

# The Social, Professional, and Legal Framework for the Problem of Pain Management in Emergency Medicine

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## Context and Challenges in the Emergency Department

The problem of harmful, unnecessary and neglected pain has been studied extensively in many health care settings over the past decade. Research has documented the incidence of untreated pain, and scholars and advocates have given the problem several names: "public health crisis,"<sup>1</sup> "oligoanalgesia,"<sup>2</sup> and "moral failing,"<sup>3</sup> among them. Articles have identified a litany of now familiar "obstacles" or "barriers" to effective pain relief.<sup>4</sup> Each of these individual obstacles or barriers has been the subject of targeted remedial action in at least some context.

The checklist approach to improving care for patients in pain, however, is likely to have only limited effect. What really appears to be operating is a complex ecosystem that supports ambivalence, denial, and even suspicion of the circumstance of patients in pain and efforts to treat them. Pain relief in emergency medicine, a relatively new setting for the study of challenges to treating pain, provides a revealing context for viewing discrete obstacles to effective pain management in medicine as part of an integrated environment into which patients with pain enter for treatment.

It is pain that drives most patients to seek care in an emergency department.<sup>5</sup> In the majority of patients, the pain that drives them is quite severe, rating an 8 of 10 on commonly used pain scales.<sup>6</sup> Emergency medicine, however, does not focus on the management and relief of pain. Pain is most commonly, and necessarily, viewed as a symptom that guides the physician to a diagnosis of an underlying pathology. It is only when pain is viewed merely as a symptom, rather than a pathology itself, that there is a problem.

The model of pain as *merely* a symptom does not serve a good number of patients coming to the ED with pain. In fact, a significant proportion of emergency patients suffer serious and debilitating chronic pain;<sup>7</sup> and approximately 11% of patients seeking treatment in the ED do so for pain related to chronic conditions.<sup>8</sup> For persons with chronic diseases associated with acute episodes of pain, including sickle cell and migraines for example, the sole purpose for the visit is pain relief. Although active diagnostic efforts may still be necessary to rule out other conditions that may be causing this particular pain episode, the treatment of the pain itself is obviously the primary objective of emergency treatment in those cases.

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Even with the need to focus on diagnosis and treatment of the condition causing the pain, however, pain management and pain relief should be a priority in emergency medicine. The ethical duty to relieve pain is well established. Although there may be ethical and medical concerns about particular pain management interventions in particular circumstances, the core ethical obligation to relieve pain is well established in medicine, including in emergency medicine. The Code of Ethics of the American College of Emergency Physicians, for example, formally recognizes an obligation to relieve pain as a part of emergency treatment.<sup>9</sup> Relieving pain and suffering has been called a “fundamental imperative for any clinician”; and, in regard to emergency medicine: “as a guiding principle of medicine and core covenant with our patients, every EP [emergency physician] must embrace providing timely and effective pain control as a fundamental duty.”<sup>10</sup> Other

equate analgesia was not provided in the first instance.<sup>16</sup>

Despite the clarity of the ethical principles and the documented outcomes of untreated pain, research on the treatment of pain in emergency medicine has revealed a pattern of inadequacy. In 1989, Wilson and Pendleton applied the term “oligoanalgesia” to the neglect of pain in the ED and documented that 56% of patients in the ED presenting with pain received no analgesia; furthermore, when narcotic analgesics were provided, they were provided in doses too low to be effective.<sup>17</sup> In particular, there is evidence of disparities in the treatment of patients for pain in the emergency department based on race and ethnicity.<sup>18</sup> This evidence mirrors racial disparities in the assessment and treatment of pain in medicine generally.<sup>19</sup> Similarly, studies have demonstrated that children receiving treatment in the ED are much less likely to receive pain medication for clearly painful conditions as compared to adults

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emergency physicians have observed that “[o]pportunities to save lives within the ED are rare, but opportunities to relieve pain are nearly infinite....”<sup>11</sup> These statements represent specific application of more general ethical norms to the particular context of emergency medicine.<sup>12</sup>

In addition to ethical norms that support serious attention to pain management generally, there are pragmatic reasons, specific to emergency medicine, that support an emphasis on pain relief as a priority. One might mistakenly view pain associated with an emergency condition as a temporary, though serious and intense, experience. Studies on the relationship between chronic pain and acute pain episodes, however, indicate that an experience of unrelieved, acute pain can make a person vulnerable to a pattern of chronic pain<sup>13</sup> or to a repeat pain episode.<sup>14</sup> Studies have also indicated that managing pain post-surgically promotes recovery, while persons with untreated pain are more likely to experience complications after medical treatment.<sup>15</sup> It seems reasonable to extend these findings to untreated pain caused by trauma or non-surgical but painful medical procedures as well. Finally, one might speculate that a patient’s experience with painful procedures could lead that person to delay or avoid necessary medical diagnosis and treatment of a later episode or a new symptom. In fact, there is some evidence that a procedure may be more painful the next time it is employed if ad-

presenting with the same conditions.<sup>20</sup> As in the case of racial disparities, the evidence of neglect of treatment for pain in children in the ED parallels identified problems in the care of children in other health care settings.<sup>21</sup> Because approximately one-third of ED visits involve treatment of children, this has been a significant concern, addressed aggressively in some hospitals.<sup>22</sup>

Empirical research on the reasons for the neglect of pain in the emergency department is quite thin. The pace of publication on issues of pain management in the ED increased significantly between 1996 and 2003,<sup>23</sup> however, and appears to have continued an exponential growth since that time, indicating a promise of more research to come.

Despite the increase in attention, the problem of undertreatment of pain in the ED persists. As in other areas of medical practice, institutional initiatives in emergency medicine, including educational interventions and the establishment of departmental protocols to improve the treatment of pain in EDs, although sometimes successful, have very often produced disappointing results.<sup>24</sup> Similarly, clinical guidelines on pain management standing alone have not been proven effective in changing physician practices.<sup>25</sup>

The lack of strong success in these efforts may be attributed to the design or implementation of the specific intervention. For example, Ducharme, in his article in this symposium, notes that practice guidelines are more

effective when there is personalized follow-up and mentoring with physicians in their own practice. The pattern of disappointing results in some of these remedies to identified barriers (for example, clinical guidelines responding to deficiencies in knowledge base), however, may reveal instead that the reasons and root causes of undertreatment of pain in the ED are still not well understood.

There is a more substantial literature on barriers to effective pain management in other areas of medical practice.<sup>26</sup> The obstacles identified generally in medical practice include financial restrictions, educational deficiencies, cultural challenges, and legal and regulatory concerns, among others. It is likely that some of the reasons for undertreatment of pain in the ED are the same as those for medical practice generally. For example, some observers and practitioners have identified deficiencies in the educational programs that prepare emergency physicians.<sup>27</sup>

Further, while financial issues, including payment and reimbursement for care, have been identified as significant barriers for pain patients outside of the hospital setting,<sup>28</sup> the emergency department faces different financial issues. For emergency medicine, financial constraints are often expressed in terms of capacity relating to patient load and crowding.<sup>29</sup> One might expect that the volume of demands on the ED negatively impact attention to pain management. At least one study, however, has indicated that staff-patient ratio (weighted by acuity of the patients' conditions) did not affect the proportion of patients who received pain medication.<sup>30</sup>

As in other settings, institutional structure and procedures may also form barriers to effective pain relief in the ED. For example, ED procedures, typically requiring at least seven steps ("patient presentation and registration, nursing assessment and triage, placement in a treatment room, primary nurse assessment and documentation, physician evaluation, physician ordering of pain medication, nursing obtaining pain medication, and finally... nursing administration of pain medication") before the patient can receive any pain medication, create a formidable barrier to timely treatment and the avoidance of unnecessary suffering.<sup>31</sup> Several studies have documented lengthy delays in the first administration of pain medication to ED patients suffering serious trauma,<sup>32</sup> and studies of patient's expectations indicate that these delays are probably a source of significant concern to patients.<sup>33</sup> Pre-hospital emergency medical services have also been identified as a target for improvement of pain relief for the emergent patient.<sup>34</sup>

The practice of emergency medicine is quite different from other areas of practice, however, and some of the

reasons for neglect of pain may also be distinctive. Because there is little empirical research on obstacles to effective pain management in the ED, most of the reasons given for the phenomenon in emergency medicine emerge from intuition and experience or are extrapolated from the few studies that exist. Further research is certainly required, but some preliminary conclusions are possible.

Distinctive reasons for undertreatment of pain in emergency departments include the prioritization of diagnosis over pain relief; inadequacies in the process of pain assessment; and a culture that supports significant detachment from patients. Recent literature has identified legal risks as an additional cause of concern for emergency physicians.<sup>35</sup> Areas of liability risk, including litigation over recklessness in the neglect of treatment for pain, spotlight systemic issues that impact the quality of treatment for pain in the ED. These include discontinuity of care, especially relating to arranging for the treatment of pain upon discharge as well as inadequate pain management by providers outside the ED; challenges of palliative care in the ED; limitations on the scope of practice of emergency health care professionals that affect the timeliness of pain management interventions; and issues around informed consent. In addition, no discussion of emergency departments would be complete with consideration of the application of the federal Emergency Medical Treatment and Labor Act (EMTALA) to the question of treatment for pain. Finally, even though emergency physicians work in a different legal environment than does the doctor in an office-based practice, they may share some concern over the risk of regulatory action for the prescription of controlled substances.<sup>36</sup>

#### *Subordination of Pain Relief to Diagnosis*

The subordination of pain relief to diagnosis in emergency medicine is likely to be one reason that interventions to relieve pain are delayed or denied in the emergency department. The emergency physician's priority is diagnosis.<sup>37</sup> Patients share this priority for diagnosis and treatment, and some evidence indicates that patients thus may simply expect to experience suffering in the emergency department resulting in lower patient demands for analgesia.<sup>38</sup> Other studies, however, indicate that patients have substantial expectations for pain relief in the ED.<sup>39</sup>

Treatment that addresses only the symptoms of pain and neglects the underlying cause is recognized as substandard emergency care.<sup>40</sup> Because both the patients and the physicians in the context of an emergency desire accurate diagnosis above all, and because emergency medicine is held to a medicolegal standard that holds them accountable for negligence in diagnosis, it

is important to address the pain-diagnosis connection as an empirical question. There has been a strong belief in emergency medicine that analgesia may impede diagnosis, and that belief has impeded pain management in the ED. Where evidence can be produced to reject the hypothesis that interventions to relieve pain hamper diagnosis, the practice of withholding analgesia in favor of diagnosis should be expected to change. In such situations, one would not need to argue whether pain relief was worth a reduction in diagnostic efficacy because the two concerns would not, in fact, conflict.

The case of pain management in the context of a patient presenting acute abdominal pain (often called "an acute abdomen") is illustrative. The well established practice and custom in emergency medicine has been to withhold pain medication from persons with acute abdominal pain until diagnosis or surgery. This practice reflects the long-held belief that interventions to relieve acute abdominal pain would confound the diagnosis of the underlying cause.<sup>41</sup>

The firmly held, persistent "common knowledge" in emergency medicine that medication of acute abdominal pain would thwart accurate diagnosis is based on a statement in a medical textbook from the 1920s. In that text, Sir Zachary Cope taught: "though it may appear cruel, it is really kind to withhold morphine until one is certain or not that surgical interference is necessary, i.e., until a reasonable diagnosis has been made."<sup>42</sup> Similar statements were included in this textbook as recently as 1979.<sup>43</sup> Even though Sir Zachary provided no evidence or citations for his statement, "physicians everywhere took Dr. Cope's opinion on this as their own."<sup>44</sup> Sir Zachary's opinion has guided doctors for more than 80 years, one generation after another, despite the fact that no study supported the practice. A study published in 1998, for example, revealed that emergency physicians in the U.S. withheld analgesia for patients with acute abdominal pain even though Sir Zachary's conclusion had been challenged in the literature nearly 20 years before.<sup>45</sup> A series of studies, each concluding that treating the patient with acute abdominal pain with morphine did not impede and perhaps even enhanced the accuracy of diagnosis, were published in the 1990s.<sup>46</sup> Studies published since that time also failed to detect any adverse impact on diagnosis.<sup>47</sup>

The American College of Emergency Physicians issued its "Clinical Policy: Critical Issues for the Initial Evaluation and Management of Patients Presenting with a Chief Complaint of Nontraumatic Acute Abdominal Pain," in 2000, revising its earlier policy of 1994.<sup>48</sup> The ACEP policy focuses on diagnostic strategies for the ED physician, but includes advice concerning pain management as well. The ACEP policy provides:

Administration of narcotics to patients with abdominal pain to facilitate the diagnostic evaluation is safe, humane, and in some cases, improves diagnostic accuracy. Incremental doses of an intravenous narcotic agent can eliminate pain but not palpation tenderness. Analgesics decrease patient anxiety and cause relaxation of their abdominal muscles, thus potentially improving the information obtained from the physical examination. There is evidence that pain treatment does not obscure abdominal findings, or cause increased morbidity or mortality.<sup>49</sup>

In the face of Sir Zachary's warning, unsupported by any evidence, and of early studies that failed to document an adverse impact on diagnosis and instead produced evidence contrary to this traditional "knowledge," the ACEP panel responsible for the Policy chose to rely on early evidence, such as it was, rather than perpetuate the traditional practice of leaving the patient to suffer, a practice that was supported in none of the studies available at that time or since. ACEP's Policy recommendation regarding pain treatment for this category of patients is clear and firmly stated. The only evidence that exists does not support the customary withholding of narcotics.

This portion of the Policy, however, is categorized as an "option" rather than an "evidence-based standard" or "guideline." Recommendations in the Policy based on a "high degree of clinical certainty" and supported by the highest level of empirical research qualify as an "evidence-based standard" in ACEP's policy. In contrast, a recommendation labeled an "option" is a "strateg[y]" for patient management based on preliminary, inconclusive, or conflicting evidence, or, in the absence of any published literature, based on panel consensus.<sup>50</sup> The Policy cites four research articles published prior to 2000 to support the option recommending attention to pain relief for ED patients with acute abdominal pain.<sup>51</sup> This level of uncertainty is not unique in medicine generally or in emergency medicine in particular. In the same Policy, for example, ACEP could not identify evidence-based standards or even guidelines for the diagnosis of several disease states that produce "commonly missed diagnoses" or for the diagnosis and management of geriatric patients as a subset of high-risk patients. Medical research of any sort is difficult in emergency medicine, and federal regulations have been developed to set up a process that accommodates some of those difficulties.<sup>52</sup> Research on pain management in this situation in the emergency department is doubly difficult, both ethically and legally, because the construction of a control group would require some number of patients to suffer without pain medication in a

situation where no current studies give any indication that medicating for pain relief has an adverse effect.

Even with its limitations, one would expect the ACEP policy and the published studies to change practice.<sup>53</sup> Some evidence, however, indicates that ED physicians still withhold analgesia for acute abdominal pain,<sup>54</sup> illustrating the difficulties in changing embedded professional custom, even when no evidence supports the practice, as well as the sometimes slow diffusion of clinical knowledge.<sup>55</sup> Another study, however, indicated that the Policy, or similar efforts, may have had an effect, although the study is ambiguous in an important respect. In a 2002 survey of emergency departments, 59 of 60 departments completing the survey responded affirmatively to a survey question that asked: "Is it your practice as a department to ever administer narcotic analgesia to acute abdomen patients prior to a surgeon's evaluation?"<sup>56</sup> A positive response to this inquiry does not indicate that it is common practice to do so, of course. The survey also asked: "in the cases when you do this, which of the following are motivations behind why you do it?" Of the reasons given, 88.1% reported that they would provide medication to alleviate patient discomfort; 86.4% believed that the literature supports the practice; and 61% responded that "it often takes too long for the surgical consult to arrive."<sup>57</sup> This latter question does indicate that there is a general awareness of the direction of current research on the matter. If clearer studies document that the practice of withholding analgesia in cases of acute abdominal pain does persist because of concerns over the impact on diagnosis, it may prove that we must look elsewhere for the reasons that pain relief is being withheld.

The implementation of ACEP's policy on pain relief for this set of patients illustrates another distinctive factor in improving practices in the ED; i.e., the relationship of emergency department physicians to the other specialists on whom they must rely for treatment of their patients. As recently as 1996, 89% of surgeons surveyed in a single-state survey responded that they still preferred that such patients receive no medication for pain prior to the surgical consult.<sup>58</sup> This survey of surgeons occurred less than two years before the survey in which 86.4% of emergency physicians indicated that the literature supported the use of pain medication in this situation. Further illustrating the conflict between these two specialties is a 2003 article in the *American Journal of Surgery* arguing that the studies that detected no difference in diagnostic effectiveness were infirm and that, based on cases "reported anecdotally and our own experiences," analgesia can alter the physical examination and lead to misdiagnoses. The authors, therefore, recommend that analgesia should be administered "only with the knowledge and consent of

the surgeon who assumes responsibility for decision-making."<sup>59</sup> This recommendation goes in the opposite direction of the ACEP Policy, and builds in significant delay in the treatment of patients with pain that may be harmful if acute pain is taken seriously and, at least under the current level of research, is unnecessary.

#### *Pain Assessment, Or You Don't Necessarily Know It When You See It*

Recognizing pain, and understanding its severity, is not a simple question of empathy borne of shared experiences. In fact, experience of physically painful incidents or stimuli is *not* shared. There is great variability in the individual experience of pain in like circumstances.<sup>60</sup> This variation is demonstrated in conflicting assessment of pain even by close intimates of the patient. Pain management in nursing homes, for example, is challenged by the tendency on the part of both health care providers and family members to underestimate pain in the elderly.<sup>61</sup> Children also suffer from the inclination of adult caregivers, even family, to discount their reports of pain.<sup>62</sup> Adequate pain assessment may require significant time,<sup>63</sup> and assessing pain in individuals with cognitive impairment, a situation confronted with some frequency in the ED, requires even more effort.<sup>64</sup> Further, strongly held assumptions that particular groups of patients, such as neonates,<sup>65</sup> do not feel or remember pain have proven mistaken; and this seems to be the case with the current widely held assumption that sedated patients receiving emergency care do not feel or remember pain.<sup>66</sup>

Perceptions of patient and physician as to the degree of pain experienced or expected are also often seriously divergent, including in the context of emergency treatment.<sup>67</sup> Formal pain assessment techniques are intended to give voice to the patient in detecting the presence and severity of pain in a way that is informative to the health care professional and can lead to appropriate interventions to relieve pain. The importance of pain assessment is evident in the fact that the Joint Commission on Accreditation of Healthcare Organizations has incorporated required pain assessment as a linchpin in the efforts to improve care of hospital patients, including specifically care provided in the emergency department.<sup>68</sup>

Many studies have identified deficiencies in pain assessment in the ED. Initial studies indicate that pain assessment is ordinarily a one-time evaluation in the ED and is not performed, or at least recorded, at important points after the initial assessment.<sup>69</sup> In particular, assessment at the point of transfer or discharge, as discussed in the context of legal risks below, is critical to satisfying the emerging standard of care.

Pain assessment is known to be particularly difficult

where the patient is unable to communicate, as can often occur in the ED because of the patient's age, mental disorder, trauma or stress.<sup>70</sup> In addition, the emergency patient's own emphasis on diagnosis and the resultant expectation of pain and suffering, noted above, probably makes pain assessment more difficult in the ED in the absence of formal inquiries of the patient by the nurse or physician and assessment techniques designed to elicit the patient's perceptions. This assumption is based on a similar phenomenon described in the case of elderly patients who are observed to underreport pain for fear of being a burden.<sup>71</sup> In addition, it appears that the expectation of pain can influence underreporting of pain.<sup>72</sup>

Intuitively, it seems that effective pain management must begin with recognizing the presence of pain.<sup>73</sup> Indeed, an increase in the employment of analgesia for pain in the ED once a formal pain assessment system is adopted has been demonstrated.<sup>74</sup> While it seems obvious that effective pain management in the emergency department requires formal pain assessment, especially in light of the divergence of perceptions between emergency physician and patient, there is some thought that the apparent connection between formal pain assessment and effective treatment is not so close.<sup>75</sup>

Particularly troubling and challenging for the implementation of patient-directed pain assessment is evidence that emergency physicians interpret patients' accounts of pain in a way that supports the physician's assessment of the underlying situation. One study reporting highly variable responses among ED doctors to identical patient reports of a need for pain relief speculates that doctors who suspect that a patient is seeking drugs for other purposes will take a report of a need for pain medication as evidence confirming drug seeking behavior, while physicians "who suspect the patient is truly in pain interpret the same statement [by the patient] as evidence that the patient is in severe pain."<sup>76</sup> In addition, physicians with more experience rather than less appear to be more likely to reject patients' reports of pain, leading one author to argue that "[w]ithout ongoing education, senior physicians risk providing less, not more, pain control."<sup>77</sup>

This phenomenon is not confined to the emergency physician or to the presentation of pain as physicians generally have been revealed to substitute their own assessment of the patient's symptoms.<sup>78</sup> Pre-existing interpretative frameworks for patients' reporting of pain are particularly troublesome because of their influence on suffering and on public policy.

#### *A Culture of Strangers under Stress?*

Consideration of the culture of the ED, including the nature of the physician-patient relationship in emer-

gency medicine, may reveal other reasons for under-treatment of pain.<sup>79</sup> Emergency physicians and nurses work in a highly stressful environment where pain and suffering are immutable and relentless companions. They must act rapidly, with the understanding that their actions may jeopardize the patient's life or health and in the face of intense uncertainty and unfamiliarity.

Influential research into the nature of the physician-patient relationship generally has discovered that "a central feature of doctor-patient interaction is the high degree of mutual uncertainty."<sup>80</sup> One has a sense that this may be exacerbated in the context of the emergency department where the doctors' patients are strangers to them, and they to their patients. In addition, while a patient's trust may bridge the inherent mutual uncertainty in the ordinary doctor-patient relationship,<sup>81</sup> there is little basis on which to build trust in the ED encounter unless the patient has a reservoir of trust banked for hospitals and doctors generally. While some patients do come to the ED with that attitude, others come with the entirely contrary experience.

The emergency department typically serves patients who are strangers to the care team.<sup>82</sup> The patient as stranger is so pronounced and profound that the issue is addressed specifically in the ACEP Code of Ethics for Emergency Physicians. The Code, in the section on Ethical Foundations of Emergency Medicine, specifically notes that "emergency physicians cannot rely on earned trust or on any prior knowledge of the patient's condition, values or wishes regarding medical treatment."<sup>83</sup> Although the statement specifically references the lack of knowledge about patient's preferences, it also has obvious implications for pain assessment, most particularly for evaluation of honesty in the report of the patient's pain.

There are other circumstances that also contribute to a more emphatic separation between physician and patient in emergency medicine as compared to other areas of practice. For example, emergency medicine is acutely aware of its role as providers of care to those persons whom everyone else has forgotten or avoids.<sup>84</sup> This self-concept of rescue unit or safety net motivates professionals in emergency medicine to undertake the care of the abandoned and rejected as a part of their professional mission. It also speaks of a differentiation or even alienation from the patients served, however, and could contribute to difficulties in pain treatment.

There is evidence in other, non-emergency health care settings that patients with whom the physician is familiar receive more effective treatment for pain than do patients who are less well known to the doctor.<sup>85</sup> It is reasonable to ask the question whether this phe-

nomenon is operational in the ED as well, because an answer to that question may produce significant insight into the problem of inadequate pain management.

In emergency medicine, the professional investment in favor of diagnosis itself also may produce an extreme form of detachment from the suffering of the patient who must be examined and treated. This detachment from patients in pain may in fact increase over time as the emergency department physician and nurse develop a tolerance for repeated and constant exposures to human suffering.<sup>86</sup> The personality of individuals attracted to emergency medicine may personally discount the seriousness of pain and discomfort both for themselves and their patients.<sup>87</sup> Maintaining a distance from the patient in pain may be a natural support for the need to proceed despite the patient's suffering.

Unfamiliarity, detachment or alienation from patients may lead to a heightened fear of being tricked or duped by patients who have no medical need for controlled substances for pain relief.<sup>88</sup> This challenge faces all physicians who treat a large number of patients in pain, but it is especially acute in the emergency department where the physician and the patient are usually unknown to one another. Experiences in which an individual takes on the mantle of "patient" but lies to the physician in order to get drugs seem to be nearly traumatic to emergency doctors and appear to breed a sense of betrayal and guardedness that can persist over the course of the physician's career. Whether frequent or not, the experience is typically not an isolated incident for doctors in the emergency department. The problem is that the disgust at being tricked can become overgeneralized and result in the denial of necessary care to patients in pain.

When reasonable attention to this risk becomes fear, it leads to exaggerated distrust of patients' reports of pain. A physician's perception that a patient is seeking drugs for secondary gain is very powerful, so powerful that it may not be dislodged by anything the patient can do or say to alleviate that concern. As discussed above, at least one study has revealed that an emergency department doctor may, in fact, interpret an identical statement in polar opposite directions. The statement is interpreted as proving the doctor's pre-existing perception whether that is proving that the patient is lying to get drugs or that the patient's claim of pain and need is genuine.<sup>89</sup> In addition, patients that fall within marginalized groups or groups that have been thought, based on evidence or not, to have higher incidence of diversion, may face a pattern of suspicion and limitations on care in a form of profiling.<sup>90</sup>

Many efforts have focused on identifying indicators, often called "red flags," that can be used in an attempt

to cope with the possibility that some individuals may lie about their symptoms in order to get prescribed controlled substances.<sup>91</sup> The usefulness of these efforts is questionable in a number of settings. The common "red flags" may be particularly unreliable when transferred from office-based medical practice to the hospital-based emergency medical practice. One commentator notes that ED doctors may be "ill advised" to rely on common "red flags" because these indicators have been developed in non-ED practice settings. For example, the request for a specific analgesic by a patient, commonly viewed as a red flag indicating a drug seeking patient, could indicate that the patient is suffering severe pain with which he or she is quite familiar.<sup>92</sup> Another notes that the patient who has been discharged from the ED with pain medication (or a prescription for pain medication) who calls back or returns because the medication is "not doing the job" is suspected of abusing the system rather than suffering from inadequate dosing or selection of drug, problems that have been documented frequently in ED practice.<sup>93</sup>

The ethical physician is alert to the patient who lies to get drugs for illicit purposes, but a serious ethical problem arises when the physician becomes hypervigilant or relies on profiling that gives only a general and often inaccurate picture of the "drug seeking" patient with the result that many patients in pain are denied necessary care. In fact, emergency physicians are likely to form suspicions about patients that are not influenced by the patient's report of pain<sup>94</sup> and that do not correlate with drug abuse screening.<sup>95</sup>

When race, socioeconomic status, source of pay for care, and related generalities are used to exclude patients from effective treatment, ethical principles of medical practice are violated. The ACEP Code of Ethics is quite clear on the ethical principle involved. The Code states that "[e]mergency physicians should act fairly toward all persons who rely on the ED for unscheduled episodic care....Provision of emergency medical treatment should not be based on gender, age, race, socioeconomic status, or cultural background. No patient should ever be abused, demeaned, or given substandard care."<sup>96</sup> A situation where individuals are denied pain relief because of their health status (because they have sickle cell or because they are chemically dependent, for example) or because of stereotypes about a specific population implicates this ethical commitment.

The problem of physician distrust of patients is a core issue in the effective treatment of patients in pain. Increasingly, calls are made that doctors and nurses must "trust the patient's report of pain." Because of the high variability of the experience of pain and the impossibility in many cases of pinpointing an organic cause, the patient's report is currently the primary, if not sole,

datum available. Certainly, the call to respond to patients' reports of pain with effective interventions is critical for improving the care of patients and it should be supplemented with an equally vigorous call to doctors, nurses and other caregivers not to trust themselves in substituting their own judgment of what the patient is or should be experiencing in terms of pain and discomfort. In particular, in the practice of emergency medicine, reliance on unproven, anecdotal "rules" – whether related to Sir Zachary's prohibition on treating pain in a patient with acute abdominal pain or profiling patients by race, socioeconomic status, or specificity in their request for pain medications – needs to be eliminated.

The issue of trusting patients' reports, however, is a complicated challenge embedded in the practice of medicine generally and inherent in the training of physicians. The intense rejection of "subjectivity" in medicine is long-standing and not confined to the issue of pain.<sup>97</sup> Improving the inadequate treatment of pain in the ED may emerge from tackling low-hanging fruit, such as requiring pain assessment at intake and at discharge, but it also needs to be understood that some of the traits that underlie current customs and practices are endemic to medicine, perhaps exacerbated in the ED environment, but not limited to the issue of pain relief.

### Legal Issues in Pain Management in the Ed

Fear of legal risk has been identified as a significant barrier to effective treatment of patients in pain in a variety of settings. Concerns over the legal environment extend as well to the ED, although the source of these concerns is particular to this context. Legal issues relating to pain management in the emergency department emerge from at least three different areas of law. They are: 1) malpractice and general tort liability; 2) the federal Emergency Medical Treatment and Labor Act (EMTALA); and 3) state and federal regulation of medical practice, especially as it relates to the prescription of controlled substances. An analysis of legal issues relating to pain management in the emergency department is relevant because the sense of legal risk has an impact on the course of treatment. Perhaps more importantly in the context of the emergency department, an analysis of legal issues reveals systemic factors that may produce inadequate treatment for pain.

#### *Malpractice and General Tort Liability*

Physicians have a well established legal duty to treat pain as a part of their medical treatment of a patient.<sup>98</sup> The doctor's legal duty to relieve pain is generally supported by policy statements and standards of professional organizations and by the standards enforced by

state licensing boards.<sup>99</sup> JCAHO standards on the assessment and treatment of pain in the emergency department also provide support for a legal duty to treat pain effectively.<sup>100</sup> ACEP has adopted several policies that assert the importance of treating pain.<sup>101</sup> A 2005 study reported that the National Guidelines Clearinghouse included 238 guidelines on "pain management," including 143 guidelines on "acute pain management" as of December 2003.<sup>102</sup> The courts rely on policy statements and practice guidelines promulgated by such organizations to establish a legal duty to which physicians and hospitals are held.

#### *Litigation Concerning Negligent Treatment for Pain*

Studies of malpractice lawsuits have concluded repeatedly that patients injured through negligence or malpractice generally do not file suit.<sup>103</sup> In considering legal risks, efforts to improve pain management may be viewed pragmatically as a method for avoiding litigation, although this conclusion is largely intuitive.

While undertreatment of pain is commonly viewed as an exacerbating factor in malpractice or negligence lawsuits, neglectful pain treatment standing alone can also form the basis of a malpractice or negligence claim. In *Bergman v. Eden Medical Center* and *Tomlinson v. Bayberry Care Center*,<sup>104</sup> the surviving family members of two patients in California filed suit against the physicians, hospitals, and nursing homes that cared for the patients. In *Bergman*, the jury returned a verdict of \$1.5 million, which the court reduced to \$250,000. In *Tomlinson*, the defendants (the patient's hospital physician, the nursing home physician, the hospital and the nursing home) entered into voluntary settlements with the plaintiffs, with undisclosed sums paid to the family.

*Bergman* and *Tomlinson* illustrate that it is possible for patients to bring suit for inadequate pain management in the absence of other negligence or malpractice. In each case, the patient was in the end stages of terminal cancer; the patient was transferred from hospital to nursing home for the final days or weeks of care; the patient received very clearly inadequate medication; and the lawsuits were both brought under the state's elder abuse statute.

The diagnosis for each of these patients was clear, and the standard interventions for pain management were well accepted but were not provided. Treatment for cancer pain and pain at the end of life areas of treatment for pain in which there is a strong medical and legal consensus. There is no concern over addiction or diversion; and the state medical boards have long viewed the use of controlled substances for cancer pain, even over a long time and in large doses, as permissible.<sup>105</sup>

Lawsuits claiming neglected pain as the only basis for



legal action face several obstacles. Many states have a cap or limit on the amount of damages that can be awarded for pain and suffering. In some states, damages for pain and suffering do not survive the death of the patient and cannot be awarded to surviving family. It is for this latter reason that the plaintiffs in *Bergman* and *Tomlinson* brought their suits under a state elder abuse statute that provided a private right of action for

## Informed consent is a serious challenge in the ED, and concerns over informed consent influence the effectiveness of interventions to increase responsiveness to patients in pain.

elderly persons and their surviving family. Under this statute, however, the plaintiffs had to prove that the providers had been reckless and not merely negligent. This is a very difficult burden to meet in medical cases where professional judgment is so often the core of the issue. The statute provided for the payment of attorneys' fees by the defendants to the plaintiff's attorneys, and these fees amounted to approximately \$500,000 in the *Bergman* case.

The threat of an avalanche of similar cases is not realistic because of the limits on this type of litigation. Furthermore, the facts of these cases as presented by the plaintiffs were quite extreme. Still, both *Bergman* and *Tomlinson* are particularly relevant to the practice of the emergency physician, even though at first glance they may be confined to terminally ill patients or patients with cancer pain. Their lesson is indeed broader, and highlights two common challenges to the quality of pain management for emergency medicine.

### *The Risks of Discontinuity of Care*

The transfer from hospital to nursing home care in both *Bergman* and *Tomlinson* resulted in a serious discontinuity in care, especially at the point of discharge and transfer. This is evident in the absence of orders or follow-up for appropriate pain medication in at least one of the cases, despite documentation of the patient's advanced cancer and consistent reports of extraordinarily severe pain.

Providing for adequate continuing pain management upon discharge from the ED is an issue for many types of ED patients. Several studies have identified serious concerns with failures to account for even basic pain management needs upon discharge.<sup>106</sup> For example, a recent study of patients with orthopedic injuries, who were experiencing "acute distress" in the ED, revealed that 43 of 144 patients received no prescription or starter pack of medication upon discharge.<sup>107</sup>

Both *Bergman* and *Tomlinson* involved inadequate orders for pain medication upon discharge. The emergency physician must pay attention to transfer and discharge planning and assure that adequate medication and follow-up orders, including those required for pain management post-discharge, are provided for the patient.<sup>108</sup> The ACEP policy on procedural sedation, for example, requires that continuing or developing pain and discomfort be addressed prior to discharge.<sup>109</sup> Evidence suggests that EDs do not ordinarily document pain assessment subsequent to the initial assessment.<sup>110</sup> An ongoing pain assessment in the ED is required for both treatment and discharge. Although there may be some question about the value of ongoing pain assessment during the course of treatment in the ED, it is difficult to understand how an appropriate post-discharge care plan for pain can be established without an assessment at discharge.

Another form of "discontinuity" of care presents a different kind of challenge to the physician practicing in the emergency department. Emergency physicians are familiar with the situation in which a patient who regularly receives care elsewhere for a chronic illness associated with pain comes to the emergency department for treatment for an exacerbation of their condition or for an acute pain episode. Emergency departments treat a significant number of chronic pain patients, accounting for more than one in ten of ED patients.<sup>111</sup> The emergency physician is not as familiar with the patient as is the patient's own physician, but it is the emergency physician's services that are required.

An even more difficult situation occurs when the ED doctor is convinced that the patient is receiving inadequate treatment, for pain or otherwise, from their own physician or the facility in which they reside. In such cases, consultation with the patient's doctor may help; serious and detailed information to the patient directly may allow the patient to take action; or admission to the hospital under the care of another attending physician may allow for more thorough assessment and a change in treatment plan.<sup>112</sup>

### *Palliative Care for Terminally Ill Patients in the ED*

*Bergman* and *Tomlinson* both involved patients who were in the very end stages of terminal cancer. In particular, transfers of dying patients from nursing homes to the hospital, often through the ED, are frequent. At least one observer describes a "popular motto" in the nursing home world: "When in doubt, ship them out. Make the patient the other guy's worry."<sup>113</sup> Emergency departments see cases in which a terminally ill patient who has been cared for in a nursing home or at home

is brought to the emergency department when death is imminent.

The admission of imminently dying patients through the ED presents challenges to the quality of care and pain management for these patients. Studies have indicated that the quality of care for such patients in the ED is not better than that received in the nursing home.<sup>114</sup> Because the emergency doctors and nurses are not familiar with the patient's medical condition or desires for treatment, interventions may be more acute than is desirable.<sup>115</sup> Emergency physicians need to be familiar with the current practices and standards for effective treatment of pain at the end of life, and hospitals should have a plan to assure that the ED is well prepared to care for or admit these patients.<sup>116</sup>

#### *Informed Consent and Pain Management in the ED*

Informed consent is a serious challenge in the ED, and concerns over informed consent influence the effectiveness of interventions to increase responsiveness to patients in pain. This influence is seen in several areas: a concern that pain relief cannot be provided without informed consent; a "common knowledge" concern that opioids will disable patients from consenting to necessary interventions, especially surgery; and finally, a concern over potential liability for patients who take medications prescribed in the ED and who then engage in behaviors that are inadvisable because of the effect of the medications.

All medical care requires the informed consent of the patient, and medical treatment provided without consent is considered a battery. A limited exception to the requirement of informed consent exists in emergency situations. The classic statement of the exception for emergency treatment declares that the exception "comes into play when the patient is unconscious or otherwise incapable of consenting, and harm from a failure to treat is imminent and outweighs any harm threatened by the proposed treatment."<sup>117</sup> The exception ordinarily would include treatment for pain in such circumstances.

The emergency exception is actually quite narrow. It certainly does not give the ED *carte blanche* to treat every ED patient without consent. It only applies where the patient's condition is urgent and the time required for consent would put the patient at serious risk of death or severe injury.<sup>118</sup> In the case of the incapacitated patient, the nurse or doctor should secure the consent of a family member or other surrogate where possible without serious harm to the patient.

In litigation alleging emergency treatment without consent, several courts have concluded that consent for emergency treatment is implied by the patient's coming to the ED.<sup>119</sup> This implied consent does not extend to sit-

uations where the physician knows that the patient objects to treatment or particular interventions, however;<sup>120</sup> and the notion of implied consent should not be relied upon too broadly. Quite frequently, an ED patient will sign a general consent form. Even with the general consent, the care provider should continue to inform the patient concerning his or her treatment; and a more specific consent should be sought for any procedure or medication with serious risks. For example, procedural sedation presents risks of damage to the central nervous system and depression of cardiac and respiratory functions. ACEP policy states that implied consent may be acceptable where the patient is unable to understand the necessary information due to altered mental status or severe pain and anxiety.<sup>121</sup> Otherwise, separate consent to sedation is recommended.<sup>122</sup>

The key components to informed consent are that the patient is able to understand what options exist as well as the consequences of choosing one over another and is able to evaluate the costs and benefits of these consequences by relating them to a framework of values and priorities.<sup>123</sup> One of the most serious problems regarding informed consent in the ED is the difficulty in ascertaining whether the patient is incapacitated. The stress and duress of an emergency condition, especially one associated with severe pain, may compromise the ability of the patient to consent; but the patient will not be legally incapacitated. The same judgment call is required for patients whose mental state is impaired by abuse of drugs or alcohol. Of course, the characteristics of the relationship between emergency doctor and patient, as described earlier, make a judgment about this individual's preferences and values quite difficult. In that regard, the latitude that courts have allowed emergency physicians in the face of challenges to a lack of informed consent reflects this situation.

ED doctors may also be concerned that opioid analgesia will incapacitate the patient and make it impossible for that patient to consent to necessary treatments. In fact, severe pain may interfere with the patient's ability to receive information and make rational risk assessments, although the patient will not be legally incapacitated, and doctors should not withhold opioid pain medication entirely for concern over incapacitating the patient.<sup>124</sup>

In regard to any medication that may impair judgment, alertness, or physical capacity, including pain medication, the physician must inform the patient clearly and accurately of these limitations prior to discharge. The physician, for example, should warn the patient specifically if the medication could interfere with driving or other similar activity and document this warning. Inadequate warnings have triggered physician liability in some cases.<sup>125</sup> At least one study of pre-

scribing upon discharge from the ED cautions ED doctors to intensify efforts in this regard because 7% of patients in that study admitted to driving while taking narcotics within 7-14 days of discharge.<sup>126</sup> Patients may choose among different options, with differing levels of effectiveness and adverse effects, for treatment of pain. Some patients may forego the most effective pain relief if it will compromise other goals.<sup>127</sup> Physicians and nurses need to educate their patients so that the patient is not making this decision based on inaccurate assumptions about the potential for sedation or addiction.

#### *Legal Significance of ED Policies, Protocols, and Guidelines*

Hospitals typically have policies, protocols, clinical pathways, and practice guidelines governing treatment in the emergency department, including for pain management and procedural sedation. The advantage of establishing written policies is that they can contribute to assuring that care in the emergency department

The question of authority arises in two ways: is the professional authorized to provide the intervention under hospital policy, and is the professional authorized to do so within his or her scope of practice under state law? The scope of practice of non-physician health care professionals varies widely among the states and significantly among individual facilities. Scope of practice is significant. If a professional exceeds his or her statutory scope of practice, it is likely, absent exculpatory circumstances, that this action will be viewed as negligence *per se* without further proof of the standard of care;<sup>128</sup> however, some states treat this situation only as evidence, but not conclusive evidence, of negligence.

Limitations on scope of practice, whether established by statute, custom, or the specific facility have a direct impact upon the treatment of emergency patients in pain. The expressed purpose of such limitations is to assure quality of care, and so they are intended to improve the care of patients and may, in fact, do so. These limitations also directly effect access to treatment through,

**The fact that EMTALA does not clearly mandate treatment for pain does not mean that such treatment is not otherwise legally required.**

meets the current standards of practice. Both the adequacy of and the violation of written policies will be at issue in malpractice or negligence litigation. Professional standards for treatment of pain in all settings are evolving quickly. It is not enough for policies to adopt traditional practices in this situation.

Written department or hospital policies are not helpful if they are violated in practice. In fact, violation of the ED's own written standards creates a strong inference of negligence. Nonconformance with hospital policies is not viewed legally as negligence *per se*; i.e., the plaintiff must prove that the treatment provided violated the appropriate standards of practice and not just the hospital's own policies. It is possible, legally, that treatment could violate hospital standards but still not be negligent. Nonconformance with the hospital's own policies and practices, however, can be very persuasive to a jury and on its own provide the legal basis for liability in a claim brought under EMTALA, as discussed below.

#### *Scope of Practice of Non-physicians*

"Scope of practice" refers to the authority of the non-physician health care professional to deliver necessary treatment. In the area of pain management, authority to administer intravenous medications; to prescribe medications that are controlled substances; and to sedate the patient for painful procedures all fall within the ambit of "scope of practice."

for example, limiting prescribing authority or requiring direct physician supervision of the non-physician professional. One of the areas of particular concern in the context of emergency treatment is the significant delay in providing treatment for the relief of severe, acute pain, as discussed earlier. Limitations on the scope of practice of emergency medical service professionals need to be examined in this context.

A related but distinct legal issue arises in the context of procedural sedation and other similar interventions. Although the procedure may be within the scope of practice allowed the professional under state licensure, the professional must also be competent by virtue of education, training and experience of performing the procedure. For example, a physician license is not limited to a particular range of medical practice, but not all physicians are competent to perform procedural sedation. ACEP policy asserts that all emergency physicians should be capable and competent in performing procedural sedation and that an anesthesiologist is not ordinarily required.<sup>129</sup>

#### **Emergency Medical Treatment and Labor Act**

If there is a 500-pound gorilla in the ED, it is the federal Emergency Medical Treatment and Labor Act (EMTALA). EMTALA requires that a hospital receiving Medicare and operating an ED provide to any individual who "comes to" the emergency department with a request for aid an "appropriate medical screen-

ing examination...to determine whether or not an emergency medical condition exists." If the hospital determines that the individual has "an emergency medical condition," the hospital must provide medical treatment to "stabilize" the condition or, alternatively, arrange for transfer through appropriate means if the patient requests transfer or if the physician (or another authorized person) certifies that the "medical benefits" of transfer outweigh the increased risks of transfer.<sup>130</sup>

ED policies and practices are organized toward documenting compliance with the Act. It is probably the most significant legal concern that EDs and emergency medicine doctors have. If the Act were to clearly establish a legal duty for pain relief, it would be likely to have a very significant effect. Unfortunately, the answer to whether EMTALA requires treatment for pain is not entirely clear.

#### *Pain Assessment in the "Appropriate Medical Screening Examination"*

The courts have consistently held that the EMTALA requirement for an "appropriate medical screening examination" to determine whether the patient has an emergency medical condition requires no more than that the hospital screen each and every ED patient in the manner of the hospital's usual policy, custom and practice.<sup>131</sup> The courts have refused to apply general professional standards of care to the screening requirement. Thus, the courts are unlikely to adopt the policies on pain management from organizations such as ACEP and JCAHO, discussed earlier, as the legal standards for compliance with EMTALA's medical screening requirement. With the implementation of the JCAHO standards on pain assessment, however, each accredited hospital now probably includes assessment for pain within their usual and customary initial and ongoing assessment and medical screening exam process. Once the hospital adopts this as practice or policy, pain assessment becomes a required element of the appropriate medical examination required under EMTALA. In addition, because the Act specifically recognizes "severe pain" as a symptom of an emergency medical condition, it may be argued that pain assessment is an essential part of any screening. Finally, courts may in the very rare case hold that a hospital's standard policies, procedures, and practices are so deficient as to amount to no medical screening at all. An evaluation of the patient's report of pain is an essential diagnostic tool, and a failure to assess pain is likely to meet this extreme standard.

If EMTALA requires pain assessment at all, it is clear that the pain assessment is required at various points during the patient's care in the ED and particularly upon discharge. The Interpretive Guidelines, issued by

the Centers for Medicare and Medicaid Services for the surveyors who test compliance with or investigate violations of EMTALA, state that CMS believes that a medical screening examination "is an ongoing process;" that "the record must reflect continued monitoring according to the patient's needs;" and that there "should be evidence of this evaluation prior to discharge or transfer."<sup>132</sup>

#### *Pain and the Emergency Medical Condition*

The statute defines "emergency medical condition" as "a medical condition manifesting itself by acute symptoms of sufficient severity (*including severe pain*) such that the absence of immediate medical attention could reasonably be expected to result in placing the health of the individual...in serious jeopardy; serious impairment to bodily functions; or serious dysfunction of any bodily organ or part."<sup>133</sup> The statute references severe pain, not as an emergency medical condition itself, but rather as a *symptom* of an emergency medical condition. Despite the explicit reference to pain as a symptom of an emergency medical condition and despite the likelihood that the hospital's customary medical screening includes a pain assessment, it is not clear that EMTALA requires *treatment* for pain. EMTALA appears, then, to adopt the traditional, though now dated, perspective of emergency medicine that pain is merely a symptom.

#### *Stabilization and the Relief of Pain*

The statutory definition seems to anticipate that a patient may have the symptom of severe pain – a manifestation of an emergency medical condition – but not actually have an emergency medical condition. The EMTALA treatment requirement is limited to that treatment required to "stabilize" the patient. Stabilization is defined as providing "such medical treatment of the condition as may be necessary to assure...that no material deterioration *of the condition* is likely to result from or occur during [transfer]."<sup>134</sup> Unless pain will result in a material deterioration of the patient's emergency medical condition, treatment for the pain itself is not required under EMTALA.

Thus, EMTALA does not ordinarily require that the ED have the patient's pain managed prior to discharge or transfer unless the pain will cause the patient's medical condition, as defined in the Act, to deteriorate as a result. This conclusion may be limited, however. Under EMTALA, the adequacy of the medical treatment required to stabilize the patient is measured against professional standards of care, not the hospital's own practices. EMTALA incorporates a malpractice standard in reviewing the adequacy of treatment of persons with an emergency medical condition. As medical practice begins to view interventions to relieve pain as essential to

minimally adequate care, the emerging standards may infiltrate EMTALA cases either through the malpractice standard for stabilization or because of new understandings and evidence of what constitutes a "material deterioration" of a patient's emergent condition and how unrelieved pain can result in such deterioration. Moreover, where the emergency medical condition is mental or emotional, conditions also within the EMTALA obligation, unrelieved pain itself may be a cause of material deterioration in the patient's medical condition.

In most EMTALA cases litigated, in fact, the complaint is the failure to diagnose and treat life-threatening medical conditions such as myocardial infarction, either because the screening examination was inadequate or because treatment was inadequate. In the typical case, the pain was addressed through medication, but the underlying condition was not.

The impact of EMTALA, if extended to encompass a duty to provide adequate pain management as a part of the duty to stabilize, would be tremendous. Emergency departments orient their documentation, and thus their procedures, toward EMTALA compliance. Nevertheless, the fact that EMTALA does not clearly mandate treatment for pain does not mean that such treatment is not otherwise legally required. Medical malpractice and other tort claims, such as those described above, will still apply.

### State and Federal Regulation of Prescribing Practices

Emergency physicians, nurses, and other professional and paraprofessional health care workers are subject to regulation through state licensure and through other state regulations involving the health and safety of patients and health care workers. Work in the ED is regulated by several federal agencies, including the Occupational Health and Safety Administration, the Food and Drug Administration, and the Centers for Medicare and Medicaid Services, among others.

Prescribing of medications that are listed as controlled substances in the schedules of the federal Controlled Substances Act (CSA)<sup>135</sup> is regulated at both the state and federal levels. Physicians' fear of regulatory scrutiny and intervention on the part of the state bureau of narcotics, the state medical licensure board, and the federal Drug Enforcement Administration (DEA) is a substantial barrier to access to effective pain relief for patients. The fear of providing controlled substances to patients with no medical need for the drugs also appears to be a substantial fear among ED physicians.<sup>136</sup> It is not clear whether this behavior on the part of emergency physicians is attributable to a fear of legal sanc-

tions or a more culturally embedded concern for being tricked by duplicitous individuals posing as patients, as discussed earlier.

The public policy concerns underlying the Controlled Substances Act and licensure sanctions for prescribing practices are the risk of addiction and the diversion of certain medications. The public policy challenge in implementing both the CSA and state standards con-

There is often confusion, for example, between "drug seeking" and "pain relief seeking" behaviors; and this confusion can penalize particular patient groups.

cerning prescribing is to establish restrictions and penalties for the dangerous or reckless prescriber while encouraging the responsible physician to treat pain aggressively. Because untreated pain is itself a public health issue, as it promotes illness and disability, a single-minded focus on diversion and addiction does not promote the public health and does not accomplish the stated goals of government oversight of prescribing practices.

Certain areas of pain management have been recognized by the regulators as requiring special attention and support. State medical boards have recognized that individuals with cancer pain or pain associated with terminal illness are not at substantial risk of addiction or diverting their medications and are likely to need large amounts of pain medication over what can be a very long period of time.<sup>137</sup> In contrast, the stereotypical setting that draws regulatory scrutiny is the physician's private office that is treating a high volume of chronic pain patients with less than minimal contact with patients or documentation of history, examination, or treatment plan.

It does not appear that emergency departments are particular targets for regulatory intervention by either state or federal authorities in regard to prescribing controlled substances for pain relief. Emergency physicians have not been targeted by these agencies generally because of the limited risk of high-volume diversion. The private office of a reckless or criminal doctor could provide a number of patients who are addicted or diverting drugs with large volumes of medication over some amount of time, although it should be clear that no data support the notion that private physician office practices are a major source of diverted drugs.

The risk of hypervigilance when emergency physicians become overly concerned with the risk of providing controlled substances to patients who may not require them for relief of pain is serious. As discussed earlier, there is often confusion, for example, between

“drug seeking” and “pain relief seeking” behaviors; and this confusion can penalize particular patient groups.<sup>138</sup> The emergency physician should engage in reasonable practices to assure that prescriptions for controlled substances meet current standards, such as those offered by the Federation of State Medical Boards,<sup>139</sup> but adjusted to the practice of emergency medicine.

In recent years, the concept of “balance” has been used to provide a common meeting ground for those concerned with diversion and abuse of prescription drugs and those concerned with improving the care of patients in pain. The term, as commonly used in this context refers to a fundamental principle that government policies to prevent misuse of controlled substances should not interfere in their essential uses for the relief of pain.<sup>140</sup> Implicit in the concept is recognition that both unrelieved pain and addiction are public health issues.

Thus, “balance” is a *regulatory* goal. It is not a principle that translates directly to clinical practice with an individual patient. Physicians surely must assess the benefits and risks of any medication for the individual. That exercise – by the physician and the patient together – involves a balancing function; but it is a balancing function of the risks and benefits *to this particular patient*, individuated by what is actually known about specific risks of addiction for particular groups of patients. This clinical assessment focuses on this patient’s particular needs, risks and overall best interests. The physician should not balance the general risk of abuse in the general population against this particular patient’s best interests.

State medical boards have made significant progress in adjusting their requirements for disciplinary actions to better reflect emerging standards of care for the treatment of patients in pain. The Federation of State Medical Boards issued guidelines for medical boards in 1998, and revised them in 2004.<sup>141</sup> These guidelines, adopted by many states,<sup>142</sup> clearly state that fostering effective pain relief is a goal of the regulatory process; that physician prescribing will not be judged by volume or chronicity alone, but rather by outcomes for the patients; and that the physician has an obligation to perform and document a physical examination of the patient and a care plan that includes appropriate follow-up. At least 23 state legislatures have enacted “intractable pain statutes” to further affirm the importance of treating pain, and to set out some guidance for appropriate regulatory oversight of prescribing practices.<sup>143</sup> In fact, some medical boards have taken disciplinary action against physicians who have neglected their patients in pain.<sup>144</sup>

At the same time as state regulatory standards and enforcement efforts are accommodating a goal of im-

proving quality of care for patients in pain while attending to their obligations to protect against addiction and diversion, the federal government has intensified its efforts against the prescribing of controlled substances for pain management, and have engaged in a strategy of high profile arrests and prosecutions of physicians. In addition, the DEA has parted ways with the approach developed in the majority of states.

The purpose of the Controlled Substances Act, enforced by the DEA, is to control illegitimate distribution of controlled substances<sup>145</sup> without interfering with legitimate medical and scientific practices. The tension between the states and the DEA on what qualifies as legitimate medical practice is growing in this issue and in others.<sup>146</sup> The ideal, however, is that the physician be guided by the same or at least consistent standards as between federal and state regulators.

In recognition of the establishment of new practice standards in the states and the inadequacy of pain management in the U.S., the DEA issued a statement in 2001 advocating a balanced regulatory policy for prescription pain medications that would account both for concerns over addiction and diversion and concerns over pain management.<sup>147</sup> In this statement, joined by 21 national organizations, the DEA recognized the regulatory balance: “We want a balanced approach that addresses the abuse problem without keeping patients from getting the care that they need and deserve.”

The DEA took another pragmatic step toward achieving a more balanced approach to its enforcement efforts in 2003, when the agency issued a “Frequently Asked Questions” document (the FAQs).<sup>148</sup> The approach to oversight of prescribing practices for pain management taken in the FAQs was consistent with the model guidelines published earlier by the Federation of State Medical Boards. This development brought state and federal efforts into harmony, allowing physicians to practice in a more predictable environment. The harmonization was particularly welcome because several states had become more interested in penalizing physicians for reckless disregard of pain through disciplinary actions and private parties had brought two very high profile personal injury cases, as discussed above.

The FAQs provided educational information to medical practitioners through a series of questions and answers about the appropriate use of opioids in the treatment of pain. The FAQs addressed the definition of pain and its treatment; how opioids work and what patients need to know; the risks in the medical use of opioid analgesics; and legal and regulatory considerations, including under what circumstances the DEA would be likely to decide to investigate and what medical professionals needed to do to comply with state and federal law.

Subsequent to their publication, the FAQs were immediately embraced by the professions that were pursuing ways to address the inadequate treatment of pain. In an effort to dispel the fear of legal sanction that was impeding appropriate prescribing, the FAQs were held out as an indication that physicians who comply with particular standards of patient care could do so without fear of investigation or sanction.<sup>149</sup> Even though emergency physicians had not been the particular targets of DEA action, the literature in emergency medicine also recognized the significance of the positive changes in the legal environment on a federal and state level.<sup>150</sup> One such article, for example, used the FAQs to encourage emergency department professionals to abandon their fear of legal risks and “appreciate the greater protections offered...when operating by acceptable medical standards.”<sup>151</sup>

Soon after the DEA issued the FAQs, however, the agency’s commitment to the “balanced” approach began to crumble. The retrenchment began in 2003, with the release of the statement “The Myth of the Chilling Effect” on the DEA’s web site.<sup>152</sup> This statement identifies the mission of the DEA: “to prevent, detect and investigate the diversion of legitimately manufactured controlled substances.” The statement does not specifically affirm the importance of the treatment of pain as did the 2001 joint statement and the FAQs. The statement asserts that “doctors operating within the bounds of accepted medical practice have nothing to fear from the DEA,” but it does not give specific guidance as to the “bounds of accepted medical practice.” The statement simply provides statistics on DEA’s enforcement efforts, noting that the agency had “pursued sanctions against less than one tenth of one percent of the registered doctors” since 1999.

What was shaken by the posting of “The Myth of the Chilling Effect” was completely disassembled by the retraction of the FAQs by the DEA in November 2004. An interim policy statement (IPS) published by the DEA in the Federal Register announced the withdrawal of the FAQs,<sup>153</sup> citing “misstatements” in the FAQs. The IPS clearly rejects the approach to oversight that had been adopted by the Federation of State Medical Boards and by many states. With the withdrawal of the FAQs and the substantive statements made in the IPS, the DEA has taken federal regulation and oversight for prescribing for pain in a direction that is the opposite of that taken by the majority of the states. In a letter to the DEA after the retraction of the FAQs, the National Association of Attorneys General expressed concern that “the state and federal policies are diverging with respect to the relative emphasis on ensuring the availability of prescription pain medications to those who need them.”<sup>154</sup>

Although the current regulatory environment, as played out by the state medical boards and the DEA, is a difficult one for doctors treating patients in pain, and particularly chronic pain patients, the emergency department physician is somewhat insulated from the fray. Federal enforcement efforts have and probably will continue to target the office-based medical practice rather than the hospital-based emergency medicine practice. Still, even if the emergency doctor is not at particular risk of enforcement activity, chronic pain patients who are ill-served by the current regulatory environment are likely to show up at the doors of the emergency department.

## Conclusion

We know little of what we need to know to improve the treatment of patients in pain who are seeking care in the emergency departments in the U.S. That we have reasons to improve that care is clear. Recognized ethical duties; enforceable legal obligations; and human compassion and empathy all drive us toward that goal. In the case of the emergency department, the seriousness of untreated pain may be underestimated if it is viewed as merely a temporary experience. Enough research exists, however, for us to be able to argue that the impact is long term.

Efforts at improving care nearly always begin with trying to discover the reason for the failure of care – discovering the “root cause,” so to speak. With neglect of pain generally, we still often deal with questions: Does information change practice? Will a change in legal enforcement policies change practice? With emergency medicine, we may have even less knowledge about the reasons physicians behave the way they do. Studying emergency medicine in context, however, gives us the opportunity to look at now familiar problems in what is a very different medical culture than either the office-based or the palliative care settings, and one which struggles with uncertainty, unfamiliarity, and subjectivity.

Further research is absolutely critical. The research needs to focus on the issues that lead emergency physicians to withhold interventions that could help patients as well as on the basic clinical research on the effectiveness and safety of certain interventions. Conducting research in the context of emergency medical care is very challenging, but it is worth it.

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