is a quantitative indicator of a process describing its quality. A quality management system is a totality of procedures for managing activities affecting quality. A consulted laboratory is a referral laboratory with whose manager(s) there is an agreement for priority transfer/and/or consultation observations at which procedures are performed not at a laboratory expecting an examination but elsewhere according to a documented manner. A referral laboratory is a laboratory/consultant to whom examination results or samples are transferred for one or more parameter(s)/tests or observations not performed on-site according to a documented manner.

## 1.9 7. Role of Medical Laboratory Professionals

Medical Laboratory Professionals are highly-skilled practitioners educated and trained in university programs which emphasize laboratory science, physiology, biochemistry, microbiology, immunology, quality control and assurance and laboratory science. In addition, they cover alternative professional areas such as genetics, molecular biology, molecular microbiology, proteomics and metagenomics. These non-routine laboratory tests also known as complex laboratory tests, are used for diagnosis, treatment and monitoring health of patients (Strain & H. Ravalico, 2021). They provide results that play an increasing important role in clinical decisions made by many healthcare professionals. MLPs in clinical laboratories or public health laboratories often bear responsibilities of laboratory service organization, management, quality assurance and consultation, etc. Clinical laboratories are mainly involved in clinical diagnosis and monitoring disease health, while public health laboratories perform all laboratory duties in the public sector including food and water safety testing, blood transfusion, disease outbreak and biosecurity. The organizations of laboratory service and clinical duties of laboratories may be totally different between countries. MLPs have had different duties and responsibilities according to the laboratory organizations. At most laboratories, however, medical doctors, clinical pathologists or chemists play the major roles in the management of laboratory service. And those who have the laboratory professional background tend to make most of the biological testing decisions and provide laboratory consultation of the services. Biomedical Engineering is a relatively new discipline or profession in the field of laboratory and healthcare sciences compared with traditional disciplines or professions. New and emerging lab-on-chip systems or devices usually employ optical, mechanical and micro biological engineering, and medical and medical physics principles. MLPs or scientists and engineers of these background attend the development of the next-generation devices for point-of-care testing, non-invasive disease screening and microbiome monitoring that may revolutionize lab testing of healthcare. The next-generation devices or systems are expected to better and thoroughly cover the large healthcare needs of patients.

### 7.1. Laboratory Technicians

Medical laboratory science is a technical field in health care that deals with the testing of samples obtained from the human body to help diagnose and treat diseases. The laboratory professional

who undertakes this work has a multi-skill, technical and scientific background with qualification in medical technology or medical laboratory science. Some of the laboratory options offered by the medical laboratory science programs are: blood bank, clinical chemistry, histopathology, microbiology, cytogenetic, molecular laboratory, professional ethics, entrepreneurship and business management, safety in the laboratory, infection control, laboratory quality management and information systems etc. There are many specialties in laboratory medicine like clinical biochemistry, clinical hematology and cytology, clinical microbiology, clinical molecular biology, clinical immunology and serology. Every specialty has a related organ system. Said organ system includes a hormonal profile, renal profile, liver function test, blood coagulation and blood count.

Laboratory technicians perform tests on blood, urine, and other bodily fluids. They work in healthcare settings where medical or clinical laboratory testing results are produced. Laboratory tests provide crucial information to diagnose, treat, and prevent disease. Laboratory technicians typically specialize in one or more human systems; for example, they may focus on working with blood (clinical pathology), imaging (radiology), or urine (urinalysis). The pathology department usually houses the blood laboratory. Here, blood is tested for abnormalities; culture & sensitivity and hematology. The specimens are transported to the laboratory to perform these tests. Various tests are conducted, and the results are made available to the clinician or physician. Every laboratory has a result reporting mechanism in place to deliver results to the clinicians (Avivar, 2012).

### 7.2. Medical Laboratory Scientists

Medical laboratory science (MLS) is a branch of healthcare that helps millions of people every day to diagnose and treat diseases. Laboratory tests are the standard of care for disease, and as a result, medical laboratory scientists work in clinical laboratories in hospitals, research institutions, and public health departments. A medical laboratory scientist (MLS) is a trained professional in the field of medical laboratory science, who usually has obtained a bachelor's degree in MLS from a program accredited by the National Accrediting Agency for Clinical Laboratory Science (Kaur, 2023).

MLS have knowledge of clinical laboratory procedures and perform laboratory testing such as high complexity tests including cell counts and differentials, blood typing, crossmatching, specimen analysis, urinalysis, and many more. Medical laboratory scientists also work with machines, computers, fluids, and many other materials. The job requires intense concentration and attention to detail while working with large quantities of information rapidly. Different procedures take different amounts of time, and the challenges vary widely throughout the day. MLS hold a vital role in the healthcare field.

A bachelor's degree in medical laboratory science (MLS) is needed to work in the field of laboratory medicine. The first three years consist of general study and science courses, including biology, chemistry, microbiology, anatomy, molecular biology, general chemistry, organic chemistry, and biochemistry (Meike, 2016). The fourth year consists of taking MLS classes and a 12-month externship at an affiliated clinical site doing clinical rotations typically focused on

hematology, immunohematology, clinical chemistry, and microbiology. Sites include ProMedica, Wood County Hospital, and University Hospitals in Cleveland.

### 7.3. Pathologists

With the advance of molecular biology techniques, pathologists have had to adapt and integrate a different set of diagnostic tools into their daily practice. They became heavily involved in diagnostic procedures based on nucleic acids and proteins in parallel with classical histopathological examination (Susman et al., 2018). Some patients can benefit from a targeted treatment only if the tumor shows certain molecular characteristics; thus, there will be adequate therapeutic tools that function based on the biology of that patient's tumor. In these circumstances, an integral part of the diagnostic procedure is the molecular analysis, and a key element for having therapeutical options for the patients is the correct preanalytical management that will guarantee the quality of the molecular profile. Since the diagnostic chain starts in the pathologist's hands, the pathology department plays one of the most significant roles in diagnosing the disease and also in making therapeutical decisions based on the molecular profile of the harvested tissues.

The quality and reproducibility of the results depend both on the reliability of the molecular techniques used and on the quality of the tissue used to perform these analyses. Both in the case of existing classical diagnostic methods and in the case of the molecular ones, the quality of the delivered tissue is of utmost importance. Most of the classical histological techniques can be applied to the study of molecules as well; however, the parameters of the techniques should be significantly optimized. The genomics techniques require more attention to the preanalytical variables to apply the most recommended methods for the intended purpose. Proteomics techniques can be applied to FFPE specimens, but only with a specific panel due to the cross-linking nature. The key elements of how a pathology laboratory deals with these challenges regarding anomic and proteomic analyses are presented.

## 1.10 8. Impact of Laboratories on Patient Care

Not all of the best practices submitted to the UNIVANTS of Healthcare Excellence award program involve laboratorians as the primary applicant. With one well-justified exception, none of the quality initiatives spotlighted at the 2020 recognition event were led by clinical laboratory professionals, despite the appreciation, importance, and contribution of laboratory medicine and healthcare excellence expressed by all presenters. On the other hand, many of the top-performing teams were led by clinicians/physicians who approached laboratory medicine for help in solving gaps in care. Many lab proposals originated and thrived through the leadership of the clinical laboratory, yet were submitted by medical colleagues and clinicians with principal investigator status (Strain & H. Ravalico, 2021).

Multiple trends have emerged from this analysis including some level of laboratory stewardship, which accounts for 19.4% of all teams with recognized best practices these have broad relevance both within and beyond the lab. Ensuring the right tests are used for the right patients at the right time is a crucial focus of laboratory excellence which has demonstrated positive impact on health outcomes and healthcare expenses through appropriate laboratory test ordering in both general and specialty care. Another key area of pathology-led excellence is the establishment and

implementation of outcome-based reference ranges. Too often, generic reference ranges are used inappropriately in clinical care, limiting disease detection and challenging potential treatment or wellness. One stand-out example is the more accurate classification of the thyroid status in pregnant mothers, using locally established, outcome-based reference ranges for thyroid stimulating hormone rather than the generic universal reference range provided by routine immunoassay platforms. A final theme, and long-standing focus of clinical laboratories, is the crucial requirement of high-quality laboratory testing.

### 8.1. Timeliness of Results

When patients and their doctors order medical laboratory tests, they want timely delivery of the results before decisions are made regarding the diagnosis or treatment of disease. Though this is always the goal, the integration of pre-analytic, analytic, and post-analytic considerations dictates how quickly and accurately results can be delivered (Strain & H. Ravalico, 2021).

Pre-analytic considerations include the test ordering protocol, specimen collection technique, location of specimen collection, specimen storage, transport, and processing protocol. Laboratory anaesthesia providers and technologists can ensure that collection protocols are followed and transportation and processing occur with the least possible delay. Properly trained phlebotomists can more efficiently and accurately draw blood specimens, thereby reducing the number of failed blood draws and repeat tests. Accurate and reproducible hematology and coagulation test results essential for safe and effective patient management require immediate mixing of blood tubes containing the anticoagulant K2EDTA or sodium citrate by inversion 8 times. In clinical laboratories located far from patient wards, prompt in-trauma room testing or transport of test specimens would ideally require use of laboratory-developed, off-machine reagents or approach similar to preanalytical pooling methodology. Preprint results with automatic generation of a message to alert the pathologist may muffle unconsumed tissue in frozen sectioning and remote consultation processes in anatomical pathology.

Analytic considerations include the siting of the analyzers; whether they are located in the laboratory or point-of-care; are they walkaway, opened, or closed; are all the required pre-analytic steps automated; and whether remote monitoring is available. Analytical changes would result in the need to consult more frequently among staff. Daily cross-section, quotient and other, and performance testing may quickly consume otherwise productive time and resources with the rise of billable analytes. Finally, the need for immediate and expert consultation may at times delay the report, and less frequent use should ideally extend the time interval and depth of knowledge of more arcane but diagnostically nuanced tests.

### 8.2. Patient Outcomes

For histopathology, the value of the laboratory is evidenced by patient outcomes. The expectation is that laboratories will be integrated into effective evidence-based healthcare to improve the outcomes achieved for the resources that are spent on healthcare. Tumor board presentations of patients with a suggested diagnosis of cancer are a prime opportunity for laboratory medicine to be engaged to ensure that the tissues and tissue processing are of high quality. Laboratory medicine being engaged is essential, as history and imaging are not sufficient for diagnosis. Pathologists are

essential in ruling out cancer, adding the comment of "no tumor" negates treatment options that have significant morbidity. By planning the sample collection, preparation, and processing, the pathologist can ensure a timely diagnosis which is the first step in healthcare.

Monitoring therapeutic interventions is a major contribution of laboratory medicine to healthcare. Laboratory medicine's engagement and integration with allied health professionals contribute to more effective healthcare. In lieu of standardization, the best practice in this area remains inequitable leading to inequitable outcomes in this area of laboratory medicine, with consequences for patient outcomes. To achieve excellence, laboratory medicine must define best practices for engagement, integration, and ensuring the needed information to clinical care teams. A foundation from which to build efforts for the engagement of laboratory medicine continues to be needed. Laboratory-facilitated virtual tumor boards, tissue collection for molecular testing, and clinical engagement in treatment monitoring practices of allied health professionals with pathologists are highlighted. All provide the essential evidence for evaluating and improving the quality of allied health care and thus patient outcomes.

Laboratory medicine leaders will find that further inquiry into these winning teams will drive laboratory medicine innovations to meet the noted needs for excellence in healthcare. Like-minded pathologists and clinical laboratory leaders have urged healthcare professionals to strategically engage laboratory medicine for value-based healthcare. The award program features widely disparate healthcare teams engaged in different disease areas aimed at improving key performance indicators for patients, payers, clinicians, and health systems. Looking deeper allows insights into actual barriers to laboratory medicine excellence in fulfilling the opportunity for the value of laboratory medicine. Innovative healthcare professionals in broadly disparate clinical areas are presenting success in care that is transformative.

### 8.3. Cost-Effectiveness

Laboratory testing can have a significant impact on direct and indirect healthcare costs through improved clinical outcomes and more efficient employment of medical resources. Some general principles of economic evaluation are discussed with emphasis on cost-effectiveness analysis and the role of the laboratory as a partner in health economic consultations. Many examples of successful CEA implementation in clinical laboratories are provided with descriptions of laboratory tests, design approaches, costs and outcomes assessment, and CEA results (Bogavac-Stanojević & Jelić-Ivanović, 2017). Gaps and prospects for health economic studies in healthcare laboratories are outlined.

Cost effectiveness (CE) is a measure for comparison of health and economic consequences of alternative healthcare programs. It is a component of economic evaluation which compares the costs and consequences of alternative courses of action in terms of both health outcomes and resources. Economic evaluations are important for assessing whether healthcare interventions are worth doing and for priority setting of health resources. There are several reasons for health economic evaluation: in general, for priority setting and resource allocation; and specifically, to promote optimal use of resources, to aid the public in understanding resource constraints and choices, and to evaluate performance. The rapid increase in the number of economic evaluations

and the boundaries of health economics have been extended. However, health economists with knowledge of both cost-effectiveness analysis and laboratory medicine are scarce. CE professional groups are sparse in laboratories, and even if they collaborate with non-laboratory-based health economists, starting points of economic evaluations are often unfeasible or erroneous.

## 1.11 9. Laboratories in Disease Management

Knowledge of the laboratory results is the heart of disease management for most clinical protocols of chronic diseases (Avivar, 2012). For example, a practitioner studying diabetes references glycosylated hemoglobin A1c results from a laboratory to assess the patient's treatment status. The intensity and nature of the inquiries vary broadly with the understanding of the laboratory results and the intelligence of the processes behind the results at each step. Many variables, including medications, lifestyle, ease of access, and costs, contribute to how well the physicians and patients exploit the information contained in the results. To explore the range of the results feedback knowledge and expectations, an intuitive diagram is introduced to track the results' information and its authority at different points in the inquiry processes. However, there exist some shortcomings in conventional and mentioned proposals by adding the modelling of additional variables and in-depth verification of the modelling. A plausible algorithm to enable disease management over distance based on those variables is presented. The proposal subject to insect verification would be of practical interest to healthcare managers (Strain & H. Ravalico, 2021).

### 9.1. Chronic Disease Monitoring

The interest in chronic disease monitoring has burgeoned in recent years. Coordinated by movements in chronic disease management and individualized therapies, the concept of monitoring chronic diseases has been rekindled globally by the advent and rapid development of quantitative Point of Care testing. Nevertheless, because chronic diseases, like many diseases, are multifactorial and multi-indicator, monitoring chronic diseases are not merely limited to the application of quantitative Point of Care testing, but also draw on emerging key technologies in translational medicine to ascertain the overall variances of a disease. Drawn recently from a range of disciplines, and the experiential clinical proof of effectiveness, meticulous integrative models have been focused on asymptomatic chronic diseases. The strengths and weaknesses of the different usage contexts and the combination schemes of the monitored technologies have been documented. However, scenario propositions for asymptomatic diseases in contemporary live formats are still scarce.

The first insight into situation modelling comes from precipitating advances in the functional assessment of realities. Significant efforts for specifying workflows, or recording the rationale of events, have been made. Some successful reporting structures and compliance models have been developed: ascription fields for the Who and What questions and correlated time frames for the When and Where questions have been introduced. In the situations of planning, dealing with, and inspiring actions, fear provides the Who question with reference to external reality, and recordability at the What level goes along with the abstract representation of formality. Planning specifies When and Where answers with the prediction of the next event. Models have been

introduced in different contexts to assimilate compliance concerns at the individual and population levels into quantitative index measures.

The concepts of chronic disease management and presymptomatic chronic disease monitoring and prevention attract a lot of interest in the health informatics community. SDM implies the comparably analyzed mechanistic descriptions of model diseases, while the occurrence of chronic diseases presumes that an enduring set of violations in the functional state of the organism with lifeworlds is answerable for its development before qualification into symptomatic phases. SDM does not by itself explicate the changes of the observable parameters in each phase, and the presymptomatic phase of a chronic disease is still undescribed. Understanding the emergence of chronic diseases in particular and adapting focused technologies for their monitoring, prevention, and management necessitates the systemic comprehension of a gradual, thickening malfunctioning in the organism of a kind, a formerly normal circumstance suddenly turned wrong.

### 9.2. Infectious Disease Control

Rapid growth in urban population leads to emergence of different health priorities, as recent outbreak of the Covid-19, rabies scare, Nipah virus and many more infectious diseases observed in both rural and urban areas. Emerging and re-emerging infectious diseases take a heavy toll on human health, as manifested by enormous loss of life and socio-economic disruption observed during the recent COVID-19 pandemic. Infectious disease control relies on understanding and acting holistically on transmission, pathogen biology, evolution and disturbance of host-pathogen interactions. It is an interconnected challenge involving disciplines from health sciences to mathematics and social sciences with the common goal of sustainable health systems. Scientific understanding of emerging diseases underpins novel technologies for detection, prevention and control. Progressive, forwardlooking policies further help guide these technologies to become practical solutions that work in the diverse cultures of humanity across the globe, progressing towards equity and sustainability (Avivar, 2012). In view of the present scenario there is a dire need of advancing the available technology in various fields of diagnostics, epidemiology, therapeutics, vaccine development, drug discovery, etc. Rapid advancements of unmatched depth and breadth in biotechnology and health informatics, as brought forth by the high-throughput technology and modern computing could galvanize the transformation needed to meet unforeseen future outbreaks as observed during the Covid-19 pandemic (Tomo et al., 2020). These flourishing technologies are advancing at an explosive pace and leading to the development/production of wide-ranging public health goods. The state-of-the-art technologies of diagnostics, epidemiology, therapeutics, vaccine development, and drug discovery are presented with prior focus on informatics which, though having matured separately, can now advance together drawing synergies from one another through device convergence.

## 1.12 10. Emerging Trends in Laboratory Medicine

Laboratory medicine is being increasingly recognized as a partner of choice by stakeholders in the healthcare ecosystem. The field has traditionally been perceived as somewhat hermit-like, with laboratory medicine professionals being asked to “just do the tests on the samples” without contributing to the patient journey or providing insights into the use of their tests. However,

laboratory medicine and healthcare systems are now coalescing around wider definitions of "value", including not only clinical efficacy and cost-efficiency but also equity and patient experience. In this environment, laboratories play a pivotal role in determining the outcomes of this care economy (Strain & H. Ravalico, 2021).

Progress to date has reaffirmed the importance of collaboration and integration across a number of constituents. Despite disparities, differences in testing practices across laboratories, approaches to systems integration and data analytics for population health monitoring or cohort identification, benchmarking has already facilitated the sharing of best practices and methodologies across laboratories. This has lit the way for the evolution of algorithm-driven operational efficiencies, and ultimately population health and predictive analytics (Ueli Blatter et al., 2022). But the initiatives are only just beginning and initial successes will likely provide incentives for more labs to adopt benchmarking and competitive collaboration over the coming years.

The partnerships entered into in the run-up to , and initial debates held during, held on 15-17 March have explored how healthcare stakeholders can cooperate better to deliver the vision. The results of these workshops, and topics explored therein, will be reported in future publications. However, the short answer is that competitions are needed to drive the outcomes of cooperation. While collaborative models exist, competition breeds a hunger for improvement that cannot thrive in purely cooperative environments. Without competition, partnerships will likely grow stagnant and lose momentum.

### 10.1. Telemedicine and Remote Testing

The COVID-19 pandemic has caused unparalleled disruption to everyday life and transformed the health landscape almost overnight. As testing needs have expanded and evolved, laboratory medicine has also undergone transformation. Specifically, safety policies have been enacted to enable working remotely, facilitating remote equipment management and laboratory oversight. Due to this, it was necessary to maintain high testing performance standards while working collaboratively with manufacturers to streamline equipment troubleshooting and repair (B. Freedman, 2015). As testing transitioned from the lab to point-of-care sites, manufacturers have built more flexibility into workflows and have worked collaboratively with laboratories and clinics to resolve issues. This collaboration has influenced the time to repair, decreased costs, and improved patient care and safety.

Telemedicine is a growing need in healthcare seeing increased interest and adoption since the start of the pandemic and laboratory medicine has much to contribute. From pre-analytical to post-analytical, laboratories have the opportunity to utilize equipment and peer-review telemedicine technologies to enhance testing efficiency, supply a remote interface for quality monitoring, and improve quality assurance (Strain & H. Ravalico, 2021). Remote auditing support of laboratories has also become essential and has allowed greater freedom of location enabling more audits to be completed without undue impact on daily operations.

As the supply chain for laboratory materials and production becomes global, maintaining compliance will be an ever-increasing challenge. Any significant disruption will have long-lasting effects leading some to believe this will precipitate a reconsideration of manufacturing location

and the need to augment local production capabilities. As supply chains are reviewed, new ideas will be tested and if they deliver value these could influence long-standing practices.

### 10.2. Artificial Intelligence in Diagnostics

Artificial intelligence (AI) has consistently been recognized among the top technology trends, often seen as a source of new growth and creative ideas (Cadamuro, 2021). Many industries are looking towards AI applications not only to improve their processes but to maintain a competitive edge. Medicine and medical laboratories appear to be no different, and their intersection with AI has received much attention both from data scientists and the medical community. Despite being a broad and vague term, AI is starting to see clearer applications than simple automation tools. AI systems can read and interpret DICOM CT, MR, and PET scans, serve as smart real-time monitoring systems on the wards, and assemble the results of blood tests to predict further risk stratification or readmission probabilities.

There is currently a great deal of published research on AI work in connection with various medical areas. On the contrary, its application in medical laboratories has mostly been on the fringes of research attention. To date, laboratory resources are often wasted or not utilized to their fullest potential because there are steps in the diagnostic process that do not maximally use laboratory expertise. It has been common knowledge among laboratory specialists that clinicians typically do not use the resources appropriately in terms of test selection - the observations are confirmed in many publications. Artificial intelligence could assist laboratory specialists, especially in complexity-adjusted and multimodal sample testing in fields like blood coagulation or microbiome testing.

Medical laboratories are at the crossroads of science and diagnostics, providing appropriate analyses predicted by laboratory medicine in response to individual patients' questions, most often requested by clinicians. Medical laboratories do not usually have direct contact with patients (but indirectly through laboratory medicine aspects): samples from patients arrive at laboratories instead of patients coming to laboratories. Patients' specimens, blood or tissues, usually arrive in a standard collection tube and only pass through a standard preanalytical track. Hence, there is no preliminary information, corresponding laboratory medicine question, or indication for what level of study the patient's specimen is to be subjected to. While the ultimate responsibility for the entire testing process is shared with the laboratories, clinicians are usually left alone with test selection and interpretation.

## 1.13 11. Ethical Considerations in Laboratory Practices

Ethical questions in laboratory practice are of growing concern as laboratory testing becomes increasingly integral to the identification and management of rare diseases, in an era of limited resources and rocketing health care costs. At the same time, the possibility of erroneous and expensive tests has heightened, while elasticity in the medical system has intensified "moral distress" for laboratory personnel facing decisions about what tests to run (Strain & H. Ravalico, 2021). Medicine generally confers agency to practitioners, but the prerogatives of medical laboratories are more ambiguous; many laboratory professionals invoke guidelines from expert organizations to inform test choices. Decisions regarding the charge for a test, a person's "primary

care physician," and a diagnosis commonly rest with a single person, or small committee, outside any one pathology department.

Ethical codes characterize laboratory professionals by what they do; by confronting a situation, weighing responsibilities and consequences, and taking a stance, the exercise expands agency beyond mere compliance to codes of conduct. Ethical codes ask their adherents to form views about right and wrong, engage in discussions about them, and recognize the limits of numbers that underlie the tests of measuring analytes. A laboratory professional's sense of responsibility must inevitably be tempered by experience and the culture of their workplace. Local politics and groupthink can enable the growth of an idea into a standard practice that subsequently constrains thought. Implementing a top-down request for change from administration will usually meet stiff resistance. Alternative standards of practice that would be more beneficial for a facility, institution, community, and health care system at large must be considered.

Generally, the exercise involves bringing a new idea, usually suggested by emerging knowledge and technologies, to some person. This course involves understanding the current operations of the laboratory, evaluating the new idea against them, and then discussing it; all stakeholders will alternate being the passive and the controlling agent in the interaction. They will gain agency by making the decision on whether and then how to add or change a test. In a flexible system and a trusting environment, a person can readily be nudged into imagining an alternative course of action. There is always the danger that the considerations that swayed the person will cross the line of equity when presented to others.

### 11.1. Patient Privacy

One of the most vital aspects of the relationship between a laboratory and its users is confidentiality. Laboratories routinely perform analyses and testing for patient material ranging from blood to urine to amniotic fluid to gut microflora. It is essential that laboratory personnel have measures in place to facilitate compliance with all regulations regarding patient privacy. Both pre-analytical and post-analytical work done by laboratory professionals involved direct patient care. The final step done by laboratory professionals is adding to the laboratory interpretation, both manually by a pathologist and automatically in oncology.

Concerns over patient privacy have escalated due to the internet creating an environment where data is shared continuously and rapidly. While most laboratory is passionate about patient confidentiality, there have been some instances of client or employee negligence leading to breaches in this confidentiality. It is important for laboratories to comply with all health guidelines set forth by the federal government in order to prevent breaches in confidentiality regarding patient information.

In the health field, the terms patient data and patient information can mean almost everything. Laboratories receive patient information in many forms and a combination of formats. Patient information is collected and stored based on the required use of this information; however, this confidential information also needs to be accessible at all times. While patient care by laboratories is very personal and may include lengthy paths for testing in an academic environment, pathology cannot be sealed in the darkroom, as on-call access to laboratory results and diagnoses is crucial

for effective patient care. This makes it difficult to prevent all access points of patient information. The digitization of pathology and laboratory medicine is vastly improving laboratory work and care provided, allowing for scanning of histological slides, automatic viewing using notes on devices such as smart phones, and computer analysis (Ueli Blatter et al., 2022). However, such methods cannot be fully secured from data breaches and hackers.

### 11.2. Informed Consent

Obtaining informed consent before conducting a study or providing treatment is one of the basic ethical requirements for the conduct of biomedical research and health care procedures (Borovečki et al., 2018). The process of obtaining informed consent is a process of information exchange. The person on whom the study will be conducted or who will undergo a certain treatment has a right to receive all relevant information related to the research or treatment in a language that the person understands. The questions of the subject have to be answered. After the subject has been provided with all the relevant information, he or she has to decide whether they want to participate in the research or not. If the answer is yes, he or she will confirm this by signing the consent form. However, it has to be emphasized that the signing of the form is not the end of the process, but the beginning of the relationship between the subject and the researcher or physician. The research ethics committee (REC) or institutional review board (IRB) has to ensure that the design of the research is in accordance with the relevant ethical standards. It has to assess whether the recognition of the moral significance of the aforementioned ethically relevant values has been adequately translated into research design and to assess the appropriateness of the design of the study the REC reviewed. This primarily entails an adequate explanation of how the design has taken into consideration the socio-cultural relevance of the proposed research. There is a difference between the informed consent process for treatment and the informed consent process in research. Informed consent obtained for the purpose of the treatment is a result of the physician-patient therapeutic relationship. The treatment is offered and the subject's consent is sought for the physician-patient therapeutic relationship. The patient is always a subject in this process, never an object. The therapy is provided after the patient has consented to the treatment, or the physician must seek the consent of another physician. The relationship between physician/researcher and patient/subject is in part the same, but it is also guided by a somewhat different set of rules: the selection of suitable subjects and appropriate treatment of those subjects, careful application of the research methodology, acquisition of high-quality data, all in the service of proving a scientific hypothesis. Informed consent in laboratory medicine can be obtained for two purposes: for a laboratory test that will lead to diagnosis and treatment, if necessary, and for establishing a more general kind of research on already obtained laboratory samples and/or aggregated laboratory data.

## 1.14 12. Regulatory Framework Governing Laboratories

Laboratories play a pivotal role in today's healthcare by providing quality controlled laboratory services in pursuit of accurate and timely diagnosis, saving patients lives, improving their quality of life and preventing the occurrence of diseases. Yet the growing uproar around laboratory pipeline transparency and accountability raises questions on how to guarantee quality even when laboratories are contracted for testing services. The answer lies within regulations. Regulations

should deal with the detection of the pressure points specific to the laboratory space, including unqualified laboratory personnel, unregulated service laboratories and unverified laboratory tools, that are currently lacking. As hospitals and authorities are funding moral therapy for the sickest patients, it is becoming easier to find material to take decisions to reimburse tests. Such decisions should also take into account which laboratory tests drive the design of clinical trials. When it comes to laboratory tests, decisions should only concern quite certain tests that have clear utility. Using machine learning algorithms trained on patients' laboratory tests, it has been shown that even very short coded laboratory tests provide information about patients' diagnosis, margins, response to therapy and prognosis (B. Freedman, 2015). Mother's laboratory results can predict the risk of early pregnancy loss, preterm arrival and health of the newborn. Just like pharmacogenetic testing, such testing is conducted for populations or subconcerning drugs that have serious side effects. It could thus either be used to inform a clinical trial design or as a "niche" test. The prior case is well understood and there is established practice. The latter needs testing along with appropriate transparency. Thus, the regulation of laboratory testing should also aim to disentangle the different cases for which the regulatory process could result in separate outcomes. Meanwhile it is crucial to contain the type of actors and events that regulation will touch. Yet more information will come with the increasing standardization of testing and reporting. How to use it responsibly is one of the oldest and hardest questions in the field of chemistry (L. Kaul et al., 2017). The development of tests thereof is considered an extremely unlikely path producing any better data. Either computational ideas can be used to rank tests, substantially improving current test batteries, or new testing modes can be tried that would produce better data directly.

Laboratories could cross argue that it is not their responsibility to verify the correct use of tests. However, they are the entities that know which tests have been used for a particular patient and laboratory tests are a core aspect of laboratory practice. Contained quality information should be acted upon for the patient's good and laboratory's protection. To this end, laboratories could be asked by authorities to produce test patent information that would indicate whether a particular test was designed to answer a particular clinical query. Subsequently compliance with disclosure norms could be checked with the help of data from test patent certification. Some laboratories are already being held accountable for acts of negligence by taking them to court. Ideally, this would leave some slack for a constant dialogue to fine-tune the regulation, and some room for laboratories to redress claims before court talks become serious. As ethical justification of a test is an evolving process, laboratories could actively engage in a continuous dialogue with both patients and authorities, also sharing internal considerations and problems regarding tests and regulation. Essay on the usefulness of tests with dubious ethical basis has appeared recently by laboratory experts showing a care for governance behind the laboratory doors.

### 12.1. Federal Regulations

The 2015 Fisher Public Relations Council Report on medical laboratory-related regulation found that "the current regulatory framework should be preserved for the foreseeable future" (L. Kaul et al., 2017). Advocacy groups that believe that laboratory-developed procedures (LDPs) should be regulated by FDA or other agencies on new devices have long advocated for a regulatory approach

that would involve a different entity, regimented groups of procedures, regulatory complexity, increased financial burdens, the closure of many smaller laboratories, damage to the operation of the overall specialty, and unmet medical needs. Other groups have mentioned more cost than benefit and a lower quality in classic devices. These possible impacts are considered globally, qualitatively, and quantitatively in this section based on these previous reports with the addition of annotations as new knowledge since the ideas were generated. These new knowledge include a broader consideration of statistics-related fanned groups of procedures/assays, the development of grade regulations in the past decade and their impacts, and mainly an expansion and emphasis on the possibly negative impacts of traditional quality pathologies on the quality of LDPs, laboratory and LDP procedures. The development of LDPs is traced briefly based on previous reports, and the non-retrospective regulation chain is inferred with emphasis placed on the new idea of the more direct negative impact of grade regulations on LDPs.

In May 2015 at a meeting of the Fisher Public Relations Council discussing medical laboratory-related regulation including custom assays, the American College of Pathologists (CAP) Liaison broke up the meeting and the speakers started being took out of order and the first report that summarized the overall view based on this meeting was written soon afterward with pictorial representation of constituents, process, and tools which was mostly preserved in this report. The report was summarized in general with laboratory procedures in the "good idea" category and mathematics-related statistical procedures in the "bad idea" category with the text largely kept there but without explicit category naming of the eight groups of possible undesirability although the grouped texts were kept. In later years, major groups were independently and comparatively characterized as "classic" or "traditional" devices and their procedures and as nuances of more general procedures/assays/devices than the corresponding devices.

### 12.2. State Regulations

State regulations can differ from federal regulations in their approach to assuring the quality of services provided by medical laboratories. Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), federal regulation is limited to assuring a laboratory’s proficiency in test performance through licensing. Laboratories found to be compliant with CLIA are then permitted to offer any test that is deemed of interest and can be performed in compliance with CLIA. While relevant and timely for newly developed medical lab tests, this historic approach has proven ineffective as many Lahl tests created and marketed by medical labs are automatically granted compliance with CLIA, ignoring the substantial evidence that a considerable number of these tests yield erroneous results ( (L. Kaul et al., 2017) ). States can improve control over LDP development by requiring predevelopment review and study of all proposed tests, including the fixation of a CLIA license enabling an LDP to begin performance even in the absence of such review. To address this important regulatory gap, the reagents, equipment, and process used to perform a proposed LDP test should be significantly different than those used in a compliance test which has been reviewed and authorized by the FDA. The FDA’s modalities for keeping the safety and effectiveness of approved tests current and valid do not apply to LDPs, and states must be very vigilant in addressing this regulatory challenge as the coming proliferation of new laboratory tests,

both simple and complex, promises to be enormous ( (B. Freedman, 2015) ). Regarding LDP mass-marketing by medical labs, current surveilling mechanisms are proactive/actual duty to be exercised by officials in elected or appointed positions. Where a breach of official position is detected subsequent punitive action can lead to civil fines and even imprisonment. The civil enforcement paradigm considerations omits the aggrieved patient's perspective in which the damage from the action can often never be rectified because erroneous results are known only a posteriori and only when they become obvious to those involved in patient care.

### 1.15 13. Global Perspectives on Laboratory Services

Gomel Region, located in the southeastern part of Belarus, borders Russia and Ukraine. The regional center is Gomel. Many highly qualified specialists built their career paths at laboratories of the regional health care institutions. Environmental features of the region dictate another approach. The report describes the structure of the regional laboratory network, its ability to provide laboratory investigations permitted for the regional health care institution, and current trends in laboratory services.

The regional laboratory network consists of 25 laboratories. Each organization has its own laboratory services, aimed mainly to obtain results for the treatment of patients in respective medical institutions. Utilization of laboratory investigation services of other health care organizations includes internal and external laboratory consultations, automatic information exchange, elaboration of clinical protocols by the health care organizations. Accessibility to laboratory investigations increases with patients' arrival to health care organizations beyond their permanent residence place. New laboratory investigations allow creating new laboratory services, with improving existing ones. Laboratory investigations play the key role in the diagnostic and therapeutic procedures.

Unedited data in medical and laboratory information systems are analyzed on the basis of regional evidence-based practice medicine on the basis of statistics. The quantitative distribution of patients, diagnosed diseases, laboratory investigations is analyzed. Data are used to provide guidance in housekeeping, current redistribution of patients amongst the health care organizations, laboratory investigations, costs, and affairs with laboratory services, the budget forecasting. Regional medical advisory is organized on a high level to improve laboratory investigations provided by the health care organizations, to perform statistical analysis of evidences from different health care organizations.

This work is regarded as a heavy burden for specialists at regional health care organizations. Each regional center implemented and widened primary care health services ambitiously. In spite of the current GDP per capita of about 6,850 USD, laboratory investigations are mainly provided by public health care institutions, including 21 public health enterprises, the central laboratory of municipal health care institution, the national center of hygiene, epidemiology and public health. The municipal health care institutions are mainly responsible for public health care. At present, the cost of a unit of laboratory investigation at public health care institution ranges from 0.58 to 312.31 USD. Planning and providing laboratory investigations and modern requirements on creation and operation of the automated or computer-based laboratory information systems, which

are prescriptive in most developed countries, the public health care institutions of Mogilev Region face a number of substantial challenging problems in organization, technical provision, and human resources.

### 13.1. Laboratory Services in Developing Countries

In developing countries, diseases like tuberculosis (TB), HIV, malaria, and hepatitis B have become prominent killers due to poor access to diagnosis and treatment. Health professionals stated that broader access to low-cost blood testing could greatly assist in control of disease spread and save lives. Nearly all countries in sub-Saharan Africa (SSA) now have policies obliging health facilities to offer laboratory services (LS), but these policies remain poorly implemented (Genet Akal & Andualem, 2018). While laboratory tests involving more than one sample or specimen would appear to be strongly needed, these are seldom available at all, much less routinely. Capacity and opportunity for LS to support patient management and treatment is largely absent, and many health facilities cannot provide even simple tests like hemoglobin measurement or malaria diagnosis (Toni Maria Tadeu & Geelhoed, 2016). Lack of routine diagnostics greatly increases reliance on guesswork and prescriptive treatment, resulting in wasteful use of medicines with often disastrous results for patients. Consequently, cheap rapid tests could offer a practical way to start somewhere in addressing the considerable backlog in LS. However, new tests are unlikely to move from available options to routine use unless this movement is managed efficiently. National health authorities would need to work with test developers to produce and distribute the rights tests, train innumerable health frontliners, and generally establish working mechanisms for LS to function. Such institutional prerequisites for LS would appear central to any broader process for planning rapid test integration into patient management.

### 13.2. International Standards

Laboratories play an important role in the identification, diagnoses, and treatment of diseases. Therefore, worldwide recognized standards are required in order for laboratory results to be interchangeable and reliable. Accreditation is the way to achieve this goal. Since 2007 the medical laboratories of the EU must be accredited according to ISO 15189. This standard includes requirements for quality assurance and competence of laboratories with the intention to improve quality of the laboratory services and of the health care as a whole. It is now the gold standard for clinical laboratories accreditation in Europe (Zima, 2017).

As laboratories produce the results on which a clinical decision is based, they are responsible to keep the patient safe and sound. ISO 15189 has some important requirements to that respect. Accreditations and periodical audits guarantee that the quality management system is keeping alive and is regularly improving the quality of laboratory services. It also guarantees that troubleshooting in the case of incidents contributes to not submit false results to the clinicians and to the provide the patient with safe services. There are unfortunately more definitions on patient safety, such as automated selection of algorithms to reporting the results that are outside the biological reference interval.

This will help to detect cases with a high clinical risk in either direction much sooner. Jointly, global electronic patient data bases with registrations of results and the intervention and treatment

given by the clinician, will monitor the quality of the provided services. ISO 15189 gives precise descriptions on the processes for selecting, evaluating and transferring samples to and from referring laboratories. Novel countries will need to adopt other specifications, such as those documented in ISO 15189:2012. All the ISO and ISAS are the requirement against which laboratories will either self and third party audited.

## 1.16 14. Future Directions in Laboratory Medicine

Laboratory medicine has never been stagnant and has constantly matured and evolved. It was revolutionized by various technical advancements, including the advent of the spectrophotometer, the microtiter plate, automated immunochemistry analyzers, and clinical mass spectrometers. More recently, it has entered the mass production of genomic methods, including sequencing and polymerase chain reaction, resulting in entirely new medical disciplines. However, laboratory medicine has been in a structural stagnation for the last couple of years. Everybody is aware of the side effects of too large or heterogeneous datasets in terms of duplicate samples and errors in data reporting. Young well-trained professionals are not satisfied with routine workflows that can hardly be expanded through standard software. Laboratory medicine has extremely high-quality standards. Still, the corresponding enormous infrastructures have remained almost unchanged for decades. Consequently, laboratory medicine has had almost non-existent contact with Big Data, and on how to get there, research activities are hardly present or published. A solution is required to prepare for the development of modern technologies, in particular of deep learning or artificial intelligence (Ueli Blatter et al., 2022). Every modern technology, such as streaming analysis of laboratory data or deep learning of diagnostic images, presupposes unfiltered access to raw laboratory medicine data. In most instances, this “Big Data” aspect is “forgotten.” At nearly all research institutions or clinics, only tiny parts are accessible through rigidly negotiated agreements. Because of this, the necessary high-level deep learning developers are often unattainable, as they run away to other disciplines with broader spontaneous collaboration openings. Subsequently, academic laboratory data becomes mute and dumb, and this regard matters will be taken over by disciplines where data proclamation is cheaper and less anchored on water. At a certain point, laboratory medicine might be degraded to a pure number generator or might disappear completely as an academic subject.

### 14.1. Innovative Research Areas

Innovative approaches taken by noteworthy award-winning initiatives led by boards of laboratory medicine professionals and clinicians, both in collaboration and in separation. Examples of trends that emerged from initiatives of pathology-led excellence, such as stewardship on laboratory testing, outcome-based reference ranges, and quality laboratory testing are explored. The relevance of laboratory medicine and its impact to patient care remain vital in preventing missed diagnosis, unnecessary treatment, and misdiagnosis resulting in overtreatment or ineffectiveness (Strain & H. Ravalico, 2021).

Laboratory testing is only valuable if executed in a high-quality manner. The original laboratory testing accuracy encompasses pre-analytical variables, including ordering, collection, preservation, and transportation of biological specimens, accurate laboratory processing, and post-

analytical factors, including accurate information entry into a laboratory information system and other data repositories, resulting in correctly interpreted and reported laboratory test results. These constituents of a high-quality laboratory testing cycle are well or better documented by ISO 15189 and the quality of laboratory testing is constantly improved and maintained by laboratories pursuing ISO 15189 accreditation. Yet, controlling laboratory errors remains challenging, as audit results on associated pre-analytical, analytical, and post-analytical errors revealed considerable discrepancies. Reassuringly, known pre-analytical errors-in-house samples and separation effects in hospital samples—may be preventive by normalizing specimen handling procedures.

Efforts innovatively commenced on interfering agents in vesting samples, to elevate the accuracy in laboratory results and in fathoming the knowledge. Clinicians' equity of correct knowledge of patient' true clinical status is challenged by the analytical difficulty of inaccurate results or the absence of results of even important but less frequently detected laboratory tests. Thus, laboratory testing within capacity and proportionate to the prevalence, suggests the assurance of performable tests only offering wide availability is paramount. Beyond the analytical ability of laboratory instruments or platforms, many confounding and challenging pre-analytical factors were undertaken and resolved, and the robustness for non-ideal specimens departing from specimen type and age was utmost explored.

### 14.2. Integration with Other Healthcare Services

Existing health-care systems suffer from fragmentation, which hinders implementation of strategy to move toward integrated patient-centered care. Despite urgent calls for systemic change, little progress has been made to promote the integration of health services, particularly at the structural level. Moreover, the systemic integration of different organizational specialties across the entire spectrum of care has received scant attention relative to the professional and functional integration of health services at sub-systems. An integrated patient-centered care framework is proposed based on a model which classifies health-care services into 3 states based on their level of integration. Understanding these states can guide health care systems toward integrated patient-centered care. The role of health information technology in governing the transition of primary care from fragmentation to integration is also discussed.

The clinical lab is the backbone of modern health care. It plays a vital role on every step of patient care: diagnosis, treatment, and follow-up. Despite this important contribution, laboratories are routinely bombarded with threats from within health systems to cut laboratory budgets, staffing, and funding to meet other system priorities. The fear is that already overwhelmed clinical labs will drown under the weight of increased demand or declining resources. If health system leaders and clinical laboratory clinicians do not recognize the value that laboratories provide, the return on investment will surely decrease. Therefore, it is imperative for all laboratory professionals to show the added value of laboratory testing through the quality of results, cost savings, and improved patient outcomes. Use of a health economics methodology like budget impact analysis was recommended to assist laboratory professionals in quantifying the financial value of laboratory tests to health systems and laboratories. Describing instances of reduced testing or misconstrued return on investment versus value can help managers recognize poorly conceived lab budget

decisions. Clinical labs should consider publishing and presenting more on added value, return on investments, and health economics to inculcate the current and next generation of laboratory professionals with the cost-effectiveness of laboratory testing.

## 1.17 15. Conclusion

The evolution of the discipline of laboratory medicine captures an enduring human story, chronicling different eras and the formation of strategic partnerships (Strain & H. Ravalico, 2021). Similar to love stories, there are many possible starting points. In addition to the tumultuous past of laboratory medicine and healthcare, on-going uncertainty may also prompt professionals to contemplate the future of their partnership. Histories are often difficult to recount and may be reduced to simplistic caricatures; examples include the laboratory medicine claims distinguished by claims for traditional services such as quality or cost-effectiveness and claims of value that emphasize the intrinsic contributions of pathology and laboratory services to deepening the understanding of disease and its consequences. Careful re-telling is needed so as to enlighten practitioners, policymakers and educators and to inspire deeper engagement and greater pursuit of health benefits toward which laboratory medicine addresses our collective resources.

Across the different participants in the practice of laboratory medicine, the on-going problems that warrant inquiry and reconstruction of the past broadly fall into three themes. The first theme is the consequential caveat emptor in the real-world performance of lab tests even as they have been studied in tightly controlled conditions. The second theme originates from the evolution of health systems towards stricter accountability accompanied by calls to measure and quantify both quality and value of health services, including laboratory medicine. The third theme relates to the corrosion of lab capacity and capability in many parts of the world, and the erosion of human capital in the form of a loss in epidemiology and intellect base. These themes shape the focus of naïve but not wholly new questions that pervade the retrospect of the partnership of laboratory medicine and health services.

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