Diagnostic Excellence and Patient Safety Strategies and Opportunities

In healthcare, discussions about diagnosis have long focused on such concerns as sensitivity and specificity, cost, and the role of new technology. Relative to these issues, matters related to patient safety in diagnosis have received less attention, even though failures in the diagnostic process harm many patients. Patient safety is often compromised by the downstream consequences of erroneous, untimely, and miscommunicated diagnoses caused by failures in both system and cognitive factors. For example, errors in the use and performance of diagnostic tests can harm patients, both from delayed and missed diagnoses and from the preventable harm from unnecessary diagnostic tests. This Viewpoint examines diagnostic safety issues in various clinical scenarios across the care continuum, with selected examples illustrating successful strategies for improvement.

**Primary Care: Cancer Screening**

In cancer screening, numerous evidence-based guidelines share the goals of providing timely diagnosis and continuity of care. For example, with colorectal cancer screening, issues of frequency (eg, every 10 years via colonoscopy vs 2 years via fecal occult blood testing), approach, and target population all have evidence-based guidelines. In 2022, the estimated 5-year survival rate for colorectal cancer is approximately 63%, but high-functioning systems such as Kaiser Permanente reported achieving rates of 77.7% in 2012. Improvements in diagnostic safety have resulted from systems thinking, subsegmenting high-risk populations through the lens of equity, closed-loop communication (wherein the receiver of information confirms and cross-checks the accuracy of the message with the sender), and safety net systems that identify and act on test results that may have been missed. The lessons learned, however, still need to be applied to most primary care screening processes.

**Emergency Department: Sepsis**

Despite considerable knowledge about sepsis, including the associated high rates of mortality and morbidity, sepsis continues to represent one of the greatest opportunities for improvement in health care. Sepsis is associated with an estimated 270 000 deaths per year, representing more deaths in the US than breast cancer, colon cancer, and prostate cancer combined.

The diagnosis of and outcomes related to sepsis identification in the emergency department (ED) have improved from several initiatives. These include mandated reporting of outcomes (eg, sepsis mortality) rather than reporting solely on process measures (eg, adherence with care bundles), establishing new clinical standards (eg, 3-hour time interval for administering fluids and antibiotics), auditing results, and culture change (eg, creating psychological safety for any member of the clinical team to suggest sepsis). Areas of disagreement in clinical practice include antibiotic stewardship vs early antibiotic administration, dynamic vs static intravenous fluid hydration strategies, and central vs peripheral line for vasopressor administration; these strategies are being informed through new evidence, which has helped reduce missed diagnoses. Significantly improved sepsis diagnosis (and outcomes) have been observed when such best practices are adopted at scale, as seen in the experience of New York state compared with other states. Key lessons to drive best practice adoption include auditing to ensure actual outcome improvement, education of clinicians, and local improvement supported by benchmarking data for prioritizing local actions.

**Inpatient Setting: Pulmonary Embolism**

Pulmonary embolism has been described as “simultaneously the most over-tested yet under-diagnosed condition in medicine," yet diagnosis of pulmonary embolism has improved with the use of structured clinical decision tools and plasma D-dimer measurement. Beyond simple algorithms, artificial intelligence (AI)-based decision support applications could potentially help foster diagnostic safety, and combining physician judgment with machine learning derived from large populations may enhance diagnostic performance. When patients with suspected pulmonary embolism are not improving as expected, AI approaches could potentially indicate that the diagnosis may be incorrect.

**Remote Care: Telehealth**

Telehealth offers a different lens from which to understand diagnostic safety, with a focus on how a patient interacts with the health system. This is a relatively unexplored area for which key safety issues have not been...
Box. Key Points for Diagnostic Excellence

- Patient safety issues have received less attention in diagnosis relative to concerns about sensitivity and specificity, cost, and the role of new technology
- The practice of diagnostic safety varies widely by clinical setting and diagnosis
- Evidence-based approaches that improve diagnostic safety deserve broader adoption

established. Rather than relying only on “clinical grade” diagnostics (eg, physical examination conducted by a physician or other health professional, objective laboratory data), telehealth encompasses variations in several factors (eg, setting, communication modality, subjective patient reports) and importantly has implications for how patient-reported data are collected and considered as part of a diagnostic workup. Furthermore, telehealth offers a window into challenges and solutions related to remote care that might benefit from lessons learned in more traditional care settings, and vice versa (eg, closed-loop communication). For example, when evaluating abdominal pain, physicians are accustomed to relying on a physical examination, and some diagnoses may be apparent from the examination, such as acute cholecystitis and incarcerated hernia. In such cases, the limitations of remote care are clear, but in many other cases the boundaries of high-quality and safe telehealth care have yet to be established. Nevertheless, telehealth may offer improved timeliness of data (ie, earlier signals), better understanding of their longitudinal nature (ie, more signals), and closer relationships to what matters to a patient (ie, prioritized signals). Improvement in telehealth diagnosis may benefit other settings, although additional research is needed in this rapidly expanding modality of care (Box).

The Near Future
What can be done to elevate diagnostic safety in the safety movement and advance best practice adoption? First, clinical and safety leaders need to understand and prioritize diagnostic errors. Those leaders must then work to create a culture that promotes transparent, nonpunitive discussions about cognitive and systemic diagnostic error and its causes. A learning system must be created, whereby diagnostic errors are identified more rigorously and systematically across the continuum of care (eg, through reporting, electronic triggers, AI, and other approaches) and analyzed for root causes. Diagnostic safety efforts must be cross-cutting and integrated with other domains to ensure that the diagnostic process is not only safe but also timely, equitable, effective, efficient, and patient centered.8 In particular, the equity lens is essential to ensure that known gaps in diagnostic performance (based on language, race, sex, socioeconomic status, and other characteristics) are eliminated. Health care organizations will need to develop system solutions to mitigate the cognitive and system origins of these errors (eg, solutions such as simulation training, AI tools, safety nets, and patient engagement tools). A new checklist that describes practical strategies for implementing comprehensive diagnostic excellence programs is a useful starting point for organizations.9

Electronic health records (EHRs) should be leveraged to provide some of the solutions but should not increase the documentation or time burden for clinicians. Some EHRs could detect and report the risk of adverse events in clinical care (eg, when a new medication is prescribed that may interact with others) and may alert clinicians if data suggest that a diagnosis may have been missed.10 New norms for “acceptable” delay durations may be established, for example, acceptable time windows for workup of rectal bleeding, and along with closed-loop processes, incorporated into expert systems.

Diagnostic safety failures are common in medical care but often have not been a focus for organizational leaders responsible for quality and safety processes. Although such errors have many potential sources, numerous evidence-based approaches to reduce errors exist, and these deserve more systematic and scaled implementation.

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