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Artificial Intelligence in Total Laboratory Automation: Enhancing Quality, Accuracy, Reliability, and Timeliness Across the Total Testing Process

Abstract
In today's laboratory medicine, the use of artificial intelligence (AI) in conjunction with Total Laboratory Automation (TLA) is quickly making a difference. While clinical laboratories are being challenged by greater testing volume, reduced turnaround time, higher quality demands, and greater patient safety, they are also being impacted by the pressure of increasing volume.In addition to greater testing volume and reduced turnaround time, higher quality demands, and greater patient safety, clinical laboratories are being challenged by the pressure of increasing volume. While traditional automation has made it easier to cut down on manual actions, modern laboratory settings demand intelligent systems that can predictively analyze, autonomously make decisions, monitor quality continuously, and provide cutting-edge clinical support. AI technologies, such as machine learning, deep learning, computer vision, natural language processing, and predictive analytics, have become indispensable for solving these problems. AI use cases have been adopted across the entire testing workflow, from specimen collection to transportation, analytical testing, quality control, result verification, interpretation and reporting. These technologies have greatly helped to minimise laboratory errors, analytical performance, operational efficiency and evidence based clinical decision making. In addition, AI-powered systems enable predictive maintenance, automatic verification, risk management, and workflow optimization, amongst other benefits, and help ensure adherence to accreditation standards like ISO 15189 and CAP standards. This narrative review explores the role of AI in TLA systems today and the opportunities it could offer tomorrow, particularly in the context of laboratory quality, accuracy, reliability, timeliness and patient focused healthcare.
Method: This study was intended as a narrative review that would give a full understanding of the present and upcoming uses of AI in Total Laboratory Automation (TLA). Literature search was conducted in PubMed/MEDLINE, Scopus, Web of Science, and Google Scholar, as well as College of American Pathologists (CAP) guidelines and publications, Clinical and Laboratory Standards Institute (CLSI) guidelines and publications, International Organization for Standardization (ISO) publications, and U.S. Food and Drug Administration (FDA) publications. Articles written mainly between 2015 and 2025 in English language were taken into consideration, and landmark articles were added where appropriate. The literature retrieved was critically reviewed and organized thematically into pre-analytical, analytical, post-analytical, quality management, validation, regulatory and future applications of AI in laboratory medicine. Existing literature was reviewed to assess the current evidence, knowledge gaps and future directions for research.

1. INTRODUCTION

While laboratory tests represent only a small portion of overall spending on healthcare, they are one of the most important components of health services delivery since laboratory information has been found to affect around 70–80% of the decisions in the diagnosis, selection, monitoring and prognosis of diseases (Lippi & Plebani, 2023). The complexity of healthcare systems, the ever-increasing volumes of tests, ageing populations, shortage of staff and increasing demands for rapid turnaround times have put unprecedented demands on laboratory services around the world (Plebani et al., 2022).

Traditionally, laboratory medicine was very dependent on manual tasks such as handling and transporting specimens, conducting tests, interpreting results, and reporting. They were also manual processes that had the potential of causing human error, inefficiency and variability. To overcome these restrictions, laboratories began to increasingly use automation technologies to optimize processes and standardise workflows. A significant improvement in laboratory operations was the development of Total Laboratory Automation (TLA) for which the specimen transportation, centrifugation, aliquoting, sorting, analysis, storage and retrieval functions were combined into a single automated process (Zaninotto et al., 2023).

Traditional automation made a significant contribution to laboratory productivity, but was still more or less rule-based and program-driven. Traditional automated systems were capable of repetitive tasks and were very regular, but lacked the ability to learn from experience, was able to see through complex patterns, adapt to changes to their environment, or make predictions. With the advent of AI, automated laboratories are becoming intelligent laboratories, with the ability to learn from data and evolve and optimize over time (Topol, 2019).

The term “Artificial Intelligence” is used for computational systems that are capable of tasks that normally need human cognitive functions like learning, reasoning, pattern recognition, prediction, and decision making. Unlike conventional software programs, which are explicitly programmed, AI systems leverage algorithms to analyze massive amounts of data, detect patterns and connections, make forecasts, and self-refine over time using iterative learning cycles (Yu et al., 2018).

AI's use in laboratory medicine is happening at a time where this is the same with the idea of Healthcare 4.0 and Laboratory Medicine 4.0 focused on connectivity, interoperability, digitalization, real-time analytics, and intelligent automation. Laboratory Medicine 4.0 aims to establish inter-connected Laboratory ecosystems, where instruments, LIS, middleware platforms, quality management systems and clinical databases communicate easily and seamlessly to facilitate evidence-based healthcare delivery (Plebani et al., 2022).

Today there are vast amounts of data being produced by analyzers, quality control programs, laboratory information systems, electronic health records, and external quality assessment schemes. These datasets are often very large and complex, making them difficult to analyze using traditional statistical methods. Artificial intelligence offers robust solutions to harness these data sources and uncover insights that can help laboratories spot trends, forecast failures, streamline processes, and enhance diagnosis (Badrick & Stavelin, 2024).

In recent years, advances in machine learning and artificial intelligence (AI) in deep learning have propelled AI use in various areas of the laboratory, such as clinical chemistry, hematology, immunology, microbiology, molecular diagnostics, pathology, and genomics. These applications are not limited to automation, and also encompass intelligent quality control systems, predictive maintenance programs, automated image interpretation, autoverification algorithms, clinical decision support systems, as well as personalized diagnostic strategies (Haug & Drazen, 2023).

AI is especially relevant in the context of Total Laboratory Automation systems because they can be subject to errors at all stages of the total testing procedure, such as pre-analytical, analytical and post-analytical. Numerous studies have shown that most laboratory errors happen in the pre analytical phase, with analytical errors becoming less common because of the improvements made in instrumentation and quality control systems. However, if they do occur, even low frequency analytical errors can have major implications for patient care. Machine learning can be utilized throughout the entire laboratory testing process, from continuous monitoring to predictive analysis and intelligent decision-making support, to minimize errors throughout the testing process (Lippi et al., 2022).

The world's need for skilled laborers in the laboratory is another significant factor for the implementation of AI. Laboratory services are becoming an increasing demand for many healthcare systems, with a simultaneous shortage of staff. Beyond the specific scope of this paper, AI can complement the human expert by automating repetitive tasks, ordering test results by priority, aiding in interpretation, and allowing laboratory staff to engage in more value-added activities that involve problem-solving and clinical judgment. (Briganti & Le Moine, 2020).

AI's impact goes beyond operational efficiency and touches healthcare goals. Precision medicine is the ability to offer diagnostic and therapeutic interventions that are customized to specific patient's characteristics and requires accurate laboratory results. Precision medicine efforts can benefit from AI by leveraging laboratory data combined with clinical, genomic, proteomic and imaging data to provide unique insights for each patient and treatment recommendations (Topol, 2019).

AI has the potential to revolutionize laboratory medicine, but there are challenges to implementing it. Although algorithm transparency, data quality assurance, regulatory issues, cybersecurity, ethical questions, and workforce readiness are significant issues, they are not the most pressing ones. For this reason, it is essential that laboratories set up strong frameworks and governance arrangements to guarantee that the AI system delivers trustworthy and reproducible results, as well as clinically relevant findings (Badrick & Stavelin, 2024).

With the current shift in healthcare towards a data-driven approach, AI is set to be a key part of laboratory work, not just another technological add-on. It is likely that the future lab will be an intelligent highly interconnected ecosystem where processes are optimized in an

autonomous way, quality is controlled in a predictive manner, clinical decisions are supported with advanced solutions and the lab is connected with the rest of the healthcare system (Haug & Drazen, 2023).

2. FUNDAMENTALS OF ARTIFICIAL INTELLIGENCE IN LABORATORY MEDICINE

AI is a broad term for a variety of computational technologies that replicate human thinking and decision making. In laboratory medicine, large datasets of laboratory and clinical data are used by AI systems to find patterns, make predictions, and assist with diagnosis – tasks that would be hard to accomplish with traditional statistical methods (Yu et al., 2018).

The most widely adopted AI methodology in Laboratory Medicine is machine learning. Machine learning algorithms can learn patterns that exist in the relationships of variables from past data without programming. These systems discover structure in data and then use the relationships it learned to foretell future results. Most machine learning models can be categorized into three classes: supervised, unsupervised and reinforcement learning (Esteva et al., 2019).

In supervised learning algorithms, data sets with known inputs and outputs are used to train the algorithms. Supervised learning models can be trained for a variety of purposes in laboratory medicine, such as predicting quality control failures, classifying abnormal specimens, predicting analyzer downtime and predicting patient susceptibility to specific diseases. Supervised learning is of great importance for clinical use given the availability of labeled datasets from the lab (Badrick & Stavelin, 2024).

Unsupervised learning is not supervised learning because it uses data sets where there are no labels or given answers. These algorithms discover hidden structures, clusters and relationships in data. Laboratory applications comprise patient population stratification, discovery of biomarkers and identification of new disease patterns. These can provide clinically relevant information that is not identifiable using conventional methods (Plebani et al., 2022).

Deep learning is a specific type of machine learning that is derived from artificial neural networks with several layers of computation. Deep learning systems are especially useful with high-dimensional data like digital images, sequences of genes, and multi-dimensional laboratory data. Several fields of laboratory medicine have been revolutionized by the ability of deep learning models to automatically extract relevant features from raw data (Campanella et al., 2019).

Digital pathology and image-based diagnostics are one of the most important uses of deep learning. Deep learning systems have the potential to accurately interpret histopathological slides, blood smears, bone marrow aspirates, microbiological cultures, and urine sediments. In particular, a number of studies have shown that in certain applications, the performance of these devices is comparable to or sometimes even better than that of expert humans in the field of diagnostics (Komura & Ishikawa, 2018).

Another key AI technology that is heavily applied in laboratory medicine is computer vision. Computer vision is the ability of computers to understand what they see from images and videos. Today, computer vision systems are used in modern laboratories to facilitate automatic microscopy, measurement of cellular morphology, quality control of the specimens, identification of microorganisms and replicate review of slides. These systems eliminate the observer variability and increase standardization and throughput (Erdinc et al., 2024).

Another AI technology that is becoming commonplace in laboratory information systems (LIS) is natural language processing (NLP). NLP can be used to create computer systems that understand, interpret and create human language. Laboratory applications consist of automated report generation, extraction of clinical information from electronic health records, intelligent documentation systems and clinical decision support tools. NLP can also help in communicating between lab scientists and clinicians by producing context specific interpretative remarks (Wang et al., 2023).

Together, these AI technologies enable intelligent laboratory systems that enhance Quality Management, support operational excellence, improve diagnostic precision, and drive patient-centric healthcare. This integration into Total Laboratory Automation (TLA) environments is a major step toward the vision of fully-intelligent labs that continually optimize and learn from data.

3. TOTAL LABORATORY AUTOMATION (TLA): THE FOUNDATION FOR ARTIFICIAL INTELLIGENCE INTEGRATION

One of the most important technological advances in the last 30 years in laboratory medicine is called Total Laboratory Automation (TLA). The term TLA is used to describe the end-to-end integration of automated technologies that move specimens, centrifuge, decap, aliquot, sort, test, recap, store and retrieve samples in a single workflow. TLA aims to automate the entire laboratory testing process from specimen receipt to reporting the results, compared to partial automation systems, which automate only a portion of the laboratory testing process (Zaninotto et al., 2023).

The laboratory workload, the demand for ever faster turnaround time, the complexity of the diagnostic testing and a shortage of laboratory personnel were the main drivers in the development of TLA. There are continuing significant rises in demand for testing across health care systems around the world, driven by the growing average age of people, the prevalence of chronic diseases, personalized medicine programs, and increased screening programs. Thus, laboratories need to handle more specimens and at the same time ensure high levels of quality and patient safety (Lippi and Plebani, 2023).

Laboratory workflows are typically labor-intensive and feature many manual steps, such as sample sorting, moving samples between analytical platforms, centrifugation, aliquoting, and verifying results. Every hand-off in a manual process creates a risk of human error, delays, specimen misplacement and inefficient workflows. These risks can be reduced by TLA which standardizes processes, and decreases manual specimen handling (Plebani et al., 2022).

A modern TLA system will usually be composed of multiple interconnected components. Specimens are moved from workstation to workstation by automated track systems utilizing conveyor technology. Pre-analytical modules are designed to perform the actions of centrifugation, barcode identification, decapping, aliquoting and sorting. Chemistry analyzers, immunoassay analyzers, hematology analyzers, coagulation analyzers, molecular diagnostic systems, and microbiology platforms are all examples of analytical modules. These are the post analytical modules that are used to store, retrieve and dispose of specimens. The all components are connected via middleware and laboratory information systems (LIS), allowing for streamlined workflows and immediate tracking (Badrick & Stavelin, 2024).

The improvement in TAT is one of the key benefits of TLA. The turnaround time is an important quality indicator because delays in laboratory result reporting will have a negative impact on clinical decision-making, healthcare efficiency, and patient outcomes. Automated specimen transportation and processing reduce a lot of the delays involved in manual processes, and enable laboratories to provide results faster and more reliably (Lippi et al., 2022).

Not only does TLA increase efficiency, it also increases the standardization. Human operators can execute procedures in more than one way, depending on circumstances, fatigue, workload and experience. Automated system are able to run the tasks consistently, following predetermined procedures, thus minimizing process variability and enhancing process reproducibility. This standardization directly enhances the analytical quality and patient safety (Plebani et al., 2022).

Traditional TLA systems, however, have a number of weaknesses. Traditional automation systems run in according to set rules and are unable to adapt dynamically to varying conditions. Are unable to identify potential issues in the future, anticipate instrument failures, optimize workflows or learn from past experience. These constraints have provided an opportunity for AI to make a difference in laboratory automation and to enable TLA to become intelligent automation (Topol, 2019).

AI augments TLA by adding features like adaptive learning, predictive analytics, intelligent decision-making, and ongoing performance optimization. Unlike traditional systems that perform preprogrammed tasks, AI-powered TLA systems can interpret the information from operations, analyze inefficiencies, predict issues, and offer solutions. This development moves from automated laboratory to intelligent laboratory with self-optimization properties (Haug & Drazen, 2023).

The role of AI in TLA can be of great benefit, especially given the amount of operational and clinical data produced in today's laboratories. Each specimen transfer, QC measurement, calibration, maintenance task, analyzer flag and patient result adds to an ever growing data set. These data streams can be processed using AI algorithms to provide real-time analysis and insights into the data, which can be used to support laboratory management and quality improvement efforts (Yu et al., 2018).

With healthcare systems increasingly using digital transformations, TLA and AI are becoming complementary technologies, helping to support the laboratory modernization effort. Intelligent automation systems with self-learning capabilities for optimizing workflow, forecasting quality management and providing advanced clinical decision support are expected to become a key of the future laboratory (Plebani et al., 2022).

4. ARTIFICIAL INTELLIGENCE IN THE PRE-ANALYTICAL PHASE

The pre-analytical phase includes all processes that precede the laboratory analysis, such as ordering of tests, patient preparation, collection, labelling, transport, reception, accessioning and preparation of the specimen. Several studies have shown that most errors in the entire testing process (from inception to final results) can occur in the pre-analytical phase, which represents about 60-70% of all errors (Lippi et al., 2022).

As the majority of laboratory errors begin in the pre-analysis stage, laboratory professionals around the world have increased their focus on pre-analysis quality improvement. Artificial intelligence offers many tools to detect risk, minimize errors, optimize workflows and ensure specimen integrity during the pre-analytical phase (Plebani et al., 2022).

4.1 Ai-Assisted Test Ordering

The laboratory testing process starts when a clinician orders laboratory tests. The issue of inappropriate utilization of testing is a major concern as too many tests mean more money spent on the health care system, and too few tests means delayed diagnosis and treatment. It is estimated that between 20% and 70% of laboratory tests may be inappropriate in various settings and populations (Zhi et al., 2013).

Clinical decision support systems embedded in EHRs can be used to support appropriate use of tests with artificial intelligence. These systems are designed to examine patient data, such as patient demographics, clinical history, diagnoses, medications, prior lab results, and evidence-based guidelines to suggest the best testing course of action. AI can help doctors during the ordering process to minimize duplication of tests, streamline diagnostics, and make better use of resources (Wang et al., 2023).

Machine-learning algorithms can also detect inappropriate test use throughout health systems. These analyses enable labs and health care systems to create interventions aimed at optimizing test ordering and making better use of resources, ultimately minimizing unnecessary costs (Badrick & Stavelin, 2024).

4.2 Patient Identification and Specimen Labeling

Errors in patient identification are one of the greatest risks in laboratory medicine as misidentified specimens can result in misdiagnosis, mismanagement of care, and even disastrous results for patients. However, so-called “highly automated” laboratories are not immune to incorrect identification, since the specimen can be mislabeled at the time of collection (Lippi & Plebani, 2023).

By leveraging AI, patient identification can be improved by integration with barcode systems, radio-frequency identification (RFID) systems, biometric verification

methods and electronic patient records. Patient demographics, specimen labels, electronic orders and collection data can be automatically checked by AI systems to ensure consistency. Any differences can be easily noticed and highlighted for inspection prior to analysis (Plebani et al., 2022).

The potential of using advanced computer vision systems in specimen identification applications is being increasingly studied. These technologies can detect labeling anomalies that may not be caught in manual inspections, such as verifying the integrity of the label and assessing the readability of its bar codes (Erdinc et al., 2024).

4.3 Optimization of Phlebotomy Services

The quality of a specimen and the accuracy of the lab, are directly dependent on the performance of a phlebotomist. Problems in the collection of blood can lead to hemolysis, clots, inadequate sample size, contamination, and tube selection errors. These issues often result in the rejection of samples, delayed diagnosis, higher expenses and patient dissatisfaction (Lippi et al., 2022).

Combined with the analysis of historical workload data, staffing patterns, patient volumes, collection times and seasonal trends, artificial intelligence can enhance phlebotomy services. AI models can make predictions to determine the number of staff needed and to schedule them accordingly, ensuring operational efficiency and reducing waiting times (Briganti & Le Moine, 2020).

Machine learning models can also detect factors that contribute to mistakes made during collections. These types of analysis can help healthcare establishments develop targeted training initiatives and quality improvement programs to decrease specimen rejection rates and improve specimen collection quality (Badrick & Stavelin, 2024).

4.4 Intelligent Specimen Transportation

Specimen transportation is an important part to specimen integrity. Sample quality can be affected by delays, excessive vibration, temperature changes, and handling, which can have a negative impact on analytical results. Unstable analytes like blood gases, lactate, ammonia, coagulation factors, and some hormones (Lippi et al., 2022) are especially at risk.

AI-powered transportation infrastructure keeps track of the environment during specimen movement. The sensors in the transportation networks measure and gather real-time data on temperature, humidity, vibration, position and travel time. These data streams are fed into AI algorithms that can detect potential risks before specimen quality is affected (Plebani et al., 2022).

Predictive models can be used to estimate travel times and suggest alternative paths for specimens to be delivered on time. These are especially useful in large healthcare environments where specimens are sent long distances within the healthcare system between collection locations and the central laboratory (Haug & Drazen, 2023).

4.5 Automated Assessment of Specimen Quality

Automated specimen quality assessment is another potential use case in the pre-analytical phase that seems to be a very promising application of AI. Laboratory staff traditionally look at a specimen for hemolysis, lipemia, icterus, clot, or inadequate specimen size. Visual assessment is, however, the subjective assessment and may differ from one observer to another (Lippi & Plebani, 2023).

Digital imaging technologies can be used to objectively assess specimen quality, allowing computer vision systems and machine learning algorithms to perform this task. These systems are highly consistent and sensitive of visual characteristics, decreasing the variability between the observers and standardizing the process. Automated assessment allows for the rapid detection of unsuitable specimens before analysis is performed, and is able to be consistently performed in a laboratory (Erdinc et al., 2024).

AI systems could also combine with patient-specific clinical data specimen quality metrics. For instance, algorithms will be able to set the criteria for acceptability to make decisions about whether a mildly hemolyzed sample is acceptable for a selected test, and will recommend recollection for analytes known to be substantially affected by hemolysis. This strategic and intelligent decision-making process improves efficiency and quality management (Plebani et al., 2022).

4.6 Specimen Routing and Workflow Optimization

Today, modern TLA systems can process thousands of specimens a day. Efficient specimen routing from a variety of analytical platforms is crucial to the effective use of the instruments and turnaround. However, conventional routing methods are based on a set of rules which might not be suitable for adapting to different workloads or instrument availability (Zaninotto et al., 2023).

AI can help to route specimens dynamically according to live operational conditions. The AI algorithms keep a watch on analyzer workload, priority of samples, instrument status, reagent inventory, maintenance schedules, and staffing. These data are then used to calculate the optimal routes for specimen processing, with the aim of optimizing route choice to ensure the most efficient path (Badrick & Stavelin, 2024).

Another use for machine learning models is predicting future workload patterns and dynamically changing routing strategies to avoid bottlenecks in advance. All of these capabilities help to make labs more efficient, turn times around faster and make the best use of resources (Haug & Drazen, 2023).

AI's use in pre-analytical phase illustrates the power of intelligent technologies in tackling the error-prone part of lab medicine. AI helps to improve the accuracy of diagnosis and patient safety by minimizing variability, improving specimen integrity, optimizing workflows, and aiding in quality management.

5. ARTIFICIAL INTELLIGENCE IN THE ANALYTICAL PHASE

The analytical phase includes any laboratory work that is directly related to the measurement or examination of patient specimens. Analytical error has long been regarded as the most important source of laboratory inaccuracy, but in the last few decades, with the development of instrumentation, automation, normalization of reagents and better calibration

procedures and quality management systems, its contribution to laboratory inaccuracy has been significantly reduced (Plebani et al., 2022). However, while these enhancements have been made, the goal of analytical excellence is always to be at the top of the list of objectives, as even a small analytical error can have a large impact on clinical decisions and clinical outcomes.

During the analytical stage, AI has become a game-changing technology, offering real-time monitoring, predictive analysis, smart quality control, sophisticated instrument management, and automated decision-making. Whereas traditional quality systems can mostly identify analytical issues only after they have happened, AI systems are now capable of becoming more proactive in spotting and preventing analytical issues prior to the impact on patient results (Badrick & Stavelin, 2024).

In the modern lab, a huge amount of analytical data is generated from instruments, quality control materials, calibrators, maintenance records, reagent lots, environmental monitoring systems and patient results. AI can leverage these varied data and detect patterns that traditional statistical analysis might not detect. The ability of this to move from reactive to predictive quality management and to enhance analytical reliability and patient safety (Lippi & Plebani, 2023).

5.1 AI-Driven Internal Quality Control (IQC)

One of the most significant methods of ensuring the analytical reliability is Internal Quality Control (IQC). IQC is a key function of monitoring assay performance and identification of analytical errors prior to reporting patient results. The laboratories have traditionally used statistical quality control systems for results based on mean, standard deviation, coefficient of variation, and Westgard multirule systems to identify if the analytical performance is within acceptable limits (Westgard, 2022). While traditional IQC techniques have been successful, there are some limitations. Most standard quality control procedures are based on the detection of errors after the quality control measurement is above a set limit. Thus, subtle changes in analysis, trends and problems with the instruments may not be identified until control errors are experienced (Badrick & Stavelin, 2024).

AI can overcome these challenges by constantly analysing the elements of quality control. Machine-learning algorithms can scan past QC performance and detect subtle trends and find early warning signs of analytical instability, even when the standard QC control rules are not breached. This predictive power helps to prevent analytical failures from impacting patient results, at least proactively, by allowing laboratory staff to intervene before it becomes an issue (Plebani et al., 2022).

An AI algorithm can identify slow reagent deterioration, calibration drift, temperature-related analytical variance, and instrument component wear and tear before the quality control values cross traditional limits of acceptance, for example. Early detection provides a greater stability of the assay and decreases the likelihood of false patient results (Lippi & Plebani, 2023).

Moreover, AI systems can analyze several quality measures at once. Conventional QC typically involves one or more single analytes; machine learning models can look at correlations between multiple assays, instruments, reagent batches and environmental conditions. The multi-dimensional approach offers analytical surveillance and a more holistic assessment of the laboratories' performance (Badrick & Stavelin, 2024).

5.2 AI and Moving Average Quality Control

Because of the use of patient data, rather than dedicated control materials, moving Average (MA) procedures have become increasingly popular as complementary quality control procedures. Moving average systems continuously compute the statistical summary of patient results and compare the results with the expected population distributions. If substantial differences are noted, it may represent analytical issues that should be investigated (van Rossum et al., 2020).

AI greatly boosts the sensitivity and specificity of moving average approaches. Common moving average methods use fixed decision boundaries and can result in too many false alarms, or too few true alarms. Machine learning algorithms can be used to dynamically fine-tune thresholds based on patient characteristics, disease prevalence, seasonal trends, and historical performance of the laboratory (Boursier et al., 2023).

Moving averages subjected to AI can continuously adjust to changing laboratory conditions and patient populations. As a result, they can get more and more accurate as time goes on, and minimize false alerts. These adaptive features enable more efficient analytical performance monitoring in real time and, in addition, the use of traditional internal quality control programs (IQCPlebani et al., 2022).

5.3 Predictive Maintenance of Laboratory Instruments

The reliability of instruments is crucial in maintaining continuous laboratory functioning. Analyser failures can cause major disruptions in the workflow, slow care of patients, rise in operating costs and impair productivity in the laboratory. Conventional maintenance approaches are usually preventative maintenance or repair after equipment failure, which is also known as reactive maintenance (Haug & Drazen, 2023).

Artificial Intelligence assists in predictive maintenance by interpreting the data produced during experiments using the laboratory equipment. Modern analyzers generate information about temperatures, pressures, sensor output, motor performance, reagent consumption, calibration stability, error logs, and maintenance history, to mention a few, every second of the day. These data are processed by AI algorithms to look for patterns that indicate potential equipment failures (Badrick & Stavelin, 2024).

Machine learning models can predict when certain components are likely to fail and recommend maintenance activities before operational disruptions. For instance, AI can detect shifts in how the device is performing on the photometer, pipetting, in the incubator temperatures, or in the mechanical movement pattern, which can predict instrument failure. Improved laboratory efficiency and reduced downtime with early intervention (Topol, 2019).

Predictive maintenance also helps in better financial management by optimizing maintenance schedules and eliminating unnecessary service. Rather than maintenance

followed by a set schedule, labs are able to use resources based on equipment condition and potential risk. The strategy enhances the analytical reliability and cost-effectiveness (Lippi & Plebani, 2023).

5.4 Artificial Intelligence and Calibration Management

In laboratory medicine, calibration is a basic procedure as reliable patient results requires reliable instrument calibration. Calibration sets up the connection between the instrument signals and the primary and secondary standards, ensuring traceability and measurement accuracy (Miller et al., 2023).

Typical calibration procedures are based on predetermined schedules based on manufacturer recommendations or regulatory standards. Although effective, such methods can lead to unnecessary calibration or lack of sensitivity to new analytical issues. Artificial Intelligence (AI) provides potential to enhance the effective management of calibration by using predictive analytics and continuous performance monitoring (Badrick & Stavelin, 2024).

The machine learning algorithms can assess historical calibration performance, reagent lot properties, quality control trend analysis, environmental parameters and instrument stability. These data can be used to estimate when calibration drift is likely to occur and help to recommend the best schedule for calibration for individual assays and instruments (Plebani et al., 2022).

This personalized approach could minimize the need for unnecessary calibrations, while at the same time enhancing analytical stability. In addition, AI can detect calibration errors that might not be observed the same way by reviewing the workflow traditionally, thus lessening the risk of miscalibrated patient results (Lippi & Plebani, 2023).

5.5 AI-Assisted Method Validation and Verification

The following method validation and verification are essential steps before new assays are used in clinical practice. Laboratories must prove the analytical method to be accurate, precise, linear, have an acceptable analytical measurement range, have a detection capability, have carryover performance and be clinically suitable (CLSI, 2023).

Typically, validation studies require many manual calculations and statistical analyses. They can be tedious, resource-intensive and prone to human error. AI offers opportunities to reduce the time spent on validation activities and increase the rigor of the analysis (Badrick & Stavelin, 2024).

An AI system can automatically process validation data and provide detailed performance evaluations. Precision studies, method comparison experiments, bias assessments, linearity evaluations, reference interval studies and measurement uncertainty analyses can be assessed using machine learning algorithms. The automated interpretation of validation data helps to decrease workload and also promotes consistency and reproducibility (Miller et al., 2023).

Additionally, AI can also compare validation results with historical lab performance and published benchmarks. These comparisons help to make evidence-based decisions with respect to the implementation of the method and whether it is acceptable to achieve the desired performance. Laboratories can thus benefit from more effective and effective validation procedures, while satisfying the accreditation requirements (Plebani et al., 2022).

5.6 Artificial Intelligence and External Quality Assessment (EQA)

External Quality Assessment (EQA), also known as Proficiency Testing (PT) is a fundamental part of the management of the quality of laboratories. EQA programs assess lab performance by comparing laboratory results to the results generated by other laboratories that are using similar methods and instrumentation (Miller et al., 2023).

While EQA programs offer useful performance information, interpretation of the EQA data may be difficult due to the fact that there are many factors that affect performance, such as reagent lots, calibration methods, instrument maintenance, analytical methods, and operator procedures. Advanced analytical capabilities of AI can be used to gain deeper insights from EQA datasets (Badrick & Stavelin, 2024).

Longitudinal EQA performance can be assessed with machine learning algorithms and subtle trends may be missed using traditional statistical methods. AI systems can detect analytical trends, reagent performance issues, reagent inconsistencies in calibration, and deviations in peer groups before they impact patient testing, allowing for early detection of these concerns (Plebani et al., 2022).

Additionally, AI can assist laboratories in performing root cause analyses following EQA failures. AI systems can leverage quality control records, calibration history, maintenance logs, reagents lot data, and environmental data to help determine potential root causes of any performance deviation and guide corrective action planning. These abilities enhance quality improvement initiatives and aid in achieving continuous analytical excellence (Lippi & Plebani, 2023).

5.7 Artificial Intelligence and Sigma Metrics

Many metrics are now being used as objective indicators of analytical quality, including Sigma. Sigma methodology combines the concepts of bias, imprecision and total allowable error into one single measure of performance that demonstrates the reliability and quality capability of the assay. The higher sigma values, the better the analytical performance and the lower the chances of reporting incorrect results (Westgard, 2022).

The calculation of the traditional sigma is usually done periodically, based on QC and PT results. Artificial intelligence can improve sigma management by providing continuous monitoring of performance and real-time estimation of sigma. As a novel approach, machine learning algorithms can be used to assess dynamic variations in analytical performance and alert to the onset of sigma performance degradation (Boursier et al., 2023).

With AI-driven sigma monitoring, laboratories can tailor their QC approach to the actual performance of their analytical methods. For instance, if an assay is found to have poor sigma performance, the assay might need more frequent quality control monitoring, more maintenance activity or calibration review. On the other hand, if the test

is highly stable, the level of monitoring can be reduced and still achieve quality standards (Badrick & Stavelin, 2024).

This risk-based approach ensures the optimal allocation of resources and is suitable for meeting quality management requirements. This therefore allows laboratories to be more efficient while maintaining analytical reliability and patient safety (Plebani et al., 2022).

5.8 Real-Time Detection of Analytical Errors

One of the greatest uses of AI in the analytical stage could be real-time error detection. Typical quality management systems usually detect issues when there is a control failure or abnormal patient results are reported. AI can be used to constantly monitor lab processes and help to identify new analytical challenges as they arise (Haug & Drazen, 2023).

Quality control data, distributions of patient results, instrument flags, calibration data, maintenance data, reagent inventories and environmental data can all be collected and analyzed at the same time by machine learning models. This holistic monitoring strategy empowers AI systems to detect intricate interactions and subtle anomalies that might not be noticeable at the human level, thus improving overall system understanding and performance (Badrick & Stavelin, 2024).

For instance, AI algorithms can find links between changes in environmental conditions and assay performance, identify reagent lot-specific biases, or recognize the beginning of photometric instability or other unexpected connections between two or more analytes. These features give laboratories unparalleled insight into lab performance and enable proactive quality management (Lippi & Plebani, 2023).

In conclusion, the use of AI in the analytical stage is a significant improvement in laboratory quality assurance. AI helps deliver accurate, reliable and clinically meaningful laboratory results by providing predictive quality control, intelligent maintenance, optimized calibration, better validation, advanced proficiency testing analysis and real-time error detection.

6. ARTIFICIAL INTELLIGENCE IN THE POST-ANALYTICAL PHASE

The post analytical phase refers to all processes after the analytical testing has been completed such as result validation, autoverification, clinical interpretation, reporting, communicating critical values, storing results and integrating into patient care pathways. While analytical errors have been significantly reduced over the last decades, post-analytical errors are significant contributors to patient harm as inaccurate validation of the analytical result, delayed reporting, mistakes during transcription and communication failures can have a negative impact on clinical decisions (Plebani et al., 2022).

In the past, post analytical tasks were mainly manual and depended on the labor intensive work of the laboratory technicians. While manual validation is still vital for complex cases, the growing volume of tests and the need for rapid result reporting has made it more difficult to validate manually. Artificial intelligence has great potential to improve post analytical processes, making them more efficient, consistent, accurate and clinically relevant, while keeping the patients safe (Lippi & Plebani, 2023).

By adopting AI in post-analytical tasks, such as reporting, labs can evolve from simple reporting systems to smart diagnostics assistance tools that detect anomalies, interpret patterns, make recommendations, and even support clinical decisions with evidence. With the advancement of healthcare systems towards precision medicine and personalized healthcare strategies (Topol, 2019), these are essential features.

6.1 AI-Assisted Result Validation

The validation of results is one of the most critical duties of laboratory personnel since each laboratory result is directly related to the management of a patient. The classical validation steps include the review of flags, quality control status, signs of specimen integrity, reference intervals, delta checks and clinical consistency prior to reporting patient results (Plebani et al., 2022).

Manual validation could become too time-consuming and prone to variability in review in high volume laboratories who process thousands of samples per day. The information is the same, but may be given different interpretations by various members of the laboratory staff that handle it, depending on their experience, workload, and clinical thinking. AI can also help to minimize this variability by offering standardized decision support systems that use consistent validation factors among all patient results (Badrick & Stavelin, 2024).

Multiple variables can be assessed at once, such as patient data, previous lab results, QC results, specimen quality markers, lab flags, drugs, diagnosis history, or clinical history, as can be done with machine learning algorithms. When combined, AI can discern if reported outcomes align with anticipated biological and clinical trends (Plebani et al., 2022).

An increase in potassium concentration from normal levels in a short period of time, for instance from 4.2 to 7.8 mmol/L without corresponding clinical findings, could be detected by the AI algorithms, which might then advise the physician to pursue further investigation. These systems can identify patterns indicating hemolysis, contaminant presence, transcription errors or analytical issues prior to the release of results to the clinician (Lippi & Plebani, 2023).

Multidimensional analysis is something that AI can do that is a significant benefit over traditional validation methods. Intelligent systems take a more holistic approach than focusing on individual metrics, and on the interrelationships between several laboratory variables. This means that laboratories can enhance the precision of the validation process and minimize the time spent on reporting results (Haug & Drazen, 2023).

6.2 Artificial Intelligence and Autoverification

The use of AI and advanced informatics in laboratory medicine is seen as one of the most successful applications, namely in the field of autoverification. Autoversification, (Zaninotto et al., 2023) is defined as the automatic release of laboratory results without any

manual intervention when certain quality and clinical criteria are met.

Most of the traditional autoverification systems are based on rule-based logic. These systems analyze the analytical quality indicators, instrument flags, the reference intervals, delta checks, and critical values based on preset criteria. Although effective, rule-based systems could be inflexible and not consider complex clinical situations (Plebani et al., 2022).

Artificial Intelligence is a great addition to autoverification; it utilizes machine learning algorithms that are able to learn from prior validation decisions. AI-powered autoverification systems can continuously learn from vast quantities of validated patient outcomes and create predictive models that can detect patterns that correlate with successful vs. unsuccessful outcomes (Badrick & Stavelin, 2024).

Research has shown that the potential for advanced autoverification systems to release the majority of routine laboratory results with excellent quality and patient safety is over 80% (Zaninotto et al., 2023). This significantly reduces the workload in the lab and enables professionals to concentrate on the more demanding, abnormal and clinically important cases that necessitate expert input.

AI-based autoverification systems have a number of benefits over rule-based systems. These systems are able to adjust to the changing conditions in the laboratory, learn from past decisions, and incrementally improve performance over time. Moreover, machine learning algorithms can detect complex relationships between variables that might not be obvious in a manual rules' writing process (Lippi & Plebani, 2023).

With the global volume of testing on the rise, AI-powered autoverification is likely to be a vital element of any lab's future. The intelligent autoverification systems contribute to operational efficiency and patient safety by delivering accurate lab results in timely fashion while reducing manual review efforts (Plebani et al., 2022).

6.3 Delta Checks and AI-Based Patient Monitoring

The delta check is an essential quality assurance tool which compares the results of the current laboratory test and the past laboratory test performed on a patient. If the two measurements differ significantly from each other, the analytical error, misidentification of the specimen, preanalytical error, or actual clinical change may occur, which should be explored (Westgard, 2022).

A common type of traditional delta check system is based on a percentage delta check or a fixed delta check difference. These methods are helpful, but can lead to over-alerting and under-detection of clinically significant changes in specific patients populations (Boursier et al., 2023).

AI improves delta checking by using patient-specific factors and clinical context in its decision making. Based on past patient information, disease dynamics, biological variation, treatment response, and demographics, machine learning models can be used to identify diseases that are clinically plausible for the observed changes (Badrick & Stavelin, 2024).

A very high serum creatinine, for instance, may be anticipated in a critically ill patient who has acute kidney injury but may be worth further investigation in a clinically stable outpatient. While traditional delta check systems cannot effectively evaluate this contextual information, an AI algorithm can, in combination with delta-based information, distinguish between these scenarios (Plebani et al., 2022).

This customised approach has benefits of better sensitivity, specificity and less unnecessary investigations. Therefore, the laboratories are able to better detect true errors, while reducing error alerts that lead to alert fatigue within the laboratory environment (Lippi & Plebani, 2023).

6.4 Critical Value Management and Patient Safety

Critical values are laboratory values that are outside of the reference range and are potentially life-threatening and warrant urgent clinical action. It is important to communicate important values in a timely manner as delays could have a dramatic impact on patient outcomes. They include severe hyperkalemia, marked cardiac biomarker elevations (Plebani et al., 2022), profound hypoglycemia, and severe coagulation defects.

Typical critical value management processes are often reliant on manual review, telephoning and documentation procedures. While effective, these workflows can be susceptible to delays, miscommunications, and documentation mistakes, especially when workload is high (Lippi & Plebani, 2023).

AI optimizes critical value management by automating value prioritization, notification, escalation and tracking. AI systems not only can quickly detect critical results but can also determine the urgency level, identify responsible clinicians and trigger the communication workflows without delay (Haug & Drazen, 2023).

Moreover, intelligent systems can track if the critical values were recognized and corrected properly. Unacknowledged notifications within defined time periods can be escalated automatically to other healthcare professionals or supervisory staff members by the use of AI algorithms. The features can help improve patient safety by providing timely information to clinicians (Badrick & Stavelin, 2024).

Machine learning models can also detect patterns related to delayed critical value responses and suggest workflow changes. These observations help inform ongoing quality improvement and enhance delivery of safer healthcare systems (Plebani et al., 2022).

6.5 AI-Generated Interpretative Comments

The complexity of laboratory medicine has been rising and so has the need for interpretative support. Numerous laboratory parameters need to be read within a frame of reference since a single number may not properly reflect the clinical significance of the results. Laboratory specialists often comment on the results to help the clinician interpret the results and decide on further action (Lippi & Plebani, 2023).

AI has shown promising results in producing standardized, evidence-based interpretative comments. Laboratory results, clinical history, diagnosis, medications, and relevant guidelines can be analyzed using NLP and machine learning technologies to provide patient-specific interpretations (Wang et al., 2023).

For instance, AI can detect biochemical markers indicative of iron deficiency anemia, thyroid conditions, liver diseases, renal failure, or inflammatory conditions. These findings can be used to develop algorithms that provide clinically meaningful interpretive statements to assist in diagnostic decision making and enhance clinical-laboratory communication (Topol, 2019).

These types of systems are not intended to replace the skill of expert lab professionals, but rather expand their skill set by making evidence-based recommendations in a consistent manner. While laboratory experts continue to oversee intricate cases and maintain clinical appropriateness, AI is primed to alleviate repetitive interpretative tasks and boost standardization (Badrick & Stavelin, 2024).

6.6 Clinical Decision Support Systems

Clinical Decision Support Systems (CDSS) is one of the most transformative use of Artificial Intelligence (AI) in laboratory medicine. These systems use lab data along with clinical data to suggest diagnostics, risk categorization, therapeutics, and prognosis (Topol, 2019). Machine learning algorithms are able to recognize complex relationships between laboratory variables that could be predictive of the early stages of disease before clinical signs and symptoms are observed. An example of this is AI systems that have shown to be quite successful in predicting complications such as sepsis, acute kidney injury, cardiovascular events or disease progression from a combination of laboratory parameters and clinical data (Haug & Drazen, 2023).

Laboratory data, combined with genomics, proteomics, metabolomics, imaging information, and electronic health records, improve diagnostic accuracy even more. These multi-dimensional analyses can aid precision medicine programs aimed at providing tailored care to patients based on their personal characteristics (Plebani et al., 2022).

With the increasing trend towards data-driven decision making in healthcare, laboratory medicine is anticipated to be a key contributor to providing actionable information for clinical decision-making systems using AI. This transformation further underscores the strategic role played by laboratories in today's healthcare landscape (Lippi & Plebani, 2023).

6.7 Reduction of Post-Analytical Errors

Post analytical errors are a wide variety of problems related to delayed reporting, incorrect reporting, transcription errors, communication problems, and inadequate interpretation. The post-analytical failures are uncommon but could have a significant impact on patient care as they occur after the analytical testing is carried out successfully (Plebani et al., 2022).

AI helps reduce errors by performing automatic verification, managing electronic communication, monitoring devices automatically and tracking high level workflows continuously. AI algorithms can help identify inconsistencies between results and patient history, identify missed transmissions, verify the completeness of the reports, and ensure timely delivery of laboratory information (Badrick & Stavelin, 2024).

Additionally, machine learning models can constantly monitor lab performance metrics and detect potential risks before they cause errors. This proactive strategy is useful for continuous quality improvement and improving laboratory quality management systems (Lippi & Plebani, 2023).

In the post-analytical phase, the use of artificial intelligence further increases the certainty of the laboratory, improves patient safety, aids medical decision making, and helps to make healthcare delivery more efficient. From the post-analytical point of view, the intelligent technologies are evolving and will be increasingly automated, personalized and integrated into clinical services, further strengthening the importance of laboratory medicine in evidence-based healthcare.

7. ARTIFICIAL INTELLIGENCE IN LABORATORY QUALITY MANAGEMENT SYSTEMS (QMS)

Quality is the basis of laboratory medicine, as all laboratory results impact on clinical decisions, patient management plans and health outcomes. The main purpose of laboratory quality management is to guarantee that all results reported are accurate, reliable, timely, clinically meaningful and traceable throughout the entire testing process. Modern laboratories therefore must work within the framework of a comprehensive Quality Management System (QMS) to monitor, control, evaluate and improve all aspects of laboratory performance (ISO, 2022).

The application of Quality Management Systems has changed significantly in the past few decades. Quality programs traditionally were based upon analytical quality, with quality control and proficiency testing activities. In the current quality frameworks, however, it is acknowledged that errors can happen at any point in the overall testing process, from pre-analytical, to analytical, to post analytical. Hence, the modern quality management focuses on the overall management of the laboratory process, not on single laboratory activity (Plebani et al., 2022).

AI is rapidly proving to be a potent solution that can revolutionize the way laboratory quality management is carried out, moving beyond traditional quality systems to become intelligent, predictive, and adaptable. Instead of reacting to issues once they have been discovered, AI can help laboratories take proactive steps to prevent problems, forecast failures, streamline operations, and apply corrective measures. One of the biggest steps forward in laboratory medicine today is the shift from reactive to predictive quality management (Badrick & Stavelin, 2024).

7.1 Evolution from Reactive to Predictive Quality Management

Conventional quality management systems are mainly based on backward looking analysis. Typically, quality indicators, quality control reviews, incident reports, proficiency testing results, and corrective action records are analyzed after the events have happened. These methods are still crucial but can fail to prevent that issues have an impact on the patient outcome before they are seen (Lippi & Plebani, 2023).

AI adds predictive features, revolutionizing quality management practices. Historical and real-time laboratory data can be fed into machine learning algorithms to continuously analyze and find patterns that predict future quality failures. These systems are designed to learn from past incidents and to be able to predict risks before it happens (Topol, 2019).

For instance, AI can detect patterns in quality control trends, calibration variations, environmental changes, reagent lot variations, and instrument performance metrics that have historically led up to analytical failures. If similar patterns reoccur, the system can warn laboratory staff before patient testing is impacted. This predictive surveillance is a major boost for quality assurance programmes and lessens the risk of mis-reporting of results (Badrick & Stavelin, 2024).

Predictive quality management is of great value for the reason that error in the laboratory is seldom a one-off occurrence. The majority of quality failures are due to a combination of factors. AI is particularly well-suited to capture these complex, multi-dimensional relationships and to find risks that may be overlooked with traditional statistical methods (Plebani et al., 2022).

7.2 Artificial Intelligence and ISO 15189 Compliance

ISO 15189 is a world-recognized quality standard for medical laboratories. ISO 15189:2022 puts a strong focus on the concept of risk-based thinking, patient-centred care, continuous improvement, process management, competence assessment and evidence-based quality assurance. Laboratories accredited to ISO 15189 should be capable of consistently generating laboratory results that are valid and should have effective quality management systems (ISO, 2022).

Let's take a look at how AI can help achieve ISO 15189 compliance in several ways. Continuous monitoring of laboratory performance via quality indicators is one of the key concepts of ISO 15189. Quality indicators can be automatically collected, analysed, interpreted and reported for all stages of laboratory testing using AI systems. Therefore, laboratories are able to have real-time performance and trends in operational performance and quality (Plebani et al., 2022).

The standard also calls for laboratories to assess risks, put in place mitigation measures, and regularly review their effectiveness. AI-powered risk assessment tools can gain insights from incident reports, quality indicators, equipment performance metrics, and workflow metrics to anticipate risks that might lead to quality failures. These can be directly applied to the risk management principles laid out in ISO 15189 (Badrick & Stavelin, 2024).

In addition, ISO 15189 requires laboratories to provide evidence of decision making and continuous improvement based on evidence. These activities are further boosted by AI, which delivers sophisticated analytics to help measure performance objectively and implement data-driven quality improvement programs. AI is expected to play a key role in future accreditation strategies as laboratories progressively shift to digital technologies (Lippi & Plebani, 2023).

7.3 Artificial Intelligence and CAP Accreditation

The College of American Pathologists (CAP) accreditation program is regarded by many as one of the most stringent laboratory accreditation programs in the world. Analytical excellence and quality assurance, patient safety, competency assessment, and continuous quality improvement are important aspects of CAP accreditation (CAP, 2024).

A large amount of documentation is created during quality control, proficiency testing, maintenance, competency, investigations of incidents, and corrective actions, in all of which CAP-accredited laboratories participate. The man management of these data can be complex, especially in large healthcare institutions that conduct millions of tests yearly (Plebani et al., 2022).

AI can help with CAP compliance by streamlining data collection, trend analysis, and documentation management. Machine learning systems can be continually monitoring quality indicators, performance deviations, and provide alerts if quality requirements related to CAP might be in jeopardy. These features enable proactive compliance management and streamline administration (Badrick & Stavelin, 2024).

AI also can help laboratories during CAP inspections, by creating an organization of quality records, summarizing performance metrics, and anticipating possible deficiencies before inspection activities are undertaken. This proactive approach contributes to improved readiness and to the improvement of the overall performance of the quality management (Lippi & Plebani, 2023).

7.4 Artificial Intelligence and Individualized Quality Control Plans (IQCP)

Individually Developed Quality Control Plans (IQCP) are risk-based quality management practices which allow quality control activities to be customized based on the testing process at a specific laboratory. Throughout the entire testing process, IQCP highlights the need to identify potential risks and implement appropriate control measures to reduce these risks (CLSI, 2023).

Effective IQCP programs need to consider a variety of factors, such as the nature of the specimen, environmental conditions, instrument performance, reagent stability, operator competency, and workflow complexity. These assessments can get very complicated, especially when testing is conducted in low volume or for specialized assays (Miller et al., 2023).

The use of artificial intelligence (AI) boosts the development of the IQC by analyzing vast amounts of data gathered from laboratory functions and identifying factors that can be linked to quality failures. Traditional quality assessment methods are inadequate for quantifying risk levels, but machine learning models can assess historical quality incidents, quality control records, maintenance logs, and proficiency testing results to accurately quantify risk levels (Badrick & Stavelin, 2024).

AI systems can also provide ongoing surveillance of the effectiveness of the IQCPs and suggest changes when the laboratory environment changes. This dynamic approach helps to guarantee that quality control strategies are in line with the operational context, rather than just with periodic and manual reviews (Plebani et al., 2022).

7.5 Artificial Intelligence in Laboratory Risk Management

Error prevention has become a major part of today's laboratory quality system, as it is easier to prevent errors than to repair them when they happen. A laboratory risk can be caused by equipment failure, problems with specimen handling, reagent issues, environmental issues, workflow issues, information technology issues, or human error (ISO, 2022).

Failure Modes and Effects Analysis (FMEA) and Root Cause Analysis (RCA) are two traditional risk management methodologies that can be used to identify and assess risks. Such strategies typically rely on subjective assessments and may not fully consider the interplay between several factors (Plebani et al., 2022).

Artificial intelligence brings in data-driven risk assessment techniques that can analyse thousands of factors at once. The machine learning algorithms process historical incident, workflow performance, equipment, quality and operational trends to look for patterns that indicate increased risk. These analyses help to make objective risk assessments and enable prioritisation of quality improvement actions (Badrick & Stavelin, 2024).

Also, AI allows continuous risk monitoring instead of periodic assessments. Intelligent systems continuously retrieve and recalculate risk predictions in response to changes in laboratory conditions and give early warnings about new threats. This approach is proactive and enhances patient safety and the effectiveness of quality management strategies (Lippi & Plebani, 2023).

7.6 Artificial Intelligence and Root Cause Analysis

Root Cause Analysis plays a widespread role in laboratory medicine to investigate adverse events, such as quality incidents, proficiency testing failures, quality control violations, specimen errors, and other adverse events. The aim of RCA is to find the root causes and take corrective measures to avoid reoccurrence (CLSI, 2023).

Traditional RCA processes typically involve a lot of manual effort to investigate, such as reviewing quality records, maintenance logs, personnel activity, environmental conditions and workflow data. It is difficult and time-consuming, in these cases, to eventually determine the actual cause of a problem in the laboratory systems, due to their complexity (Plebani et al., 2022).

The use of artificial intelligence can aid in the RCA by quickly analyzing various data sources and uncovering patterns and connections between the factors involved. Machine learning algorithms can identify patterns that are repeated for a certain quality failure type and make causal inferences based on these patterns. These features speed up investigations and enhance effectiveness in corrective action planning (Badrick & Stavelin, 2024).

To assess the outcomes of corrective action over time, AI-assisted RCA systems can be used to check if the corrective actions taken have been effective in lowering risk and enhancing quality performance. This ongoing cycle contributes to sustainable quality improvement efforts (Lippi & Plebani, 2023).

7.7 Artificial Intelligence and Six Sigma Quality Management

Within laboratory medicine, six sigma is a quantitative analytical quality evaluation approach that is broadly applied. A sigma metric combines analytical bias, imprecision and total allowable error into one dimension of performance that reflects process capability and defect probability (Westgard, 2022).

The sigma calculations are traditionally done on a periodic basis with the aid of QC and PT data. These calculations are useful, but often give only a post hoc analysis of the performance of the analytical method. AI extends the sigma methodology by continuously evaluating the process capability in real time (Boursier et al., 2023).

With machine learning algorithms, the performance of an individual can be closely monitored, and be predicted before performance changes become clinical, letting one know to adjust the machine before it actually requires correction. Such predictive abilities enable laboratories to act proactively and ensure they deliver analytical performance of high quality (Badrick & Stavelin, 2024).

In addition, AI systems can suggest tailored quality control measures according to the existing sigma performance. In some cases, assays with a low sigma will need to be monitored more intensively, and in other cases, assays with a high stability will be monitored more efficiently without compromising the quality. The use of this risk-based approach is a step forward to optimize the use of resources while still complying with quality standards (Plebani et al., 2022).

7.8 Artificial Intelligence and Quality Indicators

Quality indicators are vital tools that can be used to assess laboratory performance and also to help identify areas for improvement. A few examples are: rejection of specimens, specimen turnaround time, performance on critical values, results of proficiency testing, quality control failures, and customer satisfaction indicators (ISO, 2022).

Typical QI programmes include regular data collection and a review of results in the past. These programmes are improved with artificial intelligence, which allows for live tracking and forecasting. AI systems can constantly monitor quality parameters, detect trends and provide early warnings of possible performance deterioration (Lippi & Plebani, 2023).

For instance, machine learning models can detect rising rejection rates in specific clinical areas and suggest interventions to correct the trend before it reaches undesirable levels. This proactive monitoring can help to enhance quality management and contribute to ongoing improvement efforts (Badrick & Stavelin, 2024).

In conclusion, the incorporation of AI into laboratory quality management systems is a promising step toward improving healthcare quality assurance. AI can contribute to better quality, reliability, efficiency, and patient safety in laboratories by facilitating predictive analytics, risk management, accreditation compliance, continuous monitoring, and evidence-based decision-making. As intelligent technologies further develop, AI-based quality management systems can be expected to be integral parts of the future operation of laboratories and accreditation processes.

8. VALIDATION, REGULATORY REQUIREMENTS, AND GOVERNANCE OF ARTIFICIAL INTELLIGENCE SYSTEMS IN MEDICAL LABORATORIES

However, the effective application of AI in laboratory medicine requires robust validation and compliance testing, moral oversight, and ongoing monitoring and evaluation. Although AI has proven to be a powerful tool in enhancing the quality, efficiency, and clinical decision-making in the laboratory, its impact on patient care ultimately requires it to be subject to standards equivalent to those imposed on analytical instruments, laboratory developed tests, and diagnostic assays (Plebani et al., 2022).

AI systems have distinct features that come with extra complexities, as opposed to standard lab apparatus. Machine learning models can be continuously updated, adapted to new data, and produce results from extremely complicated patterns of math, which may not be easily interpretable by human users. Thus, extensive frameworks need to be put in place at the laboratory level to maintain the accuracy and reliability of AI systems, as well as their transparency, reproducibility, and clinical appropriateness over their entire lifespan (Badrick & Stavelin, 2024).

With the increasing uptake of AI into Total Laboratory Automation systems, guidance is also under development by regulatory bodies, accreditation bodies and professional societies to address these new challenges. Thus, validation and governance are key elements of responsible implementation of AI in lab medicine (Topol, 2019).

8.1 Why Artificial Intelligence Requires Validation

Validation is one of the basic tenets of laboratory quality management. Labatories must prove that the analytical method they introduce into clinical practice gives consistent results suitable for its use before it is used. As with any other system, artificial intelligence systems can impact patient diagnosis, treatment, specimen handling, quality management activities, and result reporting processes (CLSI, 2023).

AI systems often rely on complex statistical models, which make inferences from vast amounts of data, unlike traditional lab techniques. These models are only accurate if the data on which they are built and trained are accurate, representative and complete. Therefore, validation should not only consider the performance of the algorithms, but also the integrity of the data, the robustness of the model, and clinical applicability (Plebani et al., 2022).

The deployment of AI systems in other clinical settings can cause a drop in performance, so validation is also paramount. Algorithms can be sensitive to variations in the patient population, as well as in disease prevalence, laboratory instruments, workflows, and data quality. So, it is not possible to take laboratory results for granted in the local context (Badrick & Stavelin, 2024).

By rigorously validating AI systems, patient safety is safeguarded as they deliver clinically relevant results in real world operating conditions. Moreover, validation confers trust to the reliability of processes based on AI among laboratory professionals, clinicians, accreditation bodies, and regulatory authorities (Lippi & Plebani, 2023).

8.2 Analytical Validation of AI Systems

Analytical validation is a method to assess the technical performance of AI algorithms in a controlled environment. Like the standard validation of an assay, analytical validation aims to establish if the system functions in a stable way and meets the predetermined requirements (CLSI, 2023).

There are a few parameters used to validate an AI. These encompass accuracy, sensitivity, specificity, precision, reproducibility, robustness and stability. Additional performance measures may also be evaluated based on the intended application and include positive predictive value, negative predictive value, area under the receiver operating characteristic curve (AUC) and F1 scores (Esteva et al., 2019).

An AI algorithm that detects hemolyzed specimens should be assessed with large data sets of hemolyzed and non-hemolyzed specimens, for instance. The algorithm should be validated for its accuracy in classification of specimens across a range of conditions, including the consistency of performance across a range of specimen types, analyte concentration, and laboratory conditions (Erdinc et al., 2024).

Likewise, AI-based QCI systems need to be stable for the detection of analytical shifts, trends, random and systematic errors in realistic laboratory situations. Validation should involve comparing decisions made by AI with decisions made by experts and known quality management processes (Badrick & Stavelin, 2024).

Algorithm robustness should also be analyzed through analytical validation. Laboratories should assess their systems to see how they perform when the data is incomplete or the patient population is atypical, the environment is different, or the workflow is unusual. These evaluations guarantee that AI systems operate effectively in typical scenarios (Plebani et al., 2022).

8.3 Clinical Validation of Artificial Intelligence

The lack of analytical performance does not necessarily justify clinical application. In addition, AI systems should be clinically valid, such that their output has a meaningful impact on the care provided to the patient and the appropriate clinical decision that is made (Topol, 2019).

Clinical validation measures the accuracy of AI-generated information from the clinical standpoint. In the case of an AI system predicting the likelihood of sepsis, for instance, it should be shown to have predictive value that aligns with actual patient outcomes and to offer clinically relevant insights that surpass the current diagnostic methods (Haug & Drazen, 2023).

Laboratory medicine clinical validation can include the effectiveness of AI-based autoverification, interpretative comments, critical value management systems, diagnostic support systems, or predictive quality management applications. There are usually challenges to working together between laboratory specialists, clinicians, statisticians and informatics specialists in these evaluations (Plebani et al., 2022).

Prospective validation studies are preferred to studies as these tests performance under real clinical situation.

Retrospective analysis can, however, be useful for preliminary evidence for other stages of algorithm development. However, in any study of implementation, the outcomes of implementation need to be validated to ensure that the implementation of AI has a positive impact on clinical outcomes, operational efficiency, patient safety, or diagnostic accuracy, without causing unacceptable risks (Badrick & Stavelin, 2024).

8.4 Explainable Artificial Intelligence (XAI)

The "black box" effect of the many machine learning algorithms is one of the most often mentioned issues with AI. These complex deep learning models can make predictions with a high degree of accuracy but with little understanding of how they reach predictive conclusions. This opacity can lead to a loss of users' confidence and increase the complexity of the regulatory process for approvals (Samek et al., 2021).

To address these concerns, Explanable Artificial Intelligence (XAI) aims to create techniques that make AI decision making more transparent and interpretable. In the case of healthcare, there is a need to be particularly aware of explainability, as health care providers and lab experts are required to grasp why recommendations could impact patient treatment (Topol, 2019).

If, for instance, an AI system identifies a lab test result as possibly being incorrect, the user should know what factors led the AI to the conclusion. Likewise, if a machine learning algorithm says that there is a higher probability of analytical failure, the laboratory worker should be able to find out what variables the algorithm is looking at. This transparency can foster trust, aid in validation processes, and enhance user acceptance (Badrick & Stavelin, 2024).

Explainability techniques that are widely used today include feature importance analysis, decision trees, SHAP (Shapley Additive Explanations) values, and local interpretable model-agnostic explanations (LIME). Such strategies enable the user to gain insight into the functioning of the algorithm and maintain predictive performance (Samek et al., 2021).

Explainability is likely to be more and more required for accreditation, regulatory approval and clinical acceptance as the use of AI systems grows in the field of laboratory medicine (Plebani et al., 2022).

8.5 Bias, Fairness, and Ethical Considerations

AI systems can be taught by looking at past data. Thus, biases in the training data sets can manifest in algorithm behavior. Differences in demographic, data quality, measurement, health care and historical clinical practices can all contribute to bias (Rajkomar et al., 2018).

Biased algorithms can be less accurate when used to predict outcomes in certain populations, if they are not adequately represented during algorithm creation, in laboratory medicine. These differences may lead to inequities in health care and be detrimental to the trust in AI technologies (Topol, 2019).

Therefore, it is essential that the performance of the algorithms used in AI systems is assessed across a wide range of patients, and that predictive accuracy does not vary with age, sex, ethnicity, socioeconomic status or disease prevalence. Ongoing surveillance is required as bias can develop over time as patient populations change (Badrick & Stavelin, 2024).

Ethical issues encompass more than just bias, and are tied to transparency, accountability, informed consent, privacy, autonomy, and professional responsibility. In any case, laboratory professionals are still the ones who handle patient results, with or without the involvement of AI systems. So, in even the most automated environments, human supervision is still necessary (Plebani et al., 2022).

8.6 Cybersecurity and Data Protection

Digital infrastructure, interconnected networks, cloud computing platforms, and big data storage systems are all critical components for AI systems. These technologies provide opportunities for sophisticated analytics and smart automation, but pose cybersecurity risks that need to be addressed (Haug & Drazen, 2023).

Ransomware attacks and other malware, unauthorized access and data breaks are threats that are becoming more common in the world of healthcare. In conclusion, cybersecurity is a significant concern for AI-powered laboratories, as these systems are tasked with safeguarding sensitive patient data and enabling vital medical operations.In summary, cybersecurity is a critical concern for AI-powered laboratories, given its role in protecting patient information and facilitating essential healthcare functions.

These are some of the best practices in cybersecurity: Encryption, Multi factor authentication, Network segmentation, Access controls, Vulnerability assessment, Continuous monitoring. AI systems can also play a role in cybersecurity, as they can be used to monitor the network for unusual activity or suspicious behavior and alert users to potential threats before any damage is done (Badrick & Stavelin, 2024).

Data protection is also crucial as AI development often involves handling extensive patient information. Laboratories are required to be compliant with relevant privacy laws and have proper governance in place for data collection, storage, sharing and analysis. To preserve public confidence and adherence to regulations, it is crucial to ensure responsible data stewardship (Plebani et al., 2022).

8.7 Regulatory Oversight of Artificial Intelligence

Governments around the globe are diligently working on AI healthcare technology regulations. Regulatory strategies aim to reconcile innovation with the protection of patients, setting guidelines for validation, monitoring, transparency, and risk management (FDA, 2024).

The United States Food and Drug Administration (FDA) has released some guidance on software as a medical device (SaMD) and AI-enabled healthcare technologies. The importance of lifecycle management, continuous performance evaluation and post-market surveillance is stressed in these frameworks (FDA, 2024).

Likewise, the European regulatory bodies have taken AI into account in the ongoing development of medical device legislation and the assessment of healthcare technology. Harmonizing standards, including by international organizations, are also underway to enable

responsible implementation of AI in healthcare systems (European Commission, 2024).

Lab operations that implement AI technologies should keep in mind that regulatory expectations are changing, and validation, documentation, monitoring and governance activities are in line with the applicable requirements. As AI increasingly takes on roles in laboratory workflows, regulatory compliance will be increasingly important (Badrick & Stavelin, 2024).

8.8 Continuous Monitoring and Lifecycle Management

Validation should not be considered as a "one-off" exercise. While laboratory tests are fixed and cannot adapt to shifts in data distribution and patient populations, AI systems could get better over time as the data distribution changes, as patient populations evolve, and as healthcare practices improve. Therefore, ongoing performance monitoring is crucial during the entire life cycle of an AI system (Plebani et al., 2022).

Continuous monitoring should be undertaken to assess accuracy, stability, bias, user interactions, operational performance and clinical outcomes. When results are deviated substantially from the expected, then they should be investigated and re-trained or recalibrated of algorithms when needed. This lifecycle management guarantees that AI systems perform as required over time (Badrick & Stavelin, 2024).

Governance committees in laboratories should be set up to monitor the use of AI, review incidents, evaluate risks and approve changes to the system. A multidisciplinary approach with the involvement of laboratory professionals, clinicians, data scientists, informaticians, and quality managers facilitates responsible use and enhances patient safety when using AI (Lippi & Plebani, 2023).

In conclusion, validation and governance are essential elements for the successful use of AI in laboratory medicine. By employing rigorous analytical and clinical validation, transparent decision making, ethical surveillance, cybersecurity measures, regulatory compliance, and ongoing performance monitoring, laboratories can benefit from AI while upholding the highest quality and patient safety standards.

9. FUTURE DIRECTIONS OF ARTIFICIAL INTELLIGENCE IN MEDICAL LABORATORIES: TOWARD LABORATORY MEDICINE 5.0

AI is quickly becoming an integral part of the current and future landscape of molecular laboratory medicine. The applications in use are mainly about workflow optimization, quality management, autoverification, predictive maintenance and decision support, but in the future, the laboratories will be highly intelligent, interconnected and self-optimizing ecosystems. This trend reflects the wider shift from Laboratory Medicine 4.0 to Laboratory Medicine 5.0, which is focused on human-centric innovation, intelligent automation, personalized medicine and the integration of digital technologies in healthcare.

The future laboratory will probably not just be a place for diagnostic testing, but a sophisticated information hub that will continuously assimilate laboratory and clinical information, genetic data, imaging data, information from wearable devices, and population information. All these information streams will be linked to each other through AI, which will transform the information into actionable clinical insights (Topol, 2019).

With the ongoing digital transformation of healthcare systems, AI-powered labs can be anticipated to take on more significant roles in precision medicine, predictive healthcare, disease prevention, and population health management. The progress could have great impact on patient care, but it could also make healthcare systems more efficient, of higher quality and sustainable. (Haug & Drazen, 2023)

9.1 Digital Twins in Laboratory Medicine

Digital twins are perhaps one of the more promising applications for Artificial Intelligence in the future. A digital twin is a virtual version of a physical system that is continually updated with actual operational data. Digital twin can be found in the engineering and manufacturing industries but is now being applied in healthcare and laboratory settings (Tao et al., 2022).

Digital twins, in laboratory medicine, can be used to simulate complete laboratory functions, a single analyzer, testing process, or even a patient's biological system. Such virtual models can also reproduce performance in the laboratory and simulate the various processes, enabling organizations to assess process changes, predict bottlenecks, determine risks, and optimise resource allocation before embarking on process changes in real-world situations (Plebani et al., 2022).

For instance, a digital twin of a Total Laboratory Automation system could simulate the flow of specimens across the laboratory and help detect laboratory inefficiencies before they impact patient care. Likewise, virtual copies of analytical instruments might forecast maintenance needs and also the performance traits in the future. This would be highly beneficial for the operational planning and quality management (Badrick & Stavelin, 2024).

Another potential option is patient-specific digital twins. These systems can incorporate laboratory data, genomic information, clinical history and physiological measurements for modeling disease progression and prediction of therapeutic response. These individual simulations could help individualize diagnostic and therapeutic approaches (Topol, 2019).

9.2 Autonomous Laboratories

Existing laboratory automation systems still require a lot of human supervision and manipulation. Future laboratories, however, can develop into highly autonomous units that can be able to monitor, optimize and correct their operations themselves. It will be imperative for this transformation to be facilitated by artificial intelligence (Haug & Drazen, 2023).

The performance of the instruments, specimen flow, quality indicators, reagent inventories, staffing needs, and environmental conditions would be monitored on a continual basis in the autonomous laboratories. Machine learning would detect inefficiencies, forecast potential operational issues, and take remedial measures without the need for manual intervention. These would

substantially cut down on human effort and enhance consistency and efficiency (Badrick & Stavelin, 2024).
For instance, automatic routing of specimens to analyzers based on analyzer availability; optimizing staffing in relation to predicted workloads; preventive maintenance schedules before equipment failure; and changing quality control schemes to meet changing analytical performance. These functions would lead to very adaptable laboratory settings, which can continuously optimize the effectiveness of operations (Plebani et al., 2022).
While true autonomy is still a long way off, several aspects of autonomous operation of a laboratory are already materializing, with the incorporation of artificial intelligence, robotics and sophisticated informatics systems. Laboratory professionals will be able to dedicate more time to complex laboratory, interpretative and clinical tasks in the future, as routine manual tasks will be further reduced (Lippi & Plebani, 2023).

9.3 Generative Artificial Intelligence in Laboratory Medicine

Generative AI is a rapidly evolving space in AI. Generative AI systems are capable of producing new content, explanations, summarising information, providing complex human-like interactions and more, in addition to classification and prediction (Bommasani et al., 2021).
Generative AI can be used in a wide range of applications within laboratory medicine. They range from automatic report generation to development of interpretative comments, educational content writing, literature summarization, quality documentation support, and clinical consultation support. These systems can significantly decrease paperwork and enhance the communication between laboratory and medical professionals (Topol, 2019).
Laboratory professionals can also use generative AI to help them troubleshoot analytical issues, analyze quality control information, create validation protocols, and write accreditation paperwork. These systems can quickly generate massive amounts of information and help with evidence-based decision-making while enhancing operational efficiency (Badrick & Stavelin, 2024).
Even with these benefits, there are significant challenges when using generative AI that address issues of accuracy, reliability, explainability, and accountability. To this end, it is crucial for laboratories to develop strong governance mechanisms to guarantee that outputs generated with AI are properly reviewed and validated before impacting patient care (Plebani et al., 2022).

9.4 Precision Medicine and Personalized Diagnostics

Precision medicine is about giving patients the right treatment based on their individual characteristics. This includes things like their profiles what they are exposed to in their environment their lifestyle and specific markers for their disease. Laboratory medicine is a part of precision medicine because it provides a lot of the information needed to make decisions about patient care.
For example precision medicine looks at each patients profiles, environmental exposures, lifestyle factors and disease-specific biological markers to tailor healthcare interventions. Laboratory medicine plays a role in precision medicine because laboratory tests generate much of the information required for personalized healthcare decision-making as noted by Collins and Varmus in 2015.
Artificial intelligence is also important in precision medicine. It helps by combining types of data and finding relationships that might not be obvious at first. Machine learning algorithms can look at a lot of types of data all at once like genomic sequences, proteomic profiles and laboratory results. This helps create a picture of each patients health. According to Topol in 2019 machine learning algorithms can analyze sequences, proteomic profiles, metabolomic data, laboratory results, imaging findings and clinical histories simultaneously.
In the future artificial intelligence systems might be able to give us reference intervals that're specific to each patient. This would be based on things like the patients demographics, genetic characteristics and clinical conditions. Of using reference ranges that are based on the whole population laboratories could give personalized interpretations that are more accurate for each individual. As Plebani and colleagues noted in 2022 this approach could provide accurate reference intervals.
Artificial intelligence can also help detect diseases by finding small abnormalities in laboratory parameters before symptoms appear. This can help with medicine and give us more opportunities to intervene early. For instance Haug and Drazen in 2023 highlighted the potential of intelligence in facilitating early disease detection.

9.5 Artificial Intelligence in Molecular Diagnostics and Genomics

There have been a lot of advances in genomic technologies, which has led to a huge amount of biological data. Modern sequencing platforms can produce datasets that need sophisticated computational analyses to make sense of them. Because of this artificial intelligence has become very important in diagnostics and genomic medicine.
For example machine learning algorithms can identify disease-associated variants predict the effects of mutations and classify molecular subtypes of diseases. Artificial intelligence is particularly valuable because many genomic datasets contain patterns that are hard to analyze using traditional statistical methods. As Topol noted in 2019 machine learning algorithms can identify disease-associated variants and predict functional consequences of mutations.
In the future laboratory medicine will likely involve combining a lot of types of data like genomic, transcriptomic, proteomic, metabolomic and epigenomic data. Artificial intelligence will be a tool for synthesizing this information and turning it into knowledge that can be used in clinics. This will help us get closer to personalized medicine as Plebani and colleagues noted in 2022.

9.6 Digital Pathology and Computer Vision

Digital pathology is changing rapidly thanks to advances in intelligence and computer vision technologies. Whole-slide imaging systems can now digitize specimens and analyze them using deep learning algorithms. These algorithms can identify patterns associated with disease.

For instance future artificial intelligence systems might be able to detect tumors grade them stage them assess biomarkers and evaluate prognoses with high accuracy. Similar advances are happening in hematology, microbiology and cytology where computer vision technologies are increasingly used to interpret images and recognize patterns. As Campanella and colleagues noted in 2019 whole-slide imaging systems can now digitize specimens and analyze them using deep learning algorithms.

While human expertise will still be artificial intelligence-assisted image analysis can help improve diagnostic consistency reduce variability between observers and increase laboratory productivity. This could be especially valuable in areas where there are not specialized pathology and laboratory personnel. For example Haug and Drazen in 2023 highlighted the potential of intelligence in improving diagnostic consistency.

9.7 Federated Learning and Collaborative Artificial Intelligence

One of the big challenges in developing artificial intelligence is getting access to large and diverse datasets. Healthcare organizations often face restrictions on sharing data due to privacy regulations and ethical considerations. Federated learning has emerged as a solution to this challenge.

Federated learning allows multiple institutions to work together to develop machine learning models without sharing patient data. Instead algorithms are trained locally. Only the model parameters are exchanged between organizations. This approach preserves privacy while allowing for the development of artificial intelligence systems based on diverse populations and healthcare settings. As Rieke and colleagues noted in 2020 federated learning can facilitate collaborative quality management initiatives and multicenter diagnostic research.

For laboratory medicine federated learning could facilitate collaborative quality management initiatives, multicenter diagnostic research and the development of models that can be applied across different institutions. This could accelerate innovation while still following privacy requirements. For instance Plebani and colleagues in 2022 highlighted the potential of learning in facilitating collaborative quality management initiatives.

9.8 Workforce Transformation and the Future Role of Laboratory Professionals

The increasing use of intelligence raises questions about the future role of laboratory professionals. While there are concerns about workforce displacement most experts think that artificial intelligence will augment expertise rather than replace it.

Routine and repetitive tasks will likely become automated allowing laboratory professionals to focus on higher-level responsibilities that require thinking, clinical interpretation, quality management, innovation and collaboration between disciplines. Consequently future laboratory professionals will need to have expanded competencies in data science, informatics, artificial intelligence and digital healthcare technologies. As Badrick and Stavelin noted in 2024 future laboratory professionals will need to have expanded competencies in data science and informatics.

Educational programs and professional development initiatives will need to evolve to keep up. Laboratories will need to invest in training their workforce to ensure that personnel can effectively use intelligence technologies while still being responsible for patient safety and quality assurance. Human oversight will remain essential because artificial intelligence no matter how sophisticated cannot fully replace judgment, ethical reasoning and clinical expertise. For example Plebani and colleagues in 2022 highlighted the importance of oversight, in ensuring patient safety and quality assurance.

10. Conclusion

Artificial intelligence is really changing the future of laboratory medicine. It is turning automation systems into smart and data-driven healthcare platforms. Artificial intelligence is working with Total Laboratory Automation systems to make things better. It is improving quality and accuracy. Making things more reliable and efficient. It is also making safety better across the entire testing process. Artificial intelligence is being used in parts of the testing process. It is helping with managing specimens and quality control. It is also helping with maintenance and verifying results. Artificial intelligence is supporting decisions and managing quality. This is all according to Lippi and Plebani in 2023.

One of the things artificial intelligence is doing is changing how laboratories work. It is making them go from reacting to problems to predicting and preventing them. Artificial intelligence is looking at a lot of data. Finding risks before they cause errors. It is making workflows better. Helping with quality assurance. It is also supporting decisions based on evidence. This is really important because healthcare systems are getting busier and need to make decisions fast. Badrick and Stavelin said this in 2024.

In the future artificial intelligence will be used more in laboratory medicine. There will be twins and autonomous laboratories. There will also be federated learning and generative artificial intelligence. Molecular diagnostics and precision medicine will also be used.. For all of this to work it needs to be validated and regulated. It needs to be safe and reliable. Plebani and others said this in 2022.

Artificial intelligence should not replace laboratory professionals. It should be a tool that helps them. The laboratories that use intelligence well will be able to give patients the best care. They will be able to give reliable results. They will be able to do this on time and in a way that is centered on the patient. As Laboratory Medicine 5.0 keeps growing artificial intelligence will be a part of it. It will be a driver of innovation in healthcare systems all, over the world. Artificial intelligence will really change laboratory medicine. Make it better.

Table 1. Comparison of Previous Studies

Reference	Year	Study Type	AI/Laboratory Area	Main Contribution	Limitation
Topol	2019	Book/Review	AI in Healthcare	Introduced the concept of AI-driven medicine and precision healthcare	General healthcare, not laboratory-specific
Yu et al.	2018	Review	AI Fundamentals	Explained machine learning applications in healthcare	Early review before recent AI advances
Plebani et al.	2022	Review	Laboratory Medicine	Described Laboratory Medicine 4.0 and AI integration across laboratory workflow	Limited discussion of implementation strategies
Lippi & Plebani	2023	Review	Clinical Laboratory	Discussed AI for laboratory quality, efficiency, and workflow	Mostly conceptual
Badrick & Stavelin	2024	Review	Quality Management	Focused on AI for laboratory quality management and accreditation	Limited coverage of pre-analytical applications
Zaninotto et al.	2023	Review	Autoverification	AI-assisted autoverification and intelligent laboratory workflow	Mainly post-analytical phase
Haug & Drazen	2023	Perspective	Future Laboratory	Described future AI-enabled laboratories	Opinion-based article
Erdinc et al.	2024	Review	Deep Learning	Computer vision and deep learning in laboratory medicine	Focused mainly on image analysis
Campanella et al.	2019	Original Research	Digital Pathology	Demonstrated clinical-grade deep learning for pathology	Pathology only
Wang et al.	2023	Review	Natural Language Processing	NLP applications for reporting and decision support	Limited laboratory validation
Westgard	2022	Book	Quality Control	Sigma metrics and laboratory QC principles	Conventional QC rather than AI
Boursier et al.	2023	Review	Moving Average QC	AI-enhanced moving average quality control	Focused on QC applications
van Rossum et al.	2020	Review	Moving Average	Principles of moving average quality control	Does not include AI methods
Miller et al.	2023	Review	EQA/PT	External quality assessment and laboratory quality	Traditional quality assessment
CLSI	2023	Guideline	Validation	Laboratory validation and quality management guidance	No AI-specific recommendations
ISO 15189	2022	Standard	Accreditation	International quality management requirements	General laboratory standard
CAP	2024	Accreditation	Laboratory Quality	CAP accreditation requirements and quality standards	Not AI-focused
FDA	2024	Regulatory Guidance	AI Regulation	AI/ML-enabled medical device regulation	Device-oriented guidance
European Commission	2024	Regulation	AI Governance	European AI Act and healthcare regulation	Regulatory rather than technical
Samek et al.	2021	Book	Explainable AI	Methods for explainable AI (XAI)	General AI, not laboratory-specific
Rajkomar et al.	2018	Review	AI Ethics	Bias, fairness, and health equity	General healthcare
Rieke et al.	2020	Review	Federated Learning	Privacy-preserving AI models	Limited laboratory examples

Reference	Year	Study Type	AI/Laboratory Area	Main Contribution	Limitation
Tao et al.	2022	Review	Digital Twin	Digital twin concepts for healthcare systems	Mostly theoretical
Collins & Varmus	2015	Perspective	Precision Medicine	Foundation of precision medicine	AI not the primary focus
Komura & Ishikawa	2018	Review	Histopathology	Machine learning in pathology image analysis	Pathology-specific
Esteva et al.	2019	Review	Deep Learning	Comprehensive review of deep learning in healthcare	Broad healthcare review
Zhi et al.	2013	Systematic Review	Test Utilization	Inappropriate laboratory testing and overutilization	Predates modern AI

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