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Diagnosis Error and Diagnosis Decision Support

The year was 1999. Jason and Charlotte Maude took their 3-year-old daughter, Isabel, to the family physician for what was diagnosed as a case of the chicken pox. However, Isabel's condition quickly worsened as she developed a life-threatening complication of chicken pox called necrotizing fasciitis.

Both the family physician and the emergency room (ER) providers at the local hospital failed to recognize this complication, despite the classic clinical features. As a result, the family was reassured, and Isabel was sent home rather than being admitted and treated with antibiotics.

Forty-eight hours after her initial presentation in the ER, Isabel developed multiple organ failure. She was resuscitated, stabilized and transferred to the pediatric intensive care unit (PICU), where I was an attending physician. My colleagues and I made the correct diagnosis, but Isabel had to spend seven weeks in the PICU.

Had Isabel Maude's condition been recognized and treated on first presentation, it is highly unlikely that she would have needed intensive care. We later discovered that a journal article detailing the recognition and treatment of necrotizing fasciitis was located not far from the department where Isabel had been seen. Had this crucial piece of knowledge been immediately available to healthcare providers in the ER at the point of care, it is likely that Isabel would have been treated appropriately before her condition became life-threatening.

Instead of taking legal matters against the hospital, the Maudes and I discussed the idea of creating a system that would—for a given set of symptoms, signs and clinical features—remind clinicians of a differential diagnosis or list of likely suspects to consider. We envisioned that such a system would also provide knowledge to assist in clinical decision-making at the point of care.

At the end of 1999, after Isabel returned from the hospital, the Maudes and I started Isabel Healthcare with the objective of creating and offering a unique diagnosis decision support system (DDSS) and knowledge mobilizing system—one that would use free text or natural language and, therefore, be fast and easy for providers to apply. We set out to create a system that would decrease the incidence of diagnosis error and, ultimately, improve patient safety and quality of care through improved diagnosis decision-making.

What Is Misdiagnosis?

Misdiagnosis is a failure or delay in diagnosis. Errors can occur as a result of various single flaws within a healthcare system including a physician's lack of medical knowledge or failure to recognize patterns of disease or not considering all possible diagnoses, clinical sloppiness, lack of follow-up by a physician, failure to communicate test results, faulty data gathering and information processing, as well as failure to verify diagnosis and gather new data. Each of these flaws alone can lead to a diagnostic error that can result in inappropriate and/or inadequate treatment.

How Often Do Diagnostic Errors Occur and What Is The Impact?

A poll commissioned by the National Patient Safety foundation determined that one in six people have personally experienced a medical diagnosis error.[1] Furthermore, according to a 2005 meta-analysis, funded by the Agency for Healthcare Research and Quality and published in Advances in Patient Safety, diagnosis errors represent 10–30% of all medical error cases.[2]

Can Misdiagnosis Result in Death?

A recent study published in the Annals of Internal Medicine found that of 300 closed malpractice claims, 59% involved diagnostic errors that harmed patients and 30% resulted in death.[3] In fact, it is estimated that diagnosis errors are the cause in as many as 1 in 20 patient deaths.[4]

What Causes Diagnostic Errors?

A 2005 study published in the Archives of Internal Medicine found that cognitive error, often referred to as "premature closure," is the single most common cause of diagnosis errors.[5] Premature closure occurs when a clinician arrives at an initial diagnosis that seems to fit the facts then does not consider other reasonable possibilities.

Does Misdiagnosis Only Happen in Hospitals and Emergency Rooms?

Misdiagnosis can happen to anyone, whether in a crowded hospital or in a small family practice. However, research indicates a prevalence of misdiagnosis in the ER, where complex decision-making is paired with above-average uncertainty and stress. In fact, it is estimated that half of ER-related malpractice lawsuits involve misdiagnosis, delayed diagnosis or failure to diagnose.

How Are Diagnosis Errors Measured?

Misdiagnosis typically occurs due to cognitive error (eg, failure to consider all likely diagnoses). With the exponential increase in biomedical knowledge, it is humanly impossible for a clinician to remember the various symptoms and signs associated with all diagnostic possibilities. The breadth and depth of knowledge associated with more than 10,000 diagnoses can lead to cognitive errors and diagnostic errors that are difficult to measure. Unlike most medical errors, which are usually errors of commission, diagnosis errors are usually errors of omission and, therefore, difficult to identify. Typically, misdiagnosed cases surface through malpractice litigation, morbidity and mortality conferences, and scattered feedback from patients and physicians.

What Is The Economic Impact of Misdiagnosis?

The Institute of Medicine (IOM) estimates that $17–$29 billion is spent annually on unnecessary or inaccurate patient care as a result of misdiagnosis. If malpractice figures are added, the figure jumps significantly as was reported in 2002 by the Department of Health and Human Services. The annual report found that the average medical malpractice payment, made due to diagnosis related malpractice in the US was $307,418 per case, and 5611 diagnostic-related medical malpractice payments were made.[6]

How Can Diagnostic Errors Be Prevented?

Diagnosis reminder systems provide an effective option to prevent diagnostic errors by arming physicians with the most up-to-date and relevant clinical information. Diagnosis reminder systems decrease diagnosis errors by providing physicians with a list of likely diagnoses for a given set of signs and symptoms and the most up-to-date and relevant clinical information about the potential diagnoses. In fact, a study by the University of Virginia in December 2005 found that in 10% of cases, a diagnosis reminder system caused the user to consider a major diagnosis that had not been considered, thus, the study concluded that Web-based diagnosis reminder systems could reduce diagnostic omissions and the number of medical errors, thereby improving patient safety and quality of care.[7]

What Is the Isabel Decision Support System?

Isabel is a Web-based DDSS designed to improve the quality of diagnosis decision making at the point of care. Isabel provides an instant checklist of diagnoses for the clinician to consider. In a split second and at the point of care, Isabel addresses the question clinicians frequently ask themselves: What are the diagnoses I should be considering?

Isabel is comprised of two components: the Isabel Diagnosis Reminder System (IDRS) and the Isabel Knowledge Mobilizing System (IKMS). Given a patient's clinical features, IDRS searches through the Isabel database of more than 11,000 diagnoses and 4000 drugs and provides the clinician with a checklist of likely diagnoses and/or drugs that may be causing a patient's symptoms and signs. The IKMS provides physicians with diagnosis specific knowledge in their workflow to help answer clinical questions and improve the quality of decision-making.

How Does Isabel Work?

At the point of care, a clinician enters a patient's symptoms and clinical signs or this data is extracted from the electronic medical record. Isabel checks the symptoms and signs against its vast database to provide the clinician with a list of likely diagnoses and/or drugs that may be causing the symptoms and signs. Isabel is designed to augment and enhance a clinician's pattern recognition and cognitive skills by providing a reminder checklist of likely diagnoses that should be considered. Isabel acts as an instant reminder system and aids the diagnosis process; however, it is up to the user's clinical judgment to determine which diagnoses

to investigate and treat. Diagnosis decision-making will always remain the responsibility of the clinician who is the learned intermediary at the point of care.

Where Does the Content in the Database Come From? How Often Is the System Updated?

Isabel uses proprietary natural language processing software to search a database of widely read medical textbooks and journals for information. The Isabel database is continually updated and the quality of Isabel's results are validated each week, by a designated team of clinicians using a spectrum of clinical cases, including the New England Journal of Medicine Clinical Pathology Conference (CPC) cases. Corroborative knowledge from prestigious medical publishers Lippincott Williams and Oxford University are also included in the Isabel package and displayed to users. User group involvement ensures that Isabel is continuously enhanced in terms of software and functionality.

What Potential Benefits Does Isabel Offer Hospitals/Physicians/Patients?

The Isabel DDSS has a multitude of benefits for hospitals, physicians and patients. Most importantly, Isabel can significantly help reduce the risk of an important diagnosis being missed or delayed, thereby improving the overall quality of patient care. For hospitals and community physicians, Isabel can also be used as a teaching tool to remain up-to-date on new studies, presenting symptoms and diseases.

As a digital knowledge resource, Isabel is unique. Unlike most knowledge resources, Isabel aids the diagnosis process by analyzing a patient's symptoms and signs, constructing a list of likely diagnoses and then providing synoptic diagnosis-specific knowledge from textbooks and journals in the workflow.

By providing structure to physicians presented with complex cases Isabel can, quite literally, be a life-saver. Isabel aids the physician in identifying where to start a search and reduces the need to cross-reference symptoms from multiple sources. Physicians can then have the peace of mind that they have done due diligence and considered every option when diagnosing a patient.

Is the Isabel System Solely for Use With Complicated Medical Cases?

Isabel was not designed specifically for complicated cases; it is a valuable resource for everyday cases and can be used simply as a refresher for a physician should he/she need it. The systems enable physicians to feel confident that they have considered all possibilities. Even when presented with a so-called common case, there is always a chance it may quickly become complicated if a symptom or sign is overlooked or develops suddenly.

Has Isabel Been Validated?

A number of independent, multi-center, collaborative studies have proven Isabel's ability to reduce diagnosis error and improve patient safety and quality of care. In fact, a November 2005 study found that Isabel provided the correct diagnosis 96% of the time when key clinical features from 50 challenging Clinical Pathology Conference (CPC) cases reported in the New England Journal of Medicine were entered into the system.[2]

Does Isabel Cause Physicians to Order Unnecessary Tests?

Studies have disproved the idea that physicians spend an excessive amount of time "over-thinking" their diagnosis of patients based on the information offered. Furthermore, a recent study published in BMC Medical Informatics and Decision Making showed that no deleterious tests or treatment steps were added by clinicians following support system consultation.[8]

How Does Isabel Assist In Bioterrorism Preparedness?

In the event of a bioterrorist attack, the Isabel system includes an extensive list of bioterrorism diagnoses. This enables physicians, who may lack the necessary clinical training and experience, to distinguish bioterrorism conditions and more easily recognize and diagnose unfamiliar symptoms. Isabel addresses the knowledge gap by suggesting causative bioterrorist agents and providing up-to-date information from the Centers for Disease Control (CDC).

Does Isabel Interface with Electronic Medical Records (EMR)?

Isabel is the only DDSS that interfaces with EMRs. Data from pre-assigned fields within the EMR (age, gender, presenting/chief complaints, etc.) can be submitted to Isabel via a single click on an Isabel button in the EMR. Isabel then returns potential diagnoses. To date, Isabel interfaces with NextGen, PatientKeeper and A4 Health Systems along with a number of hospital-based EMR vendors, including Cerner, Misys, Eclipsys.

Has Isabel Been Designated for CME Credit?

Isabel has been designated for *AMA PRA Category 1 Credit™* by local accredited providers as a point-of-care learning system. Isabel has the ability to capture each individual user's session details, including queries fired, knowledge components used and impact on learning and clinical practice for collation and submission for CME accreditation.

Does the Isabel System Require Formal Training or Additional Infrastructure?

Isabel is a user-friendly, Web-based system that requires only an Internet connection.

Is Isabel Compatible With A PDA?

Isabel is formatted for use on PDA with wireless Internet connectivity. This allows physicians to access information at the bedside and across the continuum of care, from the physician's office to the hospital.

Conclusion

Clinical diagnosis errors are a serious issue for the healthcare industry accounting for 10–30% of all medical error cases. The financial cost is high, but the human cost is even greater. The implementation of clinical diagnosis decision support systems can help improve patient care, reduce costs and, most importantly, ultimately save lives.

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