

Health Care Providers' Liability Exposure for Inappropriate Pain Management

Robyn S. Shapiro

Recent studies have exposed the startling inadequacy of health care providers' knowledge about and practice of effective pain management. For example, in one study, it was reported that 79 percent of a random sample of 454 medical-surgical inpatients experienced pain during hospitalization, and that 58 percent of patients with pain considered the pain horrible or excruciating.¹ In another study, 67 percent of 2,415 randomly selected hospitalized patients had pain during the twenty-four hours prior to being interviewed, and 50 percent reported pain at the time of the interview.² In a study of seriously ill hospitalized patients reported in 1996, half of the patients complained of pain, and one-sixth reported that they experienced extremely severe pain at least half the time.³ According to one literature review, 75 percent of cancer patients have reported suffering pain,⁴ and one study estimates that 25 percent of cancer patients die with severe unrelieved pain.⁵ Chronic nonmalignant pain has been described as "an extremely prevalent problem,"⁶ and over two-thirds of nursing home residents experience serious pain.⁷

Yet, despite the clinical data, experts contend that pain can be controlled for a great percentage of patients.⁸ For example, a study evaluating the World Health Organization's guidelines for the relief of cancer pain reported that only 3 percent of the 401 dying patients in the study experienced severe pain at the time of death,⁹ and recent articles in the clinical literature contend that in up to 90 percent of cancer patients, pain can be controlled by relatively simple means.¹⁰

Decisions in two recent lawsuits suggest that proper pain management is beginning to evolve as an element of the standard of care required of health care providers. A

North Carolina jury awarded \$15 million in damages to the family of a patient whose dying days were made intolerable on account of pain mismanagement; and the Georgia Supreme Court affirmed a patient's right not only to have unwanted medical treatment discontinued but also to receive medication to manage his pain at the time. Moreover, in coming years, pain management practice guidelines, the Pain Relief Act of the Project on Legal Constraints on Access to Effective Pain Relief, and continued professional and public recognition of the importance of pain control likely will broaden liability exposure of health care providers who inappropriately manage pain.

Malpractice considerations for providers

In any professional negligence action, the claimant must prove (1) that the provider owed a duty of care to the patient; (2) that the provider violated that duty by failing to exercise reasonable care in providing treatment; (3) that the patient's injury was proximately caused by the provider's negligent conduct; and (4) that the patient suffered a compensable injury.¹¹ The scope of the provider's duty to the patient, referred to as the *standard of care*, is the degree of care customarily exercised by providers who are qualified by training and experience to perform similar services under comparable circumstances. In other words, the standard of care is defined, in large part, by reference to the customs of the profession.

Typically, a jury or other fact-finder determines case-by-case the standard of care that should have governed the provider's conduct, by evaluating evidence, often conflicting, about what standard of care should have been followed in the treatment of the patient. Evidence introduced to assist the fact-finder in determining the standard of care is primarily the testimony of experts, which in turn relies

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on learned treatises, articles in medical journals, and research reports.

Case law to date

In a 1990 North Carolina negligence lawsuit, for the first time a health care provider was held liable for failure to treat pain appropriately. In this case, *Estate of Henry James v. Hillhaven Corp.*,¹² the jury awarded \$15 million in damages to the family of Henry James, whose dying days were made intolerable by the decision of a nurse and her employer, a nursing home, to withhold or reduce pain medication ordered by the patient's physician. Mr. James was admitted to the nursing home with prostate cancer that had metastasized to his left femur and to his spine. When Mr. James entered the nursing home, he was not expected to live more than six months. The patient's personal physician prescribed 7.5 cc of oral morphine elixir every three hours as needed for pain. However, a nurse employed by the nursing home assessed Mr. James as being "addicted to morphine," and, on that basis, without the advice, consent, or orders of a physician, instituted an alternative "pain-management" plan. This plan minimized the use of pain medication by substituting a mild tranquilizer and delaying or withholding altogether the administration of analgesics.¹³

The lawsuit focused on health care providers' responsibilities to ensure the proper administration of pain medications in appropriate doses.¹⁴ Mr. James's family proved that the failure of the nurse and her employer, the nursing home, to meet this responsibility caused Mr. James to experience physical pain and suffering as well as emotional and mental anguish—"inhuman treatment" inflicted "without regard to the consequences and without care as to whether or not the patient received analgesic relief and without care that the result and procedures were torture of the human flesh."¹⁵

During the trial, medical and nursing experts testified about the proper standard of care for the administration of opioid analgesics and specifically about the administration of morphine for the relief of intractable pain. In addition, a nurse specializing in quality assurance for nursing homes testified that health care institutions have an obligation to ensure that their health care providers properly manage pain.¹⁶

The \$15 million jury verdict was resolved by settlement among the parties in an undisclosed amount. In his summary statement approving the settlement, Judge Cy A. Grant reiterated that:

"[Mr. James's family] does not allege that the conduct of the defendants caused the death of [Mr. James], but only that the conduct of the defendants caused [him] increased pain and suffering...."¹⁷

*State v. McAfee*¹⁸ also illustrates the law's recognition that pain management is an integral component of appropriate medical care. In this case, Mr. McAfee, a quadriplegic who was incapable of spontaneous respiration, sought court approval for discontinuation of his respirator. The Georgia Supreme Court affirmed his right to refuse medical treatment and held that he was also entitled to have a sedative administered at the time:

Mr. McAfee's right to be free from pain at the time the ventilator is disconnected is inseparable from his right to refuse medical treatment. The record shows that Mr. McAfee has attempted to disconnect his ventilator in the past, but has been unable to do so due to the severe pain he suffers when deprived of oxygen. His right to have a sedative (a medication that in no way causes or accelerates death) administered before the ventilator is disconnected is a part of his right to control his medical treatment.¹⁹

Although the focus of this case was the patient's right to refuse unwanted medical care, this ruling implies that at least in Georgia, providers may be held accountable for not providing measures that will help to ensure the patient's comfort.²⁰

The impact of clinical practice guidelines

Aside from these cases, courts may in the future be more inclined to include proper pain management in the standard of care required of health care providers because of the development and publication of pain management practice guidelines. The U.S. Department of Health and Human Services Agency for Health Care Policy and Research (AHCPR) was created in 1989 to "enhance the quality, appropriateness, and effectiveness of health care services and access to such services."²¹ To that end, under the authority of the Office of the Forum for Quality and Effectiveness in Health Care, AHCPR develops clinical practice guidelines to help physicians, educators, and health care practitioners prevent, diagnose, and treat diseases and other health conditions in the most effective and appropriate manner.²² AHCPR guidelines are developed by multidisciplinary panels of health professionals and consumers, on the basis of systematic reviews of relevant scientific evidence as well as professional judgment.

In 1992, AHCPR released its *Acute Pain Management Guidelines*,²³ and in 1994 it released its *Cancer Pain Management Guidelines*.²⁴ Both guidelines call (1) for a collaborative, interdisciplinary approach to the care of patients with pain, (2) for an individualized pain-control plan developed and agreed on by patients, their families, and providers, (3) for ongoing assessment and reassessment of patients' pain, (4) for the use of both drug and nondrug

therapies to manage pain, and (5) for explicit institutional policies on pain management. The guidelines also include specific pain management approaches and techniques, sample pain assessment tools, discussion of pain control in special populations, and scientific evidence regarding pain management interventions.

Practice guidelines addressing a variety of medical matters have been used in malpractice litigation as evidence of the standard of care. For example, in *Davenport v. Ephraim McDowell Memorial Hospital*²⁵—a malpractice action against a hospital, an anesthesiologist, and others—one of the plaintiff’s proposed exhibits was *Guidelines for Standards of Care and Management Standards in the Post Anesthesia Care Unit*, published by the American Society of Post Anesthesia Nurses. The appellate court indicated that such a document did not rise to the level of a learned treatise; nonetheless, it agreed with the trial court’s ruling that the document would be helpful as a guide for measuring care. Similarly in *Rodriguez v. Jackson*,²⁶ the court held that a government manual concerning tuberculosis treatment was admissible but not conclusive evidence about the standard of care; and in *Cornfeldt v. Tongen*,²⁷ the Minnesota Supreme Court held that the trial court had committed a clear error by refusing to admit into evidence the Joint Commission on the Accreditation of Healthcare Organizations’ guidelines on administering anesthesia.

The admissibility of practice parameters to establish a standard of care was recently bolstered by the U.S. Supreme Court’s decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*²⁸ In that case, the petitioners, two minor children and their parents, alleged that the children’s birth defects had been caused by their mothers’ prenatal ingestion of Bendecdin, an anti-nausea prescription drug marketed by the respondent. The respondent moved for summary judgment, claiming that Bendecdin did not cause birth defects in humans. Merrell Dow supported its claim with the affidavits of a physician and an epidemiologist who reviewed various studies involving patients who had taken the drug and concluded that Bendecdin was not a factor. The petitioners produced eight experts who concluded that Bendecdin could cause birth defects. This conclusion was based on animal studies, chemical structure analysis, and the unpublished reanalysis of previously published human statistical studies. The district court ruled that the petitioners’ expert opinion evidence was inadmissible because it was not based on technique generally accepted as reliable in the scientific community, and so it granted summary judgment for Merrell Dow. The U.S. Court of Appeals for the Ninth Circuit affirmed, citing *Frye v. United States*²⁹ for the rule that expert opinion based on a scientific technique is inadmissible unless the technique is “generally accepted” as reliable in the relevant scientific community. The U.S. Supreme Court reversed and remanded, however, noting that at least in a federal trial, the “general

acceptance” test is not a prerequisite for the admissibility of evidence. Rather, the Court said, in accordance with the Federal Rules of Evidence, that “if scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue,” a witness qualified by knowledge, skill, experience, training, or education may testify thereto.³⁰ As a result of *Daubert*, it appears that the evidentiary standard for scientific testimony is now more flexible, and that this could lead to wider admissibility of practice parameters to establish the standard of care in medical malpractice lawsuits.

Some state statutes expressly accommodate the admissibility of practice guidelines as evidence of the standard of care. A Vermont statute on malpractice arbitration panels, for example, provides that guidelines drafted by professional organizations, licensed hospitals, or quality assurance programs recognized by state law are admissible as evidence on whether the provider satisfied the standard of care.³¹

In other states, health care providers in malpractice actions have been permitted to use compliance with practice guidelines as a conclusive defense. In Maine, for instance, although claimants may not rely on the fact that a physician failed to adhere to practice parameters drafted by statutorily created “medical specialty advisory committees” to establish negligence, physicians may be absolved of any negligence if they prove that they *did* follow the parameters.³²

Absent specific statutory direction, the evidentiary weight of practice parameters admitted as evidence in a malpractice case will vary according to (1) the degree of acceptance and authority of the practice parameter; (2) how closely the parameter fits the clinical situation at hand; and (3) the validity of the research and analysis underlying the parameter. In light of AHCP’s reputation and comprehensive guideline development methodology, it is likely that its pain management guidelines (if applicable to the situation) would be admitted and carry substantial evidentiary weight in proving the standard of care in a pain management malpractice case.

The impact of state intractable pain statutes, the Pain Relief Act, and enhanced professional and public awareness

In addition to pain management guidelines, growing numbers of state intractable pain statutes, the Pain Relief Act, the development of institutional pain management policies, and enhanced public recognition of the importance of pain management will broaden liability exposure of health care providers who mismanage pain.

Several states have enacted statutes that address pain management.³³ The provisions of these statutes vary. Some provide that physicians may treat patients *other than* chemi-

cally dependent persons for pain with controlled substances;³⁴ others specify that a physician may administer controlled substances for intractable pain if he/she does so in accordance with accepted medical practice standards;³⁵ and one statute requires patients' prior written consent to pain medication.³⁶

The Pain Relief Act, developed by the Project on Legal Constraints on Access to Effective Pain Relief, a research project of the American Society of Law, Medicine & Ethics, will help to improve and further this state legislative movement. The Act's most significant provisions simply state that

Neither disciplinary action nor state criminal prosecution shall be brought against a health care provider for the prescription, dispensing, or administration of medical treatment for the therapeutic purpose of relieving intractable pain [when that provider] can demonstrate by reference to an accepted guideline that his or her practice substantially complied with that guideline....³⁷

Health professionals undertreat pain for different reasons, one of the most important being their fear of legal penalties, especially disciplinary action. Sixty-nine percent of physician respondents in a California survey stated that the potential for disciplinary action had made them more conservative in their use of opioids in pain management, and one-third reported that their patients may be suffering from neglected, treatable pain.³⁸ In addition, Dr. Russell Portenoy's recent review of the literature finds that "available data suggest that medical decisionmaking regarding the use of opioids continues to be unduly influenced by regulatory policies and fear of regulators."³⁹

The Pain Relief Act aims to increase patient access to effective pain management by removing the threat of inappropriate legal liability and disciplinary action against health care professionals. To the extent that the Act is adopted by states and is successful in its goal, it will alter pain management practice and, accordingly, the standard of care as established by clinicians' expert testimony in malpractice litigation.⁴⁰

The growing incidence of pain management policies in hospitals and long-term care facilities, and enhanced public consciousness about the ability and need to manage pain are additional factors that will help to change clinical practice and, consequently, the standard of care. Analogously, in recent years, public awareness was important in establishing the legal presumption against the use of restraints in nursing homes. Until recently, the practice of using restraints was ubiquitous in nursing homes.⁴¹ In the past several years, however, professional and public perceptions have shifted, and use of physical restraints in many instances is now considered unnecessary, improper, or even

abusive.⁴² With numerous epidemiological studies demonstrating significantly increased chances of bad clinical outcomes with prolonged use of restraints, and subsequent professional association initiatives, consumer advocacy activities,⁴³ and federal law specifying residents' rights to be free from unnecessary restraints, more institutional long-term care facilities have moved toward reduced restraints.⁴⁴

Along the same lines, it appears that changing attitudes toward pain management are changing pain management practices, and that these changed practices will set the standard of care in malpractice litigation. Increasingly, expert testimony will reflect that appropriate pain management is an integral component of professional custom, leaving the health care professional who deviates from that standard exposed to claims of negligence.

Conclusion

AHCPR's *Acute Pain Guidelines* note the ethical obligation to manage pain and relieve suffering, which is at the core of the health care professional's commitment to his/her patients. The standard of care to which health care professionals are held in law should mirror their ethical obligations to patients. Pain management guidelines, the Pain Relief Act, and growing recognition among health care providers and the public about the possibilities and importance of pain control will help establish appropriate pain management as a component of the standard of care—which will help to ensure patients of more competent and compassionate care.

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