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Legal Trends in Imaging: An Update

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Legal Trends in Imaging: An Update

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Radiologic Technology *first published a continuing education article on medical imaging legal trends in 2004. That article described medical malpractice cases involving imaging, the role of imaging in criminal trials and evolving legal concerns raised by newer imaging technologies. This article reports on the ever-expanding relationship between the law and medical imaging. Readers are cautioned that nothing contained in this article is intended as legal advice and should not be taken as such.*

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After completing this article, readers should be able to:

- *Describe the potential uses of imaging in civil law, including employee screening, lie detection and guardianship cases.*
- *Discuss current legal trends in radiological malpractice cases, including approaches to reducing malpractice exposure.*
- *Explain emerging state and federal "I'm Sorry" legislation.*
- *Discuss the growing role of imaging in criminal cases involving such issues as competency to stand trial, the insanity defense and sentencing.*
- *Recognize what would be legally valid informed consent in the context of more complicated fact patterns.*

In a sometimes uneasy partnership, the law and imaging presently are engaged in a struggle to resolve some fundamental questions. For example, consider the following hypothetical situations:

Hypothetical #1: A surgeon successfully completes an operation and then proceeds to carve his signature in the patient's abdomen. Later, the surgeon is diagnosed with a form of dementia associated with personality changes that are believed to result from progressive degeneration of certain portions of the brain. Scans provide visual evidence supporting the diagnosis. Should the surgeon be held responsible for his actions? What role might imaging play in a criminal prosecution of the physician or a civil lawsuit for monetary damages?

Hypothetical #2: A 40-year-old man who has no history of pedophilia attempts to molest his stepdaughter. He is found guilty of child molestation and sentenced to complete a 12-step program but, despite his desire to avoid prison, is unable to control his compulsive sexual behavior. A scan reveals that the man has a large brain tumor. When the tumor is removed, his sexual compulsion diminishes. Some time later the behavior returns, and another scan reveals that the tumor has grown back. To what degree should he be held criminally responsible for his actions? Would a jury or judge be swayed by viewing the brain scans and hearing accompanying expert testimony? Should he have to undergo regular scans as a condition of parole or probation?

Hypothetical #3: In 1966 Charles Whitman killed his wife and his mother. He then proceeded to the University of Texas, climbed a tower, and from there shot and killed another 13 people before police killed him. An autopsy revealed that Whitman had a tumor pressing on his amygdala, which is a portion of the brain associated with emotion, arousal and fear.[1] What if he had been captured alive and tried for the murders? The imaging technology now used with increasing regularity in criminal cases was not available in 1966, and Whitman's brain tumor might have gone undetected. Would justice have been achieved if Texas courts had imposed the death penalty?

Hypothetical #4: Some scientists assert

that functional magnetic resonance (fMR) imaging demonstrates unusual activity — areas that "light up" — in the brains of admitted pedophiles.[2,3] Should school districts and churches begin scanning applicants to screen out possible pedophiles? If an employer does not scan applicants and an employee molests a child, should the employer be liable to the child for monetary damages? At what point might insurance companies require MR scans of potential employees as a precondition for issuing an insurance policy to the employer? Many insurance companies now require that their policyholders have all applicants tested for drugs — a personal invasion once considered shocking but now advertised as a reason for choosing 1 carpet steam-cleaning company over another.

The Final Hypothetical: Producers of television shows that use polygraphs to catch cheating spouses learn that the National Research Council in 2003 concluded that polygraph is bad science.[4] Some scientists, the producers learn, believe that on fMR images, certain brain centers light up when a person is lying.[4] The television producers decide to replace polygraphs with fMR images, and a new industry of commercial MR deception detection is born. What is informed consent in these circumstances, and what if a potential television guest has a reaction to a contrast agent? Whom should the law hold responsible?

The law already has grappled with some of these challenges. A New York surgeon actually did carve his signature into his patient; once his medical condition was discovered, no one — including experts, the jury and the patient — considered him responsible for his actions.[5] The 40-year-old man described in Hypothetical #2 also existed, although the fact pattern has been expanded to pose additional questions, including whether the courts should begin requiring regular brain scans of convicted sexual predators (see Figure 1).[5] It was only after the autopsy that anyone realized what likely had led Whitman to become so suddenly, voraciously violent.[6] Now, assuming he had lived to be tried, Whitman's defense counsel might be considered ineffective if he or she did not seek a court order requiring Whitman to undergo some form of brain scan.

Scientists, ethicists and law professors currently are debating where lines should be drawn in terms of employers' use of brain scans, describing the issue as "cognitive liberty." One author summarized the dilemma particularly well by stating, "My guess is that several readers who would not acquit a child molester because of an aberrant brain scan wouldn't object to the same technology being used to weed out potential molesters.

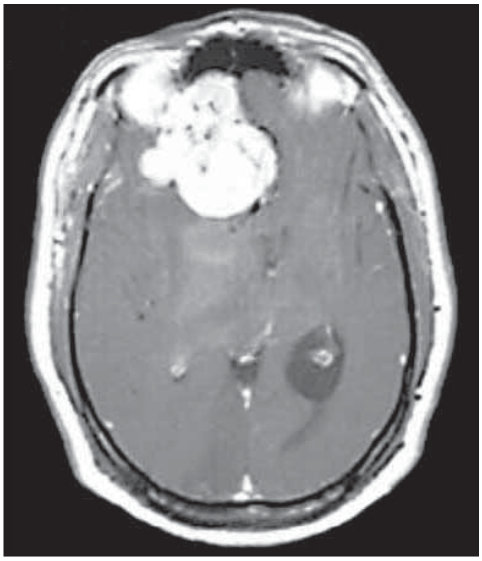

Figure 1. *Scan showing orbitofrontal damage (tumor) associated with symptoms of pedophilia and sexual misconduct in the case of a male patient. Reprinted with permission from Mobbs D, Lau HC, Jones OW, Frith CD. Law, responsibility, and the brain.* PLoS Biol. *2007;5(4):693-700. http://ssrn.com/abstract=982487. Published May 1, 2007. Accessed July 19, 2007.*

We believe in free will, but we don't want to take any chances."[2,6]

As for the final hypothetical, scientists already have used MR imaging to assess whether structural brain deficits appear in pathological liars.[7] While neuroscientists continue to debate whether the brain can distinguish true memories from false ones, 2 private companies currently offer MR imaging as a form of lie detection. One of these companies even touts fMR imaging as "the next generation of truth detection technology . . . help[ing to] protect the innocent and convict the guilty."[8-10]

These companies market their products to individual customers, lawyers, corporations and potential investors. One company, clearly targeting the federal government as a deep-pocketed potential customer, reported that the Department of Defense spends in excess of $200 million per year for polygraph testing, which could be replaced with the more reliable imaging technology — a strong statement bolstered by a claim that MR demonstrates a 90% accuracy in the clinical setting.

The companies also touted the potential uses of the technology in combating terrorism.[6] Since at least 2001, the federal government has been investing dollars into this form of lie-detection research, and university-

associated research programs have benefited.[8] In 2002, New York University bought an MR scanner.[11] Using fMR imaging, it has become one of the top programs for the study of the human brain, with scientists observing how the brain processes motivation, volition, responses to rewards and punishment, and decision making. Vanderbilt's Institute of Imaging Science has 1 of the few 7-tesla MR imaging scanners in the world, and scientists there are studying, among other topics, how the human brain reacts when asked to impose various punishments.[6]

As a result of the intensive research being conducted and cases such as those described above, new terms such as "neurolaw" have been developed to describe the impact neuroscientific discoveries have on the practice of law and traditional legal theory. This Directed Reading examines this fusion as it relates to radiologic technology.

Medical Malpractice and Radiology: Mapping the Pitfalls

How might medical mistakes be analyzed so as to prevent repetition and increase patient safety? What might be learned from actual fact patterns and discussion of recent encounters between malpractice attorneys and imaging health care providers? The following section provides answers to these questions and alerts readers to the types of medical errors currently being examined in court (see Box 1).

The Dynamics of Error

In hospitals, adverse events are the result of 2 different mechanisms. A single mistake by itself, if sufficiently serious, may cause harm to the patient.[16] More commonly, however, smaller errors combine to produce a negative result. On its own, each small error is not enough to result in harm, but the combined effect of the series of errors can bring about harm, for which the patient sues. This serial error configuration has been referred to as an "organizational accident."[17] To break the chain of causation, hospitals and other complex organizations commonly implement a series of defenses. Typical defenses include training programs, safety protocols, policies and procedures, and computerized decision support tools.[16]

Researchers use various models to conceptualize the error process, to help systems analyze where the problems lie and to anticipate and prevent future errors. One such model — the "Swiss cheese" model — explains what happens when all defenses fail and an injury occurs.[17] According to this model, a system is like a stack of Swiss cheese slices standing on end and lined up neatly. Each slice of cheese is a defense to keep errors from occurring, but each slice of "defense" is flawed by holes. If the holes in the slices of cheese happen to line up — in other words, if events occur to permit the circumnavigation of all defenses — then an adverse event results. The Swiss cheese model can be applied to the following fact pattern.

Two weeks prior to hospital admission for dehydration, an elderly woman developed right ankle and foot pain, was evaluated in the emergency department (ED) of a different hospital and then was instructed to follow up with an orthopedist as soon as possible.[16] Her family was told that she might have a fracture, and a splint was applied. The patient did not pursue any follow-up examination. When the woman was examined in the second hospital upon admission, she still had in place the splint that had been applied 2 weeks earlier on her right ankle and foot. A request for release of information was signed and faxed to the first hospital to obtain records of the

Box 1
The Basics of Medical Negligence[12-15]

To be successful in court, patients who sue their health care providers for medical malpractice must prove all of the following:

1. The health care provider owed the patient a duty to act with reasonable care and skill in providing the patient with care.
2. The health care provider breached that duty of care (ie, the health care provider failed to adhere to accepted standards of care).
3. The patient was damaged.
4. The patient's damages are attributable to the health care provider's failure to fulfill a duty to the patient (ie, there is a causal connection between the act or failure to act and the harm).

Although the possibilty of a malpractice case is real, the fear of it is perhaps exaggerated:

- Only a small percentage of people who are injured because of negligence file a claim.
- Most cases do not go to trial because they are settled, dropped or otherwise disposed of by courts before they reach that stage.
- Of those cases that go to trial, most result in verdicts favorable to the health care provider(s).

patient's previous ED evaluation for the foot and ankle injury. Requested records did not arrive promptly, the family requested an orthopedic consultation and another radiograph was taken of the right foot and ankle. The radiologist interpreted the image as showing a right ankle fracture and dislocation. The consulting orthopedist also reviewed the radiograph and then briefly examined the patient. Surgery was recommended and consent obtained.

The next morning, the patient was taken to the operating room (OR) where she was anesthetized. Prior to making an incision, the orthopedist reviewed the radiograph posted on the view box and was shocked to note that it depicted a left ankle fracture. The radiograph was labeled clearly as belonging to the patient. The orthopedist then examined both of the patient's ankles under anesthesia and found no clinical evidence of fracture or dislocation. New radiographs of both ankles were taken, revealing an intact left ankle and a right ankle with a healing fracture and no dislocation. At this point, a surgical technologist recalled that another patient underwent fixation of a left ankle fracture 2 days earlier. It was later confirmed that the radiograph posted in the operating room belonged to the patient who already had undergone surgery. The posted radiograph was mislabeled with respect to both date and patient name. Anesthesia was reversed, the patient recovered without complication, and the family was offered an apology, along with full disclosure.

Experts reviewed this adverse event for the Agency for Healthcare Research and Quality's (AHRQ) Web Morbidity and Mortality Rounds (www.webmm.ahrq.gov). The Swiss cheese model was applied and the following series of errors was identified:

- Staff at the first ED failed to communicate the fracture diagnosis clearly and unambiguously to the patient and her family.
- The first hospital failed to respond to the faxed request for patient records in a timely manner.
- The ED physician who examined the patient at the second hospital and found a normal right ankle failed to communicate this finding both to the physician responsible for admitting the patient and to the consulting orthopedist.
- The physician who admitted the patient and ordered repeat foot and ankle radiographs did not review them.[16]

With respect to the mislabeling of the radiographs, the experts found that several errors were likely. For one, a different patient's films were somehow mislabeled with the current patient's identifying information and current date. An erroneous report of findings also was generated with the wrong patient name. Additionally, the orthopedist was found to have committed the most serious errors by failing to take an adequate history of the patient's previous diagnosis and treatment and by failing to recognize that the history reported by the family did not match the diagnosis revealed by the films. Furthermore, even a brief physical examination of the patient should have revealed that the clinical presentation did not match the films purported to belong to the patient. Finally, the orthopedist recommended surgery on the basis of an incomplete evaluation, somehow obtained what was not likely genuinely "informed" consent and scheduled an operation.

The series of defenses designed to prevent these types of medical errors failed. Lines of communication were inadequate. Policies, procedures and protocols designed to prevent mislabeling of medical images were either inadequate or not implemented properly. The experts specifically recommended that the institution review its process of identifying and labeling radiographs so as to discover exactly how the mislabeling occurred. The experts also identified other failed defenses, including teamwork in the OR: Not a single person noticed the patient's normal right ankle, nor did anyone question whether the procedure should continue. The experts identified staff by job title, noting how numerous individuals, including personnel at the first ED, could have stopped the chain reaction and prevented the adverse event.

Current Error Trends in Radiology

After-hours Coverage

Several recent cases involving radiology have focused on adverse events stemming from poor, insufficient or uneven after-hours coverage. In Arkansas, a mother took her 11-year-old son to an otolaryngology surgery center where he was seen by a physician who ordered a computed tomography (CT) scan at another facility.[18] The radiologist at the second facility interpreted the CT scan as showing an abscess formation in the left hemisphere of the child's brain — a condition that allegedly required immediate surgical intervention to prevent death. The radiologist attempted to speak with the referring physician, but was unable to do so because the CT scan had not been performed until 5:56 PM and by that time the referring physician had departed for the evening. The radiologist then contacted the on-call physician for the otolaryngology center and discussed the scan results with him. The on-call physician reportedly instructed the