

The Opioid Crisis: Can Improving Diagnosis Help Solve the Problem?

By Susan Carr

Driven by increased use of opioids, the number of deaths attributed to drug overdose has grown rapidly in the United States since 19991 and climbed sharply since 2012.2 Opioid overdoses resulted in 33,091 deaths in the United States in 2015, representing 63.1% of all deaths caused by drug overdose.³ Reminiscent of Lucian Leape's vivid observation that the death toll of medical error was the equivalent of "3 jumbo-jet crashes every 2 days," 4p1851 media outlets have reported that in 2015, more people in the US died from drug overdoses than in car accidents.⁵

Harm and death caused by the use of opioids is now recognized as a public health crisis, with many groups across the country attempting to address the problem. In late 2015, the Institute for Healthcare Improvement (IHI) studied interventions related to prescription opioids and counted 33 different programs across the United States.⁶ IHI found little coordination among those programs and scant success in improving the safe use of opioids.

Diagnosis has not been examined specifically as a factor contributing to the opioid epidemic. In addition to gaining better understanding, looking at the crisis through the lens of diagnosis may

Diagnosis has not been examined also suggest new solutions. specifically as a factor contributing Background

to the opiod epidemic. Prior to the mid-1980s, because opioid drugs were known to be

addictive, prescribers typically used them to control pain only in acute circumstances, for short periods of time. Awareness grew that chronic pain was difficult to measure and often undertreated, especially in patients suffering long-term effects of cancer and degenerative conditions.⁷ As a movement to better control pain gained traction, professional organizations encouraged providers to ask patients to report pain on a numeric scale (See timeline, p2). By 2000, recording pain as an additional vital sign—along with blood pressure, temperature, pulse, and respiration—had become standard practice,6 although pain was the only vital sign for which there was no objective method for measurement. The use of prescription opioids increased as pain was acknowledged and addressed.

Also by 2000, there were indications of a growing problem with opioid abuse.8 By late 2001, evidence of diversion and abuse of one opioid in particular— OxyContin—reached a level that prompted a congressional hearing.8 In 2002, the

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COALITION TO IMPROVE DIAGNOSIS

Society of Hospital Medicine **Advances on Multiple Tracks**

When Jenna Goldstein first became aware of the Coalition to Improve Diagnosis, she knew immediately hospitalists should become involved. As director of the Center for Hospital Innovation and Improvement at the Society of Hospital Medicine (SHM), Goldstein supports physicians and hospitals working to improve the safety and quality of care. SHM had already committed itself to advancing diagnostic safety; Goldstein recognized that the Coalition offered a unique opportunity to work with other organizations on this important and challenging topic.

SHM represents more than 15,000 of the 52,000 practicing hospitalists in the United States. As physicians focused on the general medical care of inpatients, hospitalists constantly confirm and refine diagnoses.

Each year at SHM's annual meeting, a group of 30 physicians, who comprise the Quality and Patient Safety Committee, identify a limited number of topics to work on in the coming year. Anticipating the publication of the National Academy of Medicine (NAM, formerly the Institute of Medicine) report on diagnosis in the fall of 2015, the committee included diagnostic error as a priority topic for 2015-2016 and formed a subcommittee. That focus was renewed in 2016 and will be considered again this year. Mangla Gulati, MBBS, associate chief medical officer and vice president for patient safety and

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Timeline: The Opioid Crisis

- 1984 To clarify how to evaluate pain for disability claims under the Social Security Act, the US Department of Health and Human Services asks the **Institute of Medicine (IOM)** to review how pain is evaluated.⁹
- 1985 **World Health Organization** guidelines recommend the use of opioids for long-term pain related to cancer. The guidelines introduce a progressive, 3-step analgesic "ladder" of treatments: (1) Non-opioid, (2) Weak opioid, (3) Stong opioid.⁷
- 1987 The **IOM's Committee on Pain, Disability and Chronic Illness Behavior** proposes having patients self-report pain using a numerical rating scale (1–10).⁹
- 1995 In his Presidential Address to the American Pain Society, James Campbell, MD, proposes evaluating pain as the "5th vital sign."

 Consumer Assessment of Healthcare Provider and Systems survey introduced, with pain management as a key indicator of patient satisfaction.6
 - The **US Federal Drug Administration** (FDA) approves OxyContin (manufactured by Purdue Pharma), a controlled-release tablet version of the opioid oxycodone.⁸
- 2000 **Veteran's Heath Administration** publishes *Take 5. Pain: The 5th Vital Sign*, a toolkit for assessing and managing pain.¹¹
- 2001 In standards for pain assessment and treatment, the **Joint Commission on Accreditation of Healthcare Organizations** (now The Joint Commission) recommends using a numerical (1-10) scale, or a different scale if more appropriate for the patient population, consistently and on a regular basis.¹²
- 2002 The **Institute for Safe Medication Practices** warns hospitals that reliance on self-reported scales to assess pain and determine treatment may result in medication errors and harm.¹³
- 2003 **US General Accounting Office** publishes *OxyContin Abuse and Diversion and Efforts to Address the Problem.*⁸
- 2013 FDA approves labeling for Purdue Pharma's reformulated OxyContin, designed to discourage inappropriate use of the version of the drug approved in 1995. The 1995 version is withdrawn from the market due to concerns related to safety and effectiveness. FDA will not accept or approve generic versions of the 1995 OxyContin.¹⁴
- 2016 Physicians for Responsible Opioid Prescribing (PROP) petitions the Center for Medicare and Medicaid Spending to remove pain questions from the Hospital Consumer Assessment of Healthcare Providers and Systems Survey (http://www.supportprop.org/wp-content/uploads/2014/12/HCAHPS-Letter-Final-04-11-16.pdf). PROP also petitions The Joint Commission to re-examine its Pain Management Standards and treat pain as a symptom, not a vital sign (http://www.supportprop.org/wp-content/uploads/2014/12/TJC-Letter-Final-04-11-16.pdf).
- 2016 In guidelines for primary care clinicians, the **Centers for Disease Control and Prevention** emphasizes the need to address risks associated with long-term use of opioids for chronic pain (not related to cancer, palliation, or end-of-life care). 15
- 2017 **The Joint Commission** offers for public comment standards for assessing and managing acute pain, which have been revised to address the opioid epidemic.¹⁶

Institute for Safe Medication Practices warned that the trend to measure and treat pain more aggressively had led to a growing number of errors and harm, especially oversedation. ¹³ And in 2003, the US General Accounting Office (GAO) found that OxyContin had been the subject of "potentially false or misleading" advertising. ^{8(p4)}

Purdue Pharma LP promoted OxyContin, a controlled-release form of oxycodone approved by the US Federal Drug Administration (FDA) in 1995, to treat chronic pain in non-cancer patients in part by saying it was not likely to result in addiction. It turned out that the controlled-release formulation was particularly susceptible to misuse, a fact that Purdue and FDA both failed to anticipate.⁸

Pain Management and Diagnosis

Purdue marketed OxyContin heavily, and by 2001, it was the most frequently prescribed narcotic for moderate to severe pain. The GAO observed, "By 2003, nearly half of all OxyContin prescribers were primary care physicians," which raised some red flags. OxyContin was often being used as the initial treatment for pain resulting from a wide variety of conditions. It was troubling that, although they may not have had in-depth training in pain management, primary care physicians had been subjected to an unusually aggressive marketing campaign.

The problem of inadequate training in pain management is still relevant today. In 2016, it was reported that primary care practitioners prescribe more than 70% of opioid analgesics, ¹⁷ leading to questions about the degree to which physicians are treating a symptom—pain—instead of addressing the root of the pain. Gordon Schiff, MD, observes this trend regarding other medical conditions:

I think of erectile dysfunction as a prime example. We used to work up patients for underlying causes more often, before we had sildenafil (Viagra); now we just reflexively treat the symptom (written communication, March 3, 2017).

Schiff also cites examples regarding pain: treating statin-induced muscle pain with pain medication for presumed arthritis or treating back pain with pain medication without a clear diagnosis. "Treatment 'helps' since it masks the pain but can delay diagnosis by delaying the search for the underlying condition," says Schiff (written communication, March 3, 2017).

Similarly, evaluating a patient's response

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In addition to stigma and bias,

for diagnosis in these cases.

comorbidities also create a challenge

to treatment is part of the diagnostic process. Opioids are powerful at masking pain, which may defer more effective treatment—physical therapy for back pain, for example. Better understanding chronic pain and how best to diagnose and treat it would diminish the use of opioids to control pain, as well as improve care and outcomes.¹⁷

Opioid Users and Cognitive Bias

Patients who present with opioid use disorder—whether or not related to prescription medications—may experience misdiagnosis and ineffective treatment. Knowing that a patient has a history of substance abuse may interfere with a physician's ability to consider all possible causes of a medical problem and result in diagnostic error. Schiff offers a variation on the theme of cognitive bias:

Another variant is that patients are in pain and the diagnosis should be "drug withdrawal." They should be treated with opioids (unless the patient has choosen to be detoxed from opioids at this time). Here the wrong diagnosis is "bad person, drug addict, seeking drugs inappropriately." Actually, physiologically, the patient is, in the short term, in need of opiates to alleviate symptoms of withdrawal (written communication, March 3, 2017).

In addition to stigma and bias, comorbidities also create a challenge for diagnosis in these cases. People who misuse opioids may have concomitant psychiatric illnesses and are at increased risk

of hepatitis, HIV, or physical abuse—all of which are in danger of being overlooked or misdiagnosed. 18

In a relfection in JAMA's Piece of My Mind series, a medical intern describes

feeling caught among the various forces—complexity, scant training, cognitive and social biases—that make these cases so challenging:

These were the cases where I was caught between challenging patients and inconsistent supervising physicians, between the power to prescribe potent medications and learning to compassionately manage pain, and between social mores steeped in prioritizing pain treatment to one recognizing the dangers of the misuse of prescription opioid drugs. ^{19(p1701)}

He wonders if everyone else in these circumstancees feels like a trainee, too.

Fentanyl-A Further Complication

As if the problems related to opioids weren't already complicated enough, the increasing use of fentanyl adds new challenge to understanding and solving the current crisis. The CDC reports that deaths caused by synthetic opioids, which include fentanyl, increased 72% from 2014 to 2015. ^{1,20} The trend appears to have continued in 2016, and the increase is likely underreported because fentanyl is being added to heroin and other illicit drugs in ways that are hard to detect and track. ^{1,20}

In Schiff's mind, fentanyl represents another opportunity to think about making the correct etiologic diagnosis, this time related to the crisis itself. For example, if drug users die because they don't realize the heroin they've taken is laced with fentanyl, is that death due to overdose? Schiff explains:

The "cause of death" is not exactly a drug "overdose," so much as contamination of a street drug with the potent and lethal synthetic opioid. In fact, are we misdiagnosing the cause, [leading to] wrong treatment of the epidemic (patients abusing drugs thus needing to be cut off)? ... The correct diagnosis is that these are substance-dependent patients who need medical replacement (at least in short term) to avoid this risk of street drugs potentially contaminated with lethal fentanyl (written communication, March 3, 2017).

Similarly, if someone who is prepared to administer naloxone to resuscitate a drug user assumes he or she has taken heroin, not fentanyl, the dose of naloxone is likely to be inadequate. ¹⁵ More naloxone is required to counteract fentanyl than heroin; thus, diagnosing the overdose situation accurately, to the extent possible, can also be lifesaving.

Diagnosis, a Fundamental Solution

It is generally agreed that over-prescribing of opioids is at least partially to blame for the current epidemic. ^{1,21} If the science of pain were better understood and clinicians had better training and a wider variety of treatment options, the use of opioids could be constrained, with many positive effects. ¹⁷ In this way, better diagnosis should be considered a fundamental solution to the opioid crisis.

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With thanks for agreeing to be inverviewed for this article: Jenna Goldstein Mangla Gulati, MBBS Benji Mathews, MD

> Hospitalists provide a crucial link to other clinicians as patients transition in and out of the hospital.

The Coalition to Improve Diagnosis, comprised of leading healthcare organizations, has been established to bring awareness, attention, and action to the problem of diagnostic error. SIDM established and leads the Coalition. To learn more. and to view a list of the Coalition's 31 members, visit www.DxCoalition.

COALITION TO IMPROVE DIAGNOSIS

Society of Hospital Medicine Advances on Multiple Tracks

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clinical effectiveness at the University of Maryland School of Medicine, leads the Subcommittee on Diagnostic Error and is SHM's representative to the Coalition. She will become chair of the Quality

and Patient Safety Committee at SHM's annual meeting in May.

Gulati reports that closed-loop communication is one of the topics the sub-committee has emphasized. Hospitalists provide a crucial link to other clinicians as patients transition in and out of the hospital. Gulati says:

As a committee, we've talked about how to have closed-loop communication about the diagnostic errors that hospitalists discover. We would like to partner with more colleagues in outpatient and primary care. How can we communicate without blame? How can we do it so we can all learn? Post-acute care is another arena of opportunity.

SHM Commits to Improve Diagnosis

Each of the Coalition's 31 member organizations has pledged to work on collective and individual actions to improve diagnosis. In addition to working on collective efforts with the Coalition, SHM is engaged in programs for its members and will provide open access to many of the resources it develops. SHM's individual actions, which have been led by the Subcommittee on Diagnostic Error, include:

- Conduct an initial survey of SHM members to assess their level of awareness about diagnostic error and to inform future actions to advance the topic for members
- Identify key recommendations in the NAM's 2015 report, *Improving Diagnosis in Health Care*, and map them to hospitalist education, training, and practice.
- Design educational and training materials for hospitalists about diagnostic safety.
- Offer workshops and a diagnostic reasoning track at SHM's Annual Meeting, to be held in Las Vegas, May 1–3, 2017.

Benji Mathews, MD, acts as an ambassador for diagnostic safety, coordinating projects across SHM and the Society to Improve Diagnosis in Medicine, where he has been a 2016 Fellow. Mathews is section head of hospital medicine at Regions Hospital in St. Paul, Minnesota, and

director of point-of-care ultrasound for hospital medicine at HealthPartners. He is also core faculty and chair of the clinical competency committee for the internal medicine residency program at Regions. Mathews serves on SHM's Subcommittee on Diagnostic Error and Annual Meeting Planning Committee.

Mathews points out that diagnosis is central to the practice of hospital medicine:

Diagnosis is a challenging task, but it is our daily procedure. For hospitalists, it is imperative to work on getting better at our most important procedure.

Like Gulati, Mathews sees a natural role for hospitalists in "iterative feedback loops" about diagnostic errors and he observes that hospitalists often work with physicians in training:

Many hospitalists work with trainees. This is a pertinent area to model diagnostic reasoning and humility. We can encourage error awareness, disclosure, and peer support for the second victim.

He agrees that working with the Coalition is a valuable opportunity, especially given that improving diagnosis requires collaboration across healthcare and a "widespread commitment to change."

Diagnostic Reasoning at SHM2017

Mathews has worked with Gulati and others to develop a extensive educational track on diagnostic reasoning for SHM's annual meeting in May. Days 1 and 3 of the meeting feature workshops. Day 2 offers a track of breakout sessions taught by Gurpreet Dhaliwal, Andrew Olson, Robert El-Kareh, Mark L. Graber, Bob Trowbridge, Daniel Brotman, Alberto Puig, as well as Mathews and Gulati.

The program includes two "Stump the Professor" sessions and concludes with "Medical Chopped," an interactive session based on the Food Network's popular *Chopped* series. In *Chopped*, master chefs are given a limited number of ingredients—some routine, some unusual—all of which they must use to arrive at an appetizer, entrée, and dessert. Follow up discussion focuses on each contestant's thought process as he or she worked toward a solution to the challenge.

Computers and Deep Learning

neural network, the faster and more agile it becomes.

Mukherjee S. The algorithm will see you now [Annals of Medicine]. *The New Yorker*. April 3, 2017:46-53.

(The same article appears under the title "AI versus MD" in some online editions.)

For years, members of the the Society to Improve Diagnosis in Medicine have been debating the proper relationship between articifial intelligence and the diagnostic reasoning of physicians. In *The New Yorker*, Siddhartha Mukherjee considers that question and goes beyond to learn how computers learn.

Mukherjee talks with computer scientist Sebastian Thrun, who develops neural networks in computer processing that result in

develops neural networks in computer processing that result in "deep learning." Deep learning allows a computer to learn from experience and grow smarter as it looks at cases, comparing what it sees not to a set of static rules but to what it has already seen and earlier outcomes. Accomplishing what seniors hope for as they do crossword puzzles, the more the computer exercises its

With this discovery, Murherjee returns to the exam room and finds qualities in human medical practice that seem safe from obsolescence. He shadows a dermatologist through a days' worth of patients in a busy office practice. When the physician says she would welcome diagnostic *assistance* from a computer, she keeps the machine in its place. Indeed, even a computer with deep learning would not be able to duplicate the effect the dermatologist's presence has on patients. A patient with history of melanoma comes in for a check up. After 20 minutes of careful, tactile attention and reassurance from the physician, the patient is visibly relieved. Mukherjee notes, "The woman who'd had the skin exam left looking fresh and unburdened, her anxiety exfoliated." (p52)

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Reflecting on his own experience as a physician and researcher, Mukherjee notes that knowing *why* symptoms and conditions occur is part of the diagnostic process. Curiosity is crucial to learning and understanding, for humans at least. It is hard to imagine how computers would be able to assume that role, but having read Mukherjee's article, it's hard to have 100% confidence in that assumption.

The more the computer

the faster and more

agile it becomes.

exercises its neural network,

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