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A Research Agenda for the Diagnostic Process and Diagnostic Error

Progress toward improving diagnosis and reducing diagnostic error will be significantly hampered without a dedicated focus on research. A primary reason that diagnostic errors have remained an underappreciated quality challenge is the lack of information specifying the full extent of the problem. To underscore the importance of this issue, the committee sought to identify or construct an estimate of the frequency of diagnostic errors. All of the research the committee reviewed indicated that diagnostic errors are a significant and pervasive challenge, but the available research estimates were inadequate to establish a precise understanding of the incidence and nature of diagnostic errors in clinical practice today.

Absent this quantification, other issues in health care quality and safety have overshadowed diagnostic errors. And while the issue of diagnostic error has been gaining momentum in patient safety and quality improvement efforts, the relative lack of attention has resulted in substantial gaps in what is known about the diagnostic process and diagnostic error in health care today. These knowledge limitations affect not only the field of diagnosis but also the broader research enterprise. A substantial body of research relies on—and in some cases assumes that—diagnoses are correct. In research studies evaluating interventions, for example, incorrect diagnoses threaten the validity of the study outcomes and conclusions. An improved understanding of diagnosis and diagnostic error has the potential to inform and improve all areas of health research.

Thus, the committee concluded that that there is an urgent need for research on the diagnostic process and diagnostic errors. Previous chapters have highlighted the challenges to diagnosis that arise from

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specific elements of the health care work system. The lack of research on the diagnostic process and diagnostic error is an overarching challenge that affects all aspects of the diagnostic process and all elements within the work system. This chapter outlines the impediments to research on the diagnostic process and diagnostic error. The committee calls for a coordinated federal research agenda, committed funding, and significant public–private collaborations to enhance research in this critical area.

A FEDERAL RESEARCH AGENDA

The diagnostic process and the challenge of diagnostic errors have been neglected within the national health care research agenda (Berenson et al., 2014; Wachter, 2010; Zwaan et al., 2013). Input provided to the committee concluded that "although correct treatment presumes a correct diagnosis, federal resources devoted to diagnostic research are vastly eclipsed by those devoted to treatment" (Newman-Toker, 2014, p. 12). There are a number of reasons why diagnosis and diagnostic errors may be underrepresented in current research activities, including the dearth of sources of valid and reliable data for measuring diagnostic error, a lack of awareness of the problem, the perceived inevitability of the problem, a poor understanding of the diagnostic and clinical reasoning processes, a lack of applicable performance measures on diagnosis, and the need for financial and other resources to address the problem (Berenson et al., 2014; Croskerry, 2012).

A major barrier to research on diagnosis and diagnostic error is the disease-focused approach to medical research funding. For example, the National Institutes of Health's (NIH's) structure and funding mechanisms are often organized by disease or organ systems, which facilitates the study of these specific areas but impedes research efforts that seek to provide a more comprehensive understanding of diagnosis as a distinct research area. Newman-Toker (2014, p. 12) asserted that diagnostic research "invariably falls between rather than within individual Institute missions." As such, the topic of diagnosis, which cuts across all diseases and body parts, is not centralized within the NIH research portfolio, and available research funding for diagnosis often targets the diagnosis of specific diseases, but not diagnosis as a whole; the diagnosis of several diseases with similar presentations; or the diagnostic process itself.

Diagnosis and diagnostic error are not a focus of federal health services research efforts, with the exception of two special emphasis notices from the Agency for Healthcare Research and Quality (AHRQ) for diagnostic error which were published in 2007 and 2013, as well as 2015 grant opportunities (AHRQ, 2007, 2013, 2015a,b). AHRQ posted an R01 grant opportunity for "understanding and improving diagnostic safety in

ambulatory care: incidence and contributing factors" (AHRQ, 2015a) and an R18 grant opportunity on identifying strategies and interventions to improve diagnostic safety in ambulatory care (AHRQ, 2015b).

Although these initial steps are promising, the available funding for research on diagnostic error is not in alignment with the scope of the problem or with the resources necessary to improve diagnosis. The committee concluded that there is an urgent need for dedicated, coordinated federal funding for research on diagnosis and diagnostic error. **Thus, the committee recommends that federal agencies, including the Department of Health and Human Services (HHS), the Department of Veterans Affairs (VA), and the Department of Defense (DOD), should develop a coordinated research agenda on the diagnostic process and diagnostic errors by the end of 2016.** Within HHS there are a number of agencies that have the diagnostic process and diagnostic errors within their purview, including NIH, AHRQ, the Centers for Disease Control and Prevention, and the Centers for Medicare & Medicaid Services (CMS). The VA and the DOD should also be engaged in developing this research agenda. An example of cross-governmental collaboration is the joint effort by AHRQ and the National Science Foundation to evaluate how industrial and systems engineering contribute to better health care delivery. Following a workshop that outlined a research agenda, these agencies released a joint grant solicitation to fill the gaps identified during the course of the workshop (Valdez, 2010).

Given the potential for federal research in diagnosis and diagnostic error to fall between institutional missions, federal agencies need to collaborate to develop a coordinated national research agenda that addresses diagnosis and diagnostic error. **Because of the urgent need for research in these areas, federal agencies should commit dedicated funding to implementing this research agenda.** Overall federal investment in biomedical and health services research is declining (Moses et al., 2015), and the committee recognizes that funding for diagnosis and diagnostic error will likely draw resources away from other important priorities. However, given the consistent lack of resources for research on diagnosis, and the potential for diagnostic errors to contribute to significant patient harm, the committee concluded that this prioritization is necessary in order to achieve broader improvements in the quality and safety of health care. Furthermore, because much of health care (both in research and in clinical practice) relies on correct diagnoses, research in this area is likely to enhance the effectiveness of other efforts (e.g., those focused on treatment and management), and it could also potentially lead to cost savings by preventing diagnostic errors, inappropriate treatment, and related adverse events.

PUBLIC–PRIVATE COLLABORATION ON RESEARCH

In addition to federal-level research on diagnosis and diagnostic errors, there is an important role for public–private collaboration and coordination among the federal government, foundations, industry, and other organizations. Collaborative funding efforts help extend the existing financial resources and reduce duplications in research efforts. Interested parties can unite around areas of mutual interest and spearhead progress. Foundations, industry, and other stakeholders can make important contributions—financially and within their areas of expertise—to enhance knowledge in this area. **Thus, the committee recommends that the federal government should pursue and encourage opportunities for public–private partnerships among a broad range of stakeholders, such as the Patient-Centered Outcomes Research Institute (PCORI), foundations, the diagnostic testing and health information technology (health IT) industries, health care organizations, and professional liability insurers to support research on the diagnostic process and diagnostic errors.**

The scientific literature includes descriptions of various types of collaborative models that have been employed to share information, resources, and capabilities (Altshuler et al., 2010; Portilla and Alving, 2010). Organizations like Grantmakers in Health coordinate corporate and foundation funding efforts to improve health and health care delivery (GIH, 2015). An example of a public–private partnership that could be leveraged is the National Center for Interprofessional Practice and Education, which takes a cross-cutting view of health systems and health care professional education (NCIPE, 2015). Another example is the CMS Innovation Center's Health Care Payment Learning and Action Network, launched in the spring of 2015 (CMS, 2015). This model will support HHS's efforts to move from paying for volume to paying for the value of services provided (Burwell, 2015). As a part of this effort, organizations can collaborate to generate evidence. In line with Recommendation 7b, this could include generating evidence about how payment models influence the diagnostic process and the occurrence of diagnostic errors.

Zwaan and colleagues (2013) outlined potential research opportunities broadly, classified into three areas: the epidemiology of diagnostic errors, the causes of diagnostic error, and error prevention strategies. The Society to Improve Diagnosis in Medicine has formed a research committee to bring together multidisciplinary perspectives in order to advance a research agenda that seeks to address critical gaps in the evidence base (SIDM, 2015). Building on this work, the committee identified additional areas of research that could help shape a national research agenda on diagnosis and diagnostic error (see Box 8-1). This list is not exhaustive;

BOX 8-1
Potential Areas of Research

Patient and Family Engagement and the Diagnostic Process
- Effective strategies for partnering with patients in the diagnostic process; approaches for reaching diverse population groups, including those who are diverse in language, culture, and individual values, preferences, and needs.
- Development of patient-focused educational resources and shared decision-making tools/strategies in the diagnostic process.
- Patient-centered priorities in reducing diagnostic errors.
- Identification of multiple perspectives to better understand and mitigate diagnostic error (including the patient, family, primary care clinicians, specialists, other health care professionals, organizational leaders, risk management perspectives, and others).
- The impact of patient variables on the diagnostic process and outcomes.
- Disparities in accurate and timely diagnosis among populations at highest risk, including those with health literacy limitations, socioeconomic disadvantages, limited English proficiency, and racial/ethnic minority populations.

Health Care Professional Education and Training
- How health care professional schools currently train and evaluate students for diagnostic competency.
- Effective practices to teach and evaluate clinical reasoning.
- The use of simulation training to improve diagnostic performance.
- Etiology of cognitive errors (inadequate knowledge and shortcomings in cognitive processes).
- Components of intra- and interprofessional training that improve the diagnostic process.

Health Information Technology (Health IT)
- How health IT can be better leveraged to support the identification of diagnostic errors by analyzing large quantities of data to find trends, patterns, and anomalies that would not be visible otherwise.
- Development of strategies for the identification and remediation of health IT functionality and usability issues affecting diagnosis (difficulties navigating, seeing, understanding, or interacting with user interfaces/displays).
- Investigation of how health IT can be leveraged to narrow the gap between patients' actual health literacy level and that required to navigate the diagnostic process.
- Examination of the impact of computer-assisted diagnosis technology on diagnostic accuracy in medical imaging.
- Evaluation of the relationship between the amount of clinical context provided by diagnostic test orders and diagnostic error.

BOX 8-1 Continued

- Development of health IT tools to efficiently extract information from the electronic health record that is relevant to an individual patient's specific diseases and conditions, allowing the clinicians to expend more of their efforts on information integration and interpretation to provide a personalized diagnosis.
- Potential for artificial intelligence, big data, and analytics approaches to improve the diagnostic process and identify diagnostic errors and near misses.

Identification, Analysis, and Reduction of Diagnostic Errors
- National studies/surveys of health care organizations to document:
  - Current approaches and progress in the identification of diagnostic errors.
  - Evidence to improve diagnosis and reduce diagnostic errors.
  - The relationship between diagnostic variance and patient outcomes.
- A national effort to capture diagnostic delays and errors could be considered as a part of ongoing surveillance through the National Center for Health Statistics, such as the National Ambulatory Medical Care Survey and the National Hospital Ambulatory Medical Care Survey.
- Longitudinal analysis of diagnostic errors to determine when improvement efforts are succeeding.
- Disease-specific analyses of diagnostic errors and near misses.
- Development of tools and methods that can identify diagnostic errors in practice.
  - The necessary structures (Are the right tools in place to increase the likelihood of accurate and timely diagnoses?), processes (Are the appropriate steps undertaken to ensure that a diagnosis is accurate and timely?), and patient outcomes (Are both clinical outcomes and patient-reported outcomes about how the diagnostic error affected them noted?).
  - Variations research (similar to geographic variations research to identify variability of diagnostic accuracy across regions, organizations, health care professionals, settings of care, etc.).

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instead, it is meant to highlight some of the issues that were raised during committee discussions. The committee concluded that it was not feasible to prioritize specific research areas in diagnosis and diagnostic error; such prioritization will require additional time and effort beyond the scope of the study.

Because this has been an underemphasized area in research and health care delivery, there are many promising avenues for research. Chapter 3 describes the committee's proposed five purposes of measurement; re-

    o The specific elements of diagnostic error associated with different settings of care (including inpatient, outpatient, extended care, home, and community settings).

    o Methods to assess the diagnostic performance of diagnostic team members.

    o Assessment of the elements of organizational culture that promote improved diagnostic performance.

    o Effective and cost-effective approaches for identifying diagnostic errors.

    o Identification of priority conditions for which known approaches to improve diagnostic accuracy and timeliness would have a high impact.

    o Mitigation of potential adverse consequences related to assessing diagnostic errors.

    o Identification of tools that can measure interventions.

Work System Improvements
- Research on the work system factors that contribute to poor diagnostic performance, diagnostic errors, and near misses in current practice.
- Research exploring the generalizability of findings on teamwork, culture, leadership, and education from other disciplines and from broader health care quality and patient safety settings to the diagnostic process.
- Identification of cultural and other organizational characteristics of health care organizations that improve diagnosis and reduce diagnostic errors.
- Interventions that redesign the work system and assess their effects on diagnosis.

External Environment
- Impact of payment, care delivery models, and coding practices on the diagnostic process and the accuracy of diagnosis.
- Economic consequences of diagnostic errors for patients and their families, health care organizations, and the nation.
- Mechanisms to improve voluntary reporting.
- Alternative approaches to medical liability to improve disclosure, learning, and the prevention of diagnostic errors.

search in each of these areas could be very helpful. Additional research could better define the scope of the problem, identify vulnerabilities in the diagnostic process, describe the work system factors that contribute to errors, and evaluate interventions. Further measurement research could advance efforts to assess diagnostic performance in education and training environments and could consider issues related to measurement for accountability. An important area of research will be the economic impact of diagnostic errors. Today, there is limited information about the eco-

nomic consequences of diagnostic errors for patients and their families, for health care organizations, and for the country as a whole.

As discussed in Chapter 4, it is also critical to carry out more research on teamwork in the diagnostic process, patient engagement, and health care professional education. There has been limited research on teamwork in the diagnostic process, and future research efforts could help identify best practices to facilitate and support such teamwork. Furthermore, diagnostic research that includes patient and family perspectives will be critical to increasing the effectiveness of interventions, because patient actions are often needed to achieve correct diagnoses, especially in outpatient settings (Gandhi et al., 2006). To better enable patient and family engagement in the diagnostic process, further research could also elaborate on methods and tools that effectively engage patients and their families as true partners. In the area of health care professional education, research on methods to assess diagnostic competencies among health care professionals and best practices for developing clinical reasoning and other competencies essential to the diagnostic process is warranted.

Chapter 5 describes the use of health IT in the diagnostic process. A major area of research is understanding how to effectively leverage health IT to support all diagnostic team members in the diagnostic process, especially in supporting clinical reasoning tasks. For example, a better understanding of the performance diagnostic decision support tools in clinical practice is needed. In addition, research that identifies the potential adverse effects of health IT on the diagnostic process can be helpful to ensure the safe design, implementation, and use of health IT. Given the growth of mobile health applications and wearable technologies, research could also provide information on how these can be effectively incorporated in the diagnostic process.

In Chapter 6, the committee calls on health care organizations to begin monitoring the diagnostic process and to identify, learn from, and reduce diagnostic errors in clinical practice. Because there has been limited collection of this information in clinical practice, health care organizations will need to experiment and assess which approaches are effective for monitoring the diagnostic process and identifying, analyzing, and reducing diagnostic errors. Further research on developing systematic feedback mechanisms on diagnostic performance and research on best practices for the delivery of this feedback to individuals, care teams, and leadership will also be necessary. Research can also inform the design of a health care organization's work system so that it supports the work and activities of the diagnostic process.

Chapter 7 describes how voluntary reporting, medical liability, and payment and care delivery can influence the diagnostic process. There are several topics that deserve research in this area, including demonstra-

tion projects to evaluate how alternative approaches to medical liability—such as administrative health courts and safe harbors for adherence to evidence-based clinical practice guidelines—influence the occurrence and disclosure of diagnostic errors and also influence the analysis of and learning from these errors. As mentioned previously, there is also a need to understand how payment and care delivery influence the diagnostic process, diagnostic errors, and learning.

Achieving progress in reducing diagnostic errors and improving diagnosis will require an emphasis on collaboration. Collaborative research in diagnosis and diagnostic error will necessitate the involvement of multiple disciplines, and it will benefit from the use of multiple and mixed methods (Creswell et al., 2011). For instance, qualitative approaches such as cognitive work analyses of the human factors/ergonomics discipline could provide in-depth information on the types of diagnostic errors identified by health services researchers (Bisantz and Roth, 2007). This type of multidisciplinary mixed-methods research can provide the type of information that is needed to further quantify and understand the nature of diagnostic errors.

RECOMMENDATION

Goal 8: Provide dedicated funding for research on the diagnostic process and diagnostic errors

Recommendation 8a: Federal agencies, including the Department of Health and Human Services, the Department of Veterans Affairs, and the Department of Defense, should:
- **Develop a coordinated research agenda on the diagnostic process and diagnostic errors by the end of 2016.**
- **Commit dedicated funding to implementing this research agenda.**

Recommendation 8b: The federal government should pursue and encourage opportunities for public–private partnerships among a broad range of stakeholders, such as the Patient-Centered Outcomes Research Institute, foundations, the diagnostic testing and health information technology industries, health care organizations, and professional liability insurers to support research on the diagnostic process and diagnostic errors.

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