VIEWPOINT

DIAGNOSTIC EXCELLENCE

Measuring Performance of the Diagnostic Process

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A long-standing dictum in health care teaches that it is not possible to improve what is not measured. Evidence from reviews of autopsy data, malpractice claims, clinical reviews, and patient accounts suggests that health care systems fall short on diagnostic safety, quality, and equity. The problem is not only delayed and missed diagnoses but also diagnostic processes that may be costly, duplicative, and inefficient. Although measurement can inform and motivate focused attention and resources for improvement, diagnostic performance measurement has been limited. The absence of an accepted measurement approach and infrastructure to evaluate diagnostic performance presents an opportunity to consider new measurement strategies that take advantage of novel data sources and advanced analytic approaches. If diagnostic performance measurement is correctly assessed, with feedback loops to patients and clinicians, the information generated could identify and enhance understanding of missed and delayed diagnoses and provide evidence-based strategies to improve diagnosis.

Attributes of an Effective Diagnostic Measurement System. An effective measurement system begins with identifying the purpose of measurement and for whom it is intended. Diagnostic measurement can be used to drive improvement, especially when combined with real-time feedback and benchmarking to drive meaningful change in clinical practice (eg, rapid response teams for chest pain) and health system design (eg, same-day testing and surgical referral for abnormal findings on mammography). Diagnostic performance information can also be used to recognize and reward teamwork and shared decision-making between patients and members of the clinical team. Diagnostic measurement for accountability would optimally focus on system-level performance for outcomes that matter to patients and clinicians.

Challenges of Measurement for Diagnostic Quality. Measurement for diagnostic quality will need to acknowledge and account for unique challenges created by the dynamic nature of diagnosis and inherent uncertainty of the diagnostic journey. During the diagnostic process, it is not unusual, or incorrect, for working diagnostic labels to change as new information is acquired and as the patient's condition evolves both naturally and in response to interventions. The language used to communicate risk of disease and uncertainty about diagnosis is not uniform and may be overly ambiguous (eg, "cannot rule out," "consider the possibility"). Thus, attempts to standardize and measure diagnostic processes should avoid unrealistic expectations or overzealous judgments to be both accurate and fair in judgment (eg, driving performance not feasible under the conditions at the time, or expecting actions predicated on facts not available at the time of care).

Standards for diagnostic performance will change as the current understanding of disease evolves, new diagnostic technologies are introduced, and new therapies become available, and quality measures will need to be refined and updated to remain relevant, especially when diagnostic standards are in rapid evolution (eg, the rapidly changing landscape of genetic testing for cancer). Absolute requirements in measures that may lead to excess testing to optimize accuracy without consideration of potential harm from overdiagnosis should be avoided. The overuse of CT angiography for suspected pulmonary embolism is an example of a common practice that illustrates excessive testing that fails to improve outcomes, with recently reported yield rates of only 1% to 3%.[1]

Data Sources for Diagnostic Measurement. Even though current knowledge about diagnostic measurement is limited, important resources are available to build on, including the National Academy of Medicine report on improving diagnosis in health care, as well as measurement improvement frameworks.[2-4] Although these guides provide a starting point, successful diagnostic measurement may require rethinking the sources of data needed and the investments in data infrastructure that can support meaningful measurement. Current efforts to measure quality performance tend to rely on readily available data sources, such as claims-based data, rather than rich clinical data present in electronic health records, found in narrative reports, or acquired through patient surveys; these sources of information may be more relevant to diagnosis. Reliance on a single data source may not provide the information necessary to determine the accuracy and quality of a diagnosis. Claims data were not designed to provide information on presenting symptoms, the diagnostic process, or the overall diagnostic trajectory. Although claims data can document that a diagnostic study was performed, those data do not capture the clinical logic that led to the order or the results of the examination.

Although some of the data needed to understand, assess, and drive diagnostic quality may already be found in electronic records, the information is often fragmented and recorded in different forms and electronic health systems that are not always available at the point of care or easily accessed for use in a quality measure. Because the diagnostic process is often not constrained to a single episode of care and may traverse numerous clinicians, health care centers, and testing sites, methods are needed that capture, integrate, and analyze different sources and data systems. Some of these challenges can be overcome as new standards of interoperability are realized to improve access to data between sites.

Newer, more robust data sources may provide important and valuable signals to inform measurement for

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quality improvement. Clinical registries that record symptoms, not just diagnoses, could generate better evidence on optimal diagnostic pathways, especially with patient-centered data across sites of care. Because diagnosis is a key dimension of clinical guidelines, developers of improvement tools, including clinical risk calculators and decision support systems, could incorporate diagnostic measurement and improvement strategies.[5] Although new sources of data are needed, an expanded set of standardized diagnostic electronic data elements and fields, including symptoms, is also needed to effectively track and measure the association of clinical history and diagnostic information with patient outcomes. Experience with COVID-19 provides ample evidence of the importance of tracking and harmonizing important symptoms and correlating them with diagnosis and outcomes.

Analytic Approaches for Diagnostic Measurement. Measurement of diagnostic performance also could incorporate novel analytic methods, such as machine learning and natural language processing. Although some of these future-facing measures may not support immediate accountability, advances in data science offer opportunities to deal with the complexity of diagnosis that could inform diagnostic measurement and learning. New measurement approaches should build on the emerging data and computational infrastructure that drive improved diagnosis (such as the use of machine learning for cardiac monitoring to capture data for both quality measurement and improvement). New applications with potential for artificial intelligence in quality measurement will require assurances that machine learning models are explainable and equitable. The recent literature on the use of an estimated glomerular filtration rate algorithm to assess kidney function that disadvantaged Black patients for kidney transplant provides a cautionary tale about relying on data without considering potential inequities.[6]

Building a New Model for Diagnostic Measurement. Ideally, a new measurement model for diagnosis will be built in partnership with clinicians and patients. Patients would drive measurement toward meaningful diagnostic outcomes of interest, including diagnostic errors and delays. Although it remains difficult to accurately measure diagnostic errors, a new measurement model built with patients will drive more open discussion about potential solutions, including patient-reporting systems. A well-designed diagnostic measurement system could provide value-added, actionable information to clinicians and patients, but be designed to detect and avoid potential unintended consequences to patients. To avoid these potential harms, this new diagnostic approach should be built with the capacity for real-time feedback to prospectively monitor for unintended harms.

Key Points

1. Measurement is necessary to assess diagnostic safety, quality, and equity and can be a valuable guide to identify improvement strategies that work for patients and clinicians.
2. Diagnostic measurement has been limited by the lack of shared definitions for diagnostic performance or standards for excellence and inadequate data infrastructure designed for that purpose.
3. An evolving model for diagnostic measurement should consider new and novel data sources and measurement approaches.
4. Diagnostic measurement should drive toward real-time monitoring, feedback, and diagnostic support while minimizing measurement burden and avoiding unintended consequences.

To achieve the greatest benefit, priority should be given to measurement that targets the highest-risk conditions that result in the most harm from missed or delayed diagnosis (eg, cardiovascular events, infection, cancer),[7] as well as cross-cutting measures that focus on high-risk processes, including handoffs, transitions, and laboratory follow-up. Ideally, diagnostic measurement will target specific health care system shortfalls (eg, delays due to inefficient diagnostic journeys) and incorporate improvement strategies that ensure communication and referral loops among patients, clinicians, and their diagnostic tests. The medical community has an opportunity to build a new diagnostic measurement approach that provides timely, valuable, and actionable information to clinicians. Unlike current performance measurement efforts, diagnostic equity should be firmly embedded in this emerging measurement model.

Conclusions

To improve the diagnostic process in the near term, it is time to set standards for minimally acceptable diagnostic performance (eg, optimal time to diagnosis for cancer, acceptable standards of accuracy and criteria for testing) and seek actionable, timely, and meaningful information from measurement. To avoid harm, benchmarks and standards but not absolutes are needed because sensitivity and specificity trade-offs should be balanced to avoid extremes of overdiagnosis and underdiagnosis. The goal of all measurement should be to identify best practices and effective strategies to improve the diagnostic process for patients and clinicians, and whenever possible, to inform real-time decisions to optimize outcomes. Without a clear view across the whole of a patient's diagnostic journey, clinicians and health care systems cannot learn from diagnostic errors and near misses to build improvement systems that make a difference for all patients who entrust clinicians with their care.

ARTICLE INFORMATION

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