

# CLINICAL **DECISION** SOLUTIONS

## Medical Misdiagnosis Causes and Solutions

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# Summary: It All Depends on the Diagnosis

**To reduce the ever-increasing costs of healthcare — improve the quality of care.**

**To improve the quality of care — reduce the rate of medical mis-diagnosis and promote the use of evidence-based treatments.**

Improving quality is fundamental to achieving better health outcomes. Simply expanding health insurance coverage in order to achieve greater access, or attempting to lower costs by cutting the prices of covered services, will not achieve the best health and lowest healthcare costs for Americans.

The Institute of Medicine, in its 2013 report, “Best Care at Lower Costs: The Path to Continuously Learning Health Care in America,” concluded that patients get effective care only about half the time, that gaps in coordination remain widespread, that serious preventable medical mis-diagnoses are common, and that perhaps more than 30 percent of healthcare costs could be avoided by improving quality. These are not new findings; for decades, studies have been using progressively better metrics to document gaps in quality, and broad variations in costs that are related to quality.

*“Each year, in the USA, there may be more than 12 million diagnostic errors<sup>1</sup> with one in three such errors causing serious patient harm.”<sup>2</sup>*

*“The aggregate annual costs to the US healthcare system could well be as high as US \$100 billion, to as much as US \$500 billion.”<sup>3</sup>*

The global problem is likely even larger.<sup>4-8</sup>

Delivery of the best medical care relies first on carefully structured communication between patient and physician, which can be aided greatly by a CDSS.\* The result must be a correct diagnosis.

Arriving at a *correct diagnosis* is, without doubt, the foundation of all good healthcare. It explains the patient’s health issue and drives all care decisions. Misdiagnoses can be incredibly harmful to patients: they may lead to delays in treatment, lack of treatment, inappropriate treatment, and death.

Improving diagnoses also makes care more affordable. Quality care results in better outcomes with fewer complications, readmissions, and other adverse outcomes. *A business plan based on “value through improved quality of care” is the right solution for patients.*

Clinical Decision Solutions™ has developed a proprietary, AI-driven CDSS that puts this within reach. It is a critical, new entry into the field and is capable of changing healthcare for the better.

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\* Clinical Decision Support System

# The Problem Now

In an attempt to quantify the problem of mis-diagnosis in medical care, in 1998, Freedman<sup>9</sup> et al. provided a “Competency Examination in Musculoskeletal Medicine” to both medical and surgical residents; graduates of 37 U.S. medical schools. The test was reviewed and validated by orthopedic chairpersons from residency programs across the United States.

- 87% of medical residents failed.
- 82% of surgical residents failed.

The medical community was astounded. The magnitude and extent of the problems were considered “quite troubling,” with reviewers noting the dilemma: 23% of primary care physician office visits and 20% of emergency room visits were for musculoskeletal conditions.

Were U.S. physicians really this poorly educated? It appeared so; medical school curricula were changed.

A 2014 report from Johns Hopkins<sup>11</sup> estimated 80,000 – 160,000 patients per year are affected by *serious misdiagnoses* such as failing to diagnose a heart attack, stroke, or cancer. Another study<sup>12</sup> estimated 40,000 – 80,000 patients per year *die secondary to medical misdiagnoses*.

Berner<sup>13</sup> described in detail that *the majority of medical diagnoses are correct, most of the time*. There are, however, “times when these cognitive processes fail, and the final diagnosis is missed or wrong.” He pointed to a study by Isabel Healthcare<sup>14</sup> finding that *36% of the 2,201 participants had experienced a medical mistake in the past five years* involving themselves, family, or friends. Half the mistakes were described as diagnostic errors. 55% of respondents subsequently listed misdiagnosis as their greatest concern when seeing a physician in the outpatient setting.

In a 2012 *Mayo Clinic Proceedings*,<sup>25</sup> autopsy results found a misdiagnosis rate of 26%. Most recently, Van Such, et al. (*Mayo Clinic* 2017) evaluated primary care patients at the Mayo Primary Care Clinic. They noted a 21% misdiagnosis rate in the U.S.<sup>24,25</sup>



*“In 12% of cases final diagnosis confirmed the diagnoses presented at referral. Final diagnoses were better defined/refined in 66% of cases; in 21% of cases final diagnoses were distinctly different — misdiagnosis.”*

—Van Such, et al. (2017)

## Causes and Scope

Some believe the routine practice of medicine can foster the pragmatic mindset that diagnostic errors are inevitable and infrequent. Graber<sup>13</sup> et al. polled physician groups:

***“...only 1% admit to having made a diagnostic error within the last year. The concept that they, personally, could err at a significant rate is inconceivable to most physicians.”***

Is this a problem of physicians’ *overconfidence* (“I know all I need to know”) or *complacency* (“nobody’s perfect”)? We must give the profession its due respect and admit that any psychological or personality-related factors may not be so simple, determinative, or pervasive as to infect the entire field.

More simply, some experts posit that *medicine has become too complex*: “It was not long ago when it was possible for physicians to keep up with the medical literature. A diligent physician who subscribed to 3–4 leading journals in the field could manage to find the time to read through the titles of each monthly issue and, typically, many of the abstracts.”

Today, in stark contrast, a new medical article appears *at least once every 26 seconds*.<sup>16,17,18</sup> A physician in 2018 would need to read 5000 articles per day in order to digest every medical journal.<sup>19,20</sup> The conclusion becomes, inevitably:

***“It is therefore impossible for any physician to have a complete coverage of the available medical literature.”<sup>16,17,21</sup>***

## Focus on Workers’ Compensation

Workers’ Compensation is the only system of medical care in which health encounters are not reasonably well scripted by health policy guidelines.

General health insurance plans set health policy statements (i.e., *treatment guidelines*) and drug formularies. These dictate the amount and conditions under which care is provided. Care is additionally limited by cost-sharing in the form of deductibles, co-pays, and coinsurance.

Workers’ compensation systems are unique:

- an insurer cannot determine its own health policy, and
- patients shoulder no portion of the cost.

Because of the Grand Bargain of 1911, employers pay 100% of “reasonable and necessary” medical care for work injuries.\* Traditionally, physicians determined the medical necessity; but the current fee-for-service model has financially incentivized them to be aggressive with patient care. This has driven up costs to employers and can be dangerous to injured workers by encouraging unnecessary surgeries and overuse of pharmaceuticals.

Improving diagnosis should not imply the adoption of overly aggressive diagnostic and treatment strategies. Diagnostic testing has brought many improvements to medical care, but advances in it have also led to challenges, including under-reliance on traditional diagnostic tools such as careful history taking and an appropriate physical exam. Regulations and utilization review processes have become commonplace.

*The end result:* many good physicians have become less willing to accept workers’ comp patients, thus compromising the quality of *available* care.

## A Silent Cost Driver

The high rates of misdiagnosis found in general healthcare translates into significant numbers of claims arriving at the insurance carriers and third-party administrators (TPA) with incorrect diagnoses. An erroneous diagnosis can be corrected, if caught, but too often will follow a claim all the way to settlement.

This wastes claims dollars and creates inefficiencies in the adjustment process, to say nothing of the real human costs of unnecessary, inappropriate, and/or overlooked treatments.

Today, claims systems apparently remain blind to this significant cost driver.

*“For decades, diagnostic errors — inaccurate or delayed diagnoses — have represented a blind spot in the delivery of quality health care. Diagnostic errors persist throughout all settings of care and continue to harm an unacceptable number of patients.” —IOM 2015*

*“The financial toll on workers’ compensation claims payers is exorbitant. ...the current level of direct losses, which nationally is about \$65 billion, might be some \$15 billion less — if major medical misdiagnoses were prevented or promptly remedied” —Best Doctors (June 2017)*

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\* The bargain, put simply, meant employees injured at work could not sue their employers and employers would pay for medical costs and lost wages.

# Without Artificial Intelligence, Error and Waste Will Continue

- Mayo Clinic 2017:  
21% misdiagnosis rate in U.S.<sup>24</sup>
- Mayo Clinic 2012:  
26% misdiagnosis rate in U.S.<sup>25</sup>
- *Journal of Emergency Medicine*:  
Misdiagnosis rates in the ICU or Emergency Room range from 20 to 40%
- *Journal of Clinical Oncology*:  
44% misdiagnosis rate<sup>22</sup>
- The problem is not new:  
In 1991, the [Harvard Medical Practice Study](#)<sup>10</sup> found misdiagnosis in 14% of cases evaluated.
- Institute of Medicine<sup>27</sup>:  
210,000 – 440,000 U.S. deaths per year from misdiagnosis  
*Journal of Patient Safety*, 2014
- Rand Corporation<sup>28</sup>:  
30% of common surgical procedures, including coronary artery bypass graft surgery, performed were not supported by clinical studies and/or evidence-based treatment guidelines and may have resulted in complications or harm to the patients.
- IOM report estimates 30% of annual healthcare spending in the United States, approximately \$750 billion, is wasted on unnecessary services and inefficiencies.<sup>21</sup>
- For 5% of the most-expensive claims, we estimate the error rate at 50%.  
*Best Doctors* 2017

*“It’s probably one of the, if not the, most under-recognized issues in patient safety... Much of the harm that we once labeled as inevitable we’re now seeing as preventable.” —IOM 2015*

**Table 1** Sampling of Diagnostic Error Rates in Specific Conditions

Study	Conditions	Findings
Shojania et al (2002) <sup>32</sup>	Pulmonary TB	Review of autopsy studies that have specifically focused on the diagnosis of pulmonary TB; ~50% of these diagnoses were not suspected antemortem
Pidenda et al (2001) <sup>33</sup>	Pulmonary embolism	Review of fatal embolism over a 5-yr period at a single institution. Of 67 patients who died of pulmonary embolism, the diagnosis was not suspected clinically in 37 (55%)
Lederle et al (1994), <sup>34</sup> von Kodolitsch et al (2000) <sup>35</sup>	Ruptured aortic aneurysm	Review of all cases at a single medical center over a 7-yr period. Of 23 cases involving abdominal aneurysms, diagnosis of ruptured aneurysm was initially missed in 14 (61%); in patients presenting with chest pain, diagnosis of dissecting aneurysm of the proximal aorta was missed in 35% of cases
Edlow (2005) <sup>36</sup> Burton et al (1998) <sup>37</sup>	Subarachnoid hemorrhage Cancer detection	Updated review of published studies on subarachnoid hemorrhage: ~30% are misdiagnosed on initial evaluation Autopsy study at a single hospital: of the 250 malignant neoplasms found at autopsy, 111 were either misdiagnosed or undiagnosed, and in 57 of the cases the cause of death was judged to be related to the cancer
Beam et al (1996) <sup>27</sup>	Breast cancer	50 accredited centers agreed to review mammograms of 79 women, 45 of whom had breast cancer; the cancer would have been missed in 21%
McGinnis et al (2002) <sup>18</sup>	Melanoma	Second review of 5,136 biopsy samples; diagnosis changed in 11% (1.1% from benign to malignant, 1.2% from malignant to benign, and 8% had a change in tumor grade)
Perlis (2005) <sup>38</sup>	Bipolar disorder	The initial diagnosis was wrong in 69% of patients with bipolar disorder and delays in establishing the correct diagnosis were common
Graff et al (2000) <sup>39</sup>	Appendicitis	Retrospective study at 12 hospitals of patients with abdominal pain and operations for appendicitis. Of 1,026 patients who had surgery, there was no appendicitis in 110 (10.5%); of 916 patients with a final diagnosis of appendicitis, the diagnosis was missed or wrong in 170 (18.6%)
Raab et al (2005) <sup>40</sup>	Cancer pathology	The frequency of errors in diagnosing cancer was measured at 4 hospitals over a 1-yr period. The error rate of pathologic diagnosis was 2%–9% for gynecology cases and 5%–12% for nongynecology cases; errors represented sampling deficiencies, preparation problems, and mistakes in histologic interpretation
Buchweitz et al (2005) <sup>41</sup>	Endometriosis	Digital videotapes of laparoscopies were shown to 108 gynecologic surgeons; the interobserver agreement regarding the number of lesions was low (18%)
Gorter et al (2002) <sup>42</sup> Bogun et al (2004) <sup>43</sup>	Psoriatic arthritis Atrial fibrillation	1 of 2 SPs with psoriatic arthritis visited 23 rheumatologists; the diagnosis was missed or wrong in 9 visits (39%) Review of automated ECG interpretations read as showing atrial fibrillation; 35% of the patients were misdiagnosed by the machine, and the error was detected by the reviewing clinician only 76% of the time
Arnon et al (2006) <sup>44</sup>	Infant botulism	Study of 129 infants in California suspected of having botulism during a 5-yr period; only 50% of the cases were suspected at the time of admission
Edelman (2002) <sup>45</sup>	Diabetes mellitus	Retrospective review of 1,426 patients with laboratory evidence of diabetes mellitus (glucose >200 mg/dL* or hemoglobin A <sub>1c</sub> >7%); there was no mention of diabetes in the medical record of 18% of patients
Russell et al (1988) <sup>46</sup>	Chest x-rays in the ED	One third of x-rays were incorrectly interpreted by the ED staff compared with the final readings by radiologists

—Berner, E. “Overconfidence as a Cause of Diagnostic Error in Medicine”  
*Amer Jour Med* vol 121 S2-S23

## RAND Study 2018<sup>27</sup> — Poor-Quality Care

“By far the most widely shared concern about current workers’ compensation systems was the view that healthcare delivery in workers’ compensation was not coordinated with the rest of the healthcare system and that the provision of poor-quality care in isolation from the rest of healthcare severely harmed workers.”

It was further noted, “Consistent with published critiques, there was widespread concern among discussion participants about the poor quality of care provided in workers’ compensation systems (Franklin, et al., 2015). As with the U.S. healthcare system more broadly, *concerns about over-treatment and low-value care coexisted with concerns about under-treatment and insufficient access to care.*”

According to the U.S. National Academy of Medicine, improving diagnosis in healthcare is now considered, “a moral, professional, and public health imperative.”<sup>22</sup>

*A sustainable, forward-looking solution requires artificial Intelligence (AI).* That technology can parse large amounts of medical data in order to provide information and analysis relevant in any given clinical context or to trigger an event based on the findings. In the CDS model, AI doesn’t replace diagnosticians, but it *can* improve their skills and present evidence-based options grounded in truly comprehensive, up-to-date knowledge.

# Quality of Care: Evidence-based Medicine

When interacting with patients, physicians often are torn between (a) the temptation to denounce fanciful, pseudo-scientific approaches to care, and (b) the desire to avoid discounting or challenging the most misguided views of some in the patient population.

They may equally be torn between (a) the desire to be efficient and knowledgeable during an exam, and (b) the need to slip off to a workstation or bookshelf to consult a reference work.

Evidence-based medicine works. It is a systematic, corroborative method of medical practice in which decision-making is supported by facts. Knowledge gained from large clinical trials is applied directly to patient care. A logical progression of steps results in the most appropriate guidelines for treatment. This approach is more authoritative than any individual physician, and it gives credence and authoritativeness to any ensuing medical decisions.

*“Only about 20% of the knowledge clinicians use today is evidence-based.”*

*—Steven Shapiro MD, Chief Medical and Scientific Officer  
University of Pittsburgh Medical Center.*

Evidence-based medicine not only prevents over-treatment and under-treatment. 2017 data shows *an association between physician age and patient mortality*. *BMJ*<sup>28</sup> concluded, “Physicians further from training are less likely to adhere to evidence-based guidelines, might use newly proved treatments less often, and might more often rely on clinical evidence that is not up to date.”



# Clinical Decision Solutions LLC

## Proprietary Software Solution

The Clinician's Assistant™ is our web browser-based solution. It is designed to reside (a) as a hosted service on the Internet, or (b) on a private server at client sites.

This is a software application, written in PHP and utilizing the CodeIgnitor developers' framework. It runs on a typical Apache web server. It employs a single MySQL database (RDBMS) for all configuration and data, allowing a high degree of application portability. This makes it easy to migrate in the event of hardware failure, provider issues, or changes to infrastructure. This also allows an offsite service to be either the primary host or a fully redundant backup to the customer's local system.

For the client side, the Clinician's Assistant™ uses the jQuery Mobile application framework to format output appropriately regardless of the web browser or device being used (such as desktop/laptop computers or mobile devices such as tablets).

## Anatomy of an Office Visit

The process is reassuringly familiar. The Clinician's Assistant™ tracks a patient visit in a way analogous to a client physically moving through the clinic:

1. intake interview
2. history of complaint
3. physical exam
4. diagnosis and/or consultation

Initially, a client is guided by a Medical Assistant (MA). At any point, clinic personnel can move to a nearby workstation or pick up a tablet computer to see the status of the client and take the next appropriate step.



## The Next Revolution in Medical Care

Clinical Decision Solutions offers a truly transformational approach that will improve the quality *and* help contain the cost of healthcare. It is poised to become *the disruptive, new face of healthcare IT*.

CDS is a primary care, interactive, clinical decision support system designed to aid in the diagnosis and treatment of most common medical conditions, globally. The software is intuitive and time-saving for physicians and other care providers. Key metrics include:

- reduced data-entry times for doctors,
- enhanced doctor-patient interactions,
- increased diagnostic accuracy, and
- commonality of treatment.

The goal of Clinical Decision Solutions is to help improve healthcare policy — initially in workers' comp and, thereafter, in all of healthcare. We're committed to helping clinicians arrive at correct initial diagnoses. We support evidence-based medicine for consistent, quality care that limits excessive or inappropriate utilization of services.

*The result:* improved diagnostic and treatment clarity for all medical clinicians.

With artificial intelligence and clinical support systems, those who benefit the most are:

- Injured workers — they are authorized to receive the highest quality medical care, expeditiously, while being shielded from unwarranted medical procedures and/or pharmaceuticals.
- Employers — they enjoy lower workers' comp premiums, and reduced absences and disability durations.
- Job seekers — a stable job environment with improved salaries is possible due to lower costs of workers' compensation settlements.

# CDS is Changing the Game

*It's only logical: to consistently reduce healthcare costs over time--- provide better care.*

That is exactly what Clinical Decision Solutions offers. All stakeholders benefit except those profiting from excessive treatment, unnecessary utilization, inflated device or pharmaceutical sales, or disability litigation.

When diseases and injuries are being diagnosed precisely, predictably effective therapies can be standardized. This leads to the next, developing healthcare domain.

## Precision Medicine

This enables doctors and researchers to predict more accurately which treatments and prevention strategies will work for a particular disease, and for which groups of people. It contrasts with our present system, which is a one-size-fits-all approach. Today, disease treatment and prevention strategies largely are still developed for an average person, with scant consideration for differences.

The CDS software from Clinical Decisions Solutions, LLC, facilitates or improves the ability to:

- evaluate interventions, preventions, and treatments in a given clinical context.
- assess the education and competence of healthcare professionals, including their initial training and ongoing education.
- assign accountability through measurable approaches that engage both patients and caregivers in improving diagnostic performance.

Simply put, yesterday's technology will not serve the needs of tomorrow. Leaders in healthcare must think of newer IT as *key to transforming clinical practice*. It can leverage medicine's unwieldy Big Data into a primary-care tool applied to individual cases and driving better outcomes for patients, employers, and insurers.

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