

Enhancing Accuracy and Efficiency of Complete Blood Count (CBC) and Biochemistry Analysis in Medical Laboratories

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Abstract

Complete blood count (CBC) and biochemistry analysis in medical laboratories are routine tests for the diagnosis and monitoring of any disease. In a CBC test, if a sample of blood is mixed with the diluted solution, the elements that form behave in different ways. The red cells settle to the bottom of the solution, but the white cells and platelets are held in suspension. The white cells and platelets are not homogeneous in their distribution; the red cells can settle through the white cells to the bottom of the sample tube. And in biochemistry analysis, the high cost and lengthy time for the several tests for diagnosis were the main drawbacks. To overcome this problem, we are developing an automatic blood analyzer that has an accurate and efficient differential counter. This instrument will eliminate most of the manual procedures to reduce human error and provide an accurate count of different types of cells in the blood. For biochemistry analysis, we are using a Lab-on-Chip device. Since the CBC test and biochemistry analysis are the most commonly performed tests in medical laboratories, the new development of automatic analyzers and lab-on-chip devices will bring a great advantage in terms of rapid, accurate, and multiple analysis results at a low cost. With this great advantage, the new development of CBC tests and biochemistry analysis encourages further research on their clinical applications.

Keywords: *Complete blood count (CBC), biochemistry analysis, medical laboratories.*

1. Introduction

Because data is an intangible and non-storable thing without a report, the primary focus of the data bar is its accuracy and how quickly it gets from point A to point B. As any scientist would agree, a rule set or protocol that would accomplish this is the most desirable. In a

sense, a rule is an IF-AND-OR-THEN statement, a set of logical instructions that manipulate data towards a desired outcome. This outcome can be anything, and the manipulation is a change of information. This is the most elemental sense of what a test is. The successful embodiment of a test by

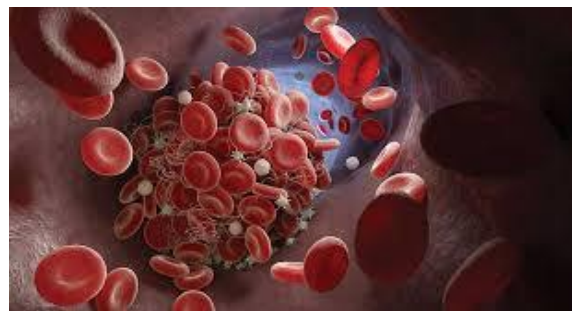
automation means more efficient and accurate analysis.

Included in this data set are many tests specifically tailored to one type of disease state. Due to the congested environment of an overflowing data pool and the demanding requisitions for these tests, this has placed the biochemistry lab findings under extreme scrutiny from the clinician. The high complexity of lab tests means an increased likelihood of error. As with the CBC, errors in the lab can have adverse effects on the patient. Data entry, which might seem insignificant, can result in a patient being misdiagnosed. With a range of different quantifiable results, data entry for the wrong patient or the wrong test in a specific patient can also yield calamitous effects. Errors such as incorrect dilutions or improper assembly of an instrument can affect the integrity of the results. In this event, a repeat test will be performed, but the loss of already consumable reagents and man hours spent to run the test now becomes a sunk cost. Any error that has changed the expected outcome of a test may not be noticed and will eventually result in misinterpretation. The demand for tight specifications and expectations has resulted in a pull for the data sets in both CBC and biochemistry tests to be both accurate and efficient. The data set here means the constellation of words and numeric values that form the complete report of a patient's findings for specific tests. (Pourbagheri-Sigaroodi et al.2020)

The complete blood count, or CBC, is a routine blood test that measures the quantity and quality of the different cells in the blood. These tests to provide accurate data are under constant scrutiny. The quantitative counts are inspected by the laboratory personnel and are rerun if and when irregularities arise. The visual examination of blood smears and their correlation with possible pathology are crucial. This is the gold standard of interpretation; however, rule-based methodologies can achieve an acceptable and sufficient result. This is a universal truth: if winged or non-winged automation is being used, the acceptable result must be both an accurate and an efficient count. These tests are a commodity, and errors in the

analysis can be both costly and detrimental to both the patient and the laboratory. The transformation of the CBC from a manual process to an automated lab test has markedly increased the rate at which these tests are now performed. An important recent study has shown that the use of the CBC has increased nearly one hundredfold in comparison to data from the mid-1970s. A similar trend has been seen throughout the biochemistry laboratory. These tests constitute an array of protocols for analyzing serum, plasma, and urine.

It has been generally accepted that a reliable and rapid laboratory test is essential for patient care. Although clinicians may not be fully aware of the hyphen error, it is a fact that it functions around the clock and around the calendar. When errors creep in, it triggers a domino effect of clinical miscalculations. A patient may be told he is responding to the diuretic for his CHF when in fact his BNP has increased. The transfusion of a cancer patient may be delayed when the scheduled CBC shows erroneously mild thrombocytopenia. CBC and biochemistry analysis represent the most common tests in the hematology and chemistry laboratories, and the results of these tests represent two of the most critical data sets in determining a patient's overall health status, so they are highly demanded.



1.1 Importance of Accurate CBC and Biochemistry Analysis

Despite the prominent position of CBC and biochemistry analysis in clinical decision-making, many studies have shown that there is measurable inaccuracy in the results produced. As a result, patients with abnormal findings may undergo unnecessary further testing to confirm the abnormality. In contrast, failure to recognize a significant abnormality can also

result in the expenditure of unnecessary further testing and incorrect treatment. The potential adverse effects of inaccurate results in these areas are increased due to the large volume of requests in primary care, which is likely to rise with the advent of testing to monitor patients with chronic diseases. In a study by Eigenbrodt et al., it was calculated that per patient evaluated for anemia with CBC, the potentially avoidable cost ranged from \$14 to \$400, depending on the source of the abnormal finding. On a national level, the degree of healthcare resources consumed by inaccurate results could be considered unacceptable. The potential for adverse effects increases further when considering the emerging model of healthcare delivery in the community. Services such as home-based care for the terminally ill or intravenous therapy for chronic diseases are provided to patients for whom attending the hospital is difficult or compromises their immune system. These patients often require monitoring of their condition, which is frequently done using mobile laboratory services that come to the home. The results of these tests are then used to adjust treatment. In these cases, there is no immediate recourse to repeated testing if the results are found to be inaccurate, and results that lead to adverse treatment effects may be difficult to trace back to their source. Finally, for acute medical admissions, delayed or incorrect interpretation of results can impact severely ill patients at a time when life-and-death decisions are being made. A recent study in a single tertiary referral center found that 85% of medical patients had a biochemistry test within 72 hours of their treatment, and the results were the sole basis of a clinical decision in 5% of cases. Considering the potential adverse effects, it is evident that maintaining and improving the accuracy of CBC and biochemistry results is an essential requirement to ensure patient safety and cost-effective healthcare. (McPherson & Pincus, 2021)

1.2 Challenges in Achieving Accuracy and Efficiency

The presence of cells on the peripheral blood smear that can mimic a variety of abnormal cells can make reaching a definitive diagnosis

difficult. For example, spherocytes can mimic lymphocytes, and many nucleated red cells can mimic myeloid precursors. In an attempt to analyze these cells, it is common for the technologist to flag the abnormal-appearing cells on the smear and request a manual differential from the pathologist. This is an inefficient process, but it is currently the best way to distinguish abnormal cells. Any hematology instrument would have difficulty analyzing these abnormal cells to provide a diagnostic CBC, and none can accurately predict what the pathologist will see and therefore has limited ability to detect true and random error. The instrument vendors are addressing these needs by developing technologies. One example is flow cytometry analysis of cells, which has greatly expanded the quantity and type of data that can be provided from an automated instrument. In the future, it may be possible to provide the data from flow cytometry analysis on a patient for every type of cell in a three-dimensional scattergram with region gates that are defined by the clinical decision points for specific diagnoses. This would permit an excellent comparison of the method to the true disease status of the patient's cells and would track changes in the patient's condition with great accuracy. Unfortunately, these technologies are very costly, and it will be some time before they are available as routine methods for CBC analysis. (Röllig et al.2020)

While it is clear that accurate and efficient results are desirable, the laboratory processing of samples for the CBC and biochemistry is complex and presents several challenges to achieving these goals. Foremost, any method or instrument used to analyze the blood must be sufficiently accurate such that the difference in a test result on the same patient sample would be due to a real change in the patient's status and not simply an experimental error. The results of such analyses over time on the same patient should reflect real changes or a lack of change in the patient's condition. Any shifts outside the reference interval should be indicative of clinical significance. This requirement of accuracy is known as analytical sensitivity. Unfortunately, this is challenging to

achieve in the analysis of the blood due to the fact that the physiological concentration of many analytes of interest is near the limits of detection of the methods available. For CBC analysis, this is complicated by the fact that the types of cells and cell abnormalities the clinician is interested in can be quite varied.

2. Improving Laboratory Processes

Although the critical and interpretative role of the clinical laboratory has received more attention in recent years, the laboratory remains largely a data-generating enterprise. The laboratory information process begins with the recording of the request and ends with its interpretation and the actions taken as a result of that interpretation. Between these two points lie the generation and transmission of the test result data. The ability of the laboratory to meet the needs of the clinician is critically dependent on the accuracy, timeliness, and completeness with which it can generate and transmit that data. It is often forgotten that the fundamental reason for performing a laboratory investigation is to obtain information to aid in the diagnosis and treatment of a patient. That investigation is only a means to an end, and it is the availability of reliable data on the patient that will allow a rational choice of action. Doctors generally have cherished the tradition of personal contact between their profession and the clinical laboratory. In many cases, the decision to perform a laboratory test at all and the choice of an investigation will be influenced by the laboratory, and additional input from the laboratory may be sought during the interpretation phase. This is a complex area, and it can be difficult to cost or measure the benefits received. But here and in the simple generation and transmission of a results report, the laboratory data must be timely and accurate if it is to serve the patients' best interests. For the purposes of this article, we shall concentrate mainly on the generation of a test result and the measures that can be taken to ensure the accuracy and efficiency of that process. (Carpenter et al.2020)



2.1 Automation and Robotics in Sample Handling

Automation in a laboratory setting largely involves the deployment of robotic systems to individualize and perform analytical tasks with little or no human involvement. This results in timely analysis, a reduction of errors, and improved assay precision. The primary need for automation in hematology was realized with the advent of multi-channel analyzers and has more recently extended to include the area of slide preparation and staining. In order to have a high level of confidence in automated CBC results obtained from various types of instrumentation, it is necessary to have a system of analysis in place to assess the accuracy of both the machine and the reagents used. This is an area that is currently lacking and is generally overcome by comparison with results obtained from manual methods. Robotic systems for sample handling are diverse and range from relatively simple track system devices for transporting specimen tubes between analyzers to highly complex and sophisticated devices that aim to replicate all aspects of manual blood film preparation. It is widely recognized that variation in slide quality can have a significant impact on the accuracy of differential and other morphological interpretations. A number of studies have shown that even minor deviations from the standard process can lead to suboptimal slide quality and poor analytical results. These findings have been the primary stimulus behind attempts to automate the blood smear, despite the general reluctance to adopt such technology due to minimal training in manual blood film

preparation and a perceived loss of professional skill in morphology interpretation.

2.2 Advanced Analytical Techniques

In this section, the author discusses new approaches to analysis that utilize recent advances in technology. The author outlines the use of flow cytometry in performing a more advanced white cell differential. Flow cytometry is an analytical process that can rapidly and efficiently analyze cells in a sample. It offers the promise of understanding the normal function of an immune system and diagnosing its disorders, providing quantitative data about the cells based on their markers. This method should decrease the number of unidentified or misidentified cells when compared to the standard methods of microscopy or automated differential, an improvement that may lead to a higher level of patient care. This would negate the need for a technologist to manually count a differential by microscopy and thus reduce the risk of inaccuracies caused by human error. The article describes the development of a rapid, cost-effective single-platform test for the diagnosis of HIV. This test uses advanced assays based on micro- or nano-molecular technology to detect both HIV antibodies and antigens in a single test. The results of a recent study demonstrate that this test has a higher specificity and sensitivity than standard diagnostic tests, and its availability will therefore improve patient care by reducing the number of false diagnoses. This unique test will thus confirm an HIV infection with a greater level of certainty while also providing a diagnosis in a single patient visit due to the rapid turnaround time. (Alsharif & Qurashi, 2021)

2.3 Quality Control Measures

(3) Audits are often seen as a means of assessing IQC and EQA. This can be a self-assessment or an accreditation visit from a national or international body. In conclusion, this part of the thesis has provided an up-to-date review of the potential areas for improvement in the laboratory analysis of blood and has illustrated the successful

attempts made by many researchers to implement changes. It is evident that the healthcare system stands to benefit greatly from these changes, but it will require time, funding, expertise, and cooperation between clinical and scientific disciplines.

(2) External quality assurance is participation in programs such as the Randox International Quality Assessment Scheme, the Dutch College of General Practitioners, or the College of American Pathologists Scheme, to name but a few. These schemes involve the regular analysis of materials sent from the organizing body that are tested by a range of methods in participating laboratories. The performance of the laboratory is then assessed, and the results are returned to the laboratory in question.

(1) Internal Quality Control, which is the control of the analysis of patient samples with materials of known values. The simplest method is to run replicates of the same sample, or, if possible, run a material with a similar matrix. This material can be run at regular intervals to ensure that the performance of the analyzer has not drifted. More advanced forms of IQC involve control charts; these are usually Levey-Jennings charts that plot analyte values against time or run number and apply statistical rules to determine if the analyzer is still in control.

Good laboratory practice and tight quality control measures need to be in place to ensure the reliability and effectiveness of the generated result. The minimum set of QC should include:

3. Enhancing Data Analysis and Interpretation

Integration of clinical decision support systems (CDSS) into the reporting software is seen by laboratory staff as a panoramic key to improving result interpretation. CDSS is somewhat reminiscent of expert systems and is designed to assist in the interpretation of patient-specific results. This would be undertaken by programming rules that reflect best practice and by providing alerts when a

result is inconsistent with a diagnosis or when a diagnosis is inconsistent with other patient parameters. Although more research and evaluation are required in this area, it is perceived that CDSS will not only enhance result interpretation but will also enhance the data entry phase by encouraging the request of specific tests to aid in diagnosis. An example of how CDSS has been utilized to improve diagnosis is given in a recent study that aimed to improve the diagnosis and management of patients with rheumatoid arthritis. The authors developed an application for mobile devices that estimated the likelihood of severe damage from rheumatoid arthritis using previously collected patient data. The application provided a simple traffic light system to indicate the level of risk and advise on the most appropriate course of action. Unbeknownst to the laboratory, the authors could request additional acute phase response proteins from patients with a high likelihood of severe damage, thus increasing the utilization of laboratory tests and the specificity of results. Training and education for laboratory staff is a fundamental yet sometimes overlooked strategy to improve the quality and efficiency of data entry and result interpretation. It is known that without sufficient knowledge of pre-analytical variables and the clinical significance of individual results, there will be difficulty in recognizing and troubleshooting errors, and pathology information will not be utilized to its full potential. Results may be overlooked or deemed irrelevant, and clarity in the reporting of abnormal results may be lacking. In order to improve knowledge in these areas, it may be useful to provide staff with learning objectives and materials specific to individual tests and to produce regular feedback on the significance and quality of the results that are reported. A recent and innovative approach taken by the UK Biomedical Scientist magazine has been the addition of multiple-choice questions to accompany certain articles, providing a simple and enjoyable way to test knowledge. (McPherson & Pincus, 2021)

3.1 Implementation of Artificial Intelligence

Methods for enhancing accuracy and efficiency of data interpretation in CBC and biochemistry

are essential. Three different machine learning predictive models—Levinson-Durbin method, an artificial Network (ANN) and a decision tree—from Caro et al (2005) study were applied to predict abnormal WBC case. Although those methods are more complex and more expensive to develop than conventional statistical analyses, this study is demonstrating its ability to be implemented in real medical practice and their possible accuracy in predicting WBC abnormality in certain diseases. Other than prediction, the interpretations of the complex data, for example, pattern recognition of the morphology of certain cells in different clinical conditions, is a good area for AI to develop. This will give an automatic differential count of the abnormal cells at a faster rate and possibly a more accurate result that a human can provide. This search and classification pattern recognition is a similar principle to the AI filtering mechanism and these systems are capable of modifying the criteria entered by the user to reach a more accurate result. Another aspect to the analysis and interpretation of complex data is AI reasoning systems, which have the ability to take the data entered and the criteria requested by the user instructor and produce very informative conclusions and, in some cases, further questions to reach more accurate results in clinical diagnosis. AI reasoning systems can range from relatively simple statistical associational models to more complex casual and logical models. This may even lead to the automation of generating up clinical report and analysis, which would be a very beneficial practical application to the field of pathology. However, it is very complex and expensive to develop expert systems, maybe beyond the financial capabilities of individual pathology laboratories. (Marshall et al.2020)

3.2 Integration of Clinical Decision Support Systems

CDSS is not a new concept; the best-known forerunner of it is probably the MYCIN system. This was developed by researchers at Stanford University in the early 1970s and the Internist-1 My long-term and very successful project started in 1982 and continues to this day. MYCIN was developed to identify bacteria

causing acute infections and to recommend antibiotics and dosages. Internist-1 systematically formulates a ranked differential diagnosis and recommends additional diagnostic tests. Characterized by the work done to date, CDSS has great potential for helping doctors and other health professionals make clinical decisions in primary care. However, its appeal will be limited, as a recent report by the NHS Health Technology Assessment Program found that there were no good-quality studies that evaluated the impact of CDSS on clinician's behavior and patient outcomes in the acute care setting.

The Clinical Decision Support System (CDSS) is a computer-based information system used to help enhance clinical decision-making. It is a system that helps doctors and other health professionals make clinical decisions. It does this by helping identify diseases, classify or diagnose diseases, suggest diagnostic tests, identify the best test to diagnose a condition, or identify a treatment. CDSS can include a variety of tools to enhance decision-making in the clinical workflow. These can include simple "if x, then y" alerts, providing information, or asking specific questions a clinician must answer in order to function.

3.3 Training and Education for Laboratory Staff

This implementation is expected to improve the efficiency and accuracy of the results obtained from chromatograms and other graphical outputs generated by the analyzers. These results will contribute to the development of the diagnostic algorithm for the project.

Initially, a basic training schedule will be designed to provide all staff members with knowledge about the preanalytical components of a specimen, how analyzers work, and what results to expect and how to interpret them. This is crucial because the project may involve staff members from different backgrounds who may have no prior knowledge of analyzer operation but are required to work with them. This training will be conducted over a short period of time. Additionally, special interaction programs will be arranged for staff members to

learn about handling and maintaining the instruments from analyzer technicians. Practical training with the instruments may also be considered. To facilitate learning, a self-learning module using animation and voiceovers may be developed. Finally, feedback will be collected from the staff to assess their understanding and the impact of the education provided. Staff members who do not show progress based on the feedback will receive additional training. This implementation will be an ongoing process integrated into the regular routine of the laboratory.

Training and education will be provided to the laboratory staff involved in the cancer research project. This training will form the foundation for future implementation of technology in diagnosing patient pathology specimens obtained from instruments like CBC and biochemistry analyzers. The success of any project and its implementation are determined by its durability, even after the project is completed. The laboratory staff needs to continuously update their knowledge and skills due to the constantly changing models of analyzers and advancements in technology. Therefore, a step-by-step training program will be designed based on the staff's basic understanding and assigned roles.

4. Ensuring Regulatory Compliance and Quality Assurance

Several factors have led to an increase in the attention given to the quality of testing within the medical laboratory. Evidence that errors in laboratory medicine cause harm to patients has been a catalyst. There is increased recognition that laboratory quality influences a high percentage of clinical decisions. In addition, in today's healthcare environment, patients, providers, payers, and regulatory agencies alike are all demanding greater accountability from healthcare providers. This is best exemplified by the public's and the healthcare industry's push for greater transparency in the quality of healthcare services provided. Finally, the Centers for Medicare and Medicaid have issued

"Revised Conditions of Participation for Laboratory and Radiologic Services," effective April 24, 2003, that place greater emphasis on establishing a culture of quality in laboratory services. With this in mind, it is vitally important that all laboratories, ranging from the small physician office laboratory to the largest independent and hospital facilities, have measures in place to ensure that quality testing is being performed. Complete blood count (CBC) and biochemistry testing are staples of laboratory medicine, and because of this success, patient care is largely dependent on the accurate and timely reporting of these test results. Because of the high dependency on these results, it is essential to ensure that all testing methodologies are in compliance with best current practices and are continuously affecting improvements in accuracy and efficiency. This section will detail recommendations on ensuring regulatory compliance and achieving quality assurance in CBC and biochemistry testing. (de Vries & Schallig, 2022)

4.1 Adherence to Accreditation Standards

To comply with these standards, the laboratory is implementing the ISO 15189 standard, the accreditation component of the international laboratory standard from the International Standards Organization (ISO). This will provide a unifying standard for developing quality management systems for laboratory processes, technical and professional competence, and ensuring the generation of accurate and reliable results. In addition, this standard will be able to provide the laboratory with sufficient documentation and accountability. According to Dr. James Nichols, PhD, a Professor of Pathology, Microbiology, and Immunology at Vanderbilt University School of Medicine, this will help "the administrator to determine the contributions of the lab to the whole clinical enterprise—in terms of both effectiveness and efficiency." This can be done through the use of quality indicators to demonstrate improved patient clinical outcomes. Overall, adherence to these accreditation standards will help improve the global impression of the laboratory and its

quality of work among patients and the medical community.

In India, medical laboratories are regulated by the Centre for Laboratory Medicine Quality Accreditation (CLMQA). The CLMQA is aimed at improving the quality and reliability of clinical laboratory services in India. This involves ensuring the humane and competent practice of laboratory medicine and the understanding of pathology by physicians and patients. To ensure this, they have very stringent standards that involve the recognition of good laboratory practice and high quality of work, improvement in patient care and service, seeking international acceptance and recognition, and encouraging communication among medical scientists. These standards are important in accomplishing the goals of CLMQA and are expected to enhance the accuracy and efficiency of laboratory testing results, thus improving patient care and safety.

4.2 Regular Calibration and Maintenance of Equipment

Regularly maintaining and calibrating the analytical instrument is critical to ensuring accuracy in CBC and biochemistry testing. Regardless of whether the instrument is new or used, periodic maintenance is required to keep it in optimal working condition. The frequency of calibration and maintenance needs to be based on the manufacturer's recommendation, service history, and laboratory experience. Preventative maintenance should be done on all instruments routinely to help decrease the amount of unscheduled downtime. Unscheduled maintenance and equipment failure can be a significant cause of error, leading to invalid results and repeat testing. A record of all maintenance and repairs should also be kept and reviewed when there are unexplained changes in quality control results. Equipment maintenance is an important and often overlooked factor in controlling analytical variability. Calibration, a component of maintenance, is the process used to establish the relationship between the measurement value and the corresponding known value of the measure. It's done by adjusting the instrument to make it more precise and

accurate, and it can involve changing the slope and intercept of the regression line. Regular maintenance and calibration help to maintain the precision and accuracy of the instrument, prevent performance drift, and ensure that the manufacturer's specifications are maintained. Specimens used in proficiency testing are often used to monitor the accuracy and precision of the instruments over time. (Rao et al.2023)

4.3 Continuous Improvement and Risk Management

The successful extent of the implications of these changes will require ongoing monitoring of QMS actual vs. optimal quality measurements. This move towards data-driven, improved optimal practice gets closer to the ideal of the Triple Aim framework for an improved healthcare system with lower costs.

The laboratory had changed their practice to using pediatric tubes in an attempt to lower sample volume. The clinical concerns for this serious data-error event were high, and the implications of change were small. A new policy was thus enacted to immediately switch back to using adult capillary tubes only if a simulated micro-hematocrit in the automated plastic tube method displayed a hematocrit value less than the patient's last value, in an attempt to restrict sample-altering procedures to those that have a higher probability of benefit and a low probability of harm. This is just one example of the use of a practical methodology for problem-solving for process improvement in a laboratory. (Kernder et al.2021)

An essential methodology to achieving this data-driven optimal process is the Plan-Do-Study-Act cycle, wherein change is implemented in small steps and effects are evaluated before actions are taken to make full implementation of change. This trial-run approach is a way to avoid implementing changes that can produce negative, unintended consequences. An example of applying this methodology to a CBC would be the resolution of a high false anemia rate attributed to inadequate sample quality. The microcytic appearance of the red blood cells was observed to be artifactual. An in-vitro simulated study

showed that an automated hematocrit was reading 5% lower than the 24-hour spun sample. This was traced to excessive anticoagulant in the microhematocrit tubes. (Govender et al.2021)

Every laboratory in the developed world should be utilizing a quality management system (QMS), which is a comprehensive approach to the development and continual refinement of the most optimal and cost-effective laboratory processes. This encompasses strategic planning for process development and identifying interventions that have the highest probability of success in improving patient outcomes.

Regularly monitoring the quality of the testing process is also a requirement for accreditation to ensure risk management through the detection of errors before they affect the patient. The complexity of ideal quality management is beyond what is currently feasible in most resource-limited settings, but its need is clear. Using prevailing practices and methodologies in a local, cost-constrained setup, one can apply the basic principles of continuous improvement to enhance critical components of the testing process in an effort to improve overall quality.

Quality improvement in laboratories can only be achieved if a strong commitment is made to educate staff and to allocate time and resources to developing new programs. A successful quality improvement program will require participation by everyone in the laboratory in an organized, task-oriented fashion. Cross-functional teams can be organized to tackle specific problem areas such as TAT, customer service, or specimen processing. Regular meetings should be scheduled to track the progress of various programs and identify any new problems. This is an ongoing process, since as one problem is solved, another may be uncovered by the disturbances caused by change. (Gunderson et al.2020)

Continuous improvement is the basis for quality enhancement, and risk minimization is the key to error reduction. Stepwise refinement of processes can lead to higher efficiency and resource utilization. This definition of quality

improvement closely relates to the goals of laboratory medicine: to achieve more efficient delivery of useful services through the application of an ongoing, systematic process. (Scott & Crock, 2020)(Vrijssen et al.2020)

5. Conclusion

One of the most common tests available in laboratories identifies hemoglobin, measures the number of red cells, and determines erythrocyte indices, leukocyte, and platelet levels. This machine is used in the diagnosis and treatment of patients in the preventive and acute care settings. Globally, a complete blood count (CBC) is often the first and most frequent laboratory test on specimens from hospitalized and critically ill patients. Despite limited new clinical activities and financial pressure, technology and product development in the field of CBC analysis have continued at a relentless pace. Recognition of the limitations and potential of both traditional and new cell counting methods continues to offer new opportunities and new programs for technological advancement. Economical simplification and accuracy of blood cell counting are important parts of both patient care and monitoring responses to treatment. The essence of the CBC as a basic test of hematologic status has withstood the test of time; thus, any barrier in cost and access will adversely impact global health. Further research and development in CBC technology can ensure more detailed and accurate information on the various cells in the blood and how they affect different disease states. An accurate CBC is most appropriate in situations where the clinical condition of the patient is not clearly indicative of the need for a CBC. Conditions where the patient has an infection, a chronic disease, anemia, and/or a pre-operative/post-operative state can often mask an abnormal blood count or lead to a change in hematologic status. Correct interpretation and appropriate use of the CBC help to attest to the presence of anemia or certain infections, monitor the effects of chemotherapy or radiation on bone marrow production, evaluate red blood cells or platelet loss, or assess the

extent of hemostatic disorders. All this is done with the intention of guiding or altering treatment, thereby improving the health and well-being of the patient. A CBC is indispensable for the initial diagnosis and following progress of anemia, a common disease affecting about 24.8% of the global population whose demographics are weighted towards occurrence in the geriatric, pediatric, and female populations. Anemia reduces patient quality of life, general functional status, and accelerates morbidity and mortality. Thus, the patient population for whom anemia is a complicating factor in other diseases will benefit from CBC monitoring and management. In order to pursue excellence in healthcare, CBC remains the cornerstone in determining the progress, success, and effectiveness of the treatment. This is almost an obligation for more severe and intensive treatments such as drugs and/or surgery for cancer, hematogenous stem cell therapy, or organ transplantation. In current and available automated hematology and instrumentation, results that are grossly abnormal will often be directly flagged to the clinician. If an error is suspected, the clinician can easily investigate the results by requesting another CBC. The term gross abnormality is subjective, but it is anticipated that all hematology system errors are detected, so count data is not used until acceptable category reproducibility is demonstrated. This often applies to new drug trials, which require CBC data among other measures for monitoring patient safety and efficacy of the drug. Any adverse effects on the patient's hematologic status, which is often an important reason for the disease states that require implementation of new drugs, must be quickly and accurately assessed in order to justify a treatment cease or change. A slightly different situation involves the outpatient setting, where it is desired to minimize general blood loss through diagnostic sampling and/or to combine CBC ordering and blood collection with other patient tests that are easily ascertainable in primary care. This requires speed, cost-effectiveness, and often reliability of results, as CBC is commonly coupled to laboratory serum.

Reference

- [1] Pourbagheri-Sigaroodi, A., Bashash, D., Fateh, F., & Abolghasemi, H. (2020). Laboratory findings in COVID-19 diagnosis and prognosis. *Clinica chimica acta*, 510, 475-482. nih.gov
- [2] McPherson, R. A. & Pincus, M. R. (2021). *Henry's clinical diagnosis and management by laboratory methods* E-book. [HTML]
- [3] Röllig, C., Kramer, M., Schliemann, C., Mikesch, J. H., Steffen, B., Krämer, A., ... & Bornhäuser, M. (2020). Does time from diagnosis to treatment affect the prognosis of patients with newly diagnosed acute myeloid leukemia?. *Blood, The Journal of the American Society of Hematology*, 136(7), 823-830. sciencedirect.com
- [4] Carpenter, C. R., Mudd, P. A., West, C. P., Wilber, E., & Wilber, S. T. (2020). Diagnosing COVID-19 in the emergency department: a scoping review of clinical examinations, laboratory tests, imaging accuracy, and biases. *Academic Emergency Medicine*, 27(8), 653-670. wiley.com
- [5] Count, C. B. (2019). *Introduction to Laboratory Medicine. Egan's Fundamentals of Respiratory Care E-Book: Egan's Fundamentals of Respiratory Care E-Book*, 342. [https://books.google.com/books?hl=ar&lr=&id=z5fFDwAAQBAJ&oi=fnd&pg=PA342&dq=Enhancing+Accuracy+and+Efficiency+of+Complete+Blood+Count+\(CBC\)+and+Biochemistry+Analysis+in+Medical+Laboratories\(books0&ots=AMZTnn6WM3&sig=0wbbsWK-ysn5WV0U4JbnJs376e4](https://books.google.com/books?hl=ar&lr=&id=z5fFDwAAQBAJ&oi=fnd&pg=PA342&dq=Enhancing+Accuracy+and+Efficiency+of+Complete+Blood+Count+(CBC)+and+Biochemistry+Analysis+in+Medical+Laboratories(books0&ots=AMZTnn6WM3&sig=0wbbsWK-ysn5WV0U4JbnJs376e4)
- [6] Alsharif, W. & Qurashi, A. (2021). Effectiveness of COVID-19 diagnosis and management tools: A review. *Radiography. nih.gov*
- [7] Marshall, C. R., Chowdhury, S., Taft, R. J., Lebo, M. S., Buchan, J. G., Harrison, S. M., ... & Medical Genome Initiative. (2020). Best practices for the analytical validation of clinical whole-genome sequencing intended for the diagnosis of germline disease. *NPJ Genomic Medicine*, 5(1), 47. nature.com
- [8] Lokwani, D. P. (2013). The ABC of CBC: Interpretation of complete blood count and histograms. JP Medical Ltd. <https://n9.cl/sg467>
- [9] Weatherby, D., & Ferguson, S. (2002). *Blood chemistry and CBC analysis: clinical laboratory testing from a functional perspective (Vol. 4)*. Weatherby & Associates, LLC. <https://n9.cl/96zmx>
- [10] de Vries, H. J. C. & Schallig, H. D. (2022). Cutaneous leishmaniasis: a 2022 updated narrative review into diagnosis and management developments. *American journal of clinical dermatology. springer.com*
- [11] Rao, A., Pang, M., Kim, J., Kamineni, M., Lie, W., Prasad, A. K., ... & Succi, M. D. (2023). Assessing the utility of ChatGPT throughout the entire clinical workflow. *MedRxiv, 2023-02. medrxiv.org*
- [12] Kernder, A., Richter, J. G., Fischer-Betz, R., Winkler-Rohlfing, B., Brinks, R., Aringer, M., ... & Chehab, G. (2021). Delayed diagnosis adversely affects outcome in systemic lupus erythematosus: cross sectional analysis of the LuLa cohort. *Lupus*, 30(3), 431-438. sagepub.com
- [13] Pagana, K. D., & Pagana, T. J. (2017). *Mosby's Manual of Diagnostic and Laboratory Tests-E-Book: Mosby's Manual of Diagnostic and Laboratory Tests-E-Book*. Elsevier Health Sciences. <https://n9.cl/7grcd>
- [14] Govender, K. N., Street, T. L., Sanderson, N. D., & Eyre, D. W. (2021). Metagenomic sequencing as a pathogen-agnostic clinical diagnostic tool for infectious diseases: a systematic review and meta-analysis of diagnostic test accuracy studies. *Journal of clinical microbiology*, 59(9), 10-1128. asm.org
- [15] Turgeon, M. L. (2022). *Clinical Laboratory Science-E-Book: Clinical Laboratory Science-E-Book*. Elsevier Health Sciences. <https://n9.cl/mxvune>
- [16] Gunderson, C. G., Bilan, V. P., Holleck, J. L., Nickerson, P., Cherry, B. M., Chui, P., ... & Rodwin, B. A. (2020). Prevalence of

- harmful diagnostic errors in hospitalised adults: a systematic review and meta-analysis. *BMJ quality & safety*, 29(12), 1008-1018. [HTML]
- [17] Hemoglobinometry, A., Red, C., & Width, R. C. D. (2015). *Principles and Practice of Clinical Hematology*. Linne & Ringsrud's Clinical Laboratory Science-E-Book: The Basics and Routine Techniques, 2, 291. <https://n9.cl/r8ww8a>
- [18] Scott, I. A. & Crock, C. (2020). Diagnostic error: incidence, impacts, causes and preventive strategies. *Medical Journal of Australia*. mja.com.au
- [19] Vrijssen, B. E. L., Naaktgeboren, C. A., Vos, L. M., van Solinge, W. W., Kaasjager, H. A. H., & Ten Berg, M. J. (2020). Inappropriate laboratory testing in internal medicine inpatients: prevalence, causes and interventions. *Annals of Medicine and Surgery*, 51, 48-53. sciencedirect.com
- [20] Chawla, R. (2014). *Practical clinical biochemistry: methods and interpretations*. JP Medical Ltd. <https://n9.cl/g8biy>
- [21] Garrels, M. M., & Oatis, C. S. (2018). *Laboratory and Diagnostic Testing in Ambulatory Care E-Book: Laboratory and Diagnostic Testing in Ambulatory Care E-Book*. Elsevier Health Sciences. <https://n9.cl/im5eb>
- [22] Willard, M. D., & Tvedten, H. (2011). *Small animal clinical diagnosis by laboratory methods*. Elsevier Health Sciences. <https://n9.cl/wu67a>
- [23] Dasgupta, A., & Wahed, A. (2013). *Clinical chemistry, immunology and laboratory quality control: a comprehensive review for board preparation, certification and clinical practice*. <https://n9.cl/bzctx>