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PROMISING RESULTS OF SCIENTIFIC RESEARCH ON THE CENTRALIZATION OF KINETIC DIAGNOSTIC LABORATORY ANALYSES IN FAMILY CLINICS

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Abstract. Numerous improvements have been developed in recent years with the goal of enhancing primary care diagnostic procedures. There is little data on how those who are directly involved in those procedures—patients, general practitioners, and medical experts like radiologists—perceive innovation in the primary care diagnostic process. End-user perspectives are essential to ensuring that activities aimed at improving the diagnostic process are successful. As a result, end users investigated possibilities and paths for the primary care diagnostic process with the help of change laboratory methodology, which uses conflicts and divergent perspectives as a source of motivation and education. Opportunities and directions were investigated in two study groups with nine and ten participants, respectively, who had four change lab sessions over the course of four months. The participants included patients, general practitioners, and medical experts. The Cultural-Historical Activity Theory served as the theoretical foundation for the analysis. This theory offers fresh perspectives for thinking, learning, and acting from and with one another by illuminating the various healthcare systems in which individuals find themselves and related conflicts and contradictions. Together with the participants, we identified conflicts and inconsistencies that exist both within and between various activity systems that are pertinent to primary care diagnostic procedures. Examples of these conflicts include those that may occur when more and quicker diagnostics are available in primary care or when cooperating parties have different motivations and interests in innovations. Participants have developed innovative directions and opportunities for the primary care diagnostic process by identifying these conflicts and inconsistencies. In addition to identifying specific artificial intelligence imaging techniques as promising to enhance the diagnostic process for acute complaints at the point-of-care, end users recognized a need for improved interchange and/or access to test results performed in hospitals to general practitioners. We developed criteria to be taken into consideration for recognizing successful innovation initiatives by exploring these paths and potential for improving and advancing the diagnostic procedure.By talking about conflicts and inconsistencies between systems, new factors for the diagnostic process's successful invention were found, and standards were developed that raise the possibility of producing innovative initiatives that show promise.

Keywords. Quality, laboratory practice, diagnostic error, diagnostic excellence, clinical microbiology, image analysis, machine learning, artificial intelligence

Introduction. Delivering effective, high-quality care while continuing to innovate patient care is a common goal in the healthcare industry. To address the numerous issues that our healthcare system is currently and will continue to face globally, innovation is essential. The number of persons with one or more chronic illnesses is rising, along with the need for treatment, partly because of an aging population, while the healthcare workforce is drastically declining. As

the overall demand for care rises, access to primary care in particular—a crucial component of healthcare performance—becomes more difficult. A well-organized and successful diagnostic process is essential to maintaining access to primary care since it serves as a vital link between primary and secondary care [1-5]. Therefore, using innovation to improve the diagnostic process can help satisfy future care demands. The organization of the diagnostic process in primary care has changed, becoming more complex as a result of innovation in the diagnostic process, including the creation and promotion of novel diagnostic tests in recent years. Innovation includes more than just creating new tests and instruments, despite the fact that this is how it is commonly understood. The introduction of new instruments, thoughts, ideas, procedures, and services with the goal of enhancing patient care is referred to as innovation in the healthcare industry. Evidently, organizational, social, and ethical factors are also included. The field of diagnostic testing is changing dramatically, moving away from traditional centralized laboratory testing and toward more accessible, quick, and decentralized techniques via point-of-care testing (POCT). Through the analysis of biological samples, centralized laboratory testing has historically been essential to the diagnosis and treatment of diseases. However, there are frequently issues with long turnaround times, expensive operations, and restricted accessibility [6-12]. Some of these restrictions were brought to light by the COVID-19 pandemic, when the demand for testing surged beyond the capacity of centralized labs. POCT is feasible and accurate outside of standard lab settings, as evidenced by the widespread use of point-of-care nucleic acid testing and at-home antigen tests for testing huge populations during the pandemic. This testing paradigm's widespread use has transformed diagnostics by offering prompt and easily accessible solutions necessary for efficient disease management and quick medical response in a variety of healthcare settings. Up to one-third of medical errors are linked to diagnostic errors, making them the third most common cause of death in the US. According to estimates from extensive observational studies of the US population, one in twenty persons may experience a diagnostic error at some point in their lives, according to a 2014 study by Singh et al. Improving Diagnosis in Health Care, a report released in 2015 by the National Academy of Medicine (NAM), formerly known as the Institute of Medicine, emphasized the urgent need to recognize and correct flaws in the diagnostic process. The paper acknowledges that healthcare organizations can only significantly lower diagnostic errors by using an integrative systems approach across medical specialties and including patient input. This method incorporates clinical laboratory practice as a crucial step in the diagnosis procedure. This narrative review will highlight the relevance of the clinical laboratory and provide an overview of current efforts and future prospects for improving diagnoses, including lowering diagnostic error [13-20]. Furthermore, the existing SAA is mainly qualitative, which restricts its capacity to connect with the severity or course of the disease. In order to overcome these restrictions, this review looks at pre-analytical and analytical aspects that affect SAA performance and investigates new quantitative methods. The combination of SAA with quantitative approaches is one recent development that shows promise for improved clinical applicability and diagnostic accuracy. Validation in long-term research can enhance SAA's considerable potential as a monitoring and diagnostic tool. Through early diagnosis and customized treatment approaches, the practical use of SAA may transform the early identification and treatment of synucleinopathies, ultimately improving patient outcomes. Innovation is frequently seen favorably. However, not every diagnostic advancement has been successful in producing the intended results. In order to ensure that innovation satisfies the demands of patients and daily practice healthcare professionals—that is, the "end-users" of the diagnostic process—these experiences recommend taking a system-level approach, taking into account relationships and dependencies between stakeholders and their contexts. There is little data on what these end users hope to see in terms of primary care diagnostic process

innovation. Further understanding of the various viewpoints of these end customers may yield fresh concepts and opportunities for diagnostic process innovation. In order to get insight from one another's viewpoints, we gathered a group of end users. A technique that can help with this learning from various disciplines and viewpoints is the change laboratory [21-26].

The main purpose of the presented manuscript is to conduct a brief analysis of the promising results of scientific research on the centralization of kinetic diagnostic laboratory analyses in family polyclinics based on the results of authoritative scientific works.

The meeting point of clinical laboratory practice and diagnostic excellence. For the purposes of this manuscript, diagnostic excellence is defined as a systems-level state that successfully combines medical knowledge, expertise, and resources to continuously and quantifiably improve diagnoses and lower the risk or occurrence of diagnostic errors while still meeting the needs of patients and health systems as a whole. The conceptual creation of the entire testing procedure is where diagnostic excellence and laboratory practice meet. The "life cycle" of a clinical laboratory test was initially described by Lundberg in 1981. The US Centers for Disease Control and Prevention (CDC) classified it as the "total testing process" (TTP) in 1986, and it was revised in 2011. "Clinicians and laboratory professionals should all be concerned about the effects of the laboratory test and whether its performance was useful for the patient or public's health," Lundberg said, highlighting the necessity of ongoing evaluation to support the added value of laboratory testing. A 2008 CDC report, Laboratory Medicine, A National Status Report, built on these earlier initiatives by arguing that the clinical laboratory offers value beyond test performance through improved collaboration with other healthcare professionals to improve health outcomes [2-10]. There were few studies at the time that connected components of the entire testing process to quick and accurate diagnoses in the patient context, with even less focus on connections with quantifiable health outcomes. This idea was reexamined in 2013 by Epner et al., who promoted an outcomes-based approach for laboratory medicine that supports diagnostic excellence by connecting laboratory procedures to precise and fast diagnoses. One example of a method that promotes diagnostic quality is antimicrobial stewardship. Antimicrobial stewardship is a multidisciplinary, system-based approach that primarily depends on timely and accurate test results to support clinical decision-making in order to enable the prompt administration of the best antibiotic to a patient diagnosed with an infectious disease. Blood culture contamination rates in the US are thought to range from 0.6 to 12.5%, with emergency room settings having the highest rates. According to expert advice, blood culture contamination shouldn't be more than 3%. The most noteworthy is how crucial it is to identify blood culture contamination while assessing a patient for septicemia, which is a major cause of hospital mortality in the United States. In keeping with the idea of diagnostic excellence, a prompt and accurate diagnosis of septicemia can increase survival [14-24].

ML's contribution to POCT advancement: strategies and effects. POCT's applications are getting more complicated as it is used more frequently in healthcare. These include conducting tests over wide geographic areas and time periods, screening varied people across a range of age groups and races, and testing panels that contain numerous biomarkers within a single cartridge. Large datasets with complex patterns and sophisticated correlations between the output testing signals and underlying diseases at the level of both the tested population and individual patients are produced by the extensive usage of POCT. Because ML algorithms can learn intricate functional correlations in a data-driven way, they are especially well-suited for these tasks36. Additionally, computational co-optimization of the sensor hardware/design—where ML techniques are employed not just for diagnostics but also to improve sensor design and performance—benefits advanced sensor designs, particularly for multiplexed sensing applications [4-11]. For instance, by extending the innate sensitivity limits of materials, the

usage of metamaterials has enhanced sensor functionality. In order to overcome the limits of manual human design and enable quicker exploration of design and manufacturing parameters, AI-based methodologies have been used in the design and production processes of metamaterials. The computational capacity of ML techniques has also greatly boosted POCT during the last ten years, allowing for more precise, high-throughput diagnostics on accessible, low-cost systems. In this Perspective, we examine how AI and ML are used in some of the most well-known POCT technologies, such as imaging-based techniques, LFAs, VFAs, and NAATs. Digital tools using machine learning (ML) to help the results' classification are necessary for a number of POCT-related use cases. For instance, POCT self-administration and reading, as well as testing by unskilled personnel, are increasing and necessitate improvements in diagnostic precision. We will examine particular ML and neural network applications and uses for distinct POCT platforms, such as paper-based LFAs and VFAs, NAAT platforms, and other imaging-based point-of-care sensors, in the sections that follow. In addition, we will talk about the integrity of machine learning, ethical issues, and regulatory obstacles. Finally, we will examine future prospects for the wider integration of AI and ML in healthcare systems [12-21].

SAA's present drawbacks and difficulties in clinical and research applications. SAA has many benefits. They can identify misfolded proteins at early illness stages and offer a better sensitivity than other diagnostic techniques (up to atto-gram levels), which may help with earlier diagnosis and intervention. Another important benefit is that the method can be applied to a variety of biological samples. Nevertheless, SAA has many drawbacks despite their potential. For starters, different assay procedures can result in inconsistent results, and the need for specialized equipment and technical know-how may make it less accessible. The difficulties with specificity, sensitivity, applicability across various PD subgroups, and wider clinical adoption are further entwined. Every drawback highlights a chance to improve, optimize, and possibly change the idea of SAA from a specialist, research-focused method to a readily available, therapeutically crucial component of PD diagnosis and treatment [11-21].

Monitoring and promoting diagnostic excellence requires quality management and quality measures. Measurement is necessary to really advance diagnostic excellence. For instance, the International Federation for Clinical Chemistry Working Group on "Laboratory Errors and Patient Safety" (IFCC WG-LEPS) developed Medical Quality Indicators that cover important laboratory processes, laboratory support processes, and laboratory outcomes. Although complete validation of these indicators is still in progress and is likely to change over time, they are a crucial tool for laboratories looking to systematically prioritize improvement actions in light of patient safety and ISO 15189's strong quality management perspective. A number of governmental and professional organizations created and/or approved quality indicators that are relevant to laboratory and clinical procedures. In laboratory and patient care settings, quality indicators are used to gauge compliance with approved methods and as metrics for fulfilling predetermined standards [5-19]. Additionally, these measures can be utilized to evaluate results across one or more enterprises and benchmark methods. You can cite examples. As mentioned above, the Model of Quality Indicators created under the IFCC WG-LEPS is intended to provide a proactive system for developing quality indicators and tracking performance, which is ultimately focused on lowering the error rate related to the entire testing process. In a similar vein, the College of American Pathologists funds Q-Probes and Q-Tracks, which serve as short-term and long-term evaluations of important procedures to support efforts to enhance quality. Governmental bodies and professional associations are researching and debating ways to improve diagnostic quality. While some adopt a more integrative approach, most of these focus on either the laboratory setting or patient care [20-26].

Based on our results, we would like to assess how project applicants (such as researchers) and grant-giving organizations apply the eight criteria. We would also like to urge others to expand on the opportunities and directions that were found. Additionally, it would be intriguing to investigate how these end users—a loosely coupled group of participants working in various (healthcare) organizations—can be given the authority to specify their needs regarding the exchange and/or access to test results and history, as well as how they can communicate their preferences to the relevant suppliers, particularly how they could assume control. Lastly, it may be required to take a closer look at the involved systems in other regions (in the Netherlands or abroad) where the organization of the diagnostic process and related systems differs from those presented in this study. Possibilities to include the lab in a plan to improve diagnostic quality. Several objectives that are seen to be crucial for enhancing diagnoses and lowering diagnostic errors were outlined in the NAM report, Improving Diagnosis in Healthcare [3-12]. The NAM report's objectives, which include developing and implementing strategies to identify, learn from, and reduce diagnostic errors and near misses in clinical practice as well as establishing a work system and culture that supports the diagnostic process and improvements in diagnostic performance, intersect with the idea of diagnostic surveillance and quality management across laboratory and patient care settings. One strategy would be to extend the notion of diagnostic stewardship—which was first presented in this manuscript—beyond the field of infectious diseases to include additional laboratory specialties from a variety of medical specialties. Additionally, it might be beneficial to concentrate on illnesses that have been found to be more prone to diagnostic errors. The three-fourths of serious misdiagnoses related to major vascular events, cancer, and infectious disorders may be one target. In both patient-care and laboratory settings, diagnostic surveillance can offer a data-driven approach to quality management that can help advance diagnostic excellence. In order to ensure that fast and correct diagnoses are made and that diagnostic errors are reduced, DMTs that incorporate patient participation may be able to spearhead this process. Significant obstacles to change include the need to prioritize initiatives due to a lack of organizational resources, ineffective information sharing between medical leadership and disciplines, resistance to change, and a culture that has divided laboratory and clinical care procedures and practices. The regulatory and accreditation criteria for laboratories, which as of 2020 generally stress greater pre- and post-analytic activities of the laboratory in collaborating with doctors to encourage accurate and prompt diagnoses, provide additional problems. The business model is impacted by practice changes that support diagnostic excellence, but there is probably a value proposition for utilization management, lowering diagnostic mistakes, and enhancing health outcomes [13-23].

Discussion. Laboratory engagement is crucial when developing plans and initiating programs to promote diagnostic quality and remove obstacles to practice adjustments. Examples given in this study indicate that laboratory techniques and knowledge can support a wide range of measures that result in prompt and correct diagnoses as well as a decrease in diagnostic errors, albeit they are not meant to be comprehensive. Additional opportunities for laboratories to use data and interact with other healthcare professionals are presented by emerging technology and communication channels. Clinicians can choose and interpret tests with the use of laboratory-informed decision support systems. Point-of-care testing and telemedicine are two developing fields of practice that merit discussion. Telemedicine is highly helpful for people that do not have easy access to medical care since it employs technology to make distant diagnosis using a variety of testing modalities. Whether at a hospital, doctor's office, or non-medical setting, point-of-care testing gives the analysis where the patient is, eliminating the need for analysis at a remote laboratory. Although these techniques do not constitute novel paradigms, their increasing importance in healthcare delivery necessitates more consideration of how they might be used to

advance diagnostic excellence [3-11]. It is now the responsibility of healthcare professionals to keep advancing methods to improve diagnoses across the medical spectrum because the practice community and patient population have a greater appreciation for improving diagnosis. Clinical laboratory experts' involvement and understanding of the entire testing process are essential to the success of many diagnoses. Accurate and timely diagnoses help clinicians and patients make decisions that ultimately lead to better health outcomes. With its great sensitivity for detecting α-synuclein aggregates essential to PD, MSA, and DLB, SAA is a revolutionary step in the early identification of synucleinopathies. However, significant obstacles—such as the necessity for standardization, difficulties with reproducibility, and the difficulty of distinguishing between synucleinopathies—require further developments. The clinical application of SAA may be improved by future developments in quantitative techniques, non-invasive sampling, and multi-biomarker integration. In order to move α-synuclein SAA from research tools to routine diagnostics, it will be essential to prioritize cross-disciplinary collaboration and longitudinal studies. This will enable earlier diagnosis, better disease distinction, and customized treatments. These advancements have the potential to enhance patient outcomes and advance the treatment of neurodegenerative illnesses. Participants of ASM CMO 2024 expressed excitement about the potential of AI to enhance quality and efficiency in clinical microbiology practice. We acknowledge that AI is starting to alter clinical microbiology practices, such as quality control, language-based information retrieval and communication, and visual data interpretation (e.g., Petri plate and microscopic pictures) [12-17]. The lack of local laboratory expertise in AI creation, limited experience in maintaining and adjusting algorithms as data evolve over time, and an unpredictable regulatory environment are some of the anticipated or present hurdles with the application of AI in clinical practice. As long as there was a POCT program in place that catered to the needs of each PHC, centralizing the majority of laboratory services offered at the PHCs and sending them to an accredited laboratory strengthened the standardization initiatives of the laboratory practice within the ten piloted PHCs, improved quality, and reduced costs (such as the analytical cost, PT enrollment for each PHC, and the pre-analytical cost resulting from rejection). Implementing staff CT programs is essential to any patient-safe services because staff competency is the human power behind the devices. Additionally, these training programs produced superior results when they worked with a reference institute. In order to standardize practices within PHCs and integrate the knowledge and abilities of the working team to obtain better quality for the patient services, it is essential to have a unifying documentation system (policies and procedures). As demonstrated by the TAT rate KPI, electronic connectivity immediately improved the pre-analytical, analytical, and post-analytical stages of laboratory testing and enabled a more efficient testing-result cycle inside the connected laboratories. In order to evaluate the quality status of the PHCs and determine the appropriate interventions and corrective actions in a timely way, KPIs must be properly defined and closely monitored. We believe that the aforementioned paradigm works well in metropolitan areas where PHCs may easily access an accredited central laboratory [18-26].

Conclusions. End users of diagnostics were able to identify opportunities and innovation directions for the diagnostic process by identifying conflicts and contradictions operating within and between various systems. End users learned from one another by bringing these conflicts and inconsistencies to light. As a result, new methods and perspectives for the diagnostic procedure emerged. A list of eight factors to take into account that raise the possibility of delivering promising innovation projects was also produced as a result of analyses of the inconsistencies raised by end users. AI-driven analyses can generate data-driven insights for healthcare workers and regulators by integrating different types of data, including laboratory results, clinical information, and social/ecological determinants.

These insights can identify trends, potential infection sources, and suggested control measures to guide future prevention efforts. However, strict regulation of AI and ML models is necessary to guarantee safety, equity, inclusivity, and dependable diagnostic performance in real-life scenarios in order to fully achieve these advantages and the broad use of AI within the healthcare community. This can be accomplished by developing a variety of training datasets and encouraging tight cooperation between academics, developers, doctors, and regulatory agencies. This will increase confidence in AI-based POCT systems and encourage their use in the diagnostics industry.

Participants of ASM CMO 2024 expressed excitement about the potential for AI to enhance quality and efficiency in clinical microbiology practice. We acknowledge that AI is starting to alter clinical microbiology practices, such as quality monitoring, language-based information retrieval and communication, and visual data interpretation (e.g., Petri plate and microscopic pictures). The lack of local laboratory expertise in AI creation, insufficient experience in maintaining and adjusting algorithms as data evolve over time, and an unpredictable regulatory environment are some of the anticipated or present issues with the use of AI in clinical practice.

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