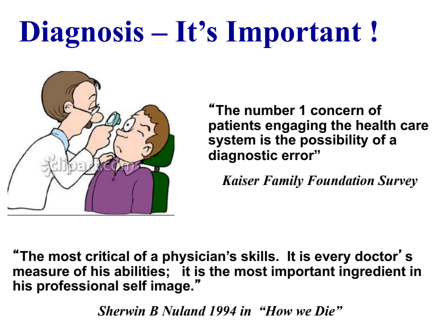
Diagnostic Error

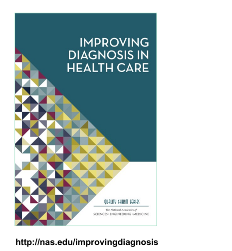
Everyone who is sick has just one goal – Returning to normal health as soon as possible. The first step, the essential step, is to make the correct diagnosis.



Clinicians in general medical settings get the diagnosis right roughly 90% of the time, which is impressive given the difficulties inherent in diagnosis. There are over 10,000 diseases, but only 500 or so are studied in medical school. There are only 200 or so symptoms, and many diseases present with the same symptoms. Diagnosis can be difficult under the best of circumstances. Inherent flaws in our healthcare systems can lead to diagnostic errors, and so can shortcomings in the diagnostic process or the clinician's clinical reasoning.

Major progress has been made over the past decade or so understanding diagnostic error. We now have a good sense of how common these errors will occur. We know why they happen, and the various causes of diagnostic error have been explored. A host of solutions have been offered, and this is exactly where the field stands today, poised to start adopting and studying these interventions in real world settings.

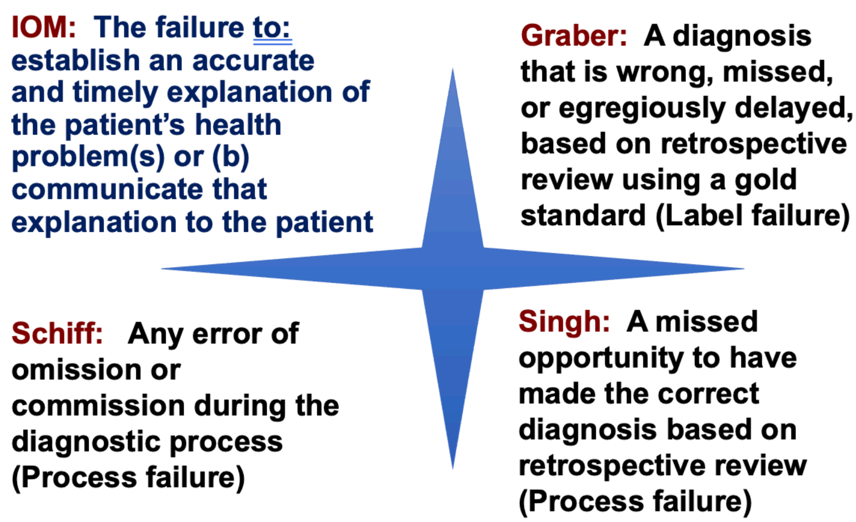
The single best source for facts about diagnostic error is the landmark, 450 page report from the National Academy of Medicine on Improving Diagnosis in Health Care, published in 2015.(1) Over 1000 papers on the topic have been published since that report, so the understanding of diagnostic error continues to evolve at a rapid clip.



Diagnostic error – What is the definition? There are several well-accepted definitions of diagnostic, and the complexity in part involves ‘diagnosis’ being both a noun and a verb: the label we attach to an illness, and the process of determining the illness. The definition created by the National Academy of Medicine incorporates both:

> ***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*

Three other definitions are in active use, capturing different aspects of the problem:



The definition of Graber focuses on the expectation that a diagnosis will be made, and that it will be correct, and timely.(2) This seems simple, but this determination can only be made in retrospect, looking back on the case. For research studies studying diagnosis in real time, the definitions of Schiff and Singh are more appropriate, which focus on breakdowns or ‘missed opportunities’ in the diagnostic process.(3, 4) Using these two definitions does not require knowing whether or not the correct diagnosis was ultimately reached; they focus just on the process itself.

How likely is diagnostic error? The risk of diagnostic error is not trivial. Different approaches all point to the reality that these errors are too frequent and cannot be ignored:

Autopsy studies: The diagnosis is wrong 10-30% of the time
Surveys: One in five patients report experience with a diagnostic error
Standardized patients: Diagnostic errors in 10-15% for classic syndromes
Chart reviews: In primary care, one in twenty patients experience a diagnostic error every year

In primary care, pediatrics, and emergency room settings, the diagnostic error rate is roughly 10%.

Diagnostic errors are less common in subspecialty practice, but there is little data on this.

In radiology and pathology, the error rate in practice is 2-4%.

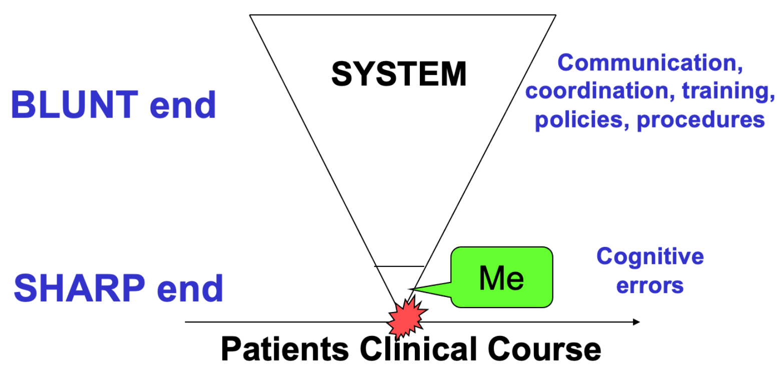
Fortunately, not every error leads to harm. In fact, the likelihood of harm after a diagnostic error is low, less than 5%. There are various reasons: The patient recovered even though the diagnosis was wrong, the error was discovered in time, or the treatment worked even though the diagnosis was wrong.

Unfortunately, given the millions of diagnoses rendered every week in this country, the aggregate amount of harm is quite large, Research studies suggest that over a half million patients will experience serious harm or death from diagnostic error in the US yearly, placing diagnostic error squarely in the 'Top 10' causes of mortality.

Diagnostic error: Why does it happen?

Diagnosis is complicated! It involves the enormous number of possible diseases, all of the variability in how they present, how they will be experienced and described by patients, and how the diagnostic process unfolds in the clinic, the ER, or the hospital.

A good approach to understand diagnostic error is to consider the 'blunt end' and the 'sharp end' of healthcare. The blunt end is the healthcare system and the diagnostic process. The sharp end focuses on the diagnostic skills of the clinician, and the cognitive processes that underlie diagnosis. Both the blunt end and the sharp end are error prone, and diagnostic errors very often involve both system and cognitive issues.



Examples of System problems:

- The 'next available' appointment is months in the future but you are sick now
- A key blood test result is delayed in being reported back to the ER
- The clinic is short-staffed; all of the appointment times are reduced to compensate
- A discharge summary fails to mention a key test that needs to be followed up
- Errors in the system aren't tracked or analyzed to improve care going forward

Examples of Cognitive errors

- The disease you have is unusual; your doctor didn't encounter it in their training
- The questions you were asked didn't include key issues that would have helped
- Something was missed on the physical exam
- The doctor settled on an incorrect diagnosis, and didn't consider other possibilities

Diagnosis is HARD!

PATIENT VARIABLES
- Stage of disease
- How it manifests
- How it is perceived
- How it is described
- When help is sought

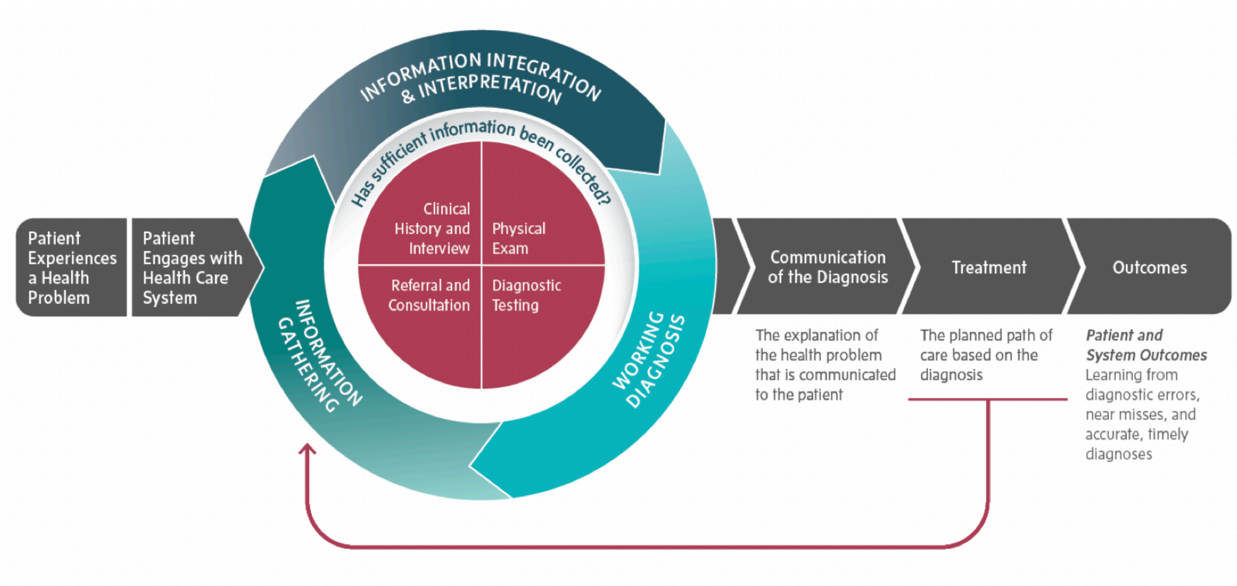
SYSTEM COMPLEXITY
- Disjointed care
- Communication barriers
- Production pressure
- Tight coupling
- Access to care & expertise

PHYSICIAN VARIABLES
- Knowledge and experience
- Access to patient data, tests, consults
- Skill in clinical reasoning
- Stress, distractions, mood, time to think

Even under the best of circumstances, diagnosis can be challenging. Every patient is different, every healthcare system has its own particular set of resources and staff, and physicians are not like pilots all trained to the same standard; they have each had different training and work experiences, and have only seen a finite set of diseases.

The Diagnostic Process

To appreciate the origins of diagnostic error, it helps to think of diagnosis as a process that plays out over time, and in various locations. The process begins when the patient seeks help and engages with a healthcare provider. The big circle represents the many steps of the clinical encounter, when the patient relates their story, the clinician asks key questions and conducts hopefully a complete physical examination, orders appropriate tests and imaging, and considers the diagnostic possibilities. The diagnosis must be communicated to the patient in simple, clear terms, along with any uncertainty. The final step involves learning from the outcome. Informing the clinician and the healthcare system whether the diagnosis was right or wrong is a critical learning opportunity that ultimately improves the process for everyone going forward.

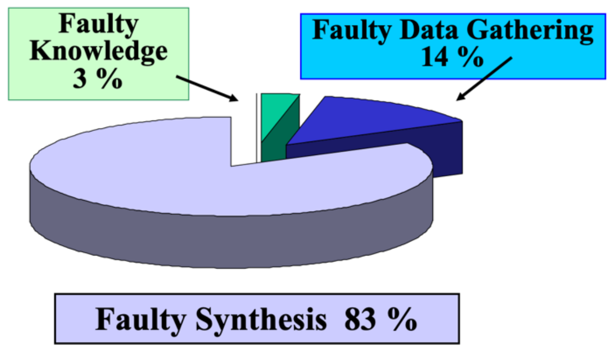


Problems can arise at any step of the diagnostic process. Problems with engagement are the #1 issues for disadvantaged patients who don't have access to, or can't afford health care. Most diagnostic errors involve some breakdown in the clinical encounter steps, and most typically these involve problems establishing the most likely diagnosis, the clinical reasoning steps.

Step of the Diagnostic Process	Example of Problems that Arise
Engagement	Delays in getting an appointment
The clinical encounter	The history is incomplete or misunderstood
	The physical exam misses a key finding
	Lab or imaging results are not available
	Cognitive errors in identifying the diagnosis
Diagnostic testing	Test results are delayed, lost, or never followed-up
Communication	The patient or another clinician assumes that a working diagnosis is correct

Clinical reasoning depends first on having an adequately broad and deep knowledge base. Secondly, all of the relevant information from the history, the physical exam, and the available diagnostic tests must be available, and interpreted appropriately. Finally, and the step most error-prone, involves the synthetic step of establishing the working diagnosis. A study of 100 diagnostic errors found that breakdowns in clinical reasoning were by far the most common type of cognitive error. Problems obtaining correct data from the patient and medical record were less common, and least common of all were cases where the clinician wasn't familiar with the disease.

The cognitive errors that clinicians make are the same ones that can befall anyone. Generally, these errors reflect breakdowns in critical thinking, and allowing some cognitive shortcut, or 'bias' to prevail. Over 150 cognitive biases have been identified, and these affect everyone, not just physicians. Some of the most commonly encountered problems are:



- **Anchoring:** Assuming that a diagnosis already suggested is correct

- **Availability:** Assuming that the correct diagnosis is the first one that comes to mind that fits all the facts

- **Premature closure**: Sticking with the first working diagnosis, without constructing a differential diagnosis and considering other possibilities

- **Blind obedience**: Assuming that the diagnosis provided by a specialist is correct without rethinking the case

- **Context errors** Choosing a diagnosis that best fits the context. Example: Assuming that a patient who is vomiting has a primary GI disorder (when it could be sepsis, drug toxicity, a CNS problem, etc)

Clinicians, like everyone, are often overly confident in their judgments and decisions. Pressure of time is an important additional factor that works against the critical thinking that characterizes best diagnostic practices. Clinicians often jump to a diagnosis too quickly, without fully considering other possibilities.

Diagnostic error: How to prevent it

Understanding why diagnostic errors occur points the way to interventions that should reduce the risk of error going forward. It will take many years to have concrete evidence that these interventions have definite impact, but given what we know now, they make sense and should be implemented now. Here's our advice:

<u>The federal government</u>   Ensure that everyone has access to quality health care, regardless of their economic status. Tens of millions of individuals in our country can't afford health care and aren't enrolled in a healthcare program.

<u>Healthcare organizations</u>   Focus on having an adequate supply of clinicians and consultants, and supporting coordinated care. Encourage specialty consultation and getting second opinions. Make sure that patients participate in cancer-screening programs, and that any abnormal test and imaging results are followed-up. A culture of learning should be the norm: Identify diagnostic errors and study each one to prevent the next one. Diagnostic errors are not a priority in all but a few healthcare organizations right now.

<u>Physicians and all clinical providers</u>   Learn more about diagnostic errors and why they occur. Be thoughtful and reflective, and always construct a differential diagnosis. Acknowledged and communicate any uncertainty about the diagnosis. Take advantage of specialty consultation, second opinions from colleagues, and use decision support and AI resources to help consider a broad range of diagnostic considerations. Make the patient your partner in diagnosis: Clearly communicate the diagnosis and any residual uncertainty, and encourage follow-up and feedback.

<u>Patients and their families</u>   Be a good historian – know your past medical history and keep records of all your tests and imaging results. Be engaged in your own care!   Ask: "What else could this be?" and make sure you get an answer; for any one set of complaints and problems, there are often many different possible causes. Make sure there is clear guidance on when to return for evaluation if your symptoms don't improve.

And…. Take advantage of cancer screenings. This is an excellent way to prevent serious problems down the road.

> ***"Improving the diagnostic process is not only possible, but it also represents a moral, professional, and public health imperative."***
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> National Academy of Medicine, 2015: Improving Diagnosis in Health Care.

How to improve health care: Achieving diagnostic excellence has always been viewed as the challenge of identifying all of the possible things that can go wrong, and fixing these. Safety experts view this as the traditional, "**Safety 1**" approach. More recently, experts in human factors and safety believe there is greater potential pursuing a '**Safety 2**" tactics that focuses on what goes *right,* not just on what goes *wrong*. In this framework, the emphasis is on building capacity and depending on resourcefulness and resiliency to meet whatever challenges get in the way of whatever challenges arise. This would first require having adequate staff resources, and clinicians who are especially well-trained, reflective, and mindful, and who have enough time to consider alternatives. It also assumes flexibility in the healthcare system and in the diagnostic process, to accommodate unexpected problems that arise.

Regardless of whether an organization prefers the Safety 1 or the Safety 2 approach, the goal is the same: Delivering on the promise of "diagnostic excellence", where diagnosis is *accurate, timely, efficient, patient-centered, and SAFE.*

1. Balogh E, Miller B, Ball J. Improving Diagnosis in Health Care. National Academy of Medicine, Washington DC 2015.
2. Graber ML, Franklin N, Gordon R. Diagnostic error in internal medicine. Arch Intern Med. 2005; 165(13):1493-9.
3. Schiff GD, Hasan O, Kim S, Abrams R, Cosby K, Lambert B, et al. Diagnostic Error in Medicine - Analysis of 583 Physician-Reported Errors. Arch Int Med. 2009; 169(20):1881-7.
4. Singh H, Giardina TD, Meyer AN, Forjuoh SN, Reis MD, Thomas EJ. Types and origins of diagnostic errors in primary care settings. JAMA Intern Med. 2013; 173(6):418-25.