

## Policy and Educational Brief



An Important View On

# **PAIN AS A 5TH VITAL SIGN**

## An Important View on Pain as a 5th Vital Sign

For two decades, much has been made of Pain as the 5th Vital Sign, a policy strategy to improve pain care initiated in the mid-1990s. “Calor, dolor, rubor and tumor,” i.e., heat, pain, redness and swelling, however, have been recognized as classical signs of a serious health problem since the 1st century.

Acceptance of Pain as the 5th Vital Sign by the American Pain Society, the Department of Veterans Affairs, The Joint Commission (TJC) and others resulted in a flurry of optimistic dialogue among advocates for improved pain care. The recent brouhaha about Pain as the 5th Vital Sign presents a negative image of this earlier discourse and stems from efforts by those who believe that it has caused or significantly contributed to the current opioid “epidemic.”<sup>1</sup>

### History

Let us review the facts about their efforts to institutionalize Pain as the 5th Vital Sign. In 1996, the American Pain Society<sup>2</sup> adopted the phrase “Pain as the 5th Vital Sign” in an initiative that stressed the equal importance of pain assessment along with the standard four vital signs. Soon thereafter, the Department of Veterans Affairs recognized the importance of such an approach and included Pain as the 5th Vital Sign in their national pain management strategy. “The Pain as a 5th Vital Sign” strategy quickly became conjoined with pain assessment and treatment standards introduced by The Joint Commission (TJC) in 2001.

#### **The Joint Commission’s standards<sup>3</sup> on pain management, as stated, are:**

*Our foundational standards are quite simple. They are:*

- *The hospital educates all licensed independent practitioners on assessing and managing pain.*
- *The hospital respects the patient’s right to pain management.*
- *The hospital assesses and manages the patient’s pain.*

#### **Requirements for what should be addressed in organizations’ policies include:**

- 1) *The hospital conducts a comprehensive pain assessment that is consistent with its scope of care, treatment, and services and the patient’s condition.*
- 2) *The hospital uses methods to assess pain that are consistent with the patient’s age, condition, and ability to understand.*
- 3) *The hospital reassesses and responds to the patient’s pain, based on its reassessment criteria.*
- 4) *The hospital either treats the patient’s pain or refers the patient for treatment. Note: Treatment strategies for pain may include pharmacologic and non-pharmacologic approaches. Strategies should reflect a patient-centered approach and consider the patient’s current presentation, the health care providers’ clinical judgment, and the risks and benefits associated with the strategies, including potential risk of dependency, addiction, and abuse.*

*PAINS is grateful to the authors of this article and believes that the views expressed by them are important. However, the views and opinions expressed are those of the authors and do not necessarily reflect the official policy or position of PAINS or any other organization associated with PAINS.*

It is important to note that there is no mention whatsoever of the word “opioids” in these standards. Additionally, the standards state “treatment strategies for pain may include pharmacologic and non-pharmacologic approaches.” The standards require “comprehensive pain assessment,” i.e., asking a patient about his or her pain score should be an aspect of, but should not be solely, the assessment. To put things in perspective, let us look at the clinical assessment/pain scoring tool PPQRSTA: Precipitating factor, Palliative factor, Quality, Radiation, Site, Severity, Temporal factor, and Associated symptoms, whereby pain represents one part of the overall picture. There are different pain etiologies such as neuropathic and inflammatory pain, which respond to different treatments. It is important to assess the underlying pain etiology/ cause to select the appropriate treatment. Unfortunately, in conjunction with embracing Pain as the 5th Vital Sign, many hospitals established standardized protocols with different doses and formulations of pharmacological therapies based on narrowly focused pain scores alone. The problem with which healthcare providers and institutions are struggling is with implementation of the standards – NOT the standards themselves.

## Kindness Kills

Attacks on the concept of pain as the fifth vital sign began as early as 2007 in a paper titled “Kindness kills: the negative impact of pain as the 5th vital sign.”<sup>4</sup> In a “position paper” authored by a single neurologist that was subsequently adopted as a guideline by the American Academy of Neurology, the author unilaterally argued that pain advocacy groups and clusters of pain specialists had successfully lobbied the Joint Commission on Accreditation of Healthcare Organizations to institute screening for Pain as the 5th Vital Sign, with a not particularly subtle suggestion of ethical wrongdoing by these groups.<sup>5</sup> Numerous others have subsequently assigned blame to this institution for the institution of screening, which they have identified as the root cause of the American opioid epidemic.<sup>6,7,8,9</sup>

One consequence of the misrepresentation of the Joint Commission standards is that, during its annual meeting in June 2016, the American Medical Association (AMA) publicly recommended that pain be removed from the vital

signs panel. AMA delegates passed a resolution urging the Joint Commission to stop requiring Pain as the 5th Vital Sign in hospitals they accredit and to encourage the Department of Health and Human Services to remove pain assessment scores from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, which is tied to reimbursement. The reason given for this was that physicians and healthcare providing institutions felt pressured to prescribe opioids which, as stated before, is NOT part of the Joint Commission’s standards.

Unfortunately, in conjunction with embracing Pain as the 5th Vital Sign, many hospitals established standardized protocols with different doses and formulations of pharmacological therapies based on narrowly focused pain scores alone. The problem with which healthcare providers and institutions are struggling is with implementation of the standards – NOT the standards themselves.

In response to all of this, the Joint Commission issued the following statement.<sup>10</sup>

### **Misconception #1: The Joint Commission endorses pain as a vital sign.**

*The Joint Commission does not endorse pain as a vital sign, and this is not part of our standards. Starting in 1990, pain experts started calling for pain to be “made visible.” Some organizations implemented programs to try to achieve this by making pain a vital sign. The original 2001 Joint Commission standards did not state that pain needed to be treated like a vital sign. The only time that The Joint Commission standards referenced the 5th vital sign was when The Joint Commission provided examples of what some organizations were doing to assess patient pain. In 2002, The Joint Commission addressed the problems in the use of the 5th vital sign concept by describing the unintended consequences of this approach to pain management and described how organizations had subsequently modified their processes.*

### **Misconception #2: The Joint Commission requires pain assessment for all patients.**

*The original pain standards stated “Pain is assessed in all patients.” This was applicable to all accreditation programs (i.e., Hospital, Nursing Care Center, Behavioral Health Care, etc.). This requirement was eliminated in 2009 from all programs except Behavioral Health Care Accreditation. Patients in behavioral health care settings were thought to be less able to bring up the fact that they were in pain and, therefore, required a more aggressive approach. The current Behavioral Health Care Accreditation standard says, “The organization screens all patients for physical pain.”*

*The current version of the standard for hospitals and programs other than Behavioral Health says, “The hospital assesses and manages the patient’s pain.” This standard allows organizations to set their own policies regarding which patients should have pain assessed based on the population served and the services delivered. Joint Commission surveyors determine whether such policies have been established and whether there is evidence that the organization’s own policies are followed. Some organizations may still follow the old standard and require pain assessment of all patients.*

### **Misconception #3: The Joint Commission requires that pain be treated until the pain score reaches zero.**

*There are several variations of this misconception, including that The Joint Commission requires that patients are treated by an algorithm according to their pain score. In fact, throughout our history we have advocated for an individualized patient-centric approach that does not require zero pain. The introduction to the “Care of Patients Functional Chapter” in 2001 started by saying that the goal of care is “to provide individualized care in settings responsive to specific patient needs.”*

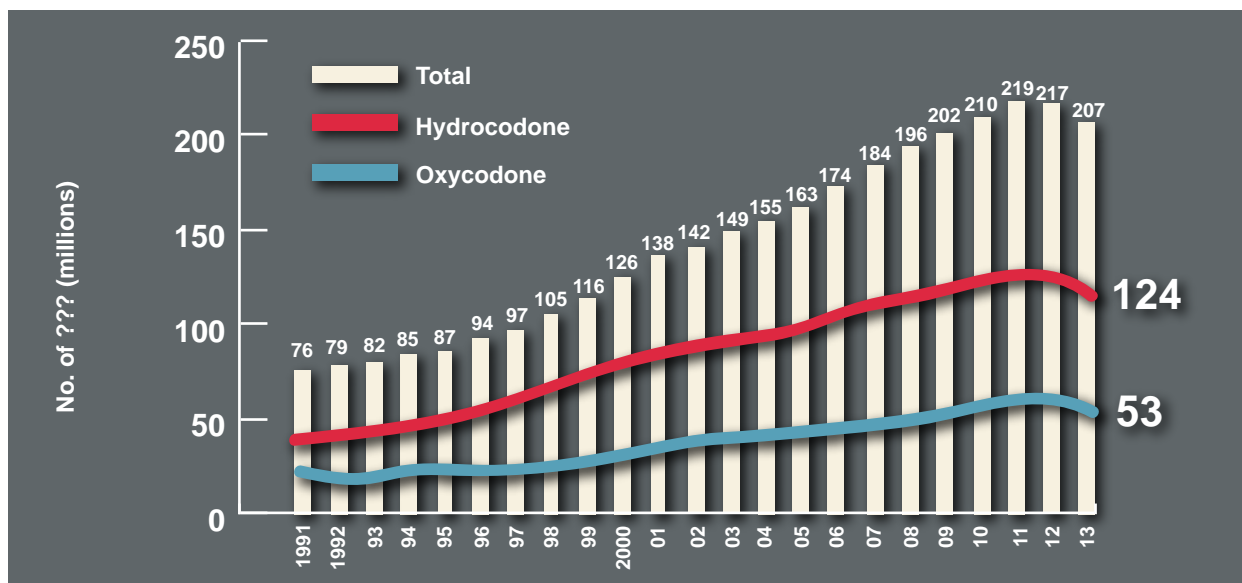
### **Misconception #4: The Joint Commission standards push doctors to prescribe opioids.**

*As stated above, the current standards do not push clinicians to prescribe opioids. We do not mention opioids at all. The note to the standard says: Treatment strategies for pain may include pharmacologic and non-pharmacologic approaches. Strategies should reflect a patient-centered approach and consider the patient’s current presentation, the health care providers’ clinical judgment, and the risks and benefits associated with the strategies, including potential risk of dependency, addiction, and abuse.*

As stated earlier, the inclusion of pain management in The Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey was included in the AMA resolution and has also come under attack from others, with accusations that the survey prevents providers from “prescribing freely.” The HCAHPS survey includes three questions to assess pain management as follows:<sup>11</sup>

- During this hospital stay, did you, the patient, need medicine for pain?
- During this hospital stay, how often was your pain well controlled?
- During this hospital stay, how often did the hospital staff do everything they could to help you with your pain?

With accusations that the above questions included on the HCAHPS survey resulted in an increase in opioid prescribing, it is important to note that opioid prescribing was already on the rise well before Centers for Medicare & Medicaid Services (CMS) initiated HCAHPS in 2006 (Figure 1)<sup>12</sup> and even before TJC standards.



**Figure 1.** Volkow ND. America’s Addiction to Opioids: Heroin and Prescription Drug Abuse. Presented at: Senate Caucus on International Narcotics Control. 14 May 2014. Available: <https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse>.

In May of 2016, CMS released a position paper in JAMA entitled “Measurement of the Patient Experience Clarifying Facts, Myths and Approaches.”<sup>13</sup> The article discussed the formula for Hospital Value Based Purchasing (HVBP) during fiscal year 2015, at which time the Patient Experience of Care domain accounted for 30% of the HVBP total performance score, which in turn affects 1.5% of CMS payment to hospitals. The pain management questions on the HCAHPS survey comprises 1 of 8 equally weighted dimensions of the Patient Experience of Care domain, with each individual dimension contributing approximately 3.75% to the total HCAHPS score. As a result, each of the 8 dimensions only had 0.056% effect on payment. Furthermore, CMS reported that “no single HCAHPS dimension has a disproportionate financial

impact.”<sup>14</sup> The authors went on to directly address opioid prescribing and stated, “...there is no empirical evidence that failing to prescribe opioids lowers a hospital’s HCAHPS scores.”<sup>15</sup> Unfortunately, despite this position statement, CMS has ruled that beginning in fiscal year 2018, scores from the pain management component of HCAHPS will no longer be included in the formula for HVBP.<sup>16</sup> The questions pertaining to pain management will still be included in the survey and reported publicly. The ruling was posted and available for comment through December 31, 2016. The AMA and others have lobbied extensively for this change, even though at no point does CMS nor the HCAHPS survey recommend the use of opioids for pain.<sup>17</sup>

## Patient-Centered Care

All of this is a universe away from “patient-centered” care. In this case, one should not blame positioning Pain as a 5th Vital Sign, but instead focus attention on the health care system at large.

Pain scores are useful when monitoring treatment response, and rejecting them eliminates one standardized method for assessing treatment response.

It is imperative to quality care to monitor pain patterns and fluctuations. Doing so helps identify acute or acute onset of chronic conditions such as stress fractures, spinal infection, fungal meningitis, or brain tumor. The TJC does not say, “Ask people if they have pain. If they do, give them opioids until their pain level is < 4.” Yet, that has become common practice in many institutions.

The appropriate response to excessive and inappropriate antibiotic use would not be to throw away all the thermometers so we can’t detect a fever. Instead, we found antibiotic stewardship programs to be effective. Disregarding pain will not magically eliminate it, nor lessen the expectation that pain should be eradicated, nor combat opioid misuse or abuse. Doing so simply conceals an issue associated with opioid overprescribing and minimizes the assessment and management of pain. Rather than eliminating pain assessment by claiming that it sets false expectations for pain management, prescribers should counsel patients prior to initiating any analgesic and establish realistic expectations.

In numerous clinical trials, clinically meaningful pain relief was defined as a 30% reduction in pain scores from baseline.<sup>18,19</sup> Unfortunately, this conversation does not frequently take place with patients. HCAHPS results from October 2014 to September 2015 surveys reveal a national average of 65% of patients reported receiving communication about medications.<sup>20</sup> Rather than eliminating pain assessment and blindly claiming it increases opioid misuse and abuse, prescribers should

talk with patients to establish meaningful functional goals of care and screen them for aberrant drug-related behavior prior to initiation of opioids in patients for whom they are indicated and prior to hospital discharge. There are various validated risk assessment tools for opioid misuse/abuse available, including the Opioid Risk Tool (ORT), the Screener and Opioid Assessment for Patients with Pain (SOAPP), and the Current Opioid Misuse Measure (COMM).<sup>21,22,23</sup>

If prescribers are appropriately educated and have access to non-opioid modalities, designating pain as the 5th vital sign and supporting the need for pain assessment should not result in inappropriate opioid prescribing. To attribute a phenomenon as complex and multi-causal as the opioid crisis to the recognition of Pain as the 5th Vital Sign, at best, ignores “a multitude of other factors” responsible for the opioid epidemic, including the lifting of prescribing regulations by state medical boards, the understanding of patients’ rights to adequate analgesia resulting in validation of physicians’ altered opioid-prescribing patterns, and patients seeking more frequent and stronger opioids.<sup>24</sup> A review of the literature indicates myriad other causes of the opioid crisis, including inadequate physician education, off-label prescription of certain opioids, a lack of access to pain management specialists, the American insurance industry’s willingness to cover the least expensive non-abuse deterrent opioid analgesics while refusing to pay for holistic, patient-centered interdisciplinary treatment, the proliferation of “pill mills,” the perception that prescription opioids are “safe” – even for recreational use, reservations regarding the safety of alternative therapies such as nonsteroidal anti-inflammatory drugs (NSAIDs), the FDA’s shortsightedness in removing standard NSAID warnings from topical NSAID products, the propagation of the term “pseudo-addiction,” and aggressive/fraudulent marketing by certain opioid manufacturers.<sup>25,26</sup>

Recently, advocates in pain and addiction medicine intent upon dramatically reducing the use of opioids for pain care, e.g., Fed Up, Physicians for Responsible Opioid Prescribing, Shatterproof, and Community Anti-Drug Coalitions, have worked hard to shape policy that will affect clinical practice, specifically opioid prescribing practice.

What many believe to be extreme measures have been promulgated by these groups in an effort to “fix” what has been labeled by the Centers for Disease Control as the opioid “epidemic” by convincing physicians, legislatures, medical boards, insurers, and the media that opioids have no benefit in chronic pain medicine. Not surprisingly, an attack on the Pain as the 5th Vital Sign has been one tactic these groups have employed. Both the AMA resolution and the CMS decision align with the policies lobbied previously by Physicians for Responsible Opioid Prescribing (PROP), one of the most prominent anti-opioid advocacy groups. The current situation is complicated by the fact that at an AMA House of Delegates meeting held three years earlier (2013), a barrier was erected by AMA that threatened to prevent important collaboration of opioid checks and balances between prescribers and pharmacists. At the meeting, Dr. Melvyn Sterling, an alternate delegate from the California Medical Association, sent a message to pharmacists: “Don’t call us, we’ll call you!” Although Dr. Sterling was speaking for himself, not the AMA, his message was widely reported and had a chilling effect on important professional relationships.

It is not surprising that these advocates have proposed an overly-simplistic explanation that Pain as the 5th Vital Sign is the root cause of the United States’ opioid crisis. In their efforts to “solve” the crisis, in collaboration with the Centers for Disease Control (CDC), they have simplistically put forth prescribing guidelines that are arbitrary, biased, and based on the weakest form of levels 3 and 4 evidence. Although they are not empirically evidence-based, it is nevertheless suggested that they are grounded on quality data.<sup>27, 28</sup> Many fear that politicism has trumped rational science and superseded the National Guideline Clearinghouse standards which state a “level A rating requires at least two consistent Class I studies.”<sup>29</sup> All 12 of the recent CDC recommended guidelines are based on case series (level 3 evidence) or expert opinion (level 4 evidence), yet assigned the highest grade A recommendation.

In attributing the acceptance of Pain as the 5th Vital Sign as a primary cause of the American opioid crisis, advocates in pain and addiction medicine intent upon dramatically reducing the use of opioids for pain care created a straw man upon which they have relied to further an agenda-based rather than an evidence-based policy platform. Authors of this article believe that for those who strive for a sagacious, moderate, and pro-patient approach to opioid therapeutics and safety must illuminate the current situation and thereby, hopefully, allow and encourage health care providers to continue to assess patients’ pain AS IF it was a vital sign.

## Disclosures

Drs. Fudin, Wegrzyn, and Raouf acknowledge that their involvement with this article was not part of their official government duties.

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For an annotated bibliography of a sample of additional articles focused around pain in 2016, go to [painsproject.org](http://painsproject.org).

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