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## Diagnosing Diagnostic Error

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Diagnostic errors are the most common errors in primary care. Diagnostic errors have been found to be the leading cause of malpractice litigation, accounting for twice as many claims and settled cases as medication errors. Diagnostic error is common, harmful, costly, and very critical to the patient-safety issues in health care. Diagnostic errors have received relatively little attention, however. Of what is known, diagnostic errors are an important source of preventable harm. Focused research in this area is highly needed because the causes of diagnostic errors are subtle and solutions are less obvious than for other types of errors. As opposed to medication errors, where the factors predisposing to their occurrence and the resultant preventive strategies are better defined, the relationship between factors

influencing the diagnostic reasoning or decision making and a diagnostic error are not as clear. This may include any failure in timely access to care; elicitation or interpretation of symptoms, signs, or laboratory results, formulation and weighing of differential diagnosis; and timely follow-up and specialty referral or evaluation. The literature reveals that diagnostic errors are often caused by the combination of cognitive errors and system failure. Increased understanding about diagnostic decision making, sources of errors, and applying some existing strategies into clinical practice would help clinicians reduce these types of errors and encourage more optimal diagnostic processes.

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**D**uring the past decade, awareness of medical errors has expanded rapidly, with the movement for patient safety promoting safer health care through systems solutions. Diagnostic errors have received relatively little attention although they are an important source of preventable harm.<sup>1-4</sup> Medication errors and related adverse drug events have been the focus of most research since the release of the Institute of Medicine report, "To Err is Human."<sup>1,5</sup> Diagnostic errors, on the other hand, have not been well studied.<sup>8</sup> Focused research in this area is highly needed because the causes of diagnostic errors are subtle and the solutions are less obvious than are those for other types of errors.<sup>6</sup> As opposed to medication errors, for which the factors predisposing to their occurrence and the resultant preventive strategies are better defined, the relationship between factors influencing the diagnostic reasoning or decision making and a diagnostic error are not as clear. Clinicians are considerably more heterogeneous when it comes to making a diagnosis, and whether they perceive diagnostic errors as a

significant problem with regard to frequency and severity of harm to the patient remains unknown. The following case scenario is an example of a type of diagnostic error commonly seen in pediatric practices. We use this case to illustrate a conceptual framework of a diagnostic error throughout this chapter.

### Case Description

A 4-year-old child was brought to the emergency department (ED) with low-grade fever, tachypnea, and hypoxemia. It was a fairly typical and busy winter season for upper respiratory disease. A chest radiograph revealed right-sided air space disease accompanied by a moderately large same-side pleural effusion and mildly enlarged heart size. A chest ultrasound confirmed a large pleural effusion. To rule out the possibility of an empyema, a surgery consultation obtained in the ED recommended that video-assisted thoracoscopic surgery (VATS) be performed the next day. The admitting team noted the child to be "tachypneic but stable" and planned to continue administering empirical antibiotics. On rounds the next morning, the inpatient team found the child to be "restless, tachypneic, with an increasing oxygen requirement," and noted an elevated B-type Natriuretic Peptide (BNP) of 4149 pg/ml. The BNP level was sent

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by the ED resident the day prior. On an informal telephone discussion with a cardiology fellow, the team concluded that the elevated BNP could be caused by the respiratory illness itself. Due to scheduling delays in the operating room, the treating physicians decided to pursue an ultrasound-guided thoracentesis rather than wait for VATS. The interventional radiologist aspirated a clear transudate that suggested the possibility of congestive heart failure. A cardiologist was called to the bedside for a stat echocardiogram, which revealed a dilated heart with an ejection fraction of 28%. The patient was found subsequently to have a cardiomyopathy secondary to an acylcarnitine deficiency.

## What are Diagnostic Errors?

Authorities and researchers have attempted to define a diagnostic error in order to understand and further investigate this nascent field of patient safety. During the inception of the Society to Improve Diagnosis in Medicine, Graber and colleagues<sup>7</sup> operationally defined a diagnostic error as “a diagnosis that was unintentionally delayed (sufficient information was available earlier), wrong (another diagnosis was made before the correct one), or missed (no diagnosis was ever made), as judged from the eventual appreciation of more definitive information.” Schiff et al.<sup>8</sup> defined it as “any mistake or error in a diagnostic process leading to a misdiagnosis or a delayed diagnosis. This may include any failure in timely access to care; elicitation or interpretation of symptoms, signs, or laboratory results, formulation and weighing of differential diagnosis; and timely follow-up and specialty referral or evaluation.” The available literature generally suggests that a diagnostic error is considered to have occurred if the diagnosis is incorrect or does not fully address the patient's problems regardless of any occurrence of an adverse event (or patient harm).

Based on these definitions, the patient in the scenario described above experienced a diagnostic error. The diagnosis was *missed* in the ED, as heart failure was wrongly diagnosed as an empyema, and an invasive procedure (i.e., VATS) was wrongly recommended and planned. One could argue that the diagnosis was simply *delayed*, as the correct diagnosis was established subsequently, and the surgical intervention had not yet been performed. Also, whether the patient suffered the complications from this error is debatable

and raises several questions. Was the duration of the delay long enough to be considered a significant delay? Did the patient endure any undesirable harm, given that the proper therapy was not carried out sooner? Was any harm due to the disease being missed or due to unnecessary testing and treatment for the wrong diagnosis? Was the clinical problem sufficiently difficult to justify considering the error a reasonable delay rather than a diagnostic failure? These challenging questions reflect how underdeveloped the science of error measurement (and their effects) is in this field.

Another proposed definition by Newman-Toker and Pronovost<sup>4</sup> is *misdiagnosis-related harm*. This consequence is defined as preventable harm that results from delay or failure to treat a condition that is actually present (when the working diagnosis was wrong or unknown) or from treatment provided for a condition that was not actually present. Based on this concept, the emphasis is on identifying harm (a resultant product) instead of a diagnosis failure (an intermediate) or diagnostic process failure as a marker for a diagnostic error. Figure 1 illustrates the proposed conceptual framework for rigorous definitions of diagnostic error.<sup>9</sup> The critical point for determining diagnostic errors then is whether any preventable harm has occurred as a result of any failures in the diagnostic process (i.e., preventable diagnostic error in Fig. 1). Once the patient experiences undesirable consequences from the delay (e.g., complications of heart failure) or received inappropriate investigative or therapeutic measures (e.g., risks and adverse effects related to a thoracentesis), a misdiagnosis-related harm has already occurred.

An important note is that not all diagnosis failures are the results of failure in the diagnostic process; hence, not all errors are preventable. Some cases involve no-fault errors (e.g., rare or undetectable/un-diagnosable conditions). Some diagnosis failures still occur even when a proper diagnostic process is followed. A standard diagnostic process for a certain clinical problem may be suboptimal in some patients (e.g., atypical cases and uncooperative patients) or certain circumstances (e.g., early-stage disease). A diagnostic-reasoning process always requires a trade-off between sensitivity vs. specificity and safety vs. efficiency and cost. Good diagnosticians apply appropriate testing and resources efficiently to make timely and accurate diagnoses. The challenge is to establish a balanced approach to reduce diagnostic errors in these specific circumstances. Proper clinical judgment and systematic approach are needed to address this particular area, the reducible diagnostic error (Fig 1).

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