Artificial Intelligence in Clinical Laboratories

About ACLA

The American Clinical Laboratory Association (ACLA) represents leading laboratories that deliver essential diagnostic health information to patients and providers by advocating for policies that expand access to the highest quality clinical laboratory services, improve patient outcomes, and advance the next generation of personalized care.

Empowering Innovation for Enhanced Patient Care

In clinical laboratories, where precision, efficiency, and quality are paramount, artificial intelligence (AI) tools, including machine learning (ML) models, are emerging as promising tools to help address workforce shortages and manage the increasing demand for healthcare services. AI is one of many ways that ACLA member laboratories are utilizing innovative technology to streamline business processes, prioritize and increase the efficiency of workflows, and synthesize data to reduce employee burnout, all to ensure the highest quality services for patients. The diagnosis and decision-making process is still reliant on the expertise of trained healthcare professionals, but AI-generated insights that take into account patient history, diagnostic test results, and medical records may assist clinicians with making a comprehensive diagnosis and formulating a treatment plan for each patient.

Applications of AI in Laboratories

AI has the potential to help laboratorians prioritize and streamline their work to increase efficiency and testing volume, leading to the ability to serve more patients and develop individualized treatment plans. The value of AI developments in laboratory medicine is based on AI's ability to quickly analyze large amounts of data, identify trends, and produce accurate insights that can support clinical decision making. AI also has the potential to help improve business operations, streamline workflow, and ease administrative burdens.

Some examples of how ACLA members are utilizing AI include:

- **Data Analysis and Reporting:** AI can synthesize and analyze data in the laboratory information systems (LIS) and peer-reviewed research to provide advanced results reporting, including additional recommended testing, potential diagnoses or patient outcomes, or clinical trial opportunities.
- **Digital Pathology:** Digital pathology is the process of digitizing physical glass slides into digital images for review by laboratorians and physicians on a computer or mobile device. AI can review digital pathology slides to flag potentially malignant results, such as tumors and cancer biomarkers, to prioritize pathologists' review and allow for additional review capacity.
- **Quality Improvements:** AI can help to serve as a quality check to flag discrepancies for laboratorians review, reducing variability in inter and intra-pathologist interpretation of results to improve accuracy and standardization of test results.
- **Simplifying Ordering Provider Processes:** Digitizing test ordering and billing processes by capturing

data and information needed for payor requests, ordering clinician information for streamlined order forms, and automating reflex test ordering as may be clinically appropriate.

- **Test Ordering Guidance:** AI tools have significant potential to optimize utilization of medical testing through evidence- and guidelines-based recommendations at the time of test ordering. Informed test ordering decisions may reduce the durations of diagnostic odysseys, close gaps in care, and reduce unnecessary testing.
- **Improving Laboratory Workflow Efficiencies:** Sorting algorithms can aid in transferring samples to the appropriate departments and testing equipment and help departments, laboratories, and ordering physicians track the status of samples and testing results.
- **Reporting Obligations:** Using AI to help meet varying state and territory reporting requirements.
- **Assessing Workforce Needs:** Utilizing AI business analytics to assess workforce needs and scheduling based on incoming specimens for testing.
- **Customer Support:** Implementing use of chat bots to answer frequently asked administrative-related questions from customers.

Key Principles to Support AI Innovation in Laboratories

As clinical laboratories continue to innovate and incorporate the use of AI to streamline processes, workflow, and data synthesis, ACLA and its members encourage policymaking to adhere to the following principles to maximize the benefit of AI tools, minimize risks, and foster innovation:

- **Regulatory Clarity:** The scope of regulatory and congressional oversight over AI tools should be clear and transparent, as predictability in oversight will help guide the development of AI tools.
- **Risk-Based Approach:** Regulation of AI tools should be sector-specific, balance risks and benefits to patients, and avoid overregulation that could stifle innovation and delay adoption. Specifically, AI regulation should take into account the risk presented by a particular use case and the context in which the tool is used, and tailor requirements accordingly. New oversight authorities should work with existing frameworks for the regulation of AI in healthcare settings to avoid unnecessarily overlapping or duplicative requirements. Additionally, any regulatory requirements should be agile and adaptable to an increasingly evolving technology.
- **Transparency and Bias Mitigation:** AI systems should provide transparency that enables users to understand the validity, reliability, and potential biases of the system. ACLA members are committed to designing AI tools in a way that mitigates potentially discriminatory or harmful bias, including by training algorithms on robust and representative datasets, and identifying any limitations of data and clearly communicating such limitations.
- **Federal Preemption:** Explicit and strong federal preemption is necessary for national uniformity and to prevent a patchwork of state laws.
- **Privacy:** Safeguarding patient data and privacy is paramount to maintain trust and uphold ethical standards in healthcare. Simultaneously, utilizing deidentified data for AI innovation enables advancements in diagnosis, treatment, and personalized medicine, ultimately improving patient outcomes. It is important to strike a thoughtful balance between protecting sensitive health information and permitting the use of deidentified data for research and development purposes to further innovation.
- **Reimbursement:** As laboratories seek to adopt and invest in new technologies, like AI, they must have

stable and predictable reimbursement, reflective of the value of diagnostics to patient care. Implementation of the Protecting Access to Medicare Act (PAMA) in 2014 resulted in significant payment cuts to the Medicare Clinical Laboratory Fee Schedule, which has not seen a payment adjustment since 2020, following three years of up to 10% payment cuts to laboratories. ACLA's PAMA reform proposal would prevent further payment reductions and enact a long-term solution that would enable sustainable reimbursement rates to provide laboratories the stability needed for investments into advanced diagnostic tools, such as AI.

ACLA is eager to engage with lawmakers as Congress contemplates legislation on AI in healthcare.