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THE ROLE OF MEDICAL LABORATORIES IN DISEASE DIAGNOSIS

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1.2 Abstract

Coronaviruses are encapsulated, positive-sense, single-stranded RNA viruses belonging to the subfamily Coronavirinae in the family Coronaviridae. These viruses have been shown to infect various hosts, such as mammals and birds. In humans, coronaviruses can lead to a wide range of respiratory tract infections, from common colds to more severe pathologies such as severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS) (Tomo et al., 2020). The current ongoing pandemic of coronavirus disease 2019 (COVID-19) originated in the Chinese city of Wuhan, Hubei province, in a seafood market. Several cases of pneumonia were reported in patients without any history of exposure to a seafood market. The novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was later identified in patients and confirmed as the etiological agent responsible for these infections. To date, SARS-CoV-2 has already affected over 180 countries, causing over 7 million confirmed cases and leading to the death of >400,000 individuals.

Clinical laboratories are a vital contributor to most of the diagnoses and management of diseases in a hospital setting. A hospital setup requires various diagnostic modalities to handle the burden of health care and to take necessary measures for patient care. Medical testing of any clinical specimen to obtain health information is considered a larger field, and a medical laboratory is the physically represented site of clinical laboratory science—a medical laboratory or clinical laboratory is a laboratory for medical sciences that conducts tests on clinical specimens in order to provide information for the diagnosis, treatment, and prevention of disease (K. Krishna & M. Cunnion, 2012).

1.3 Keywords

medical laboratories, disease diagnosis, healthcare, diagnostic tests, patient care.

1.4 1. Introduction to Medical Laboratories

Clinical laboratories play a major role in the diagnosis and disease-monitoring activities of any disease, including the current COVID-19 pandemic. Laboratories conduct various types of testing, including blood work (hematology, microbiology, and serology), tests of tissue, and other body samples. Health care providers use the results from these tests to diagnose and manage diseases. During the COVID-19 pandemic, clinical laboratories and laboratory personnel globally are challenged by the volume of testing, by new pre-analytical and analytical issues, and by the necessity of managing new diagnosis and disease-monitoring tests (Tomo et al., 2020). This crisis denotes a global drawback, weaknesses, and numerous hidden issues of laboratories in both developed and developing countries in terms of serving in clinical sessions. These hidden issues include, abrupt unawareness of clinical staff regarding various essential performances of laboratories, the different types of laboratories, and the value of precise and satisfactory sample collection, transportation, processing, storage, and actual spot diagnosis of diseases to appropriate well-timed patient treatment. A well-operated and properly organized laboratory can effectively support doctors and clinical workers by providing correct diagnosis of diseases and instant information about the treatment of the diseases (B. Freedman, 2015).

Increasing antibiotic resistance continues to rise worldwide due to a huge missing match between the actual disease and its treatment, due to a mistaken diagnosis by inadequate labs. A lab error might be an initial error affecting collection, handling, preparation, transport, identification, or labeling of specimen samples, or it might be a resulting labeling, and interpretation of patient test results. Conversely, it may be a poorly designed clinical sample requirement provision or even a misinterpretation of laboratory results. Thus, during the COVID-19 pandemic, exploration of previously unused or under-used capacity can improve the productivity of currently available laboratories. Furthermore, during this crisis situation, healthcare practitioners should promptly possess an in-depth understanding of nearby and acceptable laboratory functionalities to enable laboratories to serve society in an improved way.

1.5 2. Historical Background

Laboratory tests are used by clinicians across the world to help them decide what is the matter with a patient, or to monitor a patient's progress. Around 60-70% of medical decisions are influenced by pathology tests. The other 30% of decisions in clinical management are made solely on clinical judgement. Despite this, it is generally agreed that laboratory testing is subject to a high rate of error. Many studies recommend that speculative results are reviewed with the clinical team prior to any action being taken. 'Critical calls' have been introduced in a number of hospitals; these are used when a laboratory result is deemed to be surprising or dangerous. These call the ward/department to ensure that the result is received and that the result is not acted upon without a full understanding of possible errors or reasons for the strange result (B. Freedman, 2015).

1.6 3. Types of Medical Laboratories

There are many types of medical laboratories that offer diverse services. There are clinical laboratories, where scientists provide information for detecting, diagnosing, and treating disease; inform medical practitioners what is happening to their patients when they are unable to discern

that information themselves; and serve as sentinels, watching for trends in the occurrence of particular diseases. Clinical laboratory personnel perform a wide variety of analyses on biological samples using chemistry, hematology, microbiology, immunohematology and molecular diagnostics. Another specialization for individuals in the clinical laboratory is cytotechnology. Research laboratories, another type of medical laboratory, are essential to basic research, a role that will become increasingly important in the search for new treatments; their work centers on isolating and characterizing drugs; testing potential drugs for toxic effects, both in the test tube and in animals; and identifying which compounds emerging from the laboratory are active ingredients (Merrick et al., 2013). While clinical laboratories are primarily involved in testing and diagnosis, research laboratories are not limited by that mission. They can be more exploratory in nature, seeking to find out how things work, rather than succeeding in diagnosing a disease. In chemistry and microbiology laboratories, for example, technicians not only test cells, tissues, and body fluid samples, but also prepare specimens for microscope examination. In an accredited laboratory they are trained to perform analyses that assess the physical characteristics of blood, such as the amount of blood in the body, and the level of glycosylated hemoglobin, urea, theophylline, phenobarbital, vancomycin and glucose. Chemistry laboratories usually feature three main types of workers: laboratory testing technicians, who usually prepare specimens for analysis, clinical laboratory scientists, who usually prepare solutions and reagents used in the analysis of specimens and operate testing equipment, and chemists, who usually perform analyses on specimens. Chemistry laboratories devote more of their resources to the measurement of the sodium, potassium, and lactate dehydrogenase of specimens, while less than ten percent of their activities are devoted to testing glucose levels in the specimens. These laboratories can be found in clinics, medical offices, hospitals, and research and testing institutions. Blood samples are the most commonly analyzed specimens in chemistry laboratories, while specimens from the digestive system are rarely analyzed. Injury, poisoning, and certain other consequences of external causes are rarely diagnosed in chemistry laboratories; most usually common diagnostic services are vesicant agents, chemical products, insect stings and venomous bites, and are also less commonly analyzed at these laboratories. Blood samples are most commonly analyzed for quantitative cultural testing, screening serum tests on blood specimens, and immunoassays. Other body fluid samples and tissue cell samples are less commonly analyzed. Streptococcus tests are less common in the laboratory practice. Most of the tests in a laboratory are performed by means of nonautomated wet chemistry instruments, while only a few modern analyzers are used in the performance of testing in a chemistry laboratory. Most of the specimens in a chemistry laboratory are handled by automated robotics; technologists, on the other hand, manually handle most of the specimens in their clinical chemistry laboratory. Panic values are a way of referring to the routine handling of critical laboratory results to the attention of the doctor providing care. These values indicate the number of steps that a laboratory will take generally before notifying the requesting physician of the result. Blood smears are examined for a small number of disease states: anemia, hemoglobinopathy, or thrombocytopenia. In chemistry laboratories, point-of-care testing is performed by means of a fully automated portable analyzer, while in clinical laboratories a broad

range of tests are performed by means of desktop instruments. Specimens beyond the appropriate retention date are usually discarded. Chemicals and other substances used in the laboratory are discarded after a year, regardless of whether they were opened or not. There are various ways of testing drug levels for patient safety and infection control purposes. A results analyzer performs testing on milk specimens to ensure that the milk complies with local regulations. It is essential to comply with established procedures and accreditation requirements, or risk losing the accreditation. Medical laboratorians must follow procedures and guidelines established by the Chemistry Laboratory Medical Directorate in order that the same risk of unacceptable results shall arise at any stage of the process. It is recommended that clinical chemistry laboratories have a participatory testing program for all analyzers used in blood glucose measurement, as part of the lab's quality system. When an internal quality control result falls outside the range of acceptability, it is necessary to evaluate the result and take steps before patient results are issued. It is common practice that only activated alarms are investigated. However, it is essential that all errors and failures, whether detected automatically or by some other means, which have the potential to adversely affect results, are investigated, and appropriate action is taken to ensure patient safety. While it is necessary to comply with the relevant section of the laboratory manual, some aspects of noncompliance are not reported, for which reason such instructions are to some extent useless. Some laboratory manuals may not have been adapted to local conditions. Noncompliance sanctions should be implemented throughout the regional area that follows from a yearly monitoring of all staff. It is also customary that nitrate concentration in well-water samples is analyzed once a year and that milk samples are not tested for drug residues every year, thus diagnosing milk specimens with total bacterial count is one of the most common and widespread tests in microbiology laboratories.

3.1. Clinical Laboratories

The role played by labs in clinical decision-making processes is such that it is estimated that over 70% of medical interventions are directly related to the information provided by analytical data. For this reason, labs are a valuable source of information for public health care systems regarding diagnosis, prognosis and patient care (Tomo et al., 2020). There have been significant breakthroughs in Clinical Laboratories with improved precision and accuracy. Therefore, since the implementation of familiarization and self-validation front form measurement methods for different reagents, the responsibility engagement of labs operating throughout the entire healthcare system must be taken seriously. New biochemistry, immunochemistry and hematology auto-analyzers have provided high sample processing speeds, making it now possible to process an unprecedented number of patient tests and ensure high-quality results. Furthermore, the increase in automation and standardization levels in Clinical Laboratories has enabled quality assurance to be taken to an extreme so that both pre- and post-examination processes now have an impact close to that of the analytical phase. Both aspects have greatly contributed to a significant increase in analytical parameter prescriptions as a critical information source for clinical diagnosis (Avivar, 2012). New analytical techniques, methodologies and technologies are routinely embraced by Clinical Laboratories in order to assure that the most comprehensive service is provided. An

important example of the evolution of analytical techniques is represented by the detection of immunological reactions. For over two decades, the determination of antigens and antibodies was carried out by heterogeneous tests in an agglutination or precipitation medium. This collection of tests is referred to as "classical serology". Due to the lack of adequate resolution in terms of specificity and sensitivity, these tests have become progressively obsolete. Therefore, the development of a new series of immunochemical techniques, which have at their bases chemical reactions between liquid phases, has significantly broadened the spectrum of potentially detectable "antigen-antibody" reactions. Written communication of laboratory tests regarding critical range parameter violation is provided to hospital units. In cases of deviation from the values established as robust decision thresholds, written or electronically-generated communication between laboratories and hospital units is triggered. This active communication must be kept to a minimum as it can generate additional costs, reduce the efficiency of diagnosis and have a negative impact on hospital activities.

3.2. Research Laboratories

Since the onset of the COVID-19 pandemic, the significance and value of medical laboratory tests have undeniably matured. Efforts to advance detection capabilities hand in hand with the global community have been stepped up over the course of the last year. Meanwhile, current assessments have shown that the worldwide shortage and misdirection of diagnostic tests, as well as the analytical condition of trials, have partly restrained the steady flow of conformity between essential laboratory research results and their clinical demand and usage.

The Healthcare Quality Control Laboratory, which is typically designed as the Laboratory Department, plays a crucial role in the facility process and holds a clinically significant position, as it serves to support medical facilities investigations, apply the up-to-date laboratory technologies, promote the quality of cooperation and assure that data and study conclusions are based on a plaintive scientific foundation. The Laboratory Department occupies a separate area known as the Healthcare Pathology Laboratory located in the emergency department, which operates 24-hour shifts.

Three classes of medical labs are described based on their functionality: Clinical Laboratories, specialized in receiving pulmonic and blood specimens for studies observing the compounds of disease outbreak, Biochemical Laboratories, which are specialized in diagnosing diseases on biochemical and histopathological bases and, lastly, Research Laboratories.

Currently, in a result of numerous efforts to improve the treatment and cure of COVID-19, the pathology of the new-type coronavirus and the most effective strategies for its cure are considered to become academically known in more detail (Lippi et al., 2020). Nonetheless, as well as further essential studies are needed to evaluate vaccines, define the medicine of disease progression, and specify its prospective long-term consequences. Knowing this, the Laboratory Pathology Department, or Laboratory Department in general terms, is designed to actively engage in these studies. Access to patients with the requirement for laboratory sample collection is permitted since no clinical studies can take place without the patients participation. However, as work in the

Emergency Department may result in a big burden on healthcare providers, these specialized Laboratory Departments are most often separated.

3.3. Public Health Laboratories

There are more than 60 public health laboratories (PHLs) in the United States. PHLs typically offer a wide variety of diagnostic testing for humans and animals as well as testing of environmental samples and products. Most local and state PHLs offer bacteriology, virology, and mycology testing, but PHLs can and do perform an infinite variety of tests. These laboratories provide laboratory confirmation for certain special organisms and toxins and are part of the public health's disease surveillance enterprise. Antibiotic resistance testing, testing for bioterrorism agents, toxicology, species identification, genotyping, and susceptibility testing are among the tests PHLs offer. During disease outbreaks, public health laboratories are paramount for the accurate and timely identification of infectious organisms or toxins. In recent years, many PHLs have opened the lines of communication that facilitate transferring knowledge, technology, and old-fashioned laboratory techniques to avoid backlogs and delays in processing samples (Merrick et al., 2013). Laboratories that process a large number of stool specimens are systematically preparing for an anticipated increase in testing during an outbreak. Conventionally, PHLs receive specimens from healthcare providers and other testing sites, though recently the adaptation of methodologies had been used to provide communitywide surveillance and laboratory testing. Often, PHLs are the exclusive providers of certain tests like for example, some regional centers focus on the genotyping and identification of mycobacterium. Like any court, for examination and characterization purposes, public health laboratories conduct testing without indicating the onus of proof. In disaster response, PHLs are critical sites of laboratory support. They provide a contact network between regional laboratories. Select agent laboratories are subject to federal regulations and must adhere to strict guidelines. Most PHLs perform some tests not commonly available elsewhere in the community, offering a wide array of specialized tests.

1.7 4. Laboratory Techniques and Procedures

4.1. Sample Collection and Handling

4.2. Testing Methods

4.3. Quality Control in Laboratories

1.8 5. Role of Medical Laboratories in Diagnosis

Disease continues to be a major health burden in the developing countries. Accurate diagnosis of diseases is the first step towards proper management. There are several methods for diagnosis of diseases. Clinical evaluation by a physician is the first step in diagnosing the disease. In addition, laboratory tests are used in the form of 'sickness-detectors'. An optimal job is achieved provided the test is requested appropriately and the result is correctly interpreted. Medical laboratories in healthcare organizations can insulate the patient from the larger healthcare system by acting as the gatekeepers to testing. Because clinicians frequently order tests based on algorithmic responses to patient symptoms, laboratory protocols and knowledge of test methodology become the built-in check on unnecessary testing by entry professionals. Disease diagnosis continues to be a major cause of ill health. Only, an accurate diagnosis can lead to correct and rational treatment of a

disease. Several methods are currently in practice for disease diagnosis. The most common and widely practiced method for disease diagnosis is clinical evaluation of possible signs and symptoms by a physician. Laboratory tests are often used as simple 'sickness-detectors' to help confirm or refute clinician's working diagnosis as the next step following the history and physical examination. The goal of diagnostic testing is to identify disorders in patients with suspected disease based on patient signs and symptoms, medical history and initial physical examination. Diagnostic testing in the healthcare context provides services to assist diagnosis and appropriate therapy by pathologically examining body substances and identifying microorganisms. Blood is an appealing body substance to examine because it is easily accessible, flows throughout the body, and is a common site of changes reflected by many different diseases.

5.1. Biochemical Testing

Biochemical methods are being replaced by matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOF MS) (A. Pence & Liesman, 2020). Although there are numerous advantages to monomicrobial testing, on occasion, a clinician suspects a rare infection or wants to ensure a biosafety level organism is not being missed. Historically, mycobacteria were identified by biochemical methods using phenotypic tests, which required weeks for some slowly growing species such as Mycobacterium marinum or Mycobacterium szulgai, even when selective and nonselective agar media were employed. Although improvements in time to identification were made with the implementation of high-performance liquid chromatography, DNA probes, MALDI-TOF MS, and polymerase chain reaction for the MTB complex, there are many other species that pertain to this genus, some of which are of biosafety level concern and are not properly cultured in most clinical labs. M. tuberculosis should be cultured in a biosafety level 3 or BSL2 laboratory since there is the potential aerosolization of this organism when the broth is processed for smear preparation.

Regardless of the media type employed, the time to a positive culture for mycobacteria and many other nontuberculous mycobacterial species is prolonged, requiring long incubation times, even when culture is performed using liquid, automated methods that monitored gas produced by growing organisms in the bottle. Once growth was detected, mycobacteria were traditionally tested with biochemical methods that utilized phenotypic tests. Although a positive-pressure p-nitrobenzoic acid test is sensitive for Mycobacterium tuberculosis, no test is included for non-MTB mycobacteria. Biochemical methods are no longer recommended for identification due to their poor performance and slow turnaround times. Initial attempts at identification were made using thin-layer gas chromatography. Although it could provide identification for some species in 24 to 48 hours, most species required weeks to provide an identification. Until recently, M. avium complex, M. kansasii, and M. fortuitum complex were the only testable isolates. Although DNA probes were made available for M. tuberculosis complex in 2001, they are also no longer made. The current recommendation is to discard all mycobacteria that are tested under the program without prompt notification to the end-user, and to ship to the health department for species identification and susceptibility testing for all other isolates. Of the 25 unique MAC which tested non-MTB M. tuberculosis complex and non-MAC isolates that fell under program guidelines, only

2 were properly managed by the laboratory. This update will go into detail regarding species that were tested and the proper modules that should be cancelled based on the species tested. Additionally, since a large number of mycobacteria were tested unnecessarily, the diagnostic director recommended a reminder to the program participant regarding proper discard of suspect mycobacteria as initial step in the remedial process. Although DNA probes provide a same day turnaround time once growth is detected, they are labor-intensive and only available for MTB complex, M.avium complex, M. kansasii, and M. gordonae. MALDI-TOF MS is replacing traditional methodology for the identification of mycobacteria. There are many publications on the accuracy of MALDI-TOF MS for the identification of mycobacteria. Unfortunately, when queries were run for M. malmoense, M. fortuitum complex, M. abscessus complex, M. kansasii, M. massiliense, M. gastri, and M. simiae, the following message was obtained unknown at this time. Ten searches were attempted for each of the suspect or unusual mycobacteria and none yielded accurate results. It is not expected at this time that the program exempt any species with the limited enzyme extraction protocol, but rather species that should not have been tested in the first place. For this reason, no mycobacteria were exempted under program guidelines. An exemption request was submitted to the mycobacteriology discipline in December 2018. However, 48h signed emergency review and denial was received with no discussion or explanation of the process behind the exemption. Therefore, requests evaluation for removal from testing designation were re-submitted for selective and programmatically more notable mycobacteria. In the meantime, this update will describe a defensive action plan for mycobacteria that as of yet do not have FDA approval for detection, including a daily sortable Excel document that can be viewed, printed, and sorted by client.

Mold/API/VPC non-recommended species listing is taking place in August to early September. Still due to this hypothetical situation no exemption is expected, but again, requested evaluation for removal from testing of more significant species are re-submitted. A defense action plan between WMC and participant is being drafted and expected to be executed within two weeks of mold issuance of the non-recommended species list. Document will be updated to Knowledgebase 1795 and client apprised to review said document immediately upon availability. NCTC10394, a produce of ATCC 19567T, is not considered by CDC to be an EBA, but may confuse the immuno-compromised.

5.2. Microbiological Testing

The methods employed by clinical microbiology laboratories have evolved and expanded considerably to provide the best quality of results. Despite technological advances in detection and identification methodologies in microbiology, the quality and reliability of the results produced by the laboratory are dependent upon the observance of proper practices and conditions for each microorganism before the specimen even reaches the laboratory. Clinical laboratories in the United States have been increasingly regulated. Monitoring evaluates the quality of practices and test results, but evaluation generally focuses most significantly on the activity of the laboratory itself. However, the quality of the specimens can dramatically affect the results of laboratory testing, even with newer methodologies. A positive result from improperly obtained specimens is as

unhelpful and inaccurate as a negative or falsely negative result. Clinical laboratory scientists can play a role in educating the public, medical professionals, and patients about the correct methods to ensure that all criteria for a well-collected specimen are met. Species identification methods are so sensitive that contaminating commensals may lead to misdiagnosis. It falls to the laboratory professional to adopt strict pass/fail specimen acceptance policies in order to ensure accurate results (A. Pence & Liesman, 2020). However, finespun or rare pathogens can be missed if one is testing with restrictive pass/fail policies. Clinical laboratories have the duty of promptly and accurately communicating test results. Nonetheless, laboratories have an additional responsibility, which involves educating the public, medical professionals, and patients on the correct method of specimen collection. Analytical sensitivities of the methods used in the majority of microbial testing indicate detection limits of 103 to 104 organisms. Additional specimen is sometimes requested even if an offending microorganism has already been isolated in culture. Postmortem samples should never be obtained before antimicrobial therapy has been initiated unless the patient is pronounced dead and the sample is aseptically obtained within 15 minutes of that declaration.

5.3. Pathological Testing

A complete list of investigative and forensic laboratory sequencing instruments is proprietary to each company. Exclusions from such a list can be found and range from laboratory capacity to vendor relations. There is undoubtedly a consensus among forensic scientists that both the Illumina and 454 pyrosequencing instruments are the most widely used for DNA sequencing. Eleven out of 12 (92%) of the respondents or their labs have or continue to use one of these two platforms. Of those, Illumina was the most common (55%), followed closely by the 454 FLX Titanium (45%). There are many reasons why forensic scientists are not taking advantage of newer benchtop and nanopore sequencing instruments. The most common answer supporting such a notion was cost, suggesting the instruments and consumables were too expensive (K. Krishna & M. Cunnion, 2012). The so-called next-gen sequencing platforms are in general both faster and easier to use when compared to first generation Sanger instruments; most concerning for the forensic community, however, those same platforms can produce much longer DNA fragments, beyond what is currently found in most databasing systems. As such, the methods in place may need to be updated to be compatible with these newer sequencers. Yet, another potentially productive area for future research is the development of new DNA sequencing methods, which may be better suited for the forensics environment. This working hypothesis is supported listening to the feedback from the 14 scientists working with the 454 and Illumina sequencing instruments, all of whom have had to spend an inordinate amount of time trying to modify their current protocols. However, other less sought after instruments were able to detect C tetani in 43 minutes as well as B anthracis with high accuracy, which suggests new interest and usage could significantly improve the utility of sequencing technologies.

1.9 6. Impact of Technology on Laboratory Practices

The end of the last century, and particularly the recent years, have seen a rapid technological development in the fields of materials, biochemistry and mechatronics, enabling the emergence of a wide number of machines and information technologies which have significantly widened the

capability to automate till-now labour-intensive operations. Almost all kinds of industries, services and fields of knowledge have taken advantage from this technological revolution, except the Clinical Laboratories. Here, there have been a number of significant breakthroughs in the quality and range of the pathology analyzers. However, laboratory organization concepts have remained the same for well over half a century. In recent years, an increasing number of labs have been automating analytical operations from both a hardware and software perspective (Avivar, 2012). Own-developed applications have led to a new organization for laboratory work: continuous reduction of the number of analyzers to a single auto-analyzer per specialty; daily repetition of batched tests on the same auto-analyzer; grouping tests, regardless of analytical specialty, according to the sample tubes which can be processed by the same auto-analyzers; automatic sample carriage along lab-hood. The implementation of all these strategies was made possible by setting up a planning program for the analytical work on a day-to-day basis. The implementation of this planning application led to an eventual economic performance of the clinical lab. The number of batched apparatuses and their throughput have been of concern at the same time as trying to grasp the new criteria and ideas for clinical laboratory organization (A. Pence & Liesman, 2020).

6.1. Automation in Laboratories

On any given day, health professionals, most often in hospitals, will collect samples of tissue, blood or other body fluid from patients for analysis. Such samples are analyzed in medical laboratories for traces of the presence of diseases. They scrutinize and analyze samples of blood, tissue, and fluids using chemical analyses, microbiological cultures and other methods. Normal functioning in laboratory medicine goes hand-in-hand with health care. Hospitals would not be able to function without the information generated by laboratories. Most medical decisions depend on laboratory results. This in turn depends on a major innovation in medical laboratories efficiency, automation. This would be reflected in the implementation of clinical analyzers as making routine laboratory testing of the future. Total Automation in diagnostic medicine has resulted in rapid advancement in the hardware and software of clinical laboratory analyzers. Almost instant diagnosis by a clinician or pathologist calls for quick, reportable and accurate results, utilizing cost effective means. Several models available offer fully automated clinical analyzers constituting three major components: sample probe, different types of detectors that measure results of the reactions between reagents and samples and a microprocessor that converts the electronic readings into reportable values. The manual exchange of different detection cells allows measurement of a variety of parameters. Avidity test as one of the AIDS parameters may be scrutinized well in some of the detectors so, redundant use of the venal patient sample is always assured. Robot devices notify of the movement dynamics.

Increased cost pressures and rising testing volumes are being exacerbated by a shortage of trained technical personnel. Automation solutions are coming to the fore due to their ability to reduce both labor and operating costs in clinical laboratories as well as improved patient care. Outpatient testing results often are required before a physician sees a patient. All the more need for hospitals to promptly report results on all critical care patients. Because there is this ever-increasing demand

for urgent testing results, there is a lot of automated systems becoming available to try to take ground on that. Trying to decrease the length of time required to produce a test result. Because there are any number of other factors involved in doing the assay. Trying to minimize the human involvement in sample preparation and testing. On a laboratory perspective, it increases the throughput. With most of the analyzers and systems having a full two-way interface operation; directly from the requesting clinician, all the way through the analytical system, finalized reportable result will interface back on the computer network.

6.2. Digital Health Records

The diagnostic process occurs over time and often involves multiple healthcare professionals across different care settings. The measurement of diagnosis is further challenged by the traditional structure of health records, often in an acute care environment, which can fail to capture critical clinician and patient narrative. Indeed existing ICD-coded health encounter data do not explain how healthcare decisions are made in response to illness and results. In addition, they do not adequately capture signs and symptoms, and the detailed and often inexplicit narrative that informs otherwise simple decisions. Beyond this, recent advances in artificial intelligence and natural language processing tools also provide fertile ground to improve and enhance understanding of this process. However, the requisite granular data to facilitate good quality clinical natural language processing is typically held with paper health records, which are, by their nature, unstructured, unsearchable, and exceedingly difficult to anonymize in meaningful ways. For these reasons, paper records are often not shared beyond their originating Department or Ward, let alone across Specialties in different institutions. Such sharing is vital for effective long-term large-scale evaluation.

To ensure the seamless flow of and access to patient information, interoperable electronic systems that follow common standards are critical. Over the past decade a series of changes in the U.S. with the Health Information Technology for Economic and Clinical Health Act have necessitated significant adjustment in how patient information is captured, stored and accessed. This work focused on the impact of electronic health records on the operation of the primary care physician's (PCP) office and presented evidence supporting an alternate model suggesting a positive impact, while also highlighting their potential to improve the quality and continuity of the care process and supporting the patient-PCP interaction. It is based on 228 in-depth interviews conducted in 2009 with front-line health professionals in three study areas in New Zealand: National Health IT Plan; Rural and Remote Practice; and Longitudinal Health Records. Each area facilitated a number of individual studies, and these were synthesized using metasynthesis to inform four strategic dialogues. At a time of rapid development of health IT applications, issues and concerns were identified that are globally significant. Finally, the often-held claim that electronic health records are a technological failure due to underuse is challenged. There are important further potential benefits in addition to evidence of current contributions, particularly in the monitoring and improvement of safety and quality in health care. The results also have international significance as many countries have begun the process of implementing this technology (Georgiou et al., 2021).

6.3. Telemedicine and Remote Testing

In times of pandemic quarantines and increasing travel restrictions, telemedicine has become a vital health-provisional service. Inpatient testing strongly relies on the activity of certified medical laboratories, making the necessity to set up remote electronic support of laboratory practice in unreachable areas more evident (A. Schroeder, 2009).

Suggested here is the fourth generation of laboratory telemedicine, the telelaboratory tool providing remote consultation with a laboratory technician. It may become a part of an emergency telemedicine apparatus, using general-purpose equipment solely. The constantly flowing blood of an engaged person is under thorough biochemical control of the homeostasis system. There are inherent safety reserves in the system for any of the main physiological factors, but as soon as the reserves are depleted or the controlled function fails, an emergency threat occurs. Though the causes may be quite diverse, one of the roots is frequently a violation of the chemical concentration stability in the blood. The violations may be either sudden, like poisoning or trauma, or slow cumulating cases, like diabetes or different chronic diseases. In both cases the timely medical decision is essential.

Majority of the decisions are in fact based on the chemical blood testing, the rather challenging set of laboratory analyses. Therefore the patient should be delivered to a physical entity with a properly organized and certified medical laboratory, which leads to the understanding of the rural citizen's concerns about the health care in general and in the terms of pandemics quarantines and travel restrictions in particular. On the one hand, it may be that the main rural doctor’s station is too small to host a licensed lab; on another hand, the travel to the lab (and to the specialist as well) may be hampered under the new restrictions. With these concept in minds, we can pose a relevant question of the possibilities to provide the full-featured medical laboratory services for the virtually unreachable areas.

1.10 7. Interpreting Laboratory Results

Interpretation of blood microbiology results may be one of the most challenging functions of clinical microbiology laboratories. The treating clinician often turns to the microbiology laboratory to obtain expert advice on the probability of isolating a pathogen from a specific clinical specimen or on the clinical significance of a specific isolate obtained. The clinical microbiologist can advise the treating clinician concerning the differential diagnosis, sampling techniques, and detection methods most likely to provide the appropriate information and facilitate the diagnosis. As a bacterial pathogen, the sooner it is detected, the better the chance the patient will be cured. For the prompt diagnosis and treatment of the most serious bacterial infections, the ‘window of opportunity’ is narrow, with rapid detection methods being essential. Alongside the traditional gold-standard blood culture technique, microbiological methods that greatly reduce the time from sampling to obtaining a relevant result are gaining increasing utility. Molecular biology methods are also viable for the rapid detection and identification of pathogens directly from aseptically obtained blood samples (Kristóf & Pongrácz, 2016). When a blood culture exhibits substantial microbial growth, an important function of the microbiology laboratory is to notify the treating clinician immediately. Suitable antibiotic treatment begun immediately after the onset of

bacteraemia can vastly improve the outcome for the patient. The clinical microbiologist may provide important guidance concerning the clinical significance of blood isolates. It is observed that between one-third and one-half of blood culture isolates are either contaminants or isolates whose clinical significance is unclear. To optimally utilize blood culture and other microbiological diagnoses, direct communication between the microbiologist and the treating clinician should be established.

With more than 500 million primary care visits annually in the United States, it is estimated that it is approximately 23 million times each year that primary care physicians are not sure which diagnostic test is the best to use. Inadequacies in laboratory medicine education not only compromise patient safety but have also been shown to represent a significant budget cost with unnecessary tests that must be replicated. A laboratory formulary is analogous to a pharmaceutical formulary and can be employed in a variety of manners. Even though the number of outpatient requests for pathology in the secondary care setting is much less than primary care, test costs are a significant concern. Many laboratories now have a laboratory formulary dedicated to their specific tests, which can assist the clinician in choosing the correct test in specific situations (B. Freedman, 2015). With a greater emphasis on personalised medicine and genomic testing in the future, the tendency is to employ the laboratory formulary to address inappropriate ordering of expensive molecular and group tests.

7.1. Understanding Test Results

Patients often find themselves on the way from a hospital or a clinic, awaiting medical laboratory analysis results and they might have a lot of questions. Why are they given such unique analysis among a variety of others? What does it mean? What should be feared and what should be hoped for? What will happen after submitting the tests? Understanding the test results is a big task, especially for an outsider in the medical area. But understanding analysis' basic rewards is necessary to avoid primary fears on simple mistakes, such as those caused by violations of general rules for preparing for taking the tests. Otherwise, almost any test can be distorted (Pant et al., 2023).

No one is immune from illness, and there is a need to understand and interpret the results of medical laboratory tests. Most analysis results require different reactions to medical intervention – treatment. When conducting a medical examination, revealing a disease, the main role and responsibility in the further treatment of the disease are usually given to the doctor (oncologist, cardiologist, neurologist, etc.). He should prescribe ingested pill, physical therapy or surgical intervention for the patient. Medical treatment starts on the advice of a doctor after a laboratory test is performed – x-ray, electro cardiogram, etc. Those results will declare the current state of the body. In some cases, the patient can treat self-medication or folk remedies, only after consulting a doctor, and in some cases, it is mandatory to consult a doctor.

Detection and assessment of the prevalence of a disease condition shows the introduction of a screening method and procedure in the far future years. But the responsibilities of a laboratory scientist like most laboratory functions go beyond the mere provision of technical services to patient care. Physicians make diagnoses based on clinical and laboratory investigations. The

laboratory function is crucial to their function whether at primary care levels, the local hospital or more specialized district coverage. The clinical diagnosis has always meant different things at different levels of health care. Each discipline makes different demands on the laboratory, and blood counts are only a small part of what a virologist may want but the accuracy, reliability and timeliness of the results is critical to all of them. Beyond these basic criteria, however, there is growing evidence that many health care facilities either do not appreciate the need or are failing to benefit from the service that a laboratory can supply. This has consequences for patient management, budget surveillance and research (B. Freedman, 2015).

7.2. Common Misinterpretations

Misinterpretation and comments based on published articles in the Clinical Microbiology and Infection are presented below. Particularly, these comments refer to a study published by (Kristóf & Pongrácz, 2016) in 2016: Interpretation of Blood Microbiology Results – Function of the Clinical Microbiologist.

Molecular testing for bloodstream infections: Rapid detection of bacterial DNA can be very convenient. Nevertheless, this diagnostic test has serious drawbacks and many of the results are difficult to interpret. The advantages of PCR testing performed directly from blood are the rapid detection and the quantitative detection. This is particularly useful for the monitoring of the bacterial load during antimicrobial therapy. Nevertheless, the disadvantage is that this method detects bacterial DNA and not viable bacteria. As the DNA detected is not necessary live, there is a good correlation with the recruitment of the immune response, and the same bacterial genome or DNA can be detected many days. Furthermore, many of the results are difficult to interpret. Multiplexing capabilities are not very useful for practical reasons, or the mixing of results is not convenient. Several platforms give a semiquantitative evaluation being expressed as relative light units. Moreover, importantly, the genetic filament of eubacterium will crossreact with many of the TaqMan probes. This kind of testing shouldn't be any more suggested for clinical laboratory, unnecessary comments have to be interpreted.

Overcoming common misinterpretation of molecular blood tests for bloodstream infections: Medical microbiologists are invited to better know the technical features of the commercially available molecular tests for the diagnosis of bloodstream infections. The largest observed discrepancy was registered for genital and skin commensal species. A review evaluating the available diagnostic modalities for bloodstream infections is informative. After the review of the currently available diagnostic palette, attention should be raised to the fact that conventional blood culture testing is still necessary to assure accuracy. The direct molecular tests and the blood culture diagnostics can reveal to be complementary. Several studies showing that the two methods agree in 55-85% of cases, depending on the patient population studied. Nevertheless, such an agreement can be improved by a better sample management. Moreover, the agreement can rise to 80% of the episodes if the contaminants and the skin contaminants are excluded. Finally, to fully exploit the benefits of blood culture and to direct diagnosis, the microbiologist and the clinician should interact directly and discuss both the differential diagnosis as well as the treatment options.

1.11 8. Challenges Faced by Medical Laboratories

In an era of overlapping public service cuts by local and national government in most developing countries, medical laboratories have been identified as the poor or forgotten relatives in the medical and public health service sector. For most patients, medical laboratories represent an area they attended once or twice in life (either for a blood draw or to deliver samples); a cold and unwelcome area, full of weird terms and equipment, where stuff is done for the doctor which can give more accurate information about the state of the patient's health. Medical Laboratory Medicine is essential for the physician; approximately 70% of the entries in a patient's note deal with the result of a test performed in the medical laboratory.

However this dimension of routine laboratory testing and service is far from true in the everyday life of the medical laboratories work. In rural medical labs, the reality is much more cruel and involves very limited human and technical resources, many absent basic reagents or electric power cuts in the most critical moments. In these labs, passionate staff deals with large numbers of samples the best they can despite the bad working conditions, lack of reagents or unnecessary bureaucracy. Frequently young and inexperienced personnel is obliged to learn by doing, risking frequent accidents to themselves and the patients. And the situation should be rapidly improved.

Inappropriate ordering still represents one of the pathologies number one of laboratory medicine, causing not simply delays in diagnosis or treatment but also unnecessary exams with an ethical and economical impact for the health service. Moreover inaccurate drawing, unsuitable containers or treatments of blood specimens might ruin the resulting sample, cause artifactual findings and make impossible to read the requested examination. With an emphasis on teaching basis, the difficulty for the laboratory personnel is pervasively to cope with the gap between the applicative field and the very broad theoretical background which stands behind medical laboratory analyses. Essentially of technological consistence, this last one is hard to seize and assimilate rapidly in a professional field where operators are in contact with any specialty of medicine. Furthermore, the very complicated and extremely variable contents of laboratory medicine require a continuous update of the available information, focus only possible, in scarcely equipped departments. Holistic approaches apply only to limited sectors of laboratory medicine and the technological acceleration enormously improved the machines, but not the operators. And machines don't think: most diagnostic errors in the lab are due to wrong validation, QC performance, error in judgment on results. This tends to shift the responsibility of the error from those who really did the mistake.

8.1. Regulatory Compliance

Clinical diagnostic laboratories play a crucial role in the diagnosis and management of diseases. Patients, especially those with complex cost-effective care, often require multiple diagnostic evaluations to support optimal medical care. In addition to provision of routine laboratory tests, medical laboratories develop and provide novel tests and methodologies, some of which are offered only on a regional or local basis. Medical laboratory services and their respective practices are diverse and complex, and their quality is regulated by a combination of federal and state laws and accreditation standards, many of which are based on the Clinical Laboratory Improvement Amendments of 1988 ((L. Kaul et al., 2017)).

In recent years, there has been increasing concern expressed by certain stakeholders regarding the quality of laboratory procedures that are developed and performed within individual laboratories and not regulated by the US Food and Drug Administration (FDA). Despite strict oversight of analytic laboratory testing procedures performed in the US by a combination of federal and state regulatory and accrediting agencies, one class of clinical tests that are developed and subject to validation in each individual laboratory have been contentious in recent years. Such laboratory-developed procedures (LDPs) are typically advanced or high-complexity assays, including the emerging field of molecular diagnostics. This controversy is being fueled at least in part by the advent of new types of testing methodologies.

8.2. Staffing and Training Issues

Medical laboratories, either as stand-alone facilities or as part of healthcare facilities, play a pivotal role in the diagnosis of diseases. Laboratories rely on the results of testing performed by the laboratory staff to facilitate clinical decisions about an illness or condition and about potential treatments. Testing is performed on many types of specimens such as blood samples, urine, feces, exudates or tissue biopsies, sputum, and swabs. There is a variety of medical laboratory departments and these are staffed by wide ranging disciplines such as microbiologists, clinical biochemists, hematologists, histotechnologists, cytotechnologists, and pathologists. There are many different working environments within the laboratory and each area caters to the different testing needs of the patients.

Staffing within the laboratory setting, particularly in a resource limited setting, may be of limited capacity or lack of the required training. This may translate into certain safeguarding not being in place or monitoring of the laboratory staff not in practice. Here, basic staffing and training requirements for the medical laboratory will be addressed to ensure that the needs, not only of the laboratory staff, but of the safety of the patient and wider public health, are adhered to. Many medical laboratories have no pathologist and other staff may not hold higher education levels (Kim Ong et al., 2020). Technicians are thus left to run the majority of the laboratory whom may have only undertaken post-secondary education, usually with a focus on tasks other than disease diagnosis. Rather than using the skills of a dedicated, trained laboratory technologist, clinicians are often compelled to investigate their own testing to aid diagnosis, a method that is seldom conducive to safe practice.

When considering a new medical laboratory, as part of a new health clinic, laboratory space should be considered, specifically how to best serve the patient needs and offer a safe working environment for staff (C. Iwen et al., 2018). Staff should be cross-trained between different testing areas to ensure laboratory continuity should staff default due to illness. Proper training should be provided and qualifications and monitoring processes should be also in place to ensure optimum laboratory conditions. New lack of microscope equipment might render current STI testing practices not applicable, again prompting a deviation or stop to said activity. And of course, obtaining the wrong test results due to testing staff not being adequately trained poses unnecessary risk to patient and community. The availability of resources and risk assessment processes should

be considered in choosing the methods of testing; training of the staff rendering the testing methods and the biohazard risks the methods pose should be well thought.

8.3. Financial Constraints

In-vitro medical examination (IVD) is clinically utilized for the prevention and treatment of diseases. IVD is conducted using primary human specimens such as blood, tissue and urine, and is significant in the discovery or measurement of substances in a living organism to get the information. A clinical laboratory or a medical laboratory is a where the examinations of medical specimens and the results obtained are for the purposes of diagnosis, prevention or treatment. In-vitro diagnostics is a method that uses reagents, specimens, standard materials and systems for diagnosing the state of a patient's disease by examining those found in human body specimens or in vitro cultures. As a result of diseases become more and more diversified and complex, the range of necessary examinations is wide-ranging, and modern medical care is inconceivable without extensive use of various sorts of laboratory tests. Medical examination laboratories are present worldwide and provide a variety of tests for the diagnosis, treatment or prevention of diseases. The physician prescribes laboratory tests to aid in identifying the causes of patients' symptoms, to make judgments on their health status, and lifestyle changes or medical interventions required, or to monitor the treatment progress. In 1976, a study about a good performance of medical examinations laboratories in the condition of limited financial constraints during a period of approaching government financial cutbacks. But some publications maintain the capacity was reduced by a hard cap on tests which is below the in-attendance testing level - it eliminated the choice of which tests might be limited, and therefore a good laboratory director might not be able to retain the most important tests, especially as physicians had become accustomed to the laboratorial service. To be able to offer a wider range of tests than were available in the host laboratory in order to attract client fees. Such tests could be charged at full economic cost and so contribute to the support of the laboratory as a whole. Thus, with small loss-making but strategic wards looking elsewhere, the overall level of activity or 'through-put' within the laboratory was reduced, further throttling capacity. These arguments are supported by the results from a detailed study of the responses to government cuts in specific categories of testing by a large group of privately funded public service laboratories. On the whole, service to the electorate was comprised by a capping of activities and environment variables remained dependent on the day of the week. Specifically, service was reduced by a marked decrease in 24-hr laboratory facility throughout a large number of groups of tests. However, the dramatic reduction in medical admissions to hospitals made its impact very much more difficult. Hence, its importance in influencing the decision-making of laboratory users direction for payment was greatly reduced.

1.12 **9. Future Trends in Medical Laboratories**

And what does the future hold for clinical pathology and clinical microbiology? Probably, the organization of many hospital laboratories is not optimal at present, with the current move toward a more centralized operative fashion. Clinical microbiology has become of great interest because hazards arise from pathogens, especially in cases of antibiotic resistance. Several laboratories have developed processes permitting fast identification of pathogens. In the future, these will be

completed with rapid automated methods. The cost of the process is often compatible with testing only the front line, poorly adapted to point-of-care testing (Raoult et al., 2004). Autosystems will be produced for the same cost, allowing these tests to be performed automatically. The regimen to be tested will be decided by algorithms established with clinicians, pathology data and the rules of infections diseases departments. In the future, it is likely that microarrays will be adapted to clinical microbiology, allowing several parameters to be tested simultaneously. These systems are super fast – about 1 h – with a maintenance cost of about five to ten dollars by test and could be tested on all fronts. The pathology-driven perfect killer chemistry process is presently adapted to microbiology, which is based on several sequential monophasic processes. This process will be adapted in order to use only one reagent and the sample. It will not be possible for a cost of about $ 5 to test this kind of process on all fronts. In the present era global epidemiological trends of pathogens have been followed, but the fast trams will allow easier follow-up of epidemiological trends in hospitals and in the community. In the future, similar automation will be adapted to hospitals and other community services. At the same time automated methods will also be adapted to the molecular diagnosis, especially of a critical resistance of key antibiotics. This is a task for hospitals. Automated systems will allow them to follow this resistance, reflected by the proportion of relevant mechanisms, either by genes or by contributions of the porin MUT. The results will be organised on a UserNet server. Bacterial resistance is developed in hospitals. With the mobile information it could be followed on line. This information will be updated weekly. The pharmacokinetics of each antibiotic is itself difficult to know and will be quickly available by nuclear medicine at the same time. A joint process – the algorithm process – will quickly indicate resistance to an antibiotic except in group patients. Weekly tabulations of trends in microbial antibiotic resistance could help hospitals make empirical recommendations for antibiotic treatment, based on an analysis of the level of resistance and of norms used by the most resistant bacteria.

9.1. Personalized Medicine

Modern molecular medicine likely commenced in 1869, when Friedrich Miescher discovered DNA. A milestone was passed in 2000, when the three billion pairs of human nucleotides constituting the human genome were unraveled. Completion of DNA sequence of the human genome presented an opportunity to move the field of medicine in a predictive direction. Soon after its completion, it was obvious that the list of huge potential achievements was accompanied by even larger barriers. No one suspected how difficult translating the genome into the clinical arena would be. Among researchers, however, there was at least caution, as K. Raddassi and B. Ubhi dialogue illustrates: “I spent a decade on the 50 million-nucleotide genome of drosophila an initially fully funded project that dragged into a kind of vague state”. Several obstacles were anticipated. It was noted that drug discovery was originating in university settings was at an all-time low. Regulatory hurdles were ominously high and even academia felt the pressure of commercialization.

Dawn of the post-genomic era represented a new spring. Likely immediate changes consist of minimizing fractional use of failed medications, accelerating successful drugs scientifically,

disentangling un-enhanced effects in non-responders, and possibly the easiest, modifying drug delivery by taking metabolic or functional performance parameters rather than demographic uniformity. The Human Genome Project published a draft of the complete DNA sequence of the human genome. The final sequence was completed in April 2003. By 2016, the costs to sequence an entire exome had dropped to less than $1,000 and high-yield commercial genetic testing became available and affordable. The field is moving extremely quickly with efforts to better understand portions or the entirety of a person's genetic make-up and how to tailor drug or medical interventions based on those elements (F. Nassar et al., 2020).

9.2. Point-of-Care Testing

Point-of-Care Testing: Current Issues. Point-of-care testing (POCT) is a laboratory-medicine discipline that is rapidly evolving in its analytical scope and clinical application (B. Luppa et al., 2011). At present, POCT ranges from the simpler blood–glucose measurement to recently introduced complex viscoelastic coagulation assays. Although most medical testing has a focus on the gauging of blood or urine components, tests using other materials are also available. An example is sweat sampling. These are used in conditions such as cystic fibrosis and for drugs of abuse. Tests may be automated or rely on manually read strips. They are often competitive immunoassays but can also be used for the action measurement of an analyte. Assays may be designed for specific molecules or used to monitor chemical behaviour, as in sweat conductivity testing for total sodium ions. The mechanisms for device performance can vary. Factors that may affect device performance, and hence test accuracy, include the need for sufficient sample volumes, sample contamination, cross-reacting analytes, and environmental absorbances. Coexisting medical conditions can interfere with some tests. It is important that Point of Care Testing (PoCT) devices are functioning properly. Accurate dermatophyte identification is usually warranted in cases of tinea incognito, superficial mucosal infections, onychomycosis, in recurrent episodes of dermatophytosis despite appropriate therapy, and when the lesions are refractory to therapy. There is a need for harmonization between device standards and PoCT device precision. The rate of increase in PoCT device use outpaces that of laboratory and portable testing systems. Identifying reliable methodology from the available literature can be challenging. Consideration of analytic imprecision and examination of calibration standards are crucial in differentiating genuinely 'poor' method comparisons from those that are improperly conducted or excessively critical. Centralization is important for long-term stability and the availability of external quality assurance can help prevent temporal bias. Conversely, positive bias and high measurement ranges in PoCT devices may result in overestimation of results. Another consideration is the mode the devices are to be used in and what devices are already available in current practice. And, the effects of temperature variation on one testing system may be exacerbated in routine use with multiple systems of differing design. For the most informative comparison, the subject pool should reflect that of the target population.

9.3. Integration of AI in Diagnostics

Medical laboratories play a crucial role in disease diagnosis and patient care. Positions in medical laboratories are typically considered uneventful in the sense of providing general medical services.

However, on the other hand, the importance of this position is growing because prior to further diagnostic and treatment measures, usually, confirmation or exclusion of a disease is made in either pathology labs, or clinical labs, both of the areas relying on quantitative tests results. During only a half-day work of a normal medical laboratory during busier times an average of more than 1000 individual tasks are processed by an average of 200 different clients, doctors. In addition to statistical deduction of the severity of the number, the importance of many test results is also very high as several critical diseases, diseases with severe consequences, diseases with only a short time to initiate treatment, etc., are detected. By the help from recent improvements in technology, AI solutions could simplify many daunting endeavors in different medical fields (Cadamuro, 2021).

1.13 10. Case Studies

The quick diagnosis of an infectious disease is crucial when infectious disease emergencies occur. In these settings, medical laboratories have a pivotal role in patient recovery. In light of recent trends, medical labs operate advanced testing, including the various options for molecular diagnostic techniques to detect viruses, bacteria, and other infectious pathogens. From the viewpoint of the clinical symptoms and laboratory test results of patients, this study has proposed a method to assist in the quick and accurate diagnosis of infectious diseases during emergencies by combining the source of infection and possible infection situations (K. Krishna & M. Cunnion, 2012).

Three case studies are presented on the application of the proposed method in an infectious disease emergency to show its effectiveness. The first case study describes a non-infectious disease patient infected with MRSA during treatment. The second samples acne patients in a small clinic. An acne patient was afterwards reported to be infected by healthcare-acquired MRSA when generating the sterile insects. Equipment offered in the contact area with a patient has been observed as the source of infection and has been used to find the patient infected. The third case study involves a large number of patients with an unknown fever-resistant illness caused by a new unidentified virus. The source of contamination, an epidemic infection, and the outcome of this newly identified virus, are questionable.

The various options for molecular diagnostic techniques to detect viruses, bacteria, parasites, and other infectious pathogens are pursued to speed up the identification and early warning of a viral agent in the event of an emergency. In order to appreciate the wide-ranging implications of molecular biology's potential for infectious disease management, a brief description of the major technologies involved will be made. Clinical and economic incentives for developing new approaches to the management of infectious diseases will be described, as will the operational requirements that these technologies will need to meet.

10.1. Successful Diagnoses through Lab Testing

A 52-year-old man with a recent diagnosis of untreated HIV infection presents with 1 week of headache, neck stiffness, fever, and vomiting. A CT scan of the head is negative for hemorrhage or mass effect. CSF analysis demonstrates a pleocytosis with 650 nucleated cells of which 97% are lymphocytes. The CSF protein is 120 mg/dl and glucose is 35 mg/dl (serum glucose 80). Gram stain is negative. Culture of CSF is pending, and empiric treatment with ceftriaxone and

doxycycline for possible tick-borne infection has been initiated. The laboratory is called with the following questions: What is the possibility of obtaining a rapid CSF test for West Nile virus PCR and does it make sense? Also, what is the sensitivity and specificity of Dengue fever serologies, and when can the results be expected? An immunocompromised state due to HIV infection raises the possibility of opportunistic CNS infections such as Cryptococcus neoformans, Mycobacterium tuberculosis, or other organisms not typically considered for infection in a normal host. The safest approach is to optimize antimicrobial therapy pending the identification of an etiological agent.

The patient's clinical picture is most concerning for acute viral meningitis. In a non-endemic area during the spring to fall seasons, enteroviruses are responsible for most cases of viral meningitis in adults. West Nile virus can present with a similar clinical picture but can also have an encephalitic component leading to altered mental status. However, the patient does not have any focal neurologic findings. It is unclear if severe headache is sufficiently specific for this purpose. Symptoms are nonspecific and can overlap with other processes. In the United States, West Nile virus has been the most common cause of arboviral meningitis and encephalitis especially in the late summer and fall months. However, even in areas of high endemicity, turnaround time is typically days to a week. In the setting of an infectious disease emergency, real-time PCR has become the standard of diagnosis for many infectious disease emergencies in either monoplex or multiplex format. For most small clinical laboratories, the implementation of advanced molecular techniques is not feasible due to a high cost. 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 one day. It is anticipated that commercial real-time PCR tests will become more standardized and affordable, allowing individual laboratories to conduct tests locally, thus further reducing the turnaround time. Also, all viral diagnostic tests are dependent on the timing and quality of the specimen. Early in the illness course, viral titers can be very low and may thus confer false-negative results on laboratory testing efforts.

10.2. Failures and Lessons Learned

The purposes of this research on root cause analysis into high error rates in clinical pathology were to examine the nature of errors resulting in the high rejection rate at the pre- and postanalytical phases and to recommend preventive measures. Another aim was to explore a broader view of the applicability of root cause analysis in quality and safety aspects of the medical laboratory. There have been only a few reports describing root causes of laboratory errors. However, common failures in laboratory medicine have been often reported. Patient preparation is essential for blood collection and an appropriate phlebotomy site preparation allows the blood collection to be performed with minimal risk of contamination such as in skin puncture. There are also several factors during laboratory sample transportation. These factors were rarely communicated to the user departments in the previous procedures, resulting in many sample rejections due to transportation temperature and conditions. Also, no preventive action was taken in the laboratory even after the temperature was known to be inappropriate. The rejected sample was delivered if there was no problem in the tests. This procedure raises questions about the responsibility of the laboratory. Thus, the sample rejection due to transportation was then classified as a user failure. It

is clear that sample rejection due to wrong date/time is not included in laboratory responsibility, as the user departments should have communicated the correct instruction to the laboratory.

1.14 11. The Ethical Considerations in Laboratory Testing

The role of clinical medical laboratories within the health care industry is to aid in the diagnosis of patients' conditions in order to prevent morbidity and to monitor and/or treat existing morbid states. The findings generated within laboratories are important pre-requisites for over 80% of medical diagnoses despite accounting for only 3% of total expenditure on public health. In addition to analytical methods, medical laboratory facilities include pre- and post-analytic services and support such as specimen collection, transportation, preparation, storage, disposal and the management and transmission of results. The nature of laboratory activities within this context renders it a well-suited focal point for a range of ethical challenges and considerations. It should be expected that any consideration involving the advancement or alteration of laboratory practices should, at a minimum, account for ethical considerations in advance. Honest reporting does no good when antimicrobial susceptibility testing (AST) is not made available until after empirical therapy decisions are already made, or media containing sensitive growth supplements fail to produce growth even when the pathogen is cultured (B. Freedman, 2015). One of the most pervasive issues with the auditing and regulation of medical laboratories is the discordance between the fast pace of technological advancement and the relatively slow updating of legal frameworks to include these advancements. Depending on the source, albeit similarly observed, this discrepancy persists by as much as six years per instance. Justifying this delay in updating legislature, including the subsequent lack of concomitant compatibility with internationally recommended laboratory practices, is a lack of knowledge and the high investment required collectively by policy makers, health officials and by the regulatory agencies themselves. Inadequate knowledge of such advancements may also contribute to deficiencies in the instigation of entirely new internationally recommended laboratory practices and to differing degrees within routine local practices.

11.1. Patient Privacy

In a study of 436 outpatients of internal medicine, orthopedic surgery, and psychiatry, patients were asked about electronic medical records in general and specifically about access boundaries. Patients largely welcomed the idea of a computer-based medical record, but attached conditions to access, including physicians specifically related to care, no government agencies, and a complete listing of every time someone views their record (Wright Clayton, 2006). On average, patients wanted to be aware of every time their record was viewed by another party for treatment, payment, and health care operations purposes (even if that meant dozens a month). Patients' desires to have a say in the boundaries of access to their medical record was consistent across site, race, sex, age, and overall attitude toward electronic medical records. Findings suggest that many patients desire a degree of control over the privacy of their medical information.

The question about the privacy of medical information can be stated simply: To what extent can and should patients control what the medical record contains and who has access to it and for what purposes? Patients often have apparently conflicting views on this subject. On the one hand, we,

as patients, say that we prize privacy and that we fear that information will be used to harm us. Patients also tend to express concerns that sensitive information will not be included in the record because of concerns that it will not remain hidden. Paradoxically, however, we are quick to forgo privacy for clinical benefit, agreeing that sensitive information must be included in the record for good care and that we trust healthcare providers' use of the information. Given the conflicting desires of patients, it is not surprising that there is continuing controversy about the proper balance between privacy and utility. On the one hand is the concern about the erosion of the confidences that have been the hallmark of the healing professions. On the other hand, there is worry about the consequences of a rigid rule that might inhibit care.

11.2. Informed Consent

The process of obtaining informed consent is, at its very essence, a process of information exchange. 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/receive treatment or not. If the answer is yes, they will confirm this by signing the consent form. The research ethics committee (REC) or institutional review board (IRB) has the function of ensuring that the research design is in accordance with the relevant ethical standards. For this reason, research ethics committees have to evaluate both the informed consent process and the informed consent form used (Borovečki et al., 2018). The process of obtaining informed consent can be considered as having two elements: the gauging of the voluntariness of the subject's decision to participate, and the adequacy of the information presented to the subject. As every clinical and scientific research evaluating the ethics of laboratory medicine requires ethics committee approval, these committees should be more involved in the safe-guarding process of patients and participants. The relationship between the two sides is bilateral. Researchers have to be sure that from the clinical point of view the laboratory tests which result in severe consequences are requested with the informed consent of all participants. The same happens with the new and experimental laboratory tests. The informed consent process is part of the work that has to be documented, as well as research protocols. Here all research protocols dealing with laboratory medicine have to explain in detail which laboratory tests will be performed, and detail how they will be given informed consent. Since the research ethics committees are often multidisciplinary, laboratory medicine specialists should also participate in this activity and should evaluate such research protocols. In this way, these specialists will improve their scientific standards, as well as their ethical and legal outcomes. On the other side, laboratory medicine has to implement research ethics committees in their procedures. This kind of cooperation could prevent a large spectrum of unwanted problems. The procedures performed in medical laboratories are based on the analysis of biological material taken from patients. Always a treating physician takes this material by establishing a doctor-patient relationship. By the referral, he will describe what should be analyzed, and he will get the right results back. However, in some cases, subjects are taking blood or urine in laboratories by themselves. Other researchers are trying to prove this hypothesis and confirm that collecting blood and performing a laboratory test in a non-medical environment is not the same as in a medical environment. Thus, with the other results hypothesis is confirmed. Nevertheless, information

exchange between the laboratory technician and the patient should be standardized. In that direction is helpful to establish a reprogram of patient's instructions and to perform regular training of laboratory technician. On the other hand, in most cases of critical laboratory results are not communicated to patients, but to the referral, the treating physician.

1.15 12. Collaboration Between Laboratories and Healthcare Providers

The professional dialogue between laboratory professionals and healthcare providers is of utmost importance in optimizing laboratory services and enhancing the value of the laboratory for patient care. This paper explores that dialogue, which is essential to developing a common understanding of the correct and cost-effective ordering of laboratory tests. It addresses issues surrounding coding of laboratory tests, the interfaces between laboratory and the other information systems of a healthcare setting, disturbances in laboratory testing options, interruptions in laboratory services and the results from external quality assessment in laboratory testing of process, which are relevant to all industrialized countries.

Laboratory physicians and laboratory scientists are responsible to healthcare providers for ensuring reliability and cost-efficiency in their professional services. The practices of the laboratory are determined by these specialists, while most laboratory analyses are performed by other professionals, laboratory technicians. In further discussion the term 'laboratory professional' is used instead of a narrower concept like 'laboratory technician' or 'laboratory physician'. With the advances of technology and automation in laboratory analysis, the procedures of testing can now be done by very few people. However, the traditional division of responsibilities has been preserved. While this division can foster efficiency and productivity, it may also result in conflicts of interest and misunderstanding. Responsible laboratory professionals and healthcare providers must therefore ensure that there exist adequate channels of communication between them.

While the rapid advances in increasingly sophisticated diagnostic tests now require that the healthcare provider must delegate responsibility for a large part of the testing, modern medicine still relies on a tradition of close connection between the diagnostic processes and the activities of clinicians and surgeons. Healthcare providers have to be well informed about the whole chain of events leading from clinical symptoms, via diagnostic tests and interpretation of the test results, to further action. In some specialties and in some diagnostic tests it is obvious and natural how this chain of events works. With evidence-based laboratory medicine assuming facts from laboratory verification of medical hypothesis, laboratory tests are becoming an increasingly important part of clinical examination, and the correct understanding of what information laboratory tests can or cannot provide is vital. On the contrary, much on the potential and the limitations of different laboratory tests may not be understood by anyone without professional training in laboratory sciences.

1.16 13. Public Awareness and Education

Awareness and education of public is necessary to overcome the constraints and increase the reporting practice. Media campaign for reporting is not common in Lagos, knowledge of the over-all-notified diseases may encourage report among the laboratory scientists when there is a difference in familiarity with the existence of notifiable diseases, awareness of at least the top 20

notified diseases is necessary; and the more familiar these diseases were, the better the possibility of reporting by the laboratory scientists (D. Dairo et al., 2018). Trained laboratory personnel could play an essential role in identifying the notifiable diseases at private medical laboratories and it is necessary to notify the concern authority at the district level, it is widely understood that private laboratory scientist have good access to rural community people in search of a care.

The common ailments are malaria (38%) followed by typhoid (32%). The prevalent rate of malaria and typhoid would open a wider window for harm and assist the following officials to focus upon urging these laboratory scientists to notify in case of infections to control the probable disease outbreaks. The private medical laboratories are operating by BBS staff and they are selected by the educated people in the locality. Thus it is exceedingly assumed that these laboratories have the availability of the basic facilities needed for diagnosing diseases and recommend treatment. Keeping that assumption in mind, further measure should take place through launching of an expansive campaign to concentrate the notification of the concerned diseases diagnosed at these laboratories for the averting of any possible situation to happen.

13.1. Promoting Laboratory Services

As international health care partners attempt to improve clinical outcomes in many corners of the developing world, bottlenecks at peripheral medical laboratories must often be addressed. Through on-the-ground implementation and on-site assessment, it becomes clear that referral medical laboratories in district hospitals represent a final common pathway for the diagnosis and treatment of many serious public health risks, including HIV/AIDS, MDR-TB, and acute renal failure. In contexts of limited resources and knowledge, these risks can be more effectively managed through the structured establishment and evaluation of medical laboratory quality systems (Toni Maria Tadeu & Geelhoed, 2016).

Medical laboratories perform a vital role in the verification and investigation of a range of health conditions, through the performance of numerous diagnostic tests on diverse body fluids. Results are delivered to clinicians using an extensive referral network. A delay or error in a laboratory result can often have dire medical consequences. To function most effectively, such laboratories must fulfill a number of pre-analytical, analytical, and post-analytical criteria. The laboratory network in Tete Province is profoundly under-resourced with few functioning quality indicators. With the intention of sensitising regional medical decision-makers to these problems and aiding in the development of a systematic resolution pathway, an assessment of the district hospital laboratory network in Tete is herein presented. This situation is particularly dire in a context of decentralisation, as peripheral laboratories are required to manage an increasing patient load despite limited resources, infrastructure, supply chain reliability, and training, thereby affecting diagnostic possibilities and patient care. Actions taken to date by health authorities in Sofia Macuacua and Tete province are described, as are recommendations from the research team for a coordinated response.

13.2. Community Engagement

Public health laboratories play a key role in the diagnosis of diseases through co-ordination and facilitating the network of laboratories in diagnosing the diseases. They act as referral laboratories

for conclusive diagnosis of clinical cases when requested by peripheral laboratory. They also undertake active surveillance to diagnose diseases early in the outbreak and provide adequate support for control measures. A push based project was implemented in Pakistan to test and validate a mode of co-ordination and communication strategies between public health services and laboratory network officials without directly influencing to identify challenges and solutions for more effective disease control. The project resulted with a customized strategy that successfully boosted interest in improved laboratories and disease control measure among targeted personnel. Medical laboratories play an effective role according to the facility mapping and subsequent classification of districts and high volume sampling clusters sampled across multiple countries. Limited capacity medical laboratories are established in communities with high malaria prevalence. Geospatial monitoring of the spread of artemisinin resistance supports the capability of use space to reduce prevalences of drug resistance in human or parasitic populations. To achieve this medical laboratories must be very careful what conventions and recommendations are followed by retailers, teachers, parents, and patients. But there is potential for immediate change as a result of ongoing, market led events, and this needs to happen in collaboration with laboratory based research.

1.17 14. Conclusion

Continuing from the previous part of the text: SARS-CoV-2, a beta coronavirus genus, shares features of SARS and NL63. However, they differ significantly in symptoms, transmission, and pathogenesis. SARS and MERS lead to severe acute, atypical pneumonia with high morbidity and mortality in a few days. In contrast, COVID-19 is marked by milder infections and a broader community transmission, leading to a pandemic affecting >200 countries in just 3 months (Tomo et al., 2020). Although the virus carrier can be asymptomatic, it still has a viral load that can be infected by humans. Since the symptoms of the disease can mimic those of other respiratory diseases such as H1N1, tuberculosis, transfusion reactions, and Idiopathic Rhinitis, it is essential to perform laboratory tests to confirm if the patient is infected with SARS-CoV-2 or another disease.

SARS-CoV-2 has shone through China's studies following a pandemic in Wuhan since December 2019. As the number of infected 2019-nCoV people increased following the distribution of the spread of the disease, it was necessary to develop and analyze laboratory tests that could enhance the liver function of 2019-nCoV patients. However, the WHO prioritized 45 laboratorium tests that were appropriate for confirming pathogens, including various types of viruses and bacteria. The method used to confirm pathological pathogens is important for diagnosis. The results of laboratory examinations can provide information for the diagnosis, treatment, and prevention of diseases. Laboratory examinations should be performed accurately and quickly to aid in clinical diagnosis and treatment, as they provide objective and scientific well-rounded information. Expertise is required in examining the specimen and examining the results (N. Okeke, 2016).

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