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1 Introduction

For decades, the delivery of health care has proceeded with a blind spot: Diagnostic errors—inaccurate or delayed diagnoses—persist throughout all care settings and harm an unacceptable number of patients. Getting the right diagnosis is a key aspect of health care, as it provides an explanation of a patient's health problem and informs subsequent health care decisions (Holmboe and Durning, 2014). Diagnostic errors can lead to negative health outcomes, psychological distress, and financial costs. If a diagnostic error occurs, inappropriate or unnecessary treatment may be given to a patient, or appropriate—and potentially lifesaving—treatment may be withheld or delayed. However, efforts to identify and mitigate diagnostic errors have so far been quite limited. Absent a spotlight to illuminate this critical challenge, diagnostic errors have been largely unappreciated within the quality and patient safety movements. The result of this inattention is significant: It is likely that most people will experience at least one diagnostic error in their lifetime, sometimes with devastating consequences.

The topic of diagnosis raises a number of clinical, personal, cultural, ethical, and even political issues that commonly capture public interest. Members of the public are concerned about diagnosis and many have reported experiencing diagnostic errors. For example, a survey by Isabel Healthcare found that 55 percent of adults indicated that their main concern when visiting a family practitioner was being correctly diagnosed (Isabel Healthcare, 2006). A poll commissioned by the National Patient Safety Foundation found that approximately one in six of those surveyed had experience with diagnostic error, either personally or through a close friend or relative (Golodner, 1997). More recently, 23 percent of people surveyed in Massachusetts stated that they or someone close to them had experienced a medical error, and approximately half of these errors were diagnostic errors (Betsy Lehman Center for Patient Safety and Medical Error Reduction, 2014). In the United Kingdom, the country's National Health Service concluded that diagnosis—including diagnostic error—was the most common reason individuals complained about their health care, accounting for approximately 35 percent of complaints (Parliamentary and Health Service Ombudsman, 2014).

In addition to diagnostic errors, the public is concerned about other aspects of diagnosis, such as the value of making and communicating diagnoses at early stages in conditions such as Alzheimer's disease and amyotrophic lateral sclerosis (Lou Gehrig's disease) for which there is currently no known cure (Hamilton, 2015). There is also a growing concern about overdiagnosis, such as the assignment of diagnostic labels to conditions that are unlikely to affect the individual's health and well-being (Welch et al., 2011); the focus of clinical attention on making new diagnoses in older patients while ignoring limitations to their daily living that need immediate attention (Gawande, 2014; Mechanic, 2014); and the elevation of common behavioral traits to the level of formal diagnoses, with the attendant treatment and confidentiality implications (Hazen et al., 2013; Kavan and Barone, 2014; NHS, 2013). The Institute of Medicine (IOM) report Beyond Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Redefining an Illness brought attention to the problem that individuals with debilitating but previously non-recognized symptom complexes may be given inadequate attention by clinicians or ignored altogether because a diagnosis is lacking (IOM, 2015; Rehmeyer, 2015). Diagnoses also affect the health care that patients receive, eligibility for social security and veterans disability benefits, as well as health care research and education priorities.

The widespread challenge of diagnostic errors frequently rises to broad public attention, whether the widely reported diagnostic error of Ebola virus infection in a Dallas hospital emergency department or in the occasional report of an extraordinarily high malpractice award for failure to make a timely diagnosis of cancer or some other life threatening disease (Pfeifer, 2015; Upadhyay et al., 2014; Wachter, 2014). The subjects of diagnosis and diagnostic error have captured media interest, as indicated by television shows and columns about perplexing diagnoses and coverage of patient experiences with diagnosis (Dwyer, 2012; Genzlinger, 2012; Gubar, 2014; New York Times, 2014; Washington Post, 2014). For example, Harper's Magazine featured an essay that chronicled one patient's diagnostic journey and experience with diagnostic error through multiple clinicians, Internet searches, conversations with friends and family, and decision support tools (Julavits, 2014). Books featuring patients' experiences with diagnosis and the health care system have also been published (Cahalan, 2012; Groopman, 2007; Sanders, 2010).

Given the importance of diagnosis to patients and to health care decision making, as well as the pervasiveness of diagnostic errors in practice, it is surprising that this issue has been neglected within the quality improvement and patient safety movement (Gandhi et al., 2006; Graber et al., 2012; Newman-Toker and Pronovost, 2009; Singh, 2014). There are a number of reasons for the lack of attention to diagnostic errors. Major contributors are the lack of effective measurement of diagnostic error and the difficulty in detecting these errors in clinical practice (Graber et al., 2012; Singh, 2013). Even if they can be measured or identified, diagnostic errors may not be recognized, for example, when the error is identified by a second clinician and feedback about the error is not provided to the original clinician. There may also be debate about what constitutes a diagnostic error; even after an extensive review of a patient's chart, expert reviewers often disagree about whether or not an error has occurred (Wachter, 2010; Zwaan and Singh, 2015). Diagnostic errors may also be perceived as too difficult to address because the reasons for their occurrence are often complex and multifaceted (Berenson et al., 2014; Croskerry, 2003; Graber et al., 2005; Schiff et al., 2005; Zwaan et al., 2009). This difficulty in identifying the etiology of errors, combined with a lack of feedback on diagnostic performance in many health care settings, limits understanding and makes it more difficult to prioritize improving diagnosis and reducing diagnostic errors. Other factors that contribute to the limited focus on diagnostic error include a lack of awareness of the problem, attitudes and culture that encourage inaction and tolerance of errors, poorly understood characteristics of the diagnostic and clinical reasoning processes, and the need for financial and other resources to address the problem (Berenson et al., 2014; Croskerry, 2012).

Although diagnostic error has been largely underappreciated in efforts to improve the quality and safety of health care, this issue has garnered national attention, and there is growing momentum for change (Graber et al., 2012; Schiff and Leape, 2012; Wachter, 2010). Emerging research has found new opportunities for the identification of diagnostic errors and has led to a better understanding of the epidemiology and etiology of these errors and of potential interventions to improve diagnosis (Singh et al., 2014; Tehrani et al., 2013; Trowbridge et al., 2013; Zwaan and Singh, 2015; Zwaan et al., 2010). Patients and families who have experienced diagnostic error have become increasingly vocal about their desire to share their unique insights to help identify patterns and improve the diagnostic process for future patients (Haskell, 2014; McDonald et al., 2013).

Efforts to accelerate progress toward improving diagnosis can leverage four important movements in health care: the movements to improve patient safety, to increase patient engagement, to foster professionalism, and to encourage collaboration. Diagnostic error has been called the next frontier in patient safety, even though the challenge of diagnostic error will have

benefits beyond the realm of patient safety, as such errors are a major challenge to the quality of patient care (Newman-Toker and Pronovost, 2009). Patient engagement and the importance of shared decision making are recognized as critical aspects of improving health care quality (IOM, 2001). The current focus on professionalism emphasizes health care professionals' intrinsic motivation and commitment to provide patients with high-quality, patient-centered care (Berwick, 2015; Chassin and Baker, 2015; Madara and Burkhart, 2015). The growing recognition of health care as a team-based activity has led to greater collaboration among health care professionals, both intra- and interprofessionally (IOM, 2001; Josiah Macy Jr. Foundation and Carnegie Foundation for the Advancement of Teaching, 2010). These four movements have collectively transformed the way that health care is provided in the United States, and progress toward improving diagnosis and reducing diagnostic errors is a natural outgrowth of these movements. This report by the Committee on Diagnostic Error in Health Care synthesizes current knowledge about diagnostic error and makes recommendations on how to reduce diagnostic errors and improve diagnosis.

CONTEXT OF THE STUDY

This study is a continuation of the IOM Quality Chasm Series, which focuses on assessing and improving the quality and safety of health care. It includes the IOM reports *To Err Is Human: Building a Safer Health System* and *Crossing the Quality Chasm: A New Health System for the 21st Century.* The first report was a call to action: The committee concluded that the care patients receive is not as safe as it should be (IOM, 2000). Estimating that tens of thousands of lives are lost each year because of medical errors, the report catalyzed a movement to improve the safety of health care in America. The second report defined high-quality care broadly and set out a vision to close the chasm between what was known to be high-quality care and what patients received in practice (IOM, 2001). Together these reports stimulated widespread scrutiny of the health care system and brought about large-scale efforts to improve the quality and safety of care.

However, these reports focused primarily on the quality and safety of medical treatment rather than on the diagnostic process. The majority of quality improvement and patient safety efforts that have since followed have been focused on improving the delivery of evidence-based care and preventing the adverse outcomes of treatment, such as medication and surgical errors, and health care—associated infections.

ORIGIN OF TASK AND COMMITTEE CHARGE

In the summer of 2013, the Society to Improve Diagnosis in Medicine requested that the IOM Board on Health Care Services undertake a study on diagnostic error as a continuation of the IOM's Quality Chasm Series. With support from a broad coalition of sponsors—the Agency for Healthcare Research and Quality, the American College of Radiology, the American Society for Clinical Pathology, the Cautious Patient Foundation, the Centers for Disease Control and Prevention, the College of American Pathologists, The Doctors Company Foundation, Janet and Barry Lang, Kaiser Permanente National Community Benefit Fund at the East Bay Community Foundation, and the Robert Wood Johnson Foundation—the study began in January 2014.

An independent committee was appointed with a broad range of expertise, including diagnostic error, patient safety, health care quality and measurement, patient engagement, health policy, health care professional education, cognitive psychology, health disparities, human factors and ergonomics, health information technology (health IT), decision analysis, nursing, radiology, pathology, law, and health economics. Brief biographies of the 21 members of this Committee on Diagnostic Error in Health Care are presented in Appendix B. The charge to the committee was

to synthesize what is known about diagnostic error as a quality of care challenge and to propose recommendations for improving diagnosis (see Box 1-1).



BOX 1-1

Charge to the Committee on Diagnostic Error in Health Care.

METHODS OF THE STUDY

The committee deliberated during five in-person meetings and numerous conference calls between April 2014 and April 2015. At three of the meetings, the committee invited a number of speakers to inform its deliberations. These speakers provided invaluable input to the committee on a broad range of topics, including patient experiences with diagnostic error; the measurement, reporting, and feedback of diagnostic error; health IT design and decision support; diagnostic errors in pathology and radiology; patient safety culture; teams in diagnosis; psychiatry and diagnostic error; legal issues in diagnosis; and the prioritization of diagnostic error. The committee also held a webinar with experts in cognition and health care professional education. A number of experts and organizations provided written input to the committee on a broad array of topics. In addition to receiving this expert input, the committee reviewed an extensive body of literature to inform its deliberations.

CONCEPTUAL MODEL

To help frame and organize its work, the committee developed a conceptual model that defined diagnostic error and also illustrated the diagnostic process, the work system in which the diagnostic process occurs, and the outcomes that result from this process (see Chapters 2 and 3 for detailed information on the conceptual model). The committee developed a patient-centered definition of diagnostic error: the failure to (a) establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient.

EXAMPLES OF DIAGNOSIS AND DIAGNOSTIC ERRORS

To illustrate the complexity of the diagnostic process and the range of diagnostic errors that can occur, the committee has included a variety of examples of experiences with diagnosis and diagnostic error. The committee was honored to hear patients' and family members' experiences with diagnosis, both positive and negative; three of these experiences are described in Box 1-2. During the committee's deliberations, the United States experienced its first case of Ebola virus infection; because the diagnosis was initially missed in the emergency department, it illustrated a high-profile example of diagnostic error with important public health implications (Upadhyay et al., 2014) (see Chapter 5). Appendix D includes additional examples of diagnostic error in order to convey a broader sense of the types of diagnostic errors that can occur.



BOX 1-2

Patient and Family Experiences with Diagnosis.

ORGANIZATION OF THE REPORT

The report is organized into three major sections. Section I consists of <u>Chapters 2</u> and <u>3</u> and provides an overview of the diagnostic process and diagnostic error in health care. Section II, or Chapters 4 through 8, describes the challenges of diagnosis and is organized by the elements of

the work system: Chapter 4 discusses the diagnostic team members and the tasks they perform in the diagnostic process; Chapter 5 discusses the technologies and tools (specifically health IT) used in the diagnostic process; Chapter 6 focuses on health care organizations and their impact on the diagnostic process and diagnostic error; Chapter 7 describes the external elements that influence diagnosis, including payment and care delivery, reporting, and medical liability; and Chapter 8 highlights the research needs concerning the diagnostic process and diagnostic errors, as drawn from the previous Chapters. Section III (Chapter 9) synthesizes the committee's main conclusions and recommendations for improving diagnosis and reducing diagnostic error.

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