

POSITION STATEMENT

Data Analytics and Laboratory Medicine: Improving Healthcare Outcomes Through Big Data

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Introduction

As the delivery of healthcare continues moving toward a value-based framework that rewards performance over volume, providers are increasingly looking to leverage their clinical data to gain greater insights into patient physiology and develop new interventions that improve the quality of care. Harnessing the vast amounts of healthcare data generated by clinical laboratories is crucial to achieving these goals. With policies and

infrastructure in place to facilitate data sharing and collaborative analytics, AI/ML based systems will spur the development of evidence-based test protocols, more intelligent clinical decision support systems, and innovative personalized/precision therapies that advance patient care.

Background

Learning Health Systems

The advent of technological advances such as cloud storage have enabled healthcare systems to warehouse large quantities of clinical and administrative information. Electronic medical record (EMR) systems have led to the accumulation of vast repositories of under-studied data that hold enormous untapped potential for secondary analytics (1). The ability to harness these data is rapidly improving and health systems are beginning to invest in the analytical tools,

AACC POSITION:

AACC supports efforts within the healthcare community to better utilize the vast amounts of clinical data to improve patient care and lower healthcare costs. The emergence of artificial intelligence and machine learning (AI/ML) technology has created new opportunities for clinical laboratories to more precisely interpret data that advance evidence-based medicine and personalized therapies. To fully realize the benefits of applying a big data approach to laboratory results, policymakers and the healthcare community must promote the adoption of analytics tools, incentivize data sharing between organizations, and simplify data aggregation by ensuring test results are harmonized, and reporting systems are interoperable.

infrastructure, and human capital needed to derive actionable insights from these data. As federal incentives continue to push the healthcare system to a value-based care model, providers that fail to embrace a new “learning health system” paradigm that uses clinical data and experiences to continuously improve diagnosis and treatment may be left behind (2). With the proper infrastructure and policies in place, the wealth of data generated by clinical laboratories can be integrated with financial, administrative, and other healthcare data, and mined for insights that improve care and lower costs.

Considerations

Challenges

Data Reciprocity

High-quality evidence-based testing protocols benefit both patients and healthcare providers, but their development can be

onerous and require aggregating and analyzing evidence from a multitude of sources. Collecting real-world data from clinical laboratories in a shared repository would provide an unparalleled resource to develop new evidence-based protocols. To counteract financial incentives that encourage healthcare organizations to withhold their data for proprietary uses, data sharing infrastructure should be designed to encourage reciprocal participation. This may involve limiting database access to organizations that agree to contribute to, maintain, or curate components of the repository (3). Linking reimbursement to a framework that rewards the contribution of high-quality interoperable data could further promote reciprocity.

Accountability & Regulation

AI/ML algorithms that use laboratory data for clinical decision support systems (CDSS) pose unique potential risks such as inappropriate treatment recommendations. For example, demographic variations in datasets that underpin AI/ML applications may result in subtle performance biases that must be identified and corrected (4). As such, regulatory agencies such as the Food and Drug Administration may deem AI/ML CDSS applications subject to the premarket clearance or approval processes (5). While these risks can be mitigated through third party validation, outside review may raise concerns about patient privacy or disclosure of proprietary information. Organizations that employ AI/ML applications must therefore have robust safeguards to ensure data security, and identify who can access data and for what purpose.

Interoperability

Analytics tools are often localized within healthcare systems and applied to discrete scenarios or narrowly defined applications. Wider implementation of clinical laboratory analytics applications will require overcoming challenges associated with interoperability (the ability to exchange data consistently and accurately) and other variations in data sourced from different organizations. Inconsistencies in the way information is collected can exist even among data generated within a single facility; many tests, performed with different methods or instruments will return the same essential result, but in a different format or on a different scale. Addressing this problem is a necessary pre-condition for effective data sharing

and collaborative analytics. The federal government can facilitate interoperability by increasing funding to the Centers for Disease Control and Prevention to harmonize (i.e., standardize) test results. Healthcare organizations can also assist by ensuring that all laboratory data is coded according to standardized naming and identifier conventions.

Data Standards

The design and intended use of current common data standards limits their utility in analytics applications. The Logical Observation Identifiers Names and Codes (LOINC) is a prominent standard for identifying laboratory test results that is familiar to laboratory professionals. While this system captures a great deal of information and provides many benefits in terms of improving interoperability, its architecture lacks sufficient flexibility for analytics applications (6). Laboratorians' intimate knowledge of the shortcomings of informatics standards such as LOINC will be invaluable in the development of more comprehensive systems that can accommodate current and future AI/ML applications. Healthcare stakeholders can lay the foundation for such systems by collaborating to assemble and promulgate standardized collection and utilization rules for laboratory data.

Applications

Laboratory Operations

The utility of analytics tools extends beyond clinical applications. Existing process-management systems have been shown to streamline laboratory operations and improve the bottom line. AI/ML based systems can build on that functionality by monitoring performance data, service intervals, and the maintenance trends of complex instruments such as automated chemistry analyzers, to forecast and proactively schedule anticipated repairs. Incorporating the rate of inventory consumption, supply chain data, and disease trends could unlock additional efficiencies via just-in-time delivery of replacement parts, reagents, and other resources (7). If supply shortages are anticipated, the real-time data from multiple laboratories and healthcare providers could inform ultra-efficient allocation strategies.

Test Utilization

Inappropriate test ordering protocols cost the US

healthcare system up to \$200 billion annually (8). The downstream effects of misutilization can be serious for patients and involve missed diagnoses due to missed testing opportunities on one end of the spectrum, and follow-up visits for additional testing or unnecessary treatments that result in serious complications and injuries on the other end. Many providers struggle to stay on top of the best evidence regarding laboratory medicine as test menus grow and become more specialized (8). Analytics applications can help address this growing problem by monitoring test ordering patterns to improve guidelines, provide real-time best practice alerts, and automatically cancel duplicative, obsolete and “look-alike” test orders (9). Analyzing both laboratory and administrative or financial data may uncover hidden utilization patterns and further reduce costs (10).

Population Health

Analytics tools that incorporate clinical and demographic data can reveal relationships that facilitate more personalized treatments. If combined with demographic and genomic data, anonymized patient data captured from EMRs would provide the analytical basis to characterize a diversity of patient profiles through longitudinal tracking of health (11). AI/ML analysis of these data could enable the development of new dynamic reference ranges, personalized testing guidelines, and tailored treatment plans that improve care for patients of all ethnicities, ages, and genders.

Positions

AACC supports efforts within the healthcare community to better utilize the vast amounts of laboratory data to improve patient care and lower healthcare costs. To facilitate this approach, policymakers and the healthcare community must promote the adoption of analytics tools, incentivize data sharing between organizations, and simplify data aggregation through the harmonization of test results and improved reporting system interoperability. AACC believes the following positions are essential to achieve this goal:

Laboratory and Healthcare Community

- ▶ The healthcare community should continue to advocate for policy, regulatory, and legislative mechanisms that promote the adoption of clinical

analytics technology and encourage ethical data sharing.

- ▶ The healthcare community should collaborate to develop and promulgate standardized rules for data collection, sharing, and utilization.
- ▶ Training and education for clinical laboratory professionals should include a focus on data science.

Federal Agencies

- ▶ Regulators should engage stakeholders and experts to develop a framework to collect and evaluate real-world data for the safety and effectiveness of clinical practices that incorporate AI/ML tools or models.
- ▶ Federal agencies should provide resources and incentives that encourage providers to develop and adopt data analytics capabilities.
- ▶ Federal policy should emphasize interoperability of health data and prioritize payment reforms that promote secure, ethical, reciprocal data sharing among health systems and providers
- ▶ The federal government should increase funding for the CDC’s ongoing efforts to harmonize laboratory test results, which is vital to improving the interoperability of lab data.

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