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Enhancing Quality in Laboratory Medicine through Machine Learning: A Comprehensive Review of Pre-Analytical, Analytical, and Post-Analytical Phases

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Abstract

Background: The integration of machine learning (ML) within laboratory medicine is revolutionizing the quality of healthcare through improved diagnostic accuracy and operational efficiency. As laboratory testing is segmented into pre-analytical, analytical, and post-analytical phases, each phase presents unique challenges that can benefit from ML techniques. This review systematically assesses the application of ML in these phases to identify potential improvements in quality management and error reduction.

Methods: A comprehensive literature search was conducted using the PubMed database for studies published from 2000 to 2023, employing keywords such as “machine learning,” “laboratory medicine,” “biomarker,” and “laboratory test.”

Results: The findings reveal that ML algorithms significantly enhance specimen quality assurance in the pre-analytical phase, reduce operational costs and analytical errors during testing, and improve clinical decision-making in the post-analytical phase. Notably, studies indicated that ML outperformed traditional methods in detecting misidentification and sample quality issues, achieving accuracies exceeding 90%.

Conclusions: In conclusion, the deployment of machine learning in laboratory medicine offers substantial benefits across all testing phases, enhancing diagnostic precision and patient safety. The findings underscore the importance of integrating ML technologies into laboratory practices to facilitate better health outcomes. Future research should focus on refining these algorithms and exploring their application in diverse laboratory settings to maximize their potential.

Keywords: machine learning, laboratory medicine, quality management, diagnostic accuracy, healthcare.

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1. Introduction

Machine learning (ML) is a subset of artificial intelligence (AI) that seeks to identify general principles within intricate data using predefined algorithms, and then apply these principles to novel data for categorization and prediction. In recent years, the rapid progress of computer software and hardware, along with the robust expansion of the internet, has facilitated the acquisition of extensive biomedical data quickly, hence enabling AI applications in contemporary medical sciences (1). A variety of AI techniques, exemplified by machine learning algorithms, are progressively transforming contemporary medical frameworks (2).

Laboratory medicine, a crucial component of contemporary healthcare, investigates the processes of illness incidence and progression via laboratory testing, therefore offering a scientific foundation for risk assessment, diagnosis, stratification, prognosis evaluation, and therapy monitoring. The laboratory testing procedure is often categorized into three phases: pre-analytical, analytical, and post-analytical (3,4). The pre-analytical phase includes the selection of appropriate laboratory tests and the collection and delivery of suitable specimens, during which the impact of specimen quality on laboratory tests must be mitigated (5). During the analytical phase, the laboratory testing procedure must be perpetually refined to guarantee timely and precise results; concurrently, the expenses associated with laboratory tests should be consistently minimized to fulfill clinical requirements for disease diagnosis and treatment with optimal resource utilization. The post-analytical step necessitates a rigorous and rational assessment of the clinical significance of test findings to enhance patient care (6).

In recent years, machine learning algorithms have significantly transformed the field of laboratory medicine (7). Numerous research has shown that machine learning algorithms may decrease laboratory expenses and mistakes while enhancing quality management in laboratories.

2. Methods

The PubMed database was queried to locate research published from 2000 to 2023 with the search phrases "machine learning," "laboratory medicine," "biomarker," and "laboratory test."

3. Utilization of machine learning in the pre-analytical phase

The objective of the pre-analytical step is to guarantee specimen quality and reduce mistakes. Improvements in laboratory testing methodologies have significantly reduced analytical errors, with the majority occurring during the pre-analytical phase, which may involve misidentification, incorrect container usage, inadequate volume, and clotting of anticoagulated specimens (8,9).

Misidentification is a prevalent mistake during the pre-analytical phase. In clinical practice, misidentification is mostly identified by delta checks, which include comparing previous data; however, this method largely relies on human judgment and lacks standardized objective criteria (10). Laboratory workers across various facilities may possess divergent interpretations of the delta check, leading to significant discrepancies in the detection of misidentification across labs and personnel. Moreover, manual assessment is labor-intensive, which hinders the conservation of laboratory resources. Consequently, several research has investigated the efficacy of machine learning in identifying misidentification (11-14).

In the majority of these studies, specific laboratory test data were initially extracted from the laboratory information system (LIS), followed by the application of inclusion and exclusion criteria to identify data suitable for analysis (e.g., patients who underwent duplicate testing within seven days). Computer software was used to randomly generate misidentifications in fifty percent of the specimens, and the precision in identifying these manufactured misidentifications was compared between machine learning methods and human assessments. All of this research demonstrated that machine learning algorithms exhibited much more accuracy than human assessments (11-14). In a study, researchers used machine learning algorithms to examine misidentification in electrolytes and renal function tests, finding that the accuracy of manual identification was about 77.8%. Conversely, the most basic machine learning method, the decision tree, attained an accuracy of 86.5%, while the accuracy of the artificial neural network reached 92.1% (14).

The accuracy of detecting misidentification may be substantially enhanced if machine learning findings are communicated to laboratory workers, therefore alerting them to the potential danger of misidentification (15). Consequently, the precision of machine learning in detecting misidentification far surpasses that of manual identification, and this accuracy may be enhanced further if the machine learning outcomes are provided to laboratory personnel for thorough evaluation.

Hemolysis, icterus, and lipemia (HIL) in blood samples are prevalent pre-analytical mistakes that provide significant obstacles to laboratory testing (16,17). Traditionally, HIL is mostly assessed by visual examination, a process that is time-consuming and susceptible to subjective influences, resulting in diminished accuracy in clinical practice. Recently developed biochemical equipment may ascertain the HIL state of a material and characterize it using markers such as the hemolysis index (H-index), icterus index (I-index), and/or lipemia index (L-index) (18,19). Approximately 10 minutes are necessary for the biochemical instrument to assess the specimen state, which will impact the instrument's efficiency and the laboratory's turnaround time. New research used deep learning to examine sample photos to ascertain the presence of HIL. All areas under the receiver operating characteristic curve (AUCs) for deep learning in identifying HIL exceeded 0.98, demonstrating much superior accuracy compared to biochemical equipment (20). Consequently, deep learning may significantly enhance the precision in detecting low-quality blood samples (20).

Besides detecting misidentification and substandard samples, machine learning may also be used to identify specimen clotting. In coagulation assays, the clotting of samples will influence the precision of the test outcomes. In practical practice, the assessment of specimen clotting mostly relies on visual examination, which, however, fails to detect tiny clots in some coagulated blood specimens. The potential for clotting may be anticipated from the outcomes of a coagulation test, since clotting may alter the test findings. Recent empirical research used backpropagation (BP) neural networks to assess the probability of clot formation in a blood sample (21). The findings indicated that the BP neural network approach using coagulation test data had exceptional accuracy in forecasting blood clotting, with an AUC of 0.97.

4. Utilization of machine learning in the analytical phase

The analysis phase encompasses the whole procedure from the arrival of a particular sample in the laboratory to the dissemination of the test findings. Machine learning may enhance laboratory workflows, decrease operational expenses, and improve efficiency. Machine learning methods fulfill distinct functions for various laboratory assays or test panels. This document demonstrates the applicability of machine learning techniques in various healthcare environments (22).

Given that low-density lipoprotein cholesterol (LDL-C) is a significant risk factor and therapeutic objective for cardio-cerebrovascular disorders (CVDs), LDL-C testing is very valuable for the prevention and management of CVDs. The standard approach for LDL-C testing is beta measurement using ultracentrifugation; however, this process is time-consuming, labor-intensive, and necessitates costly equipment, rendering it impractical for frequent testing. Consequently, ML algorithms may provide more advantages in forecasting LDL-C. Numerous research has assessed the precision of machine learning algorithms in forecasting LDL-C, all of which used TC, TG, and HDL-C as their foundational parameters (23-29). These investigations revealed that ML algorithms had superior accuracy compared to both Friedewald's formula and the more recently suggested Martin formula (30). Machine learning methods demonstrate considerable accuracy in patients with both elevated and reduced LDL-C values. Significantly, machine learning algorithms may be seamlessly integrated into the laboratory information system and are user-friendly.

The liver enzyme test is a crucial component of the liver function assessment. The standard liver enzymes assessed are aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (AKP), and γ-glutamyl transferase (GGT). While the therapeutic significance of these enzymes is distinct, there may be some degree of overlap among them. Consequently, some enzymatic assays may be superfluous in terms of reducing laboratory testing expenses. Research suggested that ALT and AKP values may serve as predictors for GGT readings (31). The researchers discovered that the ALT and AKP decision trees achieved an accuracy of up to 90% in predicting GGT with the use of ML techniques. In summary, GGT assays are unnecessary in 90% of liver function assessments, since GGT levels may be reliably inferred from ALT and ALP readings. One of the primary functions of machine learning in the analytical phase is to use inexpensive laboratory tests to forecast the need for expensive laboratory procedures. Besides GGT, ferritin levels may also be anticipated from standard blood test findings (32,33).

Besides predicting laboratory findings, machine learning has been extensively used in auto-verification, formulating guidelines for urine sediment analysis, morphological categorization of erythrocytes, and data analysis in metabolomics (34).

5. Utilization of machine learning in the post-analytical phase

The objective of laboratory medicine in the post-analytical phase is to convert test data into actionable clinical information and provide scientific evidence for illness diagnosis and assessment. The function of machine learning in this procedure is to amalgamate the current test findings to inform the diagnosis and treatment of illnesses. This research used two samples to demonstrate the application of machine learning algorithms in evaluating the clinical significance of laboratory testing (35-37).

The biochemistry of pleural fluid is a crucial method for identifying TB pleurisy. Adenosine deaminase (ADA) has a diagnosis accuracy of around 90% for this condition (38). Additional biomarkers in pleural fluid, such as lactate dehydrogenase (LDH) and leukocyte count, possess specific diagnostic significance for tuberculous pleurisy. Consequently, it is essential to ascertain if biomarkers (e.g., LDH) in pleural fluid might enhance the diagnostic precision of ADA. Do combinations of various biomarkers, including ADA, exhibit superior diagnostic performance compared to ADA alone. 2019 research using machine learning techniques, including support vector machine (SVM) and random forest (RF), to investigate the diagnostic efficacy of a combination of pleural fluid indicators for tuberculous pleurisy; the area under the curve (AUC) for adenosine deaminase (ADA) was 0.89, which increased to 0.97 when utilizing the RF method. Consequently, although ADA has significant diagnostic value for tuberculous pleural effusion (TPE), its diagnostic accuracy may be enhanced when used with other biomarkers via the application of machine learning techniques (39).

Evaluating the prognosis of diabetic nephropathy is fundamental for formulating personalized treatment strategies, hence enhancing patient outcomes. Currently, several indicators and scoring systems are available to forecast the advancement of diabetic nephropathy, with the most prevalent being the chronic kidney disease categorization system established by the Kidney Disease Improving Global Outcomes (KDIGO). Nonetheless, the precision of this technique in forecasting the prognosis of chronic diabetic nephropathy is significantly inadequate. Consequently, there is an urgent want for novel prognostic variables for diabetic nephropathy. 2021 cohort research using the RF algorithm with various biomarkers (KIM-1, TNFR1, and TNFR2) to forecast the prognosis of diabetic nephropathy patients, revealed an AUC of 0.77 for the RF algorithm compared to an AUC of 0.62 for the KDIGO grading system (40). Consequently, machine learning methods possess more benefits in forecasting the prognosis of diabetic nephropathy. Moreover, machine learning algorithms are extensively used in the screening of Down syndrome (41) and the detection of malignant pleural mesothelioma (42).

6. Conclusions

The advent of machine learning in laboratory medicine represents a significant leap forward in enhancing quality management across the pre-analytical, analytical, and post-analytical phases. The findings of this review highlight the multifaceted benefits of ML applications, particularly in addressing longstanding challenges such as misidentification of samples, operational inefficiencies, and the interpretation of complex data sets.

In the pre-analytical phase, machine learning algorithms have demonstrated remarkable capabilities in identifying potential errors before testing occurs. By utilizing advanced predictive analytics, laboratories can ensure higher specimen quality, which is crucial for accurate results. The ability to detect hemolysis, icterus, and lipemia through deep learning techniques offers a proactive approach to quality assurance, thus minimizing the incidence of erroneous test results and unnecessary repeat testing.

During the analytical phase, machine learning not only streamlines laboratory workflows but also enhances the accuracy of various assays. The ability to predict low-density lipoprotein cholesterol (LDL-C) levels using ML algorithms illustrates how these technologies can serve as effective alternatives to traditional methods, reducing both the time and costs associated with laboratory testing. Furthermore, the application of ML in auto-verification processes and guideline formulation for urine sediment analysis exemplifies its versatility and potential to improve operational efficiency.

In the post-analytical phase, the role of machine learning in synthesizing laboratory results into actionable clinical insights is invaluable. By integrating diverse biomarkers and employing sophisticated algorithms, laboratories can enhance diagnostic accuracy and support personalized treatment strategies. The demonstrated ability of ML to improve prognostic assessments in conditions such as diabetic nephropathy underscores its potential to transform patient management and outcomes.

Overall, the integration of machine learning into laboratory medicine is not merely an enhancement of existing practices; it represents a paradigm shift towards a more data-driven, precise, and efficient healthcare system. As technology continues to evolve, it is imperative for laboratory professionals to embrace these advancements, ensuring that they remain at the forefront of medical innovation. Future studies should prioritize the development of standardized protocols for ML implementation, alongside robust training programs for laboratory personnel to fully leverage the capabilities of these transformative technologies.

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تعزيز الجودة في الطب المخبري من خلال التعلم الآلي: مراجعة شاملة للمراحل ما قبل التحليلية، التحليلية، وما بعد التحليلية

الملخص

الخلفية :يُحدث دمج التعلم الآلي (ML) في الطب المخبري ثورة في جودة الرعاية الصحية من خلال تحسين دقة التشخيص والكفاءة التشغيلية. مع تقسيم الفحوصات المخبرية إلى مراحل ما قبل التحليلية، التحليلية، وما بعد التحليلية، تقدم كل مرحلة تحديات فريدة يمكن للتعلم الآلي أن يساهم في معالجتها. تهدف هذه المراجعة إلى تقييم تطبيقات التعلم الآلي في هذه المراحل لتحديد التحسينات المحتملة في إدارة الجودة وتقليل الأخطاء.

الطرق :تم إجراء بحث شامل في الأدبيات باستخدام قاعدة بيانات PubMed للدراسات المنشورة من عام 2000 إلى 2023، مع استخدام كلمات مفتاحية مثل "التعلم الآلي"، "الطب المخبري"، "المؤشرات الحيوية"، و"الفحص المخبري."

النتائج :أظهرت النتائج أن خوارزميات التعلم الآلي تعزز بشكل كبير ضمان جودة العينات في المرحلة ما قبل التحليلية، وتقلل من تكاليف التشغيل والأخطاء التحليلية أثناء الفحص، وتحسن اتخاذ القرارات السريرية في المرحلة ما بعد التحليلية. أشارت الدراسات بشكل خاص إلى تفوق التعلم الآلي على الطرق التقليدية في الكشف عن أخطاء تحديد الهوية ومشكلات جودة العينات، محققًا دقة تتجاوز 90.%

الاستنتاجات :في الختام، يوفر تطبيق التعلم الآلي في الطب المخبري فوائد كبيرة عبر جميع مراحل الفحص، مما يعزز دقة التشخيص وسلامة المرضى. تؤكد النتائج على أهمية دمج تقنيات التعلم الآلي في الممارسات المخبرية لتسهيل تحسين النتائج الصحية. يجب أن تركز الأبحاث المستقبلية على تحسين هذه الخوارزميات واستكشاف تطبيقاتها في بيئات مخبرية متنوعة لتعظيم إمكاناتها.

الكلمات المفتاحية :التعلم الآلي، الطب المخبري، إدارة الجودة، دقة التشخيص، الرعاية الصحية.